

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of 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.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in June 2015.

Procedure name

- Endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia

Specialist societies

- British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)

- Royal College of Speech and Language Therapists

Description

Indications and current treatment

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.

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) or stapling techniques is a less invasive alternative to open surgery.

What the procedure involves

Endoscopic carbon dioxide laser CP myotomy for relief of dysphagia, divides the CP muscle via an endoscope using a carbon dioxide laser, as an alternative to open surgery.

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 CP muscle, which forms the upper oesophageal sphincter. The posterior wall of the junction between the pharynx and oesophagus, the level of CP muscle, is visualised. A carbon dioxide laser (set in continuous wave mode) connected to a microscope and targeted with a micromanipulator, transects the surface mucosa and then the deeper muscle, in the midline, down to the prevertebral fascia. If there is a tight stenosis, due to contracture or fibrosis of the CP muscle, then initial dilatation may be required prior to 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 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 few days, and then a normal diet.

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 CP muscle dysfunction and not for those with Zenker's diverticulum.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia. The following databases were searched, covering the period from their start to 11 June 2015: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with dysphagia.
Intervention/test	Endoscopic carbon dioxide laser cricopharyngeal myotomy
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 404 patients from 8 retrospective case series (of which 2 were comparative studies).

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia

Study 1 Pollei TR [2013]

Details

Study type	Comparative case series
Country	USA (single centre)
Recruitment period	2002-12
Study population and number	n= 153 (123 endoscopic CO₂ laser CP myotomy versus 23 endoscopic stapler CP myotomy) patients with cricopharyngeal hypertrophy (CPH) or Zenker's diverticulum (ZD) <u>patients with isolated CPH</u> : laser group 38% (47/123); stapler group 4.3% (1/23) <u>patients with ZD</u> : laser group 62% (76/123); stapler group 91% (21/23)
Age and sex	Mean 74 years; 64% (98/153) male
Patient selection criteria	Any patient who underwent a combination procedure (i.e. total laryngectomy) or a primary open CP myotomy was excluded.
Technique	<u>Endoscopic CO₂ laser CP myotomy</u> : Dohlman diverticuloscope was used in all CO ₂ laser procedures except 3. The CP bar is focused, incised and muscle cut with slow, deliberate laser strokes on a 5 W continuous setting until the buccopharyngeal fascia is visible. Bleeding is controlled by suction cautery and the mucosal edges are sutured and diverticuloscope removed. <u>Endoscopic stapler assisted CP myotomy</u> : Weerda diverticuloscope was used in all and also 3 patients from CO ₂ laser group. The stapler is placed over the entire CP bar with the posterior anvil in the diverticulum pocket. When the stapler is discharged, muscular and mucosal edges are completely sectioned and sealed. No oral intake given over night, liquid diet given for a week and then resumed to normal diet. Post-operative follow-up scheduled for 1-2 weeks later.
Follow-up	not reported
Conflict of interest/source of funding	not reported

Analysis

Follow-up issues: 6% (9/153) of the endoscopies were initially aborted before CP myotomy or diverticulotomy, but 2 of these were reattempted.

Study design issues: retrospective study, chart review was done to collect and record data.

Significant disparity between the treatment group populations in relation to preferred surgical methods, diverticuloscope sizes noted. Isolated CPH cases were treated with CO₂ laser and ZD with both methods. There was significant difference in preoperative sizes for ZD between the groups.

Study population issues: 32% (50/135) of patients had isolated CPH. 6.5% (10/153) had undergone previous interventions for ZD or CPH; 6 had open surgery, 4 had endoscopic stapler surgery. The average time from previous surgery was 4.3 years. 1 patient had a previous botulinum toxin injection.

Preoperative Modified Barium Swallowing study was performed in all patients. Objectively document CPH was presented in 88% (135/153) patients. ZD was documented in 67.3% (103/153) patients.

Key efficacy and safety findings

Efficacy				Safety			
Number of patients analysed: 146 (123 endoscopic CO₂ laser CP myotomy versus 23 endoscopic stapler CP myotomy)				Complications (n=153)			
	CO₂ laser group n=123	Stapler group n=23	p value		CO₂ laser group % (n)	Stapler group % (n)	p value
Procedure duration (minutes)	45.6	35.3	0.01	Overall complications	10.6 (13/123)	8.7 (2/23)	0.76
Duration of hospitalisation (days)	1.86	1.32	0.39	Minor complications (resolved after conservative management or observation)			
Resolution of stenosis was seen in 92.6% (44/48) patients with isolated CPH.				Pharyngeal wall mucosal tear	6	1	
ZD pouch size decreased significantly after surgery in both the CO ₂ laser and stapler groups (laser group from 45.7 mm to 29 mm, p=0.02; stapler group 37.5 mm to 22.5 mm, p=0.01)				Isolated postop fever	2	0	
Recurrence of dysphagia (during postoperative follow-up)				Aspiration pneumonia (needed hospitalization)	2	0	
	CO₂ laser group % (n)	Stapler group % (n)	p value	Pharyngeal wall hematoma*	0	0	
Symptom recurrence*	5.7 (7/153)	26 (6/23)	0.002	Dental trauma	0	1	
*13 patients had history of ZD, 3 had previous laryngectomy and radiation therapy, 1 had gastro-oesophageal reflux disease, 1 had vagal nerve injury, and 1 had oesophageal dysmobility.				Major complications	2.4	0	
Rate of revision surgery				Hypopharyngeal perforation, infection, pharyngocutaneous fistula	1	0	
	CO₂ laser group % (n)	Stapler group % (n)	p value	Complete pharyngeal wall perforation	1	0	
Revision surgery	3.3 (4/123)	4.3 (1/23)	0.77	Postoperative myocardial infarction needing catheterization or stent	1	0	
				*1 occurred during placement of diverticuloscope; myotomy not performed in this patient. No deaths occurred.			
Abbreviations used: CO ₂ , carbon dioxide; CPH, cricopharyngeal hypertrophy; NS, not significant; ZD, Zenker's diverticulum.							

Study 2 Dauer E [2006]

Details

Study type	Comparative case series (retrospective)
Country	USA (single centre)
Recruitment period	1996-2003
Study population and number	n=22 (14 endoscopic CO₂ laser CP myotomy versus 8 open CP myotomy) patients with cricopharyngeal dysfunction without a concomitant head and neck or Zenker's procedure. <u>Indications:</u> CP bar (from either a stricture or hypertonicity) with no known aetiology (8), body myotonia (4), post-polio syndrome (3), non-defined neurological syndromes (2), post-radiation fibrosis (1), vascular malformation (1), myopathy (1), dermatomyotonia (1) and connective tissue disorder (1).
Age and sex	mean age 70 years ; 41% (9/22) male
Patient selection criteria	Patients with concomitant major head and neck procedures and Zenker's diverticulum were excluded.
Technique	<u>Endoscopic CO₂ laser cricopharyngeal myotomy:</u> a Dolhman diverticuloscope or the cervical oesophagoscope is used. A 3-5 W CO ₂ laser on continuous mode mounted on a microscope is used to incise the CP muscle. Patients not given anything orally on first day, but fed on a pureed diet via a straw for first week. Antibiotics are given for 1 week. <u>Open transcervical approach</u> done using standard techniques.
Follow-up	not reported
Conflict of interest/source of funding	None declared

Analysis

Study design issues: small sample size; medical records were reviewed. Symptoms were evaluated pre and postoperatively using the Functional Outcome Swallowing Scale (FOSS stages 0-5), higher scores indicating non-oral feeding. FOSS stage was assigned by the reviewer based on the documentation. All were evaluated with manofluorography.

Population issues: Open procedure was done in patients with more complicated swallowing problems. Some needed to undergo concomitant procedures (3 laryngo-hyoid suspensions), 3 had myotomy before routine use of endoscopic approach, 1 to obtain a muscle biopsy for diagnosis and 1 had an unfavourable anatomy for the endoscopic approach. The majority had elevated intrabolus pressure gradients across the CP muscle (20 mmHg).

Key efficacy and safety findings

Efficacy			Safety		
Number of patients analysed: 22 (14 endoscopic CO₂ laser CP myotomy versus 8 open CP myotomy)			Complications:		
Outcomes				CO₂ laser group n=14	Open group n=8
	CO₂ laser group (n=14)	Open group (n=8)			
Hospital stay (median, range in days)	1 (0-3)	1 (1-25)	Fever	2	
Operative time (median, range in minutes)	29 (10-95)	87 (74-100)	Chest pain (self-limited)	1	1
Preoperative FOSS	2.4	3.4	Tracheostomy (because of medical comorbidities and prolonged ventilator dependence)	0	1
Postoperative FOSS	0.9	1.9	Pharyngocutaneous fistula (treated by dressings and tube feedings for a month)	0	1
Overall FOSS	1.5	1.5			
Overall success rate*	75%	NR			
*patients achieving a postoperative FOSS of 1 or less					
Manofluorography (MFG) results (n=11)					
All patients having both techniques who had pre and post MFG tests showed a decrease in the intrabolus pressure gradient across the CP (usually 20 mmHg or greater). Patients had multiple abnormalities on MFG (such as tongue base weakness, hypopharyngeal weakness or decreased laryngeal elevation).					
Abbreviations used: CO ₂ , carbon dioxide; CP, cricopharyngeal; FOSS, Functional Outcome Swallowing Scale; MFG, manofluorography; NR, not reported.					

Study 3 Bergeron JL [2014]

Details

Study type	Case series (retrospective)
Country	USA (single centre)
Recruitment period	2006-12
Study population and number	n=87 patients with cricopharyngeal dysfunction. Indication: Zenker's diverticulum (39), DiGeorge syndrome (2), stroke (5), nerve injury (2), radiation for head and neck cancer (15), idiopathic (16), hyperfunctional transoesophageal speech (5), dysphagia from cricopharyngeous stricture after laryngectomy (3).
Age and sex	Mean age 69.9 years; 52% (46/87) male
Patient selection criteria	Not reported
Technique	Endoscopic CO₂ laser CP myotomy: Weerda diverticuloscope or a standard laryngoscope is placed in the hypopharynx and advanced to the CP muscle. If the CP is tightly contracted to the oesophageal inlet lumen, dilation is performed to open and better visualise the oesophageal introitus. CO ₂ laser is used to divide the CP muscle until the pharynx is flush with the cervical oesophagus. Bleeding is controlled using suction cautery. Balloon dilation of the CP area is performed after myotomy in 56.3% (49/87) cases. Patients are fed on clear diet on day 0, advanced to soft diet on day 1, discharged on day 1 with soft diet for 1-2 weeks if no complications.
Follow-up	Not reported
Conflict of interest/source of funding	None

Analysis

Study design issues: retrospective chart review done for indication, history, physical examinations and swallow evaluations. Swallowing outcomes assessed using Functional Outcome Swallowing Scale (FOSS); findings were compared across patient subgroups.

Operative technique and postoperative management was similar for all patients. Procedures were done by a single surgeon. 11.5% (10/87) cases need dilation before the procedure to achieve adequate exposure. Suture closure of the overlying mucosa was done in 2 cases.

Study population issues: 31% of patients had prior treatment for CP dysfunction. The majority had dilation or botulinum toxin injection. Some of the patients in this series had Zenker's diverticulum and all had comorbidities.

Key efficacy and safety findings

Efficacy				Safety	
Number of patients analysed: 87				Complications :	
Mean time to feeding: 1.4 days					
Mean hospital stay: 1.8 days					
Swallowing outcomes across patient subgroups					
	Average preoperative FOSS score*	Average postoperative FOSS score*	p value		% (n)
All patients (n=87)	2.6	1.6	<0.001	Total	4.6% (4/87)
Zenker's diverticulum (n=39)	2.4	1.0	NR	Death (1 died within 1 month because of urosepsis, related to medical comorbidities; 1 died on day 14 as a result of complications from pre-existing pancreatic cancer)	2
Cricopharyngeal dysfunction from stroke or nerve injury (n=7)	3.3	1.8	NR	Left vocal fold paralysis (patient had continued pharyngeal weakness and aspiration of unclear cause)	1
Prior radiation (n=15)^	3.9	3.2	NR	Aspiration from emesis with gastric tube feeding during dialysis(needed intubation and bronchoscopy with complete recovery)	1
total laryngectomy (n=3)	1.9	1.7	NR		
Idiopathic (n=16)	2.8	1.9	NR		
*FOSS is a 6 point scale based on symptoms, physiologic function, diet, and compensation. Lower values indicate better function.					
^Radiation patients who were gastric tube dependent preoperatively had improvement in swallowing with surgery but most continued to require supplemental nutrition.					
91% reported subjective swallowing improvement.					
All patients who underwent CP myotomy for poor tracheoesophageal speech regained speech postoperatively.					
Recurrence of dysphagia needing subsequent surgical procedures : 14% (12/87)					
Surgical indications were ZD in 2, radiation in 7, stroke in 2, idiopathic CP dysfunction in 1.					
5 were managed with oesophageal dilation, 6 had repeat CO ₂ laser CP myotomy, and 1 with scarring following radiation for hypopharyngeal cancer had several laser procedures with dilations for recurrent scarring.					
Abbreviations used: CO ₂ , carbon dioxide; CP, cricopharyngeal; FOSS, functional outcome swallowing scale; NR, not reported; ZD, Zenker's diverticulum.					

Study 4 Lim RY [1995]

Details

Study type	Case series (retrospective)
Country	USA (single centre)
Recruitment period	1992-94
Study population and number	n=44 patients with both prediverticular and diverticular (Zenker's) cricopharyngeal dysfunction. (4 with Zenker's diverticulum)
Age and sex	Mean age 70 years (range 29 to 84 years); 45% (24/44) male
Patient selection criteria	Patients CP dysfunction identified on modified barium swallow.
Technique	Endoscopic CO₂ laser CP myotomy (without mucosal closure): in 40 patients the procedure was done under intravenous analgesia. Using a Hollinger Benjamin diverticuloscope the CP muscle or diverticulum was exposed. An operating microscope with a 10-12 W CO ₂ laser is used to incise the CP bar leaving a wedge shaped wound. Bleeding is controlled using suction cautery. Postoperative Modified Barium Swallow videofluoroscopy done. Patients are not given anything by mouth for 4-24 hours and fed with pureed diet for 10-14 days. Antibiotics are given intravenously both pre and postoperatively, and liquid analgesics are given for pain management.
Follow-up	Range 2-22 months
Conflict of interest/source of funding	Not reported

Analysis

Study design issues: retrospective study, preoperative assessments included history taking, head and neck examination, endoscopy, modified barium swallow videofluoroscopy. CP myotomy was staged in 4 groups (I to IV) based on symptoms and videofluoroscopic pictures. Preoperative manometry was used in 5 patients. Videofluoroscopy was used for evaluation of swallowing after 4 hours and repeated after 6-8 months.

Population issues: Some of the patients in this series had Zenker's diverticulum.

Key efficacy and safety findings

Efficacy	Safety								
Number of patients analysed: 44 Mean hospital stay: 0-1 day (in 90% patients) Complete healing (relief of pain and pharyngeal roughness) in 10-14 days. Overall success: 86% Improvement in swallowing outcomes (based on clinical and videofluoroscopic assessment) Patients with stages I, II, III CP dysfunction (n=40) had 100% improvement in swallowing solids and liquid diets or at least pureed food and clearance of hypo-pharyngeal secretions. Patients with ZD (n=4) showed diminished pouch but with better access through the cricopharynx.	Complications : <table border="1"> <thead> <tr> <th></th> <th>% (n)</th> </tr> </thead> <tbody> <tr> <td>Oesophageal perforations (both drained externally, given systemic antibiotics - had full recovery and improved swallowing)</td> <td>4.5 (2/44)</td> </tr> <tr> <td>Restenosis (in stage IV patients with stenosis; 2 needed revision surgery after 6-12 months, 2 died of coronary heart disease before a myotomy could be done)</td> <td>9 (4/44)</td> </tr> <tr> <td>Aspiration (in 3/11 with aspiration)</td> <td>6.8 (3/44)</td> </tr> </tbody> </table> These complications were in those without Zenker's diverticulum.		% (n)	Oesophageal perforations (both drained externally, given systemic antibiotics - had full recovery and improved swallowing)	4.5 (2/44)	Restenosis (in stage IV patients with stenosis; 2 needed revision surgery after 6-12 months, 2 died of coronary heart disease before a myotomy could be done)	9 (4/44)	Aspiration (in 3/11 with aspiration)	6.8 (3/44)
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Abbreviations used: CO ₂ , carbon dioxide; CP, cricopharyngeal; MBSS, modified barium swallow study; ZD, Zenker's diverticulum.									

Study 5 Bachy V [2013]

Details

Study type	Case series (retrospective)
Country	Belgium (single centre)
Recruitment period	2002-9
Study population and number	n=65 patients who had a failure to open the upper oesophageal sphincter (some had swallowing complaints and some had a swallowing disorder linked to a neurological disease).
Age and sex	Mean age 70 years ; 58% (38/65) male
Patient selection criteria	Patients selected on basis of clinical examination, medical history, endoscopy and videofluoroscopy. When it is not clear, a pharyngoesophageal manometry or oesophageal manometry is performed.
Technique	Endoscopic CO₂ laser CP myotomy: a diverticuloscope is placed at the base of the CP muscle on the posterior pharyngeal wall. A 10 W CO ₂ laser on continuous mode is used to incise the CP muscle. Wet cotton is used to protect the oesophagus. Fibrin glue is used to close the incision and prevent any leakage. Chest x ray done on day 1-2, patient fed intravenously until 3 rd day and antibiotics given for first week. A soft diet is given after 10 days and patient discharged on day 3.
Follow-up	Mean 47 months (range 6-99 months)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: only 49.2% (32/65) patients responded to the questionnaire survey.

Study design issues: small sample size, 2 questionnaires were used for evaluation. One focused on the intervention and patients' experiences. Overall satisfaction was assessed on a scale 0-10.

Another is the deglutition handicap index (DHI) self-assessment questionnaire. It is a validated tool by Woi-sard et al. The S domain refers to the specific swallowing symptoms, F domain relates to functional -food, nutritional status and lung function, and the E domain relates to emotional or psychosocial consequences of the disability caused by the dysphagia. For satisfaction analysis, the responses were 'never to always' and were coded in numbers from 0-4 according to voice handicap index.

Key efficacy and safety findings

Efficacy	Safety																																																					
<p>Number of patients analysed: 32 who completed follow-up questionnaires</p> <p>Improvement in outcomes</p> <table border="1" data-bbox="94 338 907 449"> <thead> <tr> <th></th> <th>n=32</th> </tr> </thead> <tbody> <tr> <td>Pain (n=31) (analog scale)</td> <td>46.9% (average of 2.5/10)</td> </tr> <tr> <td>Weight gain in 3 months (n=10) (kg)</td> <td>5.1</td> </tr> </tbody> </table> <p>Improvement in symptoms</p> <table border="1" data-bbox="94 480 907 632"> <tbody> <tr> <td>Swallowing liquids</td> <td>75% (24/32)</td> </tr> <tr> <td>Swallowing solids</td> <td>81% (26/32)</td> </tr> <tr> <td>Pleasure while eating</td> <td>81% (26/32)</td> </tr> <tr> <td>Eat a wide variety of textures</td> <td>75% (24/32)</td> </tr> </tbody> </table> <p>Satisfaction</p> <table border="1" data-bbox="94 663 907 768"> <tbody> <tr> <td>Global satisfaction (n=30) (scale 0-10)</td> <td>7.2</td> </tr> <tr> <td>Patients would undergo surgery again if needed</td> <td>83.9% (27/32)</td> </tr> </tbody> </table> <p>Swallowing improvement (DHI) outcomes</p> <table border="1" data-bbox="94 842 907 1024"> <thead> <tr> <th></th> <th>Preoperative (mean)</th> <th>Postoperative (mean)</th> </tr> </thead> <tbody> <tr> <td>Score S of DHI</td> <td>17.9</td> <td>8.91</td> </tr> <tr> <td>Score F of DHI</td> <td>19.73</td> <td>10.73</td> </tr> <tr> <td>Score E of DHI</td> <td>18.17</td> <td>11</td> </tr> <tr> <td>Global score</td> <td>55.29</td> <td>31.38</td> </tr> </tbody> </table> <p>Recurrence of dysphagia needing subsequent interventions</p> <p>13.2% (9/63) patients had a second surgery due to recurrence. The average time between the 2 procedures was 43 months (10-80 months).</p>		n=32	Pain (n=31) (analog scale)	46.9% (average of 2.5/10)	Weight gain in 3 months (n=10) (kg)	5.1	Swallowing liquids	75% (24/32)	Swallowing solids	81% (26/32)	Pleasure while eating	81% (26/32)	Eat a wide variety of textures	75% (24/32)	Global satisfaction (n=30) (scale 0-10)	7.2	Patients would undergo surgery again if needed	83.9% (27/32)		Preoperative (mean)	Postoperative (mean)	Score S of DHI	17.9	8.91	Score F of DHI	19.73	10.73	Score E of DHI	18.17	11	Global score	55.29	31.38	<p>Complications:</p> <p>Reported for all 65 patients</p> <table border="1" data-bbox="935 310 1507 678"> <thead> <tr> <th></th> <th>n=65</th> </tr> </thead> <tbody> <tr> <td colspan="2">Procedural complications</td> </tr> <tr> <td>Excess bleeding</td> <td>1</td> </tr> <tr> <td>Vascular tumour finding</td> <td>1</td> </tr> <tr> <td colspan="2">Postoperative complications</td> </tr> <tr> <td>Fistula (without mediastinitis)</td> <td>1</td> </tr> <tr> <td>Pulmonary infection</td> <td>1</td> </tr> <tr> <td>Subcutaneous emphysema</td> <td>1</td> </tr> <tr> <td colspan="2">Late complications</td> </tr> <tr> <td>Gastric bleeding (NSAID's imputed)</td> <td>1</td> </tr> </tbody> </table>		n=65	Procedural complications		Excess bleeding	1	Vascular tumour finding	1	Postoperative complications		Fistula (without mediastinitis)	1	Pulmonary infection	1	Subcutaneous emphysema	1	Late complications		Gastric bleeding (NSAID's imputed)	1
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Study 6 Takes RP [2005]

Details

Study type	Case series (prospective)
Country	Netherlands (single centre)
Recruitment period	2002-3
Study population and number	n=10 patients with idiopathic cricopharyngeal dysfunction (without Zenker's diverticulum).
Age and sex	Mean age 71 years ; 30% (3/10) male
Patient selection criteria	Not reported
Technique	Endoscopic CO ₂ laser CP myotomy (without mucosal closure): Using a Werda or Van Overbeek diverticuloscope the CP muscle or diverticulum was exposed. An operating microscope with a 4 W CO ₂ laser in continuous mode is used to incise the CP bar. Patients received a feeding tube, oral intake given on postoperative day 1, or delayed for 3 days if free air on chest radiograph done on postoperative day 1. Antibiotics were given intravenously for 1 day,
Follow-up	2-3 months
Conflict of interest/source of funding	Not reported

Analysis

Study design issues: retrospective evaluation of outcomes, preoperative assessments included clinical observation, questionnaire survey; endoscopy and modified barium swallow videofluoroscopy. Videofluoroscopy was used for evaluation of swallowing at 2 weeks and at 3 months.

Key efficacy and safety findings

Efficacy	Safety								
Number of patients analysed: 10 Mean hospital stay: 4.8 days Improvement in swallowing outcomes (based on questionnaire of subjective symptoms) All improved but all were not complaint free.	Complications : <table border="1"> <thead> <tr> <th></th> <th>% (n)</th> </tr> </thead> <tbody> <tr> <td>Subcutaneous emphysema</td> <td>10 (1/10)</td> </tr> <tr> <td>Recurrent dysphagia (due to fibrosis at the site, needed a second endoscopic procedure, sutures placed to prevent restenosis, swallowing improved after 3 months)</td> <td>10 (1/10)</td> </tr> <tr> <td>Air on chest radiograph (hospital stay prolonged and oral intake delayed until postoperative day3)</td> <td>40 (4/10)</td> </tr> </tbody> </table>		% (n)	Subcutaneous emphysema	10 (1/10)	Recurrent dysphagia (due to fibrosis at the site, needed a second endoscopic procedure, sutures placed to prevent restenosis, swallowing improved after 3 months)	10 (1/10)	Air on chest radiograph (hospital stay prolonged and oral intake delayed until postoperative day3)	40 (4/10)
	% (n)								
Subcutaneous emphysema	10 (1/10)								
Recurrent dysphagia (due to fibrosis at the site, needed a second endoscopic procedure, sutures placed to prevent restenosis, swallowing improved after 3 months)	10 (1/10)								
Air on chest radiograph (hospital stay prolonged and oral intake delayed until postoperative day3)	40 (4/10)								
Abbreviations used: CO ₂ , carbon dioxide; CP, cricopharyngeal.									

Study 7 Dawe N [2014]

Details

Study type	Case series (retrospective)
Country	UK (single centre)
Recruitment period	2006-11
Study population and number	n=13 patients with cricopharyngeal fibrosis related dysphagia following radiotherapy, with or without chemotherapy for a variety of head and neck cancers.
Age and sex	age range 47-88 years ; 72% (8/11) male
Patient selection criteria	Patients with cricopharyngeal open problems confirmed by clinical examination, multidisciplinary team discussion and videofluoroscopic swallowing study.
Technique	Endoscopic CO₂ laser CP myotomy: a Weerda diverticuloscope is placed at the base of the CP muscle on the posterior pharyngeal wall. A 2 W CO ₂ laser on continuous mode is used to incise the CP muscle. Haemostasis achieved by a diffused laser beam or adrenaline soaked pledgets. In some cases endoscopic diathermy was used.
Follow-up	range 0-11 months
Conflict of interest/source of funding	None declared

Analysis

Follow-up issues: excluded 2 patients from Modified Barium Swallow Impairment Profile (MBSImP) analysis due to insufficient videofluoroscopic data.

Study design issues: small sample size, Modified Barium Swallow Impairment Profile (MBSImP) used for retrospective rating of videofluoroscopic swallowing studies performed before and after treatment. This is a validated rating scale of the modified barium swallow study with 17 components and 3-5 associated scores describing progressive levels of oral, pharyngeal and oesophageal impairment. Results were independently assessed by 2 specialists and correlated to achieve a consensus.

A validated rated measurement of food textures for head and neck cancer was used to assess the normalcy of diet subsection of the Performance Status Scale. They are scored on a scale 0-100, higher scores indicating oral diet with fewer restrictions.

Population issues: patients presented with complex swallowing problems.

Key efficacy and safety findings

Efficacy				Safety	
Number of patients analysed: 11				Complications: procedure related complications were not recorded.	
Modified Barium Impairment Profile swallowing scores (n=11)					
	Pre-procedure	Post-procedure	p value		% (n=11)
Median total MBSImP scores	13 (95% CI 8.21, 17.79)	10 (95% CI 4.15, 15.85)	0.41 (95% CI - 4.56, 10.56)	Aspiration	36 (4/11)
Median MBSImP score of the CP specific function (variables 14 and 17)	3 (95% CI - 0.19, 6.19)	2 (95% CI 0.4, 3.6)	0.16 (95% CI - 2.57, 4.57)	Progressive fibrosis (patients had worse swallowing outcomes, 1 had a pharyngolaryngectomy due to dysfunctional larynx)	36 (4/11)
Improvement in MBSImP scores was seen in the majority of patients (7/11); lower scores indicating a better swallowing performance.					
Normalcy of diet subsection of the Performance Status scale showed variation across patient scores (n=10). The median score improved from 20/100 pre-procedure to 30/100 post procedure.					
Abbreviations used: CI, confidence interval; CO ₂ , carbon dioxide; CP, cricopharyngeal; MBSImP, modified barium swallow impairment profile.					

Study 8 Silver N [2014]

Details

Study type	Case series (retrospective)
Country	USA (single centre)
Recruitment period	not reported
Study population and number	n=10 patients with dysphagia secondary to cricopharyngeal stricture following chemoradiation, for squamous cell carcinoma of the head and neck.
Age and sex	age range 49-78 years ; 70% (7/10) male
Patient selection criteria	Patients with cricopharyngeal myotomy were identified by query of billing records using CRT codes. Patients were excluded if they had open CPM or if endoscopic myotomy was performed for reasons other than dysphagia after CRT for Squamous Cell Carcinoma of head and neck.
Technique	<u>Endoscopic CO₂ laser CP myotomy</u> : cervical oesophagoscope inserted and strictures dilated. A Weerda diverticuloscope is placed at the base of the CP muscle on the posterior pharyngeal wall. A 10 W CO ₂ laser on continuous mode is used to incise the CP muscle. No food is given orally for 24 hours and clear diet thereafter.
Follow-up	minimum 12 months
Conflict of interest/source of funding	None

Analysis

Follow-up issues: patients followed up by clinical visits and by telephone interview.

Study design issues: small sample size, preoperative and postoperative (after 1 month) Barium swallow studies performed by speech and swallow pathologists.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: 10 Radiographic resolution of the cricopharyngeal stricture reported in 90% (9/10) patients. Only 1 patient had persistent narrowing of the oesophagus postoperatively (and required additional dilatation). Improvement in dysphagia (assessed by modified Barium Swallow study) reported in 90% (9/10) patients.	Complications: none reported.
Abbreviations used: CI, confidence interval; CO ₂ , carbon dioxide; CP, cricopharyngeal; MBSImP, modified barium swallow impairment profile.	

Efficacy

Swallowing function

A retrospective comparative case series of 22 patients comparing carbon dioxide (CO₂) laser cricopharyngeal (CP) myotomy (n=14) against transcervical CP myotomy (n=8) reported that functional outcomes (Functional Outcome Swallowing Scale [FOSS] stages for dysphagia) improved after the procedure in both groups (CO₂ laser group from 2.4 to 0.9; transcervical myotomy group from 3.4 to 1.9)².

A case series of 87 patients with CP muscle dysfunction from a variety of indications, treated by CO₂ laser CP myotomy reported that FOSS scores improved from 2.6 to 1.6 (p<0.001) after surgery³.

A case series of 44 patients with both prediverticular (n=40) and diverticular (n=4) CP dysfunction treated with CO₂ laser CP myotomy reported that patients with stages I, II and III CP dysfunction (n=40) had 100% improvement in swallowing solids and liquid diets or at least pureed food and clearance of hypo-pharyngeal secretions (based on clinical and videofluoroscopic assessment). Patients with Zenker's diverticulum (n=4) showed diminished pouch but with better access through the cricopharynx⁴.

A case series of 65 patients treated with endoscopic CP myotomy reported improvement in symptoms in 32 patients who completed the self-assessment questionnaires. 75% of the patients reported they could swallow liquids and 81% of the patients reported they could swallow solids⁵.

A case series of 10 patients with dysphagia secondary to CP 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) in 90% (9/10) of patients. Radiographic resolution of the CP stricture was reported in 90% (9/10) of patients. Only 1 patient had persistent narrowing of the oesophagus postoperatively and needed additional dilatation⁸.

Symptom recurrence and revision surgery

A retrospective comparative case series of 153 patients who had endoscopic CP myotomy by either CO₂ laser (n=123) or by stapler (n=23) reported that symptom recurrence was more frequent after stapling surgery (CO₂ laser group 6% (7/153) and stapler group 26% (6/23); p=0.002). The rates of revision surgery were similar in the 2 groups (CO₂ laser group 3% (4/123) and stapler group 4% (1/23); p= 0.77)¹.

The case series of 87 patients with CP dysfunction treated by endoscopic CO₂ laser myotomy reported recurrence of dysphagia in 14% (12/87) of patients. All patients needed subsequent surgical procedures: 5 were treated by oesophageal

dilation, 6 by repeat CO₂ laser CP myotomy, and 1 patient with scarring after radiation for hypopharyngeal cancer had several laser procedures with dilations³.

The case series of 65 patients reported recurrence of dysphagia needing subsequent surgeries in 13% (9/65) of patients. The average time between the 2 procedures was 43 months (10-80 months)⁵.

Duration of procedure

The retrospective comparative case series of 153 patients who underwent either CO₂ laser assisted (n=123) or stapler assisted (n=23) endoscopic CP myotomy reported that the average duration of the procedure was longer for the CO₂ laser group than for the stapler group (45.6 minutes for CO₂ laser and 35.3 minutes for stapler; p=0.01)¹.

The retrospective comparative case series of 22 patients comparing CO₂ laser CP myotomy (n=14) against transcervical CP myotomy (n=8) reported that the median hospital stay and operative times were shorter for the laser group (hospital stay: 1 day (range 0-3) for CO₂ laser and 1 day (range 1-25) for open myotomy group; operative time: 29 (10-95) minutes for CO₂ laser and 87 (74-100) minutes for open myotomy group)².

Patient satisfaction

The case series of 65 patients reported that global satisfaction (self-assessed on a scale of 0-10) 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 needed⁵.

Safety

Perforation

Oesophageal perforations were reported in 5% (2/44) of patients in a case series of 44 patients with a follow-up period ranging from 2-22 months. Both perforations were drained externally, and the patients were given systemic antibiotics, leading to full recovery and improved swallowing⁴.

A hypopharyngeal perforation that resulted in infection and prolonged hospitalisation as a result of pharyngocutaneous fistula was reported in 1 patient in the CO₂ laser assisted CP myotomy group in a retrospective comparative case series of 153 patients who had endoscopic myotomy either by CO₂ laser (n=123) or by stapler assisted endoscopic myotomy (n=23). Further details were not reported¹.

Complete pharyngeal wall perforation was reported in 1 patient in the CO₂ laser assisted CP myotomy group in the retrospective comparative case series of 153 patients who underwent either CO₂ laser (n=123) or stapler assisted endoscopic myotomy (n=23). Further details were not reported¹.

Pharyngeal wall tears

Pharyngeal wall mucosal tears occurred during CP myotomy (as the endoscope or the stapler were introduced) in 5% (6/123) of patients in the CO₂ laser assisted CP myotomy group and 1 patient in the stapler group in the retrospective comparative case series of 153 patients who underwent either CO₂ laser (n=123) or stapler assisted endoscopic myotomy (n=23). Further details were not reported¹.

Fistula

Fistula (without mediastinitis) was reported in 1 patient immediately after the procedure in a case series of 65 patients. Further details were not reported⁵.

Aspiration pneumonia

Aspiration pneumonia (needing hospitalisation) was reported in 2% (2/123) of patients in the CO₂ laser assisted CP myotomy group in the retrospective comparative case series of 153 patients who underwent either CO₂ laser (n=123) or stapler assisted endoscopic myotomy (n=23). Both patients were managed conservatively¹.

Aspiration from emesis with gastric tube feeding during dialysis was reported in 1 patient in the case series of 87 patients. The patient needed intubation and bronchoscopy but had a complete recovery³.

Bleeding

Severe bleeding (controlled during the procedure) was reported in 1 patient in the case series of 65 patients⁵.

Late gastric bleeding (caused by nonsteroidal anti-inflammatory drugs) was reported in 1 patient in the case series of 65 patients. Further details were not reported⁵.

Infection

Pulmonary infection immediately after the procedure was reported in 1 patient in the case series of 65 patients. Further details were not reported⁵.

Fever (of unknown origin) was reported in 2 patients in the CO₂ laser group in a retrospective comparative case series of 22 patients who underwent either endoscopic CO₂ laser CP myotomy (n=14) or open CP myotomy (n=8)².

Chest pain

Chest pain (self-limited) was reported in 1 patient each in the CO₂ laser group and the open group in the retrospective comparative case series of 22 patients who had either endoscopic CO₂ laser CP myotomy (n=14) or cervical CP myotomy (n=8). No further details were reported².

Left vocal fold paralysis

Left vocal fold paralysis was reported in 1 patient who was dependent on a nasogastric tube (with preoperative Zenker's diverticulum, aspiration and continued pharyngeal weakness of unclear cause) in a case series of 87 patients³.

Fibrosis

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 after the procedure and 1 patient eventually had a pharyngolaryngectomy due to dysfunctional larynx⁷.

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 done⁴.

Validity and generalisability of the studies

- No randomised trials comparing endoscopic CO₂ laser CP myotomy with alternative treatments for CP dysfunction have been published.
- Most of the studies are retrospective case series with small sample sizes.
- Studies have included patients with a variety of aetiologies underlying CP dysfunction and dysphagia (those with muscular disorders, degenerative neurological disorders, after radiation for head and neck cancer, or idiopathic). 2 studies have also included some patients with Zenker's diverticulum.
- Study protocols varied significantly in terms of laser settings, postoperative care and feeding regimes.
- Studies that use objective and validated outcomes measures and long-term follow-up data are lacking.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Flexible endoscopic treatment of a pharyngeal pouch. NICE interventional procedure guidance IPG513 (2015). Available from <http://guidance.nice.org.uk/IPG513>
- Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia. NICE interventional procedure guidance IPG490 (2014). Available from <http://guidance.nice.org.uk/IPG490>
- Endoscopic stapling of pharyngeal pouch. NICE interventional procedure guidance IPG22 (2013). Available from <http://guidance.nice.org.uk/IPG22>

NICE guidelines

- Stroke rehabilitation. NICE guideline CG162 (2013). Available from <http://guidance.nice.org.uk/CG162>
- Improving outcomes in head and neck cancers: the manual. NICE cancer service guidance (2004). www.nice.org.uk/Guidance/CSGHN

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. XXXX Specialist Advisor Questionnaires for endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia were submitted and can be found on the [NICE website \[INSERT HYPER LINK TO MAIN IP PAGE\]](#).

Patient commentators' opinions

NICE's Public Involvement Programme sent xxx questionnaires to xxx NHS trusts for distribution to patients who had the procedure (or their carers). NICE received xxx completed questionnaires.

Section to be inserted if there is no patient commentary

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Section to be inserted if patient commentators raised no new issues

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Section to be inserted if patient commentators raised new issues

The patient commentators raised the following issues about the safety/efficacy of the procedure, which did not feature in the published evidence or the opinions of specialist advisers, and which the Committee considered to be particularly relevant:

- [insert additional efficacy and safety issues raised by patient commentators and highlighted by IPAC, add extra rows as necessary].
- [Last item in list].

Issues for consideration by IPAC

- Papers exclusively reporting endoscopic carbon dioxide laser cricopharyngeal myotomy of the Zenker's diverticulum have not been included in this review.

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6. Takes RP, Van Den Hoogen FJ et al (2005). Endoscopic myotomy of the cricopharyngeal muscle with CO2 laser surgery. *Head & Neck*. 27 (8), 703-709.
7. Dawe N, Patterson J et al (2014). Targeted use of endoscopic CO2 laser cricopharyngeal myotomy for improving swallowing function following head and neck cancer treatment. *Journal of Laryngology & Otology*. 128 (12), 1105-1110.
8. Silver N and Gal TJ (2014). Endoscopic CO2 laser management of chemoradiation-related cricopharyngeal stenosis. *Annals of Otolaryngology, Rhinology & Laryngology*. 123 (4), 252-256.

Appendix A: Additional papers on endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Belafsky PC, Spiers J (2003). Endoscopic cricopharyngeal myotomy. <i>Ear, Nose & Throat Journal</i> ; 82, 10; pg 755.	Case report n=1 patient with dysphagia (due to hypertrophy of the cricopharyngeal muscle) Endoscopic CO ₂ cricopharyngeal myotomy.	Postoperatively the patient had complete relief of dysphagia and is symptom free.	Larger and longer follow-up studies included in table 2.
Bastian R W and Muzaffar K (2001). Endoscopic laser cricopharyngeal myotomy to salvage tracheoesophageal voice after total laryngectomy. <i>Archives of Otolaryngology -- Head & Neck Surgery</i> 127 (6) 691-693.	Case report n=2 Spasm of the cricopharyngeal muscle after laryngectomy causing voice problem Endoscopic carbon dioxide laser cricopharyngeal myotomy	100% success, no complications.	Not relevant indication.
Berzofsky CE et al (2012). Variability of postoperative esophagrams after endoscopic cricopharyngeal myotomy: technique dependence. <i>Annals of Otolaryngology & Laryngology</i> 121 (3) 145-150.	Case series (retrospective) n=17 POD 1 fluoroscopic examinations of the cervical esophagus utilizing contrast dye after ECPM with CO ₂ laser	Different techniques used to address the exposed buccopharyngeal fascia following ECPM result in specific findings on the POD 1 esophagram. Recognition of these imaging differences and open communication with the fluoroscopist will avoid a misdiagnosis of a pharyngeal leak, which might cause an unnecessary delay of oral feeding and hospital discharge.	Study examined the closure techniques used the impact on patient management.
Brondbo, K (2000). Treatment of cricopharyngeal dysfunction by endoscopic laser myotomy. <i>Acta Oto-Laryngologica Supplement</i> 543 222-224.	Case series n=17 patients with cricopharyngeal dysfunction [associated conditions: central nervous disease (1), muscular disease (2), achalasia inferior (1) and previous surgery of the neck (2)] Endoscopic myotomy of the cricopharyngeal muscle with CO ₂ laser (1.5 -3.5 W), feeding tube and soft diet on postoperative day 3. Follow-up: 18 months	There were no immediate or late complications. Three patients died from other diseases, the remaining 14 patients were sent a follow-up questionnaire. All patients except one stated that their swallowing abilities had improved and more than half of the patients had gained weight.	Larger and longer follow-up studies included in table 2.

Chitose S, Sato K et al (2011). A new paradigm of endoscopic cricopharyngeal myotomy with CO2 laser. Laryngoscope 121 (3) 567-570.	Case report n=1 Mild dysphagia for 3 years. Endoscopic carbon dioxide laser cricopharyngeal myotomy (variation in operative technique).	The patient had been symptom free for 10 months.	Larger and longer follow-up studies included in table 2.
Ho AS, Morzaria S et al (2011). Carbon dioxide laser-assisted endoscopic cricopharyngeal myotomy with primary mucosal closure. Annals of Otolaryngology & Rhinology & Laryngology 120 (1) 33-39.	Comparative case series (retrospective) n=7 EPCM with primary mucosal closure versus 7 open cricopharyngeal myotomy 3-10 W CO ₂ , closed with sutures, clear diet and chest X-ray done on day 3. 2 had Zenker's diverticulum. Follow-up: CO ₂ group mean 22 months; open group 10.5 months.	All patients who had EPCM were treated successfully without complications. The operative times averaged 128 minutes. The hospitalization averaged 2.1 days. Statistically significant improvements in swallowing were seen (MDADI score from 51.3 to 77.7, p < 0.0006; FOSS score from 3.7 to 1.3, p < 0.0005), and were similar to those in the patients who had the open procedure (FOSS score from 3.0 to 1.0, p < 0.006). Trends toward decreased blood loss, a shorter hospital stay, and a lower complication rate were observed in the patients who had EPCM.	EPCM including closure of the mucosal defect (variation in operative technique to help reduce incidence of postoperative cervical emphysema and mediastinitis). Larger and longer follow-up studies included in table 2.
Lawson G, Remacle M et al (2003). Endoscopic CO2 laser-assisted surgery for cricopharyngeal dysfunction. European Archives of Oto-Rhino-Laryngology 260 (9) 475-480.	Case series (retrospective) n=29 patients with dysphagia from failed relaxation of the cricopharyngeal muscle. (2 with ZD) Endoscopic CO ₂ cricopharyngeal myotomy (10W) and closed with fibrin glue. Liquid or semisolid diet on postoperative day 3, regular diet after 10 days. Antibiotics for a week. Follow-up: mean 18 months	Postoperative videofluoroscopy showed the absence of leakage, and all patients resumed oral intake on day 2. The median self-rating score improved from 1 to 4 (poor to good) for dysphagia and from 3 to 4 for aspiration. The outcome of the flexible endoscopic evaluation of swallow improved from 2 to 4; videofluoroscopy improved from 2 to 4. No surgical complication occurred. None had recurrence.	Larger and longer follow-up studies included in table 2. This is a previous series (covering the period 1998-2001) of Bachy 2013 included in table 2. Complications in this series are similar.
Lawson G and Remacle M (2008). Ins and outs of myotomy of the upper	Case series n=31 patients with upper oesophageal dysfunction	The trans-oral approach was feasible without complications in all	Larger and longer follow-up studies included in table 2.

<p>oesophageal sphincter in swallowing disorders. B-ENT.4 (SUPPL.10) (pp 83-89).</p>	<p>(10 neurological diseases, 8 after chemoradiation, 12 failure of cricopharyngeal relaxation) Endoscopic laser-assisted myotomy Follow-up: 1 year</p>	<p>patients. Symptoms improved in most patients. There was no recurrence in the group of cricopharyngeal muscle relaxation failure; 5 out of 8 patients in the irradiation group suffered recurrence, as did 4 out of 10 neurological patients. Endoscopic laser-assisted cricopharyngeal myotomy seems to be a safe and effective technique for treating upper oesophageal dysfunction. However, complex pathology involving more than cricopharyngeal muscle leads to a high recurrence rate.</p>	<p>This is a previous series (covering the period 1998-2001) of Bachy 2013 included in table 2. Complications in this series are similar.</p>
<p>Ozgursoy OB and Salassa JR (2010). Manofluorographic and functional outcomes after endoscopic laser cricopharyngeal myotomy for cricopharyngeal bar. Otolaryngol Head Neck Surg 2010; 142: 735-40.</p>	<p>Case series and chart review n=14 (idiopathic -6, post-polio syndrome-5, undefined neurological-1, body mytosis-1, dermatomytosis-1) Endoscopic CO₂ laser CPM for CP bar without concomitant head and neck or Zenker's procedure. 4-5 W CO₂ laser used, Follow-up: 6 months</p>	<p>No major surgical complications. All patients improved at least one stage on the FOSS after surgery. There was a statistical significant decrease in the subjective FOSS stages after surgery. Videofluoroscopy showed a significant postoperative increase in the mean cross-sectional CP opening area from 32.75 to 123.52mm². Manofluorographic pressure recordings showed a significant postoperative decrease in the intrabolus pressure gradient across the CP region from 25.44 to 13.22mm Hg. The change in the intrabolus pressure gradient (IB-Gra) across the CP region showed no difference between the groups.</p>	<p>Larger studies with longer follow-up included in table 2.</p>
<p>Pitman M and Weissbrod P (2009). Endoscopic CO₂ laser cricopharyngeal myotomy. Laryngoscope 2009 119 (1) pg 45-53</p>	<p>literature review of endoscopic and transcervical cricopharyngeal myotomy</p>	<p>Endoscopic cricopharyngeal myotomy is a viable alternative to classic transcervical cricopharyngeal myotomy with equivalent outcomes and</p>	<p>Review</p>

		comparable if not less morbidity.	
Sasaki CT and Leder SB (2005). Endoscopic CO2 laser-assisted surgery for cricopharyngeal dysfunction. <i>Dysphagia</i> .20 (1) pp 65-66.	critical assessment of evidence about feeding problems of patients with neuromotor diseases.		Summary and comments on selected dysphagia literature
Tieu BH and Hunter JG (2011). Management of Cricopharyngeal Dysphagia With and Without Zenker's Diverticulum. <i>Thoracic Surgery Clinics</i> .21 (4). pp 511-517.		Cricopharyngeal dysphagia and Zenker 's diverticulum result from cricopharyngeal dysfunction, a failure of the upper esophageal sphincter to relax at the initiation of swallowing. The focus of surgical management involves a cricopharyngeal myotomy that is performed by either an open or an endoscopic approach. The endoscopic approach offers faster operating times, a shorter hospital stay, earlier time to oral intake, and lower complication rates, but a role for open cricopharyngeal myotomy remains.	Review

Appendix B: Related NICE guidance for endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia

Guidance	Recommendations
Interventional procedures	<p>Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia. NICE interventional procedure guidance IPG490 ([2014]). Available from http://guidance.nice.org.uk/IPG490</p> <p>1.1 Current evidence on the efficacy of transcutaneous neuromuscular electrical stimulation (NMES) for oropharyngeal dysphagia is limited in quality. The evidence on safety is limited in both quality and quantity but there were no major safety concerns. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</p> <p>1.2 Clinicians wishing to undertake transcutaneous NMES for oropharyngeal dysphagia should take the following actions.</p> <ul style="list-style-type: none"> • 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 is recommended. • Audit and review clinical outcomes of all patients having transcutaneous NMES for oropharyngeal dysphagia (see section 7.1). <p>1.3 NICE encourages further research into transcutaneous NMES for oropharyngeal dysphagia, which should clearly document the indications for treatment and the details of patient selection. Research should document the timing of initiation of treatment after onset of symptoms, as well as precise information about the procedure technique. Outcome measures should include freedom from tube feeding, quality of life and duration of treatment effect. NICE may review the procedure on publication of further evidence.</p> <p>Endoscopic stapling of pharyngeal pouch. NICE interventional procedure guidance IPG22 (2013). http://guidance.nice.org.uk/IPG22</p> <p>1.1 Current evidence on the safety and efficacy of endoscopic stapling of pharyngeal pouch appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.</p>

	<p>Flexible endoscopic treatment of pharyngeal pouch. NICE interventional procedure guidance IPG513 (2015). http://guidance.nice.org.uk/IPG513</p> <p>1.1 Current evidence on the efficacy and safety of flexible endoscopic treatment of a pharyngeal pouch is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.</p> <p>1.2 Flexible endoscopic treatment of a pharyngeal pouch should only be done by experienced interventional endoscopists with training in the procedure.</p>
NICE guidelines	<p>Stroke rehabilitation. NICE clinical guideline 162 (2013). Available from http://guidance.nice.org.uk/CG162</p> <p>Recommendations</p> <p>1.7 Swallowing</p> <p>1.7.1 Assess swallowing in people after stroke in line with recommendations in Stroke (NICE clinical guideline 68).</p> <p>1.7.2 Offer swallowing therapy at least 3 times a week to people with dysphagia after stroke who are able to participate, for as long as they continue to make functional gains. Swallowing therapy could include compensatory strategies, exercises and postural advice.</p> <p>1.7.3 Ensure that effective mouth care is given to people with difficulty swallowing after stroke, in order to decrease the risk of aspiration pneumonia.</p> <p>1.7.4 Healthcare professionals with relevant skills and training in the diagnosis, assessment and management of swallowing disorders should regularly monitor and reassess people with dysphagia after stroke who are having modified food and liquid until they are stable (this recommendation is from Nutrition support in adults [NICE clinical guideline 32]).</p> <p>1.7.5 Provide nutrition support to people with dysphagia in line with recommendations in Nutrition support in adults (NICE clinical guideline 32) and Stroke (NICE clinical guideline 68).</p> <p>Improving outcomes in head and neck cancers: the manual. NICE cancer service guidance (2004).</p>

Appendix C: Literature search for endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	11/06/2015	Issue 6 of 12, June 2015
HTA database (Cochrane)	11/06/2015	Issue 2 of 4, April 2015
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	11/06/2015	Issue 5 of 12, May 2015
MEDLINE (Ovid)	11/06/2015	1946 to June week 1 2015
MEDLINE In-Process (Ovid)	11/06/2015	June 10, 2015
EMBASE (Ovid)	11/06/2015	1974 to 2015 week 23
PubMed	11/06/2015	n/a
BLIC (Dialog DataStar)	11/06/2015	n/a

Trial sources searched on 24/03/2015 ([briefing search](#))

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched on 24/03/2015 ([briefing search](#))

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Database: Ovid MEDLINE(R) <1946 to June Week 1 2015>

Search Strategy:

- 1 Endoscopes/ (6110)
- 2 Endoscopy/ (42263)
- 3 Esophagoscopy/ (12256)
- 4 Esophagoscopes/ (722)

IP overview: Endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia

- 5 Surgical procedures, minimally invasive/ (18321)
- 6 (endoscop* or scope*).ti,ab. (173281)
- 7 ((minimall* or non) adj4 invasive* adj4 (surg* or procedure* or technique*).ti,ab. (25164)
- 8 ((video* or comput*) adj4 (surg* or procedure* or technique*).ti,ab. (24127)
- 9 (esophagoscop* or oesophagoscop*).ti,ab. (1869)
- 10 endoscopy, gastrointestinal/ (14704)
- 11 pharyngolaryngoscop*.ti,ab. (18)
- 12 or/1-11 (252849)
- 13 laser therapy/ (33424)
- 14 lasers, gas/ (1331)
- 15 laser*.ti,ab. (143791)
- 16 (maser* or q switched or q-switched).ti,ab. (1263)
- 17 (laser* adj4 (assisted or treat* or surg* or microsurg* or serial* or therap*).ti,ab. (40240)
- 18 (continuous adj4 wave*).ti,ab. (5880)
- 19 ((trans-oral* or "trans oral*" or transoral*) adj4 laser*).ti,ab. (327)
- 20 or/13-19 (153643)
- 21 12 or 20 (398914)
- 22 Endoscop* CO2 laser cricopharyngeal myotomy.ti,ab. (5)
- 23 ECPM.ti,ab. (9)
- 24 (CO2 or "carbon dioxide").ti,ab. (74094)
- 25 or/22-24 (74101)
- 26 21 and 25 (8089)
- 27 Dysphagia/ (15655)
- 28 aphasia/ (8647)
- 29 Zenker Diverticulum/ (600)
- 30 ((zenker* adj4 divert*) or ZD).ti,ab. (1227)
- 31 ((aphasi* or dysphagi* or cricopharyngeal*) adj4 (achalasi* or stenosi* or dysfunct* or fibros*).ti,ab. (567)
- 32 Deglutition Disorders/ or Deglutition/ (21383)
- 33 ((deglutit* or swallow* or reflux*) adj4 (difficult* or problem* or issue* or trouble* or strain* or strenuous*).ti,ab. (3341)
- 34 Laryngostenosis/ (2350)
- 35 laryngostenosis*.ti,ab. (48)
- 36 Pharyngeal muscles/ (1397)
- 37 ((pharyngeal* or cricopharyngeal* or gullet*) adj4 (spasm* or scar* or tight* or narrow*).ti,ab. (234)
- 38 ((hypopharyngeal* or pharyngeal) adj4 pouch*).ti,ab. (493)
- 39 or/27-38 (37421)
- 40 26 and 39 (220)
- 41 animal/ not human/ (3963496)
- 42 40 not 41 (207)