Case report

Patients supported for over 4 years with left ventricular assist devices

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Received 11 June 2005; received in revised form 14 November 2005; accepted 2 February 2006
Available online 23 March 2006

Abstract

Ventricular assist device implantation has become an established therapy in adults and children for bridging to heart transplantation or to aid myocardial recovery. Recently, implantation of left ventricular assist devices as definitive therapy has been recognized as a better option than pharmacological treatment in patients who are not candidates for heart transplantation. This study presents our institution’s experience with five patients successfully supported by two different left ventricular assist devices for over 4 years. This unique experience shows that left ventricular assist device support can be extended beyond 4 years with good quality of life and low risk, making it a good alternative for non-transplant candidates.

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Keywords: Left ventricular assist device; Heart transplantation; Non-transplant candidate; Heart failure; Destination therapy

1. Background

Implantation of ventricular assist devices has become an established therapy in adults and children for bridging to heart transplantation or to aid myocardial recovery. In most patients, the device remains in place for several months, due to the length of the waiting time for a donor organ, or until the patient’s own heart recovers [1]. Recently, implantation of left ventricular assist devices (LVADs) as a definitive therapy has been recognized as a better option than pharmacological treatment [2] in patients who do not qualify for subsequent heart transplantation because of contraindications or who decline heart transplantation. However, the durability of the devices and the long-term quality of life remain crucial considerations for definitive therapy.

Between January 2000 and May 2005, 211 patients were supported with an LVAD in our institution (excluding those with LVADs implanted for post-cardiotomy heart failure). Of these 44 received an LVAD with the intention-to-treat being definitive. We report data from five of these patients who have survived for longer than 4 years on continuous LVAD support.

2. Case reports

2.1. Patient 1

In a 56-year-old woman, a tumor of the hypophysis led to acromegalia and cardiomegaly. She presented with poor cardiac function despite triple inotropic medication (left ventricular end diastolic diameter 102 mm; ejection fraction 10%) and in cardiogenic shock, with mean pulmonary artery pressure over 40 mm Hg and serum creatinine of 2 mg/dl. A Novacor LVAD (WorldHeart Inc., Oakland, CA, USA) was urgently implanted. The post-operative course was uneventful and the patient was discharged home. Since the tumor is benign and slow-growing and echocardiographic studies showed insufficient decrease of left ventricular end diastolic diameter and no increase of left ventricular contractility, heart transplanta-
tion was considered to be an option but the patient opted to stay on the assist system. During support, radiation therapy of the tumor was performed. On support, the patient had to be readmitted to hospital nine times, three times for optimization of the anticoagulation therapy, three times because of infection of the drive line exit site, once for repair of a defective cable, once for a non-device related reason and once for device exchange. She performs housework as before surgery and is highly satisfied with her quality of life with the device. Monitoring of the wear of the pump bearings by measurement of the solenoid tuning (gain) and energy changes (spring latch current) [3] is performed during each ambulatory visit by a company technician. After abnormal bearing function was detected the device was electively replaced using femoro-femoral cardiopulmonary bypass without repeat sternotomy 4 years and 10 months after implantation, which is the longest support time for an implantable Novacor LVAD without pump exchange worldwide to date. As of June 1, 2005, the patient has been on mechanical support for 5 years and 1 month. During this period, she has spent only 12% of the time in hospital, including the hospital stay for device exchange.

2.2. Patient 2

A 50-year-old obese man (height 178 cm, weight 139 kg, BMI 43.9 kg/m²) had low cardiac output due to dilative cardiomyopathy despite treatment with three different inotropes. He presented elevated serum creatinine of 1.2 mg/dl and mean pulmonary pressure of over 50 mm Hg. The Novacor LVAD was implanted as an emergency procedure, the post-operative course was uneventful except for pocket bleeding requiring surgical intervention and the patient was discharged home. The patient was only able to reduce his weight to 120 kg, which was still considered to be too high for him to be listed for heart transplantation. Post-discharge he learned to ride a motorcycle. The left ventricle did not recover and remained enlarged, with poor contractility. He was admitted once for a cable defect, which was repaired. The second admission was for cardiogenic shock due to ventricular fibrillation requiring cardiopulmonary resuscitation 3 years after surgery. After the patient recovered from right heart failure and multi-organ failure resolved, an automated cardioverter-defibrillator was implanted and he was again discharged home. Despite weight reduction to 108 kg, obesity continued to preclude his active listing for heart transplantation. His advanced age precluded heart transplantation. Two years and 1 month later, malfunction of one of the pusher plates was shown by a black deposit in the vent line and the pump was exchanged, as in the two previous Novacor patients. The patient was discharged home, still refusing heart transplantation. Four months later, he was readmitted for treatment of acute pancreatitis. Two years after device exchange (after over 4 years on the device), he suffered a cerebral thromboembolic event due to an anticoagulation disorder (malfunction of the home INR assessment device). He recovered without neurological deficits, but decided to be listed for heart transplantation. As of June 1, 2005, he is still on the urgent waiting list and has been on mechanical support for 4 years and 11 months. He has been on out-of-hospital LVAD support for 94% of his total support time.

2.4. Patient 4

A 72-year-old multimorbid man with end-stage heart failure caused by ischaemic cardiomyopathy after previous coronary artery bypass grafting suffered recurrent episodes of cardiac decompensation requiring intubation and inotropic support. Although he fully recovered from decompensation, he continued to be inotropic-dependent. He was offered the chance of LVAD implantation as a permanent measure, to which he agreed. A Berlin Heart EXCOR LVAD (extracorporeal pneumatically driven ventricular assist device, Berlin Heart AG, Berlin, Germany) was implanted through a left lateral sternotomy, as described previously [4]. The patient recovered slowly but uneventfully and was discharged home, where he was able to participate in family and social life. His advanced age precluded heart transplantation. After surgery he was readmitted nine times, twice for infected cannulas, once for diarrhoea, once for pump exchange due to visible thrombus formation in the extra-corporeal pump and five times to his local hospital for fever of unknown origin. After 4 years and 4 months of good quality of life and being satisfied with his situation on the device, having spent 94% of the time at home, he underwent...
urgent surgery for anal fissures. Post-operatively, he suffered from pneumonia and later died of septic multi-organ failure.

2.5. Patient 5

A 68-year-old man with ischaemic cardiomyopathy and previous cardiac surgery performed through a median sternotomy had continuous deterioration of his cardiac function. On admission, he presented in severe cardiogenic shock with acidosis, anuria (serum creatinine 6.2 mg/dl) necessitating haemofiltration and a mean pulmonary pressure of 50 mm Hg. Cardiogenic shock progressed despite use of the intra-aortic balloon pump and high-dose therapy with four inotropic drugs (including epinephrine). A Berlin Heart EXCOR LVAD was implanted, as described for patient 4, as a rescue procedure. After a slow but uneventful recovery, the patient was discharged home, where he was able to participate in everyday life. Heart transplantation was not an option because of his advanced age. After surgery, he was readmitted 10 times, twice for infected cannuas, three times for pump exchange and five times for other reasons. As of June 1, 2005, he has been on mechanical support for 4 years and 3 months, with 85% of the time spent at home, where he is enjoying good quality of life and is fully satisfied with the situation.

3. Comments

This study presents the largest single centre experience with patients successfully treated by LVAD for over 4 years. Despite marked progress in pharmacological therapy and mechanical circulatory support, heart transplantation remains the gold standard in the treatment of patients with end-stage heart failure. However, the shortage of donor organs and the growing numbers of older patients with end-stage heart failure are stimulating the search for new options [5]. Although the multi-centre REMATCH trial showed superiority of LVAD treatment over medical therapy, none of the 68 patients survived longer than 3.5 years [6]. Our unique experience with two different devices implanted in five patients shows that support with left ventricular assist devices can be extended beyond 4 years with good quality of life and low risk, making it a good alternative for non-transplant candidates.

Our report, although representing the most frequent indications for definitive therapy (Table 1), does not reflect the true distribution of the indications in our centre. In approximately three quarters of patients implanted with a ventricular assist device as definitive therapy, the major limiting factor for heart transplantation was advanced age. Malignancy also mostly precludes heart transplantation but, if it remains in remission after appropriate treatment, the patient may have a long survival period, although this may be limited by cardiomyopathy induced by cytostatic therapy. In these patients, the ventricular assist device is an option only to overcome the situation [7]. Other reasons to implant ventricular assist devices as a definitive therapy are fixed elevated pulmonary vascular resistance or concomitant diseases. Some patients refuse heart transplantation but may change their minds later on. In this case an assist device will bridge the patient to heart transplantation.

In our centre, 63% of patients with an LVAD implanted since 2000 as a definitive therapy survived > 30 days and 41% were discharged home, while in bridged and recovered patients the figures were 71% and 58%, respectively. The main cause of early death was multi-organ failure, which in some patients did not regress after LVAD implantation and may additionally have been aggravated by right ventricular failure. Patients selected for destination therapy had elevated risk factors for early mortality: they were older (mean age 63 ± 7.8 vs. 48 ± 16.4 years), suffered mostly from ischaemic cardiomyopathy (61% vs. 54%) and presented more concomitant diseases than bridged and recovered patients.

During long-term follow-up, thromboembolic events and cerebral bleeding determine the survival of patients with an LVAD. Advanced age is also a risk factor for cerebral bleeding during long-term antithrombotic therapy [8].

As the time point of surgery becomes optimized and improvements are made in patient selection and in the design and post-operative management of the LVAD, leading to an increase in device durability and a decrease in complication rates, it is expected that more patients will benefit from the implantation of ventricular assist devices as a definitive therapy [9]. A major finding in our experience has been that the patients described in this report spent over 90% of the time on the device at home. Although standardized quality of life studies were not performed in these patients, improvement of NYHA functional class from IV to I in all patients and their participation in social and

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**Table 1**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Diagnosis</th>
<th>Sex</th>
<th>Age</th>
<th>Type of surgery</th>
<th>Device</th>
<th>Duration of support (years)</th>
<th>Reason for long-term support</th>
<th>Current status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DCMP</td>
<td>Female</td>
<td>56</td>
<td>Urgent</td>
<td>Novacor</td>
<td>5.1</td>
<td>Own wishes</td>
<td>Alive</td>
</tr>
<tr>
<td>2</td>
<td>DCMP</td>
<td>Male</td>
<td>50</td>
<td>Emergency</td>
<td>Novacor</td>
<td>4.6</td>
<td>Obesity</td>
<td>Dead</td>
</tr>
<tr>
<td>3</td>
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<td>Male</td>
<td>40</td>
<td>Urgent</td>
<td>Novacor</td>
<td>4.9</td>
<td>Own wishes</td>
<td>Alive</td>
</tr>
<tr>
<td>4</td>
<td>ICMP</td>
<td>Male</td>
<td>72</td>
<td>Urgent</td>
<td>EXCOR</td>
<td>4.3</td>
<td>Age</td>
<td>Dead</td>
</tr>
<tr>
<td>5</td>
<td>ICMP</td>
<td>Male</td>
<td>68</td>
<td>Rescue</td>
<td>EXCOR</td>
<td>4.5</td>
<td>Age</td>
<td>Alive</td>
</tr>
</tbody>
</table>

All patients on inotropic support prior to LVAD implantation.

DCMP—dilative cardiomyopathy, ICMP—ischaemic cardiomyopathy.
family life as well as outdoor activities provide evidence of increased quality of life.

During long-term support with different devices, different forms of malfunction have been described [2,10,11]. In two of the cases reported here, cable damage occurred. The fact that all three Novacor LVAD systems had to be electively replaced after 2, nearly 4 and 5 years, respectively, due to malfunction of the bearings demonstrates limited durability. However, the end-of-life specification of the Novacor LVAD is 3 years and, in two out of three cases, the device functioned properly for longer than expected. Device replacement performed with cardiopulmonary bypass may be complicated by bleeding or thromboembolic events. In our patients, two cases of device replacement were uneventful; in one case (patient 1), pocket infection developed, making additional surgery necessary.

The following specific strategies are used to achieve a marked decrease in the complication rate and to prolong quality time on the device: close monitoring of the system by a technician, special training of patients and relatives in wound care to avoid cannula or cable infection, and anticoagulation management employing phenprocoumon, aspirin and dipryidamole using INR self-assessment combined with routine ambulatory visits. During these visits platelet aggregation tests and thromboelastography are routinely performed. The patients receive standard heart failure medication consisting of ACE-inhibitors, β-blockers, diuretics, aldactone, digitalis and statins to avoid, among other problems, right heart failure.

Technical problems with the mechanical pumps may limit the support time. Pumps with a magnetically levitated impeller as designed for the INCOR axial flow pump [10] or the Terumo DuraHeart centrifugal pump may offer many years of support without wear and tear. Although initial experience is promising, these devices need to be investigated in long-term follow-up. Among over 70 patients in whom the small INCOR magnetically levitated axial flow pump was implanted in our centre three have now been supported for more than 2 years.

Transcutaneous energy transfer is another valuable feature that decreases the infection risk and increases the mobility of patients, consequently enhancing quality of life. In our patients who had a LionHeart left ventricular assist device (Arrow International, Inc., USA), transcutaneous energy transfer worked satisfactorily for 1 and 3.5 years, respectively.

In conclusion, long-term support with an LVAD is a good option to extend the lifespan of non-transplant candidates, providing good quality of life. Further improvements in device design and patient selection and measures to lower the costs are necessary for this therapy to be made available to more patients.

Acknowledgement

We would like to thank Tania Nienkarken, RN, Friedrich Kaufmann, MD, and Ewald Hennig, PhD, for medical and technical support, and Anne Gale, ELS, for editorial assistance.

References