

Endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 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 the information for the public is recommended.
 - Audit and review clinical outcomes of all patients having endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia (see further information).
- 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 (CO₂) laser CP myotomy, reported that the average Functional Outcome Swallowing Scale (FOSS) scores (on a scale 0 to 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 CO₂ 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 (CO₂ laser group improved from 2.4 to 0.9; transcervical group from 3.4 to 1.9, p values 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 CO₂ laser CP myotomy reported improvement in dysphagia (assessed by modified Barium Swallow study) and radiographic resolution of the cricopharyngeal stricture in 90% (9 of 10) of patients.
- 4.3 The case series of 87 patients with cricopharyngeal dysfunction treated by endoscopic CO₂ laser myotomy reported recurrence of dysphagia in 14% (12 of 87) of patients (timings not reported). All patients needed subsequent surgical procedures: 5 were treated by oesophageal dilation, 6 by repeat CO₂ 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 CO₂ laser (n=123) or by stapler (n=23) reported that symptom recurrence was more frequent after the stapling procedure (CO₂ laser group 6% (7 of 153), stapler group 26% (6/23); p=0.002). The rates of revision surgery were similar in the 2 groups (CO₂ laser group 3% (4 of 123), stapler group 4% (1 of 23); p=0.77).
- 4.4 A case series of 65 patients reported that global satisfaction (self-assessed on a scale of 0 to 10, with 10 being most satisfied) was 7.2, in the 30 patients who responded to the survey. 84% (27 of 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 (for example 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](#).

- 5.1 Oesophageal perforations were reported in 5% (2 of 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 CO₂ laser assisted cricopharyngeal myotomy group in a retrospective comparative case series of 153 patients who had endoscopic myotomy either by CO₂ 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 of 123) of patients in the CO₂ 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 of 123) of patients in the CO₂ 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 of 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 of 44) of patients with stage IV dysfunction in the case series of 44 patients. Two patients had revision surgery after 6 to 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 CO₂ laser group in a retrospective comparative case series of 22 patients who had either endoscopic CO₂ 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 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.

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).