Community support of patients with a left ventricular assist device: The Toronto General Hospital experience

Jane MacIver RN MSc, Heather J Ross MD MHSc, Diego H Delgado MD MSc, Robert J Cusimano MD MSc, Terrence M Yau MD MSc, Marnie Rodger RN MN, Stephen Harwood CCP, Vivek Rao MD PhD

J MacIver, HJ Ross, DH Delgado, et al. Community support of patients with a left ventricular assist device: The Toronto General Hospital experience. *Can J Cardiol* 2009;25(11):e377-e381.

BACKGROUND: Implantation of a left ventricular assist device (LVAD) is an acceptable therapy for patients with advanced heart failure. LVADs may be used as a bridge to recovery, a bridge to transplantation or as destination therapy. Although the morbidity rate of individuals on device support remains high, experience suggests that patients who are discharged home have satisfactory outcomes during support and following heart transplantation.

METHODS: A retrospective review of 24 patients implanted with an LVAD between October 2001 and December 2006 was performed. Nineteen patients received a device as a bridge to transplantation and five received a device as destination therapy. Postoperative follow-up was performed routinely in the heart function/LVAD clinic at the Toronto General Hospital (Toronto, Ontario) and all adverse events were recorded.

RESULTS: The majority of patients were men, with a mean age of 44 years and a diagnosis of dilated cardiomyopathy (62%). Seventeen patients (71%) were discharged home on support; one died, 14 were transplanted, one was explanted and one patient remains on support in the community. Post-transplant survival was 93% in patients discharged home compared with 40% transplanted during their hospital stay. Outpatients spent 56% of their overall support time at home, with only 12 readmissions totalling 120 patient days.

CONCLUSIONS: LVAD patients can be safely managed in the community. Patients who are discharged home experience better outcomes in both pre- and post-transplant survival. Successful outpatient management provides a strong foundation for the establishment of destination therapy within mechanical circulatory support programs in Canada.

Key Words: Cardiac surgery; Cardiovascular medicine; Heart transplantation; Mechanical circulatory support

In Canada, heart failure has reached epidemic proportions. It affects 500,000 Canadians and 50,000 new cases are diagnosed each year. The age-adjusted mortality rate is over 50% of all cancer deaths combined (1). Patients are considered to have advanced heart failure when, despite optimal medical therapy, they continue to have shortness of breath and fatigue at rest. Left ventricular assist devices (LVADs) are mechanical pumps that can be surgically implanted inside the body to take over the pumping action of the failing left ventricle. Implantation of an LVAD is a treatment, not a cure, and mortality on device support is high. Patients implanted with an LVAD face a six-month mortality rate of 35%, followed by 66% at one year (2). The Randomized Evaluation of Mechanical Assistance in the Treatment of Congestive Heart Failure (REMATCH) trial (3), a landmark trial examining the use of LVADs versus medical management in nontransplant-eligible patients, demonstrated that patients treated

Assistance ambulatoire chez des patients porteurs d'un dispositif d'assistance ventriculaire gauche : Expérience de l'Hôpital Général de Toronto

HISTORIQUE : La pose d'un dispositif d'assistance ventriculaire gauche (DAVG) est un traitement acceptable pour les patients atteints d'insuffisance cardiaque avancée. Les DAVG peuvent servir de solution temporaire en attendant la récupération ou la transplantation ou comme traitement définitif. Bien que le taux de morbidité des sujets porteurs d'un DAVG reste élevé, l'expérience donne à penser que les patients qui reçoivent leur congé présentent des résultats satisfaisants durant la période d'assistance et après la transplantation cardiaque.

MÉTHODE : Les auteurs ont procédé à une analyse rétrospective de 24 cas d'implantation de DAVG entre octobre 2001 et décembre 2006. Dix-neuf patients ont reçu le dispositif dans l'attente d'une transplantation et cinq, comme traitement définitif. Le suivi post-opératoire a été effectué de la manière habituelle, à la clinique de fonction cardiaque/DAVG de l'Hôpital Général de Toronto (Toronto, Ontario), et toutes les réactions indésirables ont été notées.

RÉSULTATS : La majorité des patients étaient des hommes âgés en moyenne de 44 ans et les sujets présentaient un diagnostic de cardiomyopathie dilatée (62 %). Dix-sept patients (71 %) ont reçu leur congé avec un dispositif; un est décédé, 14 ont reçu une transplantation, un a subi une explantation et un vit avec son DAVG dans la communauté. La survie post-transplantation a été de 93 % chez les patients ayant reçu leur congé à la maison, contre 40 % des sujets ayant reçu leur transplantation durant leur séjour hospitalier. Les patients ambulatoires ont passé 56 % de leur temps sous DAVG à la maison, avec 12 réadmissions seulement, totalisant 120 jours patients.

CONCLUSION : Les patients porteurs d'un DAVG peuvent être pris en charge dans la communauté sans danger. Les patients qui repartent avec leur dispositif présentent de meilleurs résultats sur le plan de la survie pré- et post-transplantation. Une prise en charge ambulatoire efficace constitue une base solide pour l'établissement du traitement définitif dans le cadre des programmes d'assistance circulatoire mécanique au Canada.

with an LVAD lived longer and had a significantly better quality of life than their medical counterparts; however, two-year survival was less than 30% in both groups.

The HeartMate XVE (Thoratec Corporation, USA) left ventricular assist system (LVAS) and the Novacor (WorldHeart Corporation, USA) LVAS are two long-term implantable systems approved for use in Canada (Figure 1). Each system consists of a large pulsatile blood pump that connects to a portable system controller. The system controller connects the pump to a power source via the driveline. The driveline exits the body in the upper right quadrant of the abdomen. LVADs can be driven electrically via alternating current power from the power base unit or from a pair of wearable rechargeable batteries. The HeartMate II rotary LVAD (Thoratec Corporation) (Figure 2) is believed to have longer durability (more than five years) and is currently under investigation at our centre as part of a multicentre

Heart Transplant Program, Peter Munk Cardiac Centre, Toronto General Hospital, University of Toronto, Toronto, Ontario

Correspondence: Dr Vivek Rao, 4N-464, Toronto General Hospital, 200 Elizabeth Street, Toronto, Ontario M5G 2C4. Telephone 416-340-3562,

fax 416-340-3337, e-mail vivek.rao@uhn.on.ca

Received for publication January 26, 2008. Accepted August 16, 2008

Figure 1 The HeartMate XVE (Thoratec Corporation, USA) left ventricular assist device. Reproduced with permission from Thoratec Corporation

clinical trial. Although the mechanism of the pump is different, the external components and routine care for patients are identical to those of the Heartmate XVE. Importantly, the HeartMate II device provides continuous flow, often resulting in recipients lacking a palpable pulse.

Literature on outpatient LVAD outcomes is limited, consisting of single-centre reports published in the early years of the collective LVAD experience. The largest North American experience was reported from Columbia-Presbyterian Hospital in New York City (New York, USA) (4) and consisted of 44 patients discharged home on the HeartMate VE (Thoratec Corporation). Total support time in this series was 4546 days, with a mean ($\pm$ SD) support duration of 103 ± 16 days. All outpatients were successfully bridged to transplant or explant, and spent the majority of support time at home. Device malfunction was the most common adverse event, with 46% of patients experiencing a minor malfunction and 6% experiencing a major malfunction. Worldwide experience and significant device enhancements have improved patient care and much of the literature is no longer relevant. In Canada, LVAD support has become an accepted standard of care for patients in advanced heart failure. Most centres recognize that LVAD patients can be safely and effectively managed in the community, and discharge patients home. However, no reports on patient outcomes have been published from Canadian centres. We reviewed our five-year experience with patients discharged from the hospital on LVAD support to determine the safety and efficacy of this practice among the Canadian patient population.

METHODS

Study population

Twenty-four consecutive patients had an LVAD implanted at the Toronto General Hospital (Toronto, Ontario) between October 2001 and December 2006. Before implantation, all patients had New York Heart Association class IV symptoms of heart failure – 19 (79%) required

Figure 2 The HeartMate II (Thoratec Corporation, USA) left ventricular assist device. Reproduced with permission from Thoratec Corporation

continuous intravenous inotropes and five (21%) required intra-aortic balloon pump. Devices implanted included 15 HeartMate XVE, seven Novacor LVAS and two HeartMate II devices. The study was approved by the Research Ethics Board at the University Health Network.

Eligibility criteria for LVAD implantation

Eligibility criteria for device implantation are outlined in Table 1. LVAD as a bridge to transplant was indicated in patients who were accepted and listed for heart transplantation. In the present sample, 19 (79%) patients were implanted as a bridge to transplant. Destination therapy was indicated in patients who were ineligible for heart transplantation due to comorbidities. The remaining five (21%) patients implanted for destination therapy were not eligible for a transplant due to refractory pulmonary hypertension ($n=3$) or a body mass index of greater than 35 kg/m^2 ($n=2$).

Preparation for discharge

The criteria for discharge were similar to others reported in the literature (5,6) and are outlined in Table 2. Once the patient and family demonstrated competence with their device, a series of hospital passes were implemented, from 4 h to overnight, to ensure they fully understood the information and were able to care for their device at home. Experience has shown that this process alleviates the fear of going home by gradually instilling confidence and reinforcing independence. When criteria were met, the patient was discharged home.

Patient follow-up

On discharge from the hospital, all patients were followed until transplantation or death in the heart function/LVAD clinic at the Toronto General Hospital. Two cardiologists with training in advanced heart failure, heart transplantation and LVADs attended the clinic. Visits occurred weekly and included a physical examination, investigation of the device, optimization of medical therapy and discussion of patient concerns. Routine echocardiographic

TABLE 1
Indications for left ventricular assist device support

1. A low-output state persists despite the use of at least 2 intravenous inotropic agents and/or intra-aortic balloon pump support. Hemodynamic parameters include:
 - Systolic blood pressure <80 mmHg;
 - Pulmonary capillary wedge pressure >20 mmHg; and
 - Cardiac index <2.0 L/min/m².
2. Left ventricular ejection fraction ≤25%
3. Mixed venous saturation <60%
4. Rising serum creatinine in association with oliguria
5. Imminent end-organ failure

TABLE 2
Criteria for discharging left ventricular assist device (LVAD) patients home

1. Documentation of patient and companion training:
 - Changing power sources and charging batteries;
 - Device alarms;
 - Changing the system controller;
 - What to do in an emergency; and
 - Stabilizing the driveline and changing the driveline dressing
2. List of emergency contacts
3. Letter for emergency medical services personnel (copy faxed to central control and copy with patient) providing:
 - Description of implanted LVAD;
 - What to do in an emergency;
 - Request for preferred transfer to the Toronto General Hospital (Toronto, Ontario); and
 - How to contact us
4. Letter for local emergency room staff (copy faxed to local emergency room and copy with patient)
5. Completion of the Patient Home Electrical Safety Guidelines:
 - Ensuring wiring up to code for equipment; and
 - Letter to electrical company requesting priority power restoration in case of power failure
6. Outpatient appointment schedule and routine echocardiograms booked
7. Signed statement of receipt and agreement for LVAS equipment

LVAS Left ventricular assist system

assessments occurred monthly or when clinically indicated, and included evaluation of inflow valve regurgitation, left and right ventricular function, and estimation of right ventricular systolic pressure. Patients with a right ventricular systolic pressure of greater than 45 mmHg were routinely started on sildenafil 12.5 mg three times per day with up-titration as needed. When patients were on optimal medical therapy and there were no active issues, visits were decreased to biweekly or monthly.

Outcomes of support

Duration of support, perioperative mortality and adverse events were evaluated based on whether the patient was in the hospital or discharged home at the time of transplant, explant or death. Definitions of adverse events are described in Appendix 1.

Statistical analysis

Data are reported as mean ± SD. All data were analyzed using SAS version 8.2 (SAS Institute Inc, USA).

RESULTS

Baseline patient characteristics

Twenty-four patients had an LVAD implanted over the duration of the study. Pre-implant patient characteristics are reported in Table 3. The

TABLE 3
Patient characteristics

Characteristic	All patients (n=24)	Discharged patients (n=17)
Age, years	44±14.3 (21–67)	43.4±13.9 (21–67)
Male sex, n (%)	21 (87)	15 (88)
Etiology, n (%)		
Dilated	15 (62)	11 (65)
Ischemic	6 (25)	3 (18)
Other	3 (12)	3 (18)
LVAD score, mean (range)	2.1 (0–8)	3 (0–5)
Bloodwork		
Serum creatinine, µmol/L	135	135
Serum sodium, mmol/L	134	134
Serum albumin, g/L	33.8	33.8
NYHA class IV, n (%)	24 (100)	17 (100)
LVEF, %	19.8±5.86 (10–38)	20.1±5.55 (13–38)
PAH, n (%)	10 (42)	6 (35)
IABP, n (%)	5 (21)	3 (18)
Intravenous inotropes, n (%)	19 (79)	10 (58)
Intention to treat, n (%)		
Bridge to transplant	19 (80)	15 (88)
Destination therapy	5 (20)	2 (12)
Implanted device		
HeartMate XVE	15 (62)	12 (71)
Novacor	7 (29)	4 (23)
HeartMate II	2 (8)	1 (6)
Support duration, days	141±152.8 (8–567)	180±165.5 (22–567)

Data presented as mean ± SD (range) unless otherwise indicated. HeartMate XVE and HeartMate II manufactured by Thoratec Corporation, USA. Novacor manufactured by WorldHeart Corporation, USA. IABP Intra-aortic balloon pump; LVAD Left ventricular assist device; LVEF Left ventricular ejection fraction; NYHA New York Heart Association; PAH Pulmonary arterial hypertension (right ventricular systolic pressure >45 mmHg)

majority of patients were men (n=21), with a mean age of 44±14 years and a diagnosis of dilated cardiomyopathy (62%). Cumulative LVAD support time for the entire sample was 3647 days, with an average of 141±153 days per patient.

Survival to hospital discharge

Seven patients (29%) remained in the hospital for the duration of their support. Cumulative LVAD support time for the inpatient group was 369 days with an average of 47±43 days. Two patients had LVAD support withdrawn within 30 days of implant and died in the intensive care unit, one from multisystem organ failure and the other from a major device malfunction. Five patients were transplanted during their initial hospital stay. Two patients died from acute rejection immediately following heart transplantation. One-year post-transplant survival in the inpatient group was 40%.

Outpatient survival

Seventeen patients (71%) met discharge criteria and went home. The cumulative support time after hospital discharge was 3278 days with an average of 180±165 days. Fifteen outpatients (88%) survived until transplant or explant. Fourteen patients were successfully bridged to cardiac transplantation, one patient showed signs of myocardial recovery and had her device explanted, one patient died from a cerebrovascular accident and the other remains at home on support. One-year post-transplant or -explant survival in the outpatient group was 93%. Patients supported for more than three months spent at least 70% of their support time at home. This increased to 94% for patients supported for more than one year (Table 4).

TABLE 4
Duration of support and time at home

	Duration of support, days				
	≤90	91–180	181–270	271–365	≥366
Patients, n	6	6	2	1	2
Mean support time, days	53	122	197	271	522
Time at home, %	29	70	74	90	94

Outpatient complications

Complications occurring in the community were low and are reported in Table 5.

Infection: The overall incidence of infection was 29%. Four patients experienced a localized driveline site infection that responded to a one-week course of oral antibiotics. Only one driveline infection was clinically relevant, requiring readmission to hospital for initiation of intravenous antibiotics. One patient developed a pocket infection requiring readmission to the hospital. His pocket was incised and drained, and vacuum-assisted closure and intravenous antibiotics were initiated. Both hospitalized patients were discharged home on home care for their intravenous antibiotics and dressing changes.

Device malfunctions: Five patients experienced a device malfunction. Four patients experienced a nonpump failure involving the system controller. Controllers were changed during urgent outpatient visits and did not require readmission to the hospital. One patient experienced pump failure of his HeartMate XVE. He was readmitted as a precaution on day 546 of support and eventually required pneumatic support of his failed device. No patient experienced hemodynamic compromise due to a device failure.

Neurological dysfunction: Two patients experienced an acute neurological event while on support and required readmission. One patient experienced a large cerebrovascular accident, was not expected to survive and, after discussion with the family, LVAD support was withdrawn. The other patient had a subarachnoid hemorrhage requiring readmission to the intensive care unit for ventilation and hemodynamic support. He recovered from his event and was discharged home following a 43-day hospitalization. He subsequently underwent heart transplantation and remains well in the community.

DISCUSSION

The purpose of the present study was to describe the outcomes of patients living in the community on LVAD support. During the five years that the study assessed, our program provided 3647 days of support to 24 patients, with 3278 days (equivalent of nine years) in the community. Overall survival to transplant or explant of LVAD-supported outpatients in our program was 90%. Our success reflects strict implant criteria established to ensure appropriate patient selection. As our team gained experience with LVAD support, we began to accept patients with higher preimplant acuity.

Seventy-one per cent of LVAD-supported patients met discharge criteria and were discharged home. Our rates are consistent with those reported in the literature (7-9) and all of our bridged patients survived until transplantation. This is noteworthy for two reasons. To begin with, only five years previously, patients requiring intravenous inotropic support before their heart transplant would have been managed in a coronary care unit until their transplant surgery. Many in our sample would not have survived. Reallocating resources to a ventricular assist device program allows patients to be implanted with a device, proceed through their hospital stay and go home until the time of transplant. At the same time, throughput in the coronary care unit is improved and more patients are able to access the care they need. Subsequently, patients discharged from the hospital are able to wait for their heart transplantation at home. The average wait time from implant to transplantation was 180 days, consistent with reports on optimal timing to transplant for patients on LVAD support (10).

TABLE 5
Outpatient complications

	Discharged patients, n	Readmission length
		of stay, days
Driveline or pocket infection	5	22
Neurological dysfunction		
CVA	1	3
SAH	1	43
Device malfunction		
Nonpump failure	4	
Pump failure	1	21
Other		
Diagnostics	1	4
CHF management	2	18
INR management	1	2
Non-LVAD	1	7
Total	17	120

CHF Congestive heart failure; CVA Cerebrovascular accident; INR International normalized ratio; LVAD Left ventricular assist device; SAH Subarachnoid hemorrhage

Complications in the community were fewer than expected and were handled without significant consequence to the patient. Driveline infection is the most commonly reported complication, both in the literature and in our sample (2,4,7,8). In the outpatient clinic, we managed 75% of the driveline infections with a single course of oral antibiotics. Device malfunctions were the second highest complication in our sample. One device stopped after 550 days of support. We identified the potential for device malfunction early and managed the patient successfully in the community for an additional six months, with readmission only when device failure was imminent. Overall, 12 patients were readmitted to the hospital for an additional 120 patient days and two of these accounted for 77% of the readmission days.

We were very cautious about our discharge criteria for the first five patients. Patients spent at least one month in the hospital before discharge home to ensure they were able to care for their device at home. After five years, our target for discharge was 14 days. To achieve this, we provided more of our teaching before implantation and frequently repeated training sessions, scheduled training with the patient and family together, and initiated passes earlier. Our experience also informed us of what issues to anticipate when patients go home, such as problems with sleeping, activity, pain and discomfort. We are able to prepare the patient and family regarding these issues before discharge and contact them daily to discuss these issues or any new concerns.

In Canada, LVAD programs exist in British Columbia, Alberta, Ontario, Quebec and Nova Scotia. Each Canadian program has a dedicated coordinator to assist with the coordination and communication of care between local care providers and the LVAD team. Local care providers include home care nurses for assistance with routine dressing changes and monitoring of vital signs in the initial postdischarge period, family physicians for age-appropriate routine health screening, vaccinations and management of non-LVAD-related health problems, and outpatient laboratories for international normalized ratio monitoring. Patients may also present to their local emergency room for urgent LVAD-related problems such as arrhythmias, infection or stroke. Each patient is instructed to carry 24 h emergency contact information so local health care providers can contact the LVAD team for urgent patient issues. When two of our patients presented unconscious to their local emergency rooms, we were contacted within 2 h of presentation. Working with the local hospital, we were able to provide them with the necessary information to help them do their job while facilitating a transfer to our facility. In both instances, the local emergency rooms were able to arrange diagnostic computed tomography

scans, begin appropriate treatment and arrange transfer to our facility within 6 h of presentation.

CONCLUSION

Our results suggest that patients with an implantable LVAD can be safely supported in the community. Patients supported in the community had better transplant outcomes than those transplanted during their hospital stay and complications were less frequent than expected. Improvements in pump technology and patient care management strategies suggest the number of patients living in the community on support will increase over time. Coordination and communication between the LVAD team and local care providers will ensure LVAD patients receive the care they need in a safe and efficient manner. Finally, the successful outpatient management of bridge-to-transplant patients provides a strong foundation for the establishment of destination therapy within mechanical circulatory support programs in Canada.

APPENDIX 1

Definitions of adverse events

Adverse event	Definition
Infection	A clinical infection accompanied by pain, fever, drainage and/or leukocytosis requiring treatment with either oral or intravenous antibiotics. A positive culture from the infected site should be present
Driveline and/or pocket infection	A positive culture from the tissue surrounding the driveline or from tissue surrounding the external housing of the pump implanted in the body
Pump, inflow or outflow tract infection	A positive culture from surfaces of the pump that contact blood
Sepsis	Evidence of systemic involvement by infection with two positive blood cultures and/or hypotension
Other infections	Infection localized to any organ system or region without evidence of systemic involvement

Data from reference 11

REFERENCES

1. Naylor CD Slaughter PM. Cardiovascular Health and Services in Ontario: An ICES Atlas. Toronto: Institute for Clinical Evaluative Sciences, 1999.
2. Deng MC, Edwards LB, Hertz MI, et al. Mechanical circulatory support device database of the International Society for Heart and Lung Transplantation: Third annual report – 2005. *J Heart Lung Transplant* 2005;24:1182-7.
3. Rose E, Gelijns A, Moskowitz A, et al. Long-term mechanical left ventricular assistance for end-stage heart failure. *N Engl J Med* 2001;345:1435-43.
4. Morales D, Catanese K, Helman D, et al. Six-year experience of caring for forty-four patients with a left ventricular assist device at home: Safe, economical, necessary. *J Thorac Cardiovasc Surg* 2000;119:251-9.
5. Andrus S, Dubois J, Jansen C, Kuttner V, Lansberry N, Lukowski L. Teaching documentation tool: Building a successful discharge. *Crit Care Nurse* 2003;23:39-48.
6. Bond A, Bolton B, Nelson K. Nursing education and implications for left ventricular assist device destination therapy. *Prog Cardiovasc Nurs* 2004;19:95-101.
7. Morgan JA, John R, Rao V, et al. Bridging to transplant with the HeartMate left ventricular assist device: The Columbia Presbyterian 12-year experience. *J Thorac Cardiovasc Surg* 2004;127:1309-16.
8. Frazier OH, Ros EA, Oz MC, et al; for the HEartMate LVAS Investigators. Multicenter clinical evaluation of the HeartMate vented electric left ventricular assist system in patients awaiting heart transplantation. *J Thorac Cardiovasc Surg* 2001;122:1186-95.
9. Miller LW, Pagani ED, Russell SD, et al; for the HeartMate II Clinical Investigators. Use of a continuous-flow device in patients awaiting heart transplantation. *N Engl J Med* 2007;357:885-96.
10. Gammie JS, Edwards LB, Griffith BP, Pierson RN III, Tsao L. Optimal timing of cardiac transplantation after ventricular assist device implantation. *J Thorac Cardiovasc Surg* 2004;127:1789-99.
11. Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS). Adverse Event Definitions – Appendix A. Manual of Operations. <www.uab.edu/ctrsearch/intermacs/document> (Version current at October 25, 2007).