



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

VALR surgical system for lung cancer and chronic obstructive pulmonary disease

April 2004



ASERNIP(S)

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



**Royal Australasian
College of Surgeons**

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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:

VALR surgical system

PURPOSE & TARGET GROUP:

The VALR surgical system is a vacuum applied silicon sleeve that is designed to apply radial compression to lung tissue, minimising air leaks and bleeding in lung surgery. It may therefore be applicable as a replacement for surgical staplers, staples, buttressing, and patching materials currently used for sealing lung tissue in the treatment of lung cancer and chronic obstructive pulmonary disease.¹

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 VALR surgical system is not listed or registered in the Australian Register of Therapeutics Goods (ARTG).

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY

Background:

Lung surgery is often associated with prolonged hospitalisation and increased morbidity due to complications caused by air leaks. Despite advances in medical technology, prolonged air leaks still remain a common postoperative problem.¹ Intraoperative air leaks can occur distant to the operative site due to surgical manipulation, trauma and pressure to the lung tissue. Reduction of air leaks often lies in their prevention, through careful dissection and tissue closing techniques.²

The VALR surgical system is a new procedure, which selectively captures lung tissue within a silicon sleeve. The radial compression applied to the tissue has been suggested to arrest both air leaks and bleeding.⁴

Clinical need and burden of disease:

Lung cancer is the leading cause of death due to cancer in Australia with more than 7,800 Australians diagnosed and about 6,700 deaths each year. One in 28 Australians will develop lung cancer by the age of 75 years.⁵ According to the Australian Bureau of Statistics, in 1998, chronic obstructive pulmonary diseases were responsible for 4.9% of total deaths in Australia.⁶

These diseases are both associated with high incidence and mortality rates. The survival rate of lung cancer patients beyond 5 years is as little as 11% for males and 14% for females, making effective surgery essential.⁵ With such large numbers of the population affected, these diseases impact heavily on health funding and resources.

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

Vallières and colleagues published a study in 2003, where the procedure was used on six patients undergoing lung lobectomy. Professor Vallières is now directing an acute feasibility study of VALR at the University of Washington. Spiration Inc, the manufacturer of the VALR surgical system, expects to commercialise the product by late 2003.³

Existing comparators:

- Staples
- Buttressing
- Sealants

Estimated cost impact:

The costs associated with this new procedure are not available. The closure cost of lung surgery in Australia is also not available. However, due to the initial reported decrease in operative time and postoperative complications using the VALR surgical procedure, it may be more cost effective.

Efficacy and safety issues:

Safety and efficacy findings are based on one case series (evidence level IV)⁷ conducted by Vallières and colleagues. The study reported on six patients who underwent lobectomy between March and May 2002 who received the vacuum-assisted lung reduction technique. The VALR system was effective in capturing an estimated 25% to 30% of loblar tissue in all patients. No air leaks were detected within the sleeve-captured tissue or in tissues adjacent to the proximal compression band. Air leaks were however detected outside the experimental field in 4/6 (66.6%) patients but these were attributed to surgical dissection and unrelated to the system evaluation. No device related abrasions

or lacerations were observed in adjacent tissue. A cumulative mean time of 8.5 minutes (range 6-13 minutes) was recorded to perform the procedure in the 6 patients.²

Ethical issues: Not applicable

Cultural or religious considerations: Not applicable

Other issues: Not applicable

Conclusion:

Limited evidence exists on the safety and efficacy of the VALR surgical system. Long-term safety and efficacy data from randomised controlled trials may be required before this procedure can be widely accepted.

Horizon Scanning Report

Full Health Technology Assessment

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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 January 2004.

Search terms used were: 'vacuum assisted lung reduction', 'pulmonary air leaks and silicon sleeve', 'VALR', 'Vallieres E', 'spiration inc' and 'xavier gonalez'