



**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

## Minimally invasive oesophagectomy

April 2004



**ASERNIP(S)**

**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:**

Minimally Invasive Oesophagectomy (alternatively known as minimally invasive esophagectomy; MIE).

**PURPOSE & TARGET GROUP:**

MIE may be an alternative treatment for dysplasia/cancer of the oesophagus. This procedure may lower morbidity and mortality rates, reduce pain and shorten recovery time compared to traditional oesophagectomy procedures (open approaches).

**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	✓	✓	

**IMPACT SUMMARY****Background:**

MIE is a surgical procedure that uses a combined thoracoscopic and laparoscopic approach and may eliminate the need for invasive thoracotomy and laparotomy incisions.<sup>1</sup>

**Clinical need and burden of disease:**

In Australia, it is estimated that 1 000 people per year will develop oesophageal cancer.<sup>2</sup> International statistics suggests that morbidity and mortality rates are similar. In 2000, 7 364 people were diagnosed with oesophageal cancer in the United Kingdom and in 2002, 7 245 people had died from the disease (8.9 deaths per 100 000 people, age standardised).<sup>3</sup> In the United States it is estimated that 14 250 people will be diagnosed with oesophageal cancer in 2004, and 13 300 will die from the disease.<sup>4</sup> Patients are often elderly, may have co-morbid disease and may be malnourished from malignant dysphagia. Oesophageal cancer is easy to diagnose, but is difficult to treat. The five-year survival rate (5 to 30% after surgery) is worse than for many other cancers. Oesophagectomies are associated with significant morbidity and mortality rates; in the United States operative mortality rates range from 8% to 23%.<sup>5</sup>

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

MIE has been offered to the majority of patients with resectable cancers in Pittsburgh, USA since 2000.<sup>6</sup> In addition, a multi-centre study with 125 patients in five different centres experienced with MIE, will be formed in the United States to assess whether MIE can be developed in other centres with similar positive outcomes.<sup>7</sup>

## Existing comparators:

Standard oesophagectomy approaches:

- transthoracic (Ivor-Lewis)
- left thoracoabdominal
- left thoracoabdominal with left neck anastomosis
- transhiatal
- photodynamic therapy (non-surgical)

## Estimated cost impact:

The cost of an oesophagectomy in Australia is not available, with the Medicare Benefits Schedule reimbursement fee (procedure only) ranging from AU\$700-2 000.<sup>8</sup> A cost analysis of MIE is not available, however it may be higher than other minimally invasive operations due to instrument costs. Potential cost savings may occur if ICU and hospitalisation were able to be reduced.<sup>9</sup>

## Efficacy and safety issues:

Short- and long-term safety and efficacy data exist from one comparative study and four case series. All studies used a thoracoscopic and laparoscopic approach.

Study details	Key efficacy findings	Key safety findings
<i>Comparative study</i>		
<b>Nguyen <i>et al.</i><sup>1</sup> 2000a, USA</b>	At follow-up, none of the patients in the MIE group with oesophageal cancer, developed local, recurrent local or metastatic disease.	Patients in the MIE group had less blood loss (mean 297[233] mL)* than TT (mean 1046[792] mL) and THE (mean 1142[785] mL).
54 patients Follow-up: mean 6.3 months		
<i>Selection criteria:</i> Transthoracic TT (n=16), blunt transhiatal THE (n=20) and MIE (n=18).	Operating times were shorter in the MIE group, (mean 364[73] min)* compared with TT (mean 437[65] min) and THE (mean 391[144] min).	Fewer transfusions were needed in the MIE group (3/18, 16.7%)* than in TT (8/16, 50%) and THE group (15/20, 75%).
Retrospective study.	Mean ICU stay was shorter in MIE group (11.3[14.2]d)*, compared with TT (23.0[22.3]d) and THE (22.3[16.1]d).	No intraoperative complications were reported in the MIE or TT group, 4/20 (15%) occurred in the THE group.
* $P < 0.05$ compared with TT and THE group.	Mean hospital stay was shorter in MIE group (6.1[11.3]d)* than in TT (9.9[16.3]d) or THE (11.1[15.7]d).	<u>Postoperative complications:</u> No major differences in the incidence of anastomotic leak (MIE 2/18 (11.1%), TT 2/16 (12.5%) and THE (2/20, 10%).
<i>Continued...</i>		
Study details	Key efficacy findings	Key safety findings
<b>Nguyen <i>et al.</i><sup>1</sup> 2000a, continued</b>	Mean intraoperative transfusion was less in MIE group (0.3[0.7]U)* than	Respiratory failure occurred in 2/18 (11.1%) patients in the MIE group.

	<p>in TT (1.8[2.2]U) or THE (6.9[5.4]U).</p>	<p>3/16 (18.8%) TT group and 3/20 (15%) THE group.</p> <p>One patient (1/16, 6%) developed gastrointestinal bleeding in the TT group.</p> <p>One patient (1/16, 6%) developed gastric conduit ischemia in the TT group.</p> <p>Pulmonary embolism occurred in 1/18 (5.5%) patients in the MIE group and 1/20 (5%) THE group.</p> <p>Delayed gastric emptying occurred in 1/18 (5.5%) patients in the MIE group.</p> <p>Chylous ascites were reported in 1/20 (5%) patients in THE group.</p> <p>One patient (1/18, 5.5%) developed a tracheal-gastric fistula and died of bronchopneumonia six months after receiving MIE.</p> <p>Hoarseness occurred in 4/20 (20%) patients in the THE group.</p> <p>One patient (1/16, 6%) developed an intra-abdominal abscess in TT group.</p> <p>30 day mortality was zero in all groups.</p> <p>One in-hospital death due to multiple organ failure occurred in the THE group on day 70.</p>
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*Case series*

<p><b>Luketich et al.<sup>7</sup>2003, USA</b></p> <p>222 patients Follow-up: mean 19 months</p> <p><i>Selection criteria:</i> Patients with high-grade dysplasia or carcinoma.</p>	<p>MIE was successfully completed in 206/222 (92.8%) patients.</p> <p>At follow-up, quality of life scores were similar to preoperative values and population norms.</p>	<p>Operative mortality was 3/222 (1.4%).</p> <p><i>Minor complications</i> (53/222, 23.9%): Atrial fibrillation and pleural effusions requiring a tube were most common.</p> <p><i>Major complications</i> (71/222, 32%): Anastomotic leak and pneumonia were most common.</p>
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*Continued...*

*Case series*

<p><b>Nguyen et al.<sup>9</sup> 2000b, USA</b></p>	<p>Mean ICU and hospitalisation was 2.6 and 8.3 days, respectively.</p>	<p>No anastomotic leaks or strictures were reported.</p>
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<p>12 patients Follow-up: mean 12.6 months</p> <p><i>Selection criteria:</i> Patients with Barrett's oesophagus with high-grade dysplasia (all but one underwent a combined thoracoscopic and laparoscopic procedure).</p>	<p>All 12 patients were alive and free of metastatic disease at follow-up.</p>	<p>5/12 (41.7%) patients had complications. One single minor complication and six major complications (respiratory insufficiency, small bowel perforation, delayed gastric emptying), were reported.</p>
<p><b>Fernando <i>et al.</i><sup>10</sup> 2000, USA</b></p> <p>28 patients Follow-up: median 13 months</p> <p><i>Selection criteria:</i> Patients with high-grade dysplasia.</p>	<p>Median ICU and hospital stay were one and five days respectively.</p> <p>One conversion to laparotomy (1/28, 3.6%), five re-operations (5/28, 17.9%).</p> <p>At follow-up, all survivors were alive and disease-free.</p>	<p>One death occurred (1/28, 3.6%).</p>
<p><b>Luketich <i>et al.</i><sup>11</sup> 2000, USA</b></p> <p>77 patients</p> <p><i>Selection criteria:</i> Patients with esophageal carcinoma, Barretts high-grade dysplasia or carcinoma <i>in situ</i> and benign miscellaneous.</p>	<p>Median ICU and hospital stay were one and seven days, respectively.</p> <p>Four nonemergent conversions to open oesophagectomy (4/77, 5.2%).</p>	<p>No operative or hospital mortalities.</p> <p>Major and minor complication rates were 27 and 55%, respectively.</p>

There is a small evidence base for the safety and efficacy of MIE as an alternative to traditional oesophagectomy procedures. However, the studies that do exist have indicated that MIE may be effective at reducing morbidity and mortality rates and recovery time.

**Ethical issues:**

Not applicable.

**Cultural or religious considerations:**

Not applicable.

**Other issues:**

- MIE is a technically complex surgery
- the outcome is highly dependent upon the surgeons' expertise in oesophageal surgery and minimally invasive techniques and the number of oesophagectomies performed at the centre.
- postoperative morbidity after MIE is related to the stage of cancer and size of tumour, therefore patient selection is important
- there are concerns regarding the adequacy of tumour clearance with MIE<sup>8</sup>
- the main surgical complications/cause of death are anastomotic leakage and cardiopulmonary problems.<sup>12</sup>

**Conclusion:**

Some evidence exists on the safety and efficacy of minimally invasive oesophagectomy as an alternative treatment to conventional oesophagectomy. The development of the multicentre trial in the United States with experienced surgeons all using the same technique, will give a clearer indication of the safety and efficacy outcomes. Since the mortality rates associated with oesophageal cancer are high, this treatment may be beneficial for those affected by the disease.

### HealthPACT decision:

With some reports of patient satisfaction and few negative outcomes, it is recommended that a further appraisal of the procedure be conducted and a horizon scanning report be produced.

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| <input checked="" type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor                            | <input type="checkbox"/> 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 October 2003.

Search terms used: minimal invasive esophagectomy, minimal invasive oesophagectomy, esophagectomy, oesophagectomy, laparoscopic and thoracoscopic esophagectomy.