Is gastric electrical stimulation superior to standard pharmacologic therapy in improving GI symptoms, healthcare resources, and long-term healthcare benefits

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The treatment of patients with symptoms of severe upper gastrointestinal (GI) motor disorders, including gastroparesis (GP), via gastric electrical stimulation (GES) was compared with the use of traditional pharmacological agents in an intensive outpatient programme (MED). The intensive outpatient programme consisted of evaluations by a multidisciplinary team, along with scheduled laboratory evaluations for nutritional, fluid and electrolyte status. It also included regular outpatient visits (two to three times a week) for intravenous fluids, oral or parenteral antiemetics, analgesics and prokinetics.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population included consecutive patients who received all their in- and outpatient care at the same hospital for a 4-year period. All patients had documented chronic nausea and vomiting, or a frequency of nausea of at least seven times per week, and most had been hospitalised frequently. In addition, all patients had symptoms for at least 1 year, had evidence of weight loss and/or needed nutritional support, and were refractory to at least two classes of available prokinetic and antiemetic drugs. The exclusion criteria included any known structural cause for the GI symptoms, pregnancy, narcotic or other chemical abuse, scleroderma, and an inability to receive most of their medical care at the authors' institution.

Setting
The setting was secondary and tertiary care. The economic study was carried out in the Memphis Medical Centre at the University of Tennessee, USA.

Dates to which data relate
The dates to which the effectiveness evidence and resources use data referred were not reported. The price year was also not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study. The patients were
prospectively studied and evaluated for symptoms, resource utility and costs.

**Study sample**
During the study period, 14 consecutive patients received GES devices from the institution. Five patients were excluded because they lived too far away to receive complete treatment (4 patients) and because of scleroderma (1 patient). Therefore, 9 patients (3 males and 6 females), with a mean age of 39.4 years, were included in the GES group as part of two FDA trials for GES. One patient was diagnosed with diabetic GP and 8 were idiopathic. Two patients in the GES group also required intermittent outpatient therapy.

Nine patients, all female, were treated with intensive medical therapy. They had a mean age of 40 years, and were treated with antiemetic, prokinetic and other medications in an outpatient programme designed to reduce inpatient stay. The nine medical control patients included all the patients enrolled in an intensive outpatient programme during the time period, with the exception of one patient with scleroderma who was excluded. One patient was diagnosed with diabetic GP and 8 were idiopathic. All MED patients had been offered GES therapy, but had either declined it or did not have medical coverage to pay for the device.

Power calculations were not reported. All patients in both GES and MED groups had documented abnormalities in solid and/or liquid gastric emptying at baseline using a standardised nuclear medicine meal. The average duration of symptoms was 86.7 (+/- 27.6) months for the GES patients and 33.3 (+/- 9.28) months for the MED patients.

**Study design**
The study was a prospective, single-centre, cohort study. The duration of follow-up was 3 years. Loss to follow-up was not reported, and neither was blinding of the outcome assessment.

**Analysis of effectiveness**
The authors did not report whether the analysis was conducted on an intention to treat basis or for treatment completers only. The primary outcome was GI symptoms. These were evaluated through deriving a total symptom score (TSS) based on each patient's self-assessment of abdominal bloating or distension, early satiety, abdominal pain, nausea and vomiting. The patients rated each symptom on a scale of 0 to 10, with 10 being the most severe. Symptom scores were then summed to calculate the TSS (range: 0 - 50).

The authors also assessed the patients' HRQOL related to health care resource usage. They calculated an investigator-derived independent outcome measure score (IDIOMS), previously known as "a diagnostic and predictive score" (ADAPS), which is a global HRQOL measure. Its assessment included three parameters associated with health care resource use:

- intensity of the service (e.g. outpatient, home health, inpatient),
- severity of illness (e.g. still working, on disability), and
- the number of non-GI organ systems involved.

Each parameter was rated on a 10-point scale, and the parameters were summed for a total score ranging from 0 to 30; the three components were added for a total score of this global HRQOL measure. IDIOMS was administered prior to treatment and at the 1-, 2- and 3-year follow-up visits. At each time point, the patients were assessed by two individuals, namely a practitioner who provided direct clinical care and a researcher in the clinical trial. The two scores were then averaged for a single composite IDIOMS score. The authors illustrated the IDIOMS tool in an appendix.

Statistical tests were performed to analyse differences in demographic characteristics and GP symptoms. The TSS was reported as the mean +/- the standard error of the mean (SEM). The data were analysed by an analysis of variance, and between-group comparisons were based on Newman-Keuls post hoc tests.
Effectiveness results
Prior to treatment, the between-group comparison indicated that the GES and MED groups were not significantly different in the TSS (37.9 +/- 2.73 versus 39.3 +/- 2.8). With treatment, the overall TSS for the GES group was significantly better than that for the MED group (F=3.03, p<0.017).

Within the GES group, the TSS significantly improved at each annual follow-up visit when compared with the TSS prior to treatment (F=9.87, p<0.001). Within the MED group, the TSS significantly improved only at the year 1 follow-up visit when compared with TSS prior to treatment (f non significant). Post hoc tests indicated that the GES and MED groups had significantly different TSS at year 2, (p=0.04). Although not stratified by individual symptoms, the greatest improvement in TSS was in the nausea and vomiting sub-scores.

Prior to treatment, the between-group comparison indicated that the GES and MED groups were not significantly different in the IDIOMS (12.6 +/- 1.6 versus 11.0 +/- 0.71). With treatment, the overall IDIOMS for the GES group was significantly better than that for the MED group (F=10.49, p<0.017).

Within the GES group, IDIOMS significantly improved at each annual follow-up visit when compared with baseline (F=14.04, p<0.001). Within the MED group, it significantly worsened at each follow-up visit (F=14.94, p<0.01).

Clinical conclusions
This preliminary study showed that, in this sample of patients with GP, GES treatment improved GI symptoms. The GI symptom scores in the GES group continued to show improvement across the study period, while their MED counterparts demonstrated a worsening in symptoms.

Measure of benefits used in the economic analysis
No summary health benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

Direct costs
To determine the health care costs, the authors totalled all hospital charges incurred for hospitalisation, medication, nutrition and outpatient services (including hospital surgical expenses and the cost of the GES device and its implantation) for each of the three follow-up years. The 3-year follow-up period began immediately following gastric stimulator implantation for the GES patients, so that the first year costs for the GES patients included the cost of device and implantation, and following enrolment in the outpatient programme for the MED patients. These study period costs (normalised to dollars per year) were then compared with the total hospital health care costs incurred during the 1 year prior to treatment. Charges for individual medical providers were not included in any of the calculations. The authors compared the total hospital health care in- and outpatient costs at 1-year baseline and 36-month post-treatment for both GES and MED. Discounting and a price year were not reported.

Statistical analysis of costs
The costs were treated stochastically. Annual medical costs and hospital days were reported as the mean +/- SEM. Within-group comparisons were analysed by an analysis of variance. Between-group comparisons were based on Newman-Keuls post hoc tests, except for annual medical costs which were analysed by nonparametric tests.

Indirect Costs
No indirect costs were reported.

Currency
US dollars ($).
Sensitivity analysis
No sensitivity analyses were carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
Prior to treatment, between-group comparisons indicated that the GES and MED groups were not significantly different in their annual health care cost ($83,700 +/- 27,000 versus $80,200 +/- 26,700). With treatment, the overall health care costs for the GES group declined over time (F=8.81, p<0.001) while those for the MED group did not (F=1.73, p=0.19).

By the end of the third year, the cumulative costs were $133,991 for the GES group and $222,470 for the MED group. The difference was $88,479.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
In this sample of patients with the symptoms of gastroparesis (GP) followed for 3 years, and compared with 1 year of baseline measures, gastric electrical stimulation (GES) was more effective than intensive medical therapy in improving long-term gastrointestinal (GI) symptoms and costs and in decreasing the use of health care resources.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. It reflected standard practice in the authors’ setting. You should decide if this represents a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective analysis. The groups had some baseline differences and the study was not randomised; these factors can alter the validity of treatment comparisons. The study referred to patients with GP. However, it was unclear whether the study sample was representative of the study population because of the selection method. Another weakness of the analysis was that no sample size was determined in the planning phase of the study and no power calculations were reported. The sample size may therefore have been too small, and hence the study might have had insufficient power to detect meaningful differences in outcomes between or within groups. The lack of reported blinding of the outcome assessment presented a further potential limitation to the reliability of the findings. However, the authors performed appropriate statistical analyses to test whether differences between the two groups were statistically significant.

Validity of estimate of measure of benefit
No summary measure of benefit was derived. The reader is therefore referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The cost analysis was performed from the perspective of a single provider. Although it was not stated, some relevant costs might have been omitted from the analysis, such as charges for individual medical providers that were not included in any of the calculations. If those charges were common to both groups, their omission is unlikely to have affected the authors’ conclusions.
The costs and the quantities were not reported separately, thus the analysis could not be easily extrapolated to other settings. The cost data were taken from the authors’ setting and a statistical analysis was performed. The costs were treated stochastically but no sensitivity analysis of the prices was conducted. Although discounting was not reported, it is recommended for studies with a follow-up period longer than 2 years. The price year was not reported, which will hamper any future reflation exercises.

Hospital charges were used to proxy prices for health care. Such charges do not reflect true opportunity costs (due to profit margin) and, in the absence of a cost-to-charge ratio, may limit the generalisability of the results beyond the authors’ clinical setting.

**Other issues**

The authors compared their findings with those from other similar studies, though they stated that they did not know of any prior reports on the longitudinal cost of care for patients suffering from GP. They did not directly address the issue of the generalisability of the results to other settings, although they recognised certain limitations of the study. For example, the small sample size, potential skewing of data due to the high mortality rate in the medical controls, and the lack of population-based control data. In addition, this sub-set of patients with GP would appear to represent a high-risk group in terms of the costs, HRQOL, morbidity and mortality. However, according to the authors, this study represents one of few works that report chronically ill GI motility patients for a long-term period, detailing both alternative treatment costs and HRQOL status. The authors also recognised the difficulty in separating treatment costs and HRQOL variables from co-morbid conditions in the small and severely ill sample of patients.

**Implications of the study**

The authors stated that the health resource measure IDIOMS is not standardised and requires extensive further evaluation to establish its psychometric properties versus other practitioner ratings and standardised measures of HRQOL. This is also true for the TSS measure. The authors believe that the combined measurement of both the IDIOMS (provider assessment) and TSS (patient assessment) offer useful, clinically based tools that merit further investigation.

In relation to the study, given the progressive nature of these diseases and the very limited pharmacological therapies available to patients, any treatment that could attenuate symptom severity and decrease health care resource use is worthy of ongoing evaluation. To continue to refine best practice treatment for these catastrophic GI illnesses, a study with a longer follow-up and cleaner study design is merited.

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