



Australian Government
Department of Health and Ageing



Horizon Scanning Technology Prioritising Summary

Robotically assisted left ventricular epicardial lead implantation

April 2004
(Updated October 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:

Robotically assisted left ventricular (LV) epicardial lead implantation for biventricular pacing.

PURPOSE & TARGET GROUP:

This new technique has been designed to be an alternative treatment for heart failure patients who require cardiac resynchronisation therapy (ventricular resynchronisation). It may lower the morbidity and mortality rates for frail patients, by avoiding standard open surgical techniques.

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
USA		✓	
Belgium		✓	
Germany		✓	

IMPACT SUMMARY**Background:**

This new minimally invasive technique uses a combined endoscopic and robotically-assisted approach for epicardial left ventricular (LV) lead placement and may offer an alternative to LV lead placement by means of a limited thoracotomy. Operations are performed under general anaesthetic with selective right lung ventilation. Robotic technology allows placement of the lead onto the posterobasal wall of the LV surface (optimum site for successful resynchronisation). Robotic assistance is also reported to improve vision of the ventricular surface, opening of the pericardium and suturing.¹

Whilst the benefits of biventricular pacing for patients undergoing ventricular resynchronisation has been demonstrated, technical limitations with the implantation of the LV lead through the coronary sinus (CS) and into a LV epicardial vein and variations in the anatomy and location of other veins result in 10% to 15% failure rate of LV lead placement and effective pacing.^{2,3} It is also reported that lead dislodgement can contribute to a further 5% to 10% of LV lead capture failures.⁴ The remedy for such cases is to perform surgical LV lead implantation via a limited thoracotomy. This can be

complicated by the debilitated health status of the patients who often have moderate to severe heart failure, resulting in higher morbidity and mortality rates.

Clinical need and burden of disease:

An estimated 300 000 Australians have chronic heart failure with 30 000 new cases diagnosed each year. Aboriginal and Torres Strait Islander people are two to three times more likely to have heart failure than other Australians.⁵ Approximately 30% to 50% of patients with chronic heart failure have interventricular conduction defects causing uncoordinated contractions of the heart. This can be detrimental to an already failing heart, leading to an increased risk of death.⁶

Heart failure patients account for 38% of health care expenditure in Australia; the direct health costs for heart failure in 1993-1994 were estimated at A\$411 million; this accounts for approximately 10% of the total expenditure in cardiovascular disease. An ageing population, improved survival rate from heart attacks, increase in diabetes and obesity may all increase the number of heart failure patients in the future.⁵

Estimated speed, geographic and practitioner use patterns of diffusion in the health system:

This technique was developed in the United States by DeRose Jr. and other American surgeons; results for 10 patients undergoing this procedure were published in April 2003.¹ Modifications of this procedure (using robotic assistance for LV lead implantation) have been used by other surgeons in Germany and Belgium.

Existing comparators:

- placement of the epicardial lead on the LV epicardium through a thoracotomy (or sternotomy)
- percutaneous implantation through insertion of a purpose-designed lead in a left lateral coronary vein through the CS ostium under fluoroscopic control.⁷

Estimated cost impact:

Exact costs for this procedure are not available. Specific costs of robotic instruments per procedure have been estimated at approximately €600-700 (approx. A\$1000; January 2004). These costs do not include capital costs of the da Vinci system (a Melbourne hospital has recently invested A\$3 million in this system). Cost savings may occur through procedural success rate, reducing treatment time and by avoiding costs associated with failure or complications.^{7, 8, 9}

Efficacy and safety issues:

Short-term safety and efficacy data exist from five case series and two case reports.

Study details	Key efficacy findings	Key safety findings
<i>Case series</i>		
DeRose <i>et al.</i> 2003, USA ¹	All 19 epicardial leads successfully	1/10 (10%) patient sustained an

10 patients	implanted in 10 patients (1 patient received only 1 lead).	intraoperative ventricular injury immediately after lead placement, which was resolved.
<i>Follow up:</i> from 3-6 mo	Mean robotic time for all cases was 83±53 min (range 30-180 min).	1/10 (10%) patient developed a left lower lobe pneumonia 3 days after robotic lead placement.
<i>Selection criteria:</i> Patients with previous failure of CS cannulation.	No blood transfusions required.	
Patients aged between 70.5±13 yr (range 49-87 yr)	No reoperations for bleeding reported.	
8/10 (80%) male	All patients (10/10; 100%) were alive and well at a mean follow-up of 25±10 weeks.	
Three patients (3/10; 30%) had previous cardiac surgery and seven (7/10; 70%) had a prior device implanted.	8/10 (80%) of patients were symptomatically improved at three month follow-up with improved exercise tolerance.	
<i>Other:</i> Used a posterolateral approach.	As a group, a statistically significant improvement was noted in QRS duration (p=0.006), NYHA class (p<0.001) and LVEF (p=0.04).	
See Table 1 after Reference section for further comparisons of operative results at baseline and 3-6 months follow-up.		
Jansens and de Cannière, Belgium ⁷ (no date reported)	Mean duration of the procedure was 2.3 h (2 pacemakers and 1 pace/defibrillator).	
3 patients	Procedural duration for the LV lead implantation was 40 min.	
<i>Follow-up:</i> mean 2.1 mo		
<i>Selection criteria:</i> Patients with chronic heart failure.	Technical difficulties were encountered (details not specified); it was suggested that tailor-made robotic tools and leads would considerably facilitate the procedure.	
<i>Other:</i> Target area was the lateral LV wall.	At follow-up all devices were functioning well. Chronic pacing and sensing thresholds of the LV leads were satisfactory.	
<i>Continued...</i>	2/3 (67%) patients reported improved functional capacity.	

AICD - Automated implantable cardioverter-defibrillator, QRS (complex) - the series of deflections in an electrocardiogram that represent ventricular activity of the heart, NYHA - New York Health Association class, LVEF - left ventricular ejection fraction.

Study details	Key efficacy findings	Key safety findings
<p>Jansen <i>et al.</i> 2003, Belgium⁸</p> <p>20 patients</p> <p><i>Follow-up:</i> mean 8 mo</p> <p><i>Selection criteria:</i> Not stated.</p>	<p>Mean duration of procedure was 2.5 h (10 pacemakers and 10 AICD).</p> <p>Mean procedural duration for LV lead implantation was 20 min.</p> <p>At follow-up all the devices were functioning well.</p> <p>All patients (20/20; 100%) reported improvement in their functional capacity.</p>	<p>3/20 (15%) patients were converted into a small left thoracotomy, all for reasons unrelated to the robotic procedure (further detail not reported).</p> <p>No major complications were reported in the early follow-up period (duration not stated).</p>
<p>Jansens <i>et al.</i> 2003, Belgium¹⁰</p> <p>15 patients</p> <p><i>Follow-up:</i> 3, 6 and 12 mo</p> <p><i>Selection criteria:</i> Patients with chronic heart failure. NYHA class III or IV with a wide QRS complex.</p> <p>11 males and 4 females with a mean age of 71.2±5.8 y. 10/15 (66.7%) had pacemakers and 5/15 (33.3%) had an indication for pacemakers including an AICD.</p> <p><i>Other:</i> See Table 2 after Reference section for postoperative clinical improvement at 4 month follow-up.</p>	<p>Mean duration of procedure was 2.5±0.8 h. The robotic endoscopic duration was 17.5±5.7 min.</p> <p>Average length of stay was 4.6±2.1 d.</p> <p>The 2 patients (2/15; 13%) who underwent a conversion, showed improvement 4 months postoperatively (p=<0.01).</p>	<p>2/15 (13%) underwent conversion to a small thoracotomy and experienced pulmonary infections that were treated with intravenous antibiotic therapy.</p> <p>Postoperative course uneventful in the remaining patients 13/15 (87%).</p>
<p>Mair <i>et al.</i> 2003, (3 country study)¹¹</p> <p>80 patients</p> <p><i>Follow-up:</i> Not stated.</p> <p><i>Selection criteria:</i> Patients with advanced heart failure and left bundle branch block.</p> <p><i>Other:</i> Epicardial LV leads for biventricular pacing were implanted by either: left lateral mini-thoracotomy, video-assisted thoracoscopic approach using lead implantation tools or a robotically enhanced telemanipulation system.</p>	<p>Acute and 3 month LV lead thresholds were satisfactory in 79/80 (99%) patients.</p> <p>Intended lead location on the LV was achieved in all patients (80/80; 100%), independent of the technique used.</p> <p>Two lead displacements were observed.</p> <p>One thoracotomy (1/80; 1%) was carried out after lead placement because the patient developed an early exit block.</p> <p>Five patients who underwent robotic surgery needed a conversion to thoracotomy. 2/5 (40%) due to technical failure of the robot, 3/5 (60%) due to massive pleural adhesions.</p>	<p>3/80 (4%) patients died in hospital from the progression of end-stage heart failure (the surgical technique used in these patients was not reported).</p> <p>3/80 (4%) patients underwent conversion to a thoracotomy due to massive pleural adhesions.</p> <p>No severe adverse events were reported with any technique.</p>
<i>Continued...</i>		

Case Report

Kleine et al. 2002, Germany ¹²	QRS complex width was reduced from 250 ms to 170 ms.	Low inotropic support was needed following carbon-dioxide inflation.
One 69-year-old female patient with dilated cardiomyopathy and suspected ventricular tachycardias.	The patient was extubated 3 h postoperatively.	No bleeding or other adverse events reported.
<i>Follow up:</i> Not stated.	Stable positioning of epicardial leads was reported.	No complications were reported postoperatively.

Other:

This was an anterolateral approach.

Morgan et al. 2003, USA ¹³	Successful lead placement was reported.	No complications or adverse events reported.
One 51-year-old female patient with chronic heart failure. Recent loss of LV pacing due to CS lead displacement, with failed attempt at replacement/revision of her pacemaker system.	Cardiac resynchronisation was re-established.	

Follow up:
Not stated.

AICD - Automated implantable cardioverter-defibrillator, QRS (complex) - the series of deflections in an electrocardiogram that represent ventricular activity of the heart, NYHA - New York Health Association class, LVEF - left ventricular ejection fraction.

There is a small evidence base for the safety and efficacy of robotically assisted LV epicardial lead implantation for biventricular pacing as an alternative to traditional open surgical procedures. However, the studies that do exist have indicated that this technique may be effective at reducing morbidity and mortality rates and recovery time.

2005 update

A search of relevant databases, online journals and the internet was conducted in October 2005, following the recommendation in April 2004 that robotically assisted left ventricular epicardial lead implantation be monitored for assessment in 18 months time. No new evidence on the safety and efficacy of this technique was retrieved.

Hence, based on the limited evidence to date it is recommended that this procedure be archived.

Ethical issues:

Not applicable.

Cultural or religious considerations:

Not applicable.

Other issues:

Robotic LV lead placement does have the possible disadvantage of requiring general anaesthetic and selective single-lung ventilation compared to standard open surgical techniques.¹

Conclusion:

Some evidence exists on the safety and efficacy of this procedure as an alternative treatment for LV epicardial lead implantation. Short and long-term efficacy data of controlled trials would be required before robotically assisted left ventricular (LV) epicardial lead implantation for biventricular pacing could be widely accepted.

2005 Update: This procedure will be monitored for a further 12 months as it has potentially high impact on current practice.

Horizon Scanning Report

Full Health Technology Assessment

Monitor

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 December 2003.

Search terms used were: robotically assisted left ventricular epicardial lead implantation for biventricular pacing, biventricular pacing, epicardial lead implantation and robot\$ assisted surgery.