Milton Keynes Clinical Commissioning Group

Referral Policy

Gastro-Electrical Stimulation

Gastro-Electrical Stimulation for intractable nausea and vomiting from idiopathic or diabetic gastroparesis following failure of conservative and pharmacological therapies is regarded as a procedure of low clinical priority and therefore not routinely funded by the Commissioner.

Background:
Gastroparesis describes a condition where there is delayed emptying of gastric content without mechanical obstruction. Symptoms include nausea, vomiting, abdominal pain, distension and bloating. In severe cases these symptoms can result in failure to maintain body weight and hydration significant enough to require hospital admission. Severe metabolic disturbance can occur. It is associated with a reduction in quality of life. The mainstay of treatment for gastroparesis is based on dietary modification and prokinetic medications. Invasive procedures are possible in more severe and intractable cases.

Gastroelectrical stimulation has been suggested as a potential treatment option for individuals with intractable gastroparesis. The treatment involves the insertion of electrodes, which are fixed to the muscle of the lower stomach. The connector end of each lead is then attached to the neurostimulator. When the neurostimulator is turned on, electrical impulses are delivered via the electrodes. The aim of gastroelectrical stimulation is reduced symptoms and enhanced gastric emptying.

This policy replaces and is based on NHSCB/B11/PS/a as commissioning of the intervention has passed from NHS England to CCGs.

The following details have been taken from **NHSCB/B11/PS/a**

Evidence summary:
NICE issued guidance on gastroelectrical stimulation in 2004 and concluded that the evidence on the safety and efficacy at that time did not appear adequate to support its use without special arrangements for audit and research. Health Improvement Scotland undertook a technology scoping report published in March 2012. The report concluded that gastroelectrical stimulation was associated with a statistically significant reduction in symptoms, frequency and severity, reduced need for hospital admissions and improvement in the quality of life for patients. The studies were mainly uncontrolled observational studies.

A literature search identified two systematic reviews, which both included meta-analyses, published in 2009 and 2012. While both reviews aimed to examine the effectiveness of gastroelectrical stimulation in patients with gastroparesis, each used different inclusion criteria, resulting in different studies being included.
The earlier review found one partially randomised study out of 13 included studies. The second review found an additional randomised trial published since the first review (out of ten included studies). The remainder of the studies included in both the analyses were uncontrolled case series. In addition, the meta-analyses used subsets of data as not all of the outcomes were reported in all papers.

The two reviews showed similar results. In each case, meta- analysis was performed, and found that gastroelectrical stimulation showed a statistically significant reduction from baseline in patient-reported symptoms severity scores relating to total nausea and vomiting. Gastric emptying at 4 hours showed statistically significant improvement from baseline.

The 2009 meta-analysis also showed statistically significant improvements in the patient reported SF36 scores and the requirement for enteral or parenteral feeding. Weight gain was evaluated but did not reach statistical significance.

Use of anti-emetic and prokinetic drugs could not be evaluated due to a lack of information on drug use.

Cost-effectiveness
No cost effectiveness studies were identified. However, the North East Treatment Advisory Group produced a costing study in response to a request from the North East Specialised Commissioning Team in 20105. Their report estimated that the cost for implantation of an Enterra™ device is between £16,000 and £18,000 per patient. This included all pre- and postoperative care but noted that additional costs could arise from the treatment of complications. There was potential to reduce costs of antiemetic medication and hospital admissions.

Safety
Reported complications of the procedure relate to the surgical nature of the insertion of the leads and neurostimulator.
These potential complications include surgical site infection, migration of the leads and perforation. The gastroelectrical stimulator had to be removed in 8% of cases reported in the second meta-analysis.

Activity and cost
The overall activity and cost of gastroelectrical stimulation was not evaluated in this review. The North East Treatment Advisory Group reported that in 2010 the manufacturer claimed that between 80 and 100 patients had an EnterraTM device implanted in the UK.

Equity

The main equity issue associated with gastroelectrical stimulation is that women appear to be disproportionally affected by gastroparesis.

The evidence base as reported in the literature for gastric electrical stimulation for gastroparesis is largely derived from low quality uncontrolled case series. The conclusions drawn from these studies are limited by bias and confounding which reduce confidence in the results. The majority of studies did not include placebo or sham stimulation. Follow-up of cases is reported against the natural history of the condition. The systematic reviews reviewed within this report did not indicate the length of treatment (medication or dietary modification) patients had received prior to being selected for a gastric electrical stimulator.

A key point of discussion that arises from an examination of the evidence is that refractory gastroparesis is not explicitly and consistently defined.

The insertion of a gastric electrical stimulator is an invasive procedure and can be associated with complications such as infection, pain and migration of the leads. The current and limited evidence that has been reviewed indicates that gastric electrical stimulation does result in an improvement from baseline in patient reported outcomes including total severity score, nausea and vomiting score in patients with gastroparesis. Gastric emptying at 2 and 4 hours has also shown to improve as has the requirement for enteral or parenteral feeding. Weight gain did not reach statistical significance in the review that included it in its analysis.

References

1. NICE. Gastroelectrical stimulation for gastroparesis. IPG103. London: National Institute for Health and Clinical Excellence, 2004.
2. Healthcare Improvement Scotland. Technologies scoping report. Number 5. Edinburgh: Healthcare Improvement Scotland, 2012. Available from: http://www.healthcareimprovementscotland.org/idoc.ashx?docid=08d260cc- a92f-4b1f-a5f6-2dfaf4daa63b&version=-1
3. O'Grady G, Egbuji JU, Du P, et al. High-frequency gastric electrical stimulation for the treatment of gastroparesis: a meta-analysis. World J Surg. 2009;33(8):1693-701.

Policy adopted by MKCCG xxx 2014