Original Article

Characteristics of patients who underwent gastric electrical stimulation vs. surgical pyloric interventions for refractory gastroparesis

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Abstract

Background: There has been recent debate comparing the efficacy of gastric electrical stimulation (GES) with pyloric intervention, but medical literature lacks clear indications for when to perform GES or pyloric intervention. This study aims to assess the effect of sociodemographic factors and hospital characteristics on the surgical technique chosen for the treatment of gastroparesis.

Methods: Data was extracted from the National Inpatient Sample between the years 2012 and 2014, using any discharge diagnosis of gastroparesis. For comparison of analysis between GES and pyloric surgical intervention, pyloroplasty, endoscopic pyloric dilation, and pyloromyotomy were considered to be pyloric interventions. The study population was divided into two groups, one which received GES and the other receiving pyloric intervention, to compare socioeconomic factors and hospital characteristics.

Results: In total, 737,930 hospitalizations had a discharge diagnosis of gastroparesis between 2012 and 2014. On weighted multivariant analysis of patients undergoing GES or pyloric intervention for gastroparesis, being female (odds ratio (OR) 1.49, 95% confidence interval (CI) 1.25–1.78; $P < 0.001$), being Hispanic (OR 1.75, 95%CI; $P < 0.001$), being in urban teaching (OR 1.41, 95%CI 1.15–1.72; $P < 0.001$), and nonteaching hospitals (OR 2.93, 95%CI 2.4–3.58; $P < 0.001$), early satiety (OR 6.70, 95%CI 1.54–31.25; $P = 0.01$), and diabetes mellitus (OR 2.14, 95%CI 1.78–2.56; $P < 0.001$) were each statistically significantly correlated with receiving GES intervention compared to pyloric intervention.

Conclusion: The racial difference, payer source, and hospital location affected the surgical intervention (GES or pyloric intervention) that patients with gastroparesis would receive.

Keywords: Gastroparesis, GES, pyloric intervention

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INTRODUCTION

Gastroparesis is a medical disorder of the stomach characterized by delayed gastric emptying in the absence of any mechanical obstruction. Symptoms usually involve nausea, vomiting, epigastric pain, bloating, and postprandial fullness. The pathogenesis usually involves gastric fundus tone abnormality, hypomotility of the antrum, or pyloric dysfunction. Pharmacological treatment is only useful in less than one-third of patients, after a year or longer.[1]

For the last two decade, high-frequency gastric electrical stimulation (GES) has been a treatment option for medically refractory gastroparesis. Several clinical studies have shown varying clinical improvement in 1 year, from 45 to 74%.[2–5] GES therapy was a significant advancement in the treatment of medically refractory gastroparesis. However, not enough medical literature is available from randomized controlled trials (RCTs) to prove its clinical safety and efficacy. The main hurdles in conducting long-term RCTs for GES with a large enough sample size is that it is an invasive procedure, and there are individual costs associated with it. Thus, researchers have been looking for alternative surgical techniques for medically refractory gastroparesis.

Over the last few years, pyloric-related therapy has emerged as a promising treatment for refractory gastroparesis. Some trials have shown that gastric peroral endoscopic pyloromyotomy (G-POEM) is 57–85% clinically beneficial at one year.[6-8] Shen *et al*.[9] recently published a study comparing G-POEM and GES, showing a response rate of 77% for G-POEM and 54% for the GES group after 2 years. However, pyloric dysfunction is only one of the components of gastroparesis' pathophysiology; there is more to it. Thus, one would not expect all gastroparesis symptoms to cease with pyloric therapy.

There has been recent debate comparing the efficacy of GES with pyloric intervention, but medical literature lacks clear indications for when to perform GES or pyloric intervention. No studies have been published about the nationwide use of these procedures. Although many factors can influence selecting one type of surgical intervention over another, socioeconomic factors and hospital characteristics have not yet been evaluated. This study aims to assess the effect of sociodemographic factors and hospital characteristics on the surgical technique chosen to treat gastroparesis.

Data source

This analysis used the 2012–2014 National Inpatient Sample (NIS) database. The NIS is part of the family of databases developed for the Healthcare Cost and Utilization Project (HCUP). It is the largest publicly available all-payer inpatient database in the United States, containing more than seven million hospital admissions per year. This database includes deidentified data on nationwide hospital admissions, including demographic information, discharge diagnoses, procedures, length of stay, hospitalization costs, and mortality. The database lists patients with a primary discharge diagnosis and up to 29 secondary discharge diagnoses.

Study population

The study population was selected using the International Classification of Diseases, Ninth Edition, Clinical modification, between 2012 and 2014. Patients who were hospitalized and discharged with a discharge diagnosis of gastroparesis (536.3) were included in the study. The exclusion criteria were age less than 18 years. Data on the patient demographics included age, gender, race, and median household income. Median household income was defined as the median income of each patient's household based on the reporting year's zip code. For payer status, patients were reported as using Medicare, Medicaid and private insurance, and being uninsured, which included self-pay or no pay. Hospitals were characterized based on total bed numbers, the hospital region, and whether they were rural/urban teaching hospitals.

The procedure-specific variables were constructed using ICD-9-Procedure Coding system codes as follows: GES (86.95 and 04.92), pyloroplasty (44.21 and 44.29), endoscopic pyloric dilation (EPD) (44.22), and pyloromyotomy (43.3). Diagnosis variables were constructed for nausea (787.02), vomiting (787.03), nausea with vomiting (787.01), early satiety (780.94), epigastric abdominal pain (789.06), bloating/flatulence (787.3), and acquired hypertrophic pyloric stenosis (537.0). For comparison of analysis between GES and pyloric surgical intervention, pyloroplasty, EPD, and pyloromyotomy were considered to be pyloric interventions. In this study, surgical intervention is usually referred to as either GES or pyloric intervention or both. The study population was divided into two groups, one which received GES and the other receiving pyloric intervention, to compare socioeconomic factors and hospital characteristics.

Statistical analysis

Statistical analysis was conducted using SPSS 27 (Statistical Package for the Social Sciences). Data were weighted using the discharge-level weight variable to create national estimates. The Chi-square test and Student's *t*-test, were used for categorical and continuous variables, respectively. Univariate analysis was initially performed to calculate

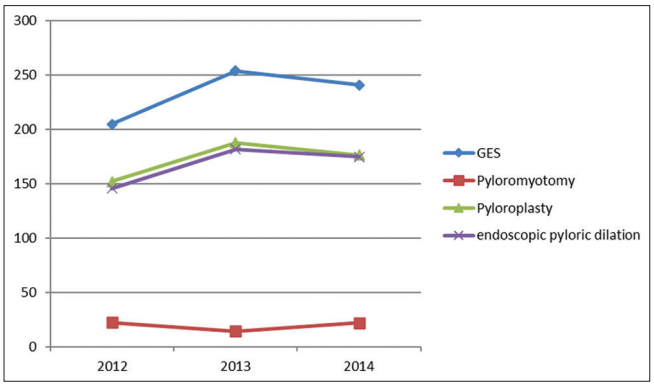

Figure 1: The line graph depicts number of respective procedures in each year

the unadjusted odds ratio (OR). Weighted multivariable regression was performed to assess independent risk factors for GES or pyloric intervention. A cutoff of $P < 0.05$ was used for statistical significance. The NIS-HCUP database was used for this study. The NIS database does not contain any patient's identifiers; therefore, we did not require any institutional review board permission for this study.

RESULTS

Gastroparesis

In total, 737,930 hospitalizations had a discharge diagnosis of gastroparesis between 2012 and 2014. Over the study period, the total number of hospital discharges for gastroparesis seemed to remain stable for 2012, 2013, and 2014 with 246,665, 242,180, and 249,085 discharges, respectively ($P < 0.001$).

Procedure

A proportion of patients (n = 4,325) with a discharge diagnosis of gastroparesis underwent surgical intervention: GES 40.9% (n = 1770), pyloromyotomy 3.4% (n = 145), pyloroplasty 30.5% (n = 1320), and EPD 28.6% (n = 1235). Over 2012 and 2013, the surgical interventions which increased were GES 24.04%, pyloroplasty 23.6%, and EPD 24.5%, but pyloromyotomy decreased 35.2%, all per 100,000 cases of gastroparesis. Over 2013 and 2014, procedures which decreased were GES 5.14%, pyloroplasty 5.9%, and EPD 3.84%, whereas pyloromyotomy increased 52.9%, all per 100,000 cases of gastroparesis, as shown in Figure 1.

Population demographics characteristics

The patient population that underwent GES placement was younger than those who underwent pyloric intervention (42.62 years vs 53.88 years, $P < 0.001$). Women mainly underwent GES rather than pyloric intervention (OR = 2; 95% confidence interval (CI) 1.74–2.32, $P < 0.0001$). White people were less likely to undergo GES over pyloric intervention (71% vs 75.9%, $P < 0.001$), whereas Black and Hispanic people were more likely to undergo GES (16.2% vs 11.8%, $P < 0.0001$) versus pyloric intervention (9.1% vs 8%, $P < 0.0001$). The median

Table 1: Comparison of gastroparesis patient demographics based on surgical intervention (GES vs. pyloric intervention). Age was reported as a mean with standard deviation (SD)

	GES n=1770	Pyloric intervention n=2555	P
Age	42.62 SD 13.44	53.88 SD 16.75	P<0.001
Gender			P<0.0001
Male	345 (19.5%)	835 (32.7%)	
Female	1425 (80.5%)	1720 (67.3%)	
Race/ethnicity			P<0.0001
White	1165 (71%)	1840 (75.9%)	
Black	265 (16.2%)	285 (11.8%)	
Hispanic	150 (9.1%)	195 (8%)	
Asian or Pacific Islander	15 (0.9%)	30 (1.2%)	
Native American	0	5 (0.2%)	
Other	45 (2.5%)	70 (2.7%)	
	Missing 130	Missing 130	
Median zip code income quartile			P=0.09
0-25%	430 (25.1%)	610 (24.2%)	
26-50%	515 (30%)	750 (29.8%)	
51-75%	375 (21.9%)	630 (25%)	
76-100%	395 (23%)	530 (21%)	
	Missing 55	Missing 35	
Primary payer			P<0.0001
Medicare	610 (34.5%)	1160 (45.5%)	
Medicaid	285 (16.1%)	380 (14.9%)	
Private insurance	795 (44.9%)	880 (34.5%)	
Self-pay	5 (0.3%)	65 (2.5%)	
No charge	0 (0%)	10 (0.4%)	
Other	75 (4.2%)	55 (2.2%)	
		Missing 5	

Table 2: Difference in hospital characteristics based on surgical Intervention (GES vs. Pyloric intervention)

	GES	Pyloric Intervention	*P*
Hospital region			*P*<0.0001
Northeast	290 (16.4%)	305 (11.9%)	
Midwest	320 (18.1%)	525 (20.5%)	
South	865 (48.9%)	1055 (41.3%)	
West	295 (16.7%)	670 (26.2%)	
Control/ownership of the hospital			*P*<0.0001
Govt, non-federal-public	315 (17.8%)	410 (16%)	
Nonprofit private	1250 (70.6%)	1685 (65.9%)	
Investor-owned private	205 (11.6%)	460 (18%)	
Teaching status of the hospital			*P*<0.0001
Rural hospital	565 (31.9%)	605 (23.7%)	
Urban non-teaching	480 (27.1%)	1170 (45.8%)	
Urban teaching	725 (41%)	780 (30.5%)	
Hospital bed numbers			*P*<0.0001
Small	420 (23.7%)	780 (30.5%)	
Medium	335 (18.9%)	660 (25.8%)	
Large	1015 (57.3%)	1115 (43.6%)	

income quartile did not have any statistical significance between GES and pyloric intervention. Medicare patients were more likely to undergo pyloric intervention than GES (45.5% vs 34.5%, $P < 0.001$), whereas Medicaid patients were more likely to undergo GES than pyloric intervention (16.1% vs 14.9%, $P < 0.0001$). Patients with private insurance had a 1.5 times higher chance of receiving GES than pyloric intervention (OR = 1.55, 95% CI 1.37–1.75; $P < 0.0001$) [Table 1].

Hospital characteristics

Patients in rural hospitals were more likely to undergo GES placement than pyloric intervention (31.9% vs 23.7%; $P < 0.001$). Patients in urban non-teaching institutions were more likely to undergo pyloric intervention than GES (45.8% vs 27.1%; $P < 0.001$). Patients in an urban teaching hospital were more likely to undergo GES than pyloric intervention (41% vs 30.5%; $P < 0.001$). In small- and medium-bed hospitals, patients were most likely to undergo pyloric surgical procedures (56.3% vs 42.6%; $P < 0.0001$). In hospitals with a large number of beds, GES intervention was 1.7 times more likely than pyloric intervention (OR = 1.74, 95% CI 1.54–1.96; $P < 0.0001$). Out of all hospital ownership types, it was mainly in no-profit private hospitals that patients received GES and pyloric intervention, at 70.6 and 65.9%. GES intervention was more likely in hospitals in the northeast and south than was pyloric intervention (65.3% vs 53.2%, $P < 0.001$), whereas pyloric intervention was more popular in the Midwest and West regions (47% vs 34.7%; $P < 0.001$) [Table 2].

Symptoms

Patients with vomiting had a 0.6% higher likelihood of receiving GES compared to pyloric intervention (OR = 1.006; 95% CI 1.002–1.009; $P < 0.001$). Patients with bloating/flatulence had 3.44 times higher chances of receiving pyloric intervention than GES (OR = 3.45; 95% CI 1.33–9.1; $P = 0.007$). Patients with diabetes mellitus (DM) had a 50% increased likelihood of receiving GES than pyloric intervention (OR = 1.5, 95% CI 1.30–1.71; $P < 0.0001$). Patients with acquired hypertrophic pyloric stenosis had a 200 times higher likelihood of receiving pyloric intervention than GES (OR = 200, 95% CI 83–500, $P < 0.001$). There was no statistical significance between GES or pyloric intervention for nausea, nausea with vomiting, or early satiety [Table 3].

A multivariant analysis was performed for GES versus pyloric intervention. It included age, gender, race, DM, nausea, vomiting, early satiety, epigastric abdominal pain, bloating/flatulence, insurance, and hospital characteristics such as region and teaching. On weighted multivariant analysis of patients undergoing GES or pyloric intervention for gastroparesis, being female, being Hispanic, being in urban teaching, and non-teaching hospitals, early satiety and DM, were each statistically significantly correlated with receiving GES intervention. On the other hand, being male, having Medicaid, self-paying, being in Midwest and West region hospitals and bloating/flatulence symptoms were more correlated with receiving pyloric intervention [Table 4].

DISCUSSION

In the analysis of gastroparesis-hospitalized patients undergoing surgical intervention, it was found that racial difference, payer source, hospital location, and bed

Table 3: Comparison of comorbid conditions between GES vs. Pyloric Intervention

	GES *n*=1770	Pylorus intervention *n*=2555	Odds ratio (95% confidence interval)	*P*
Nausea	30 (1.7%)	40 (1.6%)	1.08 (0.67-1.75)	*P*=0.74
Vomiting	10 (0.6%)	0	1.006 (1.002-1.009)	*P*<0.0001
Nausea with vomiting	65 (3.7%)	110 (4.3%)	0.85 (0.62-1.16)	*P*=0.30
Bloating/flatulence	5 (0.3%)	25 (1%)	0.29 (0.11-0.75)	*P*=0.007
Early satiety	10 (0.6%)	10 (0.4%)	1.45 (0.60-3.48)	*P*=0.41
Epigastric abd ominal pain	0	10 (0.4%)	0.996 (0.994-0.999)	*P*=0.008
DM	505 (28.5%)	540 (21.1%)	1.50 (1.30-1.71)	*P*<0.0001
Acquired hypertrophic pyloric stenosis	5 (0.3%)	940 (36.8%)	0.005 (0.002-0.012)	*P*<0.0001

Table 4: Weighted multivariable logistic regression GES versus pyloric intervention

Factor	Odds ratio for GES	95% Confidence Interval	*P*
Age	0.953	0.948-0.959	0.0001
Gender			
Male	0.67	0.56-0.80	0.0001
Race			
White	Ref	0.96-1.56	0.11
Black	1.22	1.30-2.36	0.0001
Hispanic	1.75	0.97-4.48	0.058
Asian or Pacific Islander	2.10		
Native American	0.69	0.43-1.11	0.124
Median zip code income quartile			
0-25%	Ref		
26-50%	1	0.81-1.23	0.997
51-75%	1	0.80-1.25	0.991
76-100%	1.22	0.97-1.54	0.084
Primary payer			
Private insurance	Ref		
Medicare	1	0.84-1.21	0.94
Medicaid	0.67	0.56-0.88	0.002
Self-pay	0.074	0.027-0.207	0.000
No charge	0	0	0.999
Other	1.52	0.97-2.38	0.067
Hospital region			
Northeast	Ref		
Midwest	0.67	0.51-0.88	0.003
South	1.04	0.82-1.33	0.76
West	0.54	0.41-0.71	0.0001
Teaching status of the hospital			
Rural hospital	Ref	2.4-3.58	0.0001
Urban non-teaching	2.93	1.15-1.72	0.001
Urban teaching	1.41		
Nausea and vomiting	1.07	0.70-1.65	0.76
Vomiting	0	0	0.99
Bloating/flatulence	0.19	0.059-0.59	0.004
Early satiety	6.70	1.54-31.25	0.012
Epigastric and pain	<0.005	0.00	0.999
DM	2.14	1.78-2.56	0.0001
AHPS	0.0056	0.0023-0.014	0.0001

numbers affected the surgical intervention which patients would receive. The patients who underwent GES were more likely female, Black, and Hispanic, those on Medicaid or those with private insurance. Similarly, patients admitted to non-profit hospitals with large bed numbers in the northeast, the midwest, and the southern regions were more likely to undergo GES than pyloric intervention.

In the study, patients with vomiting had a higher likelihood of undergoing GES than pyloric intervention. It was also mentioned in a 120 patients clinical study by Zoll *et al*,[10] that gastric stimulation improved nausea/vomiting, but in our analysis, this became statistically insignificant after accounting for socioeconomic and hospital characteristics. Patients with early satiety were more likely to receive GES, in contrast to other opinions contending that pyloromyotomy tended to improve early satiety and post-prandial fullness. Patients with bloating/flatulence were more likely to undergo pyloric intervention, in agreement with the other articles dealing with pyloromyotomy in relation to postprandial fullness.[11] The question remains as to who should receive GES or pyloric intervention, as there have been no clear indications for patients receiving either GES or pyloric intervention.

Clinical trials evaluating pyloric intervention's efficacy showed that it improved symptoms, especially in a vomiting and gastric emptying study.[12,13] There have been comparison studies evaluating GES or PS or both, and Zoll *et al*.[10] suggest that GES or combined GES + PS appear better for nausea/vomiting, predominantly refractory gastroparesis. However, all these studies were non-RCTs without a large enough sample size, without predefined criteria for GES surgical intervention or pyloric intervention. RCTs should be conducted to assess which symptoms improve following each surgical treatment.

The choice of surgical procedure also depends on the socioeconomic characteristics of the patients. The two most frequent sources of injustice are race and income/insurance status.[14] Black and Hispanic people more frequently received GES placement over pyloric intervention; however,

only being Hispanic persisted after adjusting for social, economic, and hospital factors. The reasons behind these racial disparities are not obvious. However, they might be related to differences in internal factors, such as genetic and environmental factors, causing a difference in gastroparesis pathophysiology. External factors might include limited access to higher-volume centres or patient inability or unwillingness to undergo surgery.[15]

Payer status is a key deciding factor in surgical care access, especially for complex and minimally invasive procedures.[16-18] Private and Medicaid patients were more likely to undergo GES placement, whereas Medicare patients underwent more pyloric intervention. Low socioeconomic gastroparesis patients are less likely to receive disease-specific intervention,[14] as there are only a few centres which perform GES placement, so people of lower socioeconomic status will not be able to afford to travel; nor will they have the proper insurance to cover their expenses for the surgical procedure. Therefore, the etiology of disparity between surgical interventions for gastroparesis also lies in differential reimbursement for novel procedures.

The use of geographic analysis to determine variations in GES or pyloric intervention has not been performed. Therefore, an analysis was conducted to determine the use of gastroparesis-specific procedures. It was found that GES intervention was more popular in north-eastern and southern hospitals, whereas pyloric intervention was more popular in the midwestern and western regions. However, after multivariate analysis, pyloric intervention remained popular only in the midwestern and western regions. Many broad-based studies have shown a difference in health outcomes based on geographic levels,[19-22] but no proper reason is known for this geographical variation with respect to surgical intervention. The hypothesis is that it might be related to patient, physician, or hospital factors. Surgeons' experience with either procedure may play a prominent role in selecting one type of surgical procedure over another.

Teaching hospitals provide medical education and clinical training to healthcare professionals. They are well known for treating rare medical conditions and receiving peripherally referred patients. Since GES is a comparatively newer therapy, one would expect it to be more prevalent in urban teaching hospitals, and it is as per this study. However, after accounting for socioeconomic and hospital characteristics, it became more common in urban non-teaching hospitals. One speculation is that teaching hospitals follow more evidence-based principles, and all RCTs[5,23–25] for GES have failed to show their superiority over medical treatment. This might be why urban teaching hospitals are moving towards pyloric intervention to treat refractory gastroparesis.

Several limitations of our study should be considered. Although NIS is the largest inpatient US database, its survey data has the potential for inaccuracies. It only includes inpatient data, so it does not include GES or pyloric intervention performed on outpatients. Additionally, since this database is reported using ICD-9 codes, bias might exist due to poor documentation. We only used procedural codes for gastroparesis patients; there is a possibility that procedures were performed for other indications.

CONCLUSION

This study showed that demographic and socioeconomic disparities exist in the surgical distribution of care for refractory gastroparesis. We need to understand gastroparesis' pathophysiology better to understand which patients will benefit from each type of surgical treatment. We need more studies, especially RCTs comparing the efficacy of both surgical interventions. These clinical trials should be conducted with an adequate sample size and should be conducted over a more extended period, for 1–2 years, to honestly assess surgical treatment durability.

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Conflicts of interest

There are no conflicts of interest.

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