NHS
National Institute for Health and Clinical Excellence

Laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease

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NICE interventional procedure guidance 431

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Healthcare Improvement Scotland

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NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for 5 years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'

Contents

1 Guidance

1.1 The evidence on the safety and efficacy of laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease (GORD) is limited in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake laparoscopic insertion of a magnetic bead band for GORD should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having laparoscopic insertion of a magnetic bead band for GORD (see section 3.1).

1.3 NICE encourages further research and collaborative data collection on laparoscopic insertion of a magnetic bead band for GORD. Clear descriptions of patient selection are particularly important. Perioperative and long-term complications should be reported, together with details of long-term efficacy, including the need for further procedures and medication to control symptoms of GORD. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 GORD is a common condition caused by failure of the sphincter mechanism at the lower end of the oesophagus. Symptoms include heartburn, regurgitation, dysphagia, chest pain, nausea and respiratory difficulties. A few patients may develop complications such as Barrett's oesophagus or oesophageal stricture.

2.1.2 Lifestyle modification and drug therapy to reduce gastric acid are the standard treatments for symptomatic patients. However, in patients with refractory symptoms, patients who develop complications despite medication or those who develop intolerance to medication, anti-reflux surgery (usually laparoscopic fundoplication) may be needed. Endoscopic treatment options have also been used.

2.2 Outline of the procedure

2.2.1 Laparoscopic insertion of a magnetic bead band for GORD aims to provide relief of reflux-related symptoms without impeding the ability to belch or vomit and with less morbidity than traditional anti-reflux surgery.

2.2.2 The procedure is done with the patient under general anaesthesia. Using a laparoscopic approach, a specially designed sizing tool is loosely wrapped around the distal oesophagus to assess the size of implant needed. The sizing tool is then removed and the implant is placed so that it encircles the distal oesophagus at the gastro-oesophageal junction. The implant is then secured in place. Intraoperative endoscopy may be used to check that the implant is correctly positioned.

2.2.3 The implant consists of a ring of interlinked titanium beads, each with a weak magnetic force that holds the beads together to keep the distal oesophagus closed. When the patient swallows, the magnetic force is overcome, allowing the ring to open. After swallowing, magnetic attraction brings the beads together and the distal oesophagus is again closed.

2.2.4 Currently, magnetic resonance imaging (MRI) is contraindicated after this procedure.

> Sections 2.3 and 2.4 describe efficacy and 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.

2.3 Efficacy

2.3.1 The evidence on efficacy consists of a single case series of 44 patients. The total mean GORD health-related quality of life symptom score improved from 25.7 at baseline to 3.8 at 1-year follow-up and 2.4 at 2-year follow-up (lower scores indicate a higher quality of life; $p<0.0001$ for both). In this case series 87% of patients were reported to be satisfied with their symptom relief at 1-year follow-up and 86% were satisfied at 2-year follow-up (actual numbers not reported).

2.3.2 There was a decrease in the mean percentage time that oesophageal pH was less than 4 (measured over 24 hours), from 12% at baseline to 3% at 1-year follow-up and 2% at 2-year follow-up ($p<0.0001$ for both).

2.3.3 Complete cessation of proton pump inhibitor use was reported for 90% of patients at 1 year and 86% of patients at 2 years (actual numbers not reported).

2.3.4 The Specialist Advisers stated that key efficacy outcomes include cessation of reflux with improved or no heartburn, regurgitation and dysphagia, and improved quality of life.

2.4 Safety

2.4.1 Persistent dysphagia needing removal of the magnetic bead band 8 months after the procedure was reported in 1 patient in the case series of 44 patients (no further details provided). Dysphagia needing removal of the magnetic bead band was reported in 3% (3/100) of patients in an unpublished case series of

100 patients. The dysphagia resolved in all 3 patients after the bands were removed 21, 31 and 93 days after insertion.

2.4.2 Vomiting needing hospitalisation or removal of the magnetic bead band was reported in 2% (2/100) of patients in the unpublished case series of 100 patients. One patient was hospitalised 2 days after the procedure for less than 2 days and the other patient had the band removed 357 days after insertion. In the same study, 2 patients had nausea that was described as serious; 1 patient was hospitalised 2 days after the procedure for less than 2 days and the other patient had the band removed 31 days after insertion (this patient also had dysphagia).

2.4.3 Odynophagia (painful swallowing) was reported in 1 patient in the unpublished case series of 100 patients; the band was removed 93 days after insertion.

2.4.4 Pain (not otherwise described) was reported in 24% of patients in the unpublished case series of 100 patients (exact numbers not reported).

2.4.5 The Specialist Advisers stated that theoretical adverse events include perforation or bleeding because of band insertion, erosion of the band through the oesophageal wall, displacement, unlocking or slippage of the band, foreign material reaction, infection, early satiety, gas bloat, and inability to vomit or belch.

2.5 Other comments

2.5.1 The Committee noted that GORD is a common condition that can cause troublesome symptoms. Patients may need long-term medication and/or 1 of a range of interventions, which do not always achieve a long-lasting result. It considered insertion of a magnetic bead band for GORD to be an innovative concept which, if shown to be safe and efficacious in further studies, could be a useful addition to the treatment options.

2.5.2 The Committee noted that studies excluded patients with hiatus hernia measuring 3 cm or more.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

3.2 For related NICE guidance see our website.

Information for patients

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

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Your responsibility
This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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