Multi-institutional, Prospective, Observational Study Comparing the Gastrografin Challenge versus Standard Treatment in Adhesive Small Bowel Obstruction

Supported by the Eastern Association for the Surgery of Trauma’s Multi-institutional and Acute Care Surgery Ad Hoc Committees

Background

The motto, “the sun should never rise and set on a complete small bowel obstruction (SBO)” has been the traditional thinking behind the treatment of patients presenting acutely with SBO.1 This treatment paradigm has shifted, however, to non-operative management first if signs of strangulation are absent. If the patient’s adhesive SBO does not resolve over the following 3-5 days, then operative exploration is warranted.

The notion of a “complete” SBO is antiquated, however.2 Instead, surgeons need to be able to predict who will and who will not require operative exploration in order to ensure symptom resolution and avoid missed strangulation obstructions.3 Several predictive models have been developed.4,5,6,7 Of these, a model exists which incorporates the Gastrografin (GG) Challenge.8 This medication, a hyperosmotic oral contrast agent, is used routinely in diagnostics imaging studies including computed tomography and gastrointestinal series. The advantage GG holds is the combination of its diagnostic and therapeutic effects.9

Originally studied via a randomized, controlled clinical trial (RCT), the GG Challenge has subsequently undergone several further attempts at RCTs with mixed results.10,11,12,13,14,15 A recent meta-analysis of these trials, however, demonstrated that the GG Challenge provided both a therapeutic and diagnostic effect.9 There were significant limitations with this meta-analysis and the trials in general; 1) heterogeneous nature of the RCTs, 2) inclusion of non-controlled studies, 3), the lack of blinding, 4) lack
of a standardized treatment protocols, 5) differing oral contrast agents, 6) differing time of contrast administration, and 7) differing timing of the follow-up abdominal radiograph.

Given these limitations, we aim to perform a prospective, observational, multi-institutional clinical trial comparing standard treatment protocols with and without the GG Challenge. The trial will be supported by the Eastern Association for the Surgery of Trauma’s (EAST) Multi-institutional and Acute Care Surgery (ACS) Committees.

Specific Aims

1. To determine, 1) the GG Challenge’s ability to predict resolution of adhesive SBO and, 2) the GG Challenge’s ability to treat adhesive SBO.
   
   **Primary outcome**: Rate of operative exploration
   
   **Secondary outcomes**: Duration of hospital stay; rate of bowel resection; rate of delayed diagnosis of strangulation obstructions; sensitivity and specificity of the GG Challenges rates; readmissions, rates of non-surgical adjuncts (i.e. percutaneous endoscopic gastrostomy tube, cecostomy tube).

2. To validate the American Association for the Surgery of Trauma’s (AAST) SBO anatomic severity of organ disease grading system in Emergency General Surgery.
   
   **Primary Outcome**: Ability of the scoring system to predict mortality as measure by the area under the receiver operating characteristic curve (AUROC).

Significance

The elucidation of whether or not the GG Challenge diagnosis and treats patients with adhesive SBO via a multi-institutional approach, backed by a major national organization, will allow for the wide spread adoption of the GG Challenge potentially decreasing rates of operative intervention, morbidity, duration of hospital stay, and costs.

Methods

We plan to perform a prospective, multi-institutional, observational trial comparing two separate SBO treatment algorithms. The appropriate algorithm will be based on the current standard of care at each participating institution. In other words, if the institution currently uses the GG Challenge as its standard of care, then they will utilize the GG Challenge algorithm. Similarly, if the institution does not use the GG Challenge, then the institution will use the Non-GG Challenge Algorithm. The AAST multi-
institutional web portal will be utilized for data collection:
https://secure.myispartner.com/Trauma/login.aspx

**Inclusion Criteria**

1) Age ≥ 18 years of age  
2) Small bowel obstruction secondary to adhesions

**Exclusion Criteria**

1) Signs and/or symptoms consistent with a strangulation obstruction  
   a. Incarcerated external hernia (i.e. inguinal hernia, incisional hernia, femoral hernia, etcetera)  
   b. Portal-venous gas  
   c. Pneumatosis intestinalis  
   d. Closed loop SBO (two independent transition points)  
   e. Internal hernia  
   f. Small bowel volvulus  
   g. Peritonitis on physical exam  
   h. Hypotension (systolic blood pressure < 90 mm Hg)  
2) Recent abdominal procedure (i.e. laparotomy or laparoscopy within 6 weeks)
Patient arrives with signs and Symptoms of SBO

Signs of ischemia

YES

NO, order CT

Operative exploration

YES

Operative exploration

NO

Presence of 3 risk factors:
- Obstipation
- Mesenteric edema
- Lack of small bowel feces sign

Prior abdominal procedure

YES

NO

Operative exploration

YES

Non-operative trial

YES

Symptom resolution

YES

Advance diet

Dismiss

Symptoms increasing or recurrent/persistent by day 4-5

NON

YES
Adhesive Small Bowel Obstruction (SBO) Protocol – Gastrografin Challenge Institutions

Patient arrives with signs and Symptoms of SBO

Signs of strangulation

Consider Operative exploration

YES

NO, order CT

Operative exploration

YES

NO

Symptoms increasing or recurrent/ persistent by day 3-5

Non-operative trial

YES

Symptom resolution

YES

Advance diet

NO

Operative exploration

YES

Prior abdominal procedure

Gastrografin Challenge

Bowel movement OR contrast within colon by 8 hours

NO

DISMISS
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Data Collection and Definition Sheet

Patient Demographics and Hospital Variables
Age (yrs): ___________________________  Patient Gender: MALE / FEMALE
Weight (kg):_________________________  Height (m):____________________
Date of Admission: ___________________  Date of Dismissal_____________________
Service of Admission: MEDICAL / SURGICAL

Patient Comorbidities and Surgical History (circle all that apply):

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<tbody>
<tr>
<td>AIDS</td>
<td>COPD</td>
<td>Connect. Tissue Dz.</td>
<td>Peptic Ulcer Dz.</td>
</tr>
<tr>
<td>DM without end organ damage</td>
<td>DM with end organ damage</td>
<td>Mild Liver Disease</td>
<td>Moderate-Severe Liver Disease</td>
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</tbody>
</table>

Hx of Crohns Disease?  YES / NO  BMI > 40?  YES / NO
Cancer Hx?  YES / NO  Type of Cancer(s)____________________
Metastatic Disease  YES / NO  Location of Mets_________________
Prior Abd/Pelvic Radiation?  YES / NO
Prior SBO admission?  YES / NO  # of prior SBO admissions:_________

Surgical History
Prior abdominal operation?  YES / NO  # of prior abdominal operations:_________
Prior exploration for SBO?  YES / NO  Prior ventral hernia repair?  YES / NO
Prior Gastric Bypass procedure?  YES / NO  Prior total colectomy:  YES / NO

History, Physical Exam, Lab, Vitals
Duration of Obstruction_________________  Peritonitis?  YES / NO
Temperature___________________________  Heart Rate___________________________
Hemoglobin (g/dL)______________________  Lactate (mmol/L)____________________
White Blood Cell (x10^9/L)______________  pH_______________________________
Serum Creatinine (mg/dL)_______________  Base Deficit________________________
Blood Urea Nitrogen (mg/dL)_____________  Albumin (g/dL)_____________________

Admission Radiographic Data
Abdominal radiograph?  YES / NO
Computed Tomography?  YES / NO
Small bowel feces sign  YES / NO  CT Gastrografin?  YES / NO
<table>
<thead>
<tr>
<th>Free intra-peritoneal fluid</th>
<th>YES / NO</th>
<th>Mesenteric edema</th>
<th>YES / NO</th>
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<tr>
<td><strong>Closed Loop</strong></td>
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**GG Challenge Results**
- Hours from GG to Abd Xray: ______________
- BM prior to Xray: YES / NO
- Transition Point?: YES / NO
- Bowel Wall Edema: YES / NO
- Contrast in Colon: YES / NO
- Exploration prior to GG results: YES / NO
- Location of Transition Point: ______________
- Maximum Distension (cm): ______________

**Operative Data**
- Exploration: YES / NO
- Type of Exploration: LAPAROTOMY / LAPAROSCOPY
- OTHER: ________________________
- Convert from Laparoscopy to Open?: YES / NO
- Date of Exploration: ______________
- Hours from Admission to OR: ______________
- Strangulation Obstruction: YES / NO
- Small Bowel resection: YES / NO
- Stoma Creation: YES / NO
- Non-therapeutic Exploration: YES / NO
- Frozen Abdomen: YES / NO
- Cecostomy tube: YES / NO
- Operative Indication: ________________________
- Perforation: YES / NO
- Anastomosis: YES / NO
- Open abdomen: YES / NO
- Unrecognized Malignant SBO: YES / NO
- Operative time (mins): ______________

**Outcomes** (see protocol for definitions)
- ICU Admission: YES / NO
- Date of ICU Admission: ______________
- Date of ICU Dismissal: ______________
- Acute Renal Failure: YES / NO
- GG Pneumonitis: YES / NO
- Deep Wound Infection: YES / NO
- Deep Incisional SSI: YES / NO
- Anastomotic leak: YES / NO
- Pneumonia: YES / NO
- Superficial SSI: YES / NO
- Organ Space SSI: YES / NO
- PEG: YES / NO
- Date of first flatus: ______________
- Date of Tolerating Clears: ______________
- Date of tolerating soft diet: ______________
- Total Parenteral Nutrition use: YES / NO
- Date of Readmission: ______________
- Readmission within 30 days: YES / NO
**Definitions**

*Strangulation Obstruction*: ischemic changes to the affected small bowel resulting from SBO

*Traditional signs of strangulation*: peritonitis, strangulated hernia or hypotension, and the CT findings of closed-loop obstruction, pneumatosis intestinalis or portal-venous gas

*Closed loop obstruction*: single, isolated segment of dilated small bowel

*Mesenteric Edema*: hazy fluid attenuation in the mesentery of the involved intestinal segment

*Small Bowel Feces Sign*: gas bubbles and debris within the “obstructed” small-bowel lumen

*Obstipation*: lack of flatus or bowel movement for 24 or more hours

*Frozen Abdomen*: Current or prior attempt at laparotomy which was aborted secondary to inability to safely enter the abdominal cavity

*Acute Renal Failure*: Threefold increase in the serum creatinine, or GFR decrease by 75 percent, or urine output of <0.3 mL/kg per hour for 24 hours, or anuria for 12 hours

*GG Pneumonitis*: Aspiration of GG leading to respiratory failure