Thoratec heartmate® left ventricular assist device: For patients with heart failure who are ineligible for heart transplantation.

December 2003
© Commonwealth of Australia 2005

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the Copyright Act 1968, all other rights are reserved. Requests and inquiries concerning reproduction and rights should be addressed to Commonwealth Copyright Administration, Attorney General’s Department, Robert Garran Offices, National Circuit, Canberra ACT 2600 or posted at http://www.ag.gov.au/cca

Electronic copies can be obtained from http://www.horizonscanning.gov.au

Enquiries about the content of this summary should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

DISCLAIMER: This summary is based on information available at the time of research and cannot be expected to cover any developments arising from subsequent improvements to health technologies. This summary is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

The Commonwealth does not guarantee the accuracy, currency or completeness of the information in this summary. This summary is not intended to be used as medical advice and it is not intended to be used to diagnose, treat, cure or prevent any disease, nor should it be used for therapeutic purposes or as a substitute for a health professional's advice. The Commonwealth does not accept any liability for any injury, loss or damage incurred by use of or reliance on the information.

The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers’ Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by Linda Mundy and Tracy Merlin from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Department of Public Health, Mail Drop 511, University of Adelaide, South Australia, 5005.
PRIORITISING SUMMARY

REGISTER ID: 0000048

NAME OF TECHNOLOGY: THORATEC HEARTMATE® LEFT VENTRICULAR ASSIST DEVICE

PURPOSE AND TARGET GROUP: PATIENTS WITH HEART FAILURE WHO ARE INELIGIBLE FOR HEART TRANSPLANTATION

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- [ ] Experimental
- [ ] Investigational
- [x] Nearly established
- [ ] Established
- [x] Established but changed indication or modification of technique
- [ ] Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- [x] Yes
- [ ] No

INTERNATIONAL UTILISATION:

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEVEL OF USE</th>
<th>Trials Underway or Completed</th>
<th>Limited Use</th>
<th>Widely Diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States (REMATCH)</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Case series, Australia</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States (economic)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IMPACT SUMMARY:

Heart failure occurs when the heart is unable to pump blood adequately to the rest of the body. The gold standard treatment for heart failure is heart transplantation however, due to a shortage of donor organs, waiting lists are long and many patients die before receiving a transplant (Rose et al 2001). The number of heart transplants conducted in Australia for the period January 1- December 31 2002 was 74. The number of patients who died while on the heart transplantation list was 10 between July 2002 – June 2003 (Australian and New Zealand Organ Donation Registry 2003). In Australia, heart failure occurs predominantly amongst those aged 75 and over and accounted for 40,942 hospitalisations and 2,612 deaths, during the period 2000-01 (AIHW 2003).

The Thoratec Corporation manufacture left ventricular assist devices (LVAD), which are generally used as a bridge to heart transplantation. The technology is available through Australian public and private hospitals for use in patients awaiting heart transplantation. The Thoratec ventricular assist device (Product number 102757) has TGA approval (ARTG No 51280). The number of claims processed by the HIC for the Medical Benefit Schedule numbers 38615 and 38618 (insertion of left ventricular assist device) were 18 for the period July 2002- June 2003.

LVADs receive blood from the left ventricle, then pump it into the aorta, utilising either an external or internal power source. The Thoratec LVAD pump and power source is externalised giving the patient limited mobility and is not ideal for out-patients. This device
also carries a high risk of infection and anticoagulation is required to prevent thromboembolism. In comparison, the Thoratec Heartmate® LVAD has an internalised pump and power source and is equipped with portable controllers to facilitate patient mobility, allowing patients to be discharged from hospital. A risk of infection may still exist, although anticoagulants are not required (Nemeh & Smedira, 2003).

Both types of LVAD can be used as a bridge to transplantation, however, the FDA (USA) recently extended the approval of the Heartmate® LVAD to allow for permanent use in patients who are ineligible for heart transplant. Criteria for these patients included class IV heart failure for ≥ 90 days despite medical therapy, a left ventricular ejection fraction of 25% or less, or peak oxygen consumption of no more than 12 ml/kg body weight/minute. The Heartmate® LVAD is not currently listed on the Australian TGA.

Rose et al (2001) conducted a randomised controlled trial of 129 patients who were ineligible for heart transplantation, 68 were assigned to receive a LVAD (Heartmate®) and 61 received optimal medical therapy. The rates of survival were 52% and 25% at one year follow-up (p=0.002) and 23% and 8% at two year follow-up (p=0.09), in the LVAD and medical therapy groups respectively. That is, there was approximately twice the survival benefit with Heartmate® at 1 year and three times the benefit at 2 years when compared to optimal medical therapy. However the frequency of serious adverse events such as bleeding, infection and device malfunction of the device in the device group was 2.4 times (95% CI, 1.9 –3.0) that of the medical therapy group. Wood et al (2001) conducted a small Australian case series. Three patients actively listed for transplantation were implanted with a Heartmate® LVAD. No deaths were recorded; patients were discharged from hospital between 24 and 45 days post-implantation; and were supported by Heartmate® for a total of 327 days.

The estimated cost of a heart transplant is A$35,000 with yearly ongoing costs of approximately A$15-20,000. No economic studies have been conducted in Australia to evaluate the cost-effectiveness of permanently implanted LVADs, however the cost of the Heartmate® device is estimated to be A$92,000 (US$65,000) with additional hospitalisation costs. Data on the lifetime of the device and potential cost-savings from patient survival are not currently available.

**CONCLUSION:**

Level II evidence indicates apparent survival benefits for the small target population (70 heart failure patients awaiting transplantation in Australia at January 2003, as well as the proportion ineligible for transplantation). It is expected that Heartmate® LVAD will diffuse rapidly throughout the Australian health system.

**HEALTHPACT ACTION:**

Therefore it is recommended that a Horizon Scanning report be conducted.

**SOURCES OF FURTHER INFORMATION:**


Morgan, J. A., Park, Y. et al (2003). 'Device related infections while on left ventricular assist device support do not adversely impact bridging to transplant or posttransplant survival', *Asaio J*, 49 (6), 748-750.


**SEARCH CRITERIA TO BE USED:**

Heart Diseases/*mortality/*surgery
*Heart-Assist Devices
*Heart Transplantation
Cardiac Surgical Procedures
Heart Failure, Congestive/*surgery/mortality/therapy
Prognosis
Risk Factors
Survival Rate