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

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Abstract *Context: Severe upper gastrointestinal (GI) motor disorders, including gastroparesis (GP), can consume significant health care resources. Many patients are refractory to traditional drug therapy. Objective: To compare symptoms, healthcare resource utilization and costs in two groups of patients with the symptoms of GP: those treated via gastric electrical stimulation (GES) and those treated with traditional pharmacological agents in an intensive outpatient program (MED). Design: A long-term comparison of patients with devices (n = 9) vs intensive medical therapy (n = 9). Setting and patients: A total of 18 eligible patients with the symptoms of GP reported for 1-year baseline and long-term treatment for 3 years. Interventions: Patients with the symptoms of GP were treated by a GES or intensive medical therapy (MED). Main outcome measures: GP Symptoms, healthcare resource utilization using investigator-derived independent outcome measure score (IDIOMS) and total hospital (inpatient and outpatient) billing costs. Results: Gastrointestinal symptoms were significantly different from baseline ($F = 3.03$, $P < 0.017$) with GP patients treated via GES showing more sustained improvement over 36 months than those treated via MED. Healthcare resource usage, measured via the IDIOMS, significantly improved at 12, 24 and 36 month follow-up for GES patients ($F = 10.49$, $P < 0.001$), compared with patients receiving medical therapy, who demonstrated further deterioration. GP patients treated via GES also proved superior to medical therapy at 24 and 36 months with regard to decreased costs ($F = 4.85$, $P < 0.001$). Within group comparisons indicated significantly reduced hospital days for both patient groups; however, no statistical differences were noted between groups in terms of hospital days. Three of nine patients in the MED group died primarily from i.v. access related problems; none of the GES patients died. Conclusion: We conclude that GES is more effective in improving long-term GI symptoms and costs, and decreasing use of healthcare resources than intensive medical therapy, in this sample of patients with the symptoms of GP followed for 3 years. Certain patients with GP form a high-risk group in terms of costs, quality of life, morbidity and mortality.*

Keywords *comparison study, costs, gastric electrical stimulation, gastrointestinal motor disorders, healthcare resources.*

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INTRODUCTION

Severe upper gastrointestinal (GI) motor disorders, including delayed emptying, or gastroparesis (GP) and chronic idiopathic pseudo-obstruction, are chronic diseases, that can consume significant health care resources and exhaust the energy of practitioners.[1] Patients with GP often have prolonged hospital stays due to dehydration and the need for nutritional support.[2] Many of these patients require long-term intravenous (i.v.) support, which can contribute to

patient morbidity and mortality.[3–5] Currently, most of these patients are treated with prokinetic medication, e.g. cholinergic agonists, motilin receptor agonists, dopamine receptor antagonists or anti-emetic medication, such as antihistamines or phenothiazines. However, several issues, including (i) removal of cisapride (a cholinergic agonist) from the US market in 2000; (ii) limited availability of domperidone (a peripheral dopamine receptor antagonist) in the US; and (iii) side effects related to metoclopramide (a central and peripheral dopamine antagonist) greatly limit patients' medical therapy options.[6] For some patients who are refractory to available medications, gastric electrical stimulation (GES) improves autonomic nervous system functioning,[7] decreases GI symptoms,[8] and enhances health-related quality of life (HRQOL).[9]

Over the years, health care costs have been studied with respect to the treatment of GI illnesses, like dyspepsia,[10,11] gastro-oesophageal disease,[12] fecal incontinence,[13] and Crohn's disease.[14] A more recent focus is to evaluate both cost factors and HRQOL. For example, Groeneveld *et al.*[15] measured HRQOL in patients with dyspepsia and peptic ulcer disease and applied these data to published models of disease management to determine cost-effectiveness. They found that strategies emphasizing early *Heliobacter pylori* eradication were cost effective for patients with peptic ulcer disease and possibly cost-effective for patients with uninvestigated dyspepsia. A similar study examined both HRQOL and cost variables in patients with refractory irritable bowel syndrome (IBS). The investigators concluded that decreased abdominal and psychological symptoms were independently associated with improved HRQOL in patients with severe IBS, suggesting that a holistic approach was most cost effective for those patients.[16] In an evaluation of surgical costs and HRQOL, Miller *et al.* found that surgical resection for local and recurrent rectal cancer was a cost-effective use of resources *vs* non-operative therapy, particularly when cost-effectiveness was calculated using patient preferences.[17] Researchers also found that IBS has a significant impact on both HRQOL and resource use, in both the US and UK, as measured by survey.[18]

The current work compared the GI symptom scores, healthcare resource usage, and cost efficacy associated with a long-term, 3-year trial of GES in 18 GP patients, nine of which were treated with GES and nine who received standard pharmacological treatment in a behavioural based outpatient program. We hypothesized that patients treated via GES would use fewer healthcare resources and demonstrate improved global costs GI symptoms and health related QOL, as compared with patients treated via more standard pharmacological treatment. We studied a group of 18 consecutive patients who received all their in- and out-patient care at our hospital for a 4-year period.

Patients

Eighteen patients with GP were prospectively studied and evaluated for symptoms, resource utility and costs. Nine patients underwent GES and nine were treated with intensive medical therapy. All 18 patients had documented chronic nausea and vomiting or nausea frequency equal to or exceeding seven times per week, and most had been hospitalized frequently. All patients in both GES and MED groups had documented abnormalities in solid and/or liquid gastric emptying at baseline using a standardized nuclear medicine meal.[19] 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. All patients were evaluated for exclusion criteria which included: any known structural cause for the GI symptoms, pregnancy, narcotic or other chemical abuse, scleroderma, and inability to receive most of their medical care at our institution. These 18 patients represented approximately 10% of the greater than 200 patients with the symptoms of GP seen annually at the University of Tennessee – Memphis Medical Center.

Gastric electrical stimulation patients Nine patients (three males and six females) with a mean age of 39.4 years, were treated with GES, as part of two FDA trials for GES. During the study period 14 consecutive patients received GES devices from our institution. Four lived at too long a distance to receive all care from our institution, and one patient was excluded because of scleroderma. The other nine patients lived close enough to receive care at University of Tennessee-Memphis. One patient was diagnosed with diabetic GP and eight were diagnosed as idiopathic. Two patients in the GES group also required intermittent outpatient therapy, all of these visits occurred at our hospital and thus their charges were included as part of this study.

Medical control patients Another nine patients (all females) with a mean age of 40 years, were treated with anti-emetic, prokinetic, and other medications in an outpatient program designed to reduce in-patient stays. These nine medical control patients included all the patients enrolled in an intensive outpatient program during this time period with the exception of one patient with scleroderma, who was excluded. All

patients lived in proximity (maximum 1 h by car) to receive care at our hospital outpatient department. One was diagnosed with diabetic GP and eight were idiopathic. All nine of the MED patients had been offered GES therapy but had either declined it or did not have medical coverage to pay for the device. One patient in the MED group did receive a GES device several years after the end of this study.

The intensive outpatient program included (i) evaluations by a multidisciplinary team (gastroenterologist, addictionist, nurse practitioner, psychologist, nutritionist, physical therapist and social worker); (ii) scheduled laboratory evaluations for nutritional, fluid and electrolyte status; and (iii) regular outpatient visits (two to three times a week) for i.v. fluids, oral or parenteral antiemetics, analgesias, and prokinetics.

Average symptom duration for the GES patients was 86.7 ± 27.6 months, while MED patients had an average symptom duration of 33.3 ± 9.28 months. The University of Tennessee Institutional Review Board approved this review of patients and outcomes.

METHODS

To evaluate GI symptoms, we calculated a total symptom score (TSS), based on each patients' self-assessment of abdominal bloating/distention, early satiety, abdominal pain, nausea, and vomiting. Patients rated each symptom on a scale of 0 to 10, with 10 being the most severe. Symptom scores were then summed to calculate TSS (range 0–50).

To assess patients' health care resource usage, we calculated an investigator-derived independent outcome measure score (IDIOMS), previously known as 'a diagnostic and predictive score' (ADAPS). Investigator-derived independent outcome measure score is a global HRQOL measure and is significantly correlated with standardized HRQOL measures, such as the Sickness Impact Profile, and with self-reports of symptom severity.[8,9] The IDIOMS assessment includes three parameters associated with healthcare resource use: intensity of service (e.g. outpatient, home health, inpatient), severity of illness (e.g. still working, on disability), and number of non-GI organ systems involved. Each parameter was rated on a 10-point scale, and the parameters are summed for a total score ranging from 0 to 30; the three components are added for a total score of this global HRQOL measure. Investigator-derived independent outcome measure score was administered prior to treatment and at the 1-, 2-, and 3-year follow-up visits. At each time point, patients were assessed by two individuals: a practitioner who provided direct clinical care and by a researcher in the clinical trial. The two scores were then averaged for a single composite IDIOMS score. Appendix illustrates the IDIOMS tool.

To assess patients' health care cost, we totalled all hospital charges incurred for hospitalization, medication, nutrition, and outpatient services (including hospital surgical expenses and the cost of the GES device and its implantation) for each of 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 enrollment in the outpatient program for the MED patients. These study period costs (normalized to dollars per year) were then compared with 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. We compared total hospital health care in- and out-patient costs at 1-year baseline and 36 month post-treatment for both GES and MED. Costs were calculated in dollars per month, summed for yearly totals, and reported as mean ± SEM. Within group comparisons were made using ANOVA, and between group comparisons were made using non-parametric test methods. Missing data for two patients (a GES patient whose cost data were missing for year 3 and a MED patient who died in year 2) in year 3 were carried forward from year 2 and a sub-analysis was performed between patients who died and those who survived.

RESULTS

A summary of study results and the between and within group analyses are shown in Table 1. Total Symptom Score, IDIOMS, and annual and cumulative medical cost results are also depicted in Figs 1–4.

Total Symptom Score is shown in Fig. 1. Prior to treatment, between group comparison indicated that GES and MED groups were not significantly different with respect to TSS (37.9 ± 2.73 *vs* 39.3 ± 2.8, respectively). With treatment, between group comparison indicated that overall TSS for the GES group was significantly better than overall TSS for the MED group ($F = 3.03$, $P < 0.017$). Within the GES group, TSS significantly improved at each annual follow-up visit when compared with TSS prior to treatment ($F = 9.87$, $P < 0.001$). Within the MED group, TSS significantly improved only at the year 1 follow-up visit when compared with TSS prior to treatment ($F =$ NS). *Post hoc* tests indicated that the GES and MED groups had significantly different TSS at year 2 ($P = 0.04$).

Table 1 Summary of results

	GES	MED	Between group comparisons	ANOVA results: Between group	ANOVA results: Within group
	TSS				
Baseline	37.9 ± 2.73	39.3 ± 2.8	NS	$F = 3.03$; $P < 0.017$	$F_{GES} = 9.87$; $P = 0.001$; F_{MED} = NS
Year 1	24.1 ± 4.8	31.7 ± 3.1	*		
Year 2	21.3 ± 5.1	36.9 ± 0.33	*		
Year 3	23.4 ± 5.4	34.8 ± 3.45	*		
	IDIOMS				
Baseline	12.6 ± 1.6	11 ± 0.71	NS	$F = 10.49$; $P < 0.017$	$F_{GES} = 14.04$; $P < 0.001$; $F_{MED} = 14.94$ $P < 0.001$
Year 1	8.3 ± 1.4	11.9 ± 0.73	*		
Year 2	7.0 ± 1.13	13.3 ± 0.62	*		
Year 3	6.4 ± 1.03	13.8 ± 0.45	*		
	Annual costs ($000's)				
Baseline	83.7 ± 27.9	80.2 ± 26.7	NS		$F_{GES} = 8.81$; $P < 0.001$; $F_{MED} = 1.73$; $P = 0.19$
Year 1	79.2 ± 26.4	85.7 ± 28.6	NS		
Year 2	23.7 ± 7.9	71.9 ± 24.0	*		
Year 3	22.1 ± 7.8	63.4 ± 22.4	*		
	Annual hospital days				
Baseline	24.8 ± 13.7	26.8 ± 8.4	NS	NS	$F_{GES} = 4.04$; $P < 0.002$; $F_{MED} = 10.6$; $P < 0.001$
Year 1	14.1 ± 9.0	13.3 ± 5.8	NS		
Year 2	3.2 ± 1.5	11.6 ± 5.4	NS		
Year 3	2.8 ± 1.8	6.4 ± 5.5	NS		

Results for TSS, IDIOMS, annual medical costs, and hospital days are reported as mean ± SEM. Data was analysed by ANOVA and between group comparisons were based on Newman–Keuls *post hoc* tests except for annual medical costs which were analysed by non-parametric tests. NS, non-significant; *$P < 0.05$.

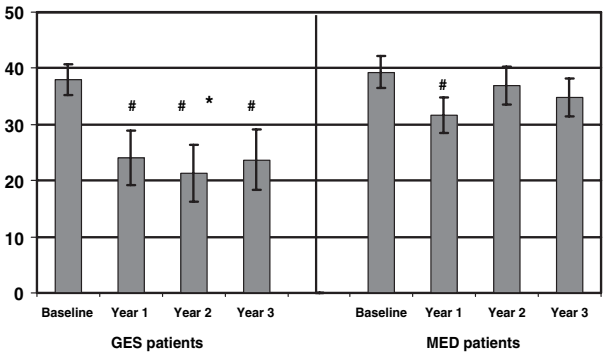

Figure 1 Total symptom scores. Within group comparison *vs* baseline: # $P < 0.05$. Between group comparison: *$P < 0.05$. Total symptom score (TSS) was significantly improved in year 1, 2 and 3 compared with baseline for the gastric electrical stimulation group, whereas MED group was significantly improved in year 1 compared with baseline. TSS was significantly different between groups in year 2.

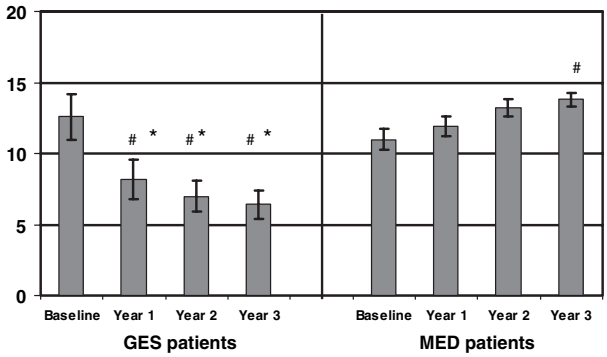

Figure 2 Investigator-derived independent outcome measure score (IDIOMS) ratings for gastric electrical stimulation (GES) and MED groups. Within group comparison: # $P < 0.05$. Between group comparison: * $P < 0.05$. IDIOMS ratings significantly decreased over time for the GES group whereas for the MED group, IDIOMS ratings significantly increased at years 2 and 3 compared with baseline. Mean IDIOMS ratings were significantly different between groups at all follow-up periods.

Although not stratified by individual symptoms, the greatest improvement in TSS was in the nausea and vomiting sub-scores.

Investigator-derived independent outcome measure score is shown in Fig. 2. Prior to treatment, between group comparison indicated that GES and MED groups were not significantly different with respect to IDIOMS (12.6 ± 1.6*vs* 11.0 ± 0.71, respectively). With treatment, between group comparison indicated that overall IDIOMS for the GES group was significantly better than overall IDIOMS for the MED group

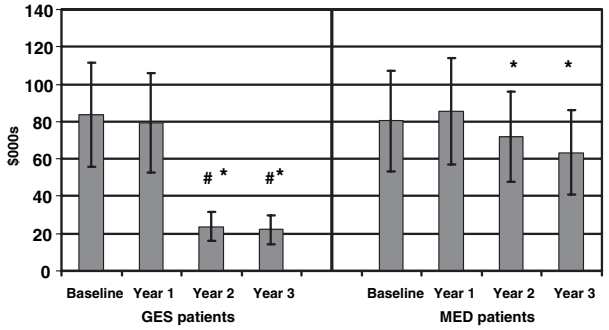

Figure 3 Annual costs. Annual costs for the gastric electrical stimulation (GES) and MED groups were obtained for medical billing records for 1-year prior to enrolment to 3 years after enrolment. Within group comparison *vs* baseline and *vs* year 1: $P < 0.05$. Between group comparison: * $P < 0.05$ GES costs in years 2 and 3 were significantly reduced compared with baseline and year 1. Cost in year 2 and year 3 were significantly different between the two groups.

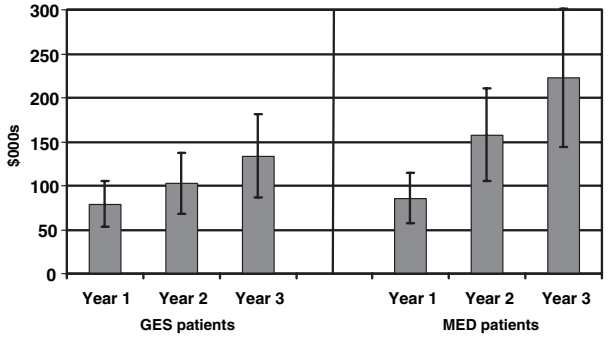

Figure 4 Cumulative costs. Cumulative costs for the first, second and third years after enrolment.

($F = 10.49$, $P < 0.017$). 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, IDIOMS significantly worsened at the year 2 and year 3 follow-up visits when compared with IDIOMS prior to treatment ($F = 14.94$, $P < 0.01$). Inter-rater reliability for IDIOMS was 0.96, $P < 0.001$ (repeated measures $N = 140$). GES patients experienced a significant improvement in IDIOMS from baseline (mean 12.6 ± 1.6) to year 3 (mean 6.4 ± 1.0) [$F = 14.04$, $P < 0.001$]. Significant differences from baseline to year 3 were noted (baseline = 11 ± 0.7; year 3 = 13.8 ±0.5) [$F = 14.94$, $P < 0.001$] for the MED group in the IDIOMS, but indicated more impairment over treatment period. Although not quantified in this study, the largest improvement in HRQOL was in the severity of illness component.

Annual health care costs are shown in Fig. 3. Prior to treatment, between group comparison indicated that GES and MED groups were not significantly different with respect to annual health care cost ($83 700 ± 27 000 *vs* $80 200 ± 26 700, respectively). With treatment, between group comparison indicated that overall health care costs for the GES group declined over time ($F = 8.81$; $P < 0.001$) but not for the MED group ($F = 1.73$; $P = 0.19$). Medical billing costs for the baseline period compared with the annual costs for the first, second, and third years of post-implantation for GES patients or enrolment for the MED patients are also shown in Fig. 3. Analysis of variance indicated that costs for the GES group declined over time ($F = 8.81$; $P < 0.001$) but not for the MED group ($F = 1.73$; $P = 0.19$). For the GES group, baseline costs were $83 665 ± 27 888, which declined slightly to $79 219 ± 26 406 at the end of the first year after enrolment. By the end of the second and third years, annual costs declined significantly, more than 70% from baseline to $23 748 ± 7916 ($P = 0.0022$) and $22 141 ± 7828 ($P = 0.0018$), respectively. For the MED group, baseline costs were $80 229 ± 26 743, which increased to $85 715 ± 28 572 at the end of the first year post-enrolment. Costs for the second and third years were $71 921 ± 23 974 and $63 426 ± 22 424. Changes in costs from baseline for the MED group, however, were not statistically significant. Second year ($P < 0.004$) and third year costs ($P < 0.004$) were significantly reduced compared with year 1 for the GES but not the MED group. Between group comparisons indicated there was no difference in annual costs at baseline between the MED and GES groups, but significant differences existed between groups emerged over the study time frame. Medical costs for the second ($P = 0.013$) and third years ($P = 0.010$) were significantly less for the GES group compared with the MED group. By the end of the third year, costs for the GES group were $41 285 less than for the MED group.

We also examined the MED group cost data with and without the three patients who died during the 3-year period. In the baseline year, the annual costs for the MED survivors was greater than for the patients who later died ($80 229 *vs* $67 152); in year 1, the average costs for the patients who later died was $112 087 *vs* $85 715 for the survivors; in the second and third years, the costs for the survivors was $74 712 and $55 443, *vs* $66 339 and $87 379 for those that died respectively.

Cumulative health care costs for year 1, 2, and 3 are shown in Fig. 4. By the end of the third year, the cumulative costs were $133 991 for the GES group and $222 470 for the MED group, a difference of $88 479.

Both groups manifested reduced length of hospital stays from baseline. In the GES group, hospital days decreased from a baseline mean of 36.4 to 2.76 days per year at the end of 36 months ($F = 4.04$, $P < 0.02$). In the MED group, hospital days decreased significantly from a baseline mean of 35.04 days a year to 6.48 days for 36 months ($F = 10.6$, $P < 0.001$). The length of stay data, and a summary of other data is shown in Table 1. Differences in hospital stay between groups were not statistically significant.

During the study period, three patients in the MED group died (one at home, two in the hospital) of i.v. access complications. No patients in the GES group died during the 3-year period.

DISCUSSION

This report is a preliminary study of a relatively small group of gastroparetic patients studied intensively in one center and comparing the outcomes of GES *vs* intensive outpatient medical therapy. In this sample of patients with GP, GES treatment improved GI symptoms, while decreasing costs and utilization of healthcare resources. The GES group GI symptom scores continued to show improvement across the study period, while their MED counterparts demonstrated a worsening in symptoms.

Use of healthcare resources (rating illness severity, intensity of service and other organ involvement) was assessed by IDIOMS, a global HRQOL measure, which served to differentiate the GES and MED groups from baseline to 3 years. While the GES patients demonstrated strong improvements in the IDIOMS from baseline to post-treatment, the MED patients demonstrated no improvement from baseline to 1 year. MED patients displayed increased impairment in IDIOMS from baseline through the second and third years, despite undergoing treatment. HRQOL has been deemed a vital measure in validating the clinical utility of a given treatment, and our previous work[8,9] has demonstrated significant correlation between IDIOMS and other HRQOL measures. Our sample of patients had proven intractable in terms of standard pharmacological treatment and had a relatively high level of disability, compared with other samples of patients with severe dyspepsia[20] or GP,[21] so the face validity of tracking healthcare resource usage in this chronically ill sample is apparent.

In this study, hospital charges (inpatient hospital charges, outpatient hospital charges, hospital medications and in- and out-patient nutritional feeding costs) were the main cost variables examined. Within group comparisons indicated that both the GES and MED groups utilized fewer hospital resources and manifested less cost with treatment, compared with baseline, over a 3-year follow-up period. Costs for the GES group for years 2 and 3 were significantly different and improved, which did not occur in the MED group. Lower costs for GES and MED patients were mainly because the length of inpatient hospital stays was reduced. Between group comparisons indicated, that the GES group costs at 1-year follow-up, even with the inclusion of initial surgical and device costs, were not significantly different from that of the MED group. However, as length of follow-up increased (year 1 to year 2, year 2 to year 3), between group comparisons consistently demonstrated the superiority of GES over MED treatment, in all cost and healthcare resource parameters. Compared with their outpatient cohorts (MED group), GES patients demonstrated a consistent pattern of reduced costs over a 3-year treatment period, showing a 73% reduction in costs from baseline to 36 months, while the MED patients showed a decrease of only 21% in costs for that time. However, both groups demonstrated a decrease in inpatient hospital days from baseline to 36 month: GES patients decrease from 36.4 to 2.76 days per year and the MED patients decreased from an average of 35.04–6.48 days.

We know of no prior reports on the longitudinal cost of care for patients suffering from GP. Bell[22] surveyed the North Carolina Hospital discharge database for the calendar year 1998 and reported an average cost per hospital visit of $7709 for patients with diabetic GP, a figure substantially lower that the annual costs for either the MED or GES groups in our study. Similarly, our costs of care for GP are significantly higher than other chronic GI disorders such as IBS where costs are reported in the range of $2952–5908 per year.[23] An argument could be made that cost-shifting *vs* cost-reduction occurred, in terms of the intensity of the medical therapy. However, it should be noted that our goal for the intensive outpatient medical therapy was to reduce hospitalizations for these patients (not reduce costs *per se*) and that goal was met. Nevertheless, the frequent outpatient visits, use of feedings and i.v. fluids, and medications certainly contributed substantially to costs for this intervention. Additionally, although our multidisciplinary team model of treatment (e.g. coordinated treatment with a gastroenterologist, nurse practitioner, psychologist, dietician, addictionist, physical therapist, social worker) was utilized in the medical therapy, our costs for treatment did not include individual provider charges. Cost for patients in the GES group also did not include any individual provider charges.

Examining patient mortality data across three years, three patients in the MED group died whereas none of

the GES patients died during that timeframe. One MED patient died in year 2, whereas the other two died during the third year. At least two of the three deaths were i.v. access related, which has previously been reported in patients with long-term i.v. access.[3–5] These deaths reduced our sample size, but highlights further the catastrophic nature of these severe GI motility disorders and the need for an intervention that can curtail venous access problems and potential life-threatening complications.

Limitations of the study include the extremely small sample size, potential skewing of data due to the high mortality rate in the medical controls and lack of population-based control data. However, 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. Given the progressive nature of these diseases[21,24] and the very limited pharmacological therapies available to patients, any treatment that can attenuate symptom severity and decrease utilization of healthcare resources is worthy of ongoing evaluation. We recognize the difficulty in separating treatment costs and HRQOL variables from co-morbid conditions in our small, and severely ill sample of patients.

Clearly, the health resource measure IDIOMS is not standardized and requires extensive further evaluation to establish its psychometric properties *vs* other practitioner ratings and standardized measures of HRQOL. This also holds true for the TSS measure and both are global measures that attempt to quantify the complex assessments of both patients and providers. However, we believe that the combined measurement of both the IDIOMS (provider assessment) and TSS (patient assessment) offer useful, clinically based tools that merit further investigation. Rockwood *et al.*[25] developed a similar tool for assessing the severity of fecal incontinence, comparing surgeon and patient ratings of symptoms, and found it to correlate significantly with a disease specific HRQOL.

Reviews of available HRQOL indices[26] suggest that use of global and or singular measures can be quite clinically useful, particularly in triaging limited resources. This work highlights the usefulness of the IDIOMS as a concise and valid measure of healthcare resource parameters, and suggests its usefulness in meta-analysis studies of patients with GP. Increasingly, researchers are arguing for more individual clinical significance in measurement of HRQOL in chronically ill patients as opposed to group data.[26,27] Clinical researchers also tout simple 'patient-friendly' HRQOL tools as enhancing clinical care delivery, especially in chronically ill patient populations.[24,26] Anecdotally, we have found that such intra-individual and ongoing measurement with patients greatly enhances their satisfaction with clinical care and improves the patient–provider relationship.

In our small sample of motility disorder patients, we conclude that GES is more effective in improving long-term GI symptoms and costs, and decreasing use of healthcare resources than intensive medical therapy, in this sample of patients with the symptoms of GP followed for 3 years and compared with 1 year of baseline measures. Clearly, even longer follow-up, with cleaner study design is merited, to continue to refine best practice treatment for these catastrophic GI illnesses. Lastly, this subset of patients with GP appear to represent a high risk group, in terms of costs, health-related QOL, morbidity and mortality. Finding tools and targeted, clinically effective treatments for such patient subsets can decrease the disproportionate drain on healthcare resources engendered by these chronically ill patients. Additionally, a more important aim here is the improved HRQOL and reduction in suffering for a population of catastrophically ill patients.

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APPENDIX: IDIOMS TOOL

Table A1 Investigator derived independent outcome measure scores (IDIOMS): a diagnostic and predictive model total scores = independent diagnostic outcome measure

Patient name:					Date:			By:	
1	2	3	4	5	6	7	8	9	10
None	Mild	Moderate			Severe			Very severe	
(A) Severity of illness (SOI)									
Mild/Moderate symptoms		Moderate symptoms			Severe symptoms			Very severe symptoms	
(B) Organs involved systems (OSI)									
(1) Gastrointestinal organ		(2) Organs			(3) Organs or systems and severe disease			>3 systems disease	
(C) Intensity of services (ISO)									
Medicines		Medicines and home health			Medicines, home medicines, health, hospitalizations			Home health multiple hospitalizations	