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Dietary Intake and Nutritional Deficiencies in Patients with Diabetic or Idiopathic Gastroparesis

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

Abstract

Background & Aims—Gastroparesis can lead to food aversion, poor oral intake, and subsequent malnutrition. We characterized dietary intake and nutritional deficiencies in patients with diabetic and idiopathic gastroparesis.

Methods—Patients with gastroparesis on oral intake (n=305) were enrolled in the NIDDK Gastroparesis Registry and completed diet questionnaires at 7 centers. Medical history, gastroparesis symptoms, answers to a block food frequency questionnaire, and gastric emptying scintigraphy results were analyzed

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

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Results—Caloric intake averaged 1,168±801 kcal/day, amounting to 58%±39% of daily total energy requirements (TER). One hundred ninety-four patients (64%) reported caloric deficient diets, defined as <60% of estimated TER. Only 5 patients (2%) followed a diet suggested for patients with gastroparesis. Deficiencies were present in several vitamins and minerals; patients with idiopathic disorders were more likely to have diets with estimated deficiencies in vitamins A, B6, C, K, iron, potassium, and zinc than diabetic patients. Only a third of patients were taking multivitamin supplements. More severe symptoms (bloating and constipation) were characteristic of patients that reported an energy-deficient diet. Overall, 32% of patients had nutritional consultation after the onset of gastoparesis; consultation was more likely among patients with longer duration of symptoms and more hospitalizations and patients with diabetes. Multivariable logistic regression analysis indicated that nutritional consultation increased the chances that daily total energy requirements were met (odds ratio=1.51, *P*=.08).

Conclusions—Many patients with gastroparesis have diets deficient in calories, vitamins, and minerals. Nutritional consultation is obtained infrequently, but is suggested for dietary therapy and to address nutritional deficiencies.

Keywords

FFQ; stomach; vomiting; clinical trial; motility disorder

Introduction

Gastroparesis is a chronic motility disorder of the stomach characterized by delayed gastric emptying (1). Symptoms include early satiety, postprandial fullness, abdominal distension, nausea, and vomiting. Patients with gastroparesis may have symptoms associated with eating resulting in food aversion and inadequate oral intake (2). Some patients have protracted nausea and vomiting, making it difficult to maintain hydration and nutritional status. Thus, patients with gastroparesis are at risk for weight loss, malnutrition, and vitamin and mineral deficiencies.

Current dietary recommendations for patients with gastroparesis include suggestions that compensate for the impairment of gastric emptying by consuming foods that are low in fat and fiber, since fat and fiber may delay gastric emptying (3, 4). In order to maintain caloric intake, small, frequent, meals are suggested (4). In some cases, to supplement their limited intake, patients drink high protein caloric liquids since liquids are better tolerated than solids. One small survey suggests that patients with gastroparesis consume a diet that is deficient in many nutrients (5). The degree of nutritional deficiency in the diets of patients with gastroparesis is not well described and the degree of adherence to the recommended diet is unknown.

The aim of this study is to characterize dietary intake and nutritional deficiencies in patients with diabetic and idiopathic gastroparesis and to determine whether dietary deficiencies differ by disease characteristics and symptoms of gastroparesis, access to nutritional consultation, etiology of gastroparesis (idiopathic vs. diabetic), body weight, and severity of the gastric emptying dysfunction.

Methods

General Study Design

The NIH NIDDK Gastroparesis Clinical Research Consortium is a cooperative network of seven clinical centers and one Data Coordinating Center. The NIDDK Gastroparesis Registry, an observational study of prospectively enrolled patients with gastroparesis and

gastroparesis-like symptoms who have met specific entry criteria, was begun in January 2007. Entry criteria for the Gastroparesis Registry included: age 18 or older, gastroparesis symptoms of at least 12 weeks duration, 4 hour gastric emptying scintigraphy results within past 6 months, and no abnormality causing obstruction assessed by upper endoscopy in past year. Registry data at enrollment included symptom questionnaires including Patient Assessment of GI Symptoms (PAGI-SYM) and the Block Brief Food Questionnaire (FFQ), a commonly used instrument estimating caloric, vitamin, and mineral intake (6). During the history, patients were asked if they have had a formal nutritional consultation for their disorder. Physical examinations included height, body weight, waist and hip measurements. Fasting laboratory blood work included hematology, chemistries, hepatic panel and etiologic lab tests. Baseline data on patients with gastroparesis, that is, delayed gastric emptying, enrolled through March 15, 2010 in the Gastroparesis Registry have been analyzed for this study. Only those with idiopathic or diabetic etiology (Type 1 or Type 2) and only patients reliant on oral nutritional intake of dietary foods have been included. Idiopathic gastroparesis patients are patients with delayed gastric emptying, and the gastroparesis not being from diabetic, postsurgical causes, or other known causes. The diabetic patients could have either Type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM) as defined by the patient and physician.

Data Accrual: Questionnaires, Gastric Emptying, Blood Tests

The Block Food Frequency Questionnaire is a commonly used instrument estimating caloric, vitamin, and mineral intake (6,7). The Block FFQ has been used to estimate daily dietary intake in patients with GERD (8), Barretts esophagus (9), and obesity (10). This study used the Block Brief 2000 FFQ which contains about 70 food items and takes 15–20 minutes to complete (7,11). It was designed to provide estimates of usual customary dietary intake over the past year including all meals and snacks. Individual portion sizes are requested and pictures are provided. The food list was developed from the NHANES III dietary recall data (12). The nutrient database was developed from the USDA Nutrient Database for Standard Reference (13).

Each patient filled out the 20 item PAGI-SYM questionnaire which assesses symptoms of gastroparesis, dyspepsia, and gastroesophageal reflux disease (14); it includes the 9 question Gastroparesis Cardinal Symptom Index (GCSI) (15,16). In the PAGI-SYM, patients are asked to assess the severity of their symptoms during the previous two weeks using a 0 to 5 scale where no symptoms = 0, very mild = 1, mild = 2, moderate = 3, severe = 4, and very severe = 5.

The severity of gastroparesis was graded on a scale originally proposed by Tack et al and reported in the ANMS review on gastroparesis (4). Severity is graded as grade 1: mild gastroparesis (symptoms controlled relatively easily 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 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).

Gastric emptying scintigraphy was performed using a low-fat, egg white meal with imaging at 0, 1, 2, 4 hours after meal ingestion, as described by a multicenter protocol (17). This protocol ensures standardized information about delayed gastric emptying across sites (18). This report focuses on patients with gastroparesis, that is, delayed gastric emptying scintigraphy of > 60% at 2 hours and/or > 10% at 4 hours. Delayed gastric emptying was graded according to gastric retention at 4 hours: mild (≤20% gastric retention at 4 hours), moderate (>20 to 35%), and severe (>35%) (18,19).

Laboratory measures suggestive of poor nutrition or inflammation were included: albumin, blood urea nitrogen (BUN), creatinine, erythrocyte sedimentation rate (ESR) and C reactive protein (CRP). These measures were categorized as follows: elevated CRP (> 0.8 mg/dL), elevated ESR (> 20 mm/hr), low albumin (< 3.5 g/dL), elevated BUN (> 20 mg/dL), and elevated creatinine (> 1.1 mg/dL for females, > 1.2 mg/dL for males).

Daily Energy Requirement / Total Energy Expenditure

The Institute of Medicine assessment of daily nutritional requirements, developed by a multidisciplinary expert panel, was used to calculate the daily caloric requirements needed to cover the total daily energy expenditure (TEE) (20, 21).

For men aged ≥19 y: TEE = 662 − (9.53 × age) + PA × [15.9 × Wt + 540 × Ht].

For women aged ≥19 y: TEE = 354 – (6.91 × age) + PA × [9.36 × Wt + 726 × Ht], where age is in years, weight in kilograms, and height in meters. For this report, we assumed that each person had low activity or sedentary level, since they had symptomatic gastroparesis. Thus, the physical activity level (PAL) of 1.2 was used with 1.0 being the physical activity (PA) coefficient for the above formulas. A caloric deficient diet was defined as <60% of daily energy requirements. A deficient intake of specific nutrients was defined as < 60% of the specified estimated Recommended Daily Intake (RDI) (20,22).

Other important diet components were assessed from the average daily intakes estimated by the Block FFQ and recommended daily intakes (20). Minimal carbohydrate needs were defined as 50 grams/day, deficient protein intake defined as < 0.6 grams/kg body weight, low fat defined as < 25% daily caloric intake from fat, low fiber defined as ≤ 10 grams/day of total fiber, ideal protein range intake defined as 10% to 30% of daily caloric intake from protein, and ideal carbohydrate range intake defined as 45% to 65% of daily caloric intake from carbohydrates. The number of daily nutrient drinks was determined from the Block FFQ question concerning intake of “instant breakfast, diet shakes, or liquid supplements.” Since the number of meals per day could not be determined from the Block FFQ, an estimate was the average of the sum of the servings of vegetables, grain, and meat. If either the estimated meals/day or servings/day of any food category was ≥ 4, then the patient was considered to eat “frequent meals.” A suggested gastroparesis diet was defined as non-deficient daily caloric intake, and being low in fat and fiber (4).

Statistical Analysis

A set of baseline characteristics including diet, demographic, anthropometric, laboratory values, gastroparesis specific medical history, gastric emptying scintigraphy and symptom severity scores from the PAGI-SYM were analyzed in both univariable and multivariable logistic regression analyses to show the pattern of these characteristics among gastroparetic patients and to also show variations in these patterns across 5 patient sub-groups (energy deficient diet, nutritional consultation after gastroparesis onset, gastroparesis etiology, body mass category, and severity of delayed gastric retention at 4 hours). Univariable results are expressed as mean ± standard deviation (SD) or by percentages, where appropriate. The statistical significance of differences in clinical features within each of the sub-groups 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 Wilcoxon rank sum test, Kruskal-Wallis test, or ordered logistic regression of the outcome on the rank of continuous predictors (23, 24). Univariate logistic regression models (one model per characteristic without adjustments for other factors) were used to assess the individual associations between each outcome measure and the baseline patient characteristics.

Multiple binary regression models for each of the sub-group analyses were developed separately. First, a sub-set of the available baseline characteristics relevant to each aim was identified. For associations with energy deficient diet, the candidate set included patient and disease characteristics and symptoms; for nutritional consultation, diet components were additionally included; and for etiology, body mass category and retention severity, only diet components and laboratory biomarkers were included. Then a series of bi-directional stepwise (forward and backward) multiple binary logistic regression analyses were used to reduce the set of characteristics associated with each sub-group (25). A P-value ≤ 0.05 was used both for the addition or deletion of candidate characteristics in the stepwise procedures and age (categorical), gender, and race (white vs non-white) were controlled for in each model. Models were further reduced using likelihood ratio tests for sets of variables. Final model selection was guided by pseudo_R2 and Akaike's Information Criterion (26). All final models for each sub-group were found to have adequate goodness of fit using the Hosmer-Lemeshow chi-square test for fit of logistic models. *P* values are two-sided, nominal, with a level of 0.05 considered to be statistically significant.

For analyses, both SAS v9.1 (SAS Institute, Cary, NC) and Stata release 11 (Stata Corp, College Station, TX) statistical software were used (27).

Results

Patients

Of 396 patients with delayed gastric emptying in the Gastroparesis Registry, 376 completed the Block Brief FFQ. Of these, 49 (13%) on either TPN or enteral feedings were excluded as we did not have accurate caloric intake on these patients from their TPN or enteral feedings. In addition, 22 patients were identified with post-surgical or other causes of gastroparesis (e.g. systemic lupus erythematoses, reflex sympathetic dystrophy), resulting in 305 patients with diabetic or idiopathic gastroparesis (204 idiopathic and 101 diabetic) with data on oral dietary intake.

Caloric Intake in Patients with Gastroparesis

Caloric intake averaged 1,168±801 kcal/day amounting to only 58±39% of patients' estimated daily energy expenditures (Table 1). The mean daily intake of each macronutrient was: carbohydrates 139±95 g; protein 45±33 g; fat 49±38 g; and fiber 9±7 g. Oral carbohydrates represented 48±11% of daily Kcal, protein represented 16±4%, fat 37±9%, and fiber 3±1%.

Overall, the patients were averaging only 1.4±1.0 meals per day. The daily intake was characterized as low in fat in only 10% of patients, low in fiber in 67% of patients, and small food portions in 37±22% of servings per day. Ten percent of patients were taking nutrient drinks more than 5 days per week. Only 5 (2%) patients were following a suggested gastroparetic diet, consisting of a non-deficient average daily caloric intake that is low in fat and fiber.

The percentage of patients taking vitamin and mineral supplementations were: multivitamins 38%; B-complex vitamins 9%; vitamin C 12%; vitamin D 16%; calcium 22%; and iron supplements 6%.

Many vitamin and mineral dietary intake deficits were present in the patients with gastroparesis (Table 2). Deficiencies for intake of vitamins and minerals from food ranged from 30 to 86% of patients. Vitamin and mineral deficits were particularly prominent for: vitamins C (49% of patients were deficient), D (61%), E (80% deficient), and K (56%), folate (68%), calcium (70%), iron (69%), magnesium (72%), and potassium (86%).

Energy Deficient Patients

There were 194 patients (64%) consuming a reported diet that was estimated to be energy deficient (<60% of daily TER). These patients consumed significantly less for each of carbohydrates (P<0.001), protein (P<0.001), fat (P<0.001), and fiber (P<0.001) (Table 1).

Patients classified as consuming an energy deficient diet were taking less estimated meals per day (0.9±0.5 vs 2.2±1.2,; P<0.001), more often having small food portions during the day (43±22% vs 29±18% of small food portions per day, P<0.001) and were taking less nutrient drinks per week (8% vs 14% taking 5 or more nutrient drinks per week, P=0.10).

Vitamin and mineral dietary deficiences were all more prevalent in patients consuming an energy deficient diet (Table 2). Micronutrient intake deficits were particularly prominent in patients consuming an energy deficient diet compared to those consuming non-deficient diets for: vitamin A (50% vs 10% of patients), thiamin (62% vs 4%), riboflavin (50% vs 2%), vitamin B_6 (55% vs 5%), vitamin B_{12} (45% vs 5%), vitamin C (66% vs 19%), vitamin D (71% vs 44%), niacin (66% vs 5%), folate (90% vs 31%) and all minerals (40% to 63% more patients were inadequate in their intake).

The patients consuming caloric deficient diets had higher symptom scores for feeling of stomach fullness (3.7±1.2 vs 3.2±1.4, P=0.005), inability to finish a meal (3.4±1.4 vs 3.1±1.5, P=0.07), feeling excessively full after a meal (3.7±1.3 vs 3.2±1.5, P=0.005), loss of appetite (3.1±1.5 vs 2.7±1.6, p=0.07), bloating (3.3±1.5 vs 2.8±1.6, p=0.005), upper abdominal pain (3.1±1.7 vs 2.7±1.8, P=0.05) and constipation (2.6±1.8 vs 2.1±1.7, P=0.02) (Table 1).

Patients consuming an energy deficient diet were similar compared to those that were not for most of the demographic, medical history, psychological function inventories, and laboratory values that were analyzed, as well as for gastric scintigraphy results. The BMI was 27.0±7.4 kg/m^2 compared to 27.1±7.4 kg/m^2 (P=0.85); 4 hour gastric retention was 30.6±21.8% vs 31.9±22.6% (P=0.69). 33.0% of patients with energy deficient diets had nutritional consultation after their gastroparesis onset compared to 31.5% (P=0.79) for patients consuming normal diets. The predominant initial symptom prompting gastroparesis evaluation was more likely to be bloating (10% vs 4%, P=0.05) and less likely to be vomiting (18% vs 30%, P=0.02) in those consuming energy deficient diets compared to those with non-deficient diets.

Multiple logistic regression was used to identify independent characteristics of patients with gastroparesis with an energy deficient diet (Table 3). Independent factors associated with an energy deficient diet were more severe symptoms of bloating (OR=1.28, P=0.009) and constipation (OR=1.23, P=0.01), and less severe symptoms of GERD (OR=0.79, P=0.03), whereas factors associated with consuming an adequate energy diet were being twice as likely to have had a hospitalization in the past year (OR=0.49, P=0.007) and more likely to have an elevated BUN (OR=0.41, P=0.02).

Nutritional Consultation after gastroparesis onset

Only 99 of 305 (32%) patients had received nutritional consultation after gastroparesis onset; these consisted of 24% of the idiopathic patients, 60% of the Type 1 diabetes mellitus (T1DM) patients, and 39% of the type 2 diabetes mellitus (T2DM) patients (P<0.0001). Vomiting, as a predominant symptom prompting evaluation for gastroparesis, was more prevalent in the patients with prior nutritional consultation than those without (27% vs 20%, P=0.15). Vomiting severity, at the time of enrollment, tended to he higher in patients having had a prior nutritional consultation than those who had not (2.3±1.8 vs 1.9±1.9, P=0.10). The patients with nutritional consultation had longer duration of symptoms of gastroparesis

at enrollment (5.7±5.9 vs 4.3±5.9 years, P=0.005) and had more hospitalizations in the past year (3.8±6.5 vs 1.4±2.8, P=0.001). Otherwise, patient and disease characteristics were very similar between the two groups.

Patients with nutritional consultation had similar intake as percent of estimated TER as those without (60±42% vs 57±38%, P=0.75) and were consuming a similar number of estimated meals per day (1.43±1.02 vs 1.36±1.03, P=0.34). These patients also consumed a similar percentage of low fat, low fiber meals: low fat diet in 9% compared to 10% and low fiber diet in 66% versus 68% of patients with and without nutritional consultations, respectively.

Multiple logistic regression was used to identify independent characteristics of patients with a nutritional consultation at gastroparesis onset. Nutritional consultation was more common in diabetic patients (overall P<0.001), particularly type 1 (OR=4.28, P<0.001) but also type 2 (OR=1.98, P=0.07) and those with more hospitalizations in the past year (OR=1.11, P=0.004). Patients receiving nutritional consultation were 1.5 times more likely to have their daily caloric intake be 85% or more of their TER than those without (overall P=0.08).

Etiology of Gastroparesis: Diabetic vs Idiopathic

Both type 1 (1,305±860, P=0.05) and type 2 (1,263±779, P=0.12) diabetic patients had a higher daily caloric intake compared to idiopathic patients (1,110±787 kcal/day) (Table 4). Patients with diabetic gastroparesis were more likely to be consuming a diet that was less percentage carbohydrate (44±9% (P=0.0004) for type 1 and 46±11% (P=0.04) for type 2 vs 50±10%), higher percent protein (17±4% (P=0.006) for type 1 and 16±3% (P=0.16) for type 2 vs 15±4%, higher % fat (39±7% (P=0.005) and 40±9% (P=0.007) vs 36±9%, and higher percent fiber (3.1±1.2% (P=0. 29) for type 1 and 3.5±1.7% (P=0.01) vs 3.0±2.7% than those with idiopathic gastroparesis. Idiopathic and both diabetic (T1DM, T2DM) gastroparesis groups had similar percentage of patients consuming an energy deficient diet (65%, 62% and 59%, overall P=0.41). Patients with diabetic gastroparesis (T1DM and T2DM) were more likely than idiopathics to have had nutritional consultation after gastroparesis onset (60% vs 39% vs 24%; P<0.0001 (T1DM), P=0.03 (T2DM)).

Idiopathic patients compared to type 1 and type 2 diabetic patients were more likely to have micronutrient deficiencies, defined as nutrient intake <60% of DRI, in vitamin B_6 (42% vs 31% (P=0.15) and 24%(P=0.02)), and vitamin K (61% vs 46% (P=0.04) and 46% (P=0.06)), and in iron compared to type 2 diabetics (73% vs 59% (P=0.06). The average daily intake as a percent of DRI of most micronutrients was lower in idiopathics compared to either diabetic group and statistically significant or near significance for vitamins A, B_6, C, K, and iron and potassium.

Multiple logistic regression analyses of patients with T1DM compared to idiopathics identified the following independent diet predictors: lower percentage of intake from sweets (OR=0.97, P=0.04), and an increased percentage of intake from fat (OR=1.07, P=0.006). An increased likelihood of an elevated ESR (OR=3.92, P=0.001), BUN (OR=7.43, P=0.001) and creatinine level (OR=4.65,P=0.003) were characteristic of T1DM patients compared to idiopathic patients (Table 5).

Characteristics identified by multiple regression analyses of T2DM compared to idiopathics included: lower percentage of intake from sweets (OR=0.97, P=0.04), and more likely to have elevated ESR (OR=3.35, P=0.003) and creatinine (OR=4.08, P=0.002)

Body Weight

Overweight/obese patients comprised 54% of gastroparetic patients in the study. The overweight/obese patients comprised 46% of idiopathic and 70% of diabetic patients (50.9%

of T1DM and 91.3% of T2DM). Overweight/obese patients consumed more calories than normal/underweight patients (1,272±886 vs 1,047±673 kcal/day; P=0.02); however, their intake as a % of TER was similar. The diets in the overweight/obese patients were higher in percent of daily kcal from fat (39±9% vs 35±9%, P<0.0001), but lower in percent carbohydrates (47±10% vs 50±10%, P<0.006) (Supplement Table 2).

The overweight/obese patients reported consuming more estimated meals per day (2.0±1.5 vs 1.7±1.2 meals per day, P=0.04), more large or extra large portions/day (21±17% vs 13±13%, P<0.0001), less small meal portions/day (31±20% vs 45±22%, P<0.0001) and fewer drank nutrient drinks 5 or more times per week (6% vs 15%, P=0.02).

Vitamin and mineral deficiencies were lower and daily intake as percent of DRI was mostly higher in overweight patients compared to normal weight individuals; however, values were not significantly different. The exception was vitamin D, which was deficient more so in overweight/obese individuals than normal/underweight individuals (67% vs 55%, P=0.03).

Overweight/obese patients were more likely to report weight gain as prompting gastroparesis evalution (32% vs 6%, P<0.001) and less likely to report weight loss (34% vs 69%, P<0.001) compared to normal weight individuals and were more likely to be T2DM (29% vs 3% T2DM, 17% vs 19% T1DM, 57% vs 78% idiopathic, P<0.001).

Independent diet and laboratory biomarker predictors for overweight/obese patients identified from multiple logistic regression included: higher percent of calories from sweets (OR=1.02, P=0.05) and fat (OR=1.06, P=0.001) and more likely to have elevated CRP (OR=2.87, P=0.001) and ESR (OR=4.29, P<0.001) (Supplement Table 4).

Gastric emptying

Nearly all of the characteristics of caloric intake and diet components analyzed were similar among the patients in the 3 categories of severity of delayed gastric retention (Supplement Table 3). While the average caloric intake was lower in patients with severe gastric retention at 4 hours (1,094±647 kcal/day) compared to those with moderate delay (1,145±852 kcal/day) and those with mild delay (1,235±868), this difference was not statistically significant (P=0.53). Multiple logistic regression of patients with severe retention identified the following diet related predictors: almost twice as likely for their daily intake to meet 60–85% of TER and almost 2 times less likely for their daily intake to meet 85% or more of the TER (overall P=0.01) and were more likely to have a lower albumin level (OR=3.32, P=0.002) than those with mild or moderate retention (Supplement Table 4).

Discussion

This report has examined dietary intake of patients with diabetic or idiopathic gastroparesis enrolled in the NIDDK Gastroparesis Registry using the Block FFQ to assess their food intake. This study has found that the majority of patients with gastroparesis consume diets deficient in calories, carbohydrates, protein, vitamins and minerals. The dietary intake of patients with gastroparesis appears to be influenced by several factors, including etiology of gastroparesis, body weight, severity of gastric emptying abnormality, and patient's symptoms. This study also shows that only a minority of patients had seen a nutritionist or followed diets that should be recommended for those with gastroparesis.

The majority of patients (64%) with gastroparesis consumed energy deficient diets. The decrease in caloric intake in patients with gastroparesis was present in both diabetic and idiopathic gastroparesis. Patients consuming caloric deficient diets had significantly higher symptom scores for stomach fullness, excessive fullness after a meal, bloating and

constipation on univariable analysis with multivariable analysis showing bloating and constipation being associated with energy deficient diets. More severe delay in gastric emptying was also associated with being less likely to meet daily total energy requirement. Ogorek et al also showed that patients with idiopathic gastroparesis consumed a diet containing fewer calories than suggested and prolonged emptying correlated with diminished intake of protein, iron, niacin, and potassium (5). The caloric intake of idiopathic patients reported in this manuscript using the Block FFQ (average of 1,168 kcal/day) agrees with that reported by Ogorek et al (average of 1,112 kcal/day) where caloric intake was estimated using a detailed 7 day diet record (5).

Classically, patients with gastroparesis are thought to be underweight. This study shows that some patients with gastroparesis can be overweight, although the proportion overweight is less than the general population (28). T2DM gastroparetic patients were more likely to be overweight than idiopathic gastroparetic patients. Although overweight/obese patients consumed more calories than normal/underweight patients, they still consumed an energy deficient diet based on gender, body weight, height, and activity level. The diet of the overweight patients with gastroparesis were higher in fat, carbohydrate, and protein. The fact that they remained overweight/obese despite consuming an energy deficient diet infers that they had a greater BMI before the onset of their symptoms or they underreported their intake. The Block FFQ asks about usual dietary intake over the past year whereas the duration of gastroparesis for these patients averaged 5 years. It is possible that while obese, these patients were losing weight compared to their pre-gastroparesis weight. This is supported by the observation that a third of these patients had weight loss as a reason for being evaluated for gastroparesis. The failure of some obese subjects to lose weight while eating a diet they report as low in calories may be due to their food intake being substantially higher than they report. This underreporting of food consumption in obese patients has been found in other studies (29). Energy expenditure estimates typically increase in error with body weight extremes, so anorexic underweight gastroparetics and obese gastroparetics may have skewed the estimates as compared to more normal weight patients. This may partially explain the estimate that overweight gastroparetics ate a similar percentage of caloric requirements as normal weight patients (29). The energy requirement estimate which is based on body weight may overestimate actual needs as BMI increases. A less likely explanation for the presence of obese patients consuming energy deficient diets is the basal metabolic rate of obese patients with gastroparesis may be lower accounting a positive energy balance (29).

Vitamin and mineral intake was below the DRIs in a large number of patients with gastroparesis – both diabetic and idiopathic patients. Idiopathic patients were more likely to have diets with deficits in vitamin B_6, vitamin K, and iron than diabetic patients. Ogorek et al also found that in patients with idiopathic gastroparesis, intake of several minerals and vitamins were deficient (5). The vitamin and mineral deficits may represent a global decrease in all food groups since iron, vitamin B_6, vitamin K are absorbed in different ways and ingested in different foods. Importantly, this study suggests that patients with gastroparesis, particularly those with idiopathic gastroparesis, may need additional vitamin and mineral supplementation. However, in this registry of patients with gastroparesis only a third of patients were taking daily multivitamins.

A low fat, low fiber diet of small portions and frequent feedings are often recommended to patients with gastroparesis (3,4,30). These suggestions are in large part empirical based on dietary factors known to influence gastric emptying and to compensate for the impairment in gastric emptying since there are no controlled trials comparing dietary treatments in these patients (31). Fat is known to slow gastric emptying. Fiber can increase bloating and may produce satiation (32). Smaller, frequent meals are recommended as large volumes slow

gastric emptying aggravating the early satiety often seen. This study shows that few patients with gastroparesis follow a gastroparesis dietary regime. This may be due to a lack of consensus as to what the optimal gastroparesis diet is, that a gastroparesis diet may not be achievable by patients, or that patients were unaware of, or did not follow recommendations.

Dietary management is often the first step in treating patients with gastroparesis (2,4). In this study, only 32% of patients had nutritional/dietary consultation after diagnosis of their gastroparesis. This suggests that dietary history and treatment are frequently neglected in patients with gastroparesis. Nutritional consultation was more frequent in patients who were sicker and hospitalized more frequently. Type 1 diabetics were more likely to have had a nutritional consult. Though not statistically significant, multiple logistic regression suggested that those with prior nutritional consultation were more likely to be meeting their daily total energy requirements. It is interesting that diabetic patients with gastroparesis were less likely to have micronutrient deficiencies perhaps reflecting their increased dietary education received. In this cross sectional study, the parameters studied at the time of enrollment in the registry could reflect the advice of prior nutritional consultation or part of the reason for the patient to see a nutritionist. Differentiation would require either a longitudinal study starting at the time of diagnosis of gastroparesis or a randomized trial of nutritional consultation compared to no consultation in patients at the time of their diagnosis of gastroparesis. Ongoing nutritional advice may be required for patients to achieve nutritional adequacy.

Caloric intake was estimated in this study with the Block FFQ, a standardized questionnaire used in many studies (6,7). Food frequency questionnaires are frequently used in epidemiology studies. The Block Brief 2000 used in this study assesses dietary intake over the last year. It has only two-thirds as many foods as the full-length Block FFQ allowing better feasibility of patients filling out the questionnaire. Total calories and macronutrients may be underestimated by the Block Brief 2000 compared to more detailed food questionnaires, but the percentages of fat, protein, etc of the diet appear reliable, and for its purpose of ranking people along the distribution of intake, it is very effective (11). There are several formulas that can be used for total energy expenditure and daily caloric requirements. One traditional formula is the Harris-Benedict equation, a classic equation developed in 1919 (33). Newer formulas, such as the one developed by the Institute of Medicine (20,21) and used here, factor in activity levels of the individuals.

In summary, many patients with gastroparesis consume diets deficient in calories, carbohydrates, protein, vitamins and minerals. Only a third of patients with gastoparesis receive nutritional counseling. Multivariable logistic regression suggested that those with prior nutritional consultation were more likely to be meeting their daily total energy requirements. A nutritional consultation by a registered dietitian may be helpful and should be considered in patients with gastroparesis. Diet compliance might be improved by several encounters rather than a single visit. Studies are indicated to determine if dietary modifications and nutritional consultation improve the intake of patients with gastroparesis to reduce nutritional deficiencies and improve symptoms.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Caloric intake, components of caloric intake, and baseline and symptom characteristics of gastroparesis patients who are and are not consuming an energy deficient diet

	All Patients (N=305)		Have Energy Deficient Diet*				
			No (N=111)		Yes (N=194)		
Characteristic	**No.**	**Statistic†**	**No.**	**Statistic†**	**No.**	**Statistic‡**	***P* value‡**
Caloric intake:							
Caloric intake (kcal/day)	305	1,168 ± 801	111	1,931 ± 829	194	731 ± 305	n/a
Intake as % of estimated total energy requirements (TER)	305	58% ± 39%	111	96% ± 40%	194	36% ± 14%	n/a
Daily carbohydrate intake (g)	305	139 ± 95	111	223 ± 102	194	90 ± 43	**<0.001**
% of daily Kcal from carbohydrates	305	48% ± 11%	111	46% ± 9%	194	49% ± 11%	**0.007**
% of daily Kcal from sweets, desserts	305	14% ± 14%	111	16% ± 14%	194	14% ± 14%	**0.04**
Daily intake < 50 g	38	12.5%	0	0.0%	38	19.6%	**<0.001**
Daily protein intake (g)	305	45 ± 33	111	75 ± 35	194	28 ± 14	**<0.001**
% of daily Kcal from protein	305	16% ± 4%	111	16% ± 4%	194	15% ± 4%	0.47
Daily intake < 0.6g/kg weight	173	56.7%	14	12.6%	159	82.0%	**<0.001**
Daily fat intake (g)	305	49 ± 38	111	83 ± 41	194	29 ± 14	**<0.001**
% of daily Kcal from fat	305	37% ± 9%	111	38% ± 8%	194	36% ± 10%	**0.01**
Daily fiber intake (g)	305	9 ± 7	111	14 ± 7	194	6 ± 4	**<0.001**
% of daily Kcal from fiber	305	3% ± 1%	111	3% ± 1%	194	3% ± 2%	0.59
Diet components (yes vs no):							
Normal caloric intake	111	36.4%	111	100.0%	194	0.0%	n/a
Low fat	29	9.5%	7	6.3%	22	11.3%	0.15
Low fiber	205	67.2%	37	33.3%	168	86.6%	**<0.001**
Ideal protein range intake	282	92.5%	106	95.5%	176	90.7%	0.13
Ideal carbohydrate range intake	168	55.1%	54	48.7%	114	58.8%	0.09
Nutrient drinks 5+ days per week	30	10.0%	15	13.8%	15	7.9%	0.10
Daily intake of cans nutrient drink	300	0.23 ± 0.55	109	0.33 ± 0.72	191	0.17 ± 0.41	0.25
Frequent servings per day	71	23.3%	56	50.5%	15	7.7%	**<0.001**
% of small food portions per day	305	37% ± 22%	111	29% ± 18%	194	43% ± 22%	**<0.001**
% of large or extra-large portions/day	305	18% ± 15%	111	23% ± 17%	194	14% ± 13%	**<0.001**

Characteristic	All Patients (N=305)		Have Energy Deficient Diet*				
			No (N=111)		Yes (N=194)		
	No.	Statistic†	No.	Statistic†	No.	Statistic‡	*P* value‡
Number of meals/day§	305	1.4 ± 1.0	111	2.2 ± 1.2	194	0.9 ± 0.5	**<0.001**
Take vitamins or mineral supplements:							
Multivitamin	117	38.4%	41	6.9%	75	39.2%	0.70
Stress-tabs or B-complex	26	8.5%	10	9.0%	16	8.3%	0.82
Antioxidant combination	18	5.9%	8	7.2%	10	5.2%	0.46
Vitamin A	5	1.6%	3	2.7%	2	1.0%	0.36
Vitamin C	37	12.1%	12	10.8%	25	12.9%	0.58
Vitamin D	48	15.7%	19	17.1%	29	15.0%	0.62
Vitamin E	21	6.9%	9	8.1%	12	6.2%	0.52
Calcium supplement	66	21.6%	19	17.1%	47	24.2%	0.15
Iron supplement	19	6.2%	8	7.2%	11	5.7%	0.59
Zinc supplement	9	3.0%	4	3.6%	5	2.6%	0.73
Follows a suggested gastroparesis diet§	5	1.6%	5	4.5%	0	0.0%	**0.006**
Demographic & anthropometric:							
Gender: females	252	82.6%	90	81.1%	162	83.5%	0.59
Age at enrollment (years)	305	42.8 ± 13.9	111	43.3 ± 14.5	194	42.6 ± 13.5	0.64
Race: white	269	88.2%	96	86.5%	173	89.2%	0.48
Hispanic: (yes vs no)	9	3.0%	3	2.7%	6	3.1%	1.00
BMI (kg/m^2)	305	27.0 ± 7.4	111	27.1 ± 7.4	194	27.0 ± 7.4	0.85
BMI category:							0.72
Underweight (<18)	17	5.6%	8	7.2%	9	4.6%	
Normal (18–24)	124	40.7%	42	37.8%	82	42.3%	
Overweight (25–30)	59	19.3%	23	20.7%	36	18.6%	
Obese (>30)	105	34.4%	38	34.2%	67	34.5%	
Waist to hip ratio (cm)	305	0.87 ± 0.11	111	0.88 ± 0.09	194	0.86 ± 0.11	0.19
Medical history:							
Type of gastroparesis:							0.41
Idiopathic	204	66.9%	71	64.0%	133	68.6%	

Characteristic	All Patients (N=305)		Have Energy Deficient Diet*				
			No (N=111)		Yes (N=194)		
	No.	Statistic†	No.	Statistic†	No.	Statistic‡	*P* value‡
Diabetic Type 1	55	18.0%	21	18.9%	34	17.5%	
Diabetic Type 2	46	15.1%	19	17.1%	27	13.9%	
Nutritional consultation after Gp onset	99	32.5%	35	31.5%	64	33.0%	0.79
Age at onset of symptoms (years):							0.24
< 25 years	67	22.0%	28	25.2%	39	20.1%	
25 – 45 years	140	45.9%	44	39.6%	86	49.5%	
45+ years	98	32.1%	39	35.1%	59	30.4%	
Average age	305	38.0 ± 14.2	111	38.0 ± 14.7	194	38.0 ± 13.9	0.93
Duration of symptoms at enrollment (yrs):							0.15
< 1.5 years	95	31.2%	27	24.3%	68	35.1%	
1.6 – 4.9 years	117	38.4%	46	41.4%	71	36.6%	
5 + years	93	30.5%	38	34.2%	55	28.4%	
Average duration	305	4.8 ± 5.9	111	5.2 ± 5.6	194	4.5 ± 6.1	0.09
Initial infectious prodrome (yes vs no)	54	17.8%	20	18.2%	34	17.5%	0.89
Predominant symptom prompting Gp evaluation:							
Nausea vs all others	108	35.4%	39	35.1%	69	35.6%	0.94
Vomiting vs all others	68	22.3%	33	29.7%	35	18.0%	**0.02**
Abdominal pain vs all others	60	19.7%	17	15.3%	43	22.2%	0.15
Bloating vs all others	23	7.5%	4	3.6%	19	9.8%	**0.05**
Gastroesophageal reflux vs all others	16	5.3%	7	6.3%	9	4.6%	0.53
All others vs all of above	30	9.8%	11	9.9%	19	9.8%	0.97
Type of gastroparesis symptom onset:¶							0.86
Acute start	155	50.8%	57	51.8%	98	50.8%	
Insidious start	148	40.5%	53	48.2%	95	49.2%	
Nature of gastroparesis symptoms:							0.54
Chronic, but stable	76	25.0%	25	22.7%	51	26.3%	
Chronic, but worsening	98	32.2%	32	29.1%	66	34.0%	
Chronic with periodic exacerbations	99	32.6%	41	37.3%	58	29.9%	
Cyclic pattern	31	10.2%	12	10/9%	19	9.8%	

Characteristic	All Patients (N=305)		Have Energy Deficient Diet*				
			No (N=111)		Yes (N=194)		
	No.	Statistic†	No.	Statistic†	No.	Statistic‡	*P* value‡
Gastroparesis severity:							0.61
Mild (grade 1)	43	14.1%	13	11.8%	30	15.5%	
Compensated (grade 2)	174	57.2%	63	57.3%	111	57.2%	
Gastric failure (grade 3)	87	28.6%	34	30.9%	53	27.3%	
Any co-morbidities (yes vs no)	288	94.4%	107	96.4%	181	93.3%	0.26
Any hospitalization in past year (yes v no)	134	43.9%	59	53.2%	75	38.7%	**0.01**
Number of hospitalizations	305	2.2 ± 4.5	111	2.7 ± 4.7	194	1.9 ± 4.4	**0.01**
Psychological function inventories:							
State Anxiety inventory average score	305	44.9 ± 13.6	111	44.3 ± 13.6	194	45.3 ± 13.6	0.55
State Anxiety inventory score ≥ 50	109	35.7%	41	36.9%	68	35.1%	0.74
Trait Anxiety inventory average score	305	43.8 ± 12.2	111	43.6 ± 12.3	194	44.0 ± 12.2	0.72
Trait Anxiety inventory score ≥ 50	103	33.8%	36	32.4%	67	34.5%	0.71
Beck Depression Inventory avg score	305	18.5 ± 10.7	111	19.1 ± 11.3	194	18.1 ± 10.3	0.58
Beck Depression inventory > 28	54	17.7%	22	19.8%	32	16.5%	0.46
Malnutrition/inflammation biomarkers:							
C-reactive protein (CRP) (mg/dL)	304	0.6 ± 1.1	111	0.7 ± 1.3	193	0.6 ± 1.0	0.80
Erythrocyte sedimentation rate (mm/hr)	305	17.7 ± 19.2	111	18.4 ± 18.9	194	17.4 ± 19.4	0.34
Albumin (g/dL)	305	4.1 ± 0.6	111	4.08 ± 0.57	194	4.04 ± 0.56	0.32
Blood urea nitrogen (BUN) (mg/dL)	305	13.3 ± 7.3	111	13.8 ± 7.6	194	12.9 ± 7.1	0.56
Creatinine (mg/dL)	305	0.89 ± 0.31	111	0.90 ± 0.33	194	0.90 ± 0.30	0.80
Gastric emptying (scintigraphy):							
Average % gastric retention at 2 hr	305	64.1 ± 17.9	111	64.4 ± 18.9	194	64.0 ± 17.4	0.70
Average % gastric retention at 4 hr	304	31.1 ± 22.1	110	31.9 ± 22.6	194	30.6 ± 21.8	0.69
Severity of delayed gastric emptying - 4hr:							0.90
Mild (0 – 20%)	126	41.5%	45	40.9%	81	41.8%	
Moderate (21%–35%)	86	28.3%	30	27.3%	56	28.9%	
Severe (> 35%)	92	30.3%	35	31.8%	57	29.4%	
PAGI-SYM symptom severity (0–5):							
Nausea severity	305	3.4 ± 1.4	111	3.3 ± 1.4	194	3.4 ± 1.4	0.62

Characteristic	All Patients (N=305)		Have Energy Deficient Diet*				
			No (N=111)		Yes (N=194)		
	No.	Statistic†	No.	Statistic†	No.	Statistic‡	*P* value‡
Retching severity	305	1.9 ± 1.7	111	1.9 ± 1.8	194	1.9 ± 1.7	0.91
Vomiting severity	305	2.0 ± 1.9	111	2.3± 1.8	194	1.9 ± 1.9	0.16
Feeling of stomach fullness severity	304	3.5 ± 1.3	110	3.2 ± 1.4	194	3.7 ± 1.2	**0.005**
Inability to finish meal severity	305	3.3 ± 1.4	111	3.1 ± 1.5	194	3.4 ± 1.4	0.07
Excessively full after meal severity	305	3.5 ± 1.4	111	3.2 ± 1.5	194	3.7 ± 1.3	**0.005**
Loss of appetite severity	305	2.9 ± 1.5	111	2.7 ± 1.6	194	3.1 ± 1.5	0.07
Bloating severity	305	3.2 ± 1.6	111	2.8 ± 1.6	194	3.3 ± 1.5	**0.005**
Visibly larger stomach severity	305	2.8 ± 1.8	111	2.5 ± 1.8	194	2.9 ± 1.8	0.11
Cardinal symptom index (GCSI) ¶	304	2.9 ± 1.0	110	2.8 ± 1.1	194	3.0 ± 1.0	**0.05**
Upper abdominal pain	305	3.0 ± 1.7	111	2.7 ± 1.8	194	3.1 ± 1.7	**0.05**
Lower abdominal pain severity	305	2.0 ± 1.6	111	1.8 ± 1.5	194	2.1 ± 1.7	0.18
GERD sub-score¶	304	1.9 ± 1.4	110	2.0 ± 1.3	194	1.9 ± 1.5	0.72
Constipation severity	305	2.4 ± 1.8	111	2.1 ± 1.7	194	2.6 ± 1.8	**0.02**
Diarrhea severity	305	1.8 ± 1.7	111	2.0 ± 1.7	194	1.7 ± 1.7	0.16

where PA = physical activity coefficient is assumed to be sedentary (PA = 1)

n/a = Characteristic not analyzed for statistical significance (equivalent to sub-group)

Abbreviation: Gp=gastroparesis

There are 2 patients in “other” category for type of gastroparesis symptom onset (1 in energy deficient category, 1 not).

Cardinal symptom index (GCSI) = (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

*Energy deficient diet (deficient caloric intake) defined as < 60% of total energy requirement (TER) based on patient's height, weight, activity using the following formula:

TER = 662 – (9.53 * age[yr]) + PA * (15.91 *weight[kg] + 539.6 * height[m]) for males,

TER = 354 – (6.91 * age[yr]) + PA * (9.36 *weight[kg] + 726 * height[m]) for females,

†Data are means ± standard deviations (SD) or percents (%).

‡The significance of difference between groups was tested with either a chi-square test for non-ordered categories or Fisher's exact test for categorical variables, or a Wilcoxon two sample test for continuous variables. All P values are two-sided,

[§] Suggested gastroparesis diet defined as: normal caloric intake, low fat, low fiber

[¶] Definitions:

Table 2

Adequacy of dietary intake from food of macronutrients, vitamins, and minerals as a percentage of Dietary Reference Intakes (DRIs) and percent of patients with nutrient deficiencies based on consuming energy deficient diet.

	Average Daily Intake* (as % of DRI† ± SD)			Percent with deficient intake* (< 60% DRI† for nutrient)		
	All Patients (N=305)	Energy Deficient Diet‡		All Patients (N=305)	Energy Def Diet‡	
		No (N=111)	Yes (N=194)		No (N=111)	Yes (N=194)
Macronutrients:						
Protein (g/d)	94% ± 67%	155% ± 72%	59% ± 29%	36.4%	0.0%	43.3%
Carbohydrates (g/d)	107% ± 73%	172% ± 78%	70% ± 33%	27.5%	1.8%	56.2%
Vitamins:						
Vit A (μg/d)	111% ± 118%	170% ± 133%	78% ± 94%	35.1%	9.9%	49.5%
Thiamin (B_1) (mg/d)	82% ± 57%	132% ± 61%	54% ± 27%	41.0%	3.6%	62.4%
Riboflavin (B_2) (mg/d)	98% ± 65%	156% ± 66%	64% ± 33%	31.2%	1.8%	47.9%
Vit B_6 (mg/d)	85% ± 61%	138% ± 65%	55% ± 29%	37.1%	5.4%	55.2%
Vit B_{12} (μg/d)	184% ± 238%	286% ± 303%	125% ± 165%	30.2%	4.5%	44.9%
Vit C (mg/d)	83% ± 79%	133% ± 94%	54% ± 52%	49.2%	18.9%	66.5%
Vit D (μg/d)	78% ± 94%	118% ± 120%	54% ± 65%	61.0%	44.1%	70.6%
Vit E (mg/d)	41% ± 31%	67% ± 55%	26% ± 15%	80.0%	50.5%	96.9%
Vit K (μg/d)	86% ± 99%	135% ± 120%	58% ± 70%	55.7%	30.6%	70.1%
Niacin (mg/d)	80% ± 60%	134% ± 66%	49% ± 25%	43.6%	4.5%	66.0%
Folate (μg/d)	53% ± 38%	85% ± 42%	35% ± 19%	68.2%	30.6%	89.7%
Minerals:						
Calcium (mg/d)	52% ± 37%	81% ± 41%	35% ± 20%	70.2%	37.8%	88.7%
Iron (mg/d)	58% ± 55%	94% ± 69%	37% ± 29%	68.9%	38.7%	86.1%
Magnesium (mg/d)	50% ± 34%	81% ± 34%	33% ± 17%	72.1%	35.1%	93.3%
Phosphorus (mg/d)	106% ± 70%	171% ± 70%	69% ± 32%	26.6%	0.0%	41.8%
Potassium (g/d)	36% ± 24%	58% ± 24%	23% ± 12%	86.2%	62.2%	100.0%
Zinc (mg/d)	76% ± 57%	125% ± 62%	48% ± 26%	47.2%	7.2%	70.1%

Deficient intake of each nutrient defined as < 60% of daily recommended intake (DRI) for nutrient

Data are means ± standard deviations (SD) or percents (%).

The significance of difference between groups was tested with either a chi-square test for non-ordered categories or Fisher's exact test for categorical variables or a Wilcoxon two sample test for continuous variables.

All *P* values <0.0001.

Vitamin A (μg) as retinol activity equivalents (RAE). Vitamin E (mg/d) as α-tocopherol.

[*] Average Daily Intake from food of each nutrient determined from the BLOCK Food Frequency Questionnaire. Average Daily Intake as % of DRI computed by: (Intake of nutrient from food per day)/ (Daily recommended intake (DRI)) * 100

[†] Dietary Reference Intakes (DRI) are the recommended intakes for individuals from the Food and Nutrition Board, Institute of Medicine, National Academies, (www.nap.edu) and include either Recommended Dietary Allowances (RDAs) if available or Adequate Intakes (AIs).

[‡] Energy deficient diet defined as average daily caloric intake (kcal/day) is < 60% of total energy requirement based on the patient's sex, height, weight, activity

Table 3

Analysis of baseline patient, disease and symptom characteristics for individual and independent associations with an energy deficient diet

Characteristics	Energy Deficient Diet*					
	Individual†			Independent‡		
	Odds Ratios	95% C.I.	*P* value	Odds Ratios	95% C.I.	*P* value
Baseline characteristics: ‡						
Gender: female	1.18	0.64–1.50	0.59	0.77	0.39–1.50	0.44
White	1.29	0.63–2.61	0.49	0.99	0.46–2.12	0.97
Age at symptom onset:			0.41			0.31
< 25 years	1.00			1.00		
25 – 45 years	1.48	0.81–2.72	0.20	1.54	0.80–2.94	0.20
> 45 years	1.18	0.63–2.21	0.61	1.06	0.54–2.07	0.87
Medical history:						
Nutritional consult	1.07	0.65–1.76	0.26	n/s	n/s	n/s
Overweight/obese (BMI ≥ 25 kg/m^2)	0.93	0.58–1.48	0.75	n/s	n/s	n/s
Etiology:			0.68			n/s
Idiopathic	1.00			n/s		
Diabetes type 1	0.86	0.47–1.60	0.64	n/s	n/s	n/s
Diabetes type 2	0.76	0.39–1.46	0.41	n/s	n/s	n/s
Any co-morbidities	0.52	0.17–1.64	0.26	n/s	n/s	n/s
Any hospitalization in past year	0.56	0.35–0.89	**0.002**	0.49	0.30–0.83	**0.007**
State-anxiety inventory ≥ 50	0.92	0.57–1.50	0.74	n/s	n/s	n/s
Initial infectious prodrome	0.96	0.52–1.76	0.89	n/s	n/s	n/s
Gastroparesis severity:			0.62			n/s
Mild (grade 1)	1.00			n/s		
Compensated (grade 2)	0.76	0.37–1.57	0.46	n/s	n/s	n/s
Gastric failure (grade 3)	0.68	0.31–1.47	0.32	n/s	n/s	n/s
Gastric retention at 4 hour:			0.90			n/s
Mild (0% – 20%)	1.00			n/s		
Moderate (21%–35%)	1.04	0.58–1.84	0.90	n/s	n/s	n/s
Severe (> 35%)	0.90	0.52–1.58	0.73	n/s	n/s	n/s

Characteristics	Energy Deficient Diet*					
	Individual†			Independent‡		
	Odds Ratios	95% C.I.	*P* value	Odds Ratios	95% C.I.	*P* value
Malnutrition/inflammation biomarkers: §						
CRP > 0.8 mg/dL	1.19	0.66–2.14	0.56	n/s	n/s	n/s
ESR > 20 mm/hr	0.94	0.56–1.56	0.80	n/s	n/s	n/s
Albumin < 3.5 g/dL	0.64	0.32–1.32	0.23	n/s	n/s	n/s
BUN > 20 mg/dL	0.50	0.24–1.01	**0.05**	0.41	0.19–0.87	**0.02**
Creatinine > 1.1 mg/dL	0.82	0.44–1.50	0.51	n/s	n/s	n/s
PAGI-SYM symptom severity §						
Nausea severity	1.04	0.88–1.23	0.64	n/s	n/s	n/s
Retching severity	1.00	0.88–1.15	0.98	n/s	n/s	n/s
Vomiting severity	0.91	0.80–1.03	0.13	n/s	n/s	n/s
Feeling of stomach fullness	1.31	1.09–1.58	**0.004**	n/s	n/s	n/s
Early satiety	1.18	1.00–1.39	**0.05**	n/s	n/s	n/s
Excessive fullness after meal	1.28	1.08–1.51	**0.004**	n/s	n/s	n/s
Loss of appetite severity	1.17	1.00–1.37	**0.05**	n/s	n/s	n/s
Bloating severity	1.24	1.06–1.44	**0.005**	1.28	1.06–1.55	**0.009**
Visible stomach distension	1.11	0.97–1.26	0.12	n/s	n/s	n/s
GERD sub-scale	0.99	0.84–1.17	0.89	0.79	0.64–0.98	**0.03**
Constipation severity	1.18	1.03–1.35	**0.02**	1.23	1.05–1.45	**0.01**
Model fit: Hosmer-Lemeshow χ^2 (8 df)					3.39	0.91

n/s = Characteristic not significant at the 0.05 level for this model

Caloric intake and diet components determined from the BLOCK Brief Food Questionnaire. TER defined as the total energy requirement for the patient.

% of each serving size/day is the average of the small, medium, large or extra-large food portions reported on the BLOCK Brief Food Questionnaire.

Deficient intake of each nutrient defined as <60% of daily recommended intake (DRI) for the nutrient CRP = C-reactive protein; ESR = Erythrocyte sedimentation rate; BUN = Blood Urea Nitrogen High creatinine defined as < 1.1 mg/dL for females, < 1.2 mg/dL for males

Symptom severity scores from the PAGI-SYM (Patient Assessment of GI Symptoms) questionnaire, scores range from 0–5

*Energy deficient diet defined as < 60% of total energy requirement (TER) estimated from the BLOCK Brief Food Questionnaire based on patient's sex, height, weight, activity (N=194), Not deficient caloric intake(N = 110)

†Individual characteristics and associated odds ratios, 95% confidence intervals (C.I.), and P values (2- sided) were determined from logistic regression models of energy deficient diets on single disease characteristics without adjustments for other factors.

‡Independent characteristics and associated odds ratios, 95% confidence intervals (C.I.), and P values (2- sided) were determined from multiple logistic regression analysis of energy deficient diets on gastroparesis disease and symptom characteristics as listed adjusted for sex, race (white vs not) and age at symptom onset.

§Definitions:

Table 4

Caloric intake, components of caloric intake and average dietary intake of nutrients from food of gastroparesis patients by gastroparesis etiology

Characteristic	Gastroparesis Etiology*						*P* value‡		
	Idiopathic (N=204)		Diabetic Type 1 (N=55)		Diabetic Type 2(N=46)				
	No.	Statistic†	No.	Statistic†	No.	Statistic†	Overall	Id vs DM1	Id vs DM2
Caloric intake: §									
Caloric intake (kcal/day)	204	1,110 ± 787	55	1,305 ± 860	46	1,263 ± 779	0.04	0.05	0.12
Intake as % of estimated total energy requirements (TER)	204	57% ± 40%	55	63% ± 42%	46	57% ± 31%	0.34	0.34	0.61
% Energy deficient diet (< 60% TER)	133	65.2%	34	61.8%	27	58.7%	0.41	0.64	0.41
Daily carbohydrate intake (g)	204	136 ± 93	55	145 ± 99	46	146 ± 100	0.40	0.54	0.49
% of daily Kcal from carbs	204	50% ± 10%	55	44% ± 9%	46	46% ± 11%	**0.0003**	**0.0004**	**0.04**
% of daily Kcal from sweets, desserts	204	16% ± 15%	55	9% ± 12%	46	12% ± 11%	**0.0002**	**<0.0001**	0.14
Daily intake < 50 g‡	26	12.8%	9	16.4%	3	6.5%	0.83	0.49	0.23
Daily protein intake (g)	204	41 ± 31	55	55 ± 40	46	49 ± 29	**0.005**	**0.02**	**0.04**
% of daily Kcal from protein	204	15% ± 4%	55	17% ± 4%	46	16% ± 3%	**0.006**	**0.006**	0.16
Daily intake < 0.6g/kg weight‡	115	56.4%	28	50.9%	30	65.2%	0.86	0.47	0.27
Daily fat intake (g)	204	45 ± 37	55	57 ± 39	46	56 ± 36	**0.002**	**0.01**	**0.02**
% of daily Kcal from fat	204	36% ± 9%	55	39% ± 7%	46	40% ± 9%	**0.0004**	**0.005**	**0.007**
Daily fiber intake (g)	204	8 ± 6	55	10 ± 7	46	11 ± 8	**0.006**	0.08	**0.01**
% of daily Kcal from fiber	204	3.0% ± 2.7%	55	3.1% ± 1.2%	46	3.5% ± 1.7%	**0.02**	0.29	**0.01**
Diet components (yes vs no):									
Normal caloric intake	71	34.8%	21	38.2%	19	41.3%	0.41	0.64	0.41
Low fat	24	11.8%	1	1.8%	4	5.0%	0.06	**0.03**	0.55
Low fiber	145	71.1%	33	60.0%	27	58.7%	**0.04**	0.12	0.10
Ideal protein range intake	184	90.2%	53	96.4%	45	97.8%	**0.03**	0.18	0.14
Ideal carbohydrate range intake	122	59.8%	24	43.6%	22	47.8%	**0.02**	**0.03**	0.14
Nutrient drinks 5+ days per week	25	12.3%	2	3.9%	3	6.7%	**0.05**	0.08	0.28
Daily intake of cans nutrient drink	203	0.26 ± 0.56	52	0.20 ± 0.64	45	0.11 ±0.34	**0.01**	0.06	0.06
Frequent meals per day	38	18.6%	16	29.1%	17	37.0%	**0.006**	0.09	0.007
% of small food portions per day	204	42% ± 23%	55	31% ± 18%	46	26% ± 16%	**<0.0001**	**0.001**	**<0.0001**

Characteristic	Gastroparesis Etiology*						P value‡		
	Idiopathic (N=204)		Diabetic Type 1 (N=55)		Diabetic Type 2(N=46)				
	No.	Statistic†	No.	Statistic†	No.	Statistic†	Overall	Id vs DM1	Id vs DM2
% of large or extra large portions/day	204	16% ± 15%	55	18% ± 16%	46	21% ± 15%	**0.009**	0.16	**0.007**
Number of meals per day	204	1.7 ± 1.30	55	2.3 ± 1.6	46	2.1 ± 1.3	**0.0002**	**0.002**	**0.004**
Takes vitamin or mineral supplements:									
Multivitamin	78	38.2%	20	36.4%	19	41.3%	0.95	0.80	0.70
Stress-tabs or B-complex	20	9.8%	2	3.6%	4	8.7%	0.26	0.18	1.00
Antioxidant combination	9	4.4%	2	3.6%	7	15.2%	0.12	1.00	**0.01**
Vitamin A	5	2.5%	0	0.0%	0	0.0%	0.17	0.59	0.59
Vitamin C	25	12.3%	8	14.6%	4	8.7%	0.93	0.65	0.50
Vitamin D	31	15.2%	7	12.7%	10	21.7%	0.71	0.65	0.28
Vitamin E	13	6.4%	5	9.1%	3	6.5%	0.62	0.55	1.00
Calcium supplement	47	23.0%	11	20.0%	8	17.4%	0.40	0.63	0.40
Iron supplement	12	5.9%	5	9.1%	2	4.4%	0.72	0.37	1.00
Zinc supplement	5	2.5%	0	0.0%	4	8.7%	0.49	0.59	0.06
Follows a suggested gastroparesis diet¶	5	2.5%	0	0.0%	0	0.0%	0.17	0.59	0.59
Nutritional consultation after Gp onset	48	23.5%	33	60.0%	18	39.1%	**<0.0001**	**<0.0001**	**0.03**
Percent deficient intake from food (< 60% DRI for nutrient):									
Macronutrients:									
Protein (g/d)	78	38.2%	19	34.6%	14	30.4%	0.34	0.62	0.32
Carbohydrates (g/d)	56	27.5%	15	27.3%	13	28.3%	0.96	0.98	0.91
Vitamins:									
Vit A (μg/d)	77	37.8%	18	32.7%	12	26.1%	0.17	0.49	0.14
Thiamin (B_1) (mg/d)	90	44.1%	22	40.0%	13	28.3%	0.11	0.58	**0.05**
Riboflavin (B_2)(mg/d)	65	31.9%	18	32.7%	12	26.1%	0.70	0.90	0.44
Vit B_6 (mg/d)	85	41.7%	17	30.9%	11	23.9%	**0.02**	0.15	**0.03**
Vit B_{12} (μg/d)	64	31.4%	17	30.9%	11	23.9%	0.51	0.95	0.32
Vit C (mg/d)	107	52.5%	24	43.6%	19	41.3%	0.10	0.25	0.17
Vit D (μg/d)	122	59.8%	36	65.5%	28	60.9%	0.55	0.45	0.89
Vit E (mg/d)	167	81.9%	39	70.9%	38	82.6%	0.25	0.07	0.91

Characteristic	Gastroparesis Etiology*						P value‡		
	Idiopathic (N=204)		Diabetic Type 1 (N=55)		Diabetic Type 2(N=46)				
	No.	Statistic†	No.	Statistic†	No.	Statistic†	Overall	Id vs DM1	Id vs DM2
Vit K (μg/d)	124	60.8%	25	45.5%	21	45.7%	**0.01**	**0.04**	0.06
Niacin (mg/d)	95	46.6%	22	40.0%	16	34.8%	0.14	0.39	0.15
Folate (μg/d)	143	70.1%	36	65.5%	29	63.0%	0.31	0.51	0.35
Minerals:									
Calcium (mg/d)	145	71.1%	37	67.3%	32	69.6%	0.62	0.58	0.84
Iron (mg/d)	148	72.6%	35	63.6%	27	58.7%	**0.05**	0.20	0.06
Magnesium (mg/d)	146	71.6%	40	72.7%	34	73.9%	0.76	0.86	0.75
Phosphorus (mg/d)	56	27.5%	15	27.3%	10	21.7%	0.62	0.98	0.43
Potassium (g/d)	181	88.7%	43	78.2%	39	84.8%	0.07	**0.04**	0.46
Zinc (mg/d)	103	50.5%	20	36.4%	21	45.7%	0.10	0.06	0.55
Malnutrition/inflammation biomarkers:									
C-reactive protein (CRP) (mg/dL)	204	0.6 ± 1.2	55	0.5 ± 0.7	45	0.7 ± 0.6	**0.03**	0.86	**0.001**
Erythrocyte sedimentation rate (mm/hr)	204	13.4 ± 14.3	55	23.8 ± 21.3	46	29.7 ± 27.3	**<0.0001**	**0.0002**	**<0.0001**
Albumin (g/dL)	204	4.1 ± 0.5	55	3.9 ± 0.7	46	3.9 ± 0.5	**0.0005**	**0.02**	**0.002**
Blood urea nitrogen (BUN) (mg/dL)	204	11.2 ± 4.7	55	17.1 ± 9.7	46	17.6 ± 9.7	**<0.0001**	**<0.0001**	**<0.0001**
Creatinine (mg/dL)	204	0.81 ± 0.19	55	1.06 ± 0.44	46	1.05 ± 0.40	**<0.0001**	**0.0003**	**<0.0001**

where PA = physical activity coefficient is assumed to be sedentary (PA = 1)

Energy deficient diet defined as average daily caloric intake (kcal/day) is < 60% of TER

*Gastroparesis etiology derived using response to the main reason for gastroparesis evaluation: idiopathic must have no prior history of diabetes

†Statistics are means ± standard deviations (SD) or percents (%).

‡The significance of difference between groups was tested with either a chi-square test for non-ordered categories or Fisher's exact test for categorical variables or a Wilcoxon two sample test for continuous variables. All *P* values are two-sided.

§Caloric intake per day, diet components and daily intake of nutrients from food are estimated from the BLOCK Food Frequency Questionnaire. Estimated total energy requirements (TER) defined as:

TER = 662 – (9.53 * age[yr]) + PA * (15.91 *weight[kg] + 539.6 * height[m]) for males,

TER = 354 – (6.91 * age[yr]) + PA * (9.36 *weight[kg] + 726 * height[m]) for females,

¶Suggested gastroparesis diet defined as: normal caloric intake, low fat, low fiber.

[//]Deficient nutrient intake defined as the average daily intake < 60% of the daily recommended intake for the nutrient, using the recommended intakes for individuals from the Food and Nutrition Board, Institute of Medicine, National Academies, 2004 (www.nap.edu) Vitamin A (μg) as retinol activity equivalents (RAE). Vitamin E (mg/d) as α-tocopherol.

Table 5

Logistic regression analysis of diet in patients with gastroparesis: Characteristics individually and independently associated with gastroparesis etiology (diabetic and idiopathic)

Characteristics Selected	Type 1 DM versus Idiopathic*						Type 2 DM versus Idiopathic*					
	Individual†			Independent‡			Individual†			Independent‡		
	Odds Ratios	95% C.I.	*P* value	Odds Ratios	95% C.I.	*P* value	Odds Ratios	95% C.I.	*P* value	Odds Ratios	95% C.I.	*P* value
Baseline characteristics: ‡												
Gender: female	0.39	0.19–0.80	0.01	0.36	0.14–0.88	**0.03**	0.41	0.19–0.90	**0.03**	0.47	0.18–1.20	0.12
White	0.28	0.12–0.65	**0.003**	0.43	0.16–1.21	0.11	0.33	0.13–0.88	**0.02**	0.41	0.14–1.16	0.09
Age at enrollment:			0.26			**0.03**						
< 35 years	1.00			1.00			*n/a* ¶		*n/a* ¶	*n/a* ¶		*n/a* ¶
35 – 50 years	1.29	0.66–2.52	0.45	1.03	0.44–2.41	0.95	1.00			1.00		
≥ 50 years	0.65	0.28–1.49	0.31	0.28	0.10–0.81	**0.02**	4.84	2.45–9.54	**<0.001**	3.43	1.59–7.37	**0.002**
Daily caloric intake (as % of Kcal) & diet components:												
Daily Intake as % TER: §			0.57			n/s			0.62			n/s
< 60% (deficient diet)	1.00			n/s			1.00			n/s		
60 – 84%	0.93	0.42–2.04	0.86	n/s	n/s	n/s	1.17	0.52–2.62	0.70	n/s	n/s	n/s
85%+	1.48	0.67–3.27	0.33	n/s	n/s	n/s	1.53	0.65–3.59	0.33	n/s	n/s	n/s
% daily Kcal from sweets	0.95	0.92–0.98	**0.01**	0.97	0.94–0.99	**0.04**	0.98	0.95–1.00	0.08	0.97	0.94–0.99	**0.04**
% daily Kcal from protein	1.10	1.03–1.19	**0.006**	n/s	n/s	n/s	1.05	0.97–1.14	0.19	n/s	n/s	n/s
% daily Kcal from fat	1.05	1.01–1.09	**0.008**	1.07	1.02–1.12	**0.006**	1.05	1.01–1.09	**0.009**	n/s	n/s	n/s
% daily Kcal from fiber	1.05	0.85–1.28	0.67	n/s	n/s	n/s	1.21	1.00–1.47	**0.05**	n/s	n/s	n/s
Nutrient drinks 5+days/week	0.28	0.06–1.24	0.10	n/s	n/s	n/s	0.51	0.15–1.76	0.29	n/s	n/s	n/s
Takes daily vitamins:												
Multivitamins	0.92	0.50–1.71	0.80	n/s	n/s	n/s	1.14	0.59–2.18	0.70	n/s	n/s	n/s
Stress-tabs	0.35	0.08–1.53	0.16	n/s	n/s	n/s	0.35	0.08–1.53	0.16	n/s	n/s	n/s
Vitamin D	0.81	0.34–1.96	0.65	n/s	n/s	n/s	1.55	0.78–3.44	0.28	n/s	n/s	n/s
Calcium supplement	0.84	0.40–1.74	0.63	n/s	n/s	n/s	0.70	0.31–1.61	0.07	n/s	n/s	n/s
Malnutrition/inflammation biomarkers: §				n/s	n/s	n/s						
CRP > 0.8 mg/dL	1.09	0.52–2.31	0.82	n/s	n/s	n/s	1.97	0.96–4.06	0.07	n/s	n/s	n/s

Characteristics Selected	Type 1 DM versus Idiopathic*						Type 2 DM versus Idiopathic*					
	Individual†			Independent‡			Individual†			Independent‡		
	Odds Ratios	95% C.I.	*P* value	Odds Ratios	95% C.I.	*P* value	Odds Ratios	95% C.I.	*P* value	Odds Ratios	95% C.I.	*P* value
ESR > 20 mm/hr	3.53	1.87–6.65	**<0.001**	3.92	1.75–8.81	**0.001**	4.62	2.35–9.07	**<0.001**	3.35	1.52–7.39	**0.003**
Albumin < 3.5 g/dL	5.02	2.19–11.5	**<0.001**	n/s	n/s	n/s	3.09	1.20–7.97	**0.02**	n/s	n/s	n/s
BUN >20 mg/dL	10.1	2.92–13.2	<0.001	7.43	2.25–24.6	**0.001**	7.70	2.89–20.5	**<0.001**	n/s	n/s	n/s
Creatinine > 1.1 mg/dL	6.20	1.68–12.9	**<0.001**	4.65	1.68–12.9	**0.003**	6.89	3.14–15.1	**<0.001**	4.08	1.65–10.1	**0.002**
Model fit: Hosmer-Lemeshow χ^2 (8 d.f.)					8.6C	0.38					7.76	0.46

n/s = Characteristic not significant at the 0.05 level in this model

n/a = Category not in model due to model instability

Total energy requirement (TER) estimated from the BLOCK Brief Food Questionnaire based on patient's sex, height, weight, activity levelCRP = C-reactive protein; ESR = Erythrocyte sedimentation rate; BUN=Blood urea nitrogen

High creatinine defined as < 1.1 mg/dL for females, < 1.2 mg/dL for males

*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=55), Diabetes type 2 (T2DM) (N=46), idiopathic (N=204)

†Individual characteristics and associated odds ratios, 95% confidence intervals (C.I.), and P values (2-sided) were determined from logistic regression models with one model per factor without adjustment for other factors.

‡Independent characteristics and associated odds ratios, 95% confidence intervals (C.I.), and P values (2-sided) were determined from multiple logistic regression analysis for each sub-group (T1DM and T2DM each compared to idiopathic) on the diet and laboratory malnutrition biomarkers characteristics and adjusting for sex, race (white vs not) and age at enrollment.

§Definitions:

¶Odds ratios, C.I.'s and P values determined from models including Age at enrollment >45 years compared to < 45 years due to insufficient numbers in the n/a category.