NICE guidance

Gastroelectrical stimulation for gastroparesis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg489

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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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 IPG103.

1 Recommendations

1.1 Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit.

1.2 During the consent process, clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device.

1.3 Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units.

1.4 Further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful.

2 Indications and current treatments

2.1 Gastroparesis is a chronic disorder in which the stomach empties more slowly than normal (delayed gastric emptying) in the absence of any type of mechanical obstruction. The most common symptoms are nausea and protracted vomiting. Other symptoms include abdominal bloating, and, in severe cases, malnutrition.

2.2 Gastroparesis most commonly occurs in people with type 1 diabetes. It can also occur in other situations such as after abdominal surgery or in association with anorexia nervosa and abdominal migraine. Some cases are idiopathic. Conservative treatment options include modification of dietary intake and medical therapy with antiemetics or prokinetics. Treatment options for chronic intractable (drug-refractory) symptoms include jejunostomy tube insertion for feeding, gastrostomy tube insertion for stomach decompression, and pyloroplasty.

2.3 Gastroelectrical stimulation is an option for treating chronic, intractable nausea and vomiting secondary to gastroparesis.

3 The procedure

3.1 Electrical stimulation is delivered via an implanted system that consists of a neurostimulator and 2 leads. Implantation is done with the patient under general anaesthesia by an open or laparoscopic approach. The stimulating electrode of each intramuscular lead is fixed to the muscle of the distal part of the stomach. The connector end of each lead is then attached to the neurostimulator, which is placed in a pocket in the abdominal wall. When the neurostimulator is turned on, electrical impulses are delivered. The rate and amplitude of stimulation can be adjusted wirelessly with a hand-held external programmer. Patients may need to return to hospital for adjustment or reprogramming of the device, to optimise the effect on gastric emptying.

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 overview.

4.1 A meta-analysis of 4 studies including 169 patients with diabetic gastroparesis treated by gastroelectrical stimulation (part of a systematic review of 601 patients) reported improvement in total symptom severity score (weighted

mean difference 8.96 [95% confidence interval {CI} 6.1 to 11.8]; p<0.00001; I^2=68.6%). A meta-analysis of 3 studies including 58 patients with idiopathic gastroparesis treated by gastroelectrical stimulation reported improvement in total symptom severity score (weighted mean difference 7.5 [95% CI 5.4 to 9.7]; p<0.00001; I^2=52.9%). A meta-analysis of 2 studies including 33 patients with post-surgical gastroparesis treated by gastroelectrical stimulation reported improvement in total symptom severity score (weighted mean difference 8.3 [95% CI 5.5 to 11.1]; p<0.00001; I^2=0%). Length of follow-up was unclear in all the analyses.

4.2 A meta-analysis of 7 studies including 378 patients with diabetic, idiopathic or post-surgical gastroparesis treated by gastroelectrical stimulation (part of a systematic review of 601 patients) reported a statistically significant improvement in gastric emptying at 4 hours (assessed using standardised radionucleotide scans of a solid meal: weighted mean difference 13.0 [95% CI 7.4 to 18.6]; p<0.00001; I^2=87.4%). Subgroup analysis showed that the improvement was statistically significant in patients with diabetic or idiopathic gastroparesis but not in patients with post-surgical gastroparesis. Length of follow-up was unclear in all the analyses.

4.3 In a systematic review of 364 patients, a meta-analysis of 4 studies including 75 patients with gastroparesis treated by gastroelectrical stimulation reported no statistically significant change in weight (weighted mean difference 3.7 [95% CI -0.2 to 7.6]; I^2=0%). Length of follow-up was not reported but 12-month outcomes were preferred.

4.4 In the systematic review of 364 patients, a meta-analysis of 8 studies including 184 patients with gastroparesis treated by gastroelectrical stimulation reported a reduction in need for nutritional support from 44% (96 out of 216) of patients at baseline to 11% (21 out of 184) at follow-up (odds ratio 5.5 [95% CI 2.8 to 11.1]; p<0.00001; I^2=27%). Length of follow-up was not reported but 12-month outcomes were preferred.

4.5 A randomised controlled trial (RCT) of 32 patients with gastroparesis of idiopathic origin reported that there was a significant reduction in weekly vomiting frequency from 61 to 87% (p<0.001) and improvements in gastroparesis symptoms, gastric emptying and days of hospitalisation (all p<0.05) at 1-year

follow-up.

4.6 The systematic review of 364 patients reported a significant improvement in Short Form-36 physical component score (weighted mean difference 8.1 [95% CI 5.0 to 11.1]) and the mental component score (weighted mean difference 8.16 [95% CI 4.9 to 11.5]), based on meta-analyses of 4 studies with 78 patients. The difference was statistically significant ($p<0.00001$) for both outcomes with no heterogeneity. Length of follow-up was not reported but 12-month outcomes were preferred.

4.7 The specialist advisers listed key efficacy outcomes as reduced symptoms, reduced need for nutritional support, improved nutritional status and reduced frequency of hospital admissions.

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 overview.

5.1 Death (within 30 days) was reported in 3% (2 out of 72) of patients treated by gastroelectrical stimulation, due to small bowel infarction and heart failure, and 3% (1 out of 31) of patients treated by gastrectomy, due to myocardial infarction, in a comparative case series of 103 patients.

5.2 Gastric perforation related to an episode of vomiting (2 months after the procedure) was reported in 1 patient in a case series of 17 patients. The device was removed and the perforation was repaired.

5.3 Device removal was reported in 11% (24 out of 221) of patients in a case series of 221 patients (timing ranged from 1 to 43 months after the procedure). Reasons were infection at the pulse generator or electrode sites (13 patients), lack of symptom improvement (6 patients), lead dislodgements (2 patients), small bowel obstruction caused by wires (1 patient), penetration of electrode into the lumen of the stomach (1 patient) and 'associated with peptic ulcer disease' (1 patient). No further details were reported. Erosion through the skin (6 patients), device

migration (1 patient) and pain at implantation site (4 patients) resulting in device removal or replacement (timing unclear) were reported in the systematic review of 364 patients.

5.4 Battery failure resulting in device replacement was reported in 2% (4 out of 221) of patients in the case series of 221 patients (timing unclear).

5.5 Lead erosion (leading to a revision procedure) was reported in less than 1% (2 out of 233) of patients in a case series of 266 patients.

5.6 Treatment failure was reported in 26% (19 out of 72) of patients treated by gastroelectrical stimulation in a case series of 103 patients. Reasons included 'failure to respond' (14 patients), device malfunction (1 patient) and damage to the device (1 patient). The device was removed in 1 patient. Thirteen patients whose symptoms failed to respond were treated by gastrectomy.

5.7 The specialist advisers listed anecdotal events as pain at the site of insertion of the subcutaneous stimulation device, and 'pins and needles' sensation from the stimulation device.

6 Committee comments

6.1 The Committee concluded that the evidence of efficacy was adequate only after prolonged debate about the design of the available randomised trials. The trials included an initial phase before randomisation in which the device was left 'on'. There was concern that any beneficial effect of the device might therefore have been carried over into the control period, so reducing the symptoms in that phase of the trial. The Committee also noted the possibility of a placebo response.

6.2 The Committee recognised that gastroparesis can be a very debilitating condition with very few treatment options, and it noted patient commentaries describing substantial improvements in quality of life with gastroelectrical stimulation.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. 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.