

**NATIONAL INSTITUTE FOR HEALTH AND CARE  
EXCELLENCE**

**Interventional procedure consultation document**

**Endoscopic carbon dioxide laser  
cricopharyngeal myotomy for relief of  
oropharyngeal dysphagia**

Difficulty in swallowing (dysphagia) can occur in conditions such as multiple sclerosis, motor neurone disease and Parkinson's disease. It can also happen after a stroke, or after radiotherapy or surgery for treating cancer in the head or neck. It is caused by spasm or scarring of the cricopharyngeal muscle, which runs around the top of the gullet.

In this procedure, an endoscope (a thin, flexible tube with a camera on the end) and a carbon dioxide laser are inserted through the mouth. The laser is used to cut through the muscle, to relieve obstruction and improve swallowing.

The National Institute for Health and Care Excellence (NICE) is examining endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

**Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.**

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 18 December 2015

Target date for publication of guidance: March 2016

## **1 Provisional recommendations**

- 1.1 Current evidence on the safety and efficacy of endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

- 1.2 Clinicians wishing to do endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia should:
- Inform the clinical governance leads in their NHS trusts.
  - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public [URL to be added at publication] is recommended.
  - Audit [URL to audit tool to be added at publication] and review clinical outcomes of all patients having endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia (see section 7.2).
- 1.3 Patient selection for endoscopic carbon dioxide laser cricopharyngeal myotomy should be done by a multidisciplinary team that specialises in managing oropharyngeal dysphagia.
- 1.4 Further research on endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia could include the publication of collaborative audit data. Reports should separate outcomes for different groups of patients; in particular for patients with primary neuromuscular dysfunction alone, those with associated pharyngeal diverticula and those with dysphagia caused by radiotherapy. Outcome measures should include dysphagia scores, quality of life, long-term outcomes and the need for further treatment. All complications should be reported. NICE may update this guidance on publication of further evidence.

## **2 Indications and current treatments**

- 2.1 Cricopharyngeal (CP) muscle dysfunction, also known as dysfunction of the upper oesophageal sphincter, occurs when the CP sphincter muscle fails to relax and open during swallowing. This may be caused by muscular or degenerative neurological disorders, or after head and neck surgery, or it may be idiopathic. Symptoms of CP muscle dysfunction include difficulty swallowing, painful swallowing, choking, regurgitation, cough, aspiration and weight loss.
- 2.2 Treatment for CP muscle dysfunction includes procedures such as swallowing rehabilitation therapy and dilatation of the oesophagus, and medical management with muscle relaxants or botulinum toxin injections. If symptoms persist, open surgery through a neck incision (transcervical CP myotomy) may be done. Endoscopic CP myotomy using diathermy, laser (such as carbon dioxide or potassium titanyl phosphate laser) or stapling techniques, is a less invasive alternative to open surgery.

## **3 The procedure**

- 3.1 Endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia divides the cricopharyngeal muscle via an endoscope using a carbon dioxide laser, as an alternative to open surgery.
- 3.2 The procedure is done with the patient in the supine position, usually under general anaesthesia. A rigid endoscope is introduced through the mouth, to visualise the cricopharyngeal muscle, which forms the upper oesophageal sphincter. The posterior wall of the junction between the pharynx and oesophagus, at the level of

cricopharyngeal muscle, is visualised. A carbon dioxide laser, (set in continuous wave mode) connected to a microscope and targeted with a micromanipulator, is used to transect the mucosa and then the deeper muscle layers, in the midline, down to the prevertebral fascia. If there is a tight stenosis, due to contracture or fibrosis of the cricopharyngeal muscle, then dilatation may be needed before myotomy to allow adequate access for the laser. Some authors recommend sealing the surgical site with fibrin glue or closure of the mucosal edges with sutures. After the procedure the patient does not eat or drink for at least 24 hours. Antibiotics are given and postoperative swallow studies are performed on day 1. If no leaks are observed, patients are allowed to drink clear fluids initially, progressing to unrestricted liquids or soft diet for a few days, and then a normal diet.

- 3.3 This procedure has been used for patients with oropharyngeal dysphagia with a number of underlying causes. This guidance addresses the use of this procedure for patients with cricopharyngeal muscle dysfunction and not for those with Zenker's diverticulum.

## **4 Efficacy**

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#). This evidence review included studies on patients with cricopharyngeal muscle dysfunction, it did not include studies that only reported the use of this procedure for Zenker's diverticulum. However, it does include mixed-case series that included some patients with Zenker's diverticulum.

- 4.1 A case series of 87 patients with cricopharyngeal (CP) muscle dysfunction from a variety of causes, treated by carbon dioxide (CO<sub>2</sub>) laser CP myotomy, reported that the average Functional Outcome Swallowing Scale (FOSS) scores (on a scale 0-5, higher scores indicating non-oral feeding) improved from 2.6 to 1.6 ( $p < 0.001$ ) after surgery (timing not reported). A retrospective comparative case series of 22 patients comparing CO<sub>2</sub> laser CP myotomy ( $n=14$ ) against transcervical CP myotomy ( $n=8$ ) reported that the mean functional outcomes (FOSS scores) improved after the procedure in both groups (CO<sub>2</sub> laser group improved from 2.4 to 0.9; transcervical group from 3.4 to 1.9,  $p$  values are not reported).
- 4.2 A case series of 10 patients with dysphagia secondary to cricopharyngeal stricture after chemoradiation for squamous cell carcinoma of the head and neck, treated by CO<sub>2</sub> laser CP myotomy reported improvement in dysphagia (assessed by modified Barium Swallow study) and radiographic resolution of the cricopharyngeal stricture in 90% (9/10) of patients.
- 4.3 The case series of 87 patients with cricopharyngeal dysfunction treated by endoscopic CO<sub>2</sub> laser myotomy reported recurrence of dysphagia in 14% (12/87) of patients (timings not reported). All patients needed subsequent surgical procedures - 5 were treated by oesophageal dilation, 6 by repeat CO<sub>2</sub> laser cricopharyngeal myotomy and one patient had several laser procedures and dilatations. A retrospective comparative case series of 153 patients who had endoscopic cricopharyngeal myotomy by either CO<sub>2</sub> laser ( $n=123$ ) or by stapler ( $n=23$ ) reported that symptom recurrence was more frequent after the stapling procedure (CO<sub>2</sub> laser group 6% (7/153), stapler group 26% (6/23);  $p=0.002$ ). The rates of revision

surgery were similar in the 2 groups (CO<sub>2</sub> laser group 3% (4/123), stapler group 4% (1/23); p=0.77).

- 4.4 The case series of 65 patients reported that global satisfaction (self-assessed on a scale of 0-10, with 10 being most satisfied) was 7.2, in the 30 patients who responded to the survey. 84% (27/32) of patients reported that they would have the procedure again if needed.
- 4.5 The specialist advisers listed key efficacy outcomes as improved swallowing and nutritional state, reduced number of aspirations and chest infections, reduced length of stay in hospital, improved patient-reported quality of life measures (e.g. FOSS, EUR-QoL), and changes in modified barium swallow study, videofluoroscopy or manometry.

## 5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#) *[add URL]*.

- 5.1 Oesophageal perforations were reported in 5% (2/44) of patients in a case series of 44 patients. Both perforations were drained externally, and the patients were given systemic antibiotics, leading to full recovery and improved swallowing. A hypopharyngeal perforation that resulted in infection and prolonged hospitalisation as a result of pharyngocutaneous fistula, and a complete pharyngeal wall perforation, were reported in 1 patient each in the CO<sub>2</sub> laser assisted cricopharyngeal myotomy group in a retrospective comparative case series of 153 patients who had

endoscopic myotomy either by CO<sub>2</sub> laser (n=123) or by stapler (n=23). Further details were not reported.

5.2 Fistula (without mediastinitis) was reported in 1 patient immediately after the procedure in a case series of 65 patients. Further details were not reported.

5.3 Mucosal tears occurred during cricopharyngeal myotomy (as the endoscope or the stapler were introduced) in 5% (6/123) of patients in the CO<sub>2</sub> laser group and 1 patient in the stapler group, in the retrospective comparative case series of 153 patients. Further details were not reported.

5.4 Left vocal fold paralysis was reported in 1 patient in a case series of 87 patients.

5.5 Severe bleeding (controlled during the procedure) was reported in 1 patient in the case series of 65 patients.

5.6 Aspiration pneumonia (needing further hospitalisation) was reported in 2% (2/123) of patients in the CO<sub>2</sub> laser group in the retrospective comparative case series of 153 patients. Both patients were managed conservatively.

5.7 Progressive fibrosis was reported in 36% (4/11) of patients in a case series of 11 patients. They presented with multiple problems with bolus propulsion and poor cricopharyngeal opening. All had worse swallowing outcomes following the procedure and 1 patient eventually had a pharyngolaryngectomy due to dysfunctional larynx.

5.8 Restenosis was reported in 10% (4/44) of patients with stage IV dysfunction in the case series of 44 patients. Two patients had

revision surgery after 6-12 months, but the other 2 patients died of coronary heart disease before a further myotomy could be done.

- 5.9 Pulmonary infection immediately after the procedure was reported in 1 patient in the case series of 65 patients. Further details were not reported.
- 5.10 Chest pain (self-limited) was reported in 1 patient in the CO<sub>2</sub> laser group in a retrospective comparative case series of 22 patients who had either endoscopic CO<sub>2</sub> laser CP myotomy (n=14) or transcervical CP myotomy (n=8). No further details were reported.
- 5.11 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: mediastinitis, dental damage, scarring and stenosis in patients who have had radiotherapy. They considered that the following were theoretical adverse events: recurrent laryngeal nerve injury, voice problems, airway fire caused by laser use and stricture of the upper oesophagus.

## **6 Committee comments**

- 6.1 The Committee noted that the available studies included patients with oropharyngeal dysphagia with a number of different underlying causes. It noted that the procedure could have different safety profiles for patients with and without associated pharyngeal diverticula, and that it could have relatively poor efficacy in patients with dysphagia after radiotherapy.

- 6.2 The Committee was advised that endoscopic carbon dioxide laser cricopharyngeal myotomy may offer the possibility of treatment to patients with severe oropharyngeal dysphagia for whom there are no other options.

## **7 Further information**

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion). This tool will be available when the guidance is published.

Bruce Campbell

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