

MECHANICAL CARDIAC ASSIST IN A COMMUNITY HOSPITAL WITHOUT TRANSPLANTATION



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ABSTRACT

More than 5 million people in the United States currently have congestive heart failure (CHF), and the number is growing rapidly. Ventricular assist devices (VADs) can benefit these patients when they develop refractory cardiogenic shock, or chronic disabling heart failure despite maximal medical therapy. VADs can also serve as a short term bridge-to-recovery in patients with cardiogenic shock after open heart surgery, myocardial infarction, or acute myocarditis. When such patients are seen in community hospitals without expertise in mechanical assist, they are usually transferred to transplant centers (the so-called “hub-and-spoke” system), during which time they often develop irreversible multi-organ damage. Lancaster General Hospital (LGH) has developed expertise in mechanical cardiac assist, and has a unique cooperative arrangement with the cardiac transplant center at the Hospital of the University of Pennsylvania (HUP) whereby VADs are inserted at LGH when indicated, and patients are transferred to HUP only if necessary.

Initial results were reported in this Journal’s inaugural issue.¹ The cumulative experience now includes 14 VAD insertions between October 2005 and December 2009. Eleven of 14 patients (79%) survived to hospital discharge. Four of these early survivors were transferred to HUP for heart transplantation, of whom three underwent successful transplantation and one was weaned from the VAD without transplantation. Of the remaining seven early survivors, one was weaned and explanted at LGH, one died during outpatient support, two were discharged home and subsequently underwent

transplantation, and three patients remain on VAD support at 20, 245, and 1,038 days.

These highly satisfactory results indicate that heart failure can be treated with state-of-the-art technology in community hospitals that collaborates with a centralized transplant program. Cardiac transplantation thus need not be disseminated to multiple low-volume sites, with the consequent added costs and poorer outcomes that would result.

Finally, LGH is now accredited for “destination therapy” in which an LVAD is implanted as permanent therapy in patients with refractory cardiogenic shock or chronic advanced heart failure who are not candidates for cardiac transplantation.

INTRODUCTION

More than 5 million people in the United States currently have congestive heart failure (CHF). Approximately 550,000 new cases are diagnosed every year, and 57,000 heart failure deaths occur annually. Further, while the overall death rate in the US population declined two percent from 1993-2003, deaths from heart failure increased 20.5 percent.² Hospital admissions for CHF already exceed 1 million each year, and there are another 3.4 million outpatient visits. As the baby-boomer generation ages, this epidemic is expected to worsen considerably.

A Ventricular Assist Device is a mechanical blood pump that assists or replaces the pumping function of the failing left ventricle (LVAD), right ventricle (RVAD), or both ventricles simultaneously (BIVAD). Most currently marketed devices are surgically implanted via a median sternotomy approach.

(Figure 1 illustrates an LVAD in place.) These devices are indicated for temporary circulatory support in patients with cardiogenic shock resulting from a conventional open heart operation, myocardial infarction, or acute myocarditis. In these patients its use is (hopefully) short lived and has been termed a bridge-to-recovery. In these scenarios the VAD is used to rest the heart for days to weeks after the inciting event, during which the native heart recovers to the extent that the VAD may be surgically removed. If the myocardial injury proves irreversible, the VAD sustains the circulation until the native heart can be replaced with a cardiac transplant, in which case it has been called a bridge-to-transplant.

Similarly, in patients with end-stage heart failure it can maintain the circulation in the face of refractory cardiogenic shock or chronic disabling heart failure, and if the clinical situation does not stabilize with clinically adequate cardiac function, the VAD can also serve as a bridge to transplant. The REMATCH Trial clearly established that VAD therapy is superior to medical treatment alone in terms of overall survival, readmissions, and quality of life.³

A more recently introduced clinical indication for prolonged VAD therapy is “destination therapy.”⁴ In these cases a patient suffering from refractory cardiogenic shock or chronic advanced heart failure

despite maximal medical therapy is not deemed a candidate for cardiac transplantation as a result of advanced age or confounding medical co-morbidities, and an LVAD is implanted with the expectation that it will be permanent.

LOGISTICS

Although community hospitals see the overwhelming majority of admissions for CHF, until recently VAD programs were confined almost exclusively to the larger academic centers. The past decade has witnessed the development of a few VAD programs at select nontransplant community hospitals. This phenomenon reflects the continued improvement in the quality of care at select community hospitals, which has prompted a redistribution of some complex cases from academic referral centers to high-quality community centers.

Both patients and health care institutions benefit; patients receive quality care closer to home, and the community hospitals, in turn, may reinvest the capital earned from providing more sophisticated health care to further improve the quality of that care for their local populations.

Paradoxically, referral centers may also benefit from the shift in specialized care to community-based hospitals. If relationships are cultivated, the



Fig 1. A Thoratec paracorporeal ventricular assist device implanted in a patient for left ventricular support.

academic center immediately gains a productive referral source. The academic referral hospitals can also help develop comprehensive community-based heart failure programs which incorporate VAD use. However, recent reports voice concerns over the poor results of VAD implantation in community hospitals, and maintain that such advanced technology should only be offered at university centers.⁵ In this report, we address these issues by presenting the clinical outcomes of a unique collaborative effort between Lancaster General Hospital (LGH) and the Hospital of the University of Pennsylvania (HUP) to develop a community-based VAD program.

METHODS

This study underwent formal expedited review by the institutional review board (IRB) at LGH. A request for waiver of informed consent was granted by the IRB.

HEART FAILURE PROGRAMS AT LGH AND HUP

Lancaster General Hospital (LGH) offers well-established and reputable cardiology and cardiac surgery services capable of treating the full gamut of complex heart-related conditions. Its designated heart failure service includes cardiac surgeons, heart failure cardiologists, nurse practitioners, a VAD coordinator, and other necessary support services. The hospital offers a dedicated inpatient heart failure unit in addition to a well-established, comprehensive outpatient heart failure clinic. We also hold a monthly multidisciplinary CHF/VAD conference attended by members of LGH's cardiology and cardiac surgery services. The intent of this conference is to achieve a consensus regarding the preferred medical and/or surgical therapy for a variety of complex heart failure patients, and to identify potential VAD candidates.



Fig 2. HeartMate XVE left ventricular assist system.

The Hospital of the University of Pennsylvania (HUP) has had a multidisciplinary heart failure program for many years that includes mechanical cardiac assist device therapy and cardiac transplantation. HUP has been involved with bridge-to-transplant clinical trials for more than a decade and has developed collaborative programs for the referral of heart transplant candidates supported by cardiac assist devices.^{6,7}

Initially there were only occasional, unplanned referrals of potential VAD and/or transplant candidates from LGH to HUP. As the heart failure program at LGH expanded, a growing need for VAD therapy in Lancaster became evident. The initial driving force was the desire to offer high-risk conventional heart surgery at LGH with the “safety net” of VAD backup, thus obviating the need to transfer such patients out of the Lancaster area for surgical treatment of their heart failure. In 2001, the heart failure team at LGH began the process of developing a center of excellence for heart failure to include a VAD program locally. LGH recognized

from the outset the merit of having experienced and reliable external support from a center that provided the option of cardiac transplantation and developed an agreement for transfer of LGH’s sickest patients if they exceeded the level of care LGH could provide. In 2004, LGH officially established its VAD program with an experienced VAD coordinator to work with heart failure nurse practitioners to assist the cardiac surgeons and heart failure cardiologists who manage the program.

The first VAD system used at LGH was the Thoratec Paracorporeal Ventricular Assist System (PVAD) (Thoratec Corp, Pleasanton, Calif). This VAD has the versatility needed for this type of program,⁸ and can be used for both temporary short-term and long-term support (Figure 1). It is suitable for patients whose heart function recovers relatively quickly and for patients who do not recover and become candidates for heart transplantation. Furthermore, the PVAD is suitable for most sizes of adult patients and can be used to support either or both ventricle(s).



Fig 3. HeartMate II left ventricular assist system

Subsequently, the implantable HeartMate XVE Left Ventricular Assist System (LVAS) (Thoratec Corp) was added to our mechanical support armamentarium (Figure 2). The HeartMate XVE has become the device of choice for patients with isolated left ventricular dysfunction who cannot tolerate anticoagulants and/or require extended outpatient support for bridge-to-transplant or destination (i.e. permanent) therapy. More recently, LGH has offered therapy with the newer generation HeartMate II LVAS, a state-of-the-art continuous flow device with markedly prolonged durability.⁹ (Figure 3). Furthermore, in May 2009 LGH obtained accreditation from the Joint Commission of American Hospital Organizations for destination therapy in end-stage heart failure patients who are nontransplant candidates.

PATIENT SELECTION AND VAD IMPLANTATION

At LGH, patients who are diagnosed with decompensated end-stage heart failure and/or cardiogenic shock (of any etiology) are promptly assessed to determine the immediate course of care. If the etiology is ischemic, patients undergo surgical or percutaneous revascularization with standby VAD support. A VAD is implanted in those patients who do not respond sufficiently to intervention and remain hemodynamically unstable. If the etiology is nonischemic cardiomyopathy, patients undergo a workup similar to that of the VAD and transplant workup at HUP. This includes complete laboratory testing, right heart catheterization, and echocardiography. The more detailed transplant workup is completed as the patient's condition allows. The decision to implant the PVAD or XVE LVAS takes place during consultation among the cardiac surgeons and heart failure cardiologists at the two institutions.

HUP/LGH COLLABORATIVE COMMUNICATION

HUP provides e-mail and telephone consultation services 24/7 for potential VAD recipients at LGH. Once a VAD has been implanted at LGH, there are frequent communications between the two institutions to mutually determine the best long-term plan for the VAD recipient. Therapeutic options include eventual explantation of the device at LGH, interhospital patient transfer for explantation or transplant listing at HUP; or discharge to home for eventual outpatient transplant work-up and/or chronic device management in HUP's VAD/transplant clinic. Heart failure practitioners from both institutions attend

combined conferences for continuing education and quality improvement during which recent cases of VAD implantations at either institution are presented. Further interaction among clinical stakeholders of both programs occurs at periodic dinner meetings or during national meetings. At HUP's weekly cardiac transplant meeting, LGH clinicians present potential VAD or transplant recipients via on-site attendance or by video teleconference.

RESULTS

Between October 2005 and December 2009, the first 14 consecutive LVAD implants were carried out at LGH. The majority of patients were men (10/14), and the average age was 53 years (range, 36 to 71 years). The indications for VAD support were postcardiotomy failure (n=6), ischemic cardiomyopathy (n=7), and alcoholic cardiomyopathy (n=1). Biventricular support (BiVAD) was required for four patients, right ventricular support (RVAD) for two patients, and left ventricular support (LVAD) for eight patients. The PVAD was used to support eight patients, while the HeartMate XVE was used to support three LVAD patients. The most recent three patients were implanted with the HeartMate II LVAD.

Four patients were transferred from LGH to HUP for inpatient transplant evaluation after their conditions stabilized; all recovered from the implant surgery. The transfers occurred on post-implant days 5, 6, 9, and 39. Three of these 4 transplant candidates underwent successful transplants at HUP after VAD support intervals of 29, 100, and 106 days. The 4th transferred patient (with alcoholic cardiomyopathy) was weaned from support and the device was explanted. One patient with post-cardiotomy cardiogenic shock was weaned after 11 days of RVAD support, the VAD was explanted, and the patient was discharged from the hospital.

Six patients were discharged home from LGH on VAD support. One underwent transplant at HUP after 59 days of HeartMate XVE support and another was transplanted after 60 days of HeartMate II support. Another patient who was discharged home with a paracorporeal LVAD died on postimplant day 119 of a massive hemorrhagic stroke. Three patients remain on outpatient HeartMate II support at 20, 245, and 1,038 days.

Of the 14 total VAD patients implanted at LGH, three died during the index hospitalization, all of multiple organ failure (post-implant days 2, 10, and

34). Follow-up on all patients was complete as of final data analysis in December 2009.

COMMENT

The early survival rate for the first 14 VAD implants at LGH was 79%. This level of success could only have been achieved with careful planning and implementation of the VAD program, including close coordination with a transplant center. By sharing resources and experience, the LGH-HUP partnership extended VAD therapy to patients previously underserved by this technology.

The “hub and spoke” concept for applying VAD technology to patients at community hospitals and then transferring them to an academic referral center is not unique. Previously published reports have indicated variable early survival rates ranging from 32% to 74% for patients transferred to academic referral centers after VAD implants at outlying hospitals.^{5,10,11} The poorer survival rates have been attributed to inclusion of patients in critical condition before implant, often beyond the limits of salvageability, and to delays in transfer until all available options at the initial site have been exhausted. Regardless of the treatment they ultimately receive, such patients can be expected to have a poor outcome. Furthermore, patient selection and the timing of the VAD implant play a critical role in outcome. In this patient population, good outcomes are best achieved by consistent, quality communication between the transplant center and the outlying hospitals.¹⁰

Regardless of etiology, cardiogenic shock is associated with a high mortality rate, due mainly to the high incidence of multiple organ failure caused by the low-flow state.¹² For the outcome to be positive, adequate circulation must be restored rapidly, but by the time most patients in refractory cardiogenic shock can be transferred to an academic referral center for VAD implant, many will have already developed irreversible multiple organ failure—despite having been given the community hospital’s most advanced therapies. The ability of community hospitals such as LGH to offer the resources and staff to implant VADs on short notice, combined with consultation with an experienced center, will likely improve survival rates for heart failure patients who live far from an academic referral center.

This concept is in sharp contrast to the conclusion of a recent report on VAD outcomes in the Medicare population in which the authors contended that

in order to improve outcomes, VAD implantation should be performed preferentially at high-volume, experienced central referral centers.⁵ The results presented herein refute that viewpoint.

We have always believed that select community hospitals with the appropriate infrastructure and external support are also capable of superior outcomes. The key components of such an infrastructure are:

- a supportive hospital administration that commits adequate resources to initiate and sustain the program;
- a well-established multidisciplinary clinical heart failure program;
- a well-structured outpatient heart failure clinic staffed by dedicated heart failure cardiologists and nurse practitioners that identifies potential VAD recipients and facilitates their care after hospital discharge;
- specialized personnel trained to treat, care for, and serve patients with VADs;
- general cardiologists who are educated about the possibilities of VADs for their patients;
- an operating room staff, including anesthesiologists, perfusionists, physician assistants, and nurses, that is available 24/7.
- financial office personnel trained in reimbursement procedures for these devices.

By pooling resources dedicated solely to the care of CHF patients, the VAD program at LGH maximizes efficiency and quality in patient care and allows a more systematic approach to treating heart failure patients. Patients are followed up routinely and their outcomes tracked in order to improve the program and patient care.

CONCLUSION

At present VAD therapy is significantly underutilized; fewer than 0.1 % of qualified patients receive VAD support—in part because so many patients are being treated at nonacademic medical centers where VAD technology is either not available or is applied too late in the patient’s clinical course. Our experience demonstrates that community-based heart failure programs with active collaboration with referral centers, such as LGH and HUP, can improve the outcomes of VAD implants in community-based hospitals over those of transfer-based programs and, in so doing, can improve the outcomes and quality of life for patients with severe CHF. Our experience further suggests that it would be reasonable for

certain successful community VAD programs to offer more advanced mechanical cardiac support, such as the newer generation axial flow pumps, as well as destination VAD therapy for nontransplant candidates with end-stage heart failure.

FINANCIAL DISCLOSURES

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