

Flexible endoscopic treatment of a pharyngeal pouch

Interventional procedures guidance

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Your responsibility

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

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

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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

1 Recommendations

- 1.1 Current evidence on the 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.

2 Indications and current treatments

- 2.1 A pharyngeal pouch, also known as Zenker's diverticulum, occurs when part of the pharyngeal lining herniates through the muscles of the pharyngeal wall. It occurs mainly in older people. Presenting symptoms include dysphagia, regurgitation of undigested food, halitosis, hoarseness and chronic cough. It sometimes causes respiratory problems because of aspiration of the pouch contents into the lungs. As the pouch enlarges, symptoms become more severe and may result in weight loss and malnutrition. In a small proportion of patients, carcinoma may develop in the pouch.
- 2.2 The traditional treatment for a pharyngeal pouch involves open surgery to the neck. This may take the form of complete removal of the pouch or division of the muscle responsible for pouch formation (sometimes combined with inversion or invagination of the pouch). Endoscopic techniques using rigid endoscopes are also used, in which the wall between the pouch and the oesophagus is divided using diathermy, lasers or a stapling technique.

3 The procedure

- 3.1 Flexible endoscopic treatment of a pharyngeal pouch aims to divide the septum between the diverticulum and oesophagus, without the need for hyperextension of the neck that may be necessary when using a rigid endoscope. It can be done without general anaesthesia and may be particularly useful for older patients with significant comorbidity or spinal stiffness.
- 3.2 Flexible endoscopic treatment of a pharyngeal pouch is done with the patient under sedation or general anaesthesia. Initially, a diagnostic endoscopy is done, identifying the normal oesophageal lumen and allowing a nasogastric tube to be inserted. Under flexible endoscopic guidance, the septum (containing the cricopharyngeus muscle) is exposed and divided. The flexible endoscope can be used with a variety of different accessories (hood, cap, overtube) to aid the procedure. Division of the septum reconnects the pouch lumen with the normal pharyngo-oesophageal pathway and also divides the part of the sphincter muscle implicated in pouch development. More than 1 treatment session may be needed to achieve adequate division of the septum and relief of symptoms.

4 Efficacy

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

- 4.1 A non-randomised study of 58 patients who had flexible endoscopic treatment or endoscopic stapling using a rigid endoscope reported mean dysphagia scores (measured on a scale of 0 to 3, with lower values meaning less severe symptoms) of 1.6 and 1.2 respectively after treatment compared with 2.8 and 2.7 respectively before treatment. Improvements in both groups were stated as being statistically significant but p values were not reported. A case series of 150 patients reported that the mean dysphagia score (measured on a scale of 0 to 4, with lower values meaning less severe symptoms) dropped from 1.9 at baseline to 0.3 at 1-month follow-up ($p < 0.01$). This improvement was maintained in 134 patients with longer-term follow-up (median follow-up was 43 months). In 5% (8 out of 150) of

patients, there was no improvement in their symptoms at the time of discharge from hospital.

- 4.2 A case series of 42 patients reported that 93% (39 out of 42) of patients had no dysphagia after a mean follow-up of 38 months. A case series of 31 patients reported that 61% (19 out of 31) of patients were successfully treated by a single procedure, with a mean follow-up of 24 months; the clinical success rate based on intention to treat was 84% (26 out of 31). A case series of 22 patients treated by a single procedure reported initial symptomatic improvement in 100% (22 out of 22) of patients. After a mean follow-up of 13 months, 68% (15 out of 22) of patients had complete or near-complete symptom resolution and 14% (3 out of 22) had moderate symptom improvement.
- 4.3 The non-randomised study of 58 patients reported recurrence of dysphagia in 1 patient who had flexible endoscopic treatment (at 14 months) and in 2 patients treated by endoscopic stapling using a rigid endoscope (at 15 and 18 months respectively). Re-treatment of the residual bridge with 1 or 2 sessions of endoscopic treatment provided successful relief of symptoms in all 3 patients. The case series of 150 patients reported symptom recurrence in 23% (31 out of 134) of patients after a median follow-up of 7 months (range 1 to 82). Of the 31 patients with recurrence, 23 patients had a second treatment, and 5 patients had a third treatment. After re-treatment, 1 patient remained symptomatic. The case series of 42 patients reported recurrent dysphagia in 7% (3 out of 42) of patients during follow-up; these occurred at 12, 22 and 60 months after initial treatment respectively. Re-treatment improved dysphagia in all 3 patients. A case series of 41 patients reported symptomatic recurrence during follow-up in 15% (5 out of 34) of patients (at 8, 9, 13, 15 and 18 months respectively).
- 4.4 The specialist advisers described the key efficacy outcome as resolution or reduction of dysphagia.

5 Safety

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

- 5.1 Oesophageal perforation (severity not stated) was reported in 27% (6 out of 22) of patients in a case series of 22 patients (method of diagnosis not described). This was managed conservatively; 4 patients were hospitalised for 3 to 5 days and 2 were observed overnight. Perforation (confirmed by endoscopy) was reported in 1 patient in a case series of 41 patients: the patient was tube fed for 7 days and had antibiotic therapy for 10 days, leading to complete resolution. Macroscopic perforations were reported in 11% (3 out of 28) of patients treated by cap-assisted flexible endoscopic treatment in a case series of 39 patients: these were immediately closed using endoclips. Suspected perforation was reported in 2% (3 out of 150) of patients in a case series of 150 patients; the patients had increased C-reactive protein levels and fever. With conservative management their symptoms and signs resolved within 2 to 14 days.
- 5.2 Bleeding was reported in 2% (2 out of 125) of patients in a case series of 125 patients (not further described). Bleeding that needed transfusion was reported in 1 patient in a case series of 42 patients; this was treated by endoscopic injection of an adrenaline solution.
- 5.3 A neck abscess developed 1 week after treatment in 1 patient in the case series of 22 patients. This was drained surgically and the patient stayed in hospital for 9 days.
- 5.4 Infection with fever lasting more than 24 hours was reported in 10% (4 out of 41) of patients in the case series of 41 patients. Antibiotics were given and perforation and mediastinitis were excluded by diagnostic tests.
- 5.5 Aspiration pneumonia after extubation was reported in 1 patient in the case series of 150 patients.
- 5.6 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers considered that the following were theoretical adverse events: septicaemia, death.

6 Committee comments

- 6.1 The Committee noted that this procedure may offer the possibility of treatment to some patients who have severe symptoms from their pharyngeal pouch and for whom other surgical treatments are not suitable.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

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

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Endorsing organisation

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