NHS
East and North Hertfordshire
Clinical Commissioning Group

Priorities Forum Statement

Number	**69**
Subject	**Gastric Electric Simulation in Gastroparesis**
Date of decision	**May 2016**
Date refreshed	**May 2017**
Date of review	**May 2019**

GUIDANCE

Recommendation

- GES may be effective in reducing nausea and vomiting symptoms and need of enteral/parenteral nutrition in patients with gastroparesis not responding to medical treatment; based on 'uncontrolled observational' studies.
- The long term efficacy is yet to be determined
- GES should not be routinely used in treatment of gastroparesis and may be considered as alternative options when all medical intervention had been exhausted and the condition is severely affecting patient's quality of life.

Introduction

- Gastroparesis is a chronic disorder in which the stomach empties more slowly than normal (delayed gastric emptying).
- Diagnosis of gastroparesis[1]
    - Symptoms: Mainly nausea and protracted vomiting. Other symptoms include abdominal bloating, pain and, in severe cases, malnutrition
    - Absence of gastric outlet obstruction/ulceration
    - Delay in gastric emptying: Visualise in gastric-emptying scan using scintigraphy of a solid-phase meal. Retention of 10% of the meal in the stomach at 4 hours is considered abnormal.
- Gastroparesis is debilitating and has a significant impact on quality of life in severe cases. Patients may need repeated visits to GP/gastroenterology services and hospital hospitalization for symptoms control and nutrition supplementation.

Epidemiology

- Common among Type 1 diabetes as part of autonomic neuropathy. Also affect a small percentage of type 2 diabetes patients
- Other causes include idiopathic and post-surgery
- Rarer causes Parkinsonism, amyloidosis, paraneoplastic disease and scleroderma

Conservative management/ Current management[1] (Appendix 1)

- Good glycaemic control in patients with diabetes mellitus
- Dietician referral- small frequent meals, low fat and fibre
- Improve nutrition- oral vitamins and supplements; if severe enteral or parenteral

nutrition
- Prokinetic/gastric simulation medications- domperidone, metoclopramide, erythromycin (short-term)
- Symptoms management- anti-emetic
- Stop opiate analgesia

Other management

- Gastric electric simulation (see below)
- Botulinum toxin injection to pylorus- not recommended, poor evidence
- Surgery- venting gastrostomy, gastrojeunostomy, pyloroplasty, and gastrectomy

Gastric electric simulation (GES)

Procedure

- Electrical stimulation is delivered through an implanted system that consists of a neurostimulator and 2 leads. The stimulating electrode of each intramuscular lead is fixed to the muscle of the distal part of the stomach using either laparotomy or laparoscopy.
- The connector end of each lead is then attached to the neurostimulator, which is placed in a small pocket in the abdominal wall through a surgical incision. When the neurostimulator is turned on, electrical impulses are delivered.
- The aim is reduced symptoms and enhanced gastric emptying.
  NB: GES is not the same as gastric pacing. GES delivers high frequency and low energy impulses while gastric pacing does the opposite.[2]

Evidence of efficacy

- Updated NICE interventional procedures guidance [IPG489], published May 2014 replaces gastroelectrical stimulation (interventional procedure guidance 103).
- NICE states that 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.[3]
- Two meta-analyses are available on this subject, O'Gardy G (2009)[4] with 13 studies (1 RCT and the rest case series) and Chu H (2012)[5] with 10 studies (2 cross over RCT and the rest case series). There are overlaps of studies between these two meta-anaylsis. The quality of most of the studies included was considered to be 'low'.
- Both reviews concluded statistically significant improvement of severity of nausea and vomiting (calculated by severity score reported by patients), improvement in total symptoms and improvement in SF-36 scores for quality of life at the end of study period; mostly at one year. Some studies reported 60-78% reduction in need for nutritional support for these patients.[4,5]
- However, there are difficulties in interpreting these results as most studies lacked a control group and relied on self-reported measures of symptom relief hence prone to bias. Confounding factors could not be eliminated and in most studies patients continue to take their regular medications for gastroparesis while on GES.
- Objectively, meta-analysis studies showed improvement in gastric emptying at 4 houtrs that was visualized through scan; further subgroup analysis revealed significant result in diabetic and idiopathic gastroparesis but not post-surgical gastroparesis.[5]
- In one of the cross-over study, there was no significant difference in symptoms severity

between the group who had their devices switch 'on' compared to the 'off' group.[4]

- The natural history of gastroparesis is poorly understood and effect of GES cannot be distinguished from the natural course of this disease which includes spontaneous resolution in some patients after a year. Even patients with longstanding disease may spontaneously improve with traditional medical care alone.
- Evidence is lacking on long-term efficacy of GES.
- Treatment failure reported in 26% (19/72) patients in one study[6] and approximately 11% to 20% of the patients had their device removed.[4,5]
- In a prospective study of 60 patients implanted with GES in a single centre, 43% of patients underwent further operations mainly for generator related cause including battery exchanges and relocations.[7]

Patient suitability

- No clearly define patient characteristics mentioned in the studies conducted
- GES is inserted in patient with chronic severe 'refractory' symptoms not responding to diet modification and medication.
- Refractory gastroparesis is not explicitly and consistently defined. Most studies consider one year conservative treatment failure or needing recurrent hospital admission as refractory cases.
- Significant improvement seen in gastroparesis secondary to type 1 diabetes compared to idiopathic and post-surgical causes (not significant)

Natural History

- Remained poorly understood
- Some studies suggest patients in the idiopathic group report symptoms improvement in one year and even in long standing patients, symptoms can improve spontaneously.

Safety

- The device was removed in 11-26% of the patients within 5 years period with various reasons cited including infection, lack of symptoms improvement, lead dislodgement, pain around device site, erosions through skin and penetration of electrodes through stomach, small bowel obstruction.
- Infection around the device site is more likely to occur in patients with diabetes mellitus.
- Death (within 30 days) was reported in 3% (2/72) of patients treated due to small bowel infarction and heart failure.[6]

Cost-effectiveness

No studies currently on cost effectiveness of treatment. It is estimated that implantation of the device cost between £16000-18000 including pre- and post-operative care. This does not take into account device follow-up post procedure and complications that arise. If the procedure is successful, this could potentially reduce health-care cost through reduce visits to GP, gastroentrology service, hospital admissions and medication cost.

Note on surgical treatment

- The most common procedures performed are partial or total gastrectomy. These procedures shown higher success compares to drainage procedures (pyloroplasty,

gastroenterostomy). Complications associated with enteral tubes are significant, and they include clogging, erosion, mechanical tube failure, site infection, excessive drainage, skin excoriation, and local discomfort.[7,8]

- Most studies came from small reported case series.
- There are no predefined criteria on the type of patients that will benefit more from surgical treatment compared to GES.
- Surgeries were generally performed on patients that are refractory to multiple medical treatments, multiple hospital admissions and symptoms affecting daily life and work.
- Sun 2013 reported symptoms improvement in obese patients who underwent surgery after failed treatment with GES. [8]
- Careful selection of patients is needed as complications from surgery can be high with reported renal failures and death. Patients would also need to be on nutrient supplements and vitamin B12 injections following surgery. It is recommended that patients underwent psychiatry assessment prior to consideration for surgical procedure.[7]

References

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3. *NICE interventional procedures guidance [IPG489] Published date: May 2014*
4. *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.*
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Human Rights and Equalities Legislation have been considered in the development of this guidance.

Appendix 1 Flow chart