Gastric electrical stimulation (Enterra Therapy system) for the treatment of gastroparesis

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CRD summary
This review concluded that the evidence to support the routine use of gastric electrical stimulation in patients with idiopathic gastroparesis, or gastroparesis associated with diabetes or surgery, is inadequate. Although the review had some limitations, the authors’ cautious conclusions seem appropriate given the limited evidence available.

Authors’ objectives
To present the current evidence on the efficacy/effectiveness, safety and efficiency of gastric electrical stimulation (GES) for the treatment of severe gastroparesis (GP).

Searching
The Cochrane Library, DARE, HTA, NHS EED, EMBASE, Web of Science and PubMed were searched from 2000 to the beginning of November 2005; the search terms were reported. Other named library collections, websites of practice guidelines, regulatory agencies and other sources were also searched. Conference abstracts and non-English language studies were excluded.

Study selection
Study designs of evaluations included in the review
Comparative studies with a follow-up of at least 1 year were eligible for inclusion, and in the absence of such studies case series were included.

Specific interventions included in the review
Studies of GES (specifically the Enterra Therapy system), involving temporary and/or permanent implantation, were eligible for inclusion. One included study compared GES with placebo.

Participants included in the review
Studies of people with severe GP, defined as delayed gastric emptying determined by nuclear scintigraphic measurement, intractable symptoms for at least 1 year, and who were refractory to drug therapy were eligible for inclusion. The patients in the included studies had GP symptoms related to type I diabetes, post-surgery and idiopathic causes.

Outcomes assessed in the review
Studies were included if they reported the primary outcomes of interest, which were symptom improvement (e.g. frequency or severity of nausea and vomiting) and the results of the gastric emptying test with nuclear scintigraphy. Other outcomes of interest were quality of life, body weight and supplementary enteral or parenteral feeding.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Studies were assessed for quality using a 30-item checklist constructed by the authors. The authors did not state how the validity assessment was performed.

Data extraction
The data were extracted using a standardised form and study authors were contacted for further data if necessary. A total symptom score (TSS) of severity and/or frequency was calculated, based on the sum of the frequency and/or
severity of vomiting, nausea, early satiety, bloating, postprandial fullness and epigastric pain. Gastric emptying results were extracted as the percentage reduction, or as the number of patients who showed normalised, unchanged or worsened gastric emptying. The authors did not state how many reviewers performed the extraction.

**Methods of synthesis**

How were the studies combined?
The studies were summarised individually in a narrative. Studies that included patients reported in past publications were discussed separately and were not included in this abstract.

How were differences between studies investigated?

Some differences between the studies were tabulated and reported in the text.

**Results of the review**

Six studies were included: 1 randomised controlled trial (RCT) (n=33), and 3 prospective and 2 retrospective case series (n=148). A prospective comparative study and 3 additional case series were also included but these reported results from patients already included in the other studies.

The case series were rated as average quality (50 to 80% of the criteria were met). The single RCT was a double-blind placebo controlled crossover trial. Follow-up was for 1 month, which did not meet the review inclusion criteria. At 1 month there was a statistically significant decrease in vomiting frequency with GES compared with placebo. All patients then received GES: vomiting frequency and TSS decreased at 12-month follow-up compared with baseline, and quality of life improved. One prospective case series, of treatment responders only, reported an average reduction in vomiting frequency of more than 90% and a reduction in the median weekly frequency of nausea to one episode per week at 12 months. Six of the 33 GES devices were removed during the year due to infection. In a second prospective case series there was a statistically significant reduction in TSS and vomiting frequency at 12 months compared with baseline, but not for gastric emptying. In the third prospective case series there was a statistically significant decrease in nausea and vomiting compared with baseline as well as an improvement in gastric emptying rates. One retrospective case series reported a statistically significant reduction in TSS and severity at 12 months compared with baseline and normalised gastric emptying in 5 of 24 patients. A second retrospective case series reported a good or excellent outcome in 19 of 29 patients and a fair to poor outcome in 8 patients. Three patients required additional procedures due to problems with the GES device.

**Cost information**

The cost of the Enterra Therapy system is US$30,000. The cost of the device and hospitalisation in the UK is £15,000 to £16,000. In Canada the total cost for the device implanted is Can$10,685 (based on costs as of May 15, 2005).

**Authors’ conclusions**

The evidence to support the routine use of GES in patients with idiopathic GP or GP associated with diabetes or surgery is inadequate.

**CRD commentary**

The review question was clearly stated and a wide range of sources were searched for studies, though the inclusion of only English language papers might have led to relevant studies being missed. The review methods were also poorly reported, so it is unclear whether appropriate precautions were taken to reduce reviewer error and bias. One RCT, which did not meet the inclusion criterion for length of follow-up, was included in the review but no other rigorous study designs were identified and the overall quality of the included studies was poor. Details of the primary studies were provided, but the data were presented as individual study descriptions with little attempt to provide a narrative synthesis. Despite these limitations in the review methodology, the authors’ cautious conclusions appear to be supported by the limited evidence presented.
Implications of the review for practice and research
Practice: The authors stated that the treatment could be considered a last resort in patients with severe symptoms after all conventional treatment regimes have failed. Due to the risks associated with the implantation of the device, implantation should be carried out by trained professionals and there should be continuous follow-up.

Research: The authors did not state any implications for further research, but noted that there are two ongoing RCTs due to report in 2006.

Bibliographic details
Moga C, Harstall C. Gastric electrical stimulation (Enterra Therapy system) for the treatment of gastroparesis. Edmonton, AB, Canada: Alberta Heritage Foundation for Medical Research. Health Technology Assessment; 37. 2006

Original Paper URL

Indexing Status
Subject indexing assigned by CRD

MeSH
Electric Stimulation Therapy /methods; Electrodes, Implanted; Gastric Emptying; Gastrointestinal Motility; Gastroparesis /therapy; Treatment Outcome

AccessionNumber
12007008031

Date bibliographic record published
29/02/2008

Date abstract record published
29/02/2008

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.