

**GpCRC**

*Gastroparesis  
Clinical Research Consortium*

**Gastroparesis Registry 2**

**Standard Operating Procedures**

**Part IV: Standard of Care for Patients  
with Gastroparesis**

07 January 2013

## GpR 2 SOP Part IV: Standard of Care

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## **GpR 2 SOP Part IV: Standard of Care**

### **1. Introduction**

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The purpose of this document is to articulate a suggested standard of care to delineate the tests and procedures used for the evaluation of patients with possible gastroparesis and a standard of care for the treatment used for routine clinical care of patients with gastroparesis. These practices are suggested to be used by investigators in the Gastroparesis Clinical Research Consortium (GpCRC) in the evaluation and care of patients with gastroparesis that are entered in the Gastroparesis Registry 2 (GpR 2). These standards were developed so that patients with gastroparesis will be appropriately evaluated, including those that are being considered to be entered in the GpR 2. Once patients are in the GpR 2, patients should be treated by their physicians. This treatment is outside of the GpR 2 protocol.

The standard of care delineated in this document is that suggested to be used for patients with gastroparesis. Use of this standard of care will assist investigators to treat patients according to accepted guidelines. This will allow treatment in a generally standard fashion across clinical centers, thereby reducing the extent to which evaluation and care at a particular center will influence diagnosis, treatment, and outcome.

This standard of care was derived by expert opinion as expressed by prior documents by the American Gastroenterological Association, the American Neurogastroenterology and Motility Society, and the American College of Gastroenterology clinical guideline and refined by the consensus of investigators of the GpCRC.

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### 2. New patient with possible gastroparesis

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#### Each patient will be evaluated for gastroparesis based on the following:

1. Presence of appropriate symptoms/signs of gastroparesis for at least 12 weeks duration with varying degrees of nausea, vomiting, early satiety, post-prandial fullness and/or abdominal pain.
2. An etiology of either diabetic, idiopathic, or post-Nissen fundoplication gastroparesis
3. Gastric emptying scintigraphy using a 4 hour low fat Egg Beaters meal as described by Tougas et al 2000 as well as gastric emptying scintigraphy of liquids<sup>2</sup>. Delayed gastric emptying using 4 hour scintigraphy of solids is considered with gastric retention at 2 hours postprandially to be >60% or at 4 hours to be >10%. Patients with a normal gastric emptying rate but with symptoms of gastroparesis may be classified as possible gastroparesis or gastroparesis-like with normal gastric emptying. General practice is to try to stop medications known to delay or accelerate gastric emptying for 3 days prior to the gastric emptying test.
4. Exclusion of gastrointestinal obstruction— generally performed with a careful history and physical examination, laboratory testing, radiographic evaluation, and upper endoscopy.

Although there are general guidelines for the evaluation of patients with gastroparesis<sup>1,3,4</sup>, the exact evaluation of a patient may differ depending on the individual case characteristics.

#### Initial evaluation of a patient with suspected gastroparesis

##### History

Gastric symptoms: dominant and associated symptoms (nausea, vomiting, pain/discomfort, early satiety, fullness, bloating), duration, frequency, onset (abrupt vs. insidious), course, precipitating/relieving factors. Nature of symptoms: cyclic vs non-cyclic. If cyclic; are cycles regular or not.

Extragastric symptoms: Other GI symptoms (diarrhea, constipation), anorexia, weight loss, weight gain, dehydration, orthostatic symptoms, poor glycemic control in diabetics, gastroesophageal reflux symptoms such as heartburn

History of infectious disorders with resultant chronic upper GI motility symptoms.

Assessment of nutritional status

Dietary intolerance

Other disorders and surgeries—especially those that might relate to symptoms of gastroparesis (e.g. diabetes, collagen vascular disease, endocrine diseases such as hypothyroidism, peptic ulcer surgery, fundoplication, surgeries involving gastric nerve plexi – as for neurofibromatosis)

Symptoms or diagnosis of overlap syndromes: migraine headaches, fibromyalgia, interstitial cystitis, endometriosis, depression.

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Hospitalizations/emergency room visits for intractable symptoms (frequency/yr)

Other medical problems

Prior surgeries

Family history of gastroparesis, GI motility disorders, overlap syndromes

Review of current medications

Clinical response to present and past medications given for patient's symptoms: acid suppressants, antiemetics, prokinetics, tricyclic anti-depressants, analgesics

#### Physical examination

Vital signs: blood pressure, pulse, temperature, weight, height, body mass index (BMI)

Abdominal examination: visible distention, tympany, bruit, succussion splash, tenderness, organomegaly

#### Laboratory tests

Complete blood count (CBC), including white blood cell count, red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, platelet count, and erythrocyte sedimentation rate

Complete metabolic panel, including sodium, potassium, chloride, carbon dioxide, calcium, blood urea nitrogen (BUN), creatinine, serum glucose

Etiologic lab tests, including antinuclear antibody (ANA) and high sensitivity C-reactive protein (hs-CRP)

Vitamins including vitamin B12 and 25-hydroxy vitamin D

Glycosylated hemoglobin (HbA1c)

Liver panel, including total protein, albumin, alkaline phosphatase, bilirubin (total), alanine aminotransferase (ALT), aspartate aminotransferase (AST)

Lipid profile, including triglycerides, total cholesterol, HDL cholesterol, and LDL cholesterol

#### Radiology

Abdominal obstruction series, if suggested by history (profound pain, bloating, or vomiting) or physical examination (distention, tympany)

Abdominal right-upper quadrant ultrasound to rule out gallbladder, liver, and pancreatic disease, if suggested by history, physical examination (RUQ pain or tenderness), or laboratory findings (elevated liver chemistries)

#### Endoscopy

Upper endoscopy (must have been done within 2 years prior to registration in GpR 2).

Esophageal, gastric and duodenal biopsies may be obtained if indicated by history, physical examination (associated bloating, diarrhea, or family history of celiac disease), or laboratory findings (unexplained microcytic anemia)

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### 2. New patient with possible gastroparesis

#### **Nuclear medicine**

Gastric emptying scintigraphy (Solid and liquid phase - % retention at 0, 0.5, 1, 2, 3, and 4 hours). Must have been done within 6 months prior to enrollment. Required standardized test meal outlined in GpR 2 SOP Part I: Clinical Center Operations, section 6.3 Gastric emptying scintigraphy procedure.

#### **Other tests which may be obtained**

Electrogastrogram with nutrient bar meal or water load  
 Antroduodenal manometry (to exclude associated small intestinal dysmotility)  
 Small bowel radiographic examination (to exclude mechanical lesions of the small intestine): Small Bowel Follow-Through, Enteroclysis, Computer Tomographic Enterography  
 Small intestinal transit testing: Scintigraphy, small intestinal barium series, lactulose breath testing  
 Hydrogen breath testing (to exclude small intestinal bacterial overgrowth)  
 Sitzmarker study, in patients with lower bowel complaints  
 Anal manometry and/or anal EMG, balloon evacuation  
 Urodynamic evaluation, in patients with urinary symptoms  
 Wireless capsule motility, testing, including gastric pH, pressure, temperature, gastric emptying

#### **Psychometric and quality of life measures, including**

Gastroparesis Cardinal Symptom Index (GCSI)  
 Block Food Questionnaire  
 SF-36 Health Survey  
 Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI-SYM)  
 Patient Assessment of Upper Gastrointestinal Disorders Quality of Life (PAGI-QOL)  
 Beck Depression Inventory  
 Rome III Questionnaire  
 Brief Pain Inventory  
 State-Trait Anxiety Inventory  
 Abdominal Pain Questionnaire  
 Nausea Profile and Vomiting Questionnaire  
 Neuropathy Total Symptoms Score-6 (NTSS-6)  
 Block Energy Expenditure Survey  
 Patient Health Questionnaire (PHQ-15)

**Autonomic testing** – standard cholinergic and adrenergic or 24 hour Holter for heart rate variability, giving an assessment of high and low frequency power

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### 2. New patient with possible gastroparesis

#### Treatment

- The general principles for treatment of symptomatic gastroparesis are to (1) correct fluid, electrolyte, and nutritional deficiencies; (2) identify and rectify the underlying cause of gastroparesis if possible; and (3) reduce symptoms<sup>5</sup>.
  - The patient's medication list should be reviewed to eliminate drugs that might exacerbate the underlying dysmotility disorder or prevent the beneficial actions of a prokinetic agent.
  - Diabetic patients should strive for reasonable glycemic control to minimize any inhibitory effects of hyperglycemia on gastric emptying<sup>1</sup>. This is often performed with the patient's endocrinologist or internist.
  - Primary treatment of gastroparesis includes dietary manipulation and the administration of antiemetic and/or prokinetic therapies.
  - A baseline gastroparetic instruction sheet will be given to the patients with suggestions to follow. Additional treatments for refractory symptoms or if pain is a dominant symptom may include the use of tricyclic anti-depressants and/or analgesic medications. Tricyclic anti-depressants will not result in improved gastric emptying and may potentially retard gastric emptying. Occasionally newer agents (Cymbalta or Lyrica) are tried on an off label basis.
  - For relatively mild disease, dietary modifications and intermittent administration of a low-dose antiemetic or prokinetic agent may provide satisfactory control of symptoms.
  - Patients with more severe manifestations of gastroparesis, such as refractory vomiting, pronounced dehydration, or chaotic glucose control, might require hospitalization, intravenous hydration, nasogastric suction to decompress the stomach, insulin for blood glucose control, and/or intravenous administration of antiemetic and prokinetic agents.
  - Consideration of surgically or endoscopically placed enteral tubes for feeding and/or venting. For enteral alimentation, post-pyloric feeding is preferable to gastric feeding<sup>1</sup>.
  - Surgical options (gastric electrical stimulation, jejunostomy placement) are considered for persistently refractory cases.
  - Other medications can be given for related overlap symptoms, such as for migraine headaches.
  - Oral intake is preferred for nutrition and hydration. Dietary counseling should be available to patients regarding meal size, frequency, and composition<sup>1</sup>.
  - Acupuncture can be considered as an alternative therapy<sup>1</sup>.
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### 3. Follow-up visits

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The frequency of follow-up visits depends on the need for diagnostic testing, the severity of symptoms and complications of gastroparesis, responses to therapy, and complications of prescribed treatments.

Patients may be seen frequently when undergoing initial evaluation, perhaps more often than once monthly depending on the clinical course.

Patients with stable, controlled symptoms will be seen every 6 months by the study physician for surveillance to evaluate for changes in clinical course or subtle toxicities from medication therapies (e.g. dystonias from prokinetic/antiemetic treatments). These surveillance visits should include an interim history, review of symptoms, updated medication list, physical examination, laboratory work, and discussion of adherence to the standard of care recommendations.

#### Items for documentation

##### History

- Review of disease course
- Assessment of current symptoms
- Assessment of nutritional status
- Other disorders and surgeries
- Review of current medications
- Response to any treatment given since last visit
- Psychosocial history – document any changes

##### Physical examination

- Vital Signs: Complete Blood Count, pulse, weight
- Optional: orthostatic vital signs
- Abdominal examination: tenderness, succussion splash

##### Laboratory tests

- If needed: Complete Blood Count, complete metabolic panel, Magnesium, Thyroid Function Test, amylase/lipase
- Optional: Erythrocyte Sedimentation Rate, C-Reactive Protein, urinalysis, Electrocardiogram
- Optional: Abdominal obstruction series

#### Treatment considerations

Discuss present treatment. Consider additional treatment with, if needed, hydration, nutrition, antiemetic agents, prokinetic agents, analgesic agents, tricyclic agents, botulinum toxin, gastric electric stimulation. Consider home IV medications if symptoms particularly severe and/or cyclic.

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## GpR 2 SOP Part IV: Standard of Care

### 4. Dietary and nutritional recommendations

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Gastroparesis, or paralysis of the stomach, refers to a stomach that empties slowly. Gastroparesis is characterized by symptoms from the delayed emptying of food, namely: bloating, nausea, vomiting or feeling full after eating only a small amount of food. Gastroparesis can occur as a result of several conditions, especially in people with diabetes. However, in many individuals with gastroparesis, the cause of the disorder is not known. It is more common in women and can have a major impact on quality of life.

The general principles for treating symptomatic gastroparesis involve several strategies. First, attempts are made to correct fluid and nutritional deficiencies that may have occurred from chronic nausea and vomiting, and/or the inability to eat normally. Second, treatments are given for the unpleasant symptoms that accompany gastroparesis. Third, the underlying cause of gastroparesis, such as diabetes, thyroid disorders, etc., is treated if possible. The treatment of patients with gastroparesis generally relies on dietary modifications, medications that enhance gastric emptying, and medications that reduce nausea and vomiting.

A number of dietary recommendations have been developed based on the understanding of normal stomach emptying of different types of foods. These dietary recommendations are likely to be of greatest benefit to those with mild to moderate disease, but are also tried in patients with more severe gastroparesis to complement other medical treatments. It is recommended that anyone with gastroparesis, but especially those with other medical problems such as diabetes or kidney disease, seek dietary counseling with a dietician to help individualize nutrition therapy and maximize nutritional benefits.

#### **Basic dietary guidelines:**

- Small, frequent meals. Reducing the meal size reduces the distention of the stomach from the meal. By eating smaller meals, patients may not feel as full or bloated and the stomach may empty faster. With the reduction in meal size, increasing the number of meals to 4-6 per day is needed to maintain adequate nutritional intake.
- Avoid foods high in fat. Fat can delay emptying of the stomach. Eating less fat-containing foods will decrease the amount of time food stays in the stomach. However, fat-containing liquids, such as milkshakes, may be tolerated and provide needed calories.
- A diet low in fiber is suggested. Fiber delays gastric emptying. In addition, fiber may bind together and cause a blockage of the stomach, called a bezoar in some patients. Examples of high fiber foods that should be avoided include oranges, berries, green beans, potato peels, apples, sauerkraut, and Brussel sprouts. Fiber supplements for treatment of constipation should also be discontinued if possible.
- Increase liquid nutrient component. High calorie liquids in small volumes can deliver energy and nutrients without exacerbating symptoms.

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### 4. Dietary and nutritional recommendations

- In some patients, carbonated beverages, with release of carbon dioxide, can aggravate gastric distention; their intake should be minimized.
- Alcohol and tobacco smoking should be avoided because both can modify gastric emptying.
- Chew food well before swallowing. Patients should avoid foods that may not easily be chewed such as broccoli, corn, popcorn, nuts, and seeds. Solid food in the stomach does not empty well. Dental problems, such as missing or broken teeth, may lead to poorly chewed food; this may add to the problem of inadequate breakdown of food into smaller particles in the stomach for passage into the small intestine for absorption.
- Taking fluids throughout the meal and sitting upright or walking for 1-2 hours after meals may help in the emptying of the meal from the stomach.
- A daily multivitamin/mineral supplement can be taken if dietary intake is inadequate.

If these measures are ineffective, the patient may be advised to consume the bulk of their meals as semi-solids or liquids, such as puréed foods or soups. Stomach emptying of liquids is often normal in patients with gastroparesis. Calorie-containing drinks, such as Hawaiian Punch or Hi C, provide fluid and calories, hence are better than water alone. Some options while on a liquid diet include milk, instant breakfast, milkshakes, yogurt, puddings, custard, cereals, and smoothies. To meet the nutritional needs of patients, it may be necessary to supplement the diet with a commercially available liquid nutrient preparation that is low in fiber such as Ensure, Boost, or even baby foods. Blenderized foods prepared by the patient may also be used as a liquid nutrient source. Any food can be blenderized; solid foods will need to be thinned with some type of liquid, such as broth, milk, juice, water. The blender should be cleaned well after each use.

There are quite a few medications that can delay stomach emptying. Check if any of the medications the patient is taking could be slowing down the stomach emptying.

If the gastroparesis is due to diabetes, an important goal is to achieve or maintain good glucose control. This is achieved more easily by frequent monitoring of blood sugar levels and adjustment of insulin. Keeping the blood sugar under control may help stomach emptying. Consult your endocrinologist if the patient's blood sugar runs > 200 mg/dL on a regular basis.

Patients with kidney disease need to follow additional dietary advice. The dietary restrictions will depend on nephrologist's assessment. Adequate protein is needed for nourishment, but too much may increase a waste product called urea that kidneys may not be able to get rid of. High sodium (salt) intake can increase blood pressure and fluid retention. Restriction of potassium varies depending on the stage of kidney disease. Generally, one should avoid high potassium foods such as bananas, oranges, kiwi, leafy greens, and broccoli. Kidneys may not be able to remove phosphorous from the blood. High phosphorous foods include dried beans, peas, nuts, and liver.

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### 4. Dietary and nutritional recommendations

Patients with chronic symptoms of gastroparesis, despite these attempts at dietary intervention and medication, may develop dehydration and malnutrition. Occasionally, patients need an alternative method to obtain fluid and nutrition. This might involve delivering fluids and nutrients directly into the small intestine, bypassing the stomach, using a jejunostomy tube. In severe cases, intravenous fluids and nutrition may need to be provided.

#### Table 1: Dietary Recommendations for Gastroparesis

- Eat smaller, more frequent meals
- Eat less fatty foods
- Avoid fiber
- Avoid foods that cannot be chewed well.

#### Table 2: Additional dietary recommendations for gastroparesis

- Liquid nutrients are better tolerated over solid food
- Good glucose control in patients with diabetes (aim for blood sugars < 180 mg/dl)
- Avoid medications that can delay stomach emptying such as:
  - Aluminum-containing antacids (Amphojel)
  - Narcotic pain medications (Percocet, Tylenol #3, Tylox, Oxycontin, and others)
  - Anticholinergic agent (Bentyl, Levsin, and others)
  - Bulk-forming agents (Metamucil, Perdiem, Fibercon, and others)

#### Table 3: Foods that are encouraged

- Breads, cereals, crackers, ground or pureed meats
- Vegetables – cooked and, if necessary, blenderized/strained
- Fruits – cooked and, if necessary, blenderized/strained
- Juices, beverages, milk products, if tolerated

#### Table 4: High fiber foods that should be avoided in gastroparesis

- Fruits - apples, berries, coconuts, figs, oranges, persimmons,
- Vegetables - Brussel sprouts, green beans, green peas, lettuce, potato peels, sauerkraut
- Bran/whole grain cereals
- Nuts and seeds
- Legumes/dried Beans – baked beans, lentils, soy beans

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### 4. Dietary and nutritional recommendations

#### A sample diet for patients with gastroparesis: sample meal plan for 6 small meals

Breakfast	1 cup cream of wheat cereal ½ cup skim milk ½ cup grape juice 1 scrambled egg
Snack	10 ounces of instant breakfast with skim milk
Lunch	½ cup vegetable soup ½ turkey sandwich ½ cup applesauce ½ cup milk 1 tablespoon mayonnaise
Snack	10 ounces banana shake made with 1 plain or vanilla yogurt, milk and sugar
Dinner	2-3 ounces baked chicken or fish ½ cup mashed potatoes 1 teaspoon margarine ½ cup spinach ½ cup milk ½ cup fruit cocktail
Snack	½ cup pudding, custard or gelatin

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### 5. References

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