

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Flexible endoscopic treatment of a pharyngeal pouch

A pharyngeal pouch is a pocket that may develop in the pharynx (throat), just above the entrance to the oesophagus (gullet). It can cause symptoms such as difficulty in swallowing, cough, and weight loss. In this procedure, an endoscope (a thin, flexible tube with a camera on the end) and special instruments are inserted through the mouth and are used to divide the tissue between the pouch and the gullet, with the aim of improving swallowing.

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

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

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

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

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

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.

- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

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

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

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

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

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

Closing date for comments: 21 November 2014

Target date for publication of guidance: February 2015

1 Provisional 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 specific 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 elderly patients with significant co-morbidity or spinal stiffness.
- 3.2 Flexible endoscopic treatment of a pharyngeal pouch is done with the patient under sedation or general anaesthesia. Unlike rigid techniques, it does not rely on neck extension to visualise the

pouch. 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 [interventional procedure overview](#).

- 4.1 A non-randomised study of 58 patients who had flexible endoscopic treatment or endoscopic stapling 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=43 months). 5% (8/150) of patients

had no improvement of their symptoms at the time of discharge from hospital.

- 4.2 A case series of 42 patients reported that 93% (39/42) of patients had no dysphagia after a mean follow-up of 38 months. A case series of 31 patients reported that 61% (19/31) 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% (26/31). A case series of 22 patients treated by a single procedure reported initial symptomatic improvement in 100% (22/22) of patients. After a mean follow-up of 13 months, 68% (15/22) of patients had complete or near-complete symptom resolution and 14% (3/22) had moderate symptom improvement.
- 4.3 The non-randomised study of 58 patients reported recurrence of dysphagia in 1 patient treated by flexible endoscopic treatment (at 14 months) and in 2 patients treated by endoscopic stapling (at 15 and 18 months respectively). Retreatment 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% (31/134) of patients after a median follow-up of 7 months (range 1–82). Of the 31 patients with recurrence, 23 patients had a second treatment and 5 patients had a third treatment. After retreatment, 1 patient remained symptomatic. The case series of 42 patients reported recurrent dysphagia in 7% (3/42) of patients during follow-up; these occurred at 12, 22 and 60 months after initial treatment respectively. Retreatment improved dysphagia in all 3 patients. A case series of 41 patients reported symptomatic recurrence during follow-up in 15% (5/34) 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 [interventional procedure overview](#).

- 5.1 Oesophageal perforation was reported in 27% (6/22) of patients in a case series of 22 patients: 4 patients were hospitalised for 3-5 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 received antibiotic therapy for 10 days, leading to complete resolution. Macroscopic perforations were reported in 11% (3/28) 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% (3/150) of patients in a case series of 150 patients; the patients had increased C-reactive protein levels and fever. They were managed conservatively and their symptoms and signs resolved within 2–14 days.
- 5.2 Bleeding was reported in 2% (2/125) of patients in the case series of 125 patients (not further described). Bleeding that needed transfusion was reported in 1 patient in the 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% (4/41) of patients in the case series of 41 patients. Antibiotics were given and perforation and mediastinitis were excluded by appropriate 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 the above, the specialist advisers listed septicaemia and death as theoretical adverse events.

6 Committee comments

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

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).

Bruce Campbell

Chairman, Interventional Procedures Advisory Committee
October 2014