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 and updated in February 2016.

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, at 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, 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 CP 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.

This procedure has been used for patients with oropharyngeal dysphagia due to 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 1December 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 442 patients from 9 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 CO_2 laser CP myotomy versus 23 endoscopic stapler CP myotomy)** patients with cricopharyngeal hypertrophy (CPH) or Zenker's diverticulum (ZD) patients with isolated CPH: laser group 38% (47/123); stapler group 4.3% (1/23) patients with ZD: 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	Endoscopic CO_2 laser CP myotomy: 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. Endoscopic stapler assisted CP myotomy: 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 overnight, 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 CO_2 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 documented CPH was presented in 88% (135/153) patients. ZD was documented in 67.3% (103/153) patients.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **146 (123 endoscopic CO_2 laser CP myotomy versus 23 endoscopic stapler CP myotomy)**

	CO_2 laser group n=123	**Stapler group n=23**	**p value**
Procedure duration (minutes)	45.6	35.3	0.01
Duration of hospitalisation (days)	1.86	1.32	0.39

Resolution of stenosis was seen in 92.6% (44/48) patients with isolated CPH.

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)

Recurrence of dysphagia (during postoperative follow-up)

	CO_2 laser group % (n)	**Stapler group % (n)**	**p value**
Symptom recurrence*	5.7 (7/153)	26 (6/23)	0.002

*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.

Rate of revision surgery

	CO_2 laser group % (n)	**Stapler group % (n)**	**p value**
Revision surgery	3.3 (4/123)	4.3 (1/23)	0.77

Safety

Complications (n=153)

	CO_2 laser group % (n)	**Stapler group % (n)**	**p value**
Overall complications	**10.6 (13/123)**	**8.7 (2/23)**	**0.76**
Minor complications (resolved after conservative management or observation)			
Pharyngeal wall mucosal tear	6	1	
Isolated postop fever	2	0	
Aspiration pneumonia (needed hospitalization)	2	0	
Pharyngeal wall hematoma*	0	0	
Dental trauma	0	1	
Major complications	**2.4**	**0**	
Hypopharyngeal perforation, infection, pharyngocutaneous fistula	1	0	
Complete pharyngeal wall perforation	1	0	
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 CO_2 laser CP myotomy versus 8 open CP myotomy)** patients with cricopharyngeal dysfunction without a concomitant head and neck or Zenker's procedure. Indications: CP bar (from either a stricture or hypertonicity) with no known aetiology (8), body mytosis (4), post-polio syndrome (3), non-defined neurological syndromes (2), post-radiation fibrosis (1), vascular malformation (1), myopathy (1), dermatomytosis (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	Endoscopic CO_2 laser cricopharyngeal myotomy: 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. Open transcervical approach 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

Number of patients analysed: **22 (14 endoscopic CO_2 laser CP myotomy versus 8 open CP myotomy)**

Outcomes

	CO_2 laser group (n=14)	**Open group (n=8)**
Hospital stay (median, range in days)	1 (0–3)	1 (1–25)
Operative time (median, range in minutes)	29 (10–95)	87 (74–100)
Preoperative FOSS	2.4	3.4
Postoperative FOSS	0.9	1.9
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).

Safety

Complications:

	CO_2 laser group n=14	**Open group n=8**
Fever	2	
Chest pain (self-limited)	1	1
Tracheostomy (because of medical comorbidities and prolonged ventilator dependence)	0	1
Pharyngocutaneous fistula (treated by dressings and tube feedings for a month)	0	1

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 CO_2 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

Number of patients analysed: **87**

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**
All patients (n=87)	2.6	1.6	<0.001
Zenker's diverticulum (n=39)	2.4	1.0	NR
Cricopharyngeal dysfunction from stroke or nerve injury (n=7)	3.3	1.8	NR
Prior radiation (n=15)^	3.9	3.2	NR
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.

Safety

Complications:

	% (n)
Total	4.6% (4/87)
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
Left vocal fold paralysis (patient had continued pharyngeal weakness and aspiration of unclear cause)	1
Aspiration from emesis with gastric tube feeding during dialysis (needed intubation and bronchoscopy with complete recovery)	1

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 CO_2 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:** **% (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) These complications were in those without Zenker's diverticulum.
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 CO_2 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 3rd 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 Woisard 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 to 4 according to voice handicap index.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **32 who completed follow-up questionnaires**

Improvement in outcomes

	n=32
Pain (n=31) (analogue scale)	46.9% (average of 2.5/10)
Weight gain in 3 months (n=10) (kg)	5.1
Improvement in symptoms	
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)
Satisfaction	
Global satisfaction (n=30) (scale 0–10)	7.2
Patients would undergo surgery again if needed	83.9% (27/32)

Swallowing improvement (DHI) outcomes

	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

Recurrence of dysphagia needing subsequent interventions

13.2% (9/68 [as reported in the paper]) patients had a second surgery due to recurrence. The average time between the 2 procedures was 43 months (10–80 months).

Safety

Complications:

Reported for all 65 patients

	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

Abbreviations used: CO_2, carbon dioxide; CP, cricopharyngeal; DHI, deglutition handicap index; NSAID, nonsteroidal anti-inflammatory drug.

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:** **% (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 day 3): 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 CO_2 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

Number of patients analysed: **11**

Modified Barium Impairment Profile swallowing scores (n=11)

	Pre-procedure	Post-procedure	p value
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)
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)

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.

Safety

Complications: procedure related complications were not recorded.

	% (n=11)
Aspiration	36 (4/11)
Progressive fibrosis (patients had worse swallowing outcomes, 1 had a pharyngolaryngectomy due to dysfunctional larynx)	36 (4/11)

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	Endoscopic CO_2 laser CP myotomy: 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.	

Study 9 Dale OT [2014]

Details

Study type	Case series (retrospective)
Country	UK (2 centres)
Recruitment period	2010–13
Study population and number	n=**38** patients with symptomatic cricopharyngeal dysfunction
Age and sex	Average age: 67 years, 62% (24/38) male
Patient selection criteria	*Inclusion criteria:* patients with symptoms of dysphagia and evidence of cricopharyngeal hypertrophy on barium swallow and/or videofluoroscopy; those treated with acid suppression medication for at least 3 months before surgery were included. Those with an established pharyngeal pouch were excluded.
Technique	Endoscopic CO_2 laser CP myotomy with mucosal repair (ECLM-MR) under general anaesthesia using a CO_2 laser and Oxford universal pouch Oesophagaoscope. Mucosal closure done with nitinol U-Clips.
Follow-up	**150 days**
Conflict of interest/source of funding	None

Analysis

Study design issues: small sample size, postoperative (after 24–48 hours) barium swallow studies were performed on 28 patients. In 4 patients it was not done due to restricted availability. Patient reported outcomes (both pre and postoperatively) were recorded for 32 patients using the Sydney Swallow Questionnaire (SSQ) and The Reflux Symptom Index (RSI) scores.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **38** Median procedure time: 58 minutes Improvement in swallowing symptoms (patient reported outcomes n=32) An improvement in swallowing scores, using the Sydney Swallow Questionnaire (SSQ) was seen in 30 subjects (94%, p<0.001). The median change in SSQ score was −605 (pre-op vs post-op). The Reflux Symptom Index (RSI) scores improved 28 subjects (88%, p<0.001, median change −9).	**Adverse events** / **% (n)** Mediastinitis (patient had prolonged period of vomiting, needed prolonged period of ventilation; was managed conservatively and made a full recovery) — 2.6% (1/38) Recurrence (2 within 6 weeks of surgery, 2 >6 months after surgery; 2 patients needed further surgical intervention) — 12.5% (4/38)

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 (CO_2) 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 (CO_2 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 CO_2 laser CP myotomy reported that FOSS scores improved from 2.6 to 1.6 ($p<0.001$) after surgery[3].

A case series of 44 patients with both prediverticular (n=40) and diverticular (n=4) CP dysfunction treated with CO_2 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 cricopharynx[4].

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 solids[5].

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 CO_2 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 dilatation[8].

Symptom recurrence and revision surgery

A retrospective comparative case series of 153 patients who had endoscopic CP myotomy by either CO_2 laser (n=123) or by stapler (n=23) reported that symptom recurrence was more frequent after stapling surgery (CO_2 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 (CO_2 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 CO_2 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 CO_2 laser CP myotomy, and 1 patient with scarring after radiation for hypopharyngeal cancer had several laser procedures with dilations[3].

The case series of 65 patients reported recurrence of dysphagia needing subsequent surgeries in 13% (9/68 [as reported in the paper]) 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 CO_2 laser assisted (n=123) or stapler assisted (n=23) endoscopic CP myotomy reported that the average duration of the procedure was longer for the CO_2 laser group than for the stapler group (45.6 minutes for CO_2 laser and 35.3 minutes for stapler; p=0.01)[1].

The retrospective comparative case series of 22 patients comparing CO_2 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 CO_2 laser and 1 day (range 1–25) for open myotomy group; operative time: 29 (10–95) minutes for CO_2 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 needed[5].

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 to 22 months. Both perforations were drained externally, and the patients were given systemic antibiotics, leading to full recovery and improved swallowing[4].

A hypopharyngeal perforation that resulted in infection and prolonged hospitalisation as a result of pharyngocutaneous fistula was reported in 1 patient in the CO_2 laser assisted CP myotomy group in a retrospective comparative case series of 153 patients who had endoscopic myotomy either by CO_2 laser (n=123) or by stapler assisted endoscopic myotomy (n=23). Further details were not reported[1].

Complete pharyngeal wall perforation was reported in 1 patient in the CO_2 laser assisted CP myotomy group in the retrospective comparative case series of 153 patients who underwent either CO_2 laser (n=123) or stapler assisted endoscopic myotomy (n=23). Further details were not reported[1].

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 CO_2 laser assisted CP myotomy group and 1 patient in the stapler group in the retrospective comparative case series of 153 patients who underwent either CO_2 laser (n=123) or stapler assisted endoscopic myotomy (n=23). Further details were not reported[1].

Fistula

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].

Aspiration pneumonia

Aspiration pneumonia (needing hospitalisation) was reported in 2% (2/123) of patients in the CO_2 laser assisted CP myotomy group in the retrospective comparative case series of 153 patients who underwent either CO_2 laser (n=123) or stapler assisted endoscopic myotomy (n=23). Both patients were managed conservatively[1].

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 recovery[3].

Bleeding

Severe bleeding (controlled during the procedure) was reported in 1 patient in the case series of 65 patients[5].

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 reported[5].

Infection

Pulmonary infection immediately after the procedure was reported in 1 patient in the case series of 65 patients. Further details were not reported[5].

Fever (of unknown origin) was reported in 2 patients in the CO_2 laser group in a retrospective comparative case series of 22 patients who underwent either endoscopic CO_2 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 CO_2 laser group and the open group in the retrospective comparative case series of 22 patients who had either endoscopic CO_2 laser CP myotomy (n=14) or cervical CP myotomy (n=8). No further details were reported[2].

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 patients[3].

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 larynx[7].

Restenosis was reported in 9% (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[4].

Validity and generalisability of the studies

- No randomised trials comparing endoscopic CO_2 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://www.nice.org.uk/guidance/IPG513
- Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia. NICE interventional procedure guidance IPG490 (2014). Available from http://www.nice.org.uk/guidance/IPG490
- Endoscopic stapling of pharyngeal pouch. NICE interventional procedure guidance IPG22 (2003). Available from http://www.nice.org.uk/guidance/IPG22

NICE guidelines

- Stroke rehabilitation in adults. NICE guideline CG162 (2013). Available from http://www.nice.org.uk/guidance/CG162
- Improving outcomes in head and neck cancers. NICE cancer service guidance (2004). Available from http://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. Five Specialist Advisor Questionnaires for endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of dysphagia were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent 16 questionnaires to 1 NHS trust for distribution to patients who had the procedure (or their carers). NICE received 2 completed questionnaires.

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

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.

References

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5. Bachy V, Matar N et al (2013). Long-term functional results after endoscopic cricopharyngeal myotomy with CO2 laser: a retrospective study of 32 cases. European Archives of Oto-Rhino-Laryngology. 270 (3), 965-968.
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 Otology, Rhinology & Laryngology. 123 (4), 252-256.
9. Dale OT, Mackeith S et al (2014). Functional outcomes following endoscopic laser cricopharyngeal myotomy with mucosal repair. Eur Arch Otorhinolaryngol. 271:1631-1634.

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. Ear, Nose & throat Journal; 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. Archives of Otolaryngology -- Head & Neck Surgery 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. Annals of Otology, Rhinology & Laryngology 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	Case series n=17 patients with cricopharyngeal dysfunction [associated conditions: central	There were no immediate or late complications. Three patients died from other diseases, the	Larger and longer follow-up studies included in table 2.

myotomy. Acta Oto-Laryngologica Supplement 543 222-224.	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	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.	
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 Otology, 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 ECPM 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 ECPM.	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	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	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

	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	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.	series are similar.
Lawson G and Remacle M (2008). Ins and outs of myotomy of the upper oesophageal sphincter in swallowing disorders. B-ENT.4 (SUPPL.10) (pp 83-89).	Case series n=31 patients with upper oesophageal dysfunction (10 neurological diseases, 8 after chemoradiation, 12 failure of cricopharyngeal relaxation) Endoscopic laser-assisted myotomy Follow-up: 1 year	The trans-oral approach was feasible without complications in all 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.	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.
Ozgursoy OB and Salassa JR (2010). Manoflurographic and functional outcomes after endoscopic laser cricopharyngeal myotomy for cricopharyngeal bar. Otolargyngol Head Neck Surg 2010; 142: 735-40.	Case series and chart review n=14 (idiopathic -6, post-polio syndrome-5, undefined neurological-1, body mytosis-1, dermatomytosis-1) Endoscopic CO_2 laser CPM for CP bar without concomitant head and neck or Zenker's procedure. 4-5 W CO_2 laser used, Follow-up: 6 months	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. Manoflurographic 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	Larger studies with longer follow-up included in table 2.

		intrabolus pressure gradient (IB-Gra) across the CP region showed no difference between the groups.	
Pitman M and Weissbrod P (2009). Endoscopic CO2 laser cricopharyngeal myotomy. Laryngoscope 2009 119 (1) pg 45-53	literature review of endoscopic and transcervical cricopharyngeal myotomy	Endoscopic cricopharyngeal myotomy is a viable alternative to classic transcervical cricopharyngeal myotomy with equivalent outcomes and comparable if not less morbidity.	Review
Sasaki CT and Leder SB (2005). Endoscopic CO2 laser-assisted surgery for cricopharyngeal dysfunction. Dysphagia.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. Thoracic Surgery Clinics.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	**Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia. NICE interventional procedure guidance IPG490 (2014).** 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. 1.2 Clinicians wishing to undertake transcutaneous NMES for oropharyngeal dysphagia should take the following actions. • 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). 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. **Endoscopic stapling of pharyngeal pouch. NICE interventional procedure guidance IPG22 (2013).** 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. **Flexible endoscopic treatment of pharyngeal pouch. NICE interventional procedure guidance IPG513 (2015).**

	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. 1.2 Flexible endoscopic treatment of a pharyngeal pouch should only be done by experienced interventional endoscopists with training in the procedure.
NICE guidelines	**Stroke rehabilitation. NICE clinical guideline 162 (2013).** **Recommendations** 1.7 Swallowing 1.7.1 Assess swallowing in people after stroke in line with recommendations in Stroke (NICE clinical guideline 68). 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. 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. 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]). 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). **Improving outcomes in head and neck cancers: the manual. NICE cancer service guidance (2004).**

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 Library)	01/12/2015	Issue 12 of 12, December 2015
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	01/12/2015	Issue 11 of 12, November 2015
HTA database (Cochrane Library)	01/12/2015	Issue 4 of 4, October 2015
MEDLINE (Ovid)	01/12/2015	1946 to November week 3 2015
MEDLINE In-Process (Ovid)	01/12/2015	November 30, 2015
EMBASE (Ovid)	01/12/2015	1974 to 2015 Week 48
PubMed	01/12/2015	N/A
JournalTOCS	01/12/2015	N/A

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

Medline search strategy

Database: Ovid MEDLINE(R) <1946 to November Week 3 2015>
Search Strategy:
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1 Endoscopes/
2 Endoscopy/
3 Esophagoscopy/
4 Esophagoscopes/
5 Surgical procedures, minimally invasive/
6 (endoscop* or scope*).ti,ab.
7 ((minimall* or non) adj4 invasive* adj4 (surg* or procedure* or technique*)).ti,ab.
8 ((video* or comput*) adj4 (surg* or procedure* or technique*)).ti,ab.
9 (esophagoscop* or oesophagoscop*).ti,ab.
10 endoscopy, gastrointestinal/
11 pharyngolaryngoscop*.ti,ab.

12 or/1-11
13 laser therapy/
14 lasers, gas/
15 laser*.ti,ab.
16 (maser* or q switched or q-switched).ti,ab.
17 (laser* adj4 (assisted or treat* or surg* or microsurg* or serial* or therap*)).ti,ab.
18 (continuous adj4 wave*).ti,ab.
19 ((trans-oral* or "trans oral*" or transoral*) adj4 laser*).ti,ab.
20 or/13-19
21 12 or 20
22 Endoscop* CO2 laser cricopharyngeal myotomy.ti,ab.
23 ECPM.ti,ab.
24 (CO2 or "carbon dioxide").ti,ab.
25 or/22-24
26 21 and 25
27 Dysphagia/
28 aphasia/
29 Zenker Diverticulum/
30 ((zenker* adj4 divert*) or ZD).ti,ab.
31 ((aphasi* or dysphagi* or cricopharyngeal*) adj4 (achalasi* or stenosi* or dysfunct* or fibros*)).ti,ab
32 Deglutition Disorders/ or Deglutition/
33 ((deglutit* or swallow* or reflux*) adj4 (difficult* or problem* or issue* or trouble* or strain* or strenuous*)).ti,ab
34 Laryngostenosis/
35 laryngostenosis*.ti,ab.
36 Pharyngeal muscles/
37 ((pharyngeal* or cricopharyngeal* or gullet*) adj4 (spasm* or scar* or tight* or narrow*)).ti,ab.
38 ((hypopharyngeal* or pharyngeal) adj4 pouch*).ti,ab.
39 or/27-38
40 26 and 39
41 animal/ not human/
42 40 not 41
43 limit 42 to ed=20150611-20151231
44 upd20151007193603.dz.
45 42 and 44
46 43 or 45