The Jarvik 2000 Heart. Clinical validation of the intraventricular position

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Abstract

Objective: Heart failure is now a public health epidemic. Donor hearts are severely restricted in availability. Permanent mechanical circulatory support or bridge to myocardial recovery are emerging alternatives. After extensive laboratory experience we sought to evaluate the intraventricular Jarvik 2000 Heart in patients with endstage heart failure. Methods: The Jarvik 2000 Heart is a novel thumb-sized left ventricular assist device (LVAD) which is fitted within the apex of the native left ventricle. A vascular graft off loads this to the descending thoracic aorta. The pump rotor spins at between 8000 and 12 000 rpm providing 5–6 litres blood flow per minute. We have used the device with skull-mounted power delivery for seven permanent implants and trans-abdominal drive line for ten bridge-to-transplant patients. Results: All patients survived the operation. Three died from non-device related complications. Survivors had early resolution of heart failure with return to NYHA I/II. All had pulsatile circulation. The device was user-friendly and imperceptible to the patient. Both the pump and native left ventricle contributed to the cardiac output during exercise. Seven patients have been transplanted successfully. All explanted devices were free from thrombus formation. Two permanent implant patients left hospital as early as 3 weeks postoperatively. Conclusions: The Jarvik 2000 is an effective user-friendly LVAD which allows early discharge from hospital. The intraventricular position has distinct advantages especially through absence of an inflow cannula. Synergy develops between the LVAD and native left ventricle. Early experience suggests that this may be a realistic LVAD to treat heart failure routinely in the outpatient setting. © 2002 Elsevier Science B.V. All rights reserved.

Keywords: Heart failure; Left ventricular assist device

1. Introduction

With improvements in biotechnology, genetic engineering and stem cell research, alternative approaches for the treatment of advanced heart failure are increasingly realistic. Until recently, the prospects for permanent mechanical circulatory support were limited by the size and complexity of first-generation pulsatile devices which restricted most patients to the hospital. An understanding that continuous flow pumps could be equally successful has stimulated the development of silent miniaturized and more user-friendly devices better suited to an unrestricted lifestyle.

Axial flow pumps have already entered the clinical arena [1,2]. The Micromed-Debakey and Thermo Cardio Systems II left ventricular assist devices (LVADs) are smaller than the Novacor and Thermo Cardio Systems pusher plate pumps but have the same anatomical connections. Both are implanted via median sternotomy with an inflow cannula in the left ventricular apex, an external pocket and a long outflow graft to the ascending aorta. The Jarvik 2000 Heart adopts a completely different approach. Measuring only 2.4 cm in diameter by 5.5 cm in length and weighing 85 g, this is the first blood pump to fit within the native heart without an inflow cannula. The pump offloads to the descending thoracic aorta and only one body cavity is opened during implantation [3].

The Jarvik 2000 Heart is now undergoing clinical trials for both bridge to transplantation (United States) and permanent mechanical circulatory support (Europe). This report describes our early clinical experience with specific reference to the benefits of the intraventricular position.
2. Patients and methods

The Jarvik 2000 Heart has been described previously [3,4]. Two different power delivery systems have been used in the clinical trials. For bridge to transplantation, a fine velour-covered cable is brought through the abdominal wall similar to existing LVADs. For permanent implants, post-auricular power transmission via a skull mounted titanium pedestal has been employed to minimize infection risk (Fig. 1).

2.1. Patient selection criteria (Table 1)

2.1.1. Bridge to transplantation (Texas Heart Institute, Houston, USA)

The Jarvik 2000 Heart has been used in ten New York Heart Association (NYHA) functional Class IV heart failure patients with small body surface area (≤2.0 m²) who were transplant waitlisted and facing imminent death from cardiogenic shock. They received intravenous inotropes or intra-aortic balloon pump support prior to implantation.

2.1.2. Destination therapy (Oxford, UK and Freiburg, Germany)

This group included six end-stage dilated cardiomyopathy patients (NYHA IV on maximum medical treatment) who were ineligible for cardiac transplantation. Inclusion criteria included cardiac index (≤2.0 l/min per m²) left ventricular ejection faction (LVEF) < 25%, maximum oxygen consumption rate (MVO₂) < 16 ml/kg per minute, creatinine clearance > 25 ml/min. and the likelihood that the patient would die in less than 3 months. Patients with insulin-dependent diabetes, previous cardiac surgery, active malignancy, or contraindication to anti-coagulation were excluded in this group. The device was implanted electively for permanent mechanical circulatory support before the terminal state.

2.2. The implant procedure

The pump was inserted via left thoracotomy into the apex of the dilated left ventricle with careful alignment parallel to the interventricular septum (Fig. 2). The outflow graft makes a gentle turn around the costophrenic angle to the descending thoracic aortic. The power line was brought through either the upper right abdominal quadrant or scalp skin via the titanium button. The distal graft anastomosis was made first. A retaining cuff was then sewn onto the apex of the left ventricle and the circumscribed muscle punched out with a cork bore instrument avoiding the papillary muscles. The system was then de-aired and the device switched on before weaning from cardiopulmonary bypass.

Initially the impeller speed was kept constant at 10 000

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<th>Table 1 Preoperative patient characteristics</th>
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* DCM, dilated cardiomyopathy; Tx, transplantation.

Fig. 1. Fluoroscopic images of the chest, neck and skull showing the Jarvik 2000 Heart in the apex of the left ventricle and the post auricular power delivery system.
rpm. The adequacy of pump flow was assessed by continuous cardiac output monitoring, acid base balance measurements, urine output and mixed venous oxygen saturation. Echocardiography was used to ensure adequate ventricular filling. Raised systemic vascular resistance caused a decrease in cardiac output and was managed with hydralazine or beta blockade. Milrinone or dobutamine were used as inotropes for the right ventricle. Anti-dysrhythmic agents and diuretics were introduced where necessary.

3. Results

3.1. Perioperative events

All patients at the three centres survived the implant procedure.

3.1.1. Bridge to transplantation

Seven patients have undergone heart transplantation and were discharged from the hospital. Two have died during support, and one continues with the device while awaiting heart transplantation. The seven transplant recipients have average follow-up period of 5.6 months (range 0.7–11.2 months), and all remain in NYHA Class I. For the series as a whole, the average duration of support has been 84 days (range 13–214), and total duration of support has been 826 days (Table 2).

3.2. Clinical outcome

3.2.1. Bridge to transplantation

Of the bridge-to-transplant patients the duration of support has ranged between 13 and 214 days (mean 84 days). Two patients had superficial abdominal power cable infection but this did not alter the clinical course. One patient had a major haemorrhage from a gastric ulcer and a separate arteriovenous malformation in the small intestine. This patient required multiple blood transfusions followed by laparotomy, cauterization of the ulcer and resection of the arteriovenous malformation. Anti-coagulation was discontinued completely in this patient whose international normalized ratio ranged from 1.0 to 1.2.

There has been no thromboembolism or infection in the device itself. No thrombus was found in explanted the devices or within the left ventricle of the seven patients successfully transplanted. These patients have an average follow-up of 5.6 months after transplantation (range 0.7–11.2 months) and all are NYHA Class I.

3.2.2. Permanent implants

The three surviving Oxford patients left hospital within 4 weeks and are NYHA I or II living in the community. Duration of support ranges from 94 to 455 days (mean 208 days). All three Freiburg patients are NYHA I or II between 14 and 93 days postoperatively (mean 41 days). There have been no device-related complications in these patients. The skull-mounted percutaneous power delivery system has healed satisfactorily without infection in all six patients and has proven user-friendly. None of the patients can hear or feel the device within the chest. All of these dilated cardiomyopathy patients have shown marked improvement in native left and right ventricular function. With the device temporarily switched off, retrograde functional aortic regurgitation from the descending thoracic aorta was measured estimated

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**Table 2**

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<th>Texas</th>
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at between 600 and 800 ml/min. This was well tolerated by the improving left ventricle. Accidental interruption of power supply led to the device being off for 45 min in one patient. There were no problems on restarting the pump.

3.3. Haemodynamic assessment

Compared to preoperative values, measured cardiac output improved considerably with LVAD support. Continuous cardiac output monitoring in the early postoperative period documented pump outputs varying between 3 and 8 l/min at a fixed pump speed of 10 000 rpm depending on afterload. Mean arterial pressure varied correspondingly from 50 to 80 mmHg. Though the pump provides continuous non-pulsatile flow reduced, pulsatility was discernible in the systemic circulation at speeds of 8000 to 11 000 rpm. At 12 000 rpm, the arterial pressure wave was virtually flattened with less than 15 mmHg pulse pressure. The progressive decrease in pulse pressure within increasing pump speed reflected the increased capture of blood flow from the left ventricle through the pump during diastole. At low pump speeds (8000 and 9000 rpm), the aortic valve opened with ejection through the left ventricular outflow tract and a diacrotic notch on the arterial pressure trace.

Even though pulsatility remained in the systemic circulation at 10 000 rpm, the diacrotic notch disappeared indicating that the aortic valve remained closed. At 10 000 and 11 000 rpm, flow through the left ventricular outflow tract was minimal. At 12 000 rpm the aortic valve remained closed, demonstrating that left ventricular volume was too low for ejection. Pulsatility was produced by ventricular preload to the pump during systole. For most patients, a pump speed of 9000 or 10 000 rpm was chosen to allow ejection through the left ventricular outflow tract. The device had no significant negative impact on left ventricular dynamics. Echocardiography confirmed left ventricular unloading at these speeds and Doppler imaging showed continuous flow through the pump with systolic augmentation. At all pump speeds, the left atrial pressure was decreased by 50% below preoperative levels.

The average plasma free haemoglobin level was 14.1 mg/dl in the bridge-to-transplant patients and 8.4 mg/dl in the permanent implants. No patient had significant haemolysis and the variety of plasma free haemoglobin level probably occurred through different laboratory baselines. The highest recorded plasma lactate dehydrogenase was 605 IU.

4. Discussion

This early experience is characterized by the user-friendly nature of the Jarvik 2000 Heart together with absence of device-related complications and freedom from haemolysis. The fact that the patients are unable to feel the device within the chest is a major advance in blood pump technology.

The intraventricular position conveys major advantages. The alignment of the pump inflow remains constant and is not altered by a change in left ventricular shape during unloading. The consistent flow pattern mitigates against turbulence and haemolysis [5]. The apex of the native heart is not tethered by an extracardiac device in a fixed pocket. Left ventricular mechanics are virtually unaltered, so much so that discontinuation of power and functional aortic regurgitation can be tolerated for long periods as ventricular function improves. The pump itself is encapsulated by blood and myocardium, lessening the risk of device and pocket infection. Only the left pleural cavity is entered at implantation so that the median sternotomy for cardiac transplantation is easier and safer.

The skull-mounted post auricular power line mimics a hearing aid and is virtually invisible when the hair grows. There has been no infection with this approach [6]. However, the miniature pump with a fine power line and no external pocket also seems less prone to conventional drive line infection. The external battery and controller are easily portable on a belt or shoulder bag. There is only one speed knob for the patient to regulate and this is usually kept constant at 9000–10 000 rpm. The user-friendly nature of the system allows discharge from hospital in less than 4 weeks followed by an unrestricted life in the community. This includes international travel by air and reinstatement of a driving licence.

Given the functional status and quality of life of our early patients, the importance of systemic pulse pressure is questionable. Most of the patients had prolonged periods with pulse pressure less than 15 mmHg with the aortic valve persistently closed during the cardiac cycle. Our preferred approach is to allow antegrade ejection through the aortic valve and promote a synergistic relationship between the pump and native left ventricle. By partially offloading, the Jarvik 2000 Heart improves the position of the left ventricle on the Frank–Starling relationship. This is a different strategy from the pusher plate LVADs which empty and completely replace the native left ventricle [7]. Echocardiography was used to ensure that lower pump speeds (9000–10 000 rpm) provided adequate offloading. In this setting lack of pulsatility suggests inadequate pre-load, inappropriate afterload or persistently poor left ventricular function. On exercise, intrinsic mechanisms boost cardiac output through increased heart rate and enhanced contractility of the offloaded left ventricle. Flow increases both through the device and via the left ventricular outflow tract. This means that sophisticated activity-responsive electronic mechanisms to increase pump speed are unnecessary. We also find that an increase in pump speed by the patient during exercise is unusual.

In summary, this early experience with the Jarvik 2000 Heart confirms the user-friendly nature of the device and low event rate. The novel intraventricular position without an inflow cannula or graft may be the key to overcoming major complications such as haemolysis, thromboembolism, and device infection.
References


