

Catheterless oesophageal pH monitoring

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 Guidance

- 1.1 Current evidence on the safety and efficacy of catheterless oesophageal pH monitoring appears adequate to support the use of this technique provided that normal arrangements are in place for consent, audit and clinical governance.

2 The procedure

2.1 Indications

- 2.1.1 Gastro-oesophageal reflux disease (GORD) is a common disorder in which a backwash of gastric juices into the oesophagus leads to inflammation and pain. Symptoms include heartburn, belching and regurgitation of gastric contents. Complications of GORD include oesophageal stricture and Barrett's oesophagus (which is associated with carcinoma of the oesophagus). The frequency of exposure to gastric acid over a given period provides a measure of the severity of the disease and can be measured by oesophageal pH monitoring. Common indications for pH monitoring include symptoms that are refractory to therapy with proton pump inhibitors, evaluation before surgery and recurrence of symptoms after anti-reflux surgery.
- 2.1.2 Ambulatory oesophageal pH monitoring is commonly undertaken by transnasal placement of a pH probe on a catheter. However, this can cause nasal and pharyngeal discomfort, which may cause the patient to alter their diet and activity, potentially giving misleading results. Catheterless oesophageal pH monitoring is suitable for patients who do not tolerate nasal intubation.

2.2 Outline of the procedure

- 2.2.1 A catheterless pH monitoring system comprises a plastic capsule that houses a pH sensor and a transmitter. After endoscopy, the capsule is inserted into the oesophagus and is attached at a chosen site on the oesophageal wall by a vacuum that draws the oesophageal mucosa into a well on the side of the capsule. A spring-loaded pin is then released across the well, tangential to the axis of the oesophagus, to fix the capsule in place. Correct placement and attachment of the capsule is confirmed endoscopically. The capsule continuously monitors oesophageal pH and transmits the data every few seconds to a small receiver worn by the patient. After a few days, the capsule detaches from the oesophageal wall and passes through the digestive tract.

2.3 Efficacy

- 2.3.1 During a randomised controlled study (n=50), the frequency of GORD symptoms was similar during catheterless and catheter-based monitoring. Overall quality-of-life scores based on the short-form SF-36 scale were also similar between the groups. Significantly more patients who underwent the catheterless monitoring (88%) than the catheter-based monitoring (48%) were willing to have a repeat test if necessary (p=0.005).
- 2.3.2 In a within-patient study of 33 patients who had both catheterless and catheter-based monitoring simultaneously, a total of 1,388 reflux episodes were recorded over a 24-hour period. Of these reflux episodes, 41% (563 out of 1,388) were recorded by both devices, 52% (724 out of 1,388) were recorded only by the catheter-based system and 7% (101 out of 1,388) only by the catheterless monitor. Overall, the concordance of reflux episodes was 88% (Kappa statistic 0.76).
- 2.3.3 A non-randomised controlled study in healthy volunteers found that, after calibration, the catheterless monitor identified significantly fewer reflux episodes (mean 37.9) during 24-hour monitoring than a catheter-based system (mean 69.8; p<0.05). Whether these findings relate to asymptomatic reflux in healthy volunteers or previously undetected disease is unclear. For more details, see the [overview](#).

- 2.3.4 The Specialist Advisers noted that catheterless oesophageal pH monitoring may provide accurate recording under conditions of normal daily activity.

2.4 Safety

- 2.4.1 Follow-up across all the studies included in the overview is based solely on the period of monitoring used; no longer-term data are available.
- 2.4.2 Among patients in a case series and in the catheterless monitoring arms of controlled studies, the incidences of chest pain reported were 5% (4 out of 85), 33% (26 out of 80) and 36% (9 out of 25). In one of these studies, 2% (2 out of 85) of patients requested immediate removal of the capsule after the 48-hour monitoring period because of chest pain.
- 2.4.3 In a randomised controlled trial, the incidence of chest pain was higher with a catheterless monitor (60%) compared with a catheter-based system (24%; $p=0.01$). However, fewer patients reported difficulty swallowing (36%) with the catheterless system than with the catheter-based approach (68%; $p=0.024$). In the same study, significantly fewer patients with the catheterless monitoring had nose pain, runny nose, throat pain, throat discomfort or headache. Also, among patients in employment, 58% of the patients with a catheterless capsule were able to return to work during monitoring, compared with 11% of those with the catheter-based system ($p=0.049$).
- 2.4.4 In a study of 44 children aged 6 to 19 years who had catheterless oesophageal pH monitoring, 95% (36 out of 38) of parents were willing to allow their child to undergo further catheterless monitoring. In this study, the 12 patients who had previously had nasal catheter monitoring were reported to prefer the catheterless method.
- 2.4.5 There were no reports in the reviewed literature of adverse events relating to the endoscopic component of the procedure. For more details, see the [overview](#).
- 2.4.6 The Specialist Advisers reported that adverse events included chest discomfort, mucosal tear, failure of the capsule to detach and failure of data retrieval. They also noted that additional theoretical complications included haemorrhage,

oesophageal perforation, oesophageal ulceration, capsule misplacement and failure to pass the capsule once detached.

2.5 Other comments

- 2.5.1 It was noted that this procedure would be particularly appropriate in children and other patients who may not tolerate the nasal intubation required for catheter-based monitoring.
- 2.5.2 It was also noted that this procedure may be unsuitable for some patients, for example patients with pacemakers.

3 Further information

- 3.1 NICE has issued [guidance on gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management](#).

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](#).