High-frequency gastric electrical stimulation for the treatment of gastroparesis: a meta-analysis

CRD summary
This review concluded that high-frequency gastric electrical stimulation may have significant benefits for patients with gastroparesis. However, given uncertainty over parts of the review process combined with the poor quality of the included studies and small sample sizes, the finding should be interpreted with caution (as acknowledged by the authors) and are unlikely to be reliable.

Authors' objectives
To evaluate the evidence for the efficacy of high-frequency gastric electrical stimulation for the treatment of gastroparesis.

Searching
MEDLINE, EMBASE, Google Scholar, ISI Proceedings, the Cochrane Library and the online registers on controlled clinical trials were searched between January 1992 to August 2008. Search terms were reported. References lists of retrieved articles were searched for additional relevant studies. The manufacturers of the gastric electrical devices were contacted for unpublished data.

Study selection
Controlled clinical trials, cohort studies and case series that evaluated the efficacy of implanted high-frequency gastric electrical stimulation for medically refractory gastroparesis were eligible for inclusion. Studies of external, temporary and/or low frequency gastric electrical stimulation were excluded, as were duplicate studies and small case series (of one to two patients).

The four primary outcomes assessed were symptom improvement, nutritional outcome, gastric emptying and device complications.

The majority of included patients presented with idiopathic gastroparesis or diabetes; small numbers of patients were post-surgical or post-transplant patients. In the only RCT, the comparator was sham stimulation.

The authors did not state how many reviewers performed the selection of studies for the review.

Assessment of study quality
The authors stated that studies were defined by methodology and the overall quality of the evidence was assessed quantitatively. Planned formal assessments of methodological quality were not undertaken.

The authors did not state how the quality assessment was conducted.

Data extraction
Two independent reviewers extracted data to calculate weighted mean differences (WMD) and corresponding 95% confidence intervals (CI) for the analysis of continuous variables and odds ratios (OR) and 95% confidence intervals for dichotomous outcomes. In studies that reported outcomes as medians and ranges, the means and variances were estimated by the methods of Hozo.

Methods of synthesis
Pooled mean differences (MDs) and odd ratios and 95% confidence intervals for each were calculated using a random-effects model. $\chi^2$ and the $I^2$ tests were used to evaluate statistical heterogeneity across the studies. The fail safe N
statistic was used to assess publication bias.

Results of the review
Thirteen studies were included in the review (n=302 patients). The only RCT (n=33 patients) was judged to be of moderate to low quality; the remaining studies (nine prospective case series and three retrospective case series) were all described as low-quality studies. The sample sizes in all the studies ranged between seven and 48 patients. The fail safe N scores ranged from 5 to 270, indicating the publication bias was unlikely for most outcomes.

Symptom improvement: There were statistically significant decreases observed in total symptom severity scores with gastric electrical stimulation treatment compared with sham gastric electrical stimulation treatment (WMD 6.52, 95% CI 1.32 to 11.73; three studies), vomiting severity scores (WMD 1.45, 95% CI 0.99 to 1.91; four studies) and nausea severity scores (WMD 1.69, 95% CI 1.26 to 2.12; four studies). Substantial statistical heterogeneity was observed for total symptom severity ($I^2=89\%$). Statistically significant improvements in quality of life scores were also observed after gastric electrical stimulation treatment, with increases shown in the Short-Form-36 Physical scores (WMD 8.05, 95% CI 5.01 to 11.10; four studies) and Mental Composite scores (WMD 8.16, 95% CI 4.85 to 11.47; four studies).

Nutritional support: Statistically significant reductions were observed in requirements for enteral or parenteral nutrition support after gastric electrical stimulation treatment (OR 5.53, 95% CI 2.75 to 11.13; eight studies). There were no significant changes in weight observed after gastric electrical stimulation treatment (WMD 3.68kg, 95% CI -0.23 to 7.58; four studies).

Gastric emptying: Beneficial changes in two-hour gastric emptying (MD 23.15% in retention, 95% CI 7.93 to 38.37; four studies) and four-hour gastric emptying (WMD 12.67% gastric residual, 95% CI 9.76 to 15.58; five studies) after gastric electrical stimulation device implantation were also observed. Statistical heterogeneity was observed for changes in two-hour gastric emptying ($I^2=98\%$).

Complication rates were reported in 10 studies and in 8.3% of patients undergoing device removal and/or replacement.

Authors' conclusions
The results showed significant benefits of high-frequency gastric electrical stimulation in the treatment of gastroparesis by improving symptom severity, nausea and vomiting, and improving mental and physical wellbeing. However, substantial caution is required when interpreting the results because of the limitations of uncontrolled studies from which the evidence for this intervention are derived.

CRD commentary
The review addressed a clear question and criteria for inclusion were stipulated. Multiple electronic sources were searched and attempts were made to identify unpublished literature. The risk of language bias was unclear as the authors did not report whether language restrictions were applied. Steps were taken to reduce reviewer error and bias in the extraction of data, but were not reported for study selection and quality assessment.

There was little information presented on how the reviewers assessed the methodological quality of the included studies, and all the studies were of low quality and comprised small numbers of patients. The findings from the uncontrolled studies included in this review were associated with a number of potential biases. Pooling of controlled and uncontrolled studies may not have been appropriate, and this analysis was subject to a substantial risk of bias. In addition, there was also little information on the participants and follow-up in the included studies. The authors acknowledged limitations regarding confounders, attrition and the variation in symptom and quality of life scores across the studies, which meant that the results from some studies were not included in the analyses.

Given a number of shortcomings, the findings of the review are unlikely to be reliable and substantial caution is required when interpreting the results given the potential for bias.

Implications of the review for practice and research
**Practice:** The authors did not state any implications for practice.
Research: The authors stated that further blinded, controlled trials, in which health scoring systems are standardised, are required to confirm the effectiveness of the intervention and which of the patients are most likely to respond to treatment.

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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.