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Title **Gastric Electrical Stimulation (Enterra™ Therapy System) for the Treatment of Gastroparesis**

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Aim

To present evidence on the efficacy/effectiveness, safety, and efficiency of gastric electrical stimulation (GES) (Enterra™ Therapy system) in treating patients with severe gastroparesis.

Conclusions and results

Ten studies met the inclusion criteria: 1 multicenter, randomized, placebo-controlled, double-blind crossover study; 1 prospective nonrandomized comparative study that compared GES therapy with medication; and 8 case series studies. Four of the 10 studies reported results from patients who were included in previous studies. The studies were generally weak in methodological design (case series) and quality of execution. A randomized crossover study compared stimulation ON and OFF with the GES device. At 1-month followup, both diabetic and idiopathic patients showed improvements in symptoms and vomiting frequency. Differences between the stimulation ON and OFF periods were statistically significant, or not, depending on how the results were analyzed. Results from the 5 case series studies that reported on patients who were not part of another published study indicated:

- Significant symptomatic improvement at 6 to 12 months after GES implantation (4 studies).
- Significant improvement in nutritional status (3 studies) at 6 to 20 months after implantation.
- Significant improvement in quality of life (2 studies) at 6- and 12-month followup.
- Reduction in supplementary enteral and parenteral feeding (4 studies) at 12-month followup, although these results were not confirmed statistically.

GES does not cause the muscle of the stomach to contract and has only a modest effect on gastric emptying. Since the mechanism of action of GES remains unclear, some authors have suggested that the symptomatic improvements may be due to a placebo effect. The most common adverse events were infection or erosion at the implant site (required removal of the system) and electrode dislodgement. Health Canada has approved the Enterra™ Therapy system as a Class 3 device to treat chronic, intractable nausea and vomiting.

Recommendations

The evidence is insufficient to support routine use of this procedure. GES should be considered as a last resort for adults with severe gastroparesis when all conventional treatment regimes have failed. GES implantation should be performed by trained professionals only.

Methods

Original studies published in English were identified by systematically searching PubMed, EMBASE, HealthSTAR, the Cochrane Library, Web of Science, library collections, and the websites of regulatory agencies, evidence based resources, health technology assessment agencies, research registers, and guidelines sites from January 2000 to November 2005. Position papers, guidance reports, and regulatory status information were included. Internet search engines were used to locate grey literature.

Further research/reviews required

Clear patient selection criteria and a system for collecting followup safety data need to be developed. Controlled studies are planned or ongoing. Once this research is published, GES should be reviewed again to determine if its safety and efficacy status has changed.

Written by

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