DigestiveHealth Matters

Information. Assistance. Support.

Participate in Your Own Health Care | Vol. 23, No. 4, ©2015 IFFGD

Highlights in this Issue

IFFGD
INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

DigestiveHealth Matters

In this Issue:

"Look for a way to lift someone up. If that's all you do, it's enough."

—Elizabeth Lesser

Solving the Biopsychosocial Puzzle in Functional Dyspepsia

By: Lukas Van Oudenhove, M.D., Ph.D., Professor, Translational Research Center for Gastrointestinal Disorders, K.U. Leuven Department of Clinical and Experimental Medicine, University of Leuven, Belgium.

Introduction

Functional dyspepsia is the most prevalent functional gastrointestinal disorder (FGID) of the upper gastrointestinal (GI) tract. It affects 10–15% of the general population worldwide. Functional dyspepsia is associated with considerable healthcare costs to individuals, healthcare providers, and society. The disorder can significantly impact the quality of life of those affected.

Dyspeptic symptoms may develop due to diseases such as peptic ulcer or gastritis. However, most people with dyspeptic symptoms that are ultimately diagnosed have functional dyspepsia.

A diagnosis of functional dyspepsia is made on the basis of the presence of a group of symptoms that frequently occur together, in the absence of any structural or metabolic disease likely to explain the symptoms. The symptoms are thought to originate in the upper digestive tract (stomach and upper small intestine), and are felt in the middle upper part of the abdomen, below the breastbone and above the navel (epigastric region).

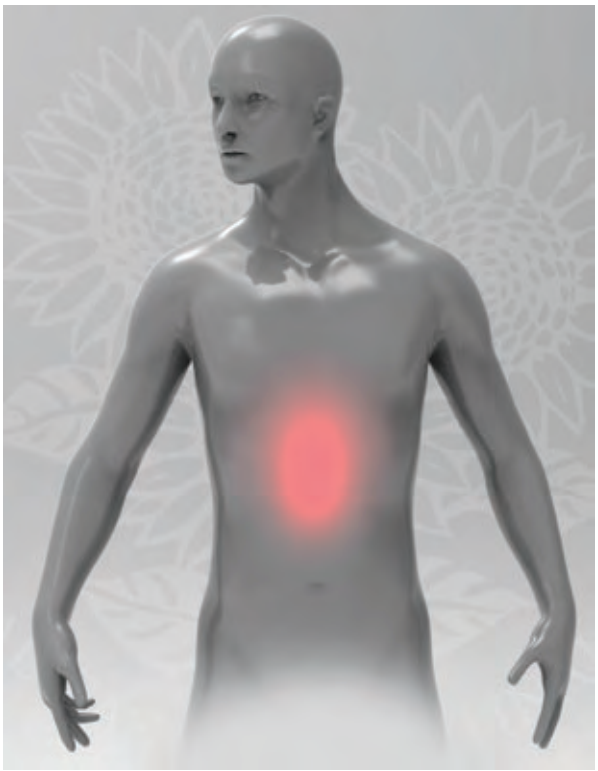
The symptoms most often include feelings of:

- Burning
- Pain
- Fullness after the meal
- Early fullness (satiation) – inability to finish a meal

Functional dyspepsia can be further subdivided based on, 1) symptoms which are most often *not* meal-related, such as epigastric pain and burning (epigastric pain syndrome), and 2) symptoms which *are* meal-related, particularly early satiation and fullness after the meal (postprandial distress syndrome).

The exact causes of functional dyspepsia are not known and likely a variety of causes can lead to symptoms. The symptom patterns can vary among individuals and multiple factors may interact in each person to shape their symptom expression. These all make treating the disorder challenging.

Dr. Van Oudenhove is the recipient of the 2013 IFFGD Research Award for Junior Investigator in Clinical Science. His research covers different areas related to motility and functional gastrointestinal disorders. These include gaining a better understanding of the complex gut-brain interactions and their role in generating symptoms. Dr. Van Oudenhove's research is helping to unravel the signals that process sensation and motility, and improve targeted treatments for conditions like functional dyspepsia.



Symptoms of functional dyspepsia are often experienced in the epigastric region, the area below the breastbone and above the navel.

The biopsychosocial model looks at functional dyspepsia, like other FGIDs, as the result of complex interactions between biological, psychological, and social factors. Our research group at the University of Leuven in Belgium has been trying to unravel the role of these different factors in functional dyspepsia. My particular interest lies in how the interaction between psychological factors (with their underlying biological mechanisms at the level of the brain), and sensitivity and motility of the GI tract (gastric sensorimotor function, regulated by the enteric and autonomic nervous systems) may play a key role in functional dyspepsia symptom expression.

Gastric Sensorimotor Function

Gastric (stomach) sensitivity, accommodation, and emptying are collectively called gastric sensorimotor functions.

Gastric Sensitivity – About 4 in 10 people with functional dyspepsia experience epigastric pain or other symptoms at lower volumes of distension of the stomach than healthy people who do not have dyspepsia. They are said to be hypersensitive to gastric distension and this is associated with the symptom of epigastric pain.

Gastric Accommodation – Gastric accommodation is the relaxation of the stomach upon meal intake. This relaxation allows an increase in volume without an increase in pressure. In about half of individuals with functional dyspepsia the stomach does not relax properly. This is linked to symptoms of early satiation.

Gastric Emptying – Delayed gastric emptying, which we measure using breath tests or with imaging techniques, is found in roughly 1 in 3 individuals with functional dyspepsia. This is associated with fullness after the meal, a common symptom of functional dyspepsia. Delayed gastric emptying is also associated with the symptoms of nausea and vomiting, which are *not* typical symptoms of functional dyspepsia.

The role of delayed gastric emptying in functional dyspepsia symptom expression is unclear. Moreover, increasing gastric emptying with the use of prokinetic/promotility drugs does not consistently improve dyspeptic symptoms.

Our research suggests that these different functions may not act independently. They may influence each other in a complex, and yet unknown, fashion.

> “The interaction between psychological factors and sensitivity and motility of the GI tract may play a key role in functional dyspepsia.”

Psychosocial Factors and Psychological Disorders

A link between normal and abnormal psychological factors (for example, daily stress and anxiety or depression) and abdominal symptoms has long been recognized. Such a link is deeply ingrained in everyday language as a result of long-standing folk knowledge. Consider, for example, such commonplace phrases as “to not be able to *stomach* something or someone” and “to trust one’s *gut* reaction.” Modern research on the role of psychosocial factors in functional dyspepsia started with the adoption of generally accepted diagnostic criteria in the late 1980s to early 1990s.

The majority of studies suggest a higher than average prevalence of anxiety and depression in individuals with functional dyspepsia. This is the case in individuals who seek help for their symptoms as well as in those with dyspeptic symptoms in the general population. While this suggests that anxiety and depression play a role in functional dyspepsia it is not known whether they contribute to functional dyspepsia symptoms or vice versa.

I strongly believe it is not productive to think about the relationship between psychological factors and functional dyspepsia symptoms in terms of simple cause and effect. Instead, interactions in both directions are likely to be at play. Where warranted, a multidisciplinary approach to the treatment of functional dyspepsia symptoms that targets psychological factors and GI function simultaneously is appropriate.

The question remains, what mechanisms underlie this reciprocal interaction between psychological and gastrointestinal functions, and symptoms of functional dyspepsia. Our research group at the University of Leuven has tried to answer this question.

Interactions between Psychosocial Factors, Gastric Function, and Symptom Reporting

We obtained data on biological (gastric sensorimotor function), psychological, and social factors, and functional dyspepsia symptom levels from a large group of individuals seen at our specialized (tertiary) medical referral center. These data allowed us to study the complex interactions between these different factors, which had mostly been studied separately before.

We found that both sensory and motor function in the stomach can be influenced by psychosocial factors or by psychological processes. We observed an association between anxiety levels with gastric hypersensitivity, and prior trauma associated with both gastric sensitivity and emptying.

In previous research our group had shown that anxiety can impair gastric accommodation in healthy controls. Our more recent work demonstrates that anxiety levels are associated with impaired accommodation in a large group of people with functional dyspepsia.

I believe an important conclusion from this work is that psychological functioning and gastric sensorimotor function interact in a complex way. The presence of one does not exclude a role of the other.

We demonstrated that physical symptom reporting is the result of a complex interaction between several groups of psychosocial factors and gastric sensitivity.

Additionally, we studied how gastric sensation is processed in the brain in people with functional dyspepsia compared to healthy people without dyspepsia. We used an imaging technique (PET scan) to measure brain activity in response to stimulated gastric distension.

In order to understand the results of this study, it is important to distinguish between brain regions and networks where bodily signals are *processed* and brain circuitry where activity in the processing regions is *modulated* (altered), including emotional and cognitive circuits. Perception of gastric signals is the result of the interaction between these two brain networks. Abnormalities in these mechanisms may underlie symptoms in functional dyspepsia in general, and the influence of psychosocial factors on symptoms in particular.

In our study, hypersensitivity of gastric sensations in individuals with functional dyspepsia showed activity patterns in similar pain processing regions as healthy controls, but at far lower gastric pressure thresholds.

Furthermore, we found lack of activation of an important pain modulatory region of the brain (anterior cingulate cortex) during gastric distension in individuals with functional dyspepsia. This may underlie the increased signaling in the pain processing regions. Anxiety was also found to interfere with the function of the pain modulatory region.

"Psychological functioning and gastric sensorimotor function interact in a complex way. The presence of one does not exclude a role of the other."

Finally, we demonstrated that a history of severe trauma (represented by physical or sexual abuse) in individuals with functional dyspepsia affects the function of a number of important pain processing and modulatory regions of the brain.

Summary

Functional dyspepsia describes a set of symptoms in the upper abdomen shaped by a complex interaction between biological, psychological, and social factors. We are gradually gaining insight into the nature of these interactions, as well as the neuro-biological mechanisms underlying them. This warrants a biopsychosocial approach to the definition, diagnosis, and treatment of functional dyspepsia. ■

Medical News Update

Treatments are Needed for Functional Dyspepsia

A survey of people with functional dyspepsia (FD) found that, although there is currently no drug approved to treat FD, respondents reported using an array of medications attempting to control symptoms. Moreover, one-half of the 114 respondents reported a willingness to take significant risks with a hypothetical medication that could cure their symptoms.

Better understanding of risk-taking behavior can help inform drug development and approval processes as well as individual treatment approaches.

Source: Lacy B, et al. *Clin Transl Gastroenterol.* January 2015.

New Study to Look at Laxative Ingredient Safety in Children

The U.S. Food and Drug Administration (FDA) is funding a new study regarding the safety in children of PEG 3350 – the active ingredient in Miralax and similar generic laxatives. The FDA notes that there is little data on its absorption in children, especially in the very young and chronically constipated. Adverse events in children given the laxative have been reported, but it is not known whether the laxatives are the cause.

PEG 3350 laxatives, which are available over-the-counter, were FDA approved for persons aged 17 and older but never approved for long-term daily use. Talk to your doctor if you have a child who is using one of these laxatives.

Source: Saint Louis C. *NY Times.* January 2015.

Fear of IBS Symptoms Impacts Quality of Life

A study of 234 individuals with irritable bowel syndrome (IBS) found fear of gastrointestinal symptoms of IBS to be strongly associated with reduced quality of life. Fear of symptoms was a stronger predictor of quality of life than symptom severity, personality style, sociodemographic variables, or overall emotional well-being.

Better understanding of the factors contributing to quality of life may help clinicians and patients assess, understand, and respond to changes in quality of life and improve IBS treatment outcomes.

Source: Lackner JM, et al. *Am J Gastroenterol.* November 2014.

Scientists Create Model Human Stomachs to Study Gastric Diseases

Using stem cells from adult donors, scientists have been able to grow pea-sized three-dimensional human stomach models under laboratory conditions. These miniature stomachs were developed to model mechanisms of infection by the bacterium *Helicobacter pylori*, which can cause gastric symptoms including nausea, bloating, and vomiting and can lead to ulcers and stomach cancer in extreme cases.

These models are expected to provide a valuable experimental model for the study of the development, functioning, and diseases of the human stomach.

Source: McCracken KW, et al. *Nature.* October 2014.

Maternal Inheritance in Adult Cyclic Vomiting Syndrome

Researchers identified a higher probability of maternal inheritance of various functional gastrointestinal (GI) disorders in a subset of adults with cyclic vomiting syndrome (CVS) compared with healthy controls (12% compared to 1%).

More research studies to identify potential causes for maternal inheritance pattern in adults are warranted to help understand the underlying mechanisms of functional GI disorders.

Source: Venkatesan T, et al. *BMC Gastroenterol.* October 2014.

Gut Microbes in IBS and Chronic Constipation

Investigators in a systematic review and analysis combining existing randomized controlled studies (meta-analysis) concluded that for some people, probiotics (beneficial microorganisms) effectively benefit irritable bowel syndrome (IBS) symptoms such as abdominal pain, bloating, and gas. However, it remains unclear which individual species and strains of probiotics are the most beneficial.

More evidence is also required before the role of prebiotics (which promote growth of probiotics) or synbiotics (which combine probiotics and prebiotics) in IBS is known. The effectiveness of all three therapies in chronic/idiopathic functional constipation (CIC) is also lacking and uncertain.

Source: Ford AC, et al. *Am J Gastroenterol.* October 2014.

Key Symptoms in Functional Dyspepsia

Researchers of a focus group study confirmed that symptoms corresponding to fullness after meals (postprandial) and early fullness (satiation) are the key symptoms for developing a patient reported outcomes (PRO) instrument for meal-related functional dyspepsia/ postprandial distress syndrome. This information is useful for creating tools to measure treatment effectiveness.

Under a program funded by the National Institutes of Health, PRO tools for various conditions are being developed, which will help design treatment plans to improve doctor-patient communication, and manage chronic conditions.

Source: Carbone F, et al. *Neurogastroenterol Motil.* September 2014.

Yoga for IBS in the Young

Researchers concluded that therapy for irritable bowel syndrome (IBS) using Iyengar yoga training – 1.5 hour sessions twice weekly for six weeks – is a safe and beneficial compliment to medical care in young people, particularly young adults.

The randomized controlled study involved an initial total of 51 participants including adolescents (ages 14–17) and young adults (ages 18–26) with IBS or recurrent abdominal pain. Physical functioning improved in adolescents and IBS symptoms, emotional distress, fatigue, and sleep quality improved in young adults.

Iyengar yoga postures are taught in a sequence to address specific problems by teachers who receive training in anatomy, physiology, and safety.

Source: Evans S, et al. *J Pediatr Gastroenterol Nutr.* August 2014.

Structure and Functions of the Gut Microbiome

In a published article, researchers describe how the understanding of human gut microbiology has undergone a leap forward over the past decade. The composition and function of the microbiome (the microbial gut community, especially bacteria), although stable over long periods, may be influenced by a number of factors including genetics, mode of birth delivery, age, diet, geographic location, and medical treatments.

Changes in the microbiome structure have been linked to inflammatory, functional, and metabolic disorders such as irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), and obesity. It remains to be known whether these changes are a contributing factor or a result of the disease.

Source: Panda S, et al. *Endocr Metab Immune Disord Drug Targets.* July 2014.

Integrated Treatments in IBS

In a review of IBS treatment studies, investigators summarized the most widely used complementary and alternative medicine (CAM) approaches that have proven effectiveness and have been endorsed by professional organizations. Examples include specific modalities of hypnotherapy, cognitive behavioral therapy, acupuncture, and yoga.

The reviewers encourage the use of both conventional medicine and CAM approaches by doctors in an integrative setting to provide the best outcome and quality of life to affected individuals.

Source: Grundmann O, Saunjoo LY. *World J Gastroenterol.* January 2014.

Nortriptyline Lacks Effectiveness in Idiopathic Gastroparesis

Researchers in a randomized controlled clinical trial concluded that, among patients with idiopathic gastroparesis, the use of the antidepressant nortriptyline compared with placebo for 15 weeks did not result in improvement in overall symptoms. These findings do not support the use of nortriptyline for idiopathic gastroparesis.

Gastroparesis remains a challenging syndrome to manage, with few effective treatments and a lack of rigorously controlled trials. Tricyclic antidepressants are often used to treat refractory symptoms of nausea, vomiting, and abdominal pain despite a lack of evidence from well-designed studies for this use.

Source: Parkman HP, et al. *JAMA.* December 2013.

Dietary Elimination Therapy for Eosinophilic Esophagitis

A review of existing data of 31 individuals demonstrated that dietary elimination therapy is a safe and effective treatment in adults with eosinophilic esophagitis (EoE). Individuals underwent either a targeted elimination diet that isolated specific food allergies or a more general 6–food elimination diet. Individuals with EoE most frequently reacted to dairy (44%), eggs (44%), wheat (22%), shellfish (11%), legumes (11%), and nuts (11%).

While both diets were difficult for individuals to stick to, the targeted diet had greater success rates. Oral steroids and diet modification are the only therapies currently available for individuals with EoE.

Source: Wolf WA, et al. *Clin Gastroenterol Hepatol.* August 2014.

Surveillance of Barrett's Esophagus Reduces Mortality from Esophageal Cancer

Researchers in a large study concluded that monitoring individuals with Barrett's esophagus (BE) in an endoscopic surveillance program to watch for signs of abnormal tissue (dysplasia) or cancer was associated with lower tumor stages and reduced esophageal cancer-related mortality than those with BE who did not participate in surveillance.

The study included 10,000 individuals in the Netherlands diagnosed with cancer of the esophagus. Nearly 800 (8%) of these had been diagnosed with BE prior to the cancer diagnosis. BE is one of several factors associated with increased risk of developing esophageal cancer. As with all cancers, early detection is critical to improving treatment outcomes.

Source: Verbeek RE, et al. *Am J Gastroenterol.* August 2014.

Biomarkers May Help Predict Risk for Barrett's Esophagus

A study of 141 veterans, mostly Caucasian males, concluded that a prediction model based on a risk score of circulating levels of several specific substances in the blood (serum biomarkers), in addition to individual demographic and clinical information (age, sex, race, and waist-to-hip ratio as well as gastroesophageal reflux [GER] frequency and duration and H. pylori status), may help identify persons at risk for Barrett's esophagus more accurately than not including the multi-biomarker risk score.

Source: Thrift AP, et. al. *Clin Gastroenterol Heptol*. August 2014.

You Can Now Take Part in the FDA Patient Perspective Initiative

On May 11, 2015, the U.S. Food & Drug Administration (FDA) will conduct a public meeting on Functional GI Disorders Patient-Focused Drug Development to gather patient input on the impact of functional GI disorders on daily life and patient views on currently available therapies to treat the functional GI disorders, such as IBS, gastroparesis, GERD symptoms despite standard therapy, and chronic idiopathic constipation.

Register now. You can attend the public meeting in person, participate in the live meeting webcast, or share comments through a public docket. FDA meeting details and registration are here: *www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm430885.htm*

Interested in helping researchers better understand IBS?

Take part in an online survey here:

www.aboutibs.org/site/treatment/studies

Preliminary News on Treatments Reported at the 2014 ACG Meeting

Here are some brief reports on research studies that were presented as summaries/abstracts at the 2014 annual American College of Gastroenterology (ACG) Scientific Meeting, a conference for medical professionals.

The data and conclusions from these findings should be considered preliminary until published in a peer-reviewed journal.

Chronic Idiopathic/Functional Constipation (CIC)

Two-thirds of patients with CIC treated with lubiprostone (Amitiza) in three pivotal phase 3 studies in the U.S. and Japan responded to the treatment after 2 weeks of therapy.

Dyspepsia and Chronic Idiopathic Constipation (CIC) with Bloating

Symptoms of functional dyspepsia (1 or more of feelings of fullness after a meal, early feeling of fullness, upper GI pain, or upper GI burning) are often reported by people with CIC with abdominal bloating. A study of CIC patients with abdominal bloating found that linaclotide (Linzess) provided significant relief for functional dyspepsia symptoms compared to placebo.

Gastroparesis

The majority of 138 patients with diabetic and idiopathic gastroparesis resistant to medical therapy (medically refractory) who were surveyed at least 6 months after being treated surgically with insertion of a gastric electric stimulator (GES) reported improvement of symptoms, especially loss of appetite, nausea, and retching (dry heaves).

Another study of 12 patients with medically refractory gastroparesis found improvement in nausea, vomiting, and nutritional parameters 5 years after GES therapy.

An evaluation of 31 patients with medically refractory gastroparesis found that after 1 year of GES those who also continued on prokinetic medications had improved symptom scores, greater weight gain, and decreased use of tube feeding (enteral nutrition) compared to those who discontinued prokinetic medications.

IBS in Children

A study involving 97 children and adolescents recently diagnosed with IBS found that two 90-minute sessions of multi-disciplinary behavioral therapy interventions significantly reduced healthcare utilization up to 4 years after diagnosis. The therapy included patient and parental education, dietary modification, exercise, relaxation techniques, and guided imagery.

IBS with Constipation (IBS-C)

Patients with IBS-C treated with linaclotide (Linzess) for up to 2 years were satisfied with treatment on average. The most frequent side-effect, diarrhea, was generally mild or moderate and easily managed.

Data from a phase 2 dose-ranging study of 424 adults to assess the safety and efficacy of plecanatide (a GC-C agonist) in patients with IBS-C concluded that the investigational therapy was well-tolerated and improved bowel habit and abdominal pain symptoms over a 12-week treatment period. (This agent is also in phase 3 trials for the treatment of chronic idiopathic constipation).

IBS with Diarrhea (IBS-D)

The investigational drug eluxadoline significantly improved IBS-D symptoms compared to placebo in patients enrolled in a study, including in those who had used loperamide without improvement in the prior year.

Another study found eluxadoline to significantly improve urgency, concluding this to be a valuable measure of response compared to placebo.

Based on results of a survey of IBS patients, researchers suggest that clinicians pay special attention in treatment plans to areas which affect quality of life, such as food avoidance, as well as to those that have effects on daily activities and relationships, especially in individuals with IBS-D.

IBS-D, IBS-C, and Mixed IBS (IBS-M)

A case series study over an 8-week period looked at treatment of 18 difficult to treat patients (14 with IBS, 2 with Crohn's disease, 2 with other bowel conditions) using the prescription oral medical food serum-derived bovine immunoglobulin/protein isolate (SBI) in addition to standards of care. Overall symptom improvement was seen in stool consistency, decreased stool frequency, abdominal pain, bloating, distension, and incontinence. The study concluded that dietary management with SBI can provide a safe and effective therapy for patients with IBS and other GI conditions.

Self-Help for IBS

Participants with IBS who completed a randomized controlled study of 6-week cognitive behavioral therapy using a self-help workbook experienced significant improvement in health related quality of life and symptom severity. Self-help workbooks designed to help manage psychological aspects of IBS can be added to medical management and may improve treatment outcomes.

Another study using a 9-week comprehensive self-management program designed for the treatment of IBS found that after 1 year the majority of participants still used some strategies from the program based on what was most effective for them. Strategies included meal timing/frequency, trigger food reduction, eating behaviors (like avoiding eating out and eating more slowly), eating a balanced diet, specific relaxation strategies, lifestyle behaviors (like exercise and hobbies), addressing thought distortions, challenging beliefs (like perfectionism and self-esteem), and problem-solving skills. ■

Congenital Sucrase-Isomaltase Deficiency (CSID)

Congenital sucrase-isomaltase deficiency (CSID) is a genetic disorder that affects a person's ability to digest certain sugars. People with this condition cannot break down the sugars sucrose and maltose, and other compounds made from simple sugar molecules (carbohydrates).

Sucrose (a sugar found in fruits and also known as table sugar) and maltose (the sugar found in grains) are called disaccharides because they are made of two simple sugars.

Disaccharides are broken down into simple sugars during digestion. Sucrose is broken down into glucose and another simple sugar called fructose, and maltose is broken down into two glucose molecules.

Other names for CSID include congenital sucrose intolerance, congenital sucrose-isomaltose malabsorption, disaccharide intolerance I, SI deficiency, or sucrase-isomaltase deficiency.

Symptoms of CSID

Congenital conditions exist at birth. CSID usually becomes apparent after an infant is weaned and starts to consume fruits, juices, and grains.

After ingestion of sucrose or maltose, an affected person will typically experience symptoms of:

- Stomach cramps,
- Bloating,
- Excess gas production, and
- Diarrhea

In a child, these digestive problems can lead to failure to gain weight and grow at the expected rate (failure to thrive) and malnutrition. Most affected children are better able to tolerate sucrose and maltose as they get older.

Symptoms can vary for a variety of reasons, including the timing of the introduction of sucrose into an infant's diet. Infants who are breast-fed or fed lactose-containing formula will often not have symptoms of CSID until they ingest juices, solid foods, or medications that are sweetened by sucrose.

How Common is CSID

The prevalence of CSID is estimated to be 1 in 5,000 people of European descent. This condition is much more prevalent in the native populations of Greenland, Alaska, and Canada, where as many as 1 in 20 people may be affected.

However, it is possible that some people remain undiagnosed and that the incidence may be higher.

Causes of CSID

Mutations in a gene (the *SI* gene) cause CSID. The *SI* gene provides instructions for producing the enzyme sucrase-isomaltase. This enzyme is found in the small intestine and is involved in the digestion of sugar and starch. It is responsible for breaking down sucrose and maltose into their simple sugar components. These simple sugars are then absorbed by the small intestine.

Mutations that cause this condition alter the structure, disrupt the production, or impair the function of sucrase-isomaltase. These changes prevent the enzyme from breaking down sucrose and maltose, causing the intestinal discomfort seen in individuals with CSID.

This condition is inherited in an autosomal recessive pattern, which means both copies of the gene in each cell have mutations.

Autosomal recessive inheritance is one of several ways that a trait, disorder, or disease can be passed down through families. An autosomal recessive disorder means two copies of an abnormal gene must be present in order for the disease or trait to develop.

The parents of an individual with an autosomal recessive condition each carry one copy of the mutated gene, but they typically do not show signs and symptoms of the condition.

Treatments

People of any age need to consume the right nutrients in their diet to ensure proper nutrition. In a person with CSID, dietary restrictions often require life-long adherence to a strict sucrose-free diet. This can vary depending on symptoms, but foods high in sucrose should be avoided. These include:

- Beets
- Peas
- Honey
- Soybean flour
- Onions

Foods high in a starch component (amylopectin) including cereals, breads, pastas, and potatoes may also need to be excluded, especially during the first few years of life. Starch tolerance is generally improved after the age of 3-4 years, and rice starch and corn starch are easier to digest.

Taking a small amount of baker's yeast along with sucrose-containing foods has been found to reduce symptoms. However, baker's yeast has an unpleasant taste.

An alternative to traditional baker's yeast is sacrosidase (Sucraid), a liquid preparation that is tasteless when mixed with water. Sacrosidase is an enzyme replacement therapy only available by prescription. Sucraid was originally approved by the U.S. Food and Drug Administration (FDA) in 1998 for treating CSID.

In a study of 14 patients with CSID treated with sacrosidase, symptoms of diarrhea, abdominal pain, and gas were either prevented or relieved, allowing children to consume a more normal, sucrose-containing diet. A later study in 28 children aged 5 months to 11 years found that sacrosidase was associated with fewer stools, a greater number of formed, or hard stools, and fewer symptoms of gas, abdominal cramps, or bloating.

The Healthcare Team

Dietary management of malabsorption disorders like CSID can be challenging. Talk to your doctor and a registered dietician about what foods may cause digestion problems. Ask about alternatives. Learn how to read food labels and what to avoid. Be aware of possible sugar content of medicines, if needed.

In children, challenges increase as they begin to exert more independence. As a parent or care provider you will want to work with your child's doctor to understand the condition and related limitations. This will provide you with the knowledge and ability to manage the child's symptoms and needs.

Working together with your healthcare providers will help ensure that proper nutrition is maintained while at the same time keeping symptoms under control. ■

Primary Sources

1. US National Library of Medicine. Congenital sucrase-isomaltase deficiency. *Genetics Home Reference.* July 2008.

2. NASPGHAN and NASPGHAN Foundation for Children's Digestive Health and Nutrition. Recognition and management of dietary carbohydrate-induced diarrhea in pediatric patients. *Monographs.* October 2011.

IFFGD INDUSTRY COUNCIL

When IFFGD began in 1991 there was little communication between patients living with functional GI and motility disorders and the companies with the means to develop treatment products and services. Subsequently, IFFGD has worked hard to make the needs of our members known – not only to the clinicians who see patients, but also to the researchers and providers of diagnostic and treatment methods and tools.

In an effort to strengthen our voice, in 1998 we formed the IFFGD Industry Council. The Council provides a forum to help ensure that the voice of our membership is heard. We invite participation from companies with a demonstrated interest in these disorders. While we are grateful to our Industry Council members for their support, we do not endorse any specific product or company. IFFGD retains unrestricted control over the planning, content, objectives, methods, and execution of all initiatives and projects. We are pleased to welcome the newest IFFGD Industry Council member, QOL Medical, LLC.

IFFGD INDUSTRY COUNCIL

Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals USA, Inc.

Salix Pharmaceuticals, Ltd.

QOL Medical, LLC

NPS Pharmaceuticals, Inc.

Ironwood Pharmaceuticals, Inc.

Ferring International PharmaScience Center US, Inc.

Entera Health, Inc.

Actavis (formerly Forest Laboratories, Inc.)

Linaclotide (Constella) Available in Europe for Treatment of IBS-C

Linaclotide is the first medicine approved by the European Commission for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adult patients. It is currently available in several European countries with the EU brand name Constella (Linzess in the U.S.).

Linaclotide, a guanylate cyclase type-C (GC-C) agonist, is a prescription drug used to relieve symptoms of abdominal pain, discomfort, bloating, and bowel symptoms in people who have IBS-C or chronic idiopathic constipation (CIC). It has been shown to be safe and effective in trials. It works by increasing the amount of fluid that flows into the bowel, allowing stool to pass more easily, and reducing visceral pain.

Linaclotide has been available in the U.S. to treat IBS-C and CIC in adults aged 18 and older since 2012. The safety and effectiveness of linaclotide for the management of IBS-C were established in two, double-blind studies in which a total of 1,604 patients were randomly assigned to take linaclotide or a placebo for at least 12 weeks. Results showed linaclotide was more effective in reducing the amount of abdominal pain and increasing the number of complete spontaneous bowel movements compared with placebo.

Linaclotide should *not* be used in patients 17 years of age or younger and should *not* be used in patients with known or suspected mechanical gastrointestinal obstruction. The most common side effect reported during clinical studies was diarrhea.

Linaclotide is being co-produced in the U.S. by Ironwood Pharmaceuticals and Actavis (Forest Laboratories). Ironwood has out-licensed linaclotide to Almirall, S.A. for development in Europe; to Astellas Pharma for development in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand; and to AstraZeneca in China.

Review Article Concludes that Bile Acid Transport Inhibitor Elobixibat is Effective in Treating Chronic Idiopathic Constipation

Elobixibat is a first-in-class compound under investigation by Ferring Pharmaceuticals for treatment of chronic idiopathic constipation (CIC), and for irritable bowel syndrome with constipation (IBS-C).

An article recently published in the journal *Therapeutic Advances in Gastroenterology* reviewed data that examined the mechanisms by which bile acids can affect symptoms in CIC and the role of the drug elobixibat in managing these symptoms. Bile acids are digestive juices that have a stimulating effect in the colon. Elobixibat reduces bile absorption in the small intestine. This stimulates bowel movements by increasing fluid secretions and motility in the colon.

The authors concluded that published research shows that elobixibat significantly affects the symptoms of CIC, with minimal and tolerable side effects.

Participants Sought for Congenital Sucrase-Isomaltase Deficiency (CSID) Genetic Prevalence Study in Children with Chronic Diarrhea or Chronic Abdominal Pain

Congenital sucrose-isomaltase deficiency (CSID) is a rare disorder that affects a person's ability to digest certain sugars. People with this condition cannot break down the sugars sucrose and maltose. Sucrose is a sugar found in fruits, and is also known as table sugar. Maltose is the sugar found in grains.

In this study, clinicians across the country are looking at using two different tests to rule out CSID, which often causes chronic diarrhea and/or abdominal pain.

If your child is 18 years of age or younger and has been experiencing chronic diarrhea or abdominal pain for at least 4 weeks, he or she may qualify to participate in this study at a site near you.

If your child is eligible, there is the potential for up to three doctor's office visits that could include: having the inside of his/her cheeks swabbed to look for common genetic mutations found in CSID patients, taking a breath test, providing a medical history review, and completing a few questionnaires.

Purpose of Study: Determine the prevalence of CSID genetic variants in subjects 18 years of age or younger with a primary symptom of chronic idiopathic diarrhea or chronic abdominal pain without constipation.

Sponsor: QOL Medical, LLC

Collaborators: 19 Medical Centers located throughout the U.S.

Contact: Healther Elser, Ph.D., 919-832-4949, *helser@qolmed.com*. Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01914003.

Medical Food in the Management of Diarrhea

EnteraGam™ is a new prescription *medical food* product to help people manage ongoing problems with chronic loose and frequent stools (diarrhea). Medical foods are required to be used under physician supervision as part of ongoing medical care for a specific condition or disease.

EnteraGam is manufactured and distributed by Entera Health, Inc. It is indicated for the clinical dietary management of intestinal disease (enteropathy) in patients who, because of therapeutic or chronic medical needs, have limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients.

The main ingredient in EnteraGam is a specially formulated protein preparation that consists of more than 50 percent of immunoglobulin (molecules involved with immune function). This ingredient, SBI (serum-derived bovine immunoglobulin/protein isolate), is made up of beef serum proteins. The proteins in SBI remain in the intestine and are not absorbed whole.

Review Looks at Effects of SBI on Managing Conditions like IBS-D

A review, which summarizes accumulated data from prior studies, concluded that specially formulated immunoglobulin sources like SBI have multiple effects which collectively serve to improve and maintain nutrient utilization, including water balance. This aids in the management of intestinal disorders (enteropathy) in patients with chronic loose and frequent stools in conditions like irritable bowel syndrome with diarrhea (IBS-D).

The mode of action appears to be combined effects on inflammation, gut barrier function, and immune balance.

The study review, by Petschow et al, was published in August 2014 in the journal, *Digestive Diseases and Sciences*. The authors are employed by Entera Health.

Study Evaluates Impact of SBI in People with IBS-D

Results from a randomized, double-blind, placebo-controlled pilot study enrolling 66 subjects suggest that nutritional therapy with SBI, the ingredient found in EnteraGam – used in addition to traditional medical care – can help manage various symptoms associated with irritable bowel syndrome with diarrhea (IBS-D). The study, by Wilson et al., was published in 2013 in the journal, *Clinical Medicine Insights: Gastroenterology*.

A total of 45 persons completed the study per the protocol, with 31 in the SBI group and 14 in a placebo group. The symptom profile of each participant was determined during the first week, followed by a six-week treatment period. Of the subjects who did not complete the study, five were lost to follow-up, three did not comply with the study requirements, one discontinued due to lack of efficacy, and two were removed at the Principal Investigator's discretion.

The safety profile of SBI in the study was similar to that of placebo. A total of four people withdrew, from both the placebo and the SBI groups, due to nausea. No serious adverse events were reported. The proportion of subjects who withdrew was not significantly different between treatment groups.

The study showed that nutritional therapy with either 10 g/day or 5 g/day of SBI in patients was well tolerated and resulted in statistically significant improvements in days with symptoms and a trend for improvement in symptom severity scores in participants with IBS-D. In particular, the 15 participants who received 10 g/day of SBI showed significant reductions in abdominal pain, loose stools, bloating, flatulence, and urgency.

The product has been extremely well tolerated for up to a year in HIV patients and up to eight months in infants. The major side effects in clinical trials (2–5%) have included mild nausea, constipation, stomach cramps, headache, and increased urination. EnteraGam is contraindicated for patients with a hypersensitivity (allergy) to beef, or any components in EnteraGam. Therefore, patients who have an allergy to beef or any component of EnteraGam should not take this product. The effect of EnteraGam on nursing mothers and the infant is unknown. The choice to administer EnteraGam in pregnant or nursing mothers is up to the clinical decision of the physician. Medical foods like EnteraGam are required by the U.S. Food and Drug Administration (FDA) regulations to be dosed and monitored by physicians as part of ongoing care for patients with chronic conditions or diseases.

Teduglutide Granted Orphan Drug Status in Japan

In January 2015 the Japanese Ministry of Health, Labor, and Welfare (MHLW) granted teduglutide (Gattex in the U.S.; Revestive in the E.U.) orphan drug status for the treatment of adult patients with short bowel syndrome (SBS).

Data Supports Long-Term Use of Gattex for Treatment of Short Bowel Syndrome

In June 2014 the U.S. Food and Drug Administration (FDA) approved updated labeling for teduglutide (Gattex) for injection to include long-term data from adult patients with Short Bowel Syndrome (SBS). The revised labeling provides important information for healthcare professionals and patients about long-term use of teduglutide.

The data, published in 2013, demonstrated that there was an increased response to treatment over time in all groups receiving teduglutide. The open-label extension study included 88 adult patients with SBS. Investigators reported that the long-term use of teduglutide in patients with SBS resulted in additional, clinically meaningful reductions in the volume and days per week of parenteral support requirements in this extension study. Thirteen patients in the study achieved complete independence from parenteral support with long-term teduglutide therapy. No new unexpected safety concerns were observed with long-term teduglutide treatment and the product's safety profile remains consistent with the product's label.

The drug works by regeneration of cells in the intestinal lining, slowing down transit through the gut and increasing blood flow, allowing for increased nutrient absorption. In studies, the drug was associated with achieving and maintaining clinically meaningful reductions in parenteral nutrition (PN) and intravenous (IV) fluid volume in adult subjects with SBS.

Teduglutide was approved by the FDA as Gattex in 2012 for treatment of adult patients with SBS who are dependent on parenteral support. To help ensure that the benefits of the drug outweigh the risks for causing other serious conditions, the drug is approved with a Risk Evaluation and Mitigation Strategy, which patients need to discuss with their doctors. While the researchers found the safety profile to be acceptable, they advise that physicians closely monitor patients beginning the drug for side effects and possible need to adjust dosage.

SBS is a rare condition related to poor absorption of nutrients. It typically occurs in people who have a significant portion of their small intestine removed due to disease or injury. They cannot absorb enough water, vitamins, and other nutrients from food and may then need to use parenteral nutrition and intravenous fluids.

Patients with SBS Sought for Long-Term Study

This global clinical study is enrolling patients with short bowel syndrome (SBS) in order to provide additional long-term data on the safety of teduglutide and on the natural history of SBS in patients in routine, real world settings. The information gathered is intended to assist health care providers in optimizing their clinical decision making in managing SBS in patients. Enrollment will include SBS patients treated and not treated with teduglutide.

Study Population: Male and female patients of any age with a diagnosis of SBS, including those who have never taken teduglutide, as well as those who have or are currently using teduglutide.

Study Follow-up Duration: 10 years

Sponsor: NPS Pharmaceuticals, Inc.

Contact: NPS Clinical Operations, phone: 908-450-5300, email: *SBSregistry@quintiles.com*; Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01990040.

FDA Considers Rifaximin for Treatment of IBS-D

The supplemental new drug application (sNDA) for the antibiotic xifaxan (Rifaximin) 550 mg has been accepted for review by the U.S. Food and Drug Administration (FDA). A decision regarding the approval status of the drug for the treatment of irritable bowel syndrome with diarrhea (IBS-D) is expected by February 28, 2015.

In July 2014 Salix Pharmaceuticals reported positive results from the TARGET 3 – Phase 3 study to evaluate the efficacy and safety of repeat 14-day treatment with xifaxan for the treatment of IBS-D in people who responded to an initial 14-day treatment course with the drug. Compared to placebo, subjects treated with xifaxan showed statistically significant improvement in IBS-related abdominal pain and stool consistency during the 4-week, treatment-free follow-up period in the double blind repeat treatment phase.

Results from the two initial Phase 3 clinical trials had reported adequate relief of multiple symptoms in patients with IBS-D. Xifaxan works by reducing or altering bacteria in the gut. It is only slightly absorbed in the gut and is generally tolerated well.

Guidance Issued in U.K. for Amitiza in Treating Chronic Idiopathic Constipation

The National Institute for Health and Care Excellence (NICE) has issued guidance on the use of lubiprostone (Amitiza) for treating chronic idiopathic constipation in the United Kingdom. The guidelines stipulate that the drug should only be considered in adults who have tried at least 2 laxatives at the highest tolerated recommended doses for at least 6 months, but who have not seen an improvement in their symptoms.

NICE clinical guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions within the National Health Service (NHS) in the United Kingdom.

Lubiprostone Study Published Showing Efficacy in Opioid-Induced Constipation

A study published in 2014 in the medical journal *Pain Medicine* examined the efficacy and safety of lubiprostone (Amitiza) for relieving symptoms of opioid-induced constipation (OIC) in chronic non-cancer pain. The study found that patients treated with lubiprostone showed significant overall improvement for abdominal discomfort, straining, constipation severity and stool consistency when compared to placebo. The authors concluded that lubiprostone was effective and well tolerated in OIC patients with chronic non-cancer pain.

Lubiprostone is a prescription drug first FDA approved in 2006 to relieve abdominal pain, bloating, and straining and produce softer and more frequent bowel movements in men and women who have chronic idiopathic constipation (CIC). It is also FDA approved to treat irritable bowel syndrome with constipation (IBS-C) in women who are at least 18 years of age. Lubiprostone works by increasing the amount of fluid that flows into the bowel and allowing the stool to pass more easily.

The drug was FDA approved in 2013 for the treatment of OIC in patients with chronic, non-cancer pain. Opioids (such as morphine and codeine) are narcotics used to treat pain. The effectiveness of lubiprostone has not been established in those taking methadone. A number of gastrointestinal (GI) symptoms are potential side effects of using opioid-based medications. The most common symptoms is constipation. Other symptoms may include decreased gastric emptying, abdominal cramping, spasm, bloating, and delayed-GI transit.

Two Studies of Lubiprostone in Pediatric Subjects with Functional Constipation Seeking Participants

Purpose of study 1: This is a 12-Week study to evaluate the efficacy, safety, and pharmacokinetics of oral lubiprostone as treatment for pediatric patients with functional constipation.

Collaborators: Sucampo Pharma Americas, LLC and Takeda

Participation: Eligible male and female patients aged 6-17 years

Sponsor: Sucampo AG

Contacts: Shadreck Mareya, Ph.D., 301-961-3400, *pedgen@sucampo.com*; Be sure to refer to this study by its *ClinicalTrials.gov* identifier: NCT02042183.

Purpose of study 2: This is a 9-Month study to evaluate the long-term safety, efficacy, and pharmacokinetics of oral lubiprostone as treatment for pediatric patients with functional constipation.

Collaborators: Sucampo Pharma Americas, LLC and Takeda

Participation: Eligible male and female patients aged 6-17 years

Sponsor: Sucampo AG

Contacts: Shadreck Mareya, Ph.D., 301-961-3400, *pedgen@sucampo.com*; Be sure to refer to this study by its *ClinicalTrials.gov* identifier: NCT02138136. ■

Looking Back at 2014

Our Commitment

IFFGD works to inform, assist, and support people affected by functional gastrointestinal (GI) and motility disorders. For over two decades, these efforts have been made possible by the support we receive from the diverse community of patients and families, physicians, industries, and policy makers who share the common goal of seeing patient care improved.

The burdens imposed by these diseases affect not only patients and families, but also healthcare practices, and society at large. We continually work to take actions needed to raise awareness and advance understanding about these complex conditions.

In 1991, before the arrival of the Internet as a primary means of communication, we started to publish a 4-page educational newsletter entitled *Participate*. Our goal was to provide information that people could use so they could take part in improving their own health, and in finding a pathway to improved care and outcomes. Later, that 4-page publication became what is today *Digestive Health Matters*.

We have always believed that quality information plays a key role in the delivery of quality care, that all stakeholders must work together, and that patients must be engaged as essential stakeholders.

Our commitment to these principles underlies the many programs and activities that each year we are able to deliver. Whether for research, education, advocacy, or awareness, you all participate. We are pleased to thank you for your contributions as we look back at some of our activities over the past year.

Support of Research

Increased research into functional GI and motility disorders is a key issue for IFFGD. In addition to advocating for more federal dollars to support scientific advancement of these conditions, we are committed to finding ways to promote and fund investigation into better understanding in this field.

Grassroots Support for Research

The Digestive Health Alliance (DHA) provides a way for people to support research for conditions they care about. Active members of the digestive health community create fundraisers on *DHA.org* and host events to raise awareness and funds, with the proceeds being donated to IFFGD to be directed toward research.

DHA Children's GI Research Network

For several years, we have provided support to the DHA Children's GI Research Network, enabling centers to pool data for research into children's GI conditions. With the recent signing into law of the *National Pediatric Research Network Act* we are now doing what we can to help ensure that the DHA Children's GI Research Network is in a positive position to apply for support from the National Institutes of Health (NIH).

Currently these seven centers are involved in the network:

- Nationwide Children's Hospital, Columbus, OH
- Children's Hospital, Louisiana State University, New Orleans, LA
- Connecticut Children's Hospital, Hartford, CT
- Children's Hospital of Wisconsin, Milwaukee, WI
- Children's Memorial Hospital, Chicago, IL
- Children's Hospital Boston, Boston, MA
- Emma Children's Hospital, Amsterdam, The Netherlands

IFFGD Gastroparesis Research Grants

In February 2014, we awarded $120,000 in grants to support research into idiopathic gastroparesis. The grants were made possible by donations to IFFGD, as well as money raised by individuals who sponsored fundraisers through DHA. We are grateful to all of you who donated in support of this research, including:

Major Contributor

- The Zebrowski Family Foundation

Contributors

- The Cheryl Aaron Memorial Fund in Pittsburgh, PA
- The Mary H. Storer Foundation
- The Annual Awareness Walks for Gastroparesis and Digestive Health in Bellingham, WA
- The Half Marathon for Gastroparesis in Pittsburgh, PA
- All of you who made individual donations

Gastroparesis is a condition where the stomach empties too slowly, resulting in symptoms that can be debilitating and in some cases life-threatening. It is challenging to diagnose and more effective treatments are needed.

After receiving applications from around the world, three were chosen by our selection committee to receive the grants, each in the amount of $40,000. The grant recipients were:

- Leo K. Cheng, Ph.D., Auckland Bioengineering Institute, The University of Auckland, New Zealand
- Braden Kuo, M.D., Massachusetts General Hospital, Boston, MA
- Richard W. McCallum, M.D., Texas Tech University Health Sciences Center, Lubbock, TX

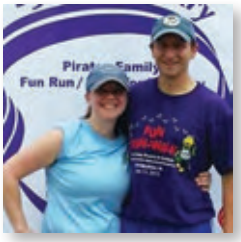
Fundraising

More and more people are stepping up to fundraise through DHA, and many are continuing to increase awareness and raise funds for gastroparesis research. Some highlights from the year are below. We are looking forward to continuing this momentum to be able to call for more grants in the future to help learn more about these complex conditions.

The 3rd Annual Awareness Walk for Gastroparesis and Digestive Health

Stephanie has hosted her event for several years now and was a contributor to our gastroparesis grants presented earlier this year. Her 2014 event featured a walk, as well as awareness items and raffle opportunities. This year Stephanie raised $2,110. Thank you for your continued hard work Stephanie!

2014 Half Marathons for Gastroparesis

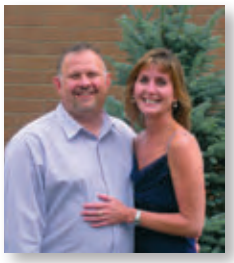


Geri put her feet to the pavement to raise funds for gastroparesis research and raised $1,310. This year she ran TWO half marathons for the cause. We are grateful to Geri for her determination and were happy to see her out running again this fall – thanks Geri!

The Go with Your Gut 5K

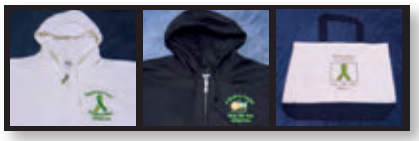
The first annual Go with Your Gut 5K, held in Hilliard, Ohio, was hosted by volunteer fundraiser Lindsay. She was also looking to raise awareness and funds for gastroparesis. Lindsay crushed her $3,000 fundraising goal, bringing in more than $9,000 to benefit gastroparesis research through the DHA and IFFGD. Way to go Lindsay!

The Cheryl Aaron Memorial Fund



Lonnie has been raising money for gastroparesis for a number of years now. After starting the fund to honor his wife, who passed away due to severe gastroparesis, Lonnie has raised more than $20,000. His dedication to this cause is an inspiration and he was one of several DHA fundraisers whose efforts made the 2014 IFFGD Gastroparesis Research Grants possible. Thanks so much Lonnie!

Gastroparesis Awareness Gear for Gastroparesis Research



Melissa is a new DHA fundraiser this year. Her storefront, The GP Fight Store (www.gpfightstore.com), sells items to help increase awareness for gastroparesis. Several times this year she donated 10% of the sales of her items – totes, hats, sweatshirts, and other gear – to DHA for gastroparesis research. We appreciate your efforts to increase the awareness and understanding of this condition Melissa!

Jason's Fund

Jason's Fund was created to help fund research into rare GI and motility disorders. Established in memory and honor of Jason Crowley, the fund is hoping to raise $5,000, and so far, $525 has been raised in support of Jason's Fund. We are grateful to its supporters for their commitment to learning more to help others facing these difficult to diagnose disorders.

Education & Support

Websites

More and more people are looking for medical information online and finding IFFGD on the Internet. Our websites address a range of topics and conditions with information that is evidence-based and accessible to a wide audience.

Remember, information about a variety of topics can be found on our family of websites:

IFFGD.org	DHA.org
aboutConstipation.org	aboutIBS.org
aboutIncontinence.org	aboutGastroparesis.org
aboutGERD.org	aboutgiMotility.org
aboutKidsGI.org	giResearch.org

Social Media

We also participate on social media to engage with the community. Join our discussions at:

Facebook.com/IFFGD

Facebook.com/DigestiveHealthAlliance

Twitter.com/IFFGD

Twitter.com/WeAreDHA

eNewsletter

Our free monthly eNewsletter provides news and information updates to the digestive health community. If you haven't done so already, we invite you to sign up to receive this monthly communication, *Digestive Health Monthly*, at *www.iffgd.org/e-news*.

Mobile App

This April, we launched our first mobile app, *IBS Info*, a resource for people looking for information about IBS and chronic constipation (CC). The app is available for iOS and Android systems. In addition to medical news updates, the app covers topics drawn from our publications library relating to IBS and CC such as:

- News updates
- Commonly asked questions & answers
- Symptoms
- Diagnoses
- Causes
- Medical treatments
- Complementary therapies
- Food and diet
- Talking to a doctor
- Managing daily living

Publications

Our print publications provide information about functional GI and motility disorders helping people better understand their conditions and more effectively work together with their healthcare providers. *Digestive Health Matters* is available online as well as in print, with distribution to people in 147 countries.

Our library of information contains more than 250 factsheets. To assist those who are just looking for the top-line basics, we began a series to address *Commonly Asked Questions* in an easy to read format. So far conditions in that series include: chronic constipation, cyclic vomiting syndrome, functional abdominal pain syndrome, gastroparesis, GERD, and IBS.

Awareness and Advocacy

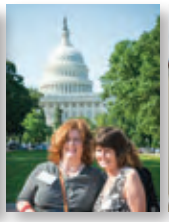
Through a variety of efforts, IFFGD is consistently working to increase awareness for functional GI and motility disorders. Whether through outreach with educational materials and websites or advocacy efforts on behalf of people who are affected, we are dedicated to continuing to bring these issues to the forefront of science and industry, as well as to the attention of government officials and members of the public.

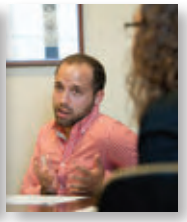
Advocacy in Action

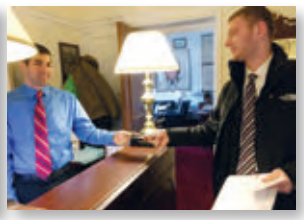
Advocating for research and advancement in Washington, D.C. is becoming increasingly important. By speaking on behalf of the digestive health community and bringing patient advocates to Capitol Hill, we are educating key decision makers on the needs of those with chronic digestive conditions in order to help influence support for activities at NIH, FDA, and other health and human services agencies.

DHA Advocacy Day 2014

The seventh annual DHA Advocacy Day took place in June. Digestive health advocates, including patients, family members, and healthcare professionals, traveled to Washington, D.C. to educate Members of Congress about the needs of the functional GI and motility disorders community.







We spoke to more than 30 Congressional offices about the importance of research, education, and awareness of functional gastrointestinal and motility disorders (FGIMDs) and discussed the key issues that are most important to us for the 2014 fiscal year. Those topics were:

- House Member co-sponsorship and Senate introduction of *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2013* (H.R. 842)
- Support for increased funding for the National Institutes of Health (NIH) to a level of at least $32 billion in Fiscal Year (FY) 2015
- Support for veterans in the FY15 Defense Appropriations bill by: House and Senate funding support of the Department of Defense (DOD) Gulf War Illness Research Program, which provides a source of funding for functional GI disorders research
- Support for funding for the *National Pediatric Research Network Act*, with funding for a pediatric FGIMD network
- Clarification regarding reasons and purpose for new guidance governing medical foods from the FDA

We are grateful to those that were able to join us and others that called in to their Representatives on Digestive Health Congressional Call-In Day. We hope that even more of you can help with these efforts in the future.

Support for Veterans

IFFGD has been speaking out for years about the effects that functional GI disorders have on our service men and women. We continue to advocate for funding for the Gulf War Illness Research Program in the DOD's Congressionally Directed Medical Research Program. Since FY2012, functional GI disorders have been included among the conditions eligible for study under this program. The funding was renewed in FY2014 and in June, the Senate Appropriations Committee included a $47.5 million increase in the Peer-Reviewed Medical Research Program in its approval of the 2015 DOD Appropriations Bill.

IFFGD also provided testimony to the U.S. Department of Veterans Affairs (VA) about functional GI disorders and Gulf War Veterans' illnesses, and the relationship between these conditions and military sexual trauma.

DDNC Public Policy Forum

On March 2–3, 2014 IFFGD again took part in the Annual Digestive Disease National Coalition (DDNC) Public Policy Forum in Washington, DC. This yearly meeting brings us together with other organizations in the field to receive legislative updates and take part in advocacy activities, allowing us another opportunity to express the concerns of the digestive health community with Members of Congress.

During the Public Policy Forum, IFFGD's founder, Nancy Norton, was honored with the DDNC Lifetime Service Achievement Award in recognition of her service and many contributions to the digestive health community.

IBS Awareness Month

In April, Congressman James Moran (VA-8) made a statement in the U.S. House of Representatives to recognize IBS Awareness Month and urge congressional colleagues to support research efforts for IBS.

Gastroparesis Awareness Month

In August our press release, *Lack of Awareness of Gastroparesis May Impact Medical Care*, was widely picked up by both general public and medical professional news outlets.

GERD Awareness Week

This November marked the 16th Annual GERD Awareness Week. Our message was, *Persistent Heartburn May Be a Sign of GERD: IFFGD reminds people of symptoms for GERD Awareness Week*.

Providing the Patient Perspective

Speaking out on behalf of patients is at the center of our advocacy efforts. For many years IFFGD has provided this perspective to healthcare providers, industry leaders, legislators, and regulatory agencies giving a voice to patients and family members.

The *2014 NIDDK Recent Advances & Emerging Opportunities* annual publication included a Patient Profile on Nancy Norton of IFFGD entitled, "Living Hour to Hour with Fecal Incontinence." This provided an opportunity to describe the patient experience of living with and managing a chronic bowel control problem, and to help make it easier for people to seek the care they need, knowing they are not alone.

IFFGD took part in a roundtable meeting of patient advocacy and professional societies organized by the AGA and the Partnership to Improve Patient Care (PIPC). The objective was to finalize recommendations for the *Patient Centered Outcomes Research Institute (PCORI)*, whose purpose is to conduct comparative effectiveness research that will lead to a better understanding of management and treatment options for patients, caregivers, and the broader health community.

Summary

Much was accomplished this past year and we are grateful to all of the supporters of IFFGD, as well as those of DHA, who make all of this possible. We celebrate these achievements, share our successes with you, and look forward to what next year will bring for all of us. Thank you for your continued support. ■

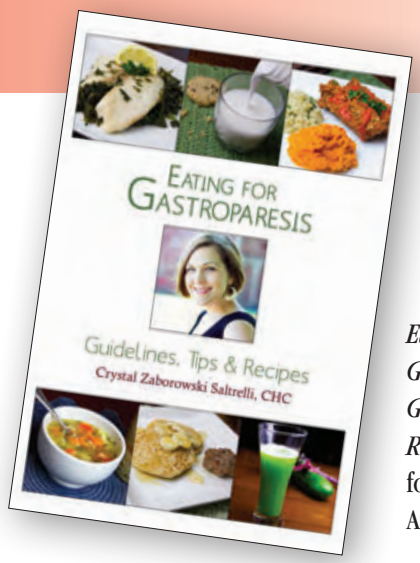
Book of Interest

Title: *Eating for Gastroparesis: Guidelines, Tips & Recipes* (Second Edition)
Author: Crystal Zaborowski Saltrelli, CHC
Publisher: CreateSpace Independent Publishing Platform
Pages: 178 (paperback)

Certified Health Coach (CHC) and long-time advocate with the DHA, Crystal Zaborowski Saltrelli recently released the new edition of her book, *Eating for Gastroparesis: Guidelines, Tips & Recipes*. Based on her experiences as a Health Coach and her own journey with gastroparesis, Zaborowski Saltrelli guides the reader through the process of making dietary changes to help manage the symptoms of gastroparesis. In the book you'll find answers to common questions, grocery lists, and over 75 nutrient-rich, gastroparesis-friendly recipes.

Excerpt from *Eating for Gastroparesis*

> Dietary modifications are a symptom-management tool, not a treatment for gastroparesis itself. This does not mean that gastroparesis does not or cannot get better, of course, just that following the dietary guidelines in this book won't necessarily address the underlying cause of the disorder. In conjunction with the other aspects of a comprehensive management plan, however, dietary changes can significantly alleviate day-to-day symptoms and support the body's natural healing mechanisms.
>
> To date, no studies have been conducted to determine which specific foods or types of foods alleviate or exacerbate symptoms in those with gastroparesis. The standard dietary instructions are based on the basic science of digestion, as well as the experience and observations of patients and clinicians over time. Similarly, the guidelines set forth in this book are based on a combination of my knowledge of nutrition, digestion, and gut health, as well as my personal experience with gastroparesis and several years coaching others with the condition. ■



Eating for Gastroparesis: Guidelines, Tips & Recipes is available for purchase at Amazon.com.

10 Guidelines of a Gastroparesis-Friendly Diet

1. Eat smaller meals.
2. Reduce dietary fat.
3. Reduce dietary fiber.
4. Limit foods with indigestible parts.
5. Choose a variety of gastroparesis-friendly, nutrient-rich foods.
6. Supplement with nutrient-rich liquids, as necessary.
7. Chew thoroughly.
8. Eat slowly, calmly, and in a relaxed environment.
9. Reduce or eliminate foods that impair gut health, provoke symptoms, and/or compromise digestion.
10. Modify the guidelines according to your symptoms, circumstances, and goals.

Recipe for Maple Sausage Hash

- 1 lb lean ground pork
- 2 medium baked sweet potatoes, peeled and diced
- 1 Tbsp coconut oil
- ½ tsp cinnamon
- ½ tsp sage
- ½ tsp thyme
- 1 tsp sea salt, to taste
- 1 Tbsp maple syrup

1. Melt coconut oil in a skillet over medium heat.
2. Add the pork to the skillet. Sprinkle with thyme and sage. Cook until no pink remains. Push to one side of the skillet.
3. Add the diced sweet potatoes to the other side of the skillet. Sprinkle with cinnamon.
4. Cook until the sweet potatoes start to brown, stirring occasionally, about 3–5 minutes. Drizzle with maple syrup.
5. Carefully mix the pork and the sweet potatoes together and serve.

Being a Champion for Digestive Health

Looking Ahead to the 114th Congress

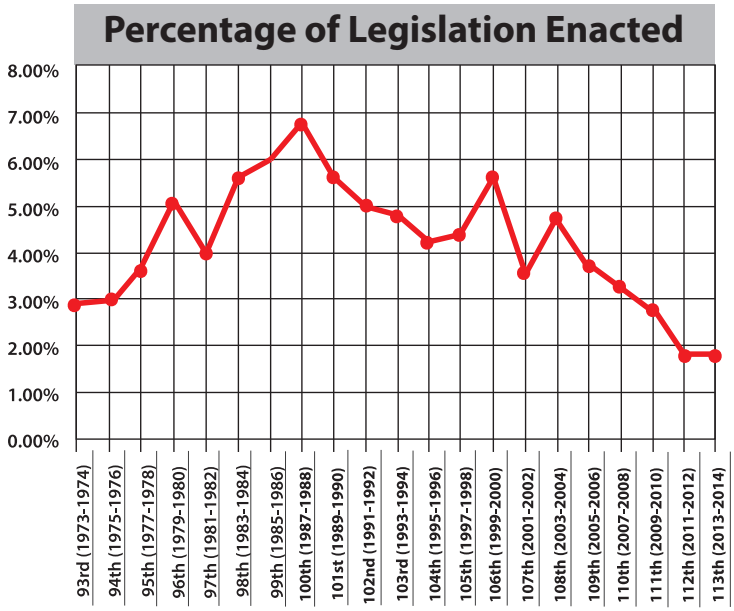
The Functional Gastrointestinal and Motility Disorders Research Enhancement Act will be reintroduced in the 114th Congress and it needs your continued support.

The 114th Congress began January 3, 2015. Every two years in January a new Congress starts over with new legislation to consider. Bills not acted on in the prior Congress can be reintroduced in the new Congress (often with a new number), and the legislative process will start again.

The Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2013 (H.R. 842) was introduced in the House of Representatives in the last Congress where it gained bipartisan support from 20 cosponsors.

Support in the 113th Congress for H.R. 842 was garnered by hundreds of digestive health advocates who reached out to their Representatives. They helped raise awareness about functional gastrointestinal and motility disorders and the needs of patients and families who daily live with these disorders.

Thank you to everyone who has taken action for this landmark bill! Continued contact with Members of Congress is needed from all of you who want improved digestive health care. We will let you know when the bill is re-introduced. ■



Members of Congress introduce thousands of bills each year. Less than 2% passed in the 113th Congress! Continued support is needed to pass most bills.

Representatives who supported H.R. 842 in the 113th Congress included:

F. James Sensenbrenner, Jr. (WI-5), sponsor

Mo Brooks (AL-5)

Julia Brownley (CA-26)

Susan Davis (CA-53)

Ed Perlmutter (CO-7)

Jim Himes (CT-4)

Bill Posey (FL-8)

Bobby Rush (IL-1)

André Carson (IN-7)

Richard Neal (MA-1)

James McGovern (MA-2)

David Price (NC-4)

Carol Shea-Porter (NH-1)

Peter King (NY-2)

Louise Slaughter (NY-25)

James Moran (VA-8)

Gerry Connolly (VA-11)

Peter Welch (VT)

Ron Kind (WI-3)

Gwen Moore (WI-4)

An Advocate's Story – By Lindsay Slivka

My name is Lindsay Slivka. I am a 36 year old wife and mother of two children. I have a doctorate in audiology and work for a hospital system performing hearing screenings on newborns.

While training for a half marathon in February 2010, I started having pain in my right side and difficulty breathing. I went through nearly every cardio-pulmonary test imaginable. I remember saying to my pulmonologist, "I have not been able to eat as much as usual for the last six weeks. I feel really full all of the time and just can't eat what I used to." His response was "I have no idea what that is all about" and told me there was nothing left for him to do for me.

I figured I had to live with my symptoms and kept going. In the fall of 2012 I called a family friend that is a gastroenterologist. He said to come in for an endoscopy and he would see if he could find anything. He called me the day after the test and was stunned to tell me I had celiac disease. In fact, there was an extreme amount of damage in my GI tract, suggesting a long standing problem. I immediately started following a gluten free diet. Over the next 5 weeks, instead of getting better, I kept getting more ill, until I could not even sip water without feeling like I was going throw up.

That is when I was diagnosed with gastroparesis.

Like many others with gastroparesis, I have gone through a number of medications, procedures, and alternative healthcare practices trying to manage my symptoms of nausea, fullness, stomach pain and chest pain. In March of 2012, a feeding tube was placed through my nose into my small intestine. Still unable to take in enough calories, I had a central line place in April 2012 and use TPN (IV nutrition) daily.

I am able to eat some food and focus on eating high quality, nutrient dense food. I have been following the Autoimmune Paleo approach for over 9 months and feel it is helping my symptoms. I find daily exercise to be incredibly helpful in keeping my symptoms under control and to help me keep a positive attitude.

It is my intention to promote advocacy and raise awareness to help the millions worldwide living gastroparesis. I am determined to find ways to manage symptoms, help others cope with gastroparesis, fund research, as well as promote awareness and advocacy through events such as the "Go With Your Gut 5k" and my website *www.navigatinggastroparesis.wordpress.com*.

Very little is known about GP and without some intense research, those of us who struggle to deal with this disease are in desperate need of help that can only come from a better understanding of why this happens.

The inaugural "Go With Your Gut 5k and 1 mile walk" was held August 23rd, 2014 in Hilliard, Ohio. We had a great turn out for our first event, over 175 people registered! We love seeing people in the t-shirts from the event! We raised over $9,000 for research for Digestive Health Alliance. We are planning the second annual event for August 22, 2015. We would love to see you there!

IFFGD

International Foundation for Functional Gastrointestinal Disorders

This issue of *Digestive Health Matters* is sponsored, in part, by Actavis (formerly Forest Laboratories, Inc.), Ferring International PharmaScience Center US, Inc., Ironwood Pharmaceuticals, Inc., and donors to IFFGD. We are grateful for their continued support of IFFGD.

Our Unique Mission: The International Foundation for Functional Gastrointestinal Disorders (IFFGD) is a nonprofit education and research organization dedicated to informing, assisting, and supporting people affected by gastrointestinal disorders. IFFGD has been working since 1991 with patients, families, physicians, practitioners, investigators, employers, regulators, and others to broaden understanding about gastrointestinal disorders and support research.

International Foundation for
Functional Gastrointestinal Disorders
IFFGD
700 W. Virginia St., #201
Milwaukee, WI 53204
Toll-free (U.S.): 888-964-2001
Business: 414-964-1799
Fax: 414-964-7176
E-mail: iffgd@iffgd.org
www.iffgd.org
www.aboutconstipation.org
www.aboutibs.org
www.aboutincontinence.org
www.aboutgastroparesis.org
www.aboutgerd.org
www.aboutgimotility.org
www.aboutkidsgi.org
www.giresearch.org
www.dha.org