Technology Brief

Total artificial heart for end-stage refractory biventricular heart failure

November 2011
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This brief was prepared by Dr Prema Thavaneswaran from ASERNIP-S.
REGISTER ID WP043

NAME OF TECHNOLOGY TOTAL ARTIFICIAL HEART

PURPOSE AND TARGET GROUP TO BE USED AS A BRIDGE-TO-TRANSPLANT DEVICE IN PATIENTS WHO ARE AT RISK OF IMMINENT DEATH FROM BIVENTRICULAR HEART FAILURE

STAGE OF DEVELOPMENT (IN AUSTRALIA)

☐ Yet to emerge
☐ Experimental
☒ Investigational
☐ Nearly established

☐ Established
☒ Established but changed indication or modification of technique
☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐ Yes
☒ No
☐ Not applicable

INTERNATIONAL UTILISATION

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**IMPACT SUMMARY**

End-stage refractory biventricular heart failure is the most life-threatening manifestation of the heart-failure syndrome. Options available to patients with this condition include palliation, placement of a biventricular assist device (BiVAD), or orthotopic heart transplantation. Unfortunately, heart transplantation is only available to a small percentage of eligible patients, due to a shortage of donor hearts, while the reported survival rate with BiVADs has been shown to be between 40% and 50%. The total artificial heart (TAH) has been developed for use as a bridge-to-transplant, with the aim of increasing the survival rate of cardiac transplant-eligible patients. This device is capable of completely restoring systemic and pulmonary blood circulation and organ perfusion in patients who are at risk of imminent death, due to end-stage refractory biventricular heart failure.

**BACKGROUND**

Heart failure is a progressive condition where the heart is unable to maintain a strong enough blood flow to meet the body’s needs (AIHW 2011). While this disease can occur suddenly, it usually develops slowly over many years, as the heart becomes gradually weaker and works less efficiently. The key risk factors for heart failure are ischaemic heart disease (present in >50% of new cases) and hypertension (present in about two-thirds of cases) (Krum et al. 2006). Other important risk factors include diseases of the heart muscle that occur as a result of alcohol abuse or infections, diseases of the heart valves, such as rheumatic heart disease, and diabetes and obesity (AIHW 2011). The co-occurrence of multiple diseases in an individual can make the diagnosis of heart failure more difficult (AIHW 2011).

Individuals with mild heart failure may have few symptoms; however, in more severe cases it can result in chronic tiredness, reduced capacity for physical activity, shortness of breath and fluid build-up in the ankles and legs.

The diagnosis of heart disease is based on clinical features, as well as appropriate investigations, which not only confirm or exclude the diagnosis of heart failure, but establish underlying causes, for which specific treatment is necessary (Krum et al 2006). Diagnostic investigations include chest x-ray and objective measurement of ventricular function, for example using echocardiography. Plasma levels of B-natriuretic peptide may also play a role in the diagnosis of heart failure, primarily as a test for exclusion (Krum et al 2006).

Lifestyle modifications including physical activity and dietary change, as well as pharmacological interventions, and in some cases surgical procedures, are used to treat
patients with heart failure. However, despite optimal medical and device management, most patients will progress to end-stage disease.

Most patients with end-stage heart failure receive left ventricular support in the form of a left ventricular assist device (LVAD), which subsequently improves both left and right ventricular function in the majority of cases. End-stage refractory biventricular heart failure is the most life-threatening manifestation of the heart-failure syndrome, and occurs in a small percentage of patients. For patients with this condition, the available options include palliation, placement of a biventricular assist device (BiVAD), or orthotopic heart transplantation. Unfortunately, due to a shortage of donor hearts, heart transplantation is only available to a small percentage of eligible patients, while the reported survival rate with BiVADs has been shown to be between 40% and 50% (Morris 2008). It is important to note that heart transplant recipients in Australia survive on average 14 years after transplantation, with one-third of patients surviving >20 years (Keogh and Pettersson 2008), whereas the average survival of eligible patients who are unable to undergo transplantation is <2 years (Lietz and Miller 2007).

The SynCardia total artificial heart (TAH) has been developed for use as a bridge-to-transplant, with the aim of increasing the survival rate of cardiac transplant-eligible patients. This device, which completely replaces a patient’s native ventricles and all four cardiac valves, is a biventricular pneumatic pulsatile pump consisting of three components: prosthetic ventricles (two), drivelines, and an external pneumatic driver. The SynCardia TAH is capable of completely restoring systemic and pulmonary blood circulation and organ perfusion in patients who are at risk of imminent death, due to end-stage refractory biventricular heart failure.

**Clinical Need and Burden of Disease**

Between 1.5% and 2% of Australians suffer from chronic heart failure (CHF), and the incidence and prevalence of this disease rise significantly with age (Krum et al 2006). The point prevalence of CHF is approximately 1% in people aged between 50 and 59 years, 10% in people aged 65 years or older and over 50% in people aged 85 years or older (Krum et al 2006). Based on international estimates and Australian data, approximately 300,000 Australians are estimated to have CHF at any one time. Additionally, extrapolation of more extensive Australian data suggests that, in the year 2000, there were more than 20,000 incident hospital admissions for CHF, mainly in those aged 70 years or older, and that it was associated with a total of 100,000 hospitalisations and contributed to 1.4 million days of hospital stay (Krum et al 2006). The burden of CHF in Australia is expected to increase significantly due to a number of factors, including the ageing population, the projected increase in the number of older people.
with common precursors of CHF such as coronary heart disease and hypertension, and an increasing prevalence of obesity and metabolic syndromes.

The proportion of patients with chronic heart failure at risk of dying from end-stage heart disease is around 9% (calculation based on recent Australian data which showed that in 2006, approximately 263,000 Australians experienced chronic heart failure, of whom 2,350 died from end-stage heart disease) (AIHW 2008). At present, between 80 and 100 heart transplants are performed annually in Australia (Keogh and Pettersson 2008). It is unclear what proportion of the Australian CHF population would be at risk of imminent death due to end-stage refractory biventricular heart failure, and would thus be eligible for implantation with a TAH; however, it is likely that this is a very small group of patients. The Medicare Benefits Schedule (MBS) does not currently list any item numbers for the insertion of TAH devices; however, item numbers for the insertion of a left or right ventricular assist device (VAD) (Item number 38615), and a left and right VAD (Item number 38618), are currently listed on the MBS. Based on MBS data, a total of 26 claims were made for services covered by the item numbers listed above, between July 2010 and June 2011 (Medicare Australia 2011).

DIFFUSION

There are currently two TAH devices that are commercially available, the SynCardia TAH (SynCardia Systems Inc, Tucson, Arizona) and the AbioCor TAH (Abiomed Inc, Danvers, Massachusetts). The AbioCor TAH received United States (US) Food and Drug Administration (FDA) conditional approval in 2006, under the Humanitarian Device Exemption (HDE) provision, and is indicated for use as a bridge to destination therapy device. The first patient was implanted with the AbioCor TAH in 2001; however, the clinical experience with the AbioCor has been limited, and this device is still in the early stages of clinical testing. The SynCardia TAH received FDA pre-market regulatory approval (PMA) in 2004, and is indicated for use as an in-hospital bridge-to-transplantation device for patients with irreversible biventricular heart failure, who are at imminent risk of death. This TAH received the CE mark in Europe in 2003, and US Centres for Medicare and Medicaid Services (CMC) reimbursement in 2008. The device has reached significant clinical use, and to date, has been implanted in more than 900 patients, in over 40 SynCardia Certified Centres worldwide.

As mentioned above, the SynCardia TAH is intended for use inside the hospital, and until recently, patients in the US who were implanted with this device were tethered to a 418 pound power supply within the hospital, the SynCardia circulatory support system (CSS), until they underwent transplantation. In Europe however, as early as 2003, stable TAH patients in Germany and France have been able to be discharged home, due to the development of a CE approved mobile 25 pound driver system for the TAH (Slepian
2011). This demonstrated that TAH patients could be successfully discharged from the hospital and resume living, and today many institutions in Europe routinely discharge TAH patients once they are stable (Slepian 2011). Discharge home has been further eased with the replacement of the initial mobile driver with a much lighter, truly portable driver, known as the SynCardia Freedom portable driver. The Freedom portable driver, which is CE approved in Europe and is in clinical use in a number of countries, is a 13.5 pound unit, with two on-board, lithium ion rechargeable batteries. This driver can be carried in a shoulder bag or worn in a backpack. Initial use of this driver has been positive, and patients have reported feeling well, and being self-ambulatory, with a significant return to normal function while at home (Slepian 2011). In the US, the FDA has recently approved an Investigational Device Exemption (IDE) trial (NCT00733447) to assess the Freedom portable driver. The purpose of this study is to confirm that the Freedom portable driver system is a suitable pneumatic driver for clinically stable TAH patients, and that patients and lay caregivers can be trained to manage the Freedom portable driver safely outside the hospital, as has long been the case in Europe.

In Australia, there are currently no TAH devices that have been approved for use listed on the Australian Register of Therapeutic Goods (ARTG). In 2010, the first Australian patient was implanted with a TAH, and another four patients have been implanted with the device since then. All five patients were implanted with the SynCardia TAH at St Vincent’s Hospital in Sydney, which is the only SynCardia Certified Centre in Australia. An Australian company, BiVACOR Pty Ltd, is currently developing a TAH device which can duplicate both sides of the heart and mimic the pumping fluctuations of a normal heart. The company is in the process of trialling the prototype in a sheep model.

**Comparators**

The majority of patients who are identified preoperatively with end-stage refractory biventricular heart failure are relegated to short-term, paracorporeal devices. Commonly used devices have included the Thoratec pVAD, iVAD, the Abiomed BVS 5000, and ABS 5000. Some groups have employed a hybrid approach in which long-term, intracorporeal devices are used for left ventricle (LV) support and a short-term device is placed for right-sided support (Morris 2008). The purpose of this is to recover the right ventricle (RV), as pulmonary hypertension decreases with chronic LV unloading. Regardless, when compared to TAH patients, the survival of patients placed on BiVADs, whether done pre-emptively or in a sequentially divided manner after initial left ventricular assist device (LVAD) placement, is markedly worse. Specifically, patients implanted with BiVADs have demonstrated survival rates of between 40% and 50%, while TAH patients have demonstrated survival rates of greater than 79% (Morris 2008).
There are a number of VADs that are currently listed on the ARTG (ARTG number 163222, 163568, 172201, and 181875). These devices are largely indicated for use in patients with end-stage left ventricular heart failure, and are not appropriate for patients suffering from end-stage refractory biventricular heart failure.

**SAFETY AND EFFECTIVENESS ISSUES**

Two studies which assessed the SynCardia TAH for the treatment of end-stage refractory biventricular heart failure were eligible for inclusion in this technology brief. Both studies examined the efficacy of the device (Kohli et al 2011, Roussel et al 2009), while the safety of the device was examined in one study (Roussel et al 2009).

*Study profile*

The purpose of the study by Kohli et al (2011) was to evaluate the blood pressure (BP) response to exercise, and exercise performance, in patients with a SynCardia TAH compared to patients with a continuous-flow HeartMate II LVAD. This is the first study to evaluate the BP response to exercise, and the feasibility of a regimented physical rehabilitation program, in patients implanted with a TAH.

In this single-centre, retrospective study, the authors identified a cohort of 37 patients with TAHs (January 2006 to May 2010) implanted with the intention to bridge to heart transplantation. In this group, 30 of the 37 patients had rehabilitation data available, and were included in the study. Of these 30 patients who participated in physical therapy, exercise data were available for 22 patients who proceeded to inpatient cardiac rehabilitation, which involved treadmill training. The authors analysed data from a total of 110 rehabilitation sessions and 2,005 minutes of treadmill exercise. Data on BP, duration of exercise, and sustainable metabolic equivalents (METs) achieved during the first eight weeks of treadmill exercise were extracted from patients records. Of the seven patients who were not included in the study, three patients underwent heart transplantation early (1 to 2 days) after implantation, three were too ill to take part in physical therapy and died (3 to 78 days) after implantation, and rehabilitation data were missing for the seventh patient.

The authors identified a cohort of 12 patients with LVADs (January 2010 to December 2010) implanted with the intention to bridge to heart transplantation. This cohort was a convenience sample comprised of clinically stable patients who survived to take part in physical therapy and/or cardiac rehabilitation. The authors analysed data from a total of 63 rehabilitation sessions, and a manual anaeroid blood pressure cuff and vascular Doppler probe were used to estimate mean arterial BP (MAP) at rest and during exercise. METS were estimated from treadmill speed and grade.
Patients in both treatment groups were similar in terms of age, BMI, serum creatinine, race, survival to heart transplant or ongoing device, medical history, and acute medical intervention prior to device implantation; however, 100% of the patients in the TAH group were male, compared with 83% in the LVAD group (P=0.02). In addition, the utilisation of antihypertensives medications, including beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers, loop diuretics, spironolactone and sildenafil, was significantly higher in the LVAD group (P<0.05 for all).

The aim of the single-centre retrospective study by Roussel et al (2009) was to assess both the comorbidity and survival of patients awaiting heart transplants while receiving circulatory support with the SynCardia TAH.

From a total of 82 patients (28 of them with Thoratec and 12 with Novacor), 42 patients (40 men, 2 women; mean age, 45.7 ± 9.5 years; range, 24 to 62 years) underwent mechanical circulatory support with a SynCardia TAH between October 1988 and December 2006. In these patients, the cause of heart failure was ischaemic cardiomyopathy in 18 patients (43%), dilated cardiomyopathy in 19 (45%), postcardiotomy heart failure in two patients (4.8%), fulminant myocarditis in two patients (4.8%), and primary graft failure-rejection in one patient (2.4%).

Prior to being implanted with the SynCardia TAH, all patients were in cardiogenic shock, in spite of maximum inotropic support. Fourteen patients (33%) were receiving intraaortic balloon pumping, six patients (14%) were receiving mechanical ventilation, and six patients (14%) had undergone cardiopulmonary resuscitation within the previous 24 hours. Four patients (9.5%) were receiving mechanical support with extracorporeal membrane oxygenation (ECMO/ECLS) or Bio-Medicus. Sixteen patients (38%) had concomitant ventricular arrhythmia.

Safety

Roussel et al (2009) reported a variety of adverse events following TAH implantation, and the major adverse event categories are presented in Table 1. The number and cause of deaths in this study are reported in more detail in the ‘Effectiveness’ section.

Importantly, no device malfunction leading to patient death was reported; however, some severe events occurred in four patients (9.5%). Bacterial pneumonias were the most frequent infections, and two patients died as a result of infection. A total of three patients (7%) had a stroke with neurologic sequelae. Repeat surgeries were performed for a variety of reasons, including atrial tamponade or bleeding, mediastinitis, device malfunction (closure of air leak), device repositioning and spontaneous splenic rupture.

With regard to renal dysfunction, 27 patients (64%) required temporary dialysis or continuous haemofiltration during TAH support. There were three cases of acute
respiratory distress syndrome that occurred immediately after TAH implantation, two of which required venovenous ECMO. In addition, tracheotomy was necessary in eight patients (19%) for prolonged mechanical ventilation. With regard to gastrointestinal tract problems, there were three cases of peptic ulcer diagnosed in a context of gastrointestinal bleeding, one case of pancreatitis, and two cases of ascites.

Table 1: Adverse events following TAH implantation reported by Roussel et al (2009)

<table>
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<tr>
<th>Adverse event category</th>
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<tr>
<td>Fit complications</td>
<td>2 (4.8%)</td>
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<tr>
<td>Device malfunction</td>
<td>4 (9.5%)</td>
</tr>
<tr>
<td>Infections</td>
<td>35 (83%)</td>
</tr>
<tr>
<td>Neurological complications</td>
<td>3 (7%)</td>
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<tr>
<td>Repeat surgeries</td>
<td>26 (62%)</td>
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<tr>
<td>Bleeding</td>
<td>22 (52%)</td>
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<tr>
<td>Renal dysfunction</td>
<td>27 (64%)</td>
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<tr>
<td>Respiratory dysfunction</td>
<td>11 (26%)</td>
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<tr>
<td>Haemolysis</td>
<td>3 (7%)</td>
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<tr>
<td>Gastrointestinal tract problems</td>
<td>6 (14%)</td>
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TAH: Total artificial heart

Effectiveness

Kohli et al (2011) reported that in TAH patients, the mean pre-exercise BP was 120/69 ± 13/13, mean exercise BP was 118/72 ±15/10, and mean post-exercise BP was 120/72 ± 14/12. In this group, the differences in systolic and diastolic BP before, during and following exercise, were not significantly different (P=0.3 for systolic and P=0.1 for diastolic) (data not shown). Similarly, no change in MAP was observed in TAH patients following the commencement of exercise (88 ± 10 versus 88 ± 11; P=0.8), in contrast to LVAD patients, who demonstrated a significant increase in MAP with the initiation of treadmill exercise (87 ±8 versus 95 ± 13; P<0.001).

In TAH patients, BP was negatively correlated with METs achieved during exercise, however this association was not statistically significant (systolic: β=-0.09, P=0.3;
diastolic: $\beta=-0.14$, $P=0.2$; MAP: $\beta=-0.1$, $P=0.4$). In contrast, in LVAD patients, MAP was positively correlated with METs achieved during exercise ($\beta=0.26$, $P=0.04$).

In spite of the abnormal response to exercise, TAH patients were able to take part in physical rehabilitation therapy at a median of 5 days (interquartile range [IQR]: 4 to 7 days) and treadmill exercise at a median of 19 days (IQR: 13 to 35 days), after TAH implantation. TAH exercising on the treadmill demonstrated a significant increase in both the duration of exercise ($P<0.001$) and METs achieved ($P<0.001$) over the course of the eight weeks of rehabilitation (Table 2).

In this group of TAH patients, four patients were still receiving support with the TAH at the time of this analysis, while 88% (23/26) of the remaining patients had undergone heart transplantation at a median of 65 days (IQR: 40 to 95 days). Those TAH patients who had participated in physical rehabilitation therapy early, demonstrated a trend towards shorter waiting periods until transplantation (60 days [IQR: 37 to 92 days] versus 89 days [IQR: 59 to 155 days], $P=0.17$), as well as significantly higher survival rates to transplantation (100% versus 70%, $P=0.02$).

Table 2: Weekly mean performance on treadmill for patients with the TAH reported by Kohli et al (2011)

<table>
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<th>Duration (minutes)</th>
<th>METs</th>
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<tr>
<td>Week 1 (n=21)</td>
<td>8.24 ± 3.34</td>
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<td>Week 2 (n=17)</td>
<td>15.19 ± 7.17</td>
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<td>Week 3 (n=16)</td>
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<td>Week 4 (n=16)</td>
<td>18.84 ± 9.31</td>
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<td>Week 5 (n=10)</td>
<td>21.90 ± 11.09</td>
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<td>Week 6 (n=10)</td>
<td>25.75 ± 10.74</td>
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<tr>
<td>Week 7 (n=9)</td>
<td>24.10 ± 12.24</td>
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<td>Week 8 (n=8)</td>
<td>31.44 ± 11.89</td>
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Plus–minus values are mean ± SD; METs: Metabolic equivalents; TAH: Total artificial heart.

Roussel et al (2009) reported that the mean implant times included an aortic cross-clamp time of 108 ± 17 minutes (range, 64 to 155 minutes) and a cardiopulmonary bypass time of 137 ± 41 minutes (range, 80 to 280 minutes). There were two patients for whom chest closure was delayed until postoperative days 2 and 5. No deaths occurred during implantation; however, one death occurred a few hours after surgery due to acute massive pulmonary oedema. Two other patients required a venovenous ECMO after TAH.
Total artificial heart for end-stage refractory biventricular heart failure: November 2011

implanation for severe hypoxemia related to acute pulmonary oedema or acute respiratory distress syndrome.

Immediately following TAH implantation, haemodynamics returned to near normal levels, with the mean cardiac output of the device at the end of postoperative week 1 reported to be 5.5 ± 0.7 L/min for the right ventricle and 5.3 ± 0.8 L/min for the left ventricle. Inotropic support was able to be weaned rapidly after TAH implantation in all patients, with the exception of six patients who suffered sepsis or multiple organ failure. Extubation of patients occurred within 20.4 ± 31 days, and patients were able to be discharged from the intensive care unit within 49 ± 46 days.

All patients implanted with a TAH remained in hospital, and were able to walk once or twice a day and exercise using stationary bicycles. Mean time on TAH support was 101 ± 86 days (range, 1 to 292 days), and a total of twelve patients (28.5%) died while on support. These deaths were due to multiorgan failure (n=6), infection (n=3) acute respiratory distress syndrome (n=2), alveolar haemorrhage (n=1). The mean time spent on TAH support for patients who died was 44 ± 60 days (range, 1 to 200 days).

A total of thirty patients (71.5%) survived to transplantation, and 27 of these patients (64.3% of the total, 88.8% of those undergoing transplantation) survived until discharge from the hospital. The three patients who died following transplantation all died during the first postoperative month. The causes of death were sepsis (n=1), graft failure (n=1), and multiple organ failure (n=1). For transplanted patients, the actuarial survival rates were 90% (n=25), 81% (n=14), and 76% (n=10) at 1, 5, and 10 years, respectively. Actuarial survival rates for all 42 patients in this study were 64% at 1 year, 58% at 5 years, and 54% at 10 years.

**COST IMPACT**

Clark et al (2004) reported on an analysis of hospital costs among CHF patients in Australia, using reimbursement of hospital activity based on Diagnostic Related Groupings. This analysis found that the lowest average cost per day of hospitalisation for such patients was $600 (year 2000 cost equivalent). Based on this conservative figure, the total cost of CHF-related hospitalisations in Australia during the year 2000 would have been $840 million. The authors suggested that hospital costs for the management of CHF in a range of other developed countries typically assume around two thirds of total CHF-related expenditure, and as such, further estimated that the total ‘direct’ cost of CHF in Australia in the year 2000 was in excess of $1 billion (Clark et al 2004). Given the significant costs of CHF-related hospitalisation, there appears to be a strong economic rationale for the TAH, particularly with the recent introduction of the SynCardia portable
Freedom portable driver, which has made the possibility of recovery at home prior to transplantation a reality.

Tatsumi et al (2007) reported on a cost-effectiveness assessment of TAHs conducted by the Institute of Medicine (IOM) in the United States. The IOM evaluated the cost-effectiveness of TAHs using patients’ opinions and levels of satisfaction with regard to their state of health prior to and following treatment, so that quality of life would be reflected in the assessment of cost-effectiveness. This enabled the IOM to fairly compare the cost-effectiveness of TAHs with that of other treatments. In this assessment, the cost-effectiveness ratio was expressed as the incremental cost per quality-adjusted life year (QALY) gained from the treatment. The IOM estimated that the incremental cost of using a TAH instead of medical treatment was $105,000 dollars per added QALY (in 1991 dollars). This cost-effectiveness ratio was higher than that for heart transplantation, which was $32,000 per QALY; however, the IOM concluded that a cost-effectiveness ratio of $105,000 per QALY for the TAH was acceptable.

As mentioned previously, the MBS does not currently list any item numbers for the insertion of TAH devices, and no TAHs are currently listed on the ARTG; however, the insertion of a left and right VAD (Item number 38618) has a reimbursement fee of $1,377.95. In Australia, the costs of the SynCardia TAH and Freedom portable driver, which were provided by the manufacturer, are $125,000 and $14,700 respectively.

**ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

There were no issues identified from the retrieved material.

**OTHER ISSUES**

Of the two studies included in this brief, one study explicitly stated that two of the authors were consultants for SynCardia Corporation, but that none of the other authors had any conflicts of interest (Kohli et al 2011). The other study failed to provide any statement regarding potential conflicts of interest (Roussel et al 2009).

**SUMMARY OF FINDINGS**

One study assessed the comorbidity and survival of patients awaiting heart transplants while receiving circulatory support with the SynCardia TAH. This study reported that optimal haemodynamic function was restored following TAH implantation. The main cause of death was multiple organ failure; however, no device dysfunction-related deaths were reported. A rate of survival to transplantation of 71.5% was reported, while long-term survival after transplantation was 76% at 10 years. Another study demonstrated that aerobic exercise training, as part of a physical rehabilitation program early after TAH implantation, is safe and feasible in a supervised setting; however, when compared with
patients on LVADs, TAH patients have a blunted BP response to exercise. The results of this study are particularly relevant, with the rehabilitation and mobility of patients following TAH implantation becoming increasingly important, as the portable SynCardia Freedom portable drive is introduced and more patients are able to return home after device implantation.

HEALTHPACT ASSESSMENT
Currently, the SynCardia TAH is the only FDA approved and CE registered TAH available worldwide. This device is used as a bridge-to-transplant in patients who are at risk of imminent death, due to end-stage refractory biventricular heart failure, and who have few other treatment options. Given the significant costs associated with this technology, it is suggested that it be targeted at eligible younger patients who have developed heart failure prematurely. There are currently two clinical trials in progress assessing this technology, one of which is an FDA approved IDE trial of the SynCardia portable Freedom portable driver. Therefore, HealthPACT have recommended that this technology be monitored for 12 months, as the results of this ongoing trial may determine whether patients can function adequately with the TAH and Freedom driver outside of the hospital setting.

NUMBER OF STUDIES INCLUDED
Total number of studies 2
Total number of Level III studies 1
Total number of Level IV studies 1

REFERENCES
Kohli HS, Canada J, Arena R et al. Exercise blood pressure response during assisted circulatory support: Comparison of the total artificial heart with a left ventricular assist


**Search criteria to be used**

Total artificial heart OR TAH OR CardioWest OR SynCardia OR Jarvik