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Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Microwave ablation for lung cancer



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

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PRIORITISING SUMMARY

REGISTER ID S000115

NAME OF TECHNOLOGY MINIMALLY INVASIVE MICROWAVE ABLATION FOR LUNG CANCER

PURPOSE AND TARGET GROUP TO OFFER PATIENTS WITH A MINIMALLY INVASIVE NON-SURGICAL TREATMENT ALTERNATIVE FOR LUNG MALIGNANCIES

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|-----------------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 151425; 152043; |
| <input type="checkbox"/> No | | 152044; 152046; |
| <input type="checkbox"/> Not applicable | | 157722 |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
China	✓		
Germany	✓		
Greece	✓		
Italy	✓		
Japan	✓		
United Kingdom	✓		
United States	✓		

IMPACT SUMMARY

Minimally invasive, image-guided, microwave ablation uses heat generated from microwave energy to destroy lung tumours. Microwave ablation potentially offers patients with significant cardiorespiratory comorbidities who may not be eligible for traditional surgical intervention with a minimally invasive, non-surgical treatment of lung cancer.

BACKGROUND

Lung cancer is a disease of uncontrolled cell growth in the tissues of the lungs. Primary lung tumours can be classified as small cell lung cancers or non-small cell lung cancers. Small cell lung cancer is aggressive, fast-growing, and accounts for approximately 15% of all diagnosed lung cancers (Dugdale et al 2009). These types of cancers are also almost exclusively associated with cigarette smoking (Dugdale et al 2009). Non-small cell lung cancer is far more common and has a slower rate of growth than small cell lung cancer. Due to the rapid growth rate of small cell lung cancer and its tendency to metastasise, these tumours are generally treated with chemotherapy and not surgery (Dugdale et al 2009). Traditional first line treatment for patients with non-small cell lung cancer (that has not spread beyond nearby lymph nodes) is surgery, which may involve the removal of the lobes of the lung (lobectomy), or a small part of the lung (wedge or segment removal), or the entire lung (pneumonectomy) (Chen 2009).

More than 20% of patients with early stage lung cancers are ineligible for surgery due to their age or underlying comorbidities (such as poor cardiorespiratory reserve) (Abbas et al 2009); in these patients, less invasive, non-surgical means of curative treatment are required (Simon et al 2005). In addition to this, postoperative mortality in patients who are considered fit for surgical resection is considerably high. Previously, radiotherapy alone or radiotherapy in conjunction with a cisplatin-based chemotherapeutic agent was the only viable alternative to surgery; however, the overall efficacy of these treatments has been proven to be significantly less than that of surgery (Wasser et al 2008).

For several decades the effect of (increased) heat on cancer cells has been known. Temperatures as low as 41°C have been shown to cause death in cancer cells in *in-vitro* models (Wasser et al 2008). This, coupled with improvements in real-time imaging (such as computer tomographic fluoroscopy), has allowed the development of minimally invasive, image-guided treatment of cancer using hyperthermia (high temperatures). Current techniques which use hyperthermia to induce cancer cell death include radiofrequency ablation, laser ablation, high-frequency ultrasound ablation, and most recently microwave ablation. Temperatures commonly used for ablation procedures generally range from 60 to 100°C; at these temperatures cellular proteins are rapidly denatured as are nucleic acid-histone protein complexes, resulting in near-instantaneous cell death, followed by coagulation necrosis over subsequent days (Wasser et al 2008). In the lung specifically, normally aerated parenchyma surrounding the tumour bed insulate the adjacent normal tissue from thermal injury (Wasser et al 2008).

The main objectives of pulmonary ablation includes eradication of all viable malignant cells in the target volume with a safety margin to ensure complete eradication and minimisation of damage to certain targeted volumes to provide good functioning reserve for the rest of the lung (Vogl et al 2009). Potential advantages of local tumour ablation over surgical resection may include selective damage, minimal treatment morbidity and mortality, less breathing impairment in patients with borderline lung function through sparing healthy lung tissue, repeatability, fairly low costs, good imaging during the procedure and at follow-up, and a gain in quality of life with less pain and short hospitalisation (Vogl et al 2009).

Of the ablative modalities utilised for lung cancer treatment, radiofrequency ablation has been in use for the longest period of time and has demonstrated the most clinical success to date. Microwave ablation is said to offer many of the benefits of radiofrequency ablation, as well as offer some theoretical advantages over radiofrequency ablation. These advantages include consistently greater intratumoral temperatures, faster ablation time, diminished procedural pain, the ability to treat without grounding pads, and larger tumour ablation volumes with use of multiple applicators (Carrafiello et al 2008).

Microwave ablation is generally performed as a percutaneous outpatient procedure under image guidance. Image guidance is used to localise the tumour, and depending on the size and location of the tumour the best percutaneous entry route, number and type of microwave applicators to be employed and the length of treatment is determined (Wolf et al 2008). Microwave applicators are typically thin 14.5 gauge antennas introduced percutaneously into the tumour bed (McTaggart and Dupuy 2007). Tumours greater than 2cm in diameter may require the use of multiple applicators concurrently (Wasser et al 2008). Actual treatment time may vary from 7-10 minutes (McTaggart and Dupuy 2007). Microwave ablation utilises electromagnetic waves to agitate adjacent water molecules, creating thermal friction and coagulative necrosis in the target tissue (Iannitti et al 2007). The energy spectrum used by microwave ablation extends from 300 MHz to 300 GHz, which is considerably higher than the frequency range used by radiofrequency ablation, although the microwave probes available for clinical use usually only operate between 900-2450 MHz (Carrafiello et al 2008).

CLINICAL NEED AND BURDEN OF DISEASE

Cancer of the lung is the most common cause of cancer in Australia and the world, and relative survival after diagnosis remain very poor compared with other types of cancer (Australian Institute of Health and Welfare 2003). Lung cancer is also the leading cause of cancer-related death in Australia, and the third leading cause of all deaths in Australia (The Australian Lung Foundation 2010). Approximately 9,100 Australians are diagnosed with lung cancer each year, 7,600 of which will eventually die as a result of the disease. This equates to almost 20 lung cancer-related deaths per day, every day of the year (The Australian Lung Foundation 2010).

In patients with lung malignancies, significant proportions have cardiorespiratory comorbidities which do not allow them to undergo traditional surgical resection (Wasser et al 2008). Of the 20-30% of patients with lung malignancies who are fit for surgical treatment, postoperative mortality is significant (Wasser et al 2008). One trial of 2,200 patients reported mortality in 6.2% of patients following pneumonectomy, 2.9% following lobectomy, and 1.4% following sublobar resection (Ginsberg et al 1983).

DIFFUSION

Since the year 2000, when the first use of thermal ablation for lung cancer was reported, there has been a rapid increase in the use of the procedure (Vogl et al 2009). In 2009 it was expected that the number of thermal ablation procedures taking place to treat thoracic malignancy would exceed 150,000 per year by 2010 (Vogl et al 2009).

There are currently three microwave ablative devices included on the Australian Register of Therapeutic Goods (ARTG) for use in Australia (Therapeutic Goods Administration [TGA] 2010). The manufacturer name and intended purpose of each device, as well as its ARTG number and start date are presented below in Table 1. It is unlikely these devices are being used to treat lung cancer in Australia, according to the Medicare Benefits Schedule (MBS) the main indications for microwave ablation are menorrhagia and prostate cancer (MBS 2010). There are also three FDA-approved microwave ablation devices in use in the United States (Abbas et al 2009).

Table 1: Microwave ablation devices with TGA approval (TGA 2010).

ARTG Number	Manufacturer	Device	Intended purpose	ARTG start date
151425	Microsulis Ltd	Hyperthermia system, microwave	A system used to deliver microwave energy to soft tissue for the purpose of coagulation and ablation	02/04/2008
152043; 152044; 152045; 152046	Valleylab Inc	Hyperthermia applicator, microwave, intracorporeal; Pump, general-purpose	Intended for use with the microwave generator for the coagulation of soft tissue. The antenna(s) work in conjunction with the microwave ablation pump and microwave pump tubing set to provide a cooled shaft suitable for use in percutaneous, laparoscopic, and intraoperative ablation procedures	02/05/2008
157722	Scanmedics Pty/Ltd	Hyperthermia system, microwave	Treat lesions using microwave hyperthermia	10/12/2008

COMPARATORS

Surgical resection with a curative intent remains the mainstay of treatment for early stage non-small cell lung cancer (Wasser et al 2008). In patients who are ineligible for surgical resection, minimally invasive, non-surgical alternatives to cancer treatment may include radiotherapy (alone, or in conjunction with chemotherapy), or modalities which utilise extreme temperature to induce cancer cell-death, including radiofrequency ablation, laser ablation, and high-frequency ultrasound ablation. In general, these hyperthermal ablative techniques differ only by their physical method of generating heat while the tissue damage they achieve is related directly to tissue temperature (Vogl et al 2009).

The main comparator for microwave ablation would be the current gold standard for the treatment of lung malignancies, which is traditional surgical resection.

SAFETY AND EFFECTIVENESS ISSUES

Two case series studies were identified as relevant for inclusion (Wolf et al 2008; He et al 2006). These studies used minimally invasive microwave ablation to treat lung malignancies with a curative intent.

Wolf et al (2008) conducted a retrospective evaluation of 50 patients (28 men, 22 women), with a mean age of 70 years (standard deviation [SD], 15 years), who underwent computed tomography (CT) guided percutaneous microwave ablation of 82 intraparenchymal pulmonary masses (in 66 ablative procedures) between November 2003 and August 2006. All of the included patients were deemed inoperable, or refused surgery. Follow-up CT was performed at 1-, 3-, and 6- month intervals after the initial ablation session, with an overall mean follow-up period of 10 months (SD, 6.8 months) for all patients. Common terminology criteria for adverse events (CTCAE¹) were used to grade the severity of the complications experienced in the patient population.

He et al (2006) retrospectively evaluated ultrasound (US) guided percutaneous microwave ablation in 12 patients with (n=16) peripheral lung cancer treated between December 2002 and September 2003. Of these patients, 12 were men and 5 women with an average age of 47.5 years (range: 31-69 years). Indications for microwave ablation included refusal of surgical resection (n=5), poor cardiopulmonary reserve (n=3), and experience of severe side effects (including vomiting, diarrhoea, renal failure) from previous chemo/radiotherapy (n=4). Contrast-enhanced CT imaging of the chest was carried out in all patients before and after the ablative session. Colour Doppler flow imaging (CDFI²) with high sensitivity was specifically used to assess blood vessels inside and in the periphery of the tumours. Overall mean follow-up was 20 months (range: 6-40 months).

Safety

There were no intraprocedural deaths reported in the study by Wolf et al (2008). One death occurred at approximately 9 months postoperatively as a result of a delayed complication (haemoptysis). Pneumothorax occurred after 39% (26/66) of procedures, the majority of which (18/26, 69%) were considered mild (grade 1) using CTCAE and did not require intervention. Twelve per cent (8/26) of pneumothorax events were considered moderate to severe (grade 2) and required chest tube placement. Intraprocedural skin burns occurred as a result of 3% (2/66) of ablation procedures; one patient's burn was grade 3 and the other grade 2. One patient (2% of procedures) experienced significant pain (5/10-point scale for chest pain) localised to the site of ablation (grade 1). Analgesic therapy offered pain relief in this patient until they were discharged with a prescription for more pain medication if necessary. Another patient (2% of procedures) was diagnosed with grade 1 postablation syndrome, defined as a constellation of productive cough with

¹ Common Terminology Criteria for Adverse Events: Grade 1: mild adverse event, Grade 2: moderate adverse event, Grade 3: severe adverse event, Grade 4: life-threatening or disabling adverse event, Grade 5: death related adverse event.

² Colour Doppler flow imaging: Grade I: there is no blood flow in the tumour, Grade II: there is one or two tiny branch vessels (<2mm in diameter) in the tumour, Grade III: there are three or four tiny branch vessels in the tumour or one or two feeding vessels (>2mm in diameter) in the tumour, Grade IV: there are more than two feeding vessels in the tumour.

or without minor haemoptysis, residual soreness in the treated area, and fever occurring several days after the procedure. All signs and symptoms were resolved in this patient within 3-4 days. Ten patients (15% of procedures) were admitted to hospital after ablation, nine of these were readmitted for continued monitoring or pneumothorax that was treated with chest tubes and wall suction, and were discharged home in 1-2 days. The remaining patient was admitted to the intensive care unit (ICU) due to acute respiratory distress syndrome and seizure activity periprocedurally (grade 4). This patient was moved from ICU to a regular ward after 1 week and discharged from hospital shortly after.

All patients reported in the study by He et al (2006) experienced mild to moderate pain in the microwave applicator insertion site during, and up to one week following, the ablation procedure. Seven patients experienced low-grade fever that subsided with symptomatic treatment and one patient experienced a slight skin scald for 1 month. Another patient had minimal pneumothorax which spontaneously absorbed in 1 week. There was no incidence of severe complication requiring surgical intervention reported in this study.

Effectiveness

Wolf et al (2008) reported initial treatment success (defined by no detectable enhancement on the initial postablation CT scans) following 95% (63/66) of ablation procedures. Technique effectiveness was proven by a low rate (6%) of reablation required within a 6 month period following the initial procedure. Recurrent (residual) disease at the ablation site was evident in 26% (13/50) of patients, with an index tumour size larger than 3cm predictive of residual disease in these patients (shown using logistic regression analysis) (P=0.01). Recurrent disease distant to the ablation site was apparent in 22% (11/50) of patients. Progressive disease within the treated lobe (but not at the ablation site) was found in 11 patients and new metastatic foci in untreated lobes or organs were found in 18% (2/11) of these patients. Consequently, 1-year local control rate was 67% (SD, 10%), with a mean of 16.2 months (SD, 1.3 months) to first recurrence distant from the ablation site.

The Kaplan-Meier median time to death from any cause for all patients was 19 months (SD, 1 month), and the 1-, 2- and 3- year actuarial survival rates were 65% (SD, 7%), 55% (SD, 9%), and 45% (SD, 11%), respectively. Analysis of cancer-specific mortality yielded a median time to death of 22 months (SD, 1 month) and 1-, 2-, and 3- year survival rates of 83% (SD, 6%), 73% (SD, 9%), and 61% (SD, 13%). Index tumour size did not affect cancer-specific mortality rates (P=0.7) or actuarial survival (P=0.52).

There were no cases of recurrence reported in the study by He et al (2006). Fifty-eight per cent (7/12) of patients survived the entire follow-up period, with deaths due to metastases occurring in the remaining patients at 10, 11, 12, 18, and 38 months postoperative. Clinical symptoms disappeared 1-4 weeks following treatment in five patients and alleviated in seven patients. Blood flow status in the tumours before and after treatment are presented in Table 2. All ablated tumours shrank following microwave ablation (remarkable shrinkage in 10 patients and mild shrinkage in 6 patients), with invisible or decreased blood flow. US guided biopsy took place in four patients and complete necrosis of treated tumours was evident in each.

Table 2: Blood flow status of 16 tumours on CDFI before and after ablation

	Grade 0	Grade I	Grade II	Grade III
Preoperation	0	4	8	4
Postoperation	10	4	2	0
P value	<0.01	<0.01	<0.01	<0.01

COST IMPACT

Procedural costs for image-guided ablative procedures are less than those associated with traditional cancer treatments, including surgery and chemotherapy (Simon et al 2005). Although this study, along with many others, refer to the potential benefit of microwave ablation and other ablative cancer treatments in regards to their cost-effectiveness, no formal cost-effectiveness studies were retrieved to support this. It is likely the ability to treat patients with lung cancer in a timely manner, reduce hospitalisation time, and improve symptoms and quality of life that is associated with microwave ablation contributes to its reduction in costs in comparison with more invasive or time-consuming cancer treatments.

Economic analysis data from one publication described the costs of various hepatocellular carcinoma treatment options in US dollars (Dodd et al 2000). In 2000, RFA generators ranged from US\$12,000 to US\$30,000 and required needle electrodes valued at US\$50 to US\$1,000 (non-reusable) (Dodd et al 2000). Microwave ablation generators cost approximately US\$45,000, with reusable needles valued at US\$500 (Dodd et al 2000).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

There were no issues identified from the retrieved material.

OTHER ISSUES

In the study by Wolf et al (2008), Valleylab (manufacturer of a microwave ablation device) provided financial support by supplying the microwave generators and antennae used to treat all of the included patients. Three of the six authors of this study were consultants for Valleylab; however, it is stated that only those authors not associated with the company had control over the inclusion of any data and information that might present as a conflict of interest for the remaining authors.

SUMMARY OF FINDINGS

The results reported in the two included case series studies suggest microwave ablation may be a safe and effective treatment for intraparenchymal and peripheral lung malignancies, using either CT or US guidance. Cancer recurrence rate and the need for reablation were low in these studies, supporting the effectiveness of this procedure. In particular, minimally invasive microwave ablation offers patients who would otherwise be inoperable with an alternative to chemo/radiotherapy, which is less invasive, easily performed and reduces hospitalisation. High-quality comparative studies comparing microwave ablation with the current gold standard treatment are required to determine if it has a place as the standard of care for patients with lung cancer.

HEALTHPACT ASSESSMENT

Based on the potential benefit of microwave ablation for treatment of lung malignancies, as well as the potential benefit of all newly emerging thermo-ablative techniques for the treatment of cancer it is recommended that a horizon scanning report be carried out on all thermo-ablative treatments across a variety of cancers.

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

NUMBER OF STUDIES INCLUDED

Total number of studies 2
Level IV evidence 2

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SOURCES OF FURTHER INFORMATION

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SEARCH CRITERIA TO BE USED

((microwave ablation) AND (lung cancer))

HEALTH PACT DECISION

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

PRIORITY RATING

High

Medium

Low