Current and future status of left ventricular assist devices in the UK

Emma J Birks

Heart failure affects over 750,000 people in the UK and 65,000 new cases are diagnosed every year. It carries a poor prognosis with a population-based study finding a 40% one-year mortality in all new diagnosed cases[1] with those in New York Heart Association (NYHA) class IV having a 60% one-year mortality. Heart failure also costs the NHS £625 million per year and is responsible for one million bed days and 5% of acute medical admissions. The prognosis from heart failure is worse than that for myocardial infarction, carcinoma of the bowel, breast cancer in women or prostate cancer in men.[2] Medical therapy with angiotensin-converting enzyme (ACE) inhibitors, beta blockers, angiotensin II receptor blockers (ARBs) and aldosterone antagonists, together with resynchronisation therapy, has improved the survival of many with heart failure. Despite optimal medical therapy, there still remains a group of patients who are in NYHA class III/IV heart failure with a very poor prognosis.

Although transplantation currently remains the 'gold standard' treatment for such patients, the numbers of useable donor hearts has significantly decreased over recent years. Now only a total of approximately 150 heart transplants are performed per year across the UK, a number totally inadequate for the population who require heart transplantation.

Left ventricular assist devices (LVADs) support the failing heart and have been increasingly used in this country over the last 10 years at both Harefield and Papworth Hospitals and, more recently, in Newcastle. They are inserted into patients with deteriorating NYHA class IV heart failure despite inotropic ± intra-aortic balloon pump support. LVADs are not only life saving in deteriorating patients who would otherwise die before a donor became available for transplantation, they also improve secondary organ function for transplantation, reduce pulmonary hypertension and allow for improvement of nutritional status. Survival after transplantation with an LVAD is now equivalent to transplantation survival without an LVAD. The most common devices currently used in the UK are the Thoratec HeartMate® 1 (figure 1), the Thoratec® PVAD and IVAD and Novacor® pulsatile pumps, and the Jarvik® 2000 (figure 2) impellar pump. Patients are now discharged home on the device with a good quality of life.

LVADs are generally used as a bridge to transplantation. The National Specialist Commissioning Advisory Group (NSCAG) has been funding 35 LVADs per year at Harefield,

Figure 1. The HeartMate® I pulsatile left ventricular assist device

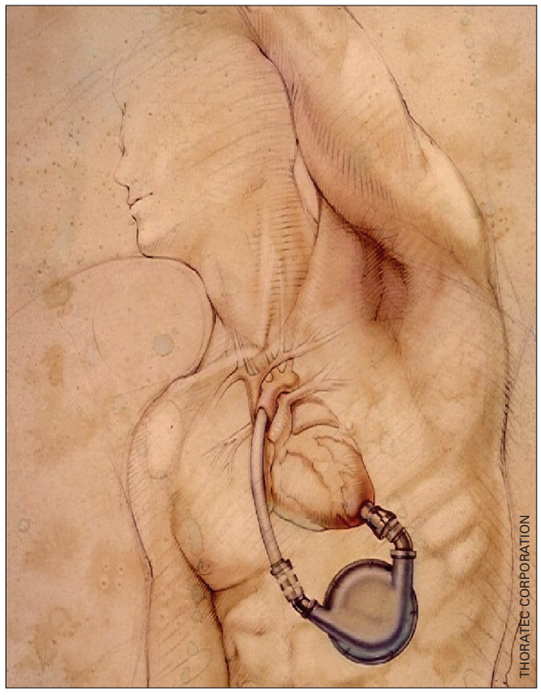

Figure 2. The Jarvik® 2000 axial flow impeller pump

Papworth and Newcastle hospitals since April 2002 in an evaluation trial – the results of this are expected shortly.

Myocardial recovery

There is now compelling evidence that unloading with an LVAD may lead to recovery of the patient's myocardial function sufficient to enable the device to be removed. This avoids the need for transplantation, immunosuppression and its associated complications and leaves the patient with an excellent quality of life. It also conserves the precious resource of a donor organ for another individual. The proportion of patients whose ventricular function has recovered sufficiently to allow removal of the device has been around 5% until recently.[3] However, at Harefield, we have recently applied a strategy of using specific pharmacological interventions to maximise the incidence of recovery in patients with dilated cardiomyopathy resulting in two thirds of this group of patients recovering sufficiently for explantation.[4] Furthermore, recovery of patients on an LVAD provides an ideal and, so far, unique opportunity to study the molecular mechanisms that occur during the reverse remodelling seen as the patient recovers. Myocardial samples obtained at the time of device insertion and removal, along with serum samples, provide an ideal opportunity to explore the myocardial and circulating factors involved in recovery of human heart failure.

LVADs are not without complications. Right heart failure and abdominal complications are early problems and, later, infection, thromboembolism, haemolysis and device failure can occur. Earlier insertion of the LVAD, before the development of multi-organ failure, improves survival and lessens the risk of these complications. With evolving LVAD technology some of these complications are now improving. The cost of LVAD implantation is high but a large proportion of the cost is still spent on research and development of the devices. This cost is expected to reduce with time as this technology develops, as survival increases and as complications lessen, enabling a wider use to increasing numbers of people with heart failure. It is hoped that the huge costs involved now are an investment for the future.

Future development

Recently, Dr Ian Gibson, Chairman of the House of Commons Select Committee for Science, Technology and Medicine, called a meeting at the House of Commons, attended by leaders in this field, to discuss the use of LVADs in the UK and their future role. It was generally felt that LVADs are at the same level of development as transplantation was 15 years ago, and that national standards for the care of LVAD patients now need to be developed in the same way that they were for transplantation. The meeting felt the role of LVADs will expand and discussions are already under way to consider extending their use to other transplant centres at the end of the evaluation trial. If this were to happen, it would be important that each centre performed an adequate number of LVAD implants to maintain both sufficient experience and the support needed to look after patients to the high standard required. The total number of LVADs funded would also need to be proportionately increased with the number of centres.

REMATCH study

The future use of these devices, particularly as patient survival increases, is likely to extend to their wider use as destination therapy – this is already happening in the US. A randomised trial, The Randomised Evaluation of Mechanical Assistance for the Treatment of Congestive Heart failure (REMATCH)[5], randomised 129 patients with end-stage heart failure to receive either optimal medical therapy (OMM) or a Heartmate I LVAD as permanent therapy. Patients were in NYHA class IV for at least 60 of 90 days despite maximal medical therapy. They were ineligible for cardiac transplantation (age over 65 years, insulin-dependent diabetes with end-organ damage, chronic renal failure or significant irreversible comorbidity). Median age was 69 years.

The one-year survival rate in the LVAD group was 52% compared to 25% in the OMM group; the two-year survival rate was 23% and 8% respectively. The survival benefit was particularly significant for those on inotropes.[6] Overall, all-cause mortality was reduced by 48%. Interestingly, the one-year survival rate for patients under 60 years was 74%. Both NYHA class and quality of life were better at follow-up in the LVAD group. The two-year survival rate is now 37% in the most recent LVAD patients and the quality of life benefit is becoming more robust. Introduction of axial flow and centrifugal designs are likely to improve LVAD survival further and lessen complications. It has been proposed that there should

now be a randomised trial in the UK of axial pumps versus OMM.

In view of the developing LVAD technology and the large number of patients suffering from severe heart failure in the UK, it is time that more resources were invested in this area. We need to identify patients who will benefit most from LVADs – either as a bridge to recovery or as a bridge to transplantation. It is also time to further evaluate the area of long-term support. We should make provision for the future development of this technology and provide more resources for training the medical and support staff required to run this programme.

The UK should be at the front of research in this cutting-edge field. It is a treatment that is clearly here to stay and it is important that LVAD support is added to other available treatments for the management of end-stage heart failure.

Conflict of interest

None declared.

References

1. Cowie MR, Wood DA, Coats AJ *et al*. Survival of patients with a new diagnosis of heart failure: a population-based study. *Heart* 2000;**83**:505-10.
2. Stewart S, MacIntyre K, Hole DJ, Capewell S, McMurray JJ. More 'malignant' than cancer? Five-year survival following a first admission for heart failure. *Eur J Heart Fail* 2001;**3**:315-22.
3. Mancini DM, Beniaminovitz A, Levin H *et al*. Low incidence of myocardial recovery after left ventricular assist device implantation in patients with chronic heart failure. *Circulation* 1998;**98**:2383-9.
4. Yacoub MH, Birks EJ, Tansley P, Henein MY, Bowles CT. Bridge to recovery: the Harefield Approach. *J Congest Heart Fail Circulat Support* 2001; **2**:27-30.
5. Rose EA, Gelijns AC, Moskowitz AJ *et al*. Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term mechanical left ventricular assistance for end-stage heart failure. *N Engl J Med* 2001;**345**:1435-43.
6. Stevenson LW, Miller LW, Desvigne-Nickens P *et al*. Left Ventricular Assist Device as Destination for Patients Undergoing Intravenous Inotropic Therapy. A subset analysis from REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure). *Circulation* 2004;**110**:975-81.

Emma J Birks
Locum Consultant in Transplantation and Mechanical Circulatory Support
Royal Brompton and Harefield NHS Trust, Harefield, Middlesex, UB9 6JH.
(email: e.birks@ic.ac.uk)

Br J Cardiol 2005;**12**:333–5