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Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Cryotherapy for Oesophageal Cancer



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

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PRIORITISING SUMMARY

REGISTER ID S000114

NAME OF TECHNOLOGY ENDSOCOPIC CRYOTHERAPY

PURPOSE AND TARGET GROUP FOR BARRETT'S OESOPHAGUS AND OESOPHAGEAL CANCER

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 numbers: 134600, 135798, |
| <input type="checkbox"/> No | 136300, 141305, 144069, |
| <input type="checkbox"/> Not applicable | 147049, 147137, 156383, |
| | 156629, 158928, 158929, |
| | 162597, 164650, 165230, |
| | 167353, 170073, 97601, 97603 |

*ARTG numbers indicate cryotherapy devices that could be utilised for Barrett's oesophagus and oesophageal cancer.

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		
Argentina	✓		

IMPACT SUMMARY

Low pressure liquid nitrogen endoscopic cryotherapy is indicated for the eradication abnormal mucosa in patients with Barrett's oesophagus and oesophageal cancer. The treatment is generally provided by a gastroenterologist in an outpatient setting. The use of cryotherapy provides an alternative therapeutic procedure for the treatment of this patient group.

BACKGROUND

The aetiology of oesophageal cancer has origins in its premalignant predecessor Barrett's oesophagus (BO). A healthy oesophagus is lined with thin, flat, tile-like squamous epithelial cells. Exposure to stomach acid, particularly as a result of gastro oesophageal reflux disease (GORD), commonly experienced as 'heart burn', causes irritation and acts as a noxious stimulus, resulting in metaplasia typical of Barrett's oesophagus. Metaplasia is the transdifferentiation of the squamous epithelial cells into columnar epithelial cells (Kumar et al 2005). Further disease progression results in dysplasia, characterised by the presence of immature epithelial cells due to the lack of cell differentiation, and often occurs in a patchy, irregular fashion usually invisible at endoscopy (Van Laethem et al 2001). This change is indicative of the early neoplastic process which can result in oesophageal cancer (adenocarcinoma).

One to three percent of patients with Barrett's oesophagus will later be diagnosed with oesophageal cancer (Shaneen & Ransohoff 2002). Once lesions are neoplastic (cancerous) the level of invasion is the determining factor of treatment success and disease remission. Oesophagectomy has traditionally been the primary treatment of high grade dysplasia and adenocarcinoma. There are two types of oesophagectomy, namely transhiatal and transthoracic, and the two differ with respect to the incisions made and the way the oesophagus is mobilised. The removed section of diseased oesophagus can be replaced with the stomach or a colonic conduit (Lalwani 2008). Oesophagectomy has a high morbidity rate of approximately 30% to 50% and complications include, but are not limited to, cardiac (arrhythmias), pneumonia, anastomotic leak, stricture and reflux (Fernando et al 2009, Lalwani 2008, Sharma 2009). Mortality has been reported to lie within 1% to 10% (Fernando et al 2009, Lalwani 2008, Sgourakis 2010, Sharma 2009). In Australia, high volume centres generally quote mortality figures around 2% (Kendall & Whiteman 2006).

Alternative endoscopic therapies have been developed to offer a less invasive approach to treatment, and may be used where lesions are confined to the mucosal tissue. These include endoscopic mucosal resection (EMR), argon plasma coagulation (APC), photodynamic therapy (PDT), radiofrequency ablation (RFA) and laser therapy.

Traditionally conservative therapy has been employed for metaplastic (non-dysplastic) or low grade dysplastic Barrett's oesophagus and involves anti-reflux therapies and endoscopic surveillance (Sharma 2009). Anti-reflux therapy includes pharmacological intervention with proton pump inhibitors (PPIs) or anti-reflux surgery (fundoplication). However, currently surveillance lacks sufficient evidence regarding the prevention and early detection of dysplastic Barrett's mucosa lesions (Sharma 2009). In addition, many authors debate the appropriate time interval for surveillance; due to the burden that such procedures impose on the health care system (Fernando et al 2009, Lalwani 2008, Sharma 2009).

Cryotherapy is an endoscopic treatment modality which achieves targeted cell death via two mechanisms, namely, direct cell injury and vascular stasis (stagnation or cessation of blood flow) (Gage & Baust 1998). The deleterious effects of low temperature on cells begins in the hypothermic range, where the structure and function of cells is disrupted. As

the temperature rate falls cell metabolism progressively halts. If continued for a sufficient amount of time the cell is so adversely affected that death may result even though the cell is not exposed to freezing temperatures. The vascular stasis achieved by cryotherapy is not dissimilar to that observed in frostbite (Gage & Baust 1998). The loss of circulation and cellular anoxia (severe lack of oxygen) is considered the main mechanism of cell injury in cryotherapy. Notably, vascular stasis is also mainly responsible for death of surrounding tissue following cryotherapy.

There are two different cryotherapy devices for use in the GI tract. Some devices use a pressurised gas released at high velocity (Cryo-Ablator, CryMed Technologies, USA), whilst others use liquid nitrogen at ambient pressure and alternatively very low catheter tip pressure. The purported advantage of the ambient pressure system (as used below in Johnston et al 2005) is that it uses liquid nitrogen at a temperature of -196°C and the very low catheter-tip pressure enables the entire cryoablation procedure to be performed under direct endoscopic visualisation in a controlled fashion. Equivalent devices already marketed in the USA with FDA 510(k) clearance include Cryo-Ablator (CryMed Technologies), W1000B (Wallach Surgical Devices), Figitronics Cryo-Plus (Cooper Surgical), Figitronics Cryo-Surg System 5900 (Cooper Surgical), UltraFreeze (Wallach Surgical Devices), Cryopro Maxi and Cryopro mini (Cortex Technology) and Cryolite (CMS) (Federal Drug Administration 2010).

CLINICAL NEED AND BURDEN OF DISEASE

In Australia, the number of principle diagnosis' of BO, other specified diseases of the oesophagus and other diseases of the oesophagus (unspecified) was 10160, 2274 and 177 respectively. In addition, the incidence of Barrett's oesophagus and has increased in Australia from 2.9 to 18.9 per 1000 endoscopies since 1992-2002 (Kendall & Whiteman 2006).

DIFFUSION

A number of cryotherapy devices (also known as cryosurgical devices) as listed above have received FDA 510(k) clearance from 2004-2006. In addition, there is currently one completed and five ongoing clinical trials in the USA (NCT identification numbers: 00628784, 00321958, 00754468, 00650988, 00747448, and 00526786). In Australia, the Therapeutics Drug Administration (TGA) has approved 18 cryotherapy (cryosurgical) devices for general-purpose use (TGA 2010). There are no published clinical trials in Australia and TGA approval of the above for mentioned cryosurgical devices is not specific for the indication of BO or oesophageal cancer. Our research indicated that this procedure is not in clinical use throughout Australia.

COMPARATORS

Other endoscopic ablation modalities include EMR, PDT, APC, RFA and laser therapy. EMR (also known as mucosectomy) involves the removal of mucosa via resecting (cutting) through the middle or deep layers of the submucosa (Johnston 2005b). In addition, EMR can also be performed for attaining specimens for histological assessment and staging as a diagnostic procedure, to determine the severity of the abnormalities. Photodynamic therapy involves the general administration of a photosensitising drug

(such as 5-aminolevulinic acid) which concentrates in the abnormal oesophageal epithelium. Application of a light endoscopically at a specified wavelength activates the concentrated drug (without harming the normal epithelial tissue), achieving targeted cell death (Johnston 2005b). However, general administration results in absorption (to a lesser extent) by other tissues in the body and therefore exposure to sunlight can cause damage to the skin and other tissues following treatment with PDT, limiting the use of this treatment in Australia. Argon plasma coagulation delivers a high monopolar current to the tissue via ionised argon gas flowing through a catheter (Waxman & Konda 2009). However, the incidence of complications (including mortality) is reported to be as high as 24 percent. Radiofrequency ablation achieves thermal injury to the tissue via radiofrequency energy which can be applied focally or circumferentially (Shaneen 2009). Finally laser therapy generates an intense beam of light which is directed toward abnormal mucosa causing thermal injury.

SAFETY AND EFFECTIVENESS ISSUES

Three clinical studies on low pressure liquid nitrogen endoscopic spray cryotherapy were identified and retrieved for inclusion in this summary. Studies were selected for inclusion based on quality and cohort size.

Study design

Greenwald et al (2010) reported the outcomes of low pressure liquid nitrogen endoscopic spray cryotherapy (CryoSpray Ablation System, CSA, USA) in 49 of 79 patients who completed therapy. All 79 patients had oesophageal carcinoma (either adenocarcinoma or squamous cell carcinoma) and cryotherapy was performed as a palliative or curative measure. Tumours were staged with endoscopic ultrasound (EUS) or endoscopic mucosal resection. All patients were deemed as either inoperable, had previous failed chemotherapy or radiation therapy, unable to tolerate chemotherapy or radiation therapy or refused oesophagectomy. Patients who previously had undergone endoscopic mucosal resection (EMR) were confirmed to have residual cancer for inclusion in the study. Patients were required to fast overnight and underwent esophagogastroduodenoscopy (EGD) prior to cryotherapy. Moderate sedation with intravenous (IV) meperidine or fentanyl and midazolam or propofol was administered according to physician preference. Spray cryotherapy with low pressure liquid nitrogen (<5 psi) with an energy delivery of 25W was performed, forming a white frost and freezing the adjacent mucosa. Each mucosal site was typically frozen for 20 seconds for 3 cycles, with at least 45 seconds between freezes to allow complete tissue thawing, verified by a return to baseline tissue colour and complete disappearance of ice crystals after reperfusion (restoration of blood flow). Patients were monitored post-procedure and discharged the same day. Procedures were repeated every 4 to 6 weeks. Treatment was deemed complete by the investigator after complete local tumour eradication determined by endoscopic appearance and biopsy, or when treatment was halted due to tumour progression, patient preference or presence of a comorbid condition precluding further endoscopy (treatment failure). In some cases cryotherapy was continued after tumour ablation to achieve eradication of dysplasia or residual intestinal metaplasia. Follow up endoscopy with oesophageal biopsy

at the treatment site was performed every 3 to 6 months after ablation was complete (Greenwald et al 2010).

Dumot et al (2009) reported the treatment outcomes of 30 of 37 patients treated with cryotherapy. The 30 patients for whom therapy outcomes are reported were all considered high-risk and non-surgical with BO associated high grade dysplasia (HGD) or intramucosal cancer (IMC) (mean age: 70 ± 11 years [range: 43-87], median body mass index (kg/m^2) of 29.8 ± 6.7 [22.1-54.9]). Twenty five patients (25/30, 83%) had HGD and five patients (5/30, 16%) had intramucosal cancer (IMC). The mean length of Barrett's oesophagus (BO) was $6.1 \pm 4.1\text{cm}$ [1-15]. Patients were eligible for the study if deemed high-risk patients for oesophagectomy based on conditions such as server heart disease (congestive heart failure), lung disease (chronic obstructive or restrictive disease), kidney disease (dialysis dependent), and liver disease (cirrhosis with portal hypertension) or if they refused surgical intervention after a thorough discussion of the experimental nature and lack of long-term follow up with all ablation therapy. Eight patients had previous endoscopic ablation (APC n = 2, PDT n = 3, EMR n = 3). Exclusion criteria included younger than 18 years, life expectancy less than 6 months, pregnancy, and inability to give informed consent. Length of BO and recurrence after previous endoscopic ablation therapy were not exclusion criteria. Patients were offered enrolment in the study when their lesion was determined unamendable to cure with EMR alone. Two independent expert GI pathologists reviewed the pathology slides from all patients to confirm the diagnosis of BO with HGD and/or IMC. Biopsy specimens from the oesophagogastric junction (EGJ) and gastric cardia were obtained by protocol and not excluded from the analysis. EMR was used for pathologic staging of all nodular areas. Patients with invasion of the submucosa or muscularis propria and no pathologic involvement of the lymph nodes (determined by EUS staging) were offered treatment under this protocol when there were no other treatment options available to them or they had already received maximal conventional chemotherapy or radiation. These patients were included in the safety data, but efficacy could not be assessed because of the small number of patients in this criterion. All patients were treated with proton pump inhibitors (PPIs) twice daily for maximal acid suppression. If complete eradication of BO was achieved in a patient the PPI was decreased to the pre-enrolment dose. Patient follow up comprised endoscopy at 3 month intervals for 12 months, then 6 month intervals for 12 months, then yearly.

Johnston et al (2005) treated 11 patients with BO (11 men, mean age 59 years) using the Cryo-Ablator device (CryMed Technologies). The mean length of BO was 4.6 cm [1-8 cm] and no patients had GORD symptoms during the study period. Upper endoscopy was performed before cryotherapy as standard, under moderate sedation. Cryoablation was applied hemi-circumferentially to areas of 4.0 cm in length. Each 4.0 cm segment was frozen for 20 seconds, permitted to thaw and then re-ablated for an additional 20 seconds. Suction was applied via a naso-gastric tube (NGT) to prevent over inflation (causing excessive distension) of the oesophagus. A single endoscopist performed all cryoablation treatments. A maximum of 3 cryotherapy applications at monthly intervals was permitted by the study protocol. The maximum length of BO permitted for cryoablation was 8 cm circumferentially. Presence of oesophageal ulceration or any new significant lesion

delayed additional cryotherapy applications until healing from the prior treatment was complete. Full digital video was obtained for all procedures to enable mapping and identification of any residual BO. Follow up comprised a telephone questionnaire one week after the procedure and endoscopy was performed at monthly intervals. Therapy was held for residual ulceration. Once endoscopic evidence of BO was gone the oesophagus was sprayed with Lugol's iodine followed by systematic biopsies according to the four-quadrant biopsy method every 2cm. Once complete resolution of BO was achieved, proven by two clear sequential 6 month biopsies, patients were released to the national surveillance registry for surveillance according to national guidelines (Johnston et al 2005).

Safety and effectiveness

Greenwald et al (2010) reported the efficacy outcomes for 49 of 79 (median age 76 years [51-93 years], interquartile range [IQR]: 17, 81% male, adenocarcinoma 94% of patients) patients eligible for efficacy analysis. The other 30 patients were still completing therapy at the time of data analysis and no patients were lost to follow up. Safety outcomes for all 79 patients were reported and no serious adverse events including perforation or haemorrhage were reported. The mean tumour length treated was 4.0 cm (standard deviation [SD]: 3.4), with the longest segment measuring 15cm. The median number of treatments per patient was 3 [1-25], IQR: 3). Fifty-three subjects had received previous therapy and 18 received concurrent therapy for their cancer. EMR was the most common treatment; others included PDT, APC and RFA. Systemic therapies included sequential chemotherapy and external beam radiation therapy. Four patients (4/49, 8%; intent-to-treat 4/79, 5%) who previously refused surgery underwent oesophagectomy due to failed eradication of the tumour by cryotherapy. A total of 332 treatments were performed in 79 patients. Benign stricture was noted in 10 (13%) of patients. All 10 had undergone previous tumour therapy, including EMR (n = 5), external beam radiation therapy (n = 2), PDT alone (n = 1), PDT and EMR (n = 1) and radiation therapy (n = 1). Five (6%) patients required additional endoscopic therapy concurrent or following cryotherapy (EMR n = 3, EMR and APC n = 1, and APC n = 1). Twenty seven (34%) patients experienced post-procedural pain requiring narcotic analgesics. Thirty of the 49 patients (62%) eligible for efficacy analysis demonstrated disease reversal with cryotherapy for luminal disease of which 3 received concurrent treatments (1 EMR and APC, 1 EMR, 1 RFA). The mean follow up after treatment was 10.6 months (SD: 8.4 months). The mean number of treatment sessions in the complete response group was 3 [range: 1 – 13, IQR 3], and the final histology was normal squamous mucosa (n = 16), intestinal metaplasia (n = 9), low grade dysplasia (n = 4) and high grade dysplasia (n = 1).

Dumot et al (2009) reported responses achieved in 27 of the 30 patients (90%) treated, of whom 5/27 (18.5%) obtained complete response at the first surveillance endoscopy (3 months). Responses were evident in 23/25 (92%) of HGD and 4/5 (80%) of IMC patients. Of the 27 patients with a response at median follow up of 12 months, 8/25 (32%) of HGD patients and 2/5 (40%) of IMC patients experienced no recurrence of dysplasia. At the last follow up (24 months) treatment response persisted in 17/25 (68%) of HGD patients and

4/5 (80%) of IMC patients. At the last follow up (24 months) 22 patients (73%, according to intent-to-treat 60%) were alive and cancer free (18 HGD, 4 IMC at baseline). At the conclusion of the study only 1/30 (3.3%) had normal mucosa (no intestinal metaplasia, LGD, HGD or IMC). Recurrence of disease occurred in 16/30 (53%) patients and retreatment was required in 11/30 (36%) patients. Minor adverse events included mild chest discomfort in less than 25% of patients (n = 7) in at least 1 treatment session, which was described as a heartburn like sensation. Three patients experienced more severe pain lasting as long as 7 days, which resolved with a short course of narcotic analgesics. Three patients had evidence of a mild to moderate stricture in the location of previous narrowing from peptic strictures or endoscopic therapy, and each of them required endoscopic dilation. One patient developed a lip ulcer caused by inadvertent contact with the cold endoscope. One major adverse event in a patient with Marfan syndrome was a gastric perforation caused by overdistention of the stomach. The patient recovered after laparotomy and is undergoing continuing serial surveillance endoscopy after focal HGD was discovered on last endoscopy.

Johnston et al (2005) defined complete histological reversal as no intestinal metaplasia in any of the post cryotherapy biopsies, including the absence of subsquamous intestinal metaplasia (buried glands). Complete reversal of BO following cryotherapy was defined as no endoscopic evidence of residual columnar-appearing epithelium at the time of upper endoscopy. Endoscopic reversal of BO was defined as a reduction in BO length of at least 1.0 cm, determined by video measurement. Of the 9 patients who completed the protocol, all achieved complete reversal of BO when combined with high-dose PPI (pharmacological) therapy. However, on 6 month follow up surveillance endoscopies 2 of the 9 patients developed fragments of intestinal metaplasia distal to the squamo-columnar junction (near the lower oesophageal sphincter). Thus complete histological eradication of BO was achieved in 7 of 9 (78%) of patients completing the protocol. Based on the intention to treat analysis 7 of 11 (64%) achieved complete histological eradication. The mean number of cryotherapy treatment sessions was 3.6 [range 1-6] and mean follow up period of 12 months [6-20 months]. Subsquamous intestinal metaplasia was observed in 2 of the 9 patients' surveillance biopsy specimens (1 segment per patient) 1 month after cryotherapy. However, both patients were clear of subsquamous intestinal metaplasia at the 6 month surveillance endoscopy. Only 2 patients (22%) had post-cryotherapy symptoms on one occasion after 46 treatments. They reported chest discomfort and mild solid-food dysphagia for one day immediately following the procedure. Only one of the two patients required analgesia for their symptoms and both resolved within 48 hours. No significant bleeding, oesophageal stricture or perforation occurred in any patients. There was no dysplasia after cryotherapy in any of the post procedural surveillance biopsy specimens at either 1 or 6 months follow up, including the two specimens that were positive for subsquamous intestinal metaplasia. Of the 11 patients enrolled, 2 were unable to complete the treatment. One patient was precluded due to a hiatal hernia preventing the complete eradication of BO. The other patient was excluded due to severe arthritis requiring the administration of high-dose non-steroidal anti-inflammatory (NSAIDS) and immunosuppressants, leading to the development of oesophageal ulcers in response to cryotherapy (Johnston et al 2005).

COST IMPACT

No cost-utility analysis literature was available. However, Johnston et al (1999) reported that whilst the projected cost of the technology is yet to be determined, the device is technically simple in design and should be significantly less expensive than devices required for PDT, APC, and laser therapy. In addition the cryotherapy device is reusable, representing a one time purchase. Catheters are disposable, comprising the consumable component of the system, however should be relatively inexpensive when compared to catheters of other endoscopic modalities (Johnston et al 1999).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

None identified.

OTHER ISSUES

Johnston is the inventor of the Cryo-Ablator (CryMed Technologies, USA) and serves as a consultant to CryMed Technologies. Additionally, Greenwald and Dumot received financial support from CSA Medical.

SUMMARY OF FINDINGS

Early peer reviewed evidence for low pressure liquid nitrogen suggests that this treatment modality is feasible, safe and effective. Reversal of disease at 12 months was experienced in 68 to 100 percent of all patients treated. Of the studies reporting major adverse events only one major complication (involving a pre-existent comorbidity) was encountered in a total of 87 patients included in this summary. Cryotherapy is also reported as an effective adjuvant therapy for multimodal treatment in conjunction with EMR, APC and RFA. Recurrence was reported in 2/9 (22%) of patients in Johnston et al (2005) and 16/30 (36%) patients in Dumot et al (2009). Greenwald et al (2010) reported 19/49 (39%) patients who had persistent tumour which did not respond to cryotherapy.

HEALTHPACT RECOMMENDATION

The current evidence for treatment of BO and oesophageal cancer with endoscopic cryotherapy is weak, limited by small patient cohorts and considerable follow-up losses. Two studies (Greenwald et al 2010 and Dumot et al 2009) were confounded by concurrent treatments, including other endoscopic modalities and/or systemic chemotherapy or radiation therapy. Nevertheless, there is early indication that this treatment modality is feasible. It is recommended this endoscopic treatment modality be monitored for 12 months.

NUMBER OF STUDIES INCLUDED

Total number of studies: 3

Level of evidence: IV

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SEARCH CRITERIA TO BE USED

Barrett's esophagus [MeSH], barret*, esophageal neoplasm [MeSH], esophag*, oesophagag*, cancer*, oncolog*, neoplas*, tumor*, tumour* carcin*, cryotherapy, cryoablation.

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