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Meal-Induced Symptoms in Children with Dyspepsia – Relationships to Sex and the Presence of Gastroparesis

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Abstract

Objectives: To test the hypothesis that in dyspeptic children, prospective symptom severity following ingestion of a meal would correlate with percent gastric retention, and those ultimately diagnosed with gastroparesis would report worse symptoms.

Study design: Prospective, single center study with 104 children with dyspepsia completing a prospective dyspepsia symptom questionnaire before and after eating a standardized Tougas meal during gastric emptying scintigraphy (**GES**). Main outcomes included correlation between gastric retention and symptoms and comparison of symptom severity between those with and without gastroparesis.

Results: 52 children (50%) had gastroparesis (gastroparesis: 12.5 ± 2.9 years, 65% female; non-gastroparesis: 13.0 ± 2.9 years, 60% female; all P>0.05). Bloating was the only symptom significantly worse in youth with gastroparesis. For the entire cohort, bloating and fullness correlated with percent retention. However, in those with gastroparesis, only nausea correlated with retention (4 hr.; r_s=0.275, *P*< .05). Girls with gastroparesis had significantly worse symptoms (except satiety) when compared with boys with gastroparesis (P<0.05).

Conclusions: Overall in children, there is little difference in symptom severity between children with gastroparesis vs. normal emptying based on current standards. However, girls with gastroparesis have worse symptoms vs. boys with gastroparesis, underscoring a need for further studies into the role of sex in gastroparesis symptoms. In all children, both bloating and fullness correlated modestly with gastric retention, and nausea correlated in those with gastroparesis.

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The other authors declare no conflicts of interest.

Keywords

Pediatrics; gastroparesis; gastric emptying scintigraphy; dyspepsia

Gastroparesis is defined as significantly delayed gastric emptying of fluids and/or solids in the absence of a mechanical obstruction.(1) Gastroparesis is diagnosed by gastric emptying scintigraphy (**GES**) during which a radiolabeled meal is given and the percent gastric retention determined.(2, 3) Gastric emptying is delayed if postprandial GES retention is greater than 60% at 2 hours and/or 10% at 4 hours.(4) These values were defined in adults and have been extrapolated for use in children. However, a recent study, although retrospective and not controlled, suggests that the 4-hour cutoff of 10% is appropriate for use in children.(5) Gastroparesis is associated with numerous symptoms including early satiety, postprandial fullness, nausea, vomiting, bloating, anorexia, and/or upper abdominal pain.

Determining the relationship between gastroparesis symptoms and the rate of gastric emptying is an area of active investigation. Previous studies in both adults and children have shown poor correlation between the percent gastric retention on GES and retrospectively determined symptom severity.(6, 7) In contrast, a systematic review and meta-analysis of adult studies including only what the authors considered appropriately performed GES (e.g., ≥3 hour study), identified a relationship between percent retention and retrospectively evaluated symptoms.(8) Whether symptoms measured prospectively during a standardized meal relate to percent retention is unclear and there is little information from pediatric studies regarding the potential relationship between individual symptoms (eg, bloating) and gastric retention.

To address this knowledge gap in pediatrics, we conducted a study to prospectively evaluate GI symptom severity and evolution during the course of GES using a standardized meal. We hypothesized that the types of GI symptoms and their severity would correlate with the degree of gastric retention and that those with gastroparesis would have more severe GI symptoms than those with normal emptying.

METHODS

Participants were children 5–18 years of age presenting to Texas Children's Hospital for a solid meal 4-hour GES from August 2018-December 2019 as part of routine clinical practice for suspected gastroparesis. Scintigraphy images were obtained immediately following ingestion of the meal and hourly for four hours.(9) Subjects were excluded if they: a) were scheduled for a GES of < 4 hours; b) had emesis of the test meal during the GES; c) had global developmental delay, autism spectrum disorder, or psychosis; d) were nonverbal and/or illiterate; e) lacked fluency in English or Spanish; f) had other GI comorbidities such as inflammatory bowel disease, celiac disease, eosinophilic esophagitis, peptic ulcer disease, GI malignancy, or gastroesophageal reflux disease responsive to medications. Demographic information obtained from the participant's electronic medical records included age, weight, sex, body mass index (**BMI**) Z-score, and medical history. We selected the child BMI Z-score as a measure of weight adjusted for height compared with a reference population with similar age and sex.(10)

The study was approved by the Baylor College of Medicine IRB. Parents provided consent and the child assent.

Symptom Questionnaire

The pediatric symptom index we used was adapted from the adult Gastroparesis Cardinal Symptoms Index (**GCSI**).(11) We included the five symptoms from the GCSI (bloating, fullness, satiety (in contrast to hunger), nausea, and chest burning) and added abdominal pain as it is a commonly reported pediatric gastroparesis symptom.(12) A child-friendly descriptor was provided for each assessed symptom (belly pain instead of abdominal pain, bloating (belly feels full of air or gas), fullness (no more space in my tummy), hunger (I want to eat), and nausea (feeling sick to your stomach-like you might throw up). In trying to keep these questions as self-reported as possible, the physician obtaining consent explained all the above symptoms to the younger children prior to the GES and sat with them if needed for the majority of study to make sure they understood the items. Each symptom's severity was rated on a visual analog scale ranging from 0 (absent symptoms) to 100 (symptom at their very worst). Subjects could choose any number from 0–100.

Study Protocol

Participants completed the symptom index immediately prior to and after ingesting the entire test meal, then every 15 minutes for the first hour, and then hourly up to 4 hours after meal ingestion. Participants had up to a maximum of 10 minutes to finish the GES meal.(9) Those taking more than 10 minutes were excluded. The standard meal consists of two eggs, two pieces of toast, strawberry jam, and 120 mL of water.(9) 500 μCi of sulfur colloid were added to the liquid eggs.(9) All subjects are told to stop promotility and anti-emetic medications 48–72 hours prior to the GES. They completed the symptom index using REDCap™ via a mobile device or tablet.(13) A tablet was provided to those participants who did not have one.

Statisical Analyses

Descriptive statistics included mean and standard deviation for continuous variables and number and percent for categorical variables, and were calculated for age, weight, ethnicity, BMI Z-score, medical history, symptom index scores, and GES results.

The six types of GI symptoms and their severity following ingestion of the GES meal were compared between children with gastroparesis versus those with normal emptying. Individual symptom scores were obtained at each time point (baseline, 0 min, 15 min, 30 min, 45 min, 60 min, 120 min, 180 min, and 240 min; each symptom was scored from 0–100 at each time point). A timed total symptom score was obtained by summing all the individual symptom scores from each time point and then obtaining the mean (given that there are six symptoms, the sum of all symptoms at each time point can range from 0–600). A complete study symptom score was obtained by summing the symptom scores from every time point and obtaining their mean (i.e., sum of individual symptom scores X 9 time points; potential range: 0–5,400).

Spearman correlation was used to assess the relationship between symptoms and GES percent retention and to assess the relationship between demographic data and GES percent retention. Differences between the gastroparesis and the normal emptying groups in continuous variables were tested using the Wilcoxon 2-sample test. Categorical variables were compared using Chi Square or Fisher exact test. Data are presented as mean ± SD except where noted. SAS software version 9.4 (SAS Institute; Cary, North Carolina) was employed.

RESULTS

Demographics and Percent Gastric Retention

Overall, 104 children completed the study (12.8 ± 2.9 years of age) of whom 52 had gastroparesis and approximately 60% were female; Table I). Six of the children with gastroparesis had abnormal retention at 2 hours and normal retention at 4 hours (Table 1). No statistical differences were noted in age, sex, race, ethnicity, or BMI Z-score between those with gastroparesis and those with normal gastric emptying (Table 1). As expected, the percent gastric retention was significantly greater for those with gastroparesis (Table 1).

Differences in Symptom Score between Gastroparesis and Normal Emptying

The timed total symptom score and the complete study symptom score did not differ between groups (Table 2). Bloating was the only symptom that was significantly greater in participants with gastroparesis at several time points (15 min: gastroparesis: 30.2 ± 29.7 vs normal emptying: 19.9 ± 25.8, P=0.04; 60 min: gastroparesis: 25.8 ± 29.8 vs normal emptying: 14.8 ± 19.8, P=0.05; 120 min: gastroparesis: 21.6 ± 26.3 vs normal emptying: 10.5 ± 15.6, P=0.01; 180 min: gastroparesis: 21.8 ± 26.8 vs normal emptying: 11.6 ± 18.1, P=0.04). Fullness was statistically greater in participants with gastroparesis only at the last time point (240 min: gastroparesis: 28.4 ± 29.9 vs normal emptying: 17.6 ± 26.0, P=0.02).

Correlation of Symptom Score with Percent Retention

Each individual symptom score was matched with the corresponding percent retention time to determine if there was a correlation, regardless of the outcome (gastroparesis vs normal emptying). For the entire cohort, bloating score correlated with percent retention at every hour (Table 3). Fullness severity correlated with retention at the second, third, and fourth hour but the correlations were modest (Table 3). Total study symptom score did not correlate with percent retention for the cohort as a whole (Table 3). Linear regression did not show a significant correlation between individual symptoms and percent retention at each hour.

Among those with gastroparesis, nausea was the only symptom that correlated with percent retention (at 240 minutes; Table 3). For those with normal emptying, the fullness score at 120 and 180 minutes correlated with percent gastric retention (Table 3). No other correlations between individual symptom scores and percent retention were noted. Similarly, total study symptom score was not related to percent gastric retention for either group (Table 3).

Symptom Severity Differences by Sex

With the exception of satiety, for the entire cohort females overall (vs. males) reported significantly worse individual symptoms (Table 4). When individual symptoms were combined into a timed symptom score, females reported significantly worse symptoms at every time point (Table 4). The total study symptom score also was significantly worse in females (Table 4). In contrast, percent retention did not differ between females and males (Table 4).

In females with gastroparesis, individual symptom scores, with the exception of satiety, were significantly worse when compared with males with gastroparesis (Table 4). The total timed symptom score and total study symptom score also were significantly worse in females with gastroparesis (Table 4). Percent retentions were similar between both females and males with gastroparesis (Table 4).

In females with normal emptying, individual symptom scores for nausea at the later time points (60–240 minutes) were worse than in males with normal emptying (Table 4). No other differences in individual symptom scores were noted between females and males with normal emptying. Similarly, the timed symptom score and total study symptom score did not differ between sexes in the normal emptying group (Table 4). Percent retentions also were similar (Table 4).

DISCUSSION

We hypothesized that symptoms would be significantly worse in those with gastroparesis compared with those with normal emptying. However, symptom severity appeared to be similar between gastroparesis vs normal emptying. Bloating was the only symptom that was significantly worse at multiple timepoints in those with gastroparesis. Thus, just by using symptoms alone, it would be nearly impossible to know which patients presenting with dyspepsia have gastroparesis. A point to be considered is that GES is usually done early in the morning, as patients need to be fasting before eating the test meal. Symptoms of gastroparesis in adults have been shown to progressively worsen during the day; thus, future studies should evaluate if differentiation between gastroparesis vs non-gastroparesis symptoms is clearer later in the day.(14)

Individual symptom scores were worse for females and this was primarily due to differences between female and male symptom scores in the gastroparesis group (Table 4). Taking into account sex provided greater insight into meal-generated symptoms (Table 3). Nearly all symptoms were worse in females versus males, and this appeared to be due primarily to the worse symptoms in girls with gastroparesis (Table 3). In contrast, sex had little impact in the normal emptying group except in the case of nausea during the latter part of the GES (Table 3).

Most of the females diagnosed with gastroparesis were 13–18 years of age, which coincides with the adolescent pubertal period. Adult studies have shown that approximately 80% of individuals presenting with gastroparesis are female and that it tends to have a predilection for young females.(15) Studies also have shown that perimenopausal women

and postmenopausal women taking estrogen and progesterone replacement have slow gastric emptying of both liquids and solids, suggesting an estrogen effect delaying gastric emptying.(16) One explanation is that gastric motility is dependent on neuronal nitric oxide, which may be regulated by estrogen.(1) Adult data has shown females with gastroparesis report worse GCSI scores and lower quality of life regardless of gastric emptying rate.(17) Our results are similar to adult findings in that despite worse symptom scores, percent gastric retention did not differ between females and males with gastroparesis (Table 3). Further studies are needed to clarify the reason(s) behind the sex-related differences in gastroparesis.

Previous reviews, systematic reviews and meta-analyses of adult studies have suggested no relationship between retrospectively reported symptoms and GES.(4, 18, 19) However, a recent systematic review and meta-analysis reviewing only adult GES studies of ≥ 3 hours duration and following other strict criteria did identify a correlation between retrospectively reported symptoms and gastroparesis.(8) Given these disparities in the pediatric and adult literature, we sought to prospectively study this issue with pediatric participants reporting symptoms in real time during GES using a standardized meal. Given the known superiority of real time symptom reporting over recall, we anticipated the results would provide a more accurate assessment of the potential relationship between symptoms and the percent gastric retention and potential symptom differences between children with gastroparesis and those with just dyspeptic symptoms.(20, 21)

We hypothesized that the intensity of the symptoms would correlate with the degree of emptying. As a group overall, bloating and fullness modestly correlated with the degree of emptying rate. However, no clear relationships were seen between symptoms and emptying in the gastroparesis or normal emptying groups (Table 4). It is possible that the larger number of participants in the entire cohort versus the gastroparesis and normal emptying group allowed for the correlations to be detected. The measured symptoms are complex, multifactorial physiologic phenomena with numerous potential contributors that likely differ among patients (e.g., strength of descending inhibitory pathways for pain, autonomic nervous system tone for nausea, and hypothalamic reactivity for satiety) that are not measured directly by GES.(22–24) Other factors, such as psychosocial distress and stress, not measured in most studies of gastric emptying, also might contribute to symptom expression. Thus, future studies assessing psychological features are warranted.

One might argue that GES might not be the optimal test to diagnose gastroparesis in children. An important limiting aspect of this testing is the absence of normal values for GES in the pediatric population. The GES cutoff values used in pediatrics have been extrapolated from adult studies. Because GES exposes subjects to radiation, it cannot be carried out in healthy children in order to obtain normal values. Therefore, labeling pediatric patients as having delayed gastric emptying based on the GES results may need to be interpreted with caution given the lack of normative data in the pediatric group. Previous studies from our group suggest this might be problematic in infants and children aged 7–10 years of age, as those groups had more difficulty completing the GES meal.(25, 26) Compared with older children, it was harder for them to complete the meal to its entirety and they less frequently tolerated the standard meal. (25, 26) Additionally, children with delayed gastric emptying were significantly smaller than those without. (25, 26) This might be due to

younger and smaller children having slower emptying compared with older children and/or the result of meal size relative to the stomach size being greater in younger and smaller children.(25, 26) However, in a study by Ng et al, of 1041 retrospectively reviewed GES studies in children, the adult-determined 4-hour cutoff of 10% appeared to be appropriate for use in children based on k-means clustering analysis.(5) This report requires further validation but lends some credence to the use of the cutoffs used in our study. Ultimately, validation of a stable isotope gastric emptying breath test for use in children or other non-invasive method would allow normal emptying rates to be derived from healthy children given that carrying out GES in healthy children is not ethical.

Another pediatric study compared percent gastric retention with symptoms collected prospectively during GES. In this small study (gastroparesis, n=17) of children 11–18 years of age, using the Multidimensional Measurement of Recurrent Abdominal Pain questionnaire and a dyspepsia questionnaire (both of which are retrospective), Wong et al did not identify differences in symptoms during the GES between gastroparesis versus those with normal emptying.(6, 27) Disparity between our study and that of Wong et al is likely due to differences in participant characteristics and method of symptom capture.(6, 27) One small pediatric study (n=17) evaluated symptoms at baseline using a modified version of the GCSI prior to administration of the meal.(28) In contrast to our study, the presence of nausea at baseline correlated with the presence of gastroparesis based on a 4-hour GES.(28) Our work extends the findings from these limited studies given the much larger sample size of the current study, the larger number of data collection time points and symptoms collected, and the identification of sex as an important variable.

There are some limitations to this study. It only included patients from a single site, which may limit the generalizability of the findings. Another limitation is the absence of normal GES values in the pediatric population as noted above.

This study has a number of strengths. First, it included a relatively large pediatric sample size with gastroparesis. Second, all subjects received the same standardized meal. Third, the subjects were a “real-world” population undergoing GES as part of routine clinical practice, further enhancing generalizability. Finally, it assessed symptoms prospectively, thus eliminating recall bias.

In conclusion, we report a large study that prospectively assessed symptoms in response to a standardized meal in children (or adults) with gastroparesis and in those with normal gastric emptying while simultaneously measuring gastric emptying rate. Symptom severity between both groups did not differ significantly, thus making clinical differentiation between gastroparesis vs normal emptying not possible based on symptoms alone. However, females with gastroparesis reported significantly worse symptoms when compared with their male counterparts. For the whole cohort, bloating and fullness correlated with the percent gastric retention during GES; however, only nausea modestly correlated with the fourth hour of the GES in subjects with gastroparesis. We hypothesize that future studies evaluating the relationship between symptoms and gastric emptying rate may benefit from the addition of psychosocial measures, performing GES later in the day, and in pubertal girls, accounting for menstrual cycle.

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Abbreviations:

GI	Gastrointestinal
GES	Gastric Emptying Scan
BMI	Body Mass Index
GCSI	Gastroparesis Cardinal Symptoms Index

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Table 1:

Demographics and Percent Gastric Retention

	All Participants (n=104)	GP (n=52)	Normal Emptying (n=52)	P
Age	12.8 ± 2.9	12.5 ± 2.9 *	13.0 ± 2.9	0.39
Sex				0.54
Males	37% (39) ^	35% (18)	40% (21)	0.06
Age Groups	5–7 years of age: 3	5–7 years of age: 2	5–7 years of age: 1	
	8–12 years of age: 20	8–12 years of age: 12	8–12 years of age: 8	
	13–18 years of age: 16	13–18 years of age: 4	13–18 years of age: 12	
Females	63% (65)	65% (34)	60% (31)	
Age Groups	5–7 years of age: 3	5–7 years of age: 1	5–7 years of age: 2	
	8–12 years of age: 23	8–12 years of age: 12	8–12 years of age: 11	
	13–18 years of age: 39	13–18 years of age: 21	13–18 years of age: 18	
Race				0.12
American Indian or Alaska Native	2% (2)	2% (1)	2% (1)	
Asian	0% (0)	0% (0)	0% (0)	
Black or African American	6% (6)	2% (1)	10% (5)	
White	74% (77)	75% (39)	73% (38)	
More than one race	4% (4)	2% (1)	6% (3)	
Unknown	13% (14)	19% (10)	8% (4)	
BMI Z-score	0.40 ± 1.40	0.1 ± 1.40	0.7 ± 1.40	0.08
Percent Retention				
1 hour	79.0 ± 12.5	84.1 ± 7.3	74.0 ± 14.4	**<0.01**
2 hours	51.1 ± 17.5	63.1 ± 10.4	39.1 ± 14.7	**<0.01**
3 hours	26.5 ± 14.6	37.9 ± 9.7	15.1 ± 8.5	**<0.01**
4 hours	10.4 ± 8.9	16.5 ± 8.6	4.4 ± 3.1	**<0.01**

*Mean ± SD,

^number,

#Significant P values (P<0.05) in **bold**

Table 2:

Mean Individual Symptom Scores

Timed Total Symptom Score	All Participants (n=104)	GP (n=52)	Normal Emptying (n=52)	P
Baseline	171.0 ± 102.8	169.2 ± 108.5	172.9 ± 97.9	0.62
0 min	222.8 ± 114.2	224.5 ± 125.3	221.1 ±103.1	0.95
15 min.	223.8 ± 109.6	232.9 ± 125.1	214.7 ± 91.9	0.59
30 min.	207.7 ± 108.3	221.0 ± 126.2	194.4 ± 86.0	0.40
45 min.	204.2 ± 106.5	212.1 ± 125.9	196.3 ± 83.1	0.77
60 min.	198.6 ± 111.1	210.2 ± 129.0	186.9 ± 89.4	0.55
120 min.	164.8 ± 100.0	186.7 ± 115.5	143.0 ± 76.7	0.07
180 min.	154.0 ± 101.1	167.9 ± 118.6	140.0 ± 78.7	0.54
240 min.	133.1 ± 100.9	149.13 ± 113.3	117.1 ± 85.0	0.23
Complete Study Symptom Score	1509.0 ± 752.0	1604.5 ± 904.0	1413.5 ± 553.4	0.44

*Mean ± SD,

#Significant P values (P<0.05) in **bold**

Table 3:

Correlation of Symptoms with Percent Gastric Retention

	Spearman Correlations and P Values		
Individual Symptom Scores	**Overall**	**GP**	**Normal Emptying**
Pain			
60 min.	0.048, 0.63	0.090, 0.53	−0.010, 0.94
120 min.	0.045, 0.65	0.197, 0.16	−0.151, 0.28
180 min.	0.008, 0.94	0.034, 0.81	−0.090, 0.52
240 min.	0.065, 0.51	0.174, 0.22	−0.064, 0.65
Bloating			
60 min.	**0.251, 0.01** #	0.200, 0.16	0.141, 0.32
120 min.	**0.280, <0.01**	0.224, 0.11	0.182, 0.20
180 min.	**0.236, 0.02**	0.087, 0.54	0.128, 0.37
240 min.	**0.215, 0.03**	0.142, 0.31	0.049, 0.73
Fullness			
60 min.	0.140, 0.16	0.065, 0.64	0.119, 0.40
120 min.	**0.273, <0.01**	0.164, 0.25	**0.299, 0.03**
180 min.	**0.236, 0.02**	0.008, 0.96	**0.327, 0.02**
240 min.	**0.230, 0.02**	0.224, 0.11	0.135, 0.34
Satiety			
60 min.	0.052, 0.60	0.144, 0.31	−0.101, 0.48
120 min.	0.084, 0.40	0.117, 0.41	−0.159, 0.26
180 min.	0.061, 0.54	0.087, 0.54	−0.141, 0.32
240 min.	0.016, 0.87	0.069, 0.63	−0.216, 0.12
Nausea			
60 min.	0.062, 0.53	0.072, 0.61	0.110, 0.48
120 min.	0.090, 0.36	0.171, 0.23	0.098, 0.49
180 min.	0.012, 0.90	−0.016, 0.91	0.113, 0.43
240 min.	0.088, 0.37	**0.275, 0.05**	−0.007, 0.96

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	Spearman Correlations and P Values		
Individual Symptom Scores	**Overall**	**GP**	**Normal Emptying**
Chest Burning			
60 min.	0.128, 0.20	0.154, 0.28	0.086, 0.54
120 min.	0.113, 0.25	0.160, 0.26	0.096, 0.50
180 min.	0.011, 0.91	−0.058, 0.68	0.032, 0.82
240 min.	0.046, 0.65	0.104, 0.46	−0.119, 0.40
Complete Study Symptom Score			
60 min.	0.142, 0.15	0.122, 0.40	0.084, 0.55
120 min.	0.181, 0.07	0.210, 0.14	0.066, 0.64
180 min.	0.104, 0.30	0.033, 0.82	0.114, 0.42
240 min.	0.150, 0.13	0.252, 0.07	−0.025, 0.86

[#]Significant P values ($P<0.05$) in **bold**

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Table 4:

Mean Individual Scores between Females and Males

Variables	All Participants (n=104)		P	GP (n=52)		P	Normal Emptying (n=52)		P
Individual Symptom Scores	**Females (n=65)**	**Males (n=39)**		**Females (n=34)**	**Males (n=18)**		**Females (n=31)**	**Males (n=21)**	
Pain									
Baseline	38.0 ± 32.4 *	24.4 ± 26.9	**0.03** #	33.3 ± 30.3	22.2 ± 27.5	0.14	43.2 ± 34.4	266 ± 26.9	0.08
0 min	39.7 ± 30.7	25.0 ± 28.4	**0.01**	41.2 ± 31.4	23.1 ± 25.5	**0.03**	38.0 ± 30.2	26.57 ± 31.2	0.10
15 min.	42.7 ± 31.5	24.2 ± 27.2	**0.01**	41.7 ± 31.2	20.7 ± 22.2	**0.02**	43.8 ± 32.4	27.2 ± 31.2	0.08
30 min.	37.4 ± 30.6	22.7 ± 26.9	**0.01**	40.8 ± 31.3	20.3 ± 24.4	**0.02**	33.7 ± 29.9	24.7 ± 29.3	0.27
45 min.	39.9 ± 30.8	21.2 ± 26.2	**<0.01**	38.7 ± 31.1	20.4 ± 24.6	**0.04**	41.2 ± 30.8	21.9 ± 28.1	**0.03**
60 min.	37.6 ± 31.0	24.9 ± 31.7	**0.02**	37.9 ± 31.7	21.5 ± 26.8	**0.04**	37.3 ± 30.8	27.8 ± 35.3	0.20
120 min.	33.6 ± 30.3	21.7 ± 27.7	**0.03**	36.5 ± 32.0	21.3 ± 27.8	0.06	30.5 ± 28.4	22.0 ± 28.3	0.27
180 min.	31.5 ± 27.4	22.1 ± 29.5	**0.04**	33.1 ± 24.3	19.1 ± 25.8	**0.04**	29.7 ± 30.6	24.7 ± 32.8	0.51
240 min.	32.3 ± 28.6	24.6 ± 32.4	0.12	32.4 ± 28.5	24.9 ± 32.5	0.28	32.2 ± 29.24	24.3 ± 33.2	0.28
Bloating									
Baseline	25.1 ± 28.5	13.9 ± 21.5	**0.02**	28.9 ± 27.3	7.7 ± 13.8	**<0.01**	21.1 ± 29.7	19.1 ± 25.6	0.82
0 min	29.0 ± 30.1	14.8 ± 20.2	**0.02**	35.4 ± 32.0	11.3 ± 16.4	**0.01**	21.9 ± 26.5	17.6 ± 22.9	0.67
15 min.	31.2 ± 30.3	14.7 ± 20.7	**<0.01**	40.6 ± 30.6	10.4 ± 13.8	**<0.01**	20.9 ± 26.7	18.4 ± 25.0	0.54
30 min.	28.3 ± 30.5	13.5 ± 18.3	**0.01**	36.2 ± 33.3	11.1 ± 14.4	**<0.01**	19.7 ± 24.9	15.6 ± 21.2	0.40
45 min.	27.2 ± 30.3	12.6 ± 17.7	**0.01**	34.5 ± 33.3	11.6 ± 16.6	**0.01**	19.1 ± 24.9	13.5 ± 19.0	0.40
60 min.	25.7 ± 29.0	11.3 ± 15.6	**0.01**	33.9 ± 32.6	10.5 ± 15.0	**0.01**	16.8 ± 21.8	11.9 ± 16.4	0.36
120 min.	20.5 ± 25.9	8.7 ± 11.2	**0.04**	28.2 ± 29.6	9.2 ± 10.9	**0.02**	12.0 ± 17.8	8.3 ± 11.6	0.65
180 min.	19.7 ± 25.0	11.7 ± 19.4	0.06	27.8 ± 29.1	10.4 ± 17.3	**0.02**	10.8 ± 15.9	12.8 ± 21.4	0.94
240 min.	19.1 ± 25.4	10.7 ± 17.6	0.11	24.4 ± 28.5	9.2 ± 16.7	**0.05**	13.2 ± 20.2	11.9 ± 18.7	0.97
Fullness									
Baseline	31.2 ± 32.2	22.4 ± 26.8	0.13	33.6 ± 30.2	12.7 ± 24.8	**<0.01**	28.7 ± 34.5	30.6 ± 26.1	0.65
0 min	56.5 ± 35.1	43.4 ± 29.8	**0.03**	60.3 ± 34.9	41.3 ± 27.8	**0.04**	52.5 ± 35.4	45.2 ± 32.0	0.36
15 min.	58.0 ± 31.4	36.3 ± 25.5	**<0.01**	64.2 ± 31.1	29.7 ± 20.6	**<0.01**	51.2 ± 30.8	42.0 ± 28.4	0.30
30 min.	49.8 ± 32.2	32.0 ± 29.5	**0.01**	57.6 ± 31.0	28.2 ± 22.6	**<0.01**	41.3 ± 31.8	35.2 ± 34.7	0.44

Variables	All Participants (n=104)		P	GP (n=52)		P	Normal Emptying (n=52)		P
Individual Symptom Scores	**Females (n=65)**	**Males (n=39)**		**Females (n=34)**	**Males (n=18)**		**Females (n=31)**	**Males (n=21)**	
45 min.	49.8 ± 32.2	30.7 ± 27.1	**<0.01**	56.1 ± 31.2	24.7 ± 23.7	**<0.01**	42.8 ± 32.4	35.9 ± 29.2	0.33
60 min.	50.3 ± 33.9	29.8 ± 25.3	**<0.01**	56.7 ± 31.9	25.4 ± 21.7	**<0.01**	43.3 ± 35.1	33.6 ± 27.9	0.31
120 min.	36.3 ± 31.2	26.3 ± 25.7	0.11	44.0 ± 29.9	25.5 ± 23.0	**0.04**	27.7 ± 30.8	27.0 ± 28.4	0.96
180 min.	34.6 ± 31.7	20.1 ± 25.4	**0.01**	40.3 ± 33.2	18.5 ± 22.8	**0.03**	28.3 ± 29.3	21.5 ± 27.9	0.27
240 min.	27.0 ± 30.1	16.3 ± 24.3	**0.03**	37.1 ± 31.7	11.8 ± 17.1	**<0.01**	15.8 ± 24.1	20.1 ± 29.0	0.97
Satiety									
Baseline	42.1 ± 32.6	43.3 ± 30.9	0.73	46.2 ± 33.6	41.8 ± 35.9	0.63	37.7 ± 31.5	44.5 ± 26.8	0.35
0 min	74.4 ± 30.0	64.4 ± 30.4	0.08	74.1 ± 31.9	58.6 ± 28.9	0.07	74.8 ± 28.2	69.5 ± 31.5	0.61
15 min.	71.4 ± 30.8	70.3 ± 30.3	0.74	73.7 ± 32.7	67.4 ± 29.6	0.33	68.9 ± 28.9	72.9 ± 31.4	0.61
30 min.	70.0 ± 32.2	69.7 ± 29.7	0.85	72.9 ± 32.3	68.4 ± 28.3	0.34	66.7 ± 32.2	70.8 ± 31.5	0.64
45 min.	67.4 ± 32.4	63.4 ± 30.8	0.46	70.4 ± 34.7	67.4 ± 30.5	0.45	64.1 ± 30.0	60.0 ± 31.4	0.85
60 min.	68.2 ± 33.8	61.1 ± 30.5	0.33	72.4 ± 36.2	62.3 ± 27.5	0.24	63.4 ± 31.0	60.1 ± 33.5	0.84
120 min.	56.2 ± 32.2	54.2 ± 31.4	0.89	61.5 ± 35.3	55.4 ± 28.0	0.48	50.3 ± 27.8	53.1 ± 34.6	0.58
180 min.	44.0 ± 32.4	48.4 ± 31.6	0.49	48.2 ± 33.5	45.1 ± 28.9	0.67	39.4 ± 31.2	51.3 ± 34.2	0.20
240 min.	32.5 ± 30.2	34.4 ± 32.3	0.81	35.9 ± 32.1	30.2 ± 24.5	0.77	28.9 ± 28.0	38.1 ± 38.0	0.64
Nausea									
Baseline	36.2 ± 31.7	27.8 ± 32.7	0.10	36.4 ± 30.6	24.3 ± 33.5	0.12	35.9 ± 33.3	30.8 ± 32.5	0.44
0 min	36.0 ± 33.6	18.7 ± 25.8	**0.01**	35.2 ± 32.2	11.0 ± 18.7	**0.01**	36.8 ± 35.6	25.3 ± 29.4	0.22
15 min.	35.6 ± 28.6	18.6 ± 27.4	**<0.01**	40.7 ± 27.9	10.6 ± 22.3	**<0.01**	30.0 ± 28.7	25.5 ± 29.9	0.40
30 min.	34.4 ± 29.3	14.6 ± 24.0	**<0.01**	37.4 ± 29.0	10.4 ± 21.5	**<0.01**	31.1 ± 29.8	18.1 ± 25.9	0.11
45 min.	32.1 ± 29.1	17.0 ± 24.4	**0.01**	33.5 ± 30.3	11.8 ± 20.1	**0.02**	30.5 ± 28.1	21.4 ± 27.3	0.12
60 min.	31.4 ± 30.8	13.5 ± 21.6	**<0.01**	29.0 ± 30.3	14.3 ± 24.0	**0.04**	34.1 ± 31.5	12.8 ± 19.8	**0.01**
120 min.	26.1 ± 27.5	12.3 ± 22.3	**<0.01**	27.0 ± 28.3	12.7 ± 25.3	**0.03**	25.1 ± 27.1	11.9 ± 19.9	**0.04**
180 min.	26.7 ± 28.7	12.2 ± 19.9	**<0.01**	26.3 ± 29.1	13.6 ± 20.6	0.06	27.2 ± 28.8	11.0 ± 19.8	**0.04**
240 min.	25.0 ± 28.3	12.0 ± 20.3	**0.01**	29.4 ± 30.9	14.3 ± 22.2	0.07	20.1 ± 24.7	10.0 ± 18.9	**0.05**
Chest Burning									
Baseline	17.5 ± 24.3	7.5 ± 16.7	**0.01**	20.1 ± 23.1	5.5 ± 15.5	**<0.01**	14.7 ± 25.6	9.2 ± 17.8	0.68
0 min	15.3 ± 24.2	10.0 ± 21.1	0.07	16.8 ± 24.7	6.8 ± 18.0	**0.05**	13.6 ± 24.0	12.7 ± 23.6	0.60

Variables	All Participants (n=104)		P	GP (n=52)		P	Normal Emptying (n=52)		P
Individual Symptom Scores	**Females (n=65)**	**Males (n=39)**		**Females (n=34)**	**Males (n=18)**		**Females (n=31)**	**Males (n=21)**	
15 min.	16.8 ± 25.4	6.3 ± 14.6	0.06	20.2 ± 26.5	3.0 ± 7.3	**0.01**	13.2 ± 24.2	9.1 ± 18.6	0.98
30 min.	13.0 ± 22.5	13.1 ± 25.8	0.32	15.6 ± 23.2	8.1 ± 17.2	0.07	10.2 ± 21.7	17.4 ± 31.2	0.60
45 min.	16.0 ± 26.0	12.5 ± 25.4	0.65	18.2 ± 24.9	2.1 ± 5.3	**0.01**	13.6 ± 27.4	21.5 ± 31.9	0.07
60 min.	14.4 ± 24.2	9.8 ± 22.3	0.10	17.9 ± 27.4	5.2 ± 13.9	**0.02**	10.5 ± 19.9	13.6 ± 27.3	0.92
120 min.	13.1 ± 21.8	6.9 ± 18.5	**0.01**	18.5 ± 25.5	7.8 ± 20.7	**0.01**	7.2 ± 15.1	6.2 ± 16.8	0.33
180 min.	14.4 ± 24.9	11.3 ± 26.7	**0.02**	20.1 ± 29.1	8.4 ± 23.9	**0.02**	8.1 ± 17.6	13.8 ± 29.3	0.38
240 min.	15.4 ± 26.0	5.1 ± 16.0	**0.01**	20.3 ± 29.7	1.3 ± 3.4	**0.01**	10.0 ± 20.3	8.3 ± 21.3	0.28
Timed Symptom Score									
Baseline	190.2 ± 109.2	139.1 ± 83.2	**0.02**	198.3 ± 118.5	114.2 ± 56.4	**0.01**	181.3 ± 99.2	160.4 ± 97.0	0.45
0 min	250.8 ± 124.8	176.2 ± 74.4	**<0.01**	262.9 ± 135.7	152.0 ± 53.2	**<0.01**	237.5 ± 112.3	196.9 ± 84.4	0.17
15 min.	255.8 ± 114.5	170.4 ± 76.3	**<0.01**	281.1 ± 124.1	141.8 ± 60.5	**<0.01**	228.1 ± 97.4	194.9 ± 81.1	0.20
30 min.	233.0 ± 115.3	165.6 ± 80.3	**<0.01**	260.5 ± 131.7	146.5 ± 71.3	**<0.01**	202.8 ± 86.5	181.9 ± 85.6	0.34
45 min.	232.3 ± 112.1	157.5 ± 77.2	**<0.01**	251.4 ± 134.5	138.0 ± 59.7	**<0.01**	211.4 ± 77.9	174.1 ± 87.5	0.12
60 min.	227.5 ± 115.9	150.3 ± 83.6	**<0.01**	247.7 ± 136.0	139.2 ± 76.7	**<0.01**	205.3 ± 85.5	159.8 ± 89.9	0.09
120 min.	185.7 ± 106.2	130.1 ± 78.3	**0.01**	215.7 ± 122.3	131.9 ± 78.3	**0.01**	152.8 ± 74.0	128.5 ± 80.2	0.19
180 min.	170.9 ± 105.8	125.8 ± 86.8	**0.02**	195.9 ± 124.2	115.1 ± 87.9	**0.01**	143.5 ± 73.8	135.0 ± 87.0	0.41
240 min.	151.2 ± 107.6	103.1 ± 81.5	**0.02**	179.5 ± 119.9	91.8 ± 72.6	**0.01**	120.1 ± 83.5	112.7 ± 89.0	0.61
Complete Study Symptom Score									
Total	1707.1 ± 795.6	1178.8 ± 536.3	**<0.01**	1385.6 ± 806.4	601.6 ± 481.9	**<0.01**	1045.0 ± 520.3	808.0 ± 501.7	0.07
Percent Retention									
1 hour	80.3 ± 11.0	77.0 ± 14.5	0.15	85.0 ± 6.0	82.4 ± 9.2	0.47	75.1 ± 12.8	72.4 ± 16.7	0.60
2 hours	52.8 ± 16.4	48.3 ± 19.0	0.28	63.6 ± 10.6	62.1 ± 10.3	0.49	40.9 ± 13.2	36.5 ± 16.8	0.43
3 hours	27.4 ± 14.0	24.9 ± 15.6	0.32	38.0 ± 9.1	37.7 ± 10.9	0.69	15.8 ± 7.7	14.0 ± 9.5	0.54
4 hours	11.0 ± 8.1	9.4 ± 10.0	0.12	17.1 ± 6.4	15.4 ± 11.9	0.08	4.4 ± 3.0	4.3 ± 3.3	0.68

*Mean ± SD,

#Significant P values (P<0.05) in **bold**

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