GPDA

Gastroparesis & Dysmotilities Association

GPDA's
Mission is to provide accurate information to patients; increase awareness to the public and medical community about *Digestive Motility Diseases;* and facilitate the search for a cure

Understanding Gastric Electrical Stimulation For The Treatment of Gastroparesis.

This pamphlet is one in a series discussing symptoms and symptom management for patients living with **Digestive Motility Diseases.**

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Understanding Gastric Electrical Stimulation

Gastroparesis can be a very confusing, and frustrating digestive illness.

This booklet has been written to provide you and your family with more information about Gastroparesis and Gastric Electrical Stimulation.

Questions may come to mind as you read through this booklet. Use the space provided on the back page to jot down your thoughts and questions. Bring this with you to your next appointment.

For further information about Gastroparesis and motility disorder, visit:

< www.digestivedistress.com>

Acknowledgments:
Thanks to Dr. Thomas Abell, M.D. for the development of this book.

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NOTES

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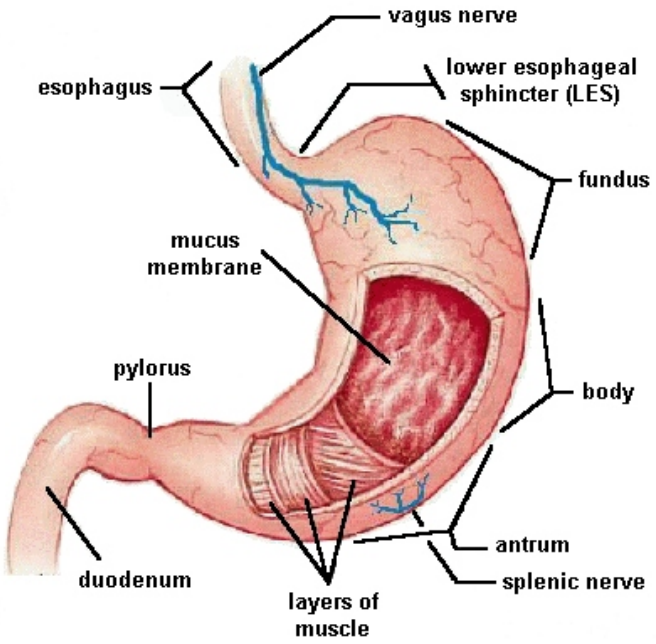
Introduction

This pamphlet has been developed to provide you with a better understanding about Gastric Electrical Stimulation or 'GES'.

Gastric Electrical Stimulation is a treatment device in use for over 10 years now, employing an implantable appliance to control nausea and vomiting associated with gastroparesis.

Understanding how your stomach works

Your stomach is a hollow, muscular organ; the workings of which are wonderfully orchestrated by chemical, nervous and electrical signals. When every system follows its function and purpose, then a meal is an enjoyable and thoughtless process. Each section of the stomach too has a specific role. The upper section, called the fundus, acts as a catchment for your meal; gently relaxing and expanding to



(source: Carlyn Iverson)

'accommodate' the food you are eating. The antrum (or lower section) has a vigorous role to play, converting the recognizable food from your fundus and churning it down to a fine slurry. This slurry is moved in a controlled metered fashion, through the pylorus valve, onto the small intestine for adsorption of your nutrients. Your antrum, then, is the work-horse and 'pump' of your stomach.

To help modulate the muscular and rhythmic activity, your stomach also has a "pacemaker" region situated near the "body", also called the "corpus" of the stomach. Specialized cells in this region send out weak electrical impulses which promote rhythmic, muscular action. The pacemaker region acts as the conductor, coordinating the symphony of action for your upper digestive region!

The variety of all of this muscular activity by the digestive system is called digestive "**motility"**.

Causes of Chronic Nausea and Vomiting

Nausea! Most people describe it as "and upset stomach" or a "queasiness". It does not have to be associated with the act of vomiting for it to be debilitating.

Vomiting is a reflexive action which empties the stomach of its contents. It can result in serious dehydration and loss of weight. When these symptoms last for many months, then it is categorized as **chronic**. A variety of problems may lead to chronic nausea and vomiting. The possible cause always needs to be investigated by your doctor.

Generally, chronic nausea and vomiting can arise from 3 sources: from the central nervous system, that is, the brain's vestibular area (middle ear); from the autonomic nervous system; or from the abdominal region (the stomach, pancreas, gallbladder/liver or small intestine).

Problems in structure, or function, in these areas can result in chronic nausea and vomiting. Also, medications, metabolic imbalances, or toxic chemicals can set-off the "vomiting center" in the brain leading to nausea and vomiting. Some causes of nausea and vomiting are reversible by treating or correcting the underlying problem.

Gastroparesis

Gastroparesis, also called 'delayed gastric emptying' is one of the most common causes of chronic nausea and vomiting. Gastroparesis is a neuro-muscular disorder of the stomach, which is characterized by "motility" weakness or failure. Food sits for hours in the stomach due to the stomach's faltering ability to grind and pump food out to the small intestine.

What causes gastroparesis?

Gastroparesis has numerous causes. Overall, the groups that make up gastroparesis sufferers are:

Idiopathic causes 36%	Parkinson's Disease 7%
Diabetics 29%.	Pseudo-obstruction 6%
Post gastric surgery 13%	Collagen Diseases 4%

(The remainder are miscellaneous causes)

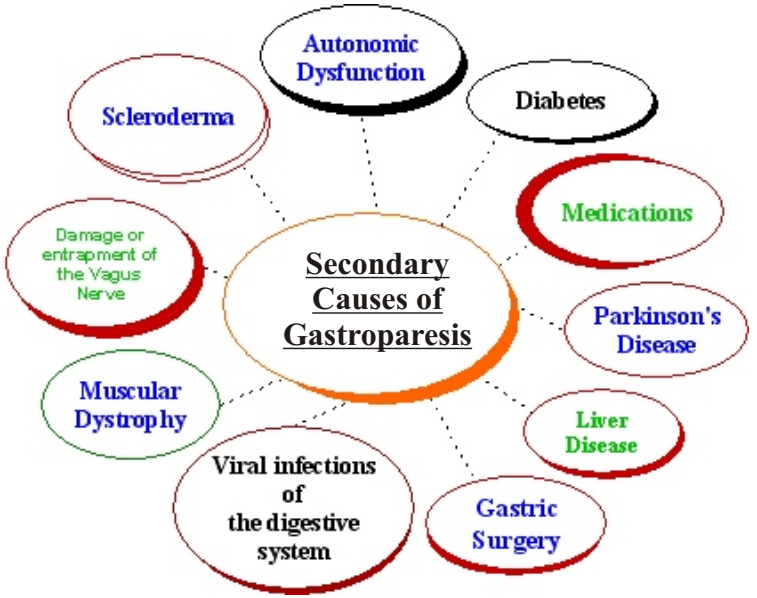
Your Autonomic Nervous System automatically controls and regulates your:
~Heart rate,
~Breathing,
~Blood pressure,
~Digestive function,
~Bladder,
~Urinary Function, and
~Body temperature.

~Idiopathic causes of gastroparesis primarily affect women and have no known cause.

~Autonomic nerve dysfunction has also been associated in some patients with Idiopathic gastroparesis.

Regardless of how one develops gastroparesis, the symptoms are similar for all.

Other causes for gastroparesis often result from as a secondary problem created by a primary – systemic – disease. Listed below are some common secondary causes of gastroparesis:



Gastroparesis reflects a diverse set of problems within the stomach.

Scientists speculate that some of the symptoms of gastroparesis are the result of:

~ Failure in the top portion of the stomach (the fundus) to relax when filling-up as food is eaten;

~ Abnormal sensitivities to the normal stretching of the stomach when food and air enter it, causing pain and a feeling of fullness;

~ Weakened muscular contractions within the lower part of the stomach (the antrum), resulting in failure to mix/grind the food and pump it out. (Food sitting in a stretched antrum is a **powerful signal to the brain communicating nausea)**;

~ Spasms in the pylorus valve (the valve between the stomach and small intestine), impeding the stomach's ability to push food through this valve;

~ Abnormal muscular tone or spasms in the small intestine hindering the stomach's ability to overcome the abnormally high pressures down stream, and resulting in food and secretions backing up;

~ Abnormal muscular rhythms in the stomach caused by a faulty or damaged pacemaker region. (These abnormal rhythms make for ineffective pumping action. The uncoordinated rhythms may be communicated back to the brain, leading to symptoms of chronic nausea.);

~ Abnormal functioning within the "Autonomic" (automatic) nervous system.

Treatments are aimed at reducing symptoms. A stepwise approach, called a treatment ladder, should be used, starting with the easiest and simplest treatments; then, if the symptom severity dictates, more complicated treatments can be applied.

Diet modification and medications are always the first steps in treatment. However, even your best effort can result in symptom flair-ups, leading to bouts of intense, uncontrolled symptoms and possible repeated hospitalizations. Be sure to keep a journal and share this information with your doctor to help determine when it is appropriate to move up the treatment ladder.

Current Treatments for Nausea and Vomiting

Initial approaches to treatment must always begin with changing your diet. Consultation with a dietitian who is knowledgeable about gastroparesis is a first step. This is especially important for diabetics.

First step on the treatment ladder:

Generally,

~Eat low fat and low fiber foods;
~Eat small frequent meals;
~Try drinking liquids apart from your meal;
~Avoid caffeinated drinks;
~Try teas made from: ginger, licorice, green tea or fennel;
~Avoid any snacks 2 to 3 hours before bedtime;
~Remain sitting-up for several hours after any meal;
~Sip on "electrolyte rich" drinks like Pedialyte;
~Stick to low fat, low fiber, liquid meal substitutes during intense symptom periods or sip on clear broths..

When symptoms are still interfering with your ability to eat, sleep, and function, then you need to step-up on the treatment ladder. The next approach is the addition of medications.

Second step on the treatment ladder:

Medications are the corner stone of treatment for any patient suffering from nausea and / or vomiting caused by gastroparesis. The aim of medical treatment is two fold, first:

~Medications called "**pro-motility**" or "**prokinetic**" drugs are used either alone or in combination to help enhance the emptying power of the stomach, and second;

~Medications called antiemetics are used to combat the nausea and/or vomiting brought about by gastroparesis.

Some of the medications used to help the stomach to empty also have anti-naueasa or anti-vomiting properties. However, used alone, they may not be sufficient to quell more severe nausea / vomiting.

Wide varieties of antiemetic drugs are available and can be prescribed in combinations to help control more severe symptoms. Some of the newer antiemetics used to treat nausea and vomiting induced by chemotherapy are very expensive, but work well for gastroparesis patients.

Antiemetics are usually taken on a regular schedule instead of an "as needed" basis and should be prescribed in easy to absorb formulations.

Further steps on the treatment ladder

Nausea and vomiting resulting in associated weight loss and episodes of dehydration warrant more aggressive treatment interventions.

To control more severe bouts of nausea and vomiting; injections, or intravenous access with medications, and intravenous fluids are needed.

As well, weight loss may have to be managed with the placement of a feeding tube to bypass the poorly functioning stomach. The tube may be temporary or more permanent. A common tube for more permanent access for nutritional support and delivery of medications is called a "J-tube"--short for: jejunostomy tube. In some situations, a tube may also be placed directly into the stomach – called: a "G--tube or gastrostomy tube. The G-tube is primarily for draining off stomach secretions or for relieving pressure from gas and secretion build-up.

Treatments may also be targeted at the pylorus valve. The use of 'botox' injections into the pylorus allows it to relax and facilitate the downward movement of food. This may bring relief from vomiting for 6 to 8 months.

Other alternative treatments

Alternative medicine and psychological support can be added at any point along the treatment ladder. Therapies such as acupuncture or acupressure, biofeedback, yoga and meditation can provide additional relief. Both biofeedback and acupuncture therapies have shown effectiveness in controlled scientific trials. Remember, your digestive disease is not caused by stress, but stress can add to your symptoms. Finding a psychologist who understands this important point can help provide you with emotional support and learn coping strategies.

GES--part of the treatment ladder

Gastric Electrical Stimulation (GES) is a device which has been in use since 1992 to treat severe nausea and vomiting of gastroparesis in patients not responding to other treatment options. It is a reversible treatment and the only treatment currently on the market researched specifically for gastroparesis. GES is a treatment that employs a surgically placed device, which includes a battery; pulse generator (pacer); and two wire leads. Similar in appearance to a heart 'pacemaker', the battery/pulse generator unit is secured just under the skin surface, while the wire leads go from the device to the stomach where they are strategically implanted just underneath the outside surface of the stomach. The system delivers an intermittent, weak, electrical impulse. Your doctor can adjusted the system to provide various energy setting in order to optimize symptom management. The battery life ranges from 5 to 8 years and is easily replaced by a quick simple surgery.

Types of Gastric Electrical Stimulation/Devices

Currently there is only one method of gastric electrical stimulation for use in humans; called: Enterra Therapy, (manufactured by Medtronic Inc.) this system uses **high frequency and low energy** for the therapeutic effect. How it works, medical research still has not figured out, but it may well work by acting upon the body's nervous system. Some researches in fact call this "**neural**" GES. The low energy requirements for the system are ideally suited for implanting the entire device within the person similar to what is done with heart pacemakers.

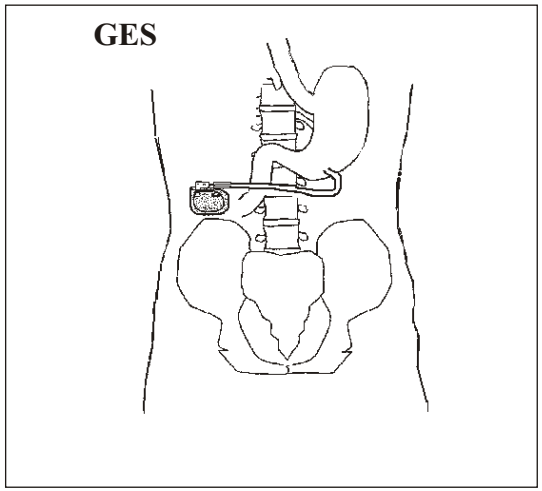
Enthusiasm for heart pacemaker research was the driving concept for application of this technology to the stomach – since the stomach, like the heart, has a natural "pace-maker" region. These pacemaker regions lend themselves to manipulation with electrical currents.

Other stimulating devices and systems have been tested, and tried, some on humans. Experiments in humans have been attempted using a **low frequency, high energy** device; called "**gastric pacing**". The delivery of **high energy** actually compels the stomach to contract and empty. One limiting factor for this device is the need for high energy. A large battery--too large to implant into the body--is needed to generate the high energy. This experimental system is cumbersome for practical purposes and inadequately tested for clinical use. Another fully implantable device, still in the experimental stage; uses multiple leads and a micro-pressor system. This is a sequential, neural, GES approach which provides high energy in order to empty the stomach.

Even though **Enterra Therapy's** low energy approach does not "pace" the stomach, the erroneous term--"stomach pacer" has stuck and is in common use to describe Enterra Therapy.

Enterra Therapy is approved for use under special regulations developed by the Food and Drug Administration (FDA). Called a "**Humanitarian Use Device (HUD).**" These regulations are intended to advance the development for new devices targeted to diagnosis or treat rare diseases/disorders.

HUD devices are not “experimental” nor are they “fully” FDA approved; they are however deemed safe by the FDA. Many insurance providers’ policies may not cover Enterra Therapy. However, Medtronic has developed patient information packages to help you with insurance appeals. Most appeals are won, but some appeals require much time and effort. Your doctor should have the contact information for a Medtronic representative to assist you. Most state Medicare policies do cover Enterra Therapy. In Canada, the Medtronic GES system is approved for use by the Therapeutic Products Directorate, Medical Device Bureau.



Who may benefit from GES

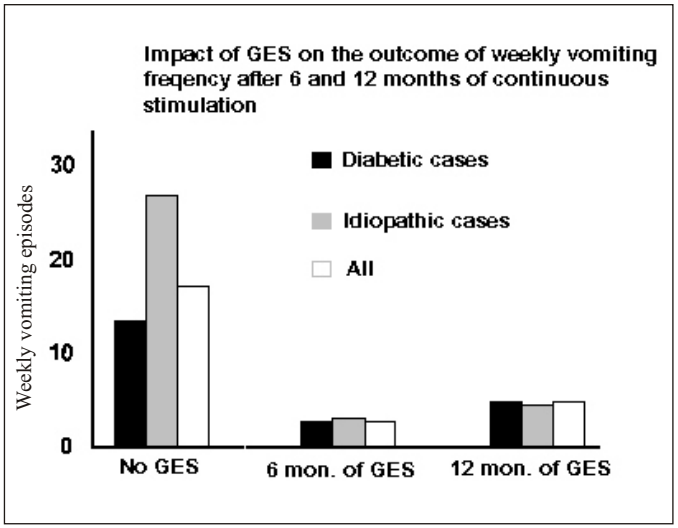
Gastric Electrical Stimulation is an effective treatment for chronic nausea and vomiting caused by gastroparesis where standard medical treatment is not working for controlling these symptoms

Individuals who are faced with dehydration, frequent hospital admissions or visits to the emergency departments, and weight loss due to their unrelenting symptoms of nausea and vomiting; and for whom no other treatments have worked to control these symptoms, should be considered for GES.

Or:
If you have tried everything and nausea and/or vomiting is still greatly interfering in you life, restricting your activities and even disrupting your sleep, then you may ask to be referred to a specialist who is familiar with the use of GES.

What improvements are seen With GES?

The graph below shows the results from GES:



Besides reducing nausea and vomiting, GES has been effective in stabilizing weight loss, decreasing numbers of days of hospitalization, and for many, regaining the ability to eat once again. In many cases, feeding tubes can be removed. Gastric Electrical Stimulation has also been shown to improve quality of life by significantly reducing the debilitating symptoms caused by gastroparesis.

The use of Temporary GES

For reasons not yet understood by medical science, GES does not work for everyone. In situations where it is uncertain if an individual will respond to GES, than a method of temporary trial with GES can be attempted to see if the patient will respond to the device.

With the use of “endoscopy” (a flexible tube which allows the doctor to see inside your stomach), the GES electrodes can be secured on the inside surface of your stomach. The endoscopy approach can either be done through an existing G-tube or, through your mouth. The two wires (leads) exit to the outside and are connected to the device. A gastric emptying study is done before, then several days to a few weeks

into continuous stimulation with GES. This assessment, along with evaluation of your over all symptoms in response to the temporary GES, helps determine if you will respond to permanent GES.

Problems with GES

Complications can arise after placement of the Gastric Electrical Stimulation device. Many of these problems are manageable and do not require discontinuation of the device.

The more common complications:

~ A "pocket" infection at the battery site;
~ An electrode pulls loose or moves;
~ A lead breaks;
~ Loose electrical connection;
~ Migration or movement of the battery unit;
~ Persistent pain at the battery unit site;
~ Perforation through the stomach during electrode placement;
~ An allergic response to the implanted materials;
~ Loss of the therapeutic effect.

As with any surgical procedure, your doctor will need to explain the risks from general anesthesia, bleeding, infections and pain that can result.

Future Perspectives

The future is promising for development of many more therapeutic devices and medications for the treatment of gastroparesis.

To help further more rapid research, a registry and database for all digestive motility disorders, beginning with gastroparesis, has been proposed by the American Motility Society. Hope is on the horizon.

Glossary of terms

Autonomic Dysfunction: an abnormal or impairment to the functioning of the Autonomic Nervous System (ANS).

Autonomic Nervous System(ANS): is a part of the overall nervous system responsible for the involuntary; or, automatic function of body systems like: heart rate, sweating, bladder control, and your digestive system control – as well as other bodily systems. The ANS has two opposing teams, the parasympathetic, and the sympathetic teams. Each helps to maintain an overall balanced regulation of our bodily systems.

Endoscopy: is a thin, flexible, lighted tube which allows the gastroenterologist to look inside your digestive tract. Some simple procedures can also be carried out using the endoscopy.

Electrodes: a solid electrical conductor through which an electrical current leaves or enters. In GES, the electrode is a small plate at the end of the lead (wire).

Gastrostomy: a surgical opening into the stomach (see below for definition of "ostomy").

Idiopathic: a medical term to denote that the primary cause of the disease or disorder is unknown. No cause can be found to explain the illness.

Jejunostomy: "ostomy" means a surgical opening to the outside of your body. The small intestine is mapped out into 3 regions; beginning from the stomach, this region is called the duodenum. The next region is called the jejunum and the final segment of the small intestine is called the ileum. So a jejunostomy is a surgical opening into the jejunum.

Secondary Causes: an identifiable primary disease creates other secondary disorders or dysfunctions involving other organs.

Scleroderma: a chronic disorder characterized by hardening and thickening of the skin. It may be localized or affect internal organs.

Vagus Nerve: in Latin, "vagus" means: "wandering". It is one of the most important nerves of the"Autonomic Nerves System" wandering from the head, all the way down to the top portion of your large intestine. It regulates your heart rate, sweating, and digestive motility as well as other automatic functions in your body.