

OHTAC Recommendation

Gastric Electrical Stimulation

August 18, 2006

OHTAC Ontario
Health Technology
Advisory Committee

Gastric Electrical Stimulation

The Ontario Health Technology Advisory Committee (OHTAC) met on August 18 2006 to review the effectiveness, safety and cost-effectiveness of gastric electrical stimulation (GES) for the treatment of: 1) severe treatment-resistant gastroparesis (GP); and 2) morbid obesity.

Gastroparesis refers to impaired gastric emptying in the absence of obstruction and may occur in association with diabetes, as a complication of gastric surgery or for unknown reasons. Symptoms consist of early satiety, nausea, vomiting, abdominal pain and malnutrition. Treatment consists of optimal blood glucose control in patients with diabetes, dietary modifications, and drugs to stimulate gastric movement or relieve nausea. For patients who are refractory to drug treatment, surgical options may include enteral tube feeding, partial or full gastric resection, or total parenteral nutrition. The incidence of severe refractory GP in Ontario is estimated to be about 20 to 150 cases per year.

Morbid obesity is defined as a body mass index of at least 40 kg/m² or at least 35 kg/m² with comorbid conditions (e.g., diabetes, hypertension, dyslipidemias, obstructive sleep apnea, and weight-related arthropathies). An expert estimated that about 160,000 to 180,000 people are morbidly obese in Ontario. Bariatric surgery is considered an intervention of last resort for patients who have attempted first-line forms of medical management, such as diet, physical activity, behavioural modification, and drugs.

GES is an implanted system that consists of a neurostimulator and 2 leads. Potential advantages of GES for the treatment of GP and morbid obesity include reversibility of the procedure and it is less invasive compared to gastric surgery. Based on the Health Technology Policy Assessment by the Medical Advisory Secretariat and following discussion, OHTAC found the following:

1. Severe Treatment-Resistant Gastroparesis

The randomized controlled trial (RCT) reviewed for GES in the treatment of nausea and vomiting due to treatment-resistant gastroparesis was of low quality due to several factors including:

- Short term duration.
- Confounding factors for diabetes patients such as status of glucose control, renal insufficiency, and use of antidiabetes medication.
- Small sample size due to early termination of enrollment.
- Placebo effect.
- Retrospective subgroup analyses.

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- Attrition of patients.
- Use of concurrent medical therapy.

2. Morbid Obesity

The quality of the RCT of GES for the treatment of morbid obesity is very low. There was no statistically significant difference in excess weight loss between the study and control groups at the end of the 6 months (1.3% for active stimulation compared to 2.4% for placebo). The percent of excess weight loss at 12 months after implantation was 2.5%. (Of note, other bariatric procedures such as gastric bypass can produce an excess weight loss of up to 80%).

There is no Schedule of Benefits code for GES. In 2005, there were less than 5 out-of-country requests (for either consultation or surgery to treat GP). The GES device is approximately CDN \$10,700; the estimated budget impact for the treatment of 20-150 patients in Ontario with severe drug-refractory GP would be approximately CDN \$107,000 to \$1.6M per year for the device cost alone. The true uptake of GES for morbid obesity is unknown in relation to other types of bariatric surgery (which are more effective).

OHTAC Recommendations

Based on the above, OHTAC recommends the following with regard to GES:

- At this time, the quality of evidence is insufficient to make a recommendation in favour of the use of gastric electrical stimulation (GES) for people with severe, treatment-resistant gastroparesis.
- OHTAC does not recommend GES for the treatment of morbid obesity as evidence of its effectiveness does not currently exist.

OHTAC will convey these recommendations to the field through their posting on OHTAC's website and the distribution of OHTAC's E-bulletin.