

Endoscopic injection of bulking agents for gastro-oesophageal reflux disease

**Understanding NICE guidance –
information for people considering the
procedure, and for the public**

April 2004

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About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called endoscopic injection of bulking agents. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether endoscopic injection of bulking agents is safe enough and works well enough for it to be used routinely for the treatment of gastro-oesophageal reflux disease.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of endoscopic injection of bulking agents and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About endoscopic injection of bulking agents

Gastro-oesophageal reflux disease (GORD) is a common condition that causes the stomach contents to pass back up, or 'reflux' into the oesophagus (gullet) and make it inflamed. It is caused by problems with the sphincter muscle, which is the ring of muscle that normally closes the opening between the oesophagus and the stomach. People with GORD can have symptoms relating to this reflux, such as heartburn, regurgitation (where the stomach contents pass back as far as the mouth) or an acid taste in the mouth. Other symptoms can include difficulty with swallowing and a cough or wheeze.

People with mild symptoms are advised to make changes to their lifestyle, such as losing weight and avoiding large meals late at night. They are usually offered treatment with medications, such as antacids or drugs called proton pump inhibitors (PPIs) that lower the amount of acid produced by the stomach. Surgery is sometimes needed for people who don't respond to this or for people who, despite treatment, reflux large amounts of stomach contents into their mouth and gullet.

Endoscopic injection of bulking agents may be an alternative to surgery. An endoscope is a small flexible telescope that is passed down the

oesophagus so the surgeon can see what he or she is doing. Before the procedure is started the patient is given medicine to help them relax and an injection of antibiotics. A very fine tube called a catheter is passed through the endoscope to where the oesophagus meets the stomach, called the 'gastro-oesophageal junction'. A special type of medical bulking agent or 'filler' is injected into the junction using the catheter. This makes the entry to the stomach narrower, so that the contents of the stomach cannot pass back. Often, four injections are given around the oesophagus during the procedure.

How well it works

What the studies said

Most of the evidence NICE looked at came from one study of 85 patients with GORD who had been using PPIs for a long time. This showed that 1 year after having the procedure, two-thirds of the patients (57 of the 85 patients) had been able to stop taking PPIs. In addition, another eight patients only needed to use half the amount of the drugs they had used before. Patients said symptoms such as heartburn and regurgitation had improved after 1 year. Other symptoms, such as the amount of acid measured in the oesophagus, improved slightly.

While the studies showed that some patients had less severe symptoms, they didn't show that the oesophagus was any less inflamed after treatment. Also, how well the treatment worked depended on how much of the bulking agent was in place, and the treatment might need to be repeated to keep this 'topped up'.

What the experts said

The experts thought that this procedure was too new to be able to decide how well it works.

Risks and possible problems

What the studies said

The most common problem reported was chest pain after the procedure. At least half the patients experienced this, but it was not severe and did not last. Other problems included problems with swallowing, nausea and fever.

What the experts said

The experts did not have any particular concerns about the safety of the procedure.

What has NICE decided?

NICE has decided that, if a doctor wants to carry out endoscopic injection of bulking agents, he or she should make sure that the patient understands what is involved and that there are still uncertainties over the safety of the procedure and how well it works. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

What the decision means for you

Your doctor may have offered you endoscopic injection of bulking agents for GORD. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of endoscopic injection of bulking agents which you need to understand before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these benefits and risks may be described above.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on endoscopic injection of bulking agents is on the NICE website (www.nice.org.uk/IPG055guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0536. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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