NHS National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Catheterless monitoring of oesophageal acidity

NICE 'interventional procedure guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used. This leaflet is about when and how catheterless monitoring of oesophageal acidity can be used in people with gastro-oesophageal reflux disease in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe gastro-oesophageal reflux disease or catheterless monitoring in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision.

Interventional procedure guidance makes recommendations on the safety of a procedure and how well it works. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

Information about NICE interventional procedure guidance 187 Issue date: July 2006



Corporate member of Plain English Campaign. 197 Committed to clearer communication.

What has NICE said?

This procedure can be offered routinely for monitoring oesophageal acidity provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

Other comments from NICE

This procedure may be particularly useful for children and for other people who are unable to have catheter-based oesophageal monitoring.

This procedure may be unsuitable for people who have a pacemaker.

Catheterless oesophageal monitoring

The procedure is not described in detail here – please talk to your specialist for a full description.

Gastro-oesophageal reflux disease (abbreviated to GORD) is a common problem where the gastric juices of the stomach wash back up (reflux) towards the mouth. These juices are very acidic and can damage the oesophagus (the tube that connects your mouth and stomach), causing inflammation (swelling) and pain. Symptoms include a burning sensation in the chest area (heartburn), burping and bringing up swallowed food back into the mouth (regurgitation).

Oesophageal monitoring measures how often the gastric juices wash back up into the oesophagus, which shows how serious your GORD is.

The acidity in the oesophagus is usually monitored with a probe inside a thin tube called a catheter. The catheter is gently pushed up through the nose, down the back of the throat and into the oesophagus. It then stays in place throughout the monitoring period.

In catheterless monitoring, a small plastic capsule containing a pH sensor and a transmitter is attached to the oesophagus wall. The acidity is measured continuously and recorded for the doctor to study at a later date. After a few days, the capsule comes away from the oesophagus and passes out of the body in the stools.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are **briefly** described below. NICE looked at three studies on this procedure.

This procedure may not be the only possible way to measure oesophageal acidity. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

How well does the procedure work?

In one study, the frequency of GORD symptoms was similar during monitoring with the catheterless and the traditional catheter-based systems. Scores for quality of life on a questionnaire were similar in the two groups of patients. More patients who had catheterless monitoring (88%) than catheter-based monitoring (48%) were willing to have another test if necessary.

In a study in which 33 patients underwent both catheterless and catheterbased monitoring, the agreement between results from the two methods was 88%.

In a study of healthy volunteers, the catheterless system identified fewer episodes of reflux than the catheter-based system. But it was not clear how to interpret this finding.

The expert advisers noted that catheterless oesphageal monitoring may provide accurate recording during normal daily life.

Risks and possible problems

The studies cover the period of monitoring only, because information about the risks and possible problems after monitoring is not available.

Chest pain occurred in between 5% (4 out of 85) and 36% (9 out of 25) of patients who had catheterless monitoring in three different studies. In one study, two patients (out of 85) asked for the capsule to be removed after the 48-hour monitoring period because of chest pain. In another study, more

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks that catheterless oesophageal monitoring is a suitable option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all. patients had chest pain with the catheterless system (60%) than with the catheter-based system (24%).

Fewer patients with the catheterless system had difficulty swallowing (36% compared with 68%) and fewer patients had nose pain, runny nose, throat pain, throat discomfort or headache. More people who had the catheterless system (58%) were able to work during monitoring than those who had catheter-based monitoring (11%).

In a study of 44 children (aged 6–19 years) who had catheterless monitoring, 95% of the children's parents were happy for their child to have another session. All 12 patients who had tried both methods of monitoring said that they preferred the catheterless method.

There have been no reports of problems during the endoscopy part of the procedure to put the capsule in place.

The expert advisers noted that adverse events included chest discomfort, tearing of the surface of the oesophagus, failure of the capsule to come away and being unable to use the data that is collected. There is also a risk of bleeding, damage to the oesophagus (such as a hole or an ulcer), the capsule being in the wrong place, and the patient being unable to pass the capsule.

More information about gastro-oesophageal reflux disease

NHS Direct online (**www.nhsdirect.nhs.uk**) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/about guidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG187

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1089).

National Institute for Health and Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

© National Institute for Health and Clinical Excellence, July 2006. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute. ISBN 1-84629-263-8 N1089 1P Jul 06