NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Gastro-oesophageal reflux disease (GORD) can occur when the ring of muscle between the food pipe (oesophagus) and the stomach does not close properly. Stomach acid can then travel up towards the throat (reflux), causing symptoms such as heartburn and nausea. This procedure is done under general anaesthesia. Using keyhole (laparoscopic) surgery, a ring of beads is placed around the outside of the food pipe, just above the stomach. Magnets inside the beads hold them together to keep the food pipe closed but are weak enough to move apart to allow food or liquid to be swallowed. The aim is to prevent acid reflux.

This is a review of NICE's interventional procedures guidance on laparoscopic insertion of a magnetic ring for GORD.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 18 August 2022

Target date for publication of guidance: December 2022

1 Draft recommendations

1.1 Evidence on the safety and efficacy of laparoscopic insertion of a magnetic ring for gastro-oesophageal reflux disease (GORD) is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.

1.2 Patient selection, and the procedure, should be done by clinicians who have specific training in the procedure, and experience in upper gastrointestinal laparoscopic surgery and managing GORD.

2 The condition, current treatments and procedure

The condition

2.1 Gastro-oesophageal reflux disease (GORD) is a common condition in which acid from the stomach flows back up into the oesophagus. It is usually caused by the sphincter at the lower end of the oesophagus becoming weakened. Symptoms of GORD can be directly related to reflux episodes (such as heartburn, regurgitation, chest pain and nausea) or be caused by complications of the disease (such as 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.

Current treatments

2.2 NICE's guideline on GORD and dyspepsia in adults: investigation and management describes managing GORD in adults. The standard treatments for symptomatic GORD are lifestyle modification and drug therapy. People may be offered antireflux

surgery (usually laparoscopic fundoplication) or bariatric surgery if their symptoms do not improve, or they develop complications despite medication or an intolerance to medication. Endoscopic interventions (such as endoscopic radiofrequency ablation at the esophagogastric junction) and electrical stimulation of the lower oesophageal sphincter can also be used.

The procedure

2.3 The aim of laparoscopic insertion of a magnetic ring for GORD is to relieve reflux-related symptoms without impeding the ability to swallow, belch or vomit.

2.4 The procedure is done 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 at the gastro-oesophageal junction, with the posterior vagus nerve trunk located outside the magnetic ring. The ends of the implant are secured together to hold it in place. Intraoperative endoscopy may be used to help identify the anatomic gastro-oesophageal junction and to assess device position.

2.5 The implant consists of a ring of interlinked beads, each with a weak magnetic force that holds the beads together to keep the distal oesophagus closed. When the person 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.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive

literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 3 systematic reviews and meta-analyses, 1 randomised controlled trial, 3 non-randomised comparative studies, 2 case series, and a review of the MAUDE database and the Ethicon's complaint database. It is presented in the summary of key evidence section in the interventional procedures overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduced reflux symptoms and reduced need for medical therapy for reflux.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, dysphagia, oesophageal erosion, and the need for device explantation and reoperation.

3.4 Two commentaries from people who have had this procedure and 1 patient organisation submission for this procedure were discussed by the committee.

Committee comments

3.5 The committee noted that the devices are intended to remain in place for life, so there should be arrangements to report complications in the long term.

3.6 The committee noted that this procedure has evolved, and the incidence of dysphagia and oesophageal spasm has reduced, over time.

3.7 The committee was informed that an MRI-compatible device is available.

3.8 The committee was informed that early postoperative management is important, including managing diet.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

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