

Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg585

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. However, 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.

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.

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.

This guidance replaces IPG431.

1 Recommendations

- 1.1 There are no major safety concerns about laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease (GORD). There is limited evidence of short-term efficacy, but evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to do laparoscopic insertion of a magnetic titanium ring for GORD should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's long-term 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 the procedure (see [section 7.1](#)).
- 1.3 This procedure should only be done by a clinician trained in upper gastrointestinal laparoscopy and with expertise in plication procedures.
- 1.4 NICE encourages further research into laparoscopic insertion of a magnetic titanium ring for GORD, and may update the guidance on publication of further evidence. Long-term outcome data and comparative trials with other anti-reflux surgery would be helpful.

2 Indications and current treatments

- 2.1 Gastro-oesophageal reflux disease (GORD) is a common problem. It is caused by conditions that disturb the sphincter function at the lower end of the oesophagus, such as a hiatus hernia. Symptoms of GORD can be broadly grouped into those directly related to reflux episodes, such as heartburn,

regurgitation, chest pain and nausea, and those caused by complications of the disease, including dysphagia and respiratory difficulties. Repeated episodes of GORD can damage the lining of the oesophagus and lead to oesophageal ulceration, oesophageal stricture and Barrett's oesophagus.

- 2.2 A NICE [clinical guideline](#) describes recommendations for the investigation and management of GORD and dyspepsia in adults. The standard treatments for symptomatic GORD are lifestyle modification and drug therapy. Patients who have refractory symptoms, develop complications despite medication or develop intolerance to medication may be considered for anti-reflux surgery (usually laparoscopic fundoplication). Several endoscopic techniques (such as endoscopic radiofrequency ablation or endoscopic injection of bulking agents) have also been used.

3 The procedure

- 3.1 The aim of laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease is to provide relief of reflux-related symptoms without impeding the ability to swallow, belch or vomit, and with less morbidity than traditional anti-reflux surgery.
- 3.2 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 ends of the implant are secured together to hold it in place. Intraoperative endoscopy may be used to check that the implant is correctly positioned.
- 3.3 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.

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 In a non-randomised comparative study of 238 patients who had laparoscopic insertion of a magnetic titanium ring or Toupet fundoplication, there was a statistically significant improvement in median Gastro-Esophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) symptom scores from 21 and 15 at baseline to 2 and 3 respectively at 3-year follow-up ($p < 0.001$ within both treatment groups; there was no statistically significant difference between the treatment groups). In a non-randomised comparative study of 415 patients who had a magnetic titanium ring or Nissen fundoplication, there was a statistically significant decrease in the median GERD-HRQL symptom scores from 21 and 19 at baseline to 3 and 4 respectively at 1-year follow-up ($p < 0.001$ within groups and $p = 0.17$ for between group comparison). In the same study, a statistically significantly higher proportion of patients who had a magnetic titanium ring, compared with those who had Nissen fundoplication, reported ability for eructation (96% versus 69%, $p < 0.001$), ability for emesis (95% versus 43%, $p < 0.001$) and absence of gas bloat (53% versus 41%, $p = 0.03$). In a case series of 100 patients who had a magnetic titanium ring, there was a 50% or greater reduction in the GERD-HRQL score for 83% (70/84; 95% confidence interval [CI] 73 to 91) of patients at 5-year follow-up; the mean score at baseline was 27 (without proton-pump inhibitors [PPIs]) compared with 4 at 5-year follow-up ($p < 0.001$).
- 4.2 In the case series of 100 patients, the median percentage time that oesophageal pH was less than 4 decreased from 11% at baseline to 3% at 1-year follow-up ($p < 0.001$).
- 4.3 In the non-randomised comparative study of 415 patients, PPI use was reported by 19% of patients who had a magnetic titanium ring and 14% of patients who had Nissen fundoplication at 1-year follow-up ($p = 0.18$). In the case series of 100 patients, 89% (76/85) of patients had reduced their average daily dose of PPIs by 50% or more at 5-year follow-up (95% CI 81 to 95); 75% of patients reported completely stopping PPIs and 9% reported PPI use only as needed. In a non-randomised comparative study of 249 patients, 82% of patients who had

laparoscopic insertion of a magnetic titanium ring reported stopping PPIs at 1-year follow-up, compared with 63% of patients who had laparoscopic fundoplication ($p=0.009$).

- 4.4 In the non-randomised comparative study of 238 patients, reoperation for recurrent symptoms of heartburn or regurgitation was reported in 2% (3/135) of patients who had a magnetic titanium ring and 4% (4/103) of patients who had Toupet fundoplication (hazard ratio 0.77, 95% CI 0.23 to 2.57, $p=0.687$). In the non-randomised comparative study of 415 patients, reoperation for recurrent symptoms was reported in less than 1% (1/201) of patients who had a magnetic titanium ring and 1% (2/214) of patients who had Nissen fundoplication.
- 4.5 In the non-randomised comparative study of 415 patients, patient satisfaction was 88% in those who had a magnetic titanium ring and 89% in those who had Nissen fundoplication ($p=0.61$) in a propensity matched analysis of 114 patient pairs; 93% and 83% of patients respectively reported that they would have the procedure again ($p=0.01$). In the case series of 100 patients, 3% and 7% of patients were dissatisfied with their condition at 1- and 5-year follow-up respectively. In a case series of 44 patients, 91% of patients were satisfied with their current condition at 5-year follow-up, compared with none at baseline.
- 4.6 The specialist advisers listed key efficacy outcomes as improved reflux symptoms, freedom from the need to take anti-reflux medication, improved quality of life, and little or no gas bloat syndrome.

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 Reoperation for device erosion was reported in 1 patient who had a magnetic titanium ring in each of 2 non-randomised comparative studies of 238 and 415 patients respectively; in both patients, the device was successfully removed through laparoscopy.
- 5.2 Gastro-oesophageal junction obstruction was reported in 1 patient each who

had a magnetic titanium ring or Nissen fundoplication in the non-randomised comparative study of 415 patients; both were successfully treated surgically.

- 5.3 Pain needing hospital readmission within 90 days of the procedure was reported in less than 1% (3/1,048) of patients in a case series of 1,048 patients. Three patients had the device removed because of pain, 1 within 90 days and 2 after 90 days. Chest pain shortly after the procedure was reported in 1 patient in a case series of 44 patients; the patient needed a short stay in hospital and the pain resolved within 1 month.
- 5.4 Device removal for dysphagia was reported in 2% (23/1,048) of patients and oesophageal dilation was reported in 6% (59/1,048) of patients in the case series of 1,048 patients. Dysphagia was reported in a statistically significantly higher proportion of patients who had a magnetic titanium ring than in those who had Toupet fundoplication in the non-randomised comparative study of 238 patients at 3-month follow-up (odds ratio 9.42, 95% confidence interval [CI] 2.22 to 20.10, $p < 0.001$), but the difference was no longer statistically significant at 1-year follow-up. Dysphagia was reported in 68% (68/100) of patients at 3-year follow-up in a case series of 100 patients, 3 of whom had the device removed. Painful swallowing was reported in 8% of patients in the same study. Difficulty swallowing was reported in 7% of patients who had a magnetic titanium ring and 11% of patients who had laparoscopic fundoplication at 1-year follow-up in a non-randomised comparative study of 249 patients ($p = 0.373$).
- 5.5 Respiratory arrest, within the first hour after the procedure, was reported in 1 patient who had a magnetic titanium ring in the non-randomised comparative study of 238 patients; the patient was successfully resuscitated without consequences. Injury to the pleura was reported in 1 patient each who had laparoscopic insertion of a magnetic titanium ring and laparoscopic fundoplication in the non-randomised comparative study of 249 patients (no further details were given).
- 5.6 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: severe postoperative chest pain that resolved within a few days without intervention. They considered that the

following were theoretical adverse events: device failure, infection of the device, and ring-induced pseudo-achalasia with reversible or permanent damage to the oesophagus.

6 Committee comments

- 6.1 At consultation, the committee was informed that the procedure is being used within the NHS, but no additional peer-reviewed evidence was provided.
- 6.2 The committee was advised that the device used for this procedure is only MRI conditional up to either 0.7 Tesla or 1.5 Tesla, depending on the model, and that this could have serious implications for patients if an MRI is needed in the future.
- 6.3 The committee was advised that patients need to eat a soft diet for a short period after the procedure.
- 6.4 The committee was informed that patient selection is important and that patients with large hiatus hernias, severe oesophagitis or a high BMI had been excluded in most of the published evidence.

7 Further information

- 7.1 This guidance requires that clinicians doing 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).
- 7.2 Patient commentary was sought but none was received.
- 7.3 For related NICE guidance, see the [NICE 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.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

Accreditation

