

Examples of Surgical & Investigational

Approaches:

1. Gastric Electrical Stimulation (GES) uses a surgically implanted battery-operated stimulator, with 2 electrodes placed in the wall of the stomach. GES may be used in some people where medications fail to adequately control nausea and vomiting.
2. An experimental procedure to treat GP is to cut the pyloric muscle at the end of the stomach to increase the speed of stomach emptying. This procedure, called pyloromyotomy, can be performed surgically or endoscopically (G-POEM).



General Information:

People who experience symptoms suggesting GP and related disorders of the stomach, should be evaluated by their doctor. Based on results of specific tests and procedures, a treatment plan can be developed with the goals of reducing GP symptoms and preventing further complications. It is important to inform the doctors about all drugs or medications that are being taken (e.g. herbal, marijuana, other prescription medications) in order to avoid unnecessary interactions and side effects of different drugs.

Hope through Research:

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Division of the National Institutes of Health (NIH) continues to support basic and clinical research on gastrointestinal motility disorders, including gastroparesis.

The NIDDK GpCRC is a consortium of clinical centers whose goals are to improve our understanding of the causes and clinical outcomes of GP and related disorders of the stomach to improve diagnostic tests and procedures and to find new treatment options and improve the quality of life of affected patients.

Current studies of the NIDDK GpCRC:

1. Registry studies are designed to periodically gather information from GP patients about their disorder. There are two registries: The Pediatric Gastroparesis Registry (for children 5-17) and the Gastroparesis Registry 3 (for adults).
2. The Buspirone for Early Satiety and Symptoms of Gastroparesis (BESST) Trial will determine if treatment with the study drug (buspirone) can improve the ability to eat a regular size meal and not feel excessively full and have to stop eating.
3. The Pathological Basis of Gastroparesis (PBG) study aims at understanding the changes in stomach muscle that occur in GP to improve future treatments of patients with GP.
4. Studies are underway examining specific muscles within the stomach and how treatments might improve their function.
5. New studies are constantly under development, including promising drugs and devices to control symptoms and improve the quality of life of patients.

The Gastroparesis Consortium Clinical Centers:

Adult:

- Johns Hopkins School of Medicine
- Massachusetts General Hospital
- Temple University
- Texas Tech University HSC El Paso
- University of Louisville
- Wake Forest University

Pediatric:

- Baylor College of Medicine
- Boston Children's Hospital
- Nationwide Children's Hospital

Pathology Center: Mayo Clinic

Scientific Data Research Center:

Johns Hopkins Bloomberg School of Public Health
For more information, visit the GpCRC website at

<https://jhuccs1.us/gpcrc/>

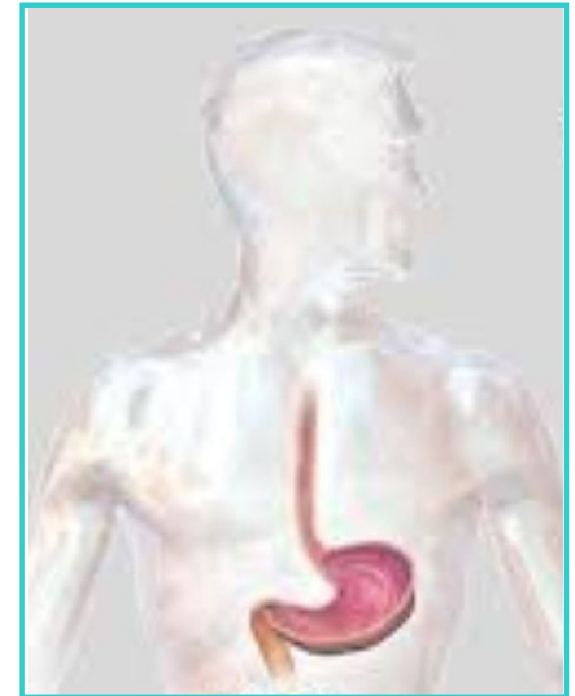
Contact Information:

Gastroparesis

A Brochure prepared by the NIDDK
Gastroparesis Clinical Research
Consortium



National Institute of
Diabetes and Digestive
and Kidney Diseases



Gastroparesis (GP) (gastro=stomach; paresis=partial paralysis) is a disorder in which the stomach does not empty its contents, including food, as properly as it should. Affected patients develop symptoms such as nausea, vomiting, fullness, inability to complete a meal, bloating and pain. GP is diagnosed by documenting a delay in gastric emptying using specialized tests. However, many patients with similar symptoms to GP have normal stomach emptying. Both conditions often adversely affect the quality of life of patients who suffer from them.

What causes Gastroparesis?

The major causes of this condition are: diabetes, damage to the vagus nerve during surgery, and neurological conditions such as Parkinson's disease. In some cases, GP is suspected to develop after a viral infection, although this usually cannot be proven. Some drugs such as narcotic pain medications also may slow stomach emptying. In most patients, however, a cause of the GP cannot be found and the disorder is termed *idiopathic* GP. In some cases, GP can improve with careful control of diabetes over time but usually GP and related disorders are chronic and persistent disorders.

What are the Changes in the Stomach?

In the stomach of patients with GP and related disorders, specialized cells that are responsible for normal function appear to be lost and/or not work well. This may be caused by changes in the surrounding immune cells called macrophages. Further research is needed to find effective ways to reverse these changes.

What are the Symptoms of Gastroparesis?

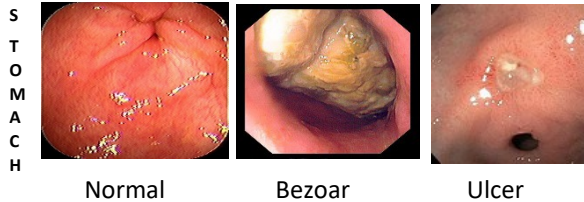
The symptoms of GP and related disorders can be mild or severe, and they may occur infrequently or daily. They include: a feeling of fullness after only few bites of food, bloating, nausea, vomiting, stomach pain, and/or lack of appetite. Patients with diabetic GP also may have difficult-to-control blood sugars - either low or high levels.

What are the Complications of Gastroparesis?

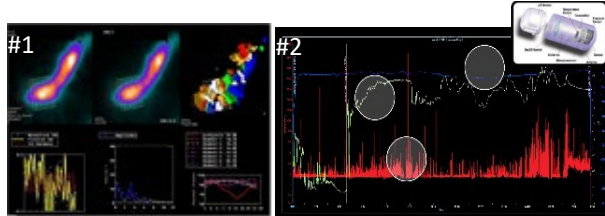
Nutritional deficiencies are common in this condition. With severe cases, weight loss may occur. In some patients, retained food and vegetable matter in the stomach may produce a solid ball of material called a bezoar that can cause pain and occasionally, blockage. In diabetic patients, adequate control of blood sugar is of utmost importance both in terms of improving symptoms and preventing further damage to the stomach and other organs.

Tests for Gastroparesis:

Tests are performed to be sure there is not a physical blockage. This often is done by looking into the stomach with an instrument called an endoscope during a test called upper endoscopy when the doctor looks into the stomach with a lighted flexible tube.



Another test measures how much food empties from the stomach over time. This test is called a gastric emptying test. An eggbeater meal with a small amount of a radioactive isotope is ingested, and a special camera is used to examine how the test meal is distributed in the stomach, how much food leaves, and how much is still left in the stomach over a 4-hour time period. GpCRC investigators are testing how to improve this technique. Here is an example (#1) of dynamic antral contraction scintigraphy measuring how the stomach contracts.



Occasionally, other tests are used to measure stomach emptying. One of them is the wireless motility capsule (#2). This is a pill-like device that, after being swallowed, sends information to a recording device worn by the patient. It also can measure how fast food takes to go through the rest of the intestines. Another test measures carbon dioxide in the breath after a special test meal to evaluate stomach emptying.

An additional specialized test assessing stomach function is electrogastrography (EGG) which measures the stomach's electrical rhythm by using electrodes placed on the abdomen.

Treatment of Symptoms:

- Adjustments of food intake based on GP dietary recommendations are often necessary and helpful. They include eating small portions of 4 to 6 meals each day rather than three large meals. The meals should be low in fat, fiber and roughage, and easy to chew and swallow. When symptoms get worse, patients often are encouraged to switch to a more liquid diet. In very severe cases with weight loss, a feeding tube may be placed in the small intestine to deliver nutrition and medications.
- Vitamin and mineral deficiencies should be corrected and it is very helpful to talk to a dietitian.
- For diabetic patients, controlling blood sugar levels may decrease gastroparetic symptoms.
- There are a few drugs that can improve gastric emptying (pro-motility or prokinetic agents). One drug is metoclopramide, which also acts to reduce nausea. This drug may cause neurological side effects in some patients (20%), hence patients need to be monitored. Another drug which works similarly to metoclopramide, but it is not approved by the Food and Drug Administration (FDA) in the U.S. is domperidone. This drug may cause heart palpitations and cardiac arrhythmias. Therefore, patients should talk to their doctor about potential risks and benefits of these two drugs and be monitored during treatment. Erythromycin is an antibiotic that also can speed up stomach emptying but the response may wear off if used over the long-term.
- Anti-nausea and anti-vomiting medications include promethazine, prochlorperazine, ondansetron and aprepitant. These can be added to the prokinetic therapies. Occasionally, scopolamine patch, dronabinol, or mirtazapine also may be prescribed for their anti-nausea effect.
- New agents are under clinical investigation. If you are interested, you are encouraged to ask your doctor about participating in these studies.