



Horizon Scanning Technology Prioritising Summary

CardioWest Total Artificial Heart

September
2005



Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical



Royal Australasian
College of Surgeons



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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 staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



Horizon Scanning Technology Prioritising Summary

Name of Technology:

CardioWest Total Artificial Heart (TAH) (Syncardia Systems Inc., Tucson, Arizona)

Purpose and Target Group:

The CardioWest TAH was designed to completely replace a patient's native ventricles and all four cardiac valves. It was developed to be used as a bridge to transplant device and aims to improve the survival rate of cardiac transplant-eligible candidates who are at risk of imminent death from biventricular failure (Syncardia 2005).

Stage of Development (in Australia): Not yet emerged in Australia

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

The CardioWest TAH is not listed or registered in the Australian Register of Therapeutic Goods (ARTG).

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Canada		✓	
France		✓	
Germany	✓		

Impact Summary:

Background

In heart failure, damage to the heart weakens the cardiovascular system and limits the ability of the heart to pump blood to other organs of the body. One of the most common causes of heart failure is coronary artery disease where narrowed arteries are less able to deliver sufficient blood and oxygen to the heart. Symptoms include shortness of breath due to pulmonary oedema, fatigue, and swollen ankles due to fluid retention.



Although survival rates have improved significantly, nearly half the patients diagnosed with heart failure will die within five years (Goldstein *et al.* 1998).

Lifestyle modifications, a range of pharmacological treatments, and sometimes surgical treatments, are used to treat congestive heart failure, but eventually most patients will progress to end-stage disease. Ideally patients who also have end stage disease would undergo heart transplantation, but there is a severe shortage of, and increased demands for, donor hearts. While waiting for a heart, patients may need some form of mechanical circulatory device such as a ventricular assist device, which acts as a 'bridge to transplantation'.

Early artificial hearts (such as the Jarvik TAH) were associated with a high incidence of death and complications. CardioWest is the successor to the Jarvik-7 and was designed as a short-term bridge to transplantation rather than a long-term option.

The CardioWest TAH is a modified version of the Symbion Jarvik-7 TAH, and is a pneumatic device which attaches to the heart's natural atria. The Jarvik-7 was renamed to CardioWest in 1993 following the modifications to its design. The ventricles of the CardioWest TAH are made of polyurethane, and blood is pumped simultaneously out of each ventricle by a disk shaped device which, powered by air pressure, forces blood from the inlet to the outlet valve of the ventricle (Texas Heart Institute 2005).

A major disadvantage of this artificial heart is the fact that the patient has to be constantly attached to a large console which pneumatically powers the device. This limits the patient's mobility considerably while on the device. However, as the device is intended to be a temporary bridge until a donor heart becomes available the period of restricted activity is not prolonged.

In October 2004, the FDA approved the CardioWest TAH for use as a bridge to transplantation device in the United States. It is important to note that the CardioWest TAH was developed to be used in a select group of transplant eligible patients who are facing imminent death due to bi-ventricular failure.

Clinical Need and Burden of Disease

An estimated 300,000 Australians are afflicted with chronic heart failure with approximately 30,000 new cases diagnosed every year (AIHW 2003). In 2003-2004, the number of patients (data collected from public hospitals) suffering from congestive heart failure or left ventricular failure was 29,346 and 10,957 respectively (AIHW 2005). Of this group, 1.5% would represent patients afflicted with acute heart failure and hence are possible candidates for extracorporeal membrane oxygenation or to have a left ventricular assist device (LVAD) implanted (Stevenson & Kormos 2001). A small proportion of this group would be patients facing imminent biventricular failure and are potential recipients of CardioWest.



Sixty five Australians were awaiting heart transplant as of 31 December 2003, six (9%) died while on the waiting list in 2003 (ANZOD 2004).

Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System

The CardioWest TAH is currently being used in the United States, France, Canada and Germany. SynCardia projects that the approximate 100 patients/year in the United States facing irreversible failure of both ventricles who are candidates for cardiac transplant could benefit significantly from the use of the CardioWest TAH (IntelliHealth 2004).

Existing Comparators

As previously stated, the CardioWest TAH was approved for use as a 'bridge to transplantation'; the following devices may be used for the same purpose:

a) Ventricular assist device (LVADs and BVADs)

- HeartMate Left Ventricular Assist Systems (Thoratec Corp., Pleasanton, California)
- Novacor Left Ventricular Assist Device (Baxter Healthcare, Oakland, California)
- Thoratec Ventricular Assist Device (Thoratec Corp., Pleasanton, California)

b) TAHs

- AbioCor (AbioMed Inc., Danvers, Massachusetts) – intended as a long term option compared to CardioWest.

Estimated Cost Impact

The CardioWest TAH costs approximately USD\$70,000 to USD\$80,000 (Arizona Daily Star 2004), and this does not include surgical/hospital expenses. The Medicare Benefits Schedule does not list any reimbursement fees for heart transplants or any artificial heart implants. For the insertion of a left or right ventricular assist device (Item number 38615), Medicare reimbursement was \$1299.90 while the reimbursement for a right and left ventricular assist device (Item number 38618) was \$1620.30. According to the Health Insurance Commission, there have been 14 claims to Medicare for insertion of a left or right ventricular assist device (Item number 38615) and 12 claims for the insertion of a right and left ventricular assist device (Item number 38618) from June 2003 to June 2004 (Medicare Australia 2005).



Efficacy and Safety Issues

List of Studies Found

Total number of studies	5
Comparative studies	2
Case series studies	3 (16 papers)

The three studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from two comparative studies and one case series have been selected for inclusion in this summary; these studies were included on the basis of patient numbers and years of experience with the use of the device. All Copeland studies were sponsored by SynCardia Inc. and patient overlap is probable between Copeland *et al.* (2004) and Copeland *et al.* (2001).

Survival to transplantation

Copeland *et al.* (2004) compared 81 heart failure patients who received the CardioWest TAH with 35 patients who did not receive any ventricular assist devices prior to cardiac transplantation (historical controls). Survival to transplantation was significantly higher in the CardioWest TAH patients (79%) compared to the control group (46%) ($p < 0.001$). In addition to this, CardioWest recipients achieved an overall survival rate of 70% one year after the transplant, a significant improvement compared to the 31% survival attained of the control group ($p < 0.001$). The treatment was considered successful (defined by the investigators as having the following characteristics 30 days post-transplant: alive, New York Heart Association Class I or II, ambulatory, non-ventilator dependent and not undergoing dialysis) in 69% of CardioWest recipients while controls achieved a 37% success rate ($p = 0.002$).

A retrospective study (Copeland *et al.* 2001) compared the safety and efficacy of the CardioWest TAH ($n = 42$), the Novacor left ventricular assist system ($n = 23$), and the Thoratec ventricular assist system ($n = 26$). The study revealed that survival to transplantation was 75% for CardioWest, 57% for Novacor and 38% for Thoratec (χ^2 analysis indicates significant association between device type and survival to explant, $p = 0.012$; CardioWest vs Thoratec; χ^2 test, $p = 0.003$) (Copeland *et al.* 2001). Survival rates from device implantation to discharge (after cardiac transplant) was 59% for CardioWest, 56% for Novacor and 33% for Thoratec (χ^2 analysis, $p = 0.72$; CardioWest vs Thoratec, $p = 0.035$).

The case series study by LePrince *et al.* (2003) revealed significant improvements with regards to survival to transplantation over time. Survival rates increased from 43% (1986-1992, $n = 63$, 32 patients received the old Jarvik-7 which is no longer manufactured) to 55% (1993-1997, $n = 36$) and finally 74% (1998-2001, $n = 36$) in heart failure patients whose main



aetiology was cardiomyopathy (98/127). This success was not duplicated in non-cardiomyopathic patients where 23% survived to transplantation prior to 1997 (n=19). However, marked improvements in this group of patients were achieved from 1998-2001 (n=10), where the patient survival to transplantation increased to 50%, this success however is partly attributed to better patient selection. Median duration of support with the CardioWest was 20 days before 1997 and escalated to 2 months after that due to shortage of donor hearts (Leprince *et al.* 2003).

Haddad *et al.* (2004) reported improvements in post-implantation survival over time similar to Leprince *et al.* (2003), with hospital survival rates improving from 61% (11/18 patients) for patients treated between 1986-1994 to 85% (11/13 patients) between 1994-2003. Haddad *et al.* (2004) attributed this improvement to changes in patient management (immediate sternal closure, early extubation, delayed transplantation, early rehabilitation and measurement of preformed reactive antibodies) as experience with the use of the device increased. As with Leprince *et al.* (2003), the duration of device support increased over time (1986-1994, 8[13.7]^{SD} days cf. 1994-2003, 17[10.7]^{SD} days), demonstrating the decline/shortage of donor hearts as more individuals are diagnosed with heart failure.

Arabia *et al.* (1997) reported a 70% (55/79 patients) survival rate for CardioWest recipients to transplantation (with 3 patients still awaiting transplantation at the time of writing). Of these, 50 patients (91%) survived the transplantation and were discharged. Mean duration of device support was 34 days (range 0-186 days).

Cardiac Output

Copeland *et al.* (2004) and Leprince *et al.* (2003) recorded patient's cardiac output post-implantation as a separate measure of CardioWest's effectiveness. Results revealed that haemodynamic status improved immediately after device implantation (Copeland *et al.* 2004, Leprince *et al.* 2003). Copeland *et al.* (2004) recorded sustained increases in cardiac index from a baseline of 1.9 to 3.2 litres/min/m² of body-surface-area, while Leprince *et al.* (2003) recorded similar findings with an increase from 1.9 [0.4] to 3 [0.5] litres /min/m². Other parameters such as mean arterial blood pressure, central venous pressure, mean systolic arterial pressure and organ perfusion pressure recorded considerable improvements as well (Copeland *et al.* 2004, Leprince *et al.* 2003).

Infections and multiorgan failure

Infection is a significant problem with implanted cardiac devices, Copeland *et al.* (2004) reported infection rates of 77% (73/95 patients, 125 events) from study entry to 30 days post-transplant (62% of infections occurred 28 days after device implantation), while Haddad *et al.* (2004) reported 39% (7/18, Group A) and 31% (4/13, Group B) infection



rates during device support. Infection contributed to death in 9% (7/81) of patients in Copeland *et al.* (2004) and was the cause of death in one patient (1%). Leprince *et al.* (2003) stated that 18% (23/127) of patients died due to sepsis (mainly pulmonary infection) while the main cause of death was multiorgan failure (MOF), being responsible for 67% of deaths (Leprince *et al.* 2003). Similarly in Copeland *et al.* (2001), 50% of all deaths were due to MOF. Copeland *et al.* (2004) reported eight deaths (10%, 8/81 patients) in the CardioWest group due to MOF (seven died before transplant, one after transplant) while Arabia *et al.* (1997) reported that that MOF was responsible for 84% (15/21 patient deaths) of deaths during device support.

Device malfunctions or complications

Copeland *et al.* (2004) reported a perforation in one of the four layers of the CardioWest left ventricular diaphragm, resulting in one patient death 124 days post-implantation. Prior to that, Copeland *et al.* (2001) reported one death at 145 days post-implantation, also due to diaphragm rupture. A case device dysfunction was reported by Leprince *et al.* (2003), but was not fatal. The dysfunction was caused by a right ventricle diaphragm rupture that led to partial occlusion of inflow and outflow valves (Leprince *et al.* 2003). Leprince *et al.* (2003) postulates that the rupture was caused by the sterilisation process which involves high temperatures. CardioWest is now sterilised by SynCardia Systems Inc. prior to delivery, the risk of rupture may be decreased. Central venous catheter entrapment of the prosthetic tricuspid valve in the right ventricle occurred in two patients, causing the device to shutdown and hence resulting in death (Copeland *et al.* 2001).

Copeland *et al.* (2004) experienced complications with fitting the device in 6% (5/81) of patients; this was rectified in three patients by repeat surgery. Poor fitting of the device contributed to the deaths of two patients (2%, 2/81) (Copeland *et al.* 2004) while Leprince *et al.* (2003) stated that two device repositions were required due to filling curve impairment in the first post-operative day; the procedure was completed without complications.

Arabia *et al.* (1997) reported one device malfunction where the CardioWest drive lines were transiently kinked (but did not result in death) and three (4%) fit complications.

Neurological events

Copeland *et al.* (2004) reported 26 neurological events in the CardioWest TAH group; 11 stroke events, four transient ischemic attacks (TIAs), five anoxic encephalopathies, one metabolic encephalopathy, four seizures and one syncope. The linearised rate of stroke was 0.05 event per month. No deaths were cause by neurologic complications in this study (Copeland *et al.* 2004). Haddad *et al.* (2004) reported one TIA in patients treated from 1986-1994 and three TIAs in patients treated from 1995-2003. Leprince *et al.* (2003) reported two



TIAs in two patients (2/127); linearised neurologic accident rate was 0.2 event per patient-year (0.016 event per patient-month). Copeland *et al.* (2001) reported a lower stroke incidence for CardioWest patients (8%) compared to Novacor (21%) and Thoratec (12%). With regards to TIAs, 8% of CardioWest patients experienced TIAs, Novacor's TIA rate was 21% while Thoratec was 4% (Copeland *et al.* 2001). Overall, neurological events appear to be fewer in CardioWest recipients. Nineteen neurological events occurred in 10 patients (13%) in Arabia *et al.* (1997)

2006 update

Safety and efficacy

A search of relevant databases, online journals and the Internet was conducted in September 2006, following the recommendation in September 2005 that CardioWest be monitored for assessment in 12 months time. Two new three case series studies and a case report on the safety and efficacy of CardioWest were identified. The case report is excluded from the following discussion due to the low quality of evidence.

The study by El-Banayosy *et al.* (2005) implanted the CardioWest in 42 patients suffering from severe cardiogenic shock to evaluate the benefits of the device in this group of patients. CardioWest implantation was uneventful in all patients with no intraoperative deaths. However, 8 patients had fit problems, with 3 of these patients having a body surface area of less than 1.7 m². Bleeding complications (blood loss greater than 1500 cc) occurred in 9 patients (21%) with 8 of them requiring re-exploration, all bleeding complication cases were not related to the procedure but instead was attributed by the authors to the fact that 35% of the patient cohort had previous mechanical circulatory support with subsequent coagulation disorders. A total of 11 patients (26%) experienced liver failure (defined as bilirubin greater than 10mg/dL), therefore requiring molecular adsorbent recirculating system therapy. Meanwhile, renal failure occurred in 3/20 patients (15%) who had no renal failure preoperatively. Four patients underwent abdominal surgery on the device for mesenteric ischemia. Haemolysis was present in 3 patients (7.1%). El-Banayosy *et al.* (2005) reported two device-related complications (4.8%), one patient had significantly higher right than left pump output with increasing signs of pulmonary congestion and weight gain after 6 months of support. The patient eventually underwent cardiac transplantation and evaluation of the CardioWest revealed that a diaphragm layer on the blood side within the pump had ruptured with subsequent thrombus formation in the intermediate room. The second patient who experienced device complications died after 5 days of CardioWest support, examination revealed that the central venous catheter wedge had advanced (unintentionally) into the tricuspid valve thus causing valve dysfunction with consecutive circulatory collapse. The mean duration



of support was 86 ± 89 days (median 51 days, range 1 to 291 days), and 11 patients (26%) underwent successful cardiac transplantation (10 discharged home). One patient died due to infection one week after cardiac transplantation. Overall, 22 patients (52%) died during device support and 9 patients (21.4%) were still on device support at the time of publication (El-Banayosy *et al.* 2005).

In the second case series study, Leprince *et al.* (2005) examined if the CardioWest TAH is suitable for patients with body surface areas (BSA) of less than 1.7 m^2 in 30 patients (Group I). The results were compared with 119 patients who had $\text{BSA} > 1.7 \text{ m}^2$ (Group II). One patient in Group I experienced a fitting problem and was left with an open chest. Meanwhile, the cardiac index between for Group I patients ($3.6 \pm 0.6 \text{ l/min/m}^2$) was significantly higher compared to Group II patients ($2.8 \pm 0.36 \text{ l/min/m}^2$) one day after implantation ($p < 0.05$). Central venous pressure post-implantation was similar between both groups (Group I: $14.7 \pm 3.8 \text{ mmHg}$, Group II: $14.5 \pm 4 \text{ mmHg}$), and so was the mean arterial pressure (Group I: $87 \pm 23 \text{ mmHg}$, Group II: $88 \pm 19 \text{ mmHg}$). In addition to his, Leprince and colleagues reported that Group I patient survival increased dramatically from 9% in 1992 to 36% between 1992 and 1997 and finally achieving 50% after 1997. Meanwhile Group II survival rates to hospital discharge increased from 15.5% before 1992, to 34.6% between 1993 and 1997 and finally 52% after 1997. Overall, it was concluded that the CardioWest can be implanted in patients with BSA between 1.5 m^2 and 1.7 m^2 with few fitting complications.

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2006 Recommendation

Recent studies have not added much to the knowledge on the effectiveness of CardioWest. The study by Leprince *et al.* (2005) revealed that the CardioWest TAH can be used in patients with BSA < 1.7m² with similar effectiveness to patients with BSA > 1.7m². While the results in the case series by El-Banayosy *et al.* (2005) practically mirror the results of previous studies except for the slightly lower survival rate of 48%. Based on the current evidence available, it is recommended that the following is conducted:

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input checked="" type="checkbox"/> Archive |

Ethical Issues

CardioWest was designed to be a bridge to transplantation, so while transplantation may be delayed ultimately patients will need to be transplanted to survive. Hence, this technology is not a viable alternative for patients who do not wish to undergo transplantation.

Cultural or Religious Considerations

See above under ethical issues.

Other Issues

No issues were identified from the retrieved material.

Conclusion:

Some evidence exists supporting the efficacy of the CardioWest TAH in improving cardiac function and hence survival in patients awaiting cardiac transplant. Only a small number of patients in Australia (~7 patients yearly based on population estimates) would be eligible for this treatment. Based on the evidence available it is recommended that the following be conducted:

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

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Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in April 2005.

Search terms used were: 'CardioWest', 'Syncardia', 'Jarvik', 'bridge to cardiac transplantation', and 'artificial heart'.

This Horizon Scanning Prioritising Summary was prepared by Mr. Irving Lee from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).