End-stage heart failure and mechanical circulatory support: feasibility of discharge from hospital

A. Oosterom, N. de Jonge, J.H. Kirkels, B.F.M. Rodermans, E. Sukkel, C. Klöpping, F. Ramjankhan, J.R. Lahpor

Background. Due to the shortage of donor hearts, mechanical circulatory support is increasingly being used as a bridge to transplantation. In order to allow for more widespread use of ventricular assist devices it is mandatory that patients are not continuously hospitalised. We present the results of our experience with patients with end-stage heart failure, discharged from hospital after implantation of a ventricular assist device and followed in an outpatient setting.

Methods. After an intensive training and education programme, focusing on the management of the percutaneous driveline and instructions on how to handle in case of an alarm or malfunction of the device, patients were discharged. They were followed in the outpatient department. All regular and unplanned visits were registered, including readmissions.

Results. Twenty-seven patients treated with a ventricular assist device were discharged from hospital. There were 37 extra visits, of these, 27 were device related resulting in 21 readmissions (0.78/patient). We treated eight infectious episodes in four patients, all device related. Furthermore seven thromboembolic episodes occurred in four patients. One patient died because of multiorgan failure seven weeks after he was readmitted with an

urosepsis. In our experience of 11.4 patient years at home while on the device, only 5% of the time was spent in hospital for complications. In comparison with patients on an assist device who stayed in hospital until transplantation, there were no more complications.

Conclusion. This study demonstrates that patients with end-stage heart failure, treated with a ventricular assist device, can be safely discharged from hospital, with an acceptable rate of readmissions. It results in a fair quality of life, with a high degree of independence of the patient. (*Neth Heart J* 2007; 15:45-50.)

Keywords: heart failure, mechanical circulatory support, discharge, ventricular assist device

Heart failure is a rapidly growing problem in health-care, associated with high morbidity and mortality rates. Despite improvements in pharmacological treatment, the prognosis still remains very poor.^{1,2} In patients with end-stage heart failure, heart transplantation is currently the only option that provides both a better life expectancy and a substantially better quality of life.³ However, the number of heart transplantations is severely limited by the increasing shortage of donor hearts. In the Netherlands, 35 to 45 heart transplants used to be performed every year; this number has, however, dropped to 25 to 30 in the last two years, despite all the measures to improve donation and despite the tendency to accept hearts from older donors and more haemodynamically unstable donors.

The low number of heart transplantations is in sharp contrast with the growing number of patients with end-stage heart failure. This discrepancy has resulted in long waiting times and consequently high (15-20%) mortality on the transplantation waiting list. Moreover, many potential transplant candidates do not even reach the waiting list, because of acute haemodynamic deterioration. In those patients mechanical circulatory support can play an important role as a bridge to transplantation. Implantable left and bi-

A. Oosterom
N. de Jonge
J.H. Kirkels
B.F.M. Rodermans
E. Sukkel
C. Klöpping
F. Ramjankhan
J.R. Lahpor

Heart Lung Centre Utrecht, University Medical Centre Utrecht, Utrecht, the Netherlands

Correspondence to: A Oosterom
Heart Lung Centre Utrecht, University Medical Centre Utrecht,
PO Box 85500, 3508 GA Utrecht, the Netherlands
E-mail: a.oosterom@umcutrecht.nl

Figure 1. Schematic diagram of the HeartMate XVE left ventricular assist device. The inflow cannula is implanted in the left ventricular apex. The outflow graft is connected end-to-side to the ascending aorta.

ventricular assist devices such as the HeartMate and Thoratec (Thoratec, Pleasanton Calif.) and the Novacor (WorldHeart, Ottawa) are the most suitable devices for this purpose, because they can support the failing heart for months or even years.

These are pulsatile devices with a maximum pump flow of 8 to 10 l/min depending on left ventricular filling. The HeartMate XVE and Novacor are electricaly driven pumps, which are fully implanted, allowing complete mobilisation of the patient. Blood enters the pump through a cannula which is inserted in the left ventricular apex and is pumped by the device through a vascular prosthesis to the ascending aorta (figure 1). Bioprosthetic valves in both cannulas provide uni-directional flow.

A previous model of the HeartMate was pneumatically driven, like the Thoratec PVAD (pneumatic) and IVAD (implantable) devices. The Thoratec IVAD is an implantable device, in contrast to the Thoratec PVAD, which is placed extra-abdominally. Mobilisation with the paracorporeal Thoratec device is still possible, although partly hampered by the pump and the driving console. The Thoratec PVAD/IVAD is not only be used as a left ventricular assist device, but also as a biventricular assist device (figure 2). In this set-up two independent serial pump systems are applied, one taking blood through a cannula from the right

atrium or right ventricle, delivering to the pulmonary artery through a vascular graft and the other from the left ventricle to the ascending aorta.

Since the start of the bridge to transplantation programme in our hospital in 1993, we have treated 76 patients with refractory end-stage heart failure with a ventricular assist device. The results in this selected group of very sick patients are encouraging with 75% of the patients being successfully bridged to transplantation.⁴ The functional recovery in these patients after implantation of a ventricular assist device is remarkably good and comparable with the situation after heart transplantation.⁵

Serum BNP levels completely normalise after implantation of an assist device, which suggests that they result in complete haemodynamic unloading.⁶ In the early years of mechanical support, all patients remained hospitalised until they were transplanted. Clearly, this was not an ideal situation for the patient and his/her relatives and furthermore this resulted in important logistical problems due to the long-term occupation of hospital beds. Because of the highly specialised novel therapy and lack of knowledge about the long-term complications at that time it did not seem justified to discharge the patients from hospital. Later on, with growing experience worldwide and further refinement of the assist devices, discharge from hospital and follow-up in an outpatient setting seemed feasible, and was gradually introduced.

The aim of this study is to investigate whether this policy of discharge from hospital with a ventricular assist device is feasible and does not lead to excess mortality or other unexpected complications. The results of this cohort were compared with those of the patients treated with mechanical circulatory support before we started our discharge programme.

Figure 2. A Thoratec Paracorporeal Bi-VAD in situ.

Methods

Of the 77 patients with refractory end-stage heart failure who underwent implantation of a ventricular assist device in our centre, the first 25 remained hospitalised until transplantation. We registered complications in these patients, while in hospital, and used these for comparison.

In 2000 we started our discharge programme. Since then, 52 patients have been treated with an assist device. Of these patients, four recent implants are still hospitalised, because they are not yet able to go home. Six patients died after implantation; four because of multiorgan failure, one due to ischaemic colitis and one due to a massive cerebral infarction.

Of the remaining 42 patients, eight patients could not be discharged because of ongoing driveline or pocket infections or thromboembolic complications. So, in principle, 34 patients could be discharged from hospital. However, for seven patients this proved not to be possible at that time because the patients or relatives were too anxious to cope with potential problems and the handling of the device.

The remaining 27 patients (64%) could be discharged after intensively educating the patient and relatives. Even when the patient apparently lacked direct social support at home, it was possible to discharge these patients.

Our instruction programme starts in the first week after leaving the intensive care unit. We teach the patient and relatives how the VAD system runs under normal conditions as well as how to handle in case of an alarm or malfunction of the device. In case of malfunction they have to be capable of changing the driving console, reverting to hand-pumping to maintain the circulation.

Daily care of the percutaneous driveline is an important part of our education programme, because driveline infections are an important problem leading to high morbidity and sometimes mortality.

When the patient has recovered from the operation and is fully mobilised, daytrips back home are undertaken, under the escort of a technician and a nurse practitioner, allowing the patient to get used to life at home while on an assist device. The local ambulance station and the general practitioner are contacted and informed of the time of discharge and what to do in case of an emergency. A 24-hour telephone help line is provided for outpatients, in case of technical or medical problems. Once every four weeks the patients visit our outpatient clinic where they are seen by the nurse practitioner and the VAD technician, under medical supervision, to monitor their progress. Once every three months they are also seen by the cardiologist, or more often if it is necessary. All patients participate in a supervised training programme while they are at home.

Results

Of the 27 patients discharged while on mechanical circulatory support, 20 received a HeartMate device (4

pneumatic, 16 electric), two a Novacor device and five a pneumatic Thoratec device (two with a paracorporeal Bi-VAD and two with a paracorporeal LVAD and one with an implantable Bi-VAD). At this moment, 22 have had their transplants and four are still waiting at home; one patient died of a urosepsis, after readmission.

The patients were discharged 56 ± 15 days (range 34–81) after the implantation of the device. The mean period while on circulatory support at home was 160 ± 106 days (range 3–428). So, in total, our cumulative experience with patients on an assist device in an outpatient setting is 4157 days (11.4 patient years).

Apart from the scheduled visits to our hospital, there were 37 extra visits because of new complaints. Of these 37 visits, ten were unrelated to the assist device: respiratory infections (3), gout, hyperthyroidism, suspected gallstone, rectal bleeding, gastritis, high fever after influenza vaccination and urosepsis. In four of these cases the patient had to be admitted.

Of the device-related extra visits (27), ten of these problems could be managed in the outpatient setting. The reasons for these visits were improper alarm (1), high pump rate (1), haemolysis (2), driveline infections (4), probable TIAs causing temporary impaired vision (1) and renal infarction (1).

In five cases patients were admitted for inappropriate alarms. After changing the driving console they could be discharged again. In 12 cases, patients were admitted for other reasons: device-related infections (4), thromboembolic complications (5), and a strange sound coming from the device, haemolysis, and ileus.

Of the 27 VAD patients discharged from hospital, 14 were never readmitted. The remaining 13 patients had to be readmitted 21 times (0.78 admission/patient; 1.8 admissions/patient year). In 19 cases, the patient could be discharged again after 11 ± 10 days (range 1–32) (figure 3). The total number of readmission days was 210, only 5% of the total experience of patient days at home. Two patients could not be discharged because of a non-device-related infection and another felt too unsafe to go home after two cerebral infarctions.

Figure 3. Number of readmissions per patient.

Table 1. Complications after discharge from hospital in patients with mechanical circulatory support.

	Treatment in outpatient setting	Readmission
Device-related complications	10	17
Improper alarms	1	5
High pump rate	1	
Haemolysis	2	1
Infections		
- Pocket/driveline	4	3
- Systemic		1
Thromboembolic complications	1 Renal infarction	2 CVAs
	1 Retinal embolus	1 Retinal embolus
		1 TIA
		1 Blood clot inlet
Ileus		1
Strange sound from device		1
Non-device-related problems	6	4
Respiratory infection	3	
Gout	1	
Hyperthyroidism	1	
Suspected gallstones	1	
Rectal bleeding		1 (under ascal)
Gastritis		1
High fever (after vaccination)		1
Urosepsis		1

CVA=cerebral vascular accident, TIA=transient ischaemic attack.

Infections

In our cohort of 27 discharged patients, one patient was readmitted three days after discharge with a severe urosepsis probably related to the suprapubic catheter, which was inserted because of prostate hypertrophy. This patient died seven weeks later due to multiorgan failure. Furthermore there were eight infections in four patients, all device related. These consisted of six driveline or pocket infections and two systemic infections. Two patients, both on a HeartMate VAD, were readmitted because of fever and positive blood cultures with *Staphylococcus aureus*. They were treated with intravenous antibiotics and were transplanted after 14 and 27 days, respectively. Another patient, with a Novacor device, was readmitted twice for pocket infections, requiring surgical exploration (table 1). Furthermore, four episodes of localised pocket infection were seen in patients with a HeartMate VAD, one of them was readmitted for surgical exploration.

Thromboembolic complications

In this group, seven thromboembolic episodes were reported in four patients. One patient with a paracorporeal Thoratec LVAD suffered two cerebral infarctions, one patient with an implantable Thoratec BiVAD suffered two episodes of transient cerebral ischaemia leading to impaired vision, and in one patient with a pneumatic

HeartMate the diagnosis of a renal infarction and transient central facialis paresis was made (table 1). One patient with an electrical HeartMate demonstrated low flow because of a clot on the inlet valve of the device, diagnosed with echo. All of these patients were successfully transplanted and do not have any limitations caused by the thromboembolic complications. All of them are working fulltime or attending school.

Complications in hospitalised patients

For comparison, we investigated all complications in the 25 patients treated with a VAD before we started our discharge programme (1993-2000). Of these 25 patients, five died perioperatively due to multiorgan failure. One patient died after 164 days because of mechanical failure of the device. Another patient died 433 days after implantation due to a cerebral embolus.

The 20 patients who survived the perioperative period were supported for 175 ± 113 days; a total experience of 3799 days while on the device, or 10.4 patient years. In these 20 patients, there were three thromboembolic episodes in two patients. Twelve episodes of device-related pocket infections were noted in eight patients. Furthermore, three episodes of non-device-related infections in two patients were registered (two urinary tract infections and one respiratory tract infection).

In four patients reconstructive surgery of the abdominal wall had to be performed because of imminent perforation.

In this group of 20 LVAD patients it was remarkable that we had six episodes of mechanical failure in six patients: this resulted in the death of one patient. The other five mechanical failures could be handled by replacing the driving console, without further sequelae for the patient. All mechanical failure involved the pneumatic HeartMate device; nowadays newer systems have not shown these problems.

Discussion

In this study, we have demonstrated that discharging patients with a ventricular assist device from hospital is safe and feasible and did not result in mortality while at home. On 21 occasions a patient was readmitted. Almost all could be discharged again, apart from one patient with a non-device-related infection and one suffering from two cerebral infarctions, after which discharge was not possible because of anxiety on the part of the patient and his spouse. This resulted in a very long admission period of eight months until transplantation.

For comparison we used the cohort of patients with a ventricular assist device before we started our discharge programme (1993-2000). Although this is a historical comparison we think it is allowed, because the patients and devices do not differ much before and after 2000, apart from some technological improvements.

Others have also demonstrated the feasibility of discharge, although readmission rates vary considerably between centres (2.5/patient vs. 0.82/patient).^{7,8}

The main complications after VAD insertion are thromboembolic and infectious problems. What is remarkable in this small series of patients is that two out of five patients with a Thoratec device were responsible for four thromboembolic episodes, despite intensive anticoagulation with aspirin and coumarins. In contrast, in our patients discharged with a HeartMate, two out of 20 suffered three thromboembolic complications, while only on a low-dose aspirin. This low incidence of thromboembolic complications with the HeartMate device has already been reported.^{9,10}

In four of the 27 patients we had to deal with eight infectious episodes related to the assist device. Most of them were treated with antibiotics and in four cases surgical exploration was necessary. In five cases we had to readmit the patient for his treatment. Six of the eight infectious episodes were noted in patients with a HeartMate device. The high incidence of pocket infections, especially in these patients, is thought to be related to the constant to and fro movement of the driveline, resulting in chronic inflammation of the skin and subcutaneous tissue around it. Since the introduction of an abdominal immobilisation binder, limiting this erosive motion of the driveline, the incidence of driveline infections has dramatically

decreased. The two other infectious episodes occurred in patients with a Novacor device. Remarkably the five patients with a Thoratec assist device did not show any infection problems.¹¹⁻¹⁴

Apart from complications and readmissions it is important to consider the patient's quality of life while on a ventricular assist device. As reported previously, exercise tolerance while on the device is good and almost comparable to that after heart transplantation.⁵ Although we did not perform structured quality of life analysis in this group, all patients were affirmative of a good quality of life while at home on the device.

The only exception was the patient who suffered two cerebral infarctions. Other studies have confirmed the good quality of life while at home.^{15,16} The general feeling of a good quality of life in our patient group is further supported by the fact that several patients judged themselves capable of driving a car. The Dutch authorities (CBR) approved this for the patients with an electric HeartMate. It is evident that this improved the feeling of independence of these patients enormously.

As a consequence of the decreasing number of donor hearts, an important problem is the increase in waiting time until transplantation. When we started mechanical support in 1993, the mean waiting time while on the device was 118 days. In the past five years the mean waiting time has increased to 225 days, with an extreme of 557 days. The further decrease in donor hearts in the past two years in the Netherlands will probably lead to an even longer duration of support while on the device. Therefore it is very important that these patients can live a reasonably normal life at home, awaiting transplantation.

Conclusion

This study demonstrates that patients with end-stage heart failure, treated with a ventricular assist device, can be safely discharged from hospital without increased mortality and with a low rate of readmissions (0.78/patient). It results in an acceptable quality of life, with a high degree of independence of the patient. It is hoped that further technical improvements in the devices in the future will allow even more extended periods of mechanical support as a bridge to transplantation, or even as an alternative to transplantation. ■

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