Efficacy of Gastric Electrical Stimulation for Gastroparesis: US/European Comparison

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Abstract

Background: Gastric electrical stimulation (GES) is used in both the US and Europe, but little research has investigated the demographics of gastroparesis patients receiving GES by geographic location.

Methods: We compared data from 380 patients, 296 female and 84 males, mean age 42 years, 246 idiopathic (ID), 107 diabetic (DM), and 27 post-surgical (PS). The statistical significance was calculated by Chi-square test and a P-value obtained for ID, DM, and PS. The statistical significance was calculated by Fischer exact test and a P-value obtained comparing male vs. female.

Results: European centers had 61 GES patients compared to 319 from the US. In Europe, 100% of patients had gastric emptying test (GET) values available; in the US, it was 75% of patients. European centers had more DM patients (59%) than the US (22%), and a smaller proportion of ID patients (25%) than the US (72%). There was a statistical difference between the causes of gastroparesis in the patients receiving GES (P-value < 0.00001). There was also significant difference in the gender of the patients receiving GES, with a greater proportion of women in the US (P value = 0.0023).

Conclusions: Comparing GES in US vs. Europe demonstrated significant differences in gastroparesis demographics and percentage of patients with GET data. After analyzing the previously discussed results and reviewing recent updates in evidence-based medicine guidelines, the discrepancy and variance in patient populations in the US and Europe emphasizes the need for a database that allows better

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analysis and treatment of gastroparesis patients worldwide including stimulation therapies.

Keywords: Gastroparesis; Nausea and vomiting; Gastric electrical stimulation; Diabetes; Health delivery

Introduction

Gastroparesis is characterized by clinical symptoms that may consist of bloating, anorexia, nausea, vomiting, early satiety and abdominal pain [1-3]. The etiology of gastroparesis is varied and includes diabetic, idiopathic, viral, autoimmune, and post-surgical gastroparesis [2, 3]. Often patients present with concomitant overlap syndromes, consisting of migraine headaches, interstitial cystitis, fibromyalgia, and systemic hypercoagulability [4-6]. The diagnosis is based on clinical presentation, full-thickness gastric biopsy, electrophysiological recording, and radionuclide emptying studies [7, 8]. Initial screening and diagnosis of gastroparesis rely on distinguishing the patient's symptom pattern as chronic or cyclic; this is a separate entity from cyclic vomiting syndrome [4, 9]. Up to 50% of diabetic gastroparesis patients, and many idiopathic gastroparesis patients, have a cyclic pattern [4]. Family history assessment is important, especially in the assessment of overlapping diseases, such as cyclic vomiting, clotting disorders, migraine, fibromyalgia, interstitial cystitis, bladder dysfunction, endometriosis, and depression [6, 10]. It is also important to be able to differentiate gastroparesis from gastroparesis like syndrome (GLS). These two diseases are incredibly difficult to differentiate by gastric emptying testing (GET) alone [11]. Recent investigations into distinguishing the two based on interstitial cells of Cajal (ICC) loss and fibrosis of the pylorus (with gastroparesis patients having worse features comparatively) are proving as better methods to determine which patients would benefit from more invasive therapies [12]. These diseases may have an impact on outcome, but not always a negative one for gastric electrical stimulation (GES) patient selection.

GES is an accepted therapy for drug-refractory gastroparesis; however, reports of efficacy have varied among centers. We aimed to compare the efficacy and the cause of GES at different centers from around the world using the latest comparative data available.

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Figure 1. The European centers (a) has a larger mean proportion of DGP patients compared to US centers (b) (59% vs. 22%) and a smaller mean proportion of IGP patients (25% vs. 72%). The figures show the number of patients (IGP, DGP, PGP) at each centre (A-H).

Materials and Methods

Consecutive patients with symptoms of gastroparesis who had gastric electric stimulators placed were evaluated at several centers in Western Europe and the US (Fig. 1a, b). The centers were selected by availability of data and willingness to share the results of evaluation and treatment. Seventy-five percent of US patients did not have formal GET studies, as there was not a standardized procedure in place at one of the US centers. For each center, the patients were recorded by: demographics (age and sex); underlying diagnosis (idiopathic gastroparesis (IGP), diabetic gastroparesis (DGP), and post-surgical gastroparesis (PGP)); percentage of centers where GET criteria were used; months since implant; percentage change gastrointestinal total symptom score (TSS). TSS included nausea, vomiting, anorexia/early satiety, bloating/distention, and abdominal pain, with a maximum score of 20. Data were normalized to a standardized scale if needed for analysis. Raw data were compared for the previously mentioned data points. Statistical significance was evaluated by Fischer exact test and P-value obtained for gender differences. Statistical significance was evaluated by Chi-square test and P-value obtained comparing IGP, DGP, and PGP. Each center had full regulatory and/or IRB approval for their site. All patients underwent informed consent as required by their respective institutions.

Results

Three hundred and eighty patients were available for analysis

tying data on each patient studied, while 75% of the patients studied at the US centers had baseline gastric emptying data recorded. The European patients were followed for a mean of 35 months after implant and the US centers followed the patients for a mean of 49 months after GES implant. Vomiting was decreased by 62% after GES implant in the European centers and by 45% in the US centers. In the European centers, the patients' TSS was decreased by 48%, while the US study population had a decrease of 38% in their TSS after GES implant. In Table 2, the gender characteristics of the patient populations in the US were compared to the European centers to determine if there was a significant difference. There was a

from eight centers (four in the US and four in Europe). Out of 380 total patients, there were 296 females and 84 males with a mean age of 42 years. The details of US vs. Europe are noted in

Table 1. The proportion of males to females was 1:4.2 in the US

centers, while it was 1:1.7 in the European centers. There were

246 patients with IGP, 107 patients with DGP, and 27 patients

with PGP. All of the European centers had baseline gastric emp-

significant difference in the gender populations between the two (P < 0.05). In Table 3, the number of patients with the three analyzed categories of gastroparesis was compared to assess for significant difference in the patient populations. There was noted to be a significant difference in etiology between the two regions (P < 0.05).

Discussion

This brief report is the first comparison of implantation of gastric electrical stimulators between the US and Europe. Many

Center	Number of patients	Sex: F	Sex: M	Age	IGP	DGP	PGP	GET	Months	Change in TSS
Europe	61	38	23	41	15	36	10	100%	35	-48
US	319	258	61	42	231	71	17	75%	49	-38
Combined	380	296	84	42	246	107	27	88%	47	-38.5

The proportion of males to females was 1:4.2 in the US and 1:1.7 in Europe. Values for GET, months since implant, change in vomiting, and change in total symptom score (TSS) are presented as means. IGP: idiopathic gastroparesis; DGP: diabetic gastroparesis; GET: gastric emptying test; F: female; M: male.

Table 1. Data From US and European Centers

Table 2.	Fisher Exact Test to Determine Gender Differences in
Gastropa	aresis Patients by Region

	Male	Female	Totals	P-value (< 0.05)
Europe	23	38	61	
United States	61	258	319	
Totals	84	269	380	< 0.05

of the patients appear similar in terms of GI symptoms and in age from the available data; however, sex distribution favors females in the US vs. Europe. Several other important differences are noted between the US and Europe from the numbers reported here. First, there are many more GES implants reported in the US than Europe. Secondly, the use of baseline GETs seems to be reported more, at least in this series, in Europe than the US. This is especially interesting, because 25% of GES patients in the US did not have a standardized GET study. Third, the percentage of diabetic patients implanted in Europe is higher than in the US.

It is becoming increasingly apparent that there is a difference in the manner by which patients are diagnosed, treated, and monitored in the US vs. Europe. Figure 2 details the algorithm by which gastroparesis patients are assessed and treated in the US vs. Europe, with differences highlighted in bold [13-15]. It should be noted that the difference between the two methodologies is that domperidone is approved and used in the treatment of gastroparesis in Europe but is not formally approved by the FDA in the US.

Recent investigations into the mechanism of gastroparesis have found that the loss of the ICC play a major role in pathogenesis. Their function is to regulate smooth muscle contractility by modulating slow wave progression [13, 14]. Recent studies have shown a reduction in these cells in biopsies of patients with gastroparesis. With this in mind, a literature investigation into the effectiveness of GES in treating gastroparesis was performed. Five meta-analyses and seven controlled trials were highlighted discussing GES as a treatment modality for gastroparesis (Tables 4 and 5) [16-28]. There was a generally favorable assessment of GES as a treatment for refractory gastroparesis (Table 5) [21-28].

As more GES devices are implanted worldwide, the need for an international registry is apparent. This would allow for increased standardization and comparison of outcomes in these patients. Having these data would allow for improved selection of appropriate candidates for GES [16, 17]. The lack of up-to-date data shows some of the difficulties in obtaining comparative data. Several recent articles have shown activities in both the US and Europe that may eventually lead to

Table 3. Difference Between the Etiologies of Gastropathy

 Treated with GES by Region

	IGP	DGP	PGP	Totals	P-value (< 0.05)
Europe	15	36	10	61	
United States	231	71	17	319	
Totals	246	107	27	380	< 0.05



Figure 2. Algorithm for diagnosis and treatment of gastroparesis in US vs. Europe (European differences in bold).

new advances in GES technology [29]. In addition, other new technologies, such as full thickness gastric biopsies and gastric electrical mapping, may reveal a better understanding of the underlying pathophysiology of gastroparesis, and this too may lead to advances in GES technology [30].

Further investigation and clarification is needed in differentiating GLS from functional dyspepsia (FD). GLS is defined as gastroparesis-like symptoms with normal gastric scintigraphy [31]. FD is defined by the Rome IV criteria and must include: 1) bothersome postprandial fullness, early satiation, epigastric pain, or epigastric burning and 2) no evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms. These criteria must be fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis [32]. There is substantial overlap between these two diagnoses, and, in the literature, there is occasionally even mention of FD with delayed GET [33]. This displays the difficulty in categorizing this disease process. The use of FD vs. GLS when discussing gastroparesis type symptoms with normal GET appears to vary based on geographical location, with FD being used more frequently in Europe and GLS more often in the US. There seems to be a growing movement away from categorizing these as separate entities, and rather as being along a spectrum of disease

Study title	Authors	General conclusion
NICE guidance on gastroelectrical stimulation for gastroparesis	Kong (2015) [17]	Severe diabetics with severe symptoms may benefit from therapy.
High-frequency gastric electrical stimulation for the treatment of gastroparesis: a meta-analysis	O'Grady et al (2009) [20]	Beneficial in improving symptoms in patients with gastroparesis.
Systematic review and meta-analysis: gastric electrical stimulation for gastroparesis	Levinthal et al (2017) [19]	Argues against the use of GES outside of strict clinical trials as viable treatment option.
Gastric electrical stimulation with the Enterra system: a systematic review	Lal et al (2015) [16]	GES appears to offer significant improvement in symptom control in a subset of patients.
Treatment of high-frequency gastric electrical stimulation for gastroparesis	Chu et al (2012) [18]	GES is an effective modality for treating gastroparesis refractory to less invasive treatment.

Table 4. Metanalyses Assessing Effectiveness of Gastric Electrical Stimulation

[33]. Recent studies have demonstrated patient improvement in symptom scores for FD and GLS with medical management and even GES in patients with symptoms of gastroparesis but normal GET [31, 34]. Further refinement and determination of specific definitions would allow for a more uniform treatment pattern for patients. By this, perhaps better and more effective treatments could be achieved.

An additional factor in future treatment of gastroparesis will be the emerging role of pyloric therapies in the treatment of gastroparesis, especially in patients with markedly delayed gastric emptying and who are refractory to other therapies. These possible future interventions include gastric peroral endoscopic pyloromyotomy (G-POEM), the process by which the plyoric muscles are endoscopically incised [35]. There has been recent investigation into this procedure as a viable option for refractory gastroparesis, and perhaps offers another means by which to treat this disease [36, 37]. Though this is a promising intervention, it has not been rigorously studied or evaluated, and, like GES, would also benefit from an international database for more comprehensive investigation [38].

Conclusions

This is the first international trial comparison of the use of GES for patients with the symptoms of gastroparesis confirming ef-

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Table 5.	Controlled	I rials A	Assessing	Effectiveness of	Gastric	Flectrical	Stimulation
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Study title	Authors	General conclusion
A double-masked, randomized, placebo-controlled trial of temporary endoscopic mucosal gastric electrical stimulation for gastroparesis	Abell et al (2011) [23]	Temporary GES may improve symptoms such as vomiting.
Gastric electrical stimulation is associated with improvement in pancreatic exocrine function in humans	Luo et al (2004) [25]	GES had noted effects on autonomic control, improvement in exocrine pancreatic enzyme release, and improvement in GI symptoms.
Gastric electrical stimulation for medically refractory gastroparesis	Abell et al (2003) [22]	GES set to high-frequency/low-energy decreased vomiting frequency and GI symptoms.
Gastric electrical stimulation with Enterra therapy improves symptoms of idiopathic gastroparesis	McCallum et al (2013) [26]	GES implanted with ON stimulation was shown to decrease vomiting symptoms and days of hospitalizations.
Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study	McCallum et al (2010) [27]	GES for 6 weeks significantly reduced vomiting and gastroparetic symptoms for diabetic gastroparesis.
Effectiveness of gastric electrical stimulation in gastroparesis: results from a large prospectively collected database of a national gastroparesis registry	Abell et al (2015) [24]	Patients treated with GES had clinically significant improvement in gastroparesis symptoms.
Gastric electrical stimulation (GES) for refractory vomiting: results of a prospective multicenter double- blinded randomized controlled cross-over trial	Ducrotte et al (2017) [21]	GES was associated with significant reduction of symptoms in both diabetic and non diabetic gastroparesis patients.
Is gastric electrical stimulation superior to standard pharmacologic therapy in improving GI symptoms, healthcare resources, and long-term healthcare benefits?	Cutts et al (2005) [28]	GES was found to be more effective in improving long-term GI symptoms, decreased costs, and less use of healthcare resources than intensive medical therapy.

fectiveness of GES. The specific localities studied, both US and Europe, reveal similarities but also differences between centers, particularly with respect to diabetic to IGP proportions. Ongoing prospective comparisons of outcome data are feasible and may be warranted with the continued clinical use of GES. In addition, the need for an up-to-date, hopefully online, database in registry format for international GES implants seems apparent.

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Author Contributions

Jordan Burlen, Minesh Mehta, and Matt Runnels: data analysis, manuscript preparation. Stina Andersson, Philippe Ducrotte, Guillaume Gourcerol, Greger Lindberg, Greg Fullarton, Hasse Abrahamsson, Amar Al-Juburi, Chris Lahr, Hani Rashed, and Thomas Abell: manuscript design, data acquisition, data analysis, manuscript preparation.

Conflict of Interest

Dr. Abell was an investigator, consultant and licensor to Medtronic when this data was collected.

Disclosures

EXACTS (European Across American Comparative Trial of Stimulation) is formed by: ASSESS (Associated Southern Sites of Electrical Stimulation Studies): T. Abell, M. Runnels, A. Al-Juburi, C. Lahr, H. Rashed, J. Burlen, M. Mehta; and EDGES (European Data of Gastric Electrical Stimulation): H. Abrahamsson, S. Andersson, P. Ducrotte, G. Gourcerol, G. Fullarton, G. Lindberg.

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