



Horizon Scanning Technology Prioritising Summary

CorCap™ Cardiac Support Device

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).



Name of Technology:

CorCap™ Cardiac Support Device (CSD)

Purpose and Target Group:

In heart failure, the heart becomes progressively enlarged and less efficient due to increasing pressure within the heart. The CorCap™ CSD is a mesh-like device that is surgically implanted around the heart. This cardiac support device was designed to prevent further dilation and thus prevent further deteriorations in heart function as well as prevent or delay the onset of end-stage disease.

Stage of Development (in Australia):

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

The CorCap™ CSD 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
Europe	✓		
United States	✓		
Canada	✓		
Australia	✓		

Impact Summary:

Background

In congestive heart failure, the heart is unable to pump sufficient blood (or the ability to do so is limited to an elevated filling pressure) leading to inadequate delivery of oxygen to other parts of the body. This leads to enlargement of the heart and eventually end-stage heart disease if left untreated.

Pharmacological therapy using angiotensin-converting enzyme inhibitors and β -blockers is the current standard of care for the management of heart failure. However, the efficacy of these drugs may be limited without the ability to halt the progression of heart failure (Oz et al. 2003).



The CorCap™ CSD was developed by Acorn Cardiovascular Inc™ (St. Paul, Minnesota) and is a mesh-like jacket that is slipped over the heart during surgery. The device is designed to provide circumferential myocardial wall support, thus reducing wall stress and myocyte stretch (Acorn Cardiovascular 2005). The CorCap™ CSD was designed with bidirectional compliance so that it stretches more in the longitudinal direction (base to apex) than in the circumferential (transverse) direction (Oz *et al.* 2003). This distinct characteristic of the device has the effect of reshaping the heart from a sphere to a more normal ellipsoidal shape. This may improve heart function by preventing the progression of ventricular remodelling, thus enabling more efficient pumping. The CorCap™ CSD is not intended to be used in severe heart failure where a left ventricular assist device (LVAD) might be considered.

Clinical Need and Burden of Disease

Based on overseas findings it has been estimated that at least 300 000 Australians have chronic heart failure with 30 000 new cases diagnosed each year (Australian Institute of Health and Welfare Bulletin 2003). Direct healthcare costs for chronic heart failure in Australia were estimated to be AUD\$411 million in 2001 and this includes AUD\$140 million for hospitalisation and AUD\$135 million for nursing home costs (National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand, Chronic Heart Failure Clinical Practice Guidelines Writing Panel, 2001).

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

The Corcap™ CSD received the CE mark of approval in Europe in 2000 with 340 patients using the device since then (Heart Center Online 2005). The Acorn Clinical Trial is currently underway and compares treatment outcomes of the CorCap™ CSD with traditional therapies. To date, 300 patients have been enrolled into this trial which spans across multiple centres in Europe, Australia and North America.

In addition to this, the device has been available to a small number of centres (three centres in Italy and one in Sweden) in a Limited Market Release Surveillance Study (Livi *et al.* 2005).

The FDA rejected the CorCap™ CSD (July 2005) on the grounds that the device's ability to extend patient lifespan was not demonstrated in the clinical trials (Moore 2005).

Existing Comparators

Since the CorCap™ was developed to be an adjunctive therapy with medical and surgical management of heart failure, the comparators were limited to other ventricular devices that mechanically reduce myocardial wall stress and prevent cardiac dilatation.

- Myosplint (Myocor® Inc., Maple Grove, Minnesota)



The Myosplint device was designed to directly address the increased left ventricle sphericity in heart failure patients. It consists of an implantable transventricular splint and two epicardial pads that are adjusted to draw the wall of the left ventricle together and thereby reduce its radius. Ventricular shape change is accomplished by placing three Myosplints bisecting the left ventricle with epicardial pads that will disperse some of the stress on the left ventricular wall to the epicardium. Clinical safety and efficacy studies are currently underway in the United States and Europe.

- **Cardioclasp™** (Cardioclasp Inc., Cincinnati, Ohio)

Cardioclasp™ is a passive cardiac support device that consists of two indenting bars to reshape the left ventricle. It reduces ventricular wall stress and thus may improve systolic function. This device is currently undergoing animal testing.

Estimated Cost Impact

The costs associated with this new product are not available. Acorn Cardiovascular Inc. claims that the CorCap™ is a cost-effective option compared to other alternative surgeries. The Medicare Benefits Schedule does not list a specific item for cardiac transplants. However, the reimbursement fees for the insertion of a left/right ventricular assist device is \$1325.90 (Item number 38615) while the reimbursement fees for the insertion of a right and left ventricular assist device is \$1652.70 (Item number 38618) (Medicare Australia 2005).

Efficacy and Safety Issues

List of Studies Found

Total number of studies	13
Randomised Controlled Trials (preliminary)	1
Case series studies	12

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

Safety and efficacy data from one randomised clinical trial (preliminary results) and seven case series studies have been selected for inclusion in this summary; these studies were selected based on patient numbers and follow-up duration.

The ACORN Cardiac Support Device trial is a randomised controlled trial that enrolled 300 patients with heart failure and left ventricular systolic dysfunction (LVSD) who did not require cardiac artery bypass graft surgery (CABG). Of the 300 patients, 193/300 (64%) patients were listed for mitral valve surgery and they were randomised to: no additional procedure (n=102) or additional CSD (n=91). The remaining 107 patients who did not require mitral valve surgery were also randomised to receive the CSD (n=57) or not to



receive it (n=50) in addition to optimal medical therapy. The primary outcomes was a composite of patient mortality, major cardiac procedures and change in New York Heart Association (NYHA) class. For this composite outcome, there was a significant difference in favour of CorCap™ recipients compared with the controls (p=0.024). When each of the components are analysed separately, CorCap™ recipients did not differ to controls with regards to mortality (p=0.59) and serious adverse events (p=0.33). However, CorCap™ significantly reduced major cardiac procedures associated with worsening heart failure compared to controls (p=0.01) and significantly improved NYHA functional class (p=0.028). CorCap™ recipients exhibited significant improvements in structural and functional endpoints. This was evident in the reduction of left ventricular diastolic volume (LVEDV) (p=0.008), left ventricular systolic volume (LVESV) (p=0.02), reduction in left ventricular end diastolic dimension (LVEDD) (p=0.02) and change to a more natural elliptical shape (p=0.031). Significant improvements were reported in quality of life scores (Minnesota Living with Heart Failure and SF36 General Health Domain) (p=0.04 and p=0.0015 respectively) and core lab NYHA (p=0.048) as well (CorCap CSD PMA Clinical Summary 2005). However avoidance of surgery could be influenced by surgeon choice, the fact that no blinding was implemented in this study could mean that the differences may be due to bias rather than a true effect.

The paper by Oz *et al.* (2003) documents the results of all patients involved in the CorCap™ CSD initial safety and feasibility studies. This includes a series of 48 patients in total, with 33 having concomitant heart surgery. Of these, data for 25/48 (52%) patients were available at 12 months follow-up, 13/25 (52%) patients had concomitant heart surgery while the remaining 12 (12/25, 48%) received CSD-only treatment. NYHA class significantly improved from 2.7 [0.5] to 1.7 [0.7] (n=26). Structural and functional parameters significantly improved as well with significant (p<0.05) decreases in LVEDD and left ventricular end systolic dimension (LVESD) (72.8 [7.1] mm to 64.1 [10.6] mm, n=25 and 62.8 [8.1] mm to 54.7 [12.0] mm, n=23 respectively). Additionally, left ventricular ejection fraction (LVEF) improved significantly (23.6 [8.0]% to 29.9 [12.2]%, n=23) while mitral regurgitation (MR) severity was significantly reduced (1.6 [1.0] to 0.5 [0.7], n=22). When the data of the 12 CSD-only patients were analysed exclusively, similar results were observed, with significant (p<0.05) reduction in LVEDD and LVESD (72.7 [5.5] mm to 64.4 [5.4] mm, n=12 and 64.4 [5.4] mm to 56.9 [5.7] mm, n=12, respectively), improvement of LVEF (22.7 [5.6]% to 28.6 [8.2]%, n=12), reduced severity of MR (1.1 [0.5] to 0.5 [0.8], n=12) and improvement in NYHA class (2.5 [0.5] to 1.8 [0.7], n=12). The significant decrease in LVEDD and LVESD indicates that the CSD was successful in reducing heart size and preventing further ventricular remodelling while improvement in LVEF and reduction in MR severity point towards improved myocardial function.

The results from the CorCap™ European Limited Market Release Surveillance Study (conducted in Italy and Sweden, 29 patients) (Livi *et al.* 2005) indicates that most patients



exhibit an improvement of at least one NYHA functional class post-implantation. Baseline NYHA class significantly improved to 2.0 [0.6] from a baseline of 2.7[0.6] at three months ($p<0.05$), further improvement from baseline was recorded at 6 months (1.8 [0.6], $p<0.05$), and 12 months (1.6 [0.5], $p<0.05$) post-implantation. LVEDD significantly decreased from the baseline mean of 69 [7] mm to 60 [9] mm at three months ($p<0.05$), this was sustained at six months (60 [9] mm, $p<0.05$) and a slight decrease at 12 months (58 [8] mm, $p<0.05$) was recorded. LVEF also improved from 20 [10]% to 32 [12]% at three months, 33 [10]% at six months and 33 [13]% at 12 months. Additionally, MR severity decreased from 2.4 [1.2] at baseline to 0.59 [0.5] at three months ($p<0.05$), 1.00 [1.0] at six months ($p<0.05$) and 1.06 [0.9] at 12 months ($p<0.05$) (Livi *et al.* 2005).

Lembcke *et al.* (2004) studied the effects of the CSD on left ventricular structure and function in 14 patients (7 with concomitant mitral valve repair, 7 with CSD only). This study reported that myocardial mass was significantly decreased at six to nine months post-surgery (298.6 [79.6] g to 263.1 [76.8] g, $p<0.05$). This significant reduction in muscle mass was persistent after separating the data for the seven patients who underwent concomitant mitral valve repair and the seven who received CSD as the only treatment (320.7 [97.0] g to 282.6 [96.1] g, $p<0.05$; and 276.4 [56.4] g to 243.7 [51.5] g, $p<0.05$, respectively). This indicates that the CSD could be reducing the size of the heart not only via its girdling effect but possibly by actual reduction of muscle mass. This may point towards true reverse-modelling of the heart by the CorCap™ CSD, but the evidence is limited.

To assess the risks associated with this device, Raman *et al.* (2000) conducted a study consisting five patients with symptomatic heart failure and ischemic cardiomyopathy who received the CorCap™ CSD as an adjunct to CABG. These patients were a subgroup of the 48 patients who were analysed in Oz *et al.* (2003). No early deaths or significant adverse clinical events were observed post-operatively. Two patients required a combination of milrinone and norepinephrine treatment perioperatively. While another patient required intraaortic balloon counterpulsation for two days postoperatively. After 12 months follow-up, there were no late deaths or readmissions for heart failure in this group of patients (Raman *et al.* 2001). Additionally, coronary angiography was performed at 6 months follow-up and revealed that all grafts were patent with no indications of the CSD impinging on the grafts, anastomoses or epicardial coronary arteries (Raman *et al.* 2000).

Excessive fibrosis around the CSD and the subsequent development of constrictive physiology was a concern during the initial safe and efficacy studies. Utilising pressure-loop analysis, Kleber *et al.* (2001 & 2002) examined 11 patients. There was no evidence for constrictive physiology due to the presence of the CSD as implicated by the lack of changes in haemodynamic data, right atrial pressure, ratio of right atrial and right ventricular pressure, the pressure of dip-plateau waveforms and the absolute difference between right and left



ventricular pressure. Additionally, Kleber *et al.* (2001 & 2002) conducted coronary angiography and flow velocity studies using a Doppler wire and intracoronary injections of adenosine in the same group of patients. There were no signs of vascular constriction due to the CSD and coronary flow reserve was maintained at 2.9 [0.6] at three months, 3.1 [0.9] at six months, and 3.2 [0.4] at 12 months. Oz *et al.* (2003) stated that out of the 48 patients that received the CSD during the initial safety and efficacy studies, there were 17/48 (35%) deaths. However, the authors claim that no deaths or adverse events were CSD related (Oz *et al.* 2003).

Ethical Issues

No issues were identified from the retrieved material.

Cultural or Religious Considerations

No issues were identified from the retrieved material.

Other Issues

All CorCap™ CSD studies were funded by Acorn Cardiovascular Inc.

Conclusion:

Although one randomised controlled trial of CorCap™ has been carried out, the results favouring CorCap™ are largely driven by differences in additional surgery, an outcome which is susceptible to bias in this unblinded study. However, the randomised controlled trial and case series do indicate some effect of CorCap™ on reducing heart size. Due to the limited evidence available, it is recommended that the following be conducted:

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

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Sources of Further Information:

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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 March 2005.

Search terms used were: 'CorCap', 'Cardiac support device', 'Acorn device', 'passive heart containment' and 'heart mesh wrap'.

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).