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Similarities and Differences between Diabetic and Idiopathic Gastroparesis

The NIDDK Gastroparesis Clinical Research Consortium (GpCRC)[*,†]

Abstract

Background & Aims—Gastroparesis can be diabetic or idiopathic, yet little is known about differences in their presentation. We compared clinical characteristics, symptoms, and gastric emptying in patients with type-1 or -2 diabetic (DG) or idiopathic (IG) gastroparesis.

Methods—We analyzed data from 416 patients with gastroparesis who were enrolled in the NIDDK Gastroparesis Registry; 254 had IG (most were female and Caucasian), and 137 had DG (78 had type-1 and 59 had type-2). Registry data included detailed histories, physical examinations, results from gastric emptying scintigraphy (GES), and responses to validated symptom questionnaires.

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Members of the Gastroparesis Clinical Research Consortium are listed in supplemental table 1.

No conflicts of interest exist.

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Results—Patients with type-2 DM were an average of 13 years older at the onset of symptoms of gastroparesis and heavier than patients with IG. Patients with type-1 DM had more hospitalizations in the past year than patients with IG. Symptoms that prompted evaluation more often included vomiting for DG and abdominal pain for IG. Patients with DG had more severe retching and vomiting than those with IG, whereas patients with IG had more severe early satiety and postprandial fullness sub-scores. Compared to IG, gastric retention, was greater in patients with type-1DM. More than 50% of patients with type-1 DM had severe retention (>35% at 4 hours); they took prokinetic agents more frequently and were more likely to receive gastric electric stimulation.

Conclusions—There are similarities and differences in clinical characteristics of DG and IG. Gastroparesis is a heterogeneous disorder; its etiology affects symptoms and severity. Long-term studies are needed to determine if the differences in symptoms and gastric emptying affect progression and treatment responses.

Keywords

stomach disorder; nausea; vomiting; gastric emptying; digestion; NIDDK Gastroparesis Clinical Research Consortium

INTRODUCTION

Gastroparesis can result from several disorders including diabetic gastroparesis (DG) and idiopathic gastroparesis (IG) (1,2). Symptoms of gastroparesis are variable. Early satiety, postprandial fullness, and vomiting are associated with delayed emptying in functional dyspepsia (3,4). In IG, increasing gastric retention is associated with increasing severity of vomiting (5). Abdominal pain can be present in some patients and seems to be more prevalent in IG (6,7). In diabetes, abdominal fullness and bloating have been associated with delayed gastric emptying (8).

DG and IG appear to have different pathophysiology. Patients with DG may have vagal nerve dysfunction, whereas patients with IG do not (9). Common cellular abnormalities are loss of interstitial cells of Cajal, inflammatory infiltrate, and decreased nerve fibers (10,11). Nitric oxide synthase expression appears to be decreased in more IG patients compared to DG (11).

Most studies of gastroparesis have combined patients with DG and IG, but whether DG and IG differ in their phenotypic presentation is not known. The aim of this study was to describe the similarities and differences between patients with DG and IG, focusing on demographics, symptom profiles, gastric emptying, and quality of life.

METHODS

The National Insitutes of Diabetes and Digestive and Kidney Diseases Gastroparesis Clinical Research Consortium is a cooperative network of seven clinical centers and one Data Coordinating Center. The Gastroparesis Registry (GpR) (ClinicalTrials.gov Identifier: NCT00398801) was implemented as an observational study of patients with gastroparesis. Enrolled patients met specific entry criteria: 18 years or older; symptoms of at least 12 weeks duration; delayed gastric emptying; and no structural abnormality on upper endoscopy.

During interviews, case report forms were completed including data relating to symptoms, associated medical conditions, and medication and supplemental therapies. Clinical severity of gastroparesis (12) was graded as grade 1: mild gastroparesis (symptoms relatively easily

controlled and able to maintain weight and nutrition on a regular diet); grade 2: compensated gastroparesis (moderate symptoms with only partial control with use of daily medications, able to maintain nutrition with dietary adjustments); grade 3: gastric failure (refractory symptoms that are not controlled as shown by the patient having ER visits, frequent doctor visits or hospitalizations and/or inability to maintain nutrition via an oral route).

The Patient Assessment of Upper GI Symptoms (PAGI-SYM) questionnaire assesses symptoms of gastroparesis, dyspepsia, and gastroesophageal reflux disease (13) including symptoms of the Gastroparesis Cardinal Symptom Index (GCSI) (14). Severities of symptoms during the previous two weeks were graded from 0 to 5: no symptoms = 0 and very severe = 5.

Disease-specific quality of life was assessed with Patient Assessment of Upper Gastrointestinal Disorders Quality of Life (PAGI-QOL) survey, which scores 30 factors from 0 (none of the time) to 5 (all of the time) over the past 2 weeks (15). Overall PAGI-QOL scores were calculated by taking means of all subscores after reversing item scores; a mean PAGIQOL score of 0 represents poor quality of life while 5 reflects the best life quality.

The Medical Outcomes Study 36-Item Short-Form Health Survey version 2 (SF-36v2) was used to assess the patients' views of overall physical and mental health. The 8 subscales were standardized to the 1998 U.S. general population with a mean (±SD) of 50±10. A higher score reflects higher quality of life (16).

Psychological functioning was assessed using Beck Depression Inventory (BDI) and State-Trait Anxiety Inventory (STAI). BDI is a 21-question inventory assessing depression, cognition, and physical well-being (17). Each answer is scored on a scale of 0 to 3. Higher total scores indicate more severe depressive symptoms. STAI consists of 20 questions relating to state anxiety (a temporary or emotional state) and 20 questions pertaining to trait anxiety (long standing personality trait anxiety with a general propensity to be anxious) (18).

Investigator derived independent outcomes measure score (IDIOMS) includes parameters associated with healthcare resource use: intensity of service, severity of illness, and number of non-GI organ systems involved (19). Each parameter is rated on a 10-point scale are summed for a total score ranging from 0 to 30.

Gastric emptying scintigraphy (GES) was performed using a low-fat, egg white meal with imaging at 0, 1, 2, 4 hours (20,21). Delayed gastric emptying (gastric retention >60% at 2 hours and/or >10% at 4 hours) was graded according to the gastric retention at 4 hours: mild (≤20% gastric retention at 4 hours), moderate (>20 to 35%), and severe (>35%) (21).

This report focuses on patients with either IG or DG enrolled from January 2007 to March 15, 2010. Since studies with DG have suggested some differences between T1DM and T2DM (23), the data in diabetic patients are reported for T1DM and T2DM. Some data included in this manuscript were included in prior publications of earlier, smaller cohort of subjects in the GpR on idiopathic gastroparesis (5) and psychological dysfunction in gastroparesis (23).

Statistical Methods

We conducted an exploratory analysis of a set of baseline characteristics of scientific merit including demographic, lifestyle, anthropometric, gastroparesis specific medical history, symptom severity scores, gastric emptying results, medications, co-morbidities, psychological inventory scores and quality of life assessments. The set of characteristics

were analyzed using univariable and multivariable logistic regression analyses for each of the gastroparesis sub-groups of interest (idiopathic, T1DM, T2DM). Univariable results are expressed as mean±standard deviation (SD) or by percentages. Statistical significance of differences in clinical features comparing all diabetics and each of the diabetic subgroups with idiopathics was tested using either a chi-square test for non-ordered categories, Fisher's exact test, or a Cochran-Armitage test for trend for ordered categorical features. Continuous features were analyzed using a Kruskal-Wallis test (24).

Independent characteristics associated with either T1DM and IG or T2DM and IG were determined from fitting the pooled set of characteristics with significance at the 0.05 level from bi-directional stepwise (both forward and backward) multiple binary logistic analyses (25). Both final models had respectable goodness of fit using the Hosmer-Lemshow Goodness of Fit test.

P values are two-sided, nominal, with a level of 0.05 considered to be statistically significant. Both SAS v9.1 (SAS Institute, Cary, NC) and Stata release 11 (Stata Corp, College Station, TX) statistical software were used (26).

RESULTS

Study subjects

Of 416 patients with gastroparesis, 25 patients were diagnosed with other causes of gastroparesis (e.g., post-surgical) and were too few to be included. There were 391 patients with IG or DG enrolled into the NIDDK GpR at the time of data analyses (November 15, 2010): 254 patients with IG and 137 with DG (78 patients with T1DM and 59 patients with T2DM).

Demographics

The majority of the patients were women (83% overall) regardless of etiology; IG patients were most likely to be female (idiopathic: 89%, T1DM: 71%, T2DM: 76%; p<0.001) (Table 1). Most patients were Caucasian (85% overall); IG were more commonly Caucasian (90% IG, 77% T1DM, 76% T2DM; p=0.001). Patients with T2DM were older at enrollment (41±14 years for IG, 39±11 T1DM, 53±11 T2DM; p<0.001) and heavier (BMI of 25.7±6.9 kg/m^2 for IG, 26.1±6.0 T1DM, 33.4±7.5 T2DM; p<0.001) than IG. Overall, 71% of patients with T2DM were obese (BMI>30 kg/m^2) compared to 26% for IG and 28% for T1DM.

Symptoms

T2DM were older at onset of symptoms (36±15 years IG, 34±10 T1DM, 49±11 T2DM; p<0.001) (Table 2). T1DM had a longer duration of symptoms (4.9±6.6 years IG, 6.2±6.3 T1DM, 4.1±3.3 T2DM; p=0.06). DG and IG had similar percentages of patients reporting an acute onset of symptoms (51% IG, 59% T1DM, 46% T2DM; p>0.05) and an initial prodrome present at the start of their symptoms (19% IG, 14% T1DM, 14% T2DM; p=0.24). Nausea was the most common symptom prompting evaluation for gastroparesis for T2DM: 84% IG, 85% T1DM, 95% T2DM. Vomiting was the most common symptom prompting evaluation for T1DM and T2DM: 60% IG, 89% T1DM, 92% T2DM; p<0.001. Abdominal pain was more often a symptom prompting evaluation for IG (76% IG, 60% T1DM, 70% T2DM; p=0.01). The nature of gastroparesis symptoms was similar among the different etiologies: 20% having chronic but stable symptoms, 33% having chronic but worsening symptoms, 33% having chronic symptoms with periodic exacerbation, and 10% having a cyclic pattern. Patients with T1DM were more likely to have grade 3 gastroparesis severity (29% IG, 49% T1DM, 39% T2DM; p<0.001).

The symptoms with highest severity at enrollment were stomach fullness and postprandial fullness for IG, nausea for T1DM, and stomach fullness for T2DM. DG had more severe retching (1.8±1.8 IG, 2.4±1.7 T1DM, 2.5±1.7 T2DM; p=0.001) and T1DM had more severe vomiting (2.0±1.9 IG, 2.7±1.8 T1DM, 2.4±1.7 T2DM; p=0.003) than IG, whereas IG patients had more severe early satiety (3.6±1.4 IG, 2.9±1.5 T1DM, 3.2±1.2 T2DM; p<0.001), postprandial fullness (3.7±1.3 IG, 3.3±1.5 T1DM, 3.5±1.3 T2DM; p=0.02), and upper abdominal pain (3.1±1.7 IG, 2.8±1.9 T1DM, 2.8±1.7 T2DM; p=0.10). IG had more severe stomach fullness (3.7±1.2 IG, 3.2±1.6 T1DM, 3.6±1.0 T2DM; p=0.03) than T1DM.

Gastric emptying

Gastric retention was greater in T1DM (28±19% at 4 hours for IG, 47±27 T1DM, 33±24 T2DM; p<0.001) (Table 2). Patients with T1DM were more likely to have severe gastroparesis (>35% retention at 4 hours) than IG: 29.3% IG, 53.9% T1DM, 32.2% T2DM (p≤0.001).

Treatment

More than half of patients were treated with a prokinetic agent, antiemetic agent, and proton pump inhibitor (Table 3). Prokinetic use at enrollment was higher in DG compared to IG (49% IG, 69% T1DM, 64% T2DM; p<0.001). Among the prokinetic agents, the use of metoclopramide was higher in DG compared to IG (21% IG, 45% T1DM, 39% T2DM; p<0.001), with similar use of domperidone (22% IG, 24% T1DM, 21% T2DM) and erythromycin (6% IG, 10% T1DM, 3% T2DM). There was no significant difference in use of antiemetic agents or narcotic pain medications. Patients with T1DM were more likely than IG to be treated with gastric electric stimulation: 5.9% IG, 15.4% T1DM, 3.4% T2DM (p=0.01).

Hospitalizations, comorbidities, and quality of life

T1DM patients had more hospitalizations over the prior year than IG (1.6±3.0 IG, 5.1±6.4 T1DM, 2.7±5.7 T2DM; p<0.001) (Table 3). Hospitalizations for T1DM patients, as compared to IG, were more likely due to intractable nausea/vomiting (41% IG, 72% T1DM, 44% T2DM; p<0.001) and dehydration (32% IG, 65% T1DM, 41% T2DM; p<0.001).

Patients with T2DM had higher number of comorbidities than IG (3.7±2.8 IG, 4.0±2.8 T1DM, 5.6±3.5 T2DM; p<0.001). IG had an increase in endometriosis and migraine headaches, whereas T2DM had an increase in coronary artery disease.

Total investigator derived independent outcome measures score (IDIOMS) was highest for DG (13.5±4.7 IG, 17.5±5.4 T1DM, 15.1±4.7 T2DM; p<0. 001). The components “other significant illness” and “intensity of services” were highest for T1DM (Supplementary Table 2).

Similar results were obtained in the psychological inventories, BDI and STAI, for IG and DG (Table 3). There was a slight increase in feelings of hopelessness as assessed by BDI and a slight increase in the trait anxiety score in T1DM patients compared to IG.

The overall impairment in quality of life, as assessed by PAGI-QOL and the SF-36v2, is shown in Table 3. Using SF-36, both types of patients averaged scores well below the U.S. average. DG patients perceived a lower general health view than IG patients (p<0.001). On average, T2DM have lower physical health summary scores than IG (34.0±10.3 IG, 32.6±10.0 T1DM, 29.6±9.2 T2DM; p=0.005), while T1DM patients report lower mental health summary scores than IG (37.6±12.5 IG, 34.2±12.4 T1DM, 37.3±13.0 T2DM;

p=0.03). Using PAGI-QOL, IG reported more negative impact on their well-being concerning their diet due to gastrointestinal issues compared to those with DG (p=0.002).

Multivariable analysis

Multivariable analyses was performed to identify independent characteristics among gastroparesis subgroups (idiopathic, T1DM, T2DM) (Table 4). T1DM compared to IG were more likely to have severe gastric retention on GES (OR=4.44; p<0.001), were more often taking prokinetic agents (OR=2.07; p=0.03), more often had gastric electric stimulator (OR=3.69; p=0.01), and had more hospitalizations in the last year (OR=1.16; p<0.001). T1DM were more likely to have a lower mental health summary score (OR=0.96; p=0.01). Idiopathics had more severe inability to finish a meal (OR=0.76; p=0.02), lower QOL for diet due to their gastroparesis issues (OR=1.60; p=0.003) and were more often Caucasian (OR=0.32; p=0.004).

Patients with T2DM compared to IG were more likely to have a higher QOL on general activities due to gastroparesis issues (OR=2.75; p<0.001), but had lower physical and mental health summary scores (OR=0.88; p<0.001, OR=0.93; p=0.001, respectively). T2DM had more severe retching than idiopathics (OR=1.26; p=0.04), were more likely to be over 45 years at onset of symptoms (OR=3.64; p<0.001), and were more likely to be overweight or obese (OR=5.45; p<0.001). In contrast, IG were more often white (OR=0.23; p=0.001) and had more severe symptoms of lower abdominal pain (OR=0.66; p=0.002).

DISCUSSION

This study reports on a large series of patients with gastroparesis and highlights the similarities and differences among IG and DG. Our study identifies that while there are many similarities, there are differences in the symptoms, gastric emptying abnormalities, and quality of life among patients with GP depending upon the etiology. There is a striking female predominance in both IG and DG, but more so for IG. Patients with IG had more early satiety compared to patients with DG, who had more severe retching, and for T1DM, greater retention on gastric emptying scintigraphy and gastric failure.

Nausea was nearly universal in the patients with gastroparesis, being a reason for gastroparesis evaluation in both DG and IG. Patients with DG had more severe vomiting and retching than IG whereas IG had more severe early satiety and excessive fullness. On multivariable analysis, the main symptom differences were more severe early satiety in IG compared to T1DM and more abdominal pain in patients with IG compared to T2DM and more severe retching in T2DM. Few other studies have compared the symptoms of DG and IG. Upper abdominal pain has been reported to be more common in IG compared to DG (6,7). Symptoms during GES of stomach fullness and abdominal pain were more severe in IG than DG (27). Another study reported patients with DG experience greater nausea (28).

The heterogeneity of symptoms among patients with GP may stem from different pathogenic mechanisms. DG, but not IG, is characterized by vagal nerve dysfunction (9). The differential perception of nausea in DG versus IG has been suggested to be due to autonomic neuropathy (28). Abdominal pain has been reported to be an important symptom for some patients with gastroparesis (6,7). Abdominal pain may be associated with hypersensitivity to gastric distension (29), and not to severity of delayed gastric emptying (7). Thus, IG may have more sensory and/or accommodation dysfunction with abdominal pain and fullness predominating; whereas DG may be more motor dysfunction-induced symptoms with vomiting and delayed emptying predominating.

An acute onset of symptoms was reported in approximately half of the patients in each of the IG, T1DM, and T2DM. An initial prodrome was present at the start of symptoms in a minority, approximately 15% of cases, without significant differences among the three groups. Infectious prodrome suggesting a viral etiology with damage to the enteric nervous system and ICCs, is usually thought of for IG (30,31). Our results suggest this may also apply for DG.

Gastroparesis occurs more commonly in females. This has been reported for IG (2,5) and was confirmed in this large study for both IG and DG. The female predominance in gastroparesis is poorly understood. Females also predominated in DG, a disorder where the delayed gastric emptying is thought to be from vagal nerve impairment and hyperglycemia. Female patients may be overrepresented since symptoms of functional gastrointestinal disorders are more prevalent in females and symptoms trigger diagnostic work-up. However, the female predominance is unlikely to be only due to this as it was also present in patients with severe delays in gastric emptying and in diabetics. Patients with T2DM were older and heavier. This may relate to the type of patients that develop T2DM irrespective of gastroparesis (32).

Gastric retention on GES was greater in T1DM than in IG. Interestingly, the T1DM group also had greater vomiting severity, while on multivariable analysis; the idiopathic group had more severe early satiety. In DG, T2DM have more nausea and early satiety although patients with T1DM have severe gastric retention than patients with T2DM (23). HgbA1c averaged 8.3% for T1DM and 7.4% for T2DM, compared to 5.4% for patients with IG. However, glucose levels were not assessed during the gastric emptying tests or when symptom assessments were made and symptoms were not assessed during the gastric emptying test. Hyperglycemia is known to slow gastric emptying and might impact on symptom severity (33).

This study captured treatment the patients were taking at the time of enrollment. Each group used prokinetic agents and antiemetic agents. DG were more likely to be taking prokinetic medications compared to IG whereas there was no significant difference for the use of antiemetic agents or narcotic pain medications. Interestingly, the increase in prokinetic use by diabetics is comprised almost exclusively of an increase in use of metoclopramide in this group while erythromycin and domperidone use were similar across etiologies. More patients were treated with gastric electric stimulation if they had T1DM than if they had IG, which probably reflects the current opinion that stimulation improves predominantly nausea and vomiting particularly in DG (34,35). This may also be explained by the longer duration and more severe symptoms of patients with DG.

Comorbidities were prevalent across the patient groups. This may reflect the tertiary referral nature of the patients entering this registry. Patients with DG appear to be more ill than patients with IG. DG had a higher number of comorbidities and hospitalizations than IG. The investigator derived independent outcome measures score was highest for T1DM; the components of intensity of services score and other significant illness score were highest for T1DM (20). T1DM patients had a lower SF-36 mental health summary score, while T2DM patients had lower physical and mental health summary scores compared to IG.

In summary, this large series of patients with gastroparesis highlights similarities and differences among patients with DG and IG. Gastroparesis is a heterogeneous disorder not only in symptoms but also in its severity. Patients with IG have more early satiety whereas patients with DG have more severe retching and greater gastric retention. Thus, in clinical practice, although patients with gastroparesis have a variety of similarities in their clinical presentation, patients with IG can have abdominal pain and less severe delayed gastric

emptying, whereas DG have more nausea and vomiting and more delayed gastric emptying. Longitudinal follow-up of these patients will determine if these differences in symptoms and gastric emptying influence the natural history and responses to treatment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Demographic, lifestyle and physical characteristics

Characteristic	Idiopathic (N=254) N (% or mean)*	Type 1 Diabetic (N=78) N (% or mean)*	Type 2 Diabetic (N=59) N (% or mean)*	Pairwise *P* value† Id vs. All DM	Id vs. T1DM	Id vs. T2DM
Demographic:						
Gender: Female	225 (88.6%)	55 (70.5%)	45 (76.3%)	**<0.001**	**0.001**	**0.01**
Age at enrollment (years):				**0.02**	**0.03**	**<0.001**
18 –30	76 (29.9%)	21 (26.9%)	1 (1.7%)			
31 – 44	82 (32.3%)	33 (42.3%)	15 (25.4%)			
45 –59	70 (27.6%)	23 (29.5%)	24 (40.7%)			
60+	26 (10.2%)	1 (1.3%)	19 (32.2%)			
Average age at enrollment (years)	41.0 ± 14.2	38.9 ± 10.9	53.1 ± 11.0	**0.004**	0.37	**< 0.001**
Ethnicity: any Hispanic	7 (2.8%)	7 (9.0%)	5 (8.5%)	**0.01**	**0.03**	**0.05**
Race:				**0.001**	**0.008**	**0.01**
White	229 (90.2%)	60 (76.9%)	45 (76.3%)			
Black	16 (6.3%)	13 (16.7%)	10 (17.0%)			
Other	9 (3.5%)	5 (6.4%)	4 (6.8%)			
Marital status: Married or with partner	148 (58.3%)	42 (53.9%)	38 (64.4%)	0.98	0.49	0.39
College degree or higher (yes)	84 (33.1%)	15 (19.2%)	12 (20.3%)	**0.005**	**0.02**	0.06
Currently employed (yes)	128 (50.4%)	27 (34.6%)	20 (33.9%)	**0.002**	**0.01**	**0.02**
Missed work for > 2 weeks from gastroparesis	82 (32.3%)	21 (26.9%)	10 (17.0%)	**0.04**	0.37	**0.02**
Occupation category (best for lifetime)				**0.05**	0.46	**0.007**
Laborer	23 (9.1%)	10 (12.8%)	14 (23.7%)			
Professional	130 (51.2%)	35 (44.9%)	29 (49.2%)			
Other	101 (39.8%)	33 (42.3%)	16 (27.1%)			
Income: $50,000+ (yes vs no)	146 (57.5%)	36 (46.2%)	25 (42.4%)	**0.01**	0.08	**0.04**
Lifestyle factors:						
Ever smoked regularly‡ (yes vs no)	84 (33.1%)	23 (29.5%)	23 (39.0%)	0.38	0.27	0.56
Frequency of drinking in past year:				0.36	0.73	0.27
Never	154 (60.6%)	51 (65.4%)	39 (66.1%)			

Characteristic	Idiopathic (N=254) N (% or mean)*	Type 1 Diabetic (N=78) N (% or mean)*	Type 2 Diabetic (N=59) N (% or mean)*	Pairwise *P* value† Id vs. All DM	Id vs. T1DM	Id vs. T2DM
Monthly or less	68 (26.8%)	19 (24.4%)	17 (28.8%)			
More than monthly	32 (12.6%)	8 (10.3%)	3 (5.1%)			
Anthropometric:						
BMI (kg/m^2)	25.7 ± 6.9	26.1 ± 6.0	33.4 ± 7.5	**< 0.001**	0.37	**< 0.001**
BMI category:				**< 0.001**	0.36	**< 0.001**
Underweight (<18 kg/m^2)	19 (7.5%)	2 (2.6%)	0 (0.0%)			
Normal (18– 24 kg/m^2)	117 (46.1%)	37 (47.4%)	8 (13.6%)			
Overweight (25–30 kg/m^2)	53 (20.9%)	17 (21.8%)	9 (15.3%)			
Obese (>30 kg/m^2)	65 (25.6%)	22 (28.2%)	42 (71.2%)			

*Values are mean ± standard deviation or n (%). Id=Idiopathic, DM=Diabetic, T1DM=Type 1 Diabetic, T2DM=Type 2 Diabetic

†*P* values (two-sided) determined from either a chi-square test for non-ordered categories, a Fisher's exact test or the Cochran-Armitage trend test for ordered categories for categorical variables, or a Kruskal-Wallis test for continuous variables.

‡Smoked regularly defined as smoking more than 20 packs of cigarettes in a lifetime or greater than 1 cigarette a day for one year

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Table 2

Medical history, symptom severity and gastric retention

Characteristic	Idiopathic (N=254) N (% or mean)*	Type 1 Diabetic (N=78) N (% or mean)*	Type 2 Diabetic (N=59) N (% or mean)*	Pairwise *P* value† Id vs. All DM	Id vs. T1DM	Id vs. T2DM
Medical history:						
Age at onset of symptoms (years):				**0.05**	**0.02**	**< 0.001**
< 25	68 (26.8%)	21 (26.9%)	1 (1.7%)			
25 – 45	114 (44.9%)	46 (59.0%)	25 (42.4%)			
45+	72 (28.4%)	11 (14.1%)	33 (55.9%)			
Average age	36.1 ± 14.6	33.7 ± 10.4	48.8 ± 10.9	**0.01**	0.11	**< 0.001**
Duration of symptoms at enrollment (yrs):				0.29	**0.04**	0.64
< 1.5	80 (31.5%)	16 (20.5%)	17 (28.8%)			
1.6 – 4.9	95 (37.4%)	29 (37.2%)	26 (44.1%)			
5 +	79 (31.1%)	33 (42.3%)	16 (27.1%)			
Average duration	4.9 ± 6.6	6.2 ± 6.3	4.1 ± +3.3	0.15	0.06	0.38
Initial infectious prodrome: (yes vs no)	47 (18.5%)	11 (14.1%)	8 (13.6%)	0.24	0.37	0.45
Symptoms prompting evaluation for gp:						
Nausea	214 (84.3%)	66 (84.6%)	56 (94.9%)	0.19	0.94	**0.03**
Vomiting	152 (59.8%)	69 (88.5%)	54 (91.5%)	**< 0.001**	**< 0.001**	**< 0.001**
Bloating	146 (57.5%)	44 (56.4%)	37 (62.7%)	0.75	0.87	0.46
Early satiety	146 (57.5%)	37 (47.4%)	44 (74.6%)	0.75	0.12	**0.02**
Post prandial fullness	136 (53.5%)	44 (56.4%)	39 (66.1%)	0.18	0.66	0.08
Abdominal pain	193 (76.0%)	47 (60.3%)	41 (69.5%)	**0.01**	**0.007**	0.30
Diarrhea	98 (35.6%)	35 (44.9%)	30 (50.9%)	0.09	0.32	0.08
Constipation	112 (44.1%)	32 (41.0%)	34 (57.6%)	0.44	0.63	0.06
Anorexia	32 (12.6%)	12 (15.4%)	17 (28.8%)	**0.03**	0.53	**0.02**
Weight loss	118 (46.5%)	41 (52.6%)	31 (52.5%)	0.25	0.35	0.40
Weight gain	45 (17.7%)	14 (18.0%)	14 (23.7%)	0.57	0.96	0.24
Gastroesophageal reflux	137 (53.9%)	43 (55.1%)	35 (59.3%)	0.57	0.85	0.45
Problems with diabetes control	0 (0.0%)	39 (50.0%)	27 (45.8%)	**< 0.001**	**< 0.001**	**< 0.001**

Characteristic	Idiopathic (N=254) N (% or mean)*	Type 1 Diabetic (N=78) N (% or mean)*	Type 2 Diabetic (N=59) N (% or mean)*	Pairwise *P* value† Id vs. All DM	Id vs. T1DM	Id vs. T2DM
Other	17 (6.7%)	5 (6.4%)	2 (3.4%)	0.53	0.93	0.54
Predominant symptom prompting evaluation:				**0.01**	0.06	0.08
Nausea	92 (36.2%)	26 (33.3%)	19 (32.2%)			
Vomiting	48 (18.9%)	25 (32.1%)	19 (32.2%)			
Abdominal pain	56 (22.1%)	10 (12.8%)	7 (11.9%)			
Other	8 (22.8%)	17 (21.8%)	14 (23.7%)			
Type of gastroparesis symptom onset†:				0.64	0.21	0.49
Acute start	129 (50.8%)	46 (59.0%)	27 (45.8%)			
Insidious start	125 (49.2%)	32 (41.0%)	30 (50.7%)			
Other	0 (0.0%)	0 (0.0%)	2 (3.4%)			
Nature of gastroparesis symptoms:				0.98	0.98	0.98
Chronic, but stable	56 (22.1%)	16 (20.8%)	12 (20.3%)			
Chronic, but worsening	84 (33.2%)	27 (35.1%)	20 (33.9%)			
Chronic with periodic exacerbations	87 (34.4%)	26 (33.8%)	20 (33.9%)			
Cyclic pattern	26 (10.3%)	8 (10.4%)	7 (13.2%)			
Gastroparesis severity†:				**0.002**	**<0.001**	0.32
Mild (grade 1)	37 (14.6%)	3 (3.9%)	9 (15.3%)			
Compensated (grade 2)	143 (56.5%)	36 (46.8%)	27 (45.8%)			
Gastric failure (grade 3)	73 (28.9%)	38 (49.4%)	23 (39.0%)			
Other, not graded	1 (0.5%)	0 (0.0%)	0 (0.0%)			
Gastric failure (grade 3) (yes vs no)	73 (28.9%)	38 (49.4%)	23 (39.0%)	**0.001**	**<0.001**	0.12
PAGI-SYM symptom severity (0–5):						
Nausea severity	3.5 ± 1.4	3.4 ± 1.3	3.2 ± 1.2	0.22	0.75	0.09
Retching severity	1.8 ± 1.8	2.4 ± 1.7	2.5 ± 1.7	**0.001**	**0.009**	**0.008**
Vomiting severity	2.0 ± 1.9	2.7 ± 1.8	2.4 ± 1.7	**0.002**	**0.003**	0.09
Feeling of stomach fullness severity	3.7 ± 1.2	3.2 ± 1.6	3.6 ± 1.0	**0.04**	**0.03**	0.36
Inability to finish meal severity	3.6 ± 1.4	2.9 ± 1.5	3.2 ± 1.2	**<0.001**	**<0.001**	**0.007**
Excessively full after meal severity	3.7 ± 1.3	3.3 ± 1.5	3.5 ± 1.3	**0.02**	**0.04**	0.11
Loss of appetite severity	3.1 ± 1.5	2.8 ± 1.6	2.8 ± 1.4	0.12	0.26	0.20

Characteristic	Idiopathic (N=254) N (% or mean)*	Type 1 Diabetic (N=78) N (% or mean)*	Type 2 Diabetic (N=59) N (% or mean)*	Pairwise *P* value† Id vs. All DM	Id vs. T1DM	Id vs. T2DM
Bloating severity	3.3 ± 1.5	2.8 ± 1.7	3.4 ± 1.4	0.13	**0.02**	0.82
Visibly larger stomach severity	2.9 ± 1.8	2.5 ± 1.8	2.9 ± 1.7	0.29	0.11	0.91
Gastroparesis Cardinal Symptom Index (GCSI)≠	3.0 ± 1.0	2.8 ± 1.1	3.0 ± 1.0	0.59	0.30	0.76
Upper abdominal pain	3.1 ± 1.7	2.8 ± 1.9	2.8 ± 1.7	0.10	0.25	0.15
Upper abdominal discomfort	3.3 ± 1.5	2.9 ± 1.8	3.2 ± 1.5	0.15	0.12	0.53
Lower abdominal pain severity	2.2 ± 1.7	2.3 ± 1.7	1.8 ± 1.4	0.55	0.61	0.10
Lower abdominal discomfort severity	2.3 ± 1.7	2.3 ± 1.6	1.9 ± 1.5	0.44	0.86	0.13
GERD subscore≠	2.0 ± 1.4	2.0 ± 1.4	1.9 ± 1.3	0.83	0.94	0.78
Constipation severity	2.4 ± 1.8	2.3 ± 1.7	2.4 ± 1.6	0.71	0.62	0.96
Diarrhea severity	1.9 ± 1.7	2.0 ± 1.8	1.8 ± 1.6	0.98	0.67	0.64
Gastric emptying (scintigraphy):						
Average % gastric retention at 2 hr	62.7 ± 16.6	71.3 ± 19.8	61.2 ± 21.9	**0.02**	**<0.001**	0.55
Average % gastric retention at 4 hr	28.4 ± 18.7	46.8 ± 27.1	32.7 ± 23.9	**< 0.001**	**< 0.001**	0.36
Severity of delayed gastric emptying - 4hr:				**0.001**	**< 0.001**	0.81
Normal (0 – 20%)	109 (43.1%)	14 (18.0%)	26 (44.1%)			
Moderate (21% – 35%)	70 (27.7%)	22 (28.2%)	14 (23.7%)			
Severe (> 35%)	74 (29.3%)	42 (53.9%)	19 (32.2%)			

*Values are mean ± standard deviation or n (%). Id=Idiopathic, DM=Diabetic, T1DM=Type 1 Diabetic, T2DM=Type 2 Diabetic

†*P* values (two-sided) determined from either a chi-square test for non-ordered categories, a Fisher's exact test or the Cochran-Armitage trend test for ordered categories for categorical variables, or a Kruskal-Wallis test for continuous variables.
P value for the characteristic was computed after excluding the " other" category.

≠Definitions:
Gastroparesis Cardinal Symptom Index = (nausea sub-score + postprandial fullness sub-score + bloating sub-score)/3 where:
Nausea sub-score = (nausea + retching + vomiting)/3
Postprandial fullness/early satiety sub-score = (stomach fullness + inability to finish meal + excessively full + loss of appetite)/4
Bloating sub-score = (bloating + large stomach)/2
GERD sub-score = (heartburn day + heartburn lying down + chest discomfort day + chest discomfort night + reflux day + reflux night + bitter taste)/7

Table 3

Treatment, comorbidities, psychological function and quality of life

Characteristic	Idiopathic (N=254) N (% or mean)*	Type 1 Diabetic (N=78) N (% or mean)*	Type 2 Diabetic (N=59) N (% or mean)*	Pairwise *P* value† Id vs. All DM	Id vs. T1DM	Id vs. T2DM
Medications use (current) and treatment:						
Proton pump inhibitors, other GI meds	193 (76.0%)	62 (79.5%)	49 (83.1%)	0.25	0.52	0.24
Prokinetic meds for gastroparesis	125 (49.2%)	54 (69.2%)	38 (64.4%)	**<0.001**	**0.002**	**0.04**
Antiemetics for gastroparesis	154 (60.6%)	55 (70.5%)	39 (66.1%)	0.12	0.11	0.44
Any NSAI pain relieving in past 6 months‡	153 (60.2%)	42 (53.9%)	40 (67.8%)	0.94	0.32	0.28
Narcotic pain med	109 (42.9%)	36 (46.2%)	28 (47.5%)	0.47	0.61	0.53
Any pain modulators	42 (16.5%)	21 (26.9%)	17 (28.8%)	**0.009**	**0.05**	**0.03**
Any antidepressants	83 (32.7%)	30 (38.5%)	20 (33.9%)	0.45	0.35	0.86
Any anxiolytics	39 (15.4%)	7 (9.0%)	11 (18.6%)	0.55	0.15	0.53
Any estrogen, progestin, HRT	60 (23.6%)	12 (15.4%)	12 (20.3%)	0.16	0.12	0.59
Has gastric electric stimulator (yes vs no)	15 (5.9%)	12 (15.4%)	2(3.4%)	0.12	**0.01**	0.75
Hospitalizations & comorbidities:						
Any hospitalization in past year	112 (44.1%)	57 (73.1%)	27 (45.8%)	**<0.001**	**<0.001**	0.82
Average number of hospitalizations past year	1.6 ± 3.0	5.1 ± 6.4	2.7 ± 5.7	**< 0.001**	**< 0.001**	0.59
Average number of comorbidities	3.7 ± 2.8	4.0 ± 2.8	5.6 ± 3.5	**0.003**	0.40	**< 0.001**
Co-morbidity, ever diagnosed (yes vs no):						
Endometriosis	40 (15.6%)	4 (5.1%)	7 (11.9%)	**0.03**	**0.01**	0.45
Cholelithiasis or any gallbladder disease	89 (35.0%)	21 (26.9%)	25 (42.4%)	0.77	0.18	0.29
Migraine headaches	103 (40.6%)	19 (24.4%)	22 (37.3%)	**0.04**	**0.01**	0.64
Major depression	54 (21.3%)	22 (28.2%)	19 (32.2%)	0.06	0.20	0.07
Severe anxiety disorder	31 (12.2%)	8 (10.3%)	5(8.5%)	0.42	0.64	0.42
Beck Depression Index (BDI) (past 2 weeks):						
Inventory score	18.7 ± 11.0	21.6 ± 12.9	18.6 ±1 0.0	0.78	0.11	0.76
Score>28 (severely depressed)	47 (18.5%)	20 (25.6%)	10 (17.0%)	0.42	0.17	0.78
Feelings of hopelessness	26 (10.2%)	15 (19.2%)	8 (13.6%)	0.06	**0.03**	0.46
State-Trait Anxiety Inventory (STAI):						

Characteristic	Idiopathic (N=254) N (% or mean)*	Type 1 Diabetic (N=78) N (% or mean)*	Type 2 Diabetic (N=59) N (% or mean)*	Pairwise *P* value† Id vs. All DM	Id vs. T1DM	Id vs. T2DM
State anxiety score	45.2±13.4	47.7±14.1	44.6±12.9	0.37	0.13	0.77
State anxiety score ≥ 50 (severe)	91 (35.8%)	37 (47.4%)	18 (30.5%)	0.40	0.07	0.44
Trait anxiety score	43.9±12.1	47.3±12.7	43.7±12.9	0.16	**0.03**	0.83
Trait anxiety score ≥ 50 (severe)	87 (34.3%)	35 (44.9%)	17 (28.8%)	0.47	0.09	0.42
Quality of Life (PAGI-QOL) (past 2 weeks) §						
Daily activities sub-score	2.2 ± 1.2	2.2 ± 1.3	2.4 ± 1.2	0.99	0.46	0.37
Clothing sub-score	2.9 ± 1.8	3.0 ± 1.7	3.0 ± 1.7	0.67	0.73	0.75
Diet sub-score	1.4 ± 1.2	1.7 ± 1.2	1.8 ± 1.3	**0.002**	**0.01**	**0.01**
Relationship sub-score	2.9 ± 1.5	2.8 ± 1.7	3.1 ± 1.5	0.91	0.53	0.35
Psychological sub-score	2.7 ± 1.4	2.4 ± 1.5	2.8 ± 1.4	0.36	0.07	0.58
Total score	2.4 ± 1.1	2.4 ± 1.1	2.6 ± 1.2	0.50	0.88	0.19
SF-36v2 Health Survey (past 4 weeks):§						
Current general health perception	32.3 ± 9.8	26.6 ± 7.4	27.9 ± 6.7	**<0.001**	**<0.001**	**0.002**
Emotional problems limit your daily work	36.9 ± 15.2	32.1 ± 14.8	33.0 ± 15.7	**0.006**	**0.01**	0.08
Physical health component summary score	34.0 ± 10.3	32.6 ± 10.0	29.6 ± 9.2	**0.02**	0.31	**0.005**
Mental health component summary score	37.6 ± 12.5	34.2 ± 12.4	37.3 ± 13.0	0.10	**0.03**	0.85

*Values are mean ± standard deviation or n (%). Id=Idiopathic, DM=Diabetic, T1DM=Type 1 Diabetic, T2DM=Type 2 Diabetic

†*P* values (two-sided) determined from either a chi-square test for non-ordered categories, a Fisher's exact test or the Cochran-Armitage trend test for ordered categories for categorical variables, or a Kruskal-Wallis test for continuous variables.

‡Any pain relieving medication includes any analgesics, non-steroidal anti-inflammatory (NSAI), or aspirin medications taken in past 6 months.

§Subscales derived from the Patient Assessment of Upper Gastrointestinal Disorders-Quality of Life (PAGI-QOL). Scales have been recoded so that a higher score reflects a higher QOL.
Scores on the Medical Outcomes Study 36-Item Short-Form Health Survey V2 (SF-36v2) standard recall were normalized to the 1998 U.S. general population with a mean (± SD) of 50± 10, except for the Health Transition item. A higher score reflects higher QOL or better health outcome.

Table 4

Multivariable logistic regression analysis for characteristics independently associated with gastroparesis etiology

	Diabetes Type 1 Vs Idiopathic*			Diabetes Type 2 Vs Idiopathic*		
Characteristics Selected	**Odds Ratios†**	**95% CI**	***P* value**	**Odds Ratios†**	**95% CI**	***P* value**
Demographic:						
Gender: female	2.27	1.05–4.91	**0.04**	n/s	n/s	n/s
White, non-Hispanic	0.32	0.15–0.68	**0.004**	0.23	0.09–0.54	**0.001**
Anthropometric:						
Overweight‡	n/s	n/s	n/s	5.45	2.34–12.69	**<0.001**
Symptoms:						
Age at symptom onset:						
< 25 years-45 years	n/s			1.00		
> 45 years	n/s	n/s	n/s§	3.64	1.78–7.46	**<0.001**
PAGI-SYM symptom severity‡						
Retching severity	n/s	n/s	n/s	1.26	1.01–1.58	**0.04**
Inability to finish meal	0.76	0.59–0.96	**0.02**	n/s	n/s	n/s
Lower abdominal pain severity	n/s	n/s	n/s	0.66	0.51–0.86	**0.002**
Gastric emptying scintigraphy:						
Severity gastric retention 4 hr:			**0.001**			n/s
Mild (0% – 20%)	1.00			n/s		
Moderate (21% – 35%)	3.53	1.49–9.34	**0.004**	n/s	n/s	n/s
Severe (> 35%)	4.44	1.97–9.98	**<0.001**	n/s	n/s	n/s
Treatment & hospitalizations:						
Currently takes prokinetics	2.07	1.06–4.01	**0.03**	n/s	n/s	n/s
Has gastric electric stimulation	3.69	1.31–10.42	**0.01**	n/a	n/a	n/a
Number of hospitalizations in past year	1.16	1.08–1.25	**<0.001**	n/s	n/s	n/s
Psychological function & QOL:						
PAGI-QOL Activity sub-score‡	n/s	n/s	n/s	2.75	1.64–4.65	**<0.001**
PAGI-QOL Diet sub-score‡	1.60	1.17–2.20	**0.003**	n/s	n/s	n/s

Characteristics Selected	Diabetes Type 1 Vs Idiopathic* Odds Ratios†	95% CI	*P* value	Diabetes Type 2 Vs Idiopathic* Odds Ratios†	95% CI	*P* value
SF-36 physical health summary score≠	n/s	n/s	n/s	0.88	0.83–0.93	**<0.001**
SF-36 mental health summary score≠	0.96	0.93–0.99	**0.01**	0.93	0.89–0.97	**0.001**

*Gastroparesis etiology derived using response to the main reason for gastroparesis evaluation and report of diagnosed diabetes: idiopathic must have no prior history of diabetes: Diabetes type 1 (T1DM) (N=78), Diabetes type 2 (T2DM) (N=58), idiopathic (253 in T1DM analyses, 254 in T2DM analyses)

†Independent characteristics and associated odds ratios and 95% confidence intervals (CI) were determined from fitting the pooled set of characteristics with significance at the 0.05 level from bi-directional multivariable logistic regression analysis for each sub-group (T1DM and idiopathic, T2DM and idiopathic).
n/a = Characteristic not in model due to instability of model because of multicollinearity
n/s = Characteristic not significant at the 0.05 level
If a characteristic in the full candidate set was not significant in either of the 2 models, then it was not presented in the table, i.e., Hispanic (yes vs no), married or not, college education (yes vs no), currently work, usual occupation (laborer, professional, other), income≥$50K, duration of gastroparesis symptoms at study enrollment, initial infectious prodrome, predominant symptom prompting gastroparesis evaluation (nausea, vomiting, abdominal pain or other), acute symptom onset (versus insidious), gastroparesis severity, PAGI-SYM severity scores: (nausea, vomiting, fullness, excessively full after meal, appetite loss, bloating, distended stomach, upper abdominal pain, GERD sub-scale, constipation, diarrhea severity), currently take proton pump inhibitors, anti-emetics, any NASI, any narcotics, pain modulators, antidepressants, any anxiolytics, any hormones, any hospitalization in past year, number of comorbidities, ever diagnosed with major depression or anxiety, State or Trait Anxiety Inventory score≥50, BDI>28, PAGI-QOL:(clothing, relationship, psychological subscores).
GCSI was not significant in either model.

≠Definitions:
Overweight or obese (BMI > 25 kg/m2)
Symptom severity scores from the PAGI-SYM (Patient Assessment of GI Symptoms) questionnaire, scores range from 0–5
GERD severity sub-scale = average of the sum of heartburn day, heartburn lying down, chest discomfort during the day, chest discomfort during the night, reflux during the day, reflux during the night, and bitter taste severity scores
Subscales derived from the Patient Assessment of Upper Gastrointestinal Disorders-Quality of Life (PAGI-QOL). Scales have been recoded so that a higher score reflects a higher QOL.
SF-36v2 Health Survey scores standardized to 1998 U.S. general population with a mean (± SD) of 50± 10, in which a higher score reflects a better health outcome.

§Though statistically insignificant, odds ratios and P values determined in the T1DM model using Age at symptom onset: 25–45 yrs, 45+ years compared to < 25 years. The 2 category variable was used in the T2DM model due to insufficient numbers in the <25 years category.