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Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

TandemHeart® Percutaneous Ventricular Assist Device

September 2006
(Updated October 2007)



ASERNIP'S

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**



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Enquiries about the content of the report should be directed to:

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

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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 Mr. Irving Lee from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



Name of Technology:

TandemHeart® percutaneous ventricular assist device (Cardiac Assist Inc., Pennsylvania).

Purpose and Target Group:

The TandemHeart percutaneous ventricular assist device (pVAD) is used for the treatment of patients with cardiogenic shock after acute myocardial infarction.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged

The TandemHeart pVAD is currently not available in Australia. Hence it is not listed or registered in the Australian Register of Therapeutic Goods database.

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Europe		✓	

Impact Summary:

Background

Cardiogenic shock is characterised by inadequate circulation of blood due to decreased pumping ability of the heart that results in global hypoperfusion. Cardiogenic shock occurs in 7-10% of those with acute myocardial infarction (AMI) (Thiele *et al.* 2001) and is the leading cause of death in these patients. For those who have received rapid revascularization, the mortality rate is 30-50% and approximately 70% if revascularization is not performed (Brandler & Sinert 2006).

Symptoms of cardiogenic shock are similar to those of shock, with patients in major distress and experiencing laboured breathing, impaired circulation, decreased urine output and altered mentation, indicative of end organ dysfunction. Cardiogenic shock has been defined as (Thiele *et al.* 2001, Thiele *et al.* 2005, Burkhoff *et al.* 2006b):



- sustained systolic blood pressure of ≤ 90 mm Hg or vasopressors required to maintain > 90 mm Hg,
- cardiac index ≤ 2.2 l/min/m²,
- pulmonary congestion or pulmonary capillary wedge pressure ≥ 15 mm Hg, and
- evidence of end-organ hypoperfusion (urine output < 30 ml, cold extremities, altered mental state, serum lactate > 2 mmol/L).

The initial management of cardiogenic shock involves fluid resuscitation in order to offset hypervolemia and hypotension. Placement of a central line is often required and allows vascular access for multiple infusions as well as invasive monitoring of central venous pressure and pulmonary capillary wedge pressure. Pharmacological interventions include drugs that provide haemodynamic support such as dopamine, norepinephrine, and epinephrine (vasoconstrictors) which will help preserve perfusion pressure thus optimising blood flow to organs (Brandler & Sinert 2006).

More aggressive treatment modalities include percutaneous coronary intervention and the use of intra-aortic balloon pumping (IABP). IABP has been the method of choice for providing mechanical assistance in patients suffering from cardiogenic shock, however despite the fact that IABP can increase cardiac output and improve coronary artery blood flow it is not a definitive treatment. This is due to the fact that IABP support lacks the efficiency to reverse cardiogenic shock in patients with severe depression of left ventricular function as IABP does not have active cardiac support and requires a certain residual level of left ventricular function to be successful (Thiele *et al.* 2005). In an attempt to overcome the limitations of IABP, total circulatory support utilising extracorporeal membrane oxygenation can be used. However, this method suffers the drawbacks of extracorporeal circulation such as activation of cellular elements, the need of an oxygenator, and implantation surgery (Thiele *et al.* 2001). A new percutaneous left ventricular assist device, TandemHeart®, was developed to address the shortcomings of IABP and extracorporeal membrane oxygenation.

The Tandemheart percutaneous ventricular assist device is a low-speed centrifugal continuous-flow pump with a low blood surface contact area (to reduce the risk for hemolysis and thromboemboli), which is placed outside the body. This device requires the percutaneous insertion of cannulas through the femoral vein and advanced across the intraatrial septum into the left atrium. The TandemHeart pump withdraws oxygenated blood from the left atrium and propels it utilising a magnetically-driven, six-bladed impeller through the outflow port and returns the blood to one or both femoral arteries via arterial cannulas. The pump also has a proprietary fluid-infusion system that provides cooling and lubrication to the impeller and enhances thromboresistance. The system provides localized anticoagulation to the blood inside the pump, reducing the need for systemic anticoagulation (Cardiac Assist 2006). In patients with cardiogenic shock it can be used for short-term circulatory support to obtain stabilization or as a bridge to definitive surgical treatment.



Clinical Need and Burden of Disease

From 1999 to 2000, there were 28002 hospital admissions (40 to 90 year-olds) in Australia where the principal diagnosis was AMI and the length of stay was greater than 2 days (or the patient died within 2 days of admission). This therefore equates to an admission rate of 351 per 100,000 population aged 40 to 90 years (Australian Institute of Health and Welfare 2005). Based on previous studies, 7% to 10% of AMI patients will suffer from cardiogenic shock (Thiele *et al.* 2001), resulting in an estimated 1960 to 2800 cases of cardiogenic shock from 1999 to 2000 in Australians aged between 40-90 years.

The overall in-hospital mortality rate for patients suffering from cardiogenic shock is 57%, in which individuals older than 75 years have a higher mortality rate of 64.1% compared to 39.5% in individuals younger than 75 years (Brandler & Sinert 2006).

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

The TandemHeart pVAD has been 510(k) approved by the Food and Drug Administration (FDA) for short-term use and is the only device of its kind that has been approved for critical support during cardiogenic shock in the United States. The TandemHeart pump was approved by the FDA on 11 November 2000 while the transeptal cannula set (which is part of the TandemHeart set) was approved on 23 May 2003. Despite the fact that the TandemHeart pump was approved in 2000, it was not marketed and sold to hospitals until the transeptal cannula set was approved in 2003.

In addition to this, TandemHeart is CE approved in Europe (Cardiac Assist 2006).

Existing Comparators

- Intra-aortic balloon pump
- Ventricular assist devices

Estimated Cost Impact

It is reasonable to assume that the use of TandemHeart would be substantially more expensive than IABP. In comparison to ventricular assist devices (VAD), the TandemHeart would only amount to a fraction of the cost of a VAD. However, this would be an unfair comparison due to the fact that VADs can provide long-term support while the TandemHeart is for short-term support. The exact cost of the TandemHeart system was not revealed in our searches. Medicare Benefits Schedule reimbursement fees for procedures related to cardiogenic shock treatments are listed in Table 1.



Table 1 Medical Benefits Schedule of fees for procedures related to cardiogenic shock (Medicare Australia 2006)

Category	Item Number	Benefit (AUD)	Number of Claims (July 2004 to June 2005)
Percutaneous insertion of intra-aortic balloon pump.	38362	333.10	344
Insertion of intra-aortic balloon pump by arteriotomy.	38609	414.70	61
Removal of intra-aortic balloon pump with closure of artery by direct suture.	38612	464.85	24
Removal of intra-aortic balloon pump with closure of artery by patch graft.	38613	583.45	1
Transluminal balloon angioplasty of one coronary artery, percutaneous or by open exposure, excluding associated radiological services or preparation, and excluding aftercare	38300	446.10	940
Transluminal balloon angioplasty of more than one coronary artery, percutaneous or by open exposure, excluding associated radiological services or preparation and excluding aftercare	38303	571.90	105
Adjustment and repositioning of extra-corporeal membrane oxygenation, bypass or ventricular assist device cannulae by open operation.	38627	579.50	8

Efficacy and Safety Issues

List of Studies Found

Total number of studies	10
Randomised controlled trials	2
Case series studies	5
Case reports	3

The studies included in this summary are highlighted in bold in the reference list. Two randomised controlled trial and two case series studies were included. The two randomised controlled trials (Burkhoff *et al.* 2006a, Thiele *et al.* 2005), was selected for inclusion as it was the highest level of evidence currently available on TandemHeart. The two case series studies (Burkhoff *et al.* 2006, Thiele *et al.* 2001) were selected based on the fact that they have larger patient cohorts compared to other case series studies.



Safety

A recently published randomised controlled trial (Burkhoff *et al.* 2006a), tested the hypothesis that the TandemHeart pVAD would provide superior haemodynamic support compared to IABP in 42 patients. The randomisation process was not stated; however clinical sites which have no prior experience with TandemHeart were permitted to treat the first patient with the pVAD in a 'roll-in' phase before initiation of randomisation. As a result of this, 9 patients were treated in the 'roll-in' phase, 14 were randomised to IABP and 19 were randomised to TandemHeart pVAD. A total of 6 patients (32%) from the TandemHeart group died during support, substantially more compared to 2 patient (14%) deaths in the IABP group. There was one instance of pVAD failure and one event where the pVAD had to be removed due to a device-related problem (blood clotting within the cannula). Overall, TandemHeart patients experienced 3.1 adverse events per patient compared to 2.6 events per patient in the IABP group (not significant, $p = 0.50$). No specific adverse events that were related to the performance of the transseptal puncture or insertion of the transseptal cannula were reported. The number of severe or serious adverse events was similar between all patient groups, with a frequency of 1.3 per patient in the TandemHeart group, 1.2 per patient in the IABP group and 1.1 per patient in the roll-in group (Burkhoff *et al.* 2006a).

A randomised controlled study conducted by Thiele *et al.* (2005), compared the safety and efficacy of TandemHeart against IABP in patients suffering from cardiogenic shock complicating AMI, undergoing first line treatment (percutaneous coronary intervention). Of the 86 patients screened, 45 were excluded due to: age > 75 years, mechanical disease, cerebral damage or severe peripheral artery disease. Forty-one patients were randomised utilising sealed envelopes, resulting in 20 patients randomised to IABP and 21 patients to the TandemHeart pVAD. One patient from the Tandemheart group experienced rapid improvement post-PCI and hence did not receive the pVAD. However, this patient was included in all analyses in accordance with the intention-to-treat principle. Revascularization was performed on 56% of patients in each group before device implantation and no complications were encountered during implantation. The median duration of cardiac support was 4.0 days for the IABP group and 3.5 days for the pVAD group ($p = 0.82$). Seven patients (33.3%) in the pVAD group (0 on IABP) developed limb ischemia after the insertion of a 17 French cannula, necessitating repair by surgical approach in three patients and percutaneous approach in four patients. Blood transfusions were required in 19 (90.4%) pVAD patients during the follow-up period of 30 days, a significantly higher number than the IABP group (8 patients, 40%) ($p = 0.002$). The pVAD group required median of 8.0 units of packed red blood cells vs median of 0 units in the IABP group ($p < 0.001$). Consistent with this trend, the pVAD group required more fresh frozen plasma (15 vs. 4, $p = 0.003$) and platelets (5 vs. 0, $p = 0.04$) compared to the IABP patients. Disseminated intravascular coagulation (DIC) was detected in 13 (61.9%) pVAD patients and 3 (15%)



IABP patients. DIC in 8 of the affected pVAD patients was severe and required haemorrhagic diathesis, while DIC in the 3 IABP patients was resolved with substitution of antithrombin III. The use of extracorporeal oxygenation with the pVAD showed a trend towards a higher rate of fever (17 vs 10, $p = 0.08$) compared to conventional IABP, this was reflected by the higher inflammation rate as indicated by the peak white blood cell count (median 19.1, IQR 15.8 to 24.7 Gpt/L* vs. median 15.1, IQR 13.8 to 19.3 Gpt/L, $p = 0.03$) (Thiele *et al.* 2005). Mortality rates during support were similar between the two treatment groups, with 4 patient deaths in each group (pVAD: 4/21, 19%; IABP: 4/20, 25%). Patient deaths in the pVAD group occurred between 2 and 4 days post-treatment due to multiorgan dysfunction syndrome (MODS) despite circulatory support while all four IABP deaths occurred within 24 hours after PCI due to MODS. An additional five deaths occurred in each group post-weaning (during the 30 day follow-up), therefore resulting in an overall mortality rate of 43% in the pVAD group and 45% in the IABP group (Thiele *et al.* 2005).

The case series by Burkhoff *et al.* (2006b) included 13 patients up to the age of 78 with cardiogenic shock; this was secondary to AMI in 8 of the patients. Nine of the patients were being supported by IABP. The mean support duration for the TandemHeart was 60 ± 44 hrs, with a mortality rate of 23% (3/13 patients) during the support period. Ten (76.9%) patients survived to device explant, six (46.2%) of which were successfully bridged to cardiac surgery (4 patients) or PCI (2 patients) Three of these died before hospital discharge implying total mortality of 46%. The remaining seven patients survived at least 6 months. Blood transfusions (packed red blood cells) were required in 8 patients (61.5%). A total of 7 (53.8%) patients survived to discharge and were alive at the end of the 6 months follow-up visit. The most common device-related adverse event reported was distal leg ischemia ($n = 3$) and bleeding from the cannulation site ($n = 4$). All device-related adverse events were resolved, with the exception of one case of right ventricular failure and one case of cannulation site infection; both events were unresolved at the time of patient death (Burkhoff *et al.* 2006b).

In an earlier case series of 18 patients with cardiogenic shock as a result of AMI, Thiele *et al.* 2001 reported that 5/18 (27.8%) patients required packed red blood cell transfusion due to arterial access site bleeding. Lower limb ischemia was detected in 2/18 (11.1%) patients with peripheral arterial occlusive disease several hours after the implantation of a 17F arterial cannula, this was resolved with the surgical implantation of an accessory antegrade cannula into the right common femoral artery. A total of four (22.2%) patient deaths were documented during the support duration and an additional four deaths (22.2%) occurred after weaning from TandemHeart; resulting in an overall 30-day mortality rate of 44.4%. One patient who died during support experienced profound arterial hypotension due to dislodgement of a standard length arterial cannula (6.5 cm) during routine nursing care. As a

* Gpt/L: Giga particle per litre – a unit of concentration for a substance of interest.



safety measure, 18 cm-long arterial cannulas were used in subsequent patients (Thiele *et al.* 2001).

Efficacy

In the randomised trial by Burkhoff *et al.* (2006a), haemodynamic success (defined as: **1**) patient did not die during support or within 24 hours of device removal, **2**) cardiac index (CI) was ≥ 2.2 l/kg per minute, **3**) pulmonary capillary wedge support (PCPW) was ≤ 24 mmHg, and **4**) Mean arterial pressure was ≥ 70 mmHg) was achieved in 2 IABP patients (14%) and 7 TandemHeart patients (37%). Patients receiving pVAD support achieved significantly greater increase in cardiac index (Δ CI: Roll-in = 1 l/min/M², pVAD = ~ 0.6 l/min/M²) compared to IABP patients (Δ CI: IABP = ~ 0.25 l/min/M²). Greater decreases in PCPW were reported for the pVAD recipients as well (Δ PCPW: Roll-in = -6 mmHg pVAD = -11 mmHg) when compared to IABP patients (Δ PCPW: IABP = -4 mmHg) ($p < 0.05$ when pVAD compared to IABP)[†]. Cardiac output significantly increased by 2.1 ± 1.3 l/min for roll-in patients ($p < 0.05$ vs baseline) and 1.2 ± 0.8 l/min for pVAD patients ($p < 0.05$ vs baseline), while a non-significant increase of 0.6 ± 0.6 l/min ($p > 0.05$) was noted for IABP patients. Mean arterial pressure (MAP) did not change significantly for IABP patients (+ 0.1 mmHg) but was significantly higher for roll-in (Δ MAP = 17 mmHg, $p < 0.005$) and TandemHeart (Δ MAP = 7 mmHg, $p < 0.005$) patients. The overall 30 day survival rate was 53% (10/19 patients) in the TandemHeart group, 64% (9/14 patients) in the IABP group, and 55.6% (5/9 patients) in the roll-in group ($p > 0.05$). If TandemHeart patients and roll-in patients were pooled, the survival rate would be 54% which is similar to the IABP group. Bridging to another therapy was undertaken in 7 TandemHeart (3 LVAD, 1 extracorporeal membrane oxygenation, 2 percutaneous coronary intervention, 1 mitral valve repair) and 5 IABP (4 left ventricular assist device, 1 percutaneous coronary intervention) patients from the randomised group. Of these, 5 TandemHeart patients and 3 IABP patients survived at least 30 days after bridging (Burkhoff *et al.* 2006a).

Thiele *et al.* (2005) stated that the median time to the establishment of left ventricular assist was 25 minutes in the TandemHeart pVAD group, significantly longer than the median of 11.5 minutes in the IABP group ($p < 0.001$). The baseline haemodynamic characteristics were similar between both treatment groups. For the primary endpoint of the cardiac power index (CPI), the median baseline was 0.22 in each group and this increased to 0.37 W/m² in the pVAD group compared with 0.28 W/m² in the IABP group ($p=0.004$). This level of improvement was maintained throughout the 72 hour follow-up period. In addition to this, significantly larger improvements for cardiac output, PCWP, pulmonary artery pressure

[†] Note: All numbers for Δ CI, Δ PCPW and Δ MAP are approximations based on graphs presented by Burkhoff *et al.* (2006a) in Figure 2 of the publication.



(PAP) and serum lactate were achieved in pVAD patients compared to IABP patients (Table 2).

Table 2: Haemodynamic parameters pre- and post-IABP and pVAD implantation (Thiele *et al.* 2005)

	Pre-IABP Median (IQR)	Pre-pVAD Median (IQR)	p-value	Post IABP Median (IQR)	Post-pVAD Median (IQR)	p-value
Cardiac output (L/min)	3.0 (2.5-4.0)	3.5 (3.3-4.2)	0.29	3.3 (2.9-4.3)	4.5 (4.0-5.4)	0.007
PCWP (mmHg)	27.0 (20.0-30.0)	20.0 (18.0-23.0)	0.02	21.5 (17.0-26.0)	16.0 (12.5-19.0)	0.003
PAP mean (mmHg)	32.5 (27.5-38.0)	28.0 (24.5-34.8)	0.45	28.5 (25.5-33.5)	24.5 (20.0-26.0)	0.007
Serum lactate (mmol/L)	3.8 (3.5-6.7)	4.5 (3.1-6.5)	0.53	3.25 (2.7-7.0)	2.8 (2.3-3.5)	0.03

In addition to the haemodynamic improvements, pVAD support resulted in substantial improvement to renal function as indicated by an increase in median urine output per hour from 30 to 80 ml/h ($p = 0.02$). In contrast, IABP patients exhibited minor improvements from median of 28 to 30 ml/h ($p = 0.18$). Overall, Thiele *et al.* (2005) reported that TandemHeart pVAD provides circulatory support that is significantly more effective compared to IABP, however, the use of the pVAD will result in increased complications as well.

The study conducted by Burkhoff *et al.* (2006) utilised the TandemHeart system to support patients presenting with cardiogenic shock before the application of therapeutic intervention, in contrast to the study by Thiele *et al.* (2005) which utilised TandemHeart to treat haemodynamic instability after successful PCI. During TandemHeart pVAD support, mean \pm SD cardiac index (CI) increased from 2.10 ± 0.61 to 2.5 l/min/m², while MAP increased from 71 to 82mm Hg. Mean PCWP decreased from 27 mmHg to 16 mmHg, however central venous pressure did not change significantly. Prior to TandemHeart support, baseline serum creatinine level averaged 1.6 ± 0.8 mg/dl ($n=11$) and did not change significantly post-support (1.3 ± 0.4 mg/dl) ($p = 0.14$). In addition to this, bilirubin values remained relatively similar before and during pVAD support (baseline: 1.0 ± 0.8 mg/dl, $n = 11$; pVAD: 1.2 ± 1.2 mg/dl, $n = 12$) ($p = 0.5$). Burkhoff *et al.* (2006) reported that there was no significant difference in plasma free haemoglobin levels before and during TandemHeart support, therefore indicating that there was no significant haemolysis due to Tandemheart support (baseline mean: 7.0 ± 9.9 mgm/dl; pVAD mean: 5.5 ± 3.8 mg/dl) ($p = 0.7$). There was no significant difference in platelet counts before and during TandemHeart support (baseline mean: 255 ± 201 ; pVAD mean: 186 ± 92) ($p = 0.1$).



Haemodynamic results collected 2 hours post-pVAD support initiation in the Thiele *et al.* (2001) study revealed that the use of TandemHeart significantly improved all haemodynamic parameters during the duration of the support ($p < 0.001$); with mean values for, cardiac output: 3.5 ± 0.8 to 4.8 ± 1.1 L/min, cardiac index: 1.7 ± 0.3 to 2.4 ± 0.6 L/min/m², mean blood pressure: 63.1 ± 7.8 to 80.2 ± 8.9 mm Hg ($p < 0.001$), PCWP: 20.8 ± 3.6 to 14.2 ± 3.5 mm Hg. Meanwhile, significant reduction in metabolic acidosis (pH: 7.33 ± 0.11 to 7.37 ± 0.1 , $p = 0.01$) and serum lactate levels (4.7 ± 2.6 to 3.0 ± 1.7 mmol/L, $p < 0.001$) were recorded. In a subgroup of patients with infarct-related ventricular septal defect (VSD), mean left-to-right-shunt volume was reduced from 4.5 ± 0.8 L/min to 2.0 ± 1.0 L/min, shunt flow ratio was reduced from 2.6 ± 0.4 to 1.6 ± 0.2 and the effective CI was increased from 1.4 ± 0.3 to 2.0 ± 0.4 L/min/m² after pVAD support. Overall, cardiogenic shock was reversed in all but one patient who suffered from right ventricular failure (Thiele *et al.* 2001).

Ethical Issues

No issues were identified from the retrieved material.

Cultural or Religious Considerations

No issues were identified from the retrieved material.

Other Issues

No issues were identified from the retrieved material.

Recommendation

Current research indicates that the Tandemheart pVAD is capable of reversing cardiogenic shock and has the potential to outperform IABP. However, despite the evidence that the TandemHeart pVAD appears to improve haemodynamic parameters, the value of these improvements have to be considered in the light of the higher complication rates as well as the 30-day mortality rate (~44% to 53%) (Burkhoff *et al.* 2006a, Thiele *et al.* 2005, Burkhoff *et al.* 2006b, Thiele *et al.* 2001) which is comparable to that of IABP (30% to 50%). It is important to note that despite the expectation that the pVAD would overcome the limitations of IABP in cardiogenic shock patients with severely depressed left ventricular function (Thiele *et al.* 2005); none of the patient groups in the included studies had substantial depression of left ventricular function. Perhaps the use of the device in these patients would better highlight its value, however this remains to be proven and further research is warranted in view of these points. It is therefore 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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Sources of further information:

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Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network of Agencies for Health Technology Assessment, relevant online journals and the Internet was conducted in July 2006.

Search terms used were: 'TandemHeart', 'percutaneous ventricular assist', 'ventricular assist device', and 'cardiac assist ventricular device'.

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).



2007 update

A search of relevant databases, online journals and the Internet was conducted in October 2007, following the recommendation in September 2006 that TandemHeart be monitored for 12 months. One new comparative study and six new case reports were identified from the available literature.

Safety and effectiveness issues

The potential clinical benefits of TandemHeart was examined by Tanaka et al. (2007) in seven patients who underwent percutaneous aortic balloon valvuloplasty (PABV) and four patients who underwent PABV with no ventricular assist device support. All patients were classified as high-risk surgical candidates due to advanced age, comorbidities and low mean ejection fraction (0.30 ± 0.14). Patient outcomes are summarised in the table below:

Table 1: Comparison of haemodynamic characteristics with or without TandemHeart

		TandemHeart	
		Yes	No
Ejection fraction	before	0.24 ± 0.09	-
	after	0.27 ± 0.08 ($p=0.28$)	-
Aortic valve area	before	0.59 ± 0.11	0.60 ± 0.00
	after	0.88 ± 0.22 ($p=0.006$)	1.06 ± 0.34 ($p=0.3$)
Aortic valve gradient	before	61.5 ± 20.9	53.3 ± 13.6
	after	44.6 ± 15.1 ($p=0.02$)	27.7 ± 14.2 ($p<0.0001$)

Echocardiography revealed that patients with TandemHeart support had significantly improved aortic valve area ($p=0.006$) and aortic valve gradient ($p=0.02$) (Table 1), indicating improved aortic valve function. In addition, the procedure was deemed technically successful in all seven patients who received TandemHeart support during PABV (survived up to 1 month post-treatment). The average output of TandemHeart in these patients was 3.0 ± 0.7 l/min (Tanaka et al. 2007). Meanwhile, patients who underwent PABV without ventricular assist device support achieved significant improvement in aortic valve gradient ($p<0.0001$). Aortic valve area did not increase significantly post-procedure (Table 1), but this increase may be clinically significant. Two deaths were observed, one due to cardiac arrest during the procedure and the other due to brady/asystolic cardiac arrest one day post-treatment. There were no incidences of aortic regurgitation or significant haemolysis (Tanaka et al. 2007).

The investigators stated that the use of TandemHeart for circulatory support during PABV preserved haemodynamic stability regardless of the patient's intrinsic cardiac function and enable precise placement of the valvuloplasty balloon. This translates to better patient safety, as evidenced by the death rates. Nevertheless, the use of TandemHeart is associated with significantly longer procedure times (336 min vs. 183 min, $p=0.011$) and may require surgical repair of the TandemHeart insertion site (4/7 patients in this study) (Tanaka et al. 2007).



Recent case series reports have investigated the use of TandemHeart as a bridge to recovery from myocarditis (Chandra et al. 2007), active cardiopulmonary resuscitation (Idelchik et al. 2007), severe pulmonary artery hypertension (Rajdev et al. 2007a) and acute fulminant myocarditis (Khalife and Kar 2007); and have reported encouraging results. Another case report demonstrated that the TandemHeart can be implanted through the Amplatzer septal occluder (Cook et al. 2007) while Rajdev et al. (2007b) reported success with TandemHeart assisted PABV for bicuspid valve stenosis with bivaluridin anticoagulation.

Summary of findings

The new evidence published within the last 12 months has been limited by low patient numbers and were generally designed to explore potential alternative applications of TandemHeart. It appears evident that the TandemHeart does confer clinical benefits when utilised, however the issues highlighted previously, such as complication and mortality rates when the device is utilised to reverse cardiogenic shock, have not been addressed in any of the retrieved studies.

2007 HealthPACT action

Based on the lack of development within the last 12 months, it is recommended that TandemHeart is archived.

Number of studies included

Total number of studies	7
Level III-2 intervention evidence	1
Case reports	6

References

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