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# Prospective, Observational Validation of a Multivariate Small-Bowel Obstruction Model to Predict the Need for Operative Intervention

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- BACKGROUND:** We published previously a model predictive of the need for exploration in small-bowel obstruction. We aimed to validate and refine the model, hypothesizing that the model would be predictive, would prevent delayed management of strangulation, and would be successfully improved.
- STUDY DESIGN:** Data from 100 consecutive patients with small-bowel obstruction and concurrent CT were collected prospectively. New features evaluated included obstipation and the absence of colonic gas on CT.
- RESULTS:** Overall mortality was 8%. Twenty-nine patients had all 4 clinical features, 22 of whom required operative exploration (concordance index = 0.75), confirming the validity of the old model. Intraabdominal free fluid (odds ratio [OR]: 2.6, 95% CI: 1.0 to 6.9) and vomiting (OR: 1.5, 95% CI: 0.5 to 4.5) were not predictive of operative exploration; however, mesenteric edema (OR: 4.2, 95% CI: 1.1 to 15.8) and lack of the small-bowel feces sign were (OR: 3.5, 95% CI: 1.4 to 8.8). Obstipation was associated with the need for exploration (OR: 2.8, 95% CI: 1.2 to 6.6), but absence of colonic gas was not. A new model was equally predictive of the need for exploration: mesenteric edema (OR: 5.6, 95% CI: 1.5 to 20.7), lack of the small-bowel feces sign (OR: 5.1, 95% CI: 1.9 to 13.6), and obstipation (OR: 3.2, 95% CI: 1.2 to 8.3). The concordance index for this new model was 0.77.
- CONCLUSIONS:** Our current prospective study validated our original model and was successfully improved. Our new model demonstrated equivalent predictive ability and was simpler to use. When all 3 features of the new model are present, strong consideration for early operative exploration should be entertained and may decrease the rate of missed strangulation obstructions. (*J Am Coll Surg* 2011;212:1068–1076. © 2011 by the American College of Surgeons)
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As trauma surgeons transition to a model of acute care surgery, lessons learned from trauma can be applied to emergency general surgery. A key part of the development of emergency surgery systems will require implementation of practice management guidelines to standardize care throughout an institution and a region. Not only do guide-

lines standardize interventions, but their utilization improves outcomes and decreases costs.<sup>1,2</sup> The traditional treatment of small-bowel obstruction (SBO) was originally based on the tenet, “the sun should never rise and set on a complete small bowel obstruction (SBO).”<sup>3</sup> As experience with nonoperative management grew, however, the focus of care switched from predominantly operative management to nasogastric tube decompression with fluid resuscitation if the traditional signs of strangulation were absent. The downsides to this approach were a higher proportion of missed strangulation obstructions, a greater need for small-bowel resections, and prolonged durations of stay.<sup>4</sup>

Recently we published a model based on a detailed retrospective review of patient records that used data from the available clinical scenario of the patient at the time of admission.<sup>5</sup> The model developed was successful in predicting the need for operative intervention in the setting of SBOs. The goals of that study and the model generated

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were to prevent unrecognized strangulation obstructions and to predict those patients who would require operative treatment in an effort to improve patient outcomes and decrease the duration of hospital stays. The model was based on the presence of 4 clinical features that were predictive on multivariate analysis of the need for operative intervention during that hospitalization. These 4 features were (1) history of vomiting and features on CT of (2) intraperitoneal free fluid, (3) mesenteric edema, and (4) lack of the small-bowel feces sign. When all 4 signs were present, use of the model would have demonstrated a dramatic improvement in mortality with early operative exploration. As a retrospective study, however, there were inherent drawbacks. Before incorporation into practice management guidelines, the model required validation in a separate cohort. In addition, we believed that the ability to further refine the model was possible by studying prospectively a collected cohort and evaluating 2 additional variables: obstipation and the lack of colonic gas on CT. Therefore, the aim of the current study was to validate these previously identified 4 clinical features and to study 2 new features to determine whether their inclusion would improve the model. We hypothesized that the 4 clinical features would continue to be predictive of the need for operative treatment and that addition of the 2 new features would improve the predictive ability of the model.

## METHODS

Authorization by the Mayo IRB was obtained to identify prospectively 100 consecutive patients admitted between July and December 2009 with a diagnosis of acute SBO who underwent concurrent CT. Patients with a known history of ascites or a laparotomy/laparoscopy within 6 weeks of admission were excluded. No therapeutic intervention was performed as part of the protocol. The attending surgeon and patient had total decision-making ability on the course of treatment. Clinical data were recorded, including age, sex, and past history of SBO, abdominal operations, herniae, diabetes mellitus, cardiovascular comorbidities, abdominal radiation, Crohn disease, malignancy, distension, peritonitis, vomiting, fever, tachycardia (heart rate  $>100$  beats/minute), lactic acidosis (serum lactate  $>2.3$  mmol/L with a concurrent base deficit  $>2$  mmol/L), leukocytosis (white blood count  $>10^9$ /L), and the new clinical feature of obstipation defined as the lack of flatus for 24 or more hours. The CT features were evaluated by a board-certified radiologist (PWE) who was blinded to other patient characteristics. The features evaluated included vomiting as well as the 3 predictive CT features identified by our previous study—free intraperitoneal fluid, small-bowel feces sign (gas bubbles and debris

within the “obstructed” small-bowel lumen), and mesenteric edema (hazy fluid attenuation in the mesentery of the involved intestinal segment); also included was the new feature of interest—the absence of colonic gas on CT.<sup>6-8</sup> Additional CT features recorded were the presence of small-bowel dilation, small-bowel air-fluid levels, thickened small-bowel wall, “vascular swirling” (swirled appearance of mesenteric fat or vessels at the root of the mesentery), “definite” transition point (decompressed small bowel distal to dilated small bowel), findings suggestive of a closed-loop obstruction (single, isolated segment of dilated small bowel), pneumatosis intestinalis, portal venous gas, and free intraperitoneal air.<sup>9-11</sup> Traditional signs of strangulation obstruction were defined as symptoms of SBO concurrent with the clinical signs of peritonitis, strangulated hernia or hypotension, and the CT findings of closed-loop obstruction, pneumatosis intestinalis or portal venous gas. The need for operative exploration was based on consensus of the 4 surgeon investigators (MDZ, SFH, MGS, MPB) after retrospective review of the patients’ hospital course. Postoperative morbidities were reported using the revised Accordion Severity Grading System criteria, and postoperative mortality was defined by 30-day or in-hospital death.<sup>12</sup>

## CT methodology

Seventy-eight of the 100 CT examinations were performed on site at Mayo Clinic Rochester. Imaging characteristics included contiguous images of 5-mm thickness or less obtained through the abdomen and pelvis using several different types of multidetector CT scanners (Siemens Sensation 64, Sensation Open, and Sensation 16 [Siemens Medical Solutions] and GE LightSpeed Pro 16, LightSpeed 16, and LightSpeed Ultra [GE Medical Systems]). The CT examinations performed at outside institutions used a variety of CT scanners and scan techniques; importantly, all were deemed to be of adequate quality to evaluate the CT parameters of interest. Intravenous contrast material was administered in 80 of 100 patients. Oral contrast (diatrizoate meglumine, Bracco Diagnostics Inc) was administered in 59 of 100 patients.

## Power statement

The global likelihood ratio statistic for the 4-feature multivariable model developed using the first 100 patients was 32.3 with 4 degrees of freedom ( $p < 0.001$ ). This value was much greater than the 9.5 needed for a chi-square test with 4 degrees of freedom and a significance level of 0.05. As such, we concluded that studying an additional 100 patients should provide sufficient power to evaluate the same 4 features in a multivariable setting.

### Analysis of data

Comparisons between patient groups were evaluated using chi-square, Fisher exact, 2-sample Student's *t*-, and Wilcoxon rank-sum tests as appropriate. Associations with small-bowel ischemia and the need for an operation during hospitalization were evaluated using logistic regression models and summarized with odds ratios (ORs) and 95% CIs. The predictive ability for each model was described with some more appropriate and sophisticated statistical analysis that can be understood readily in principle. We used a concordance index (*c*-index), which is a measure of the predictive ability of a model and is equivalent to the area under the receiver operating characteristic curve. This analysis uses the *c*-index that ranges from 0.5 to 1.0, with values of 0.5 indicating no predictive ability and 1.0 indicating perfect predictive ability. The predictive probability for the need for operation was calculated for each patient in the validation sample based on the published model with the original 4 features (vomiting, free intraperitoneal fluid, small-bowel feces sign, and mesenteric edema) and compared with observed frequencies. For potential refinement of the model, 2 additional features (obstipation and absence of colonic gas) were added to the logistic regression model, and a best subset was identified.

### RESULTS

The average age of the new cohort was 65 years (range 21 to 93 years) with an equal sex representation (50 men and 50 women). Overall clinical and CT features are summarized in Table 1 and are compared with those of the retrospective cohort from which the model was devised. There were prominent and significant differences within the patient cohorts, with the latter demonstrating higher incidences of vascular comorbidities and prior malignancies and CT findings of the small-bowel feces sign, mesenteric engorgement, transition point, and mesenteric swirling. The mean duration of stay was 11.5 days (median 8 days, range 0 to 65 days), with postoperative complication and mortality rates of 37% and 8%, respectively. Grading of morbidity by the Accordion Severity Grading System was grade 0 (61%), grade 1 (2%), grade 2 (13%), grade 3 (10%), grade 4 (4%), grade 5 (2%), and grade 6 (8%).<sup>10</sup> Of the 100 patients, 51 met the indications for operative intervention by the surgeon investigators' consensus, of whom 49 were treated operatively and 2 died as a result of malignant obstructions without operations. Of the 49 patients who were deemed safe by the surgeon investigators' consensus for nonoperative management, 47 were treated successfully with nonoperative measures and 2 underwent negative explorations. Mean durations of stay for patients who did and did not need an operation were 17 and 6 days, respectively ( $p <$

0.001). Morbidity and mortality rates were greater for patients meeting indications for operative intervention compared with the rates for those who did not meet the criteria for operative intervention (59% versus 14%;  $p < 0.001$  and 17% versus 0%;  $p < 0.001$ , respectively). Of the 51 patients treated operatively, 13 patients had strangulation obstruction at exploration. There were 19 patients who had the traditional signs of a strangulation obstruction upon admission, 9 of whom had small-bowel ischemia at operative exploration (47%). Ten of these 19 patients underwent emergent operative exploration, and 9 were treated nonoperatively upon admission. Ultimately, 16 of the 19 patients underwent operative exploration during that hospital stay. Univariate associations of clinical and CT features with the need for operative intervention and strangulation obstruction are summarized in Table 2 and Table 3, respectively.

In total, 36 patients had a history of malignancy, 31 (86%) of which were gastrointestinal or genitourinary in origin. Of these 36, 21 patients (58%) had a malignant SBO. Seven of these 21 patients (33%) died within 30 days of admission as a result of their malignant SBO, 5 of whom underwent operative exploration; 4 of these 7 patients died in house, and 3 died in hospice. Three of the 21 patients (14%) with malignant SBO had a strangulation obstruction, 1 of whom died after a 36-hour delay in diagnosis.

### Model validation

Two of the 4 features identified previously, mesenteric edema and the lack of the small-bowel feces sign, were predictive of the need for operative intervention in the multivariate analysis (Table 4). Among the 100 patients, 29 had the combination of vomiting, lack of the small-bowel feces sign, free intraperitoneal fluid, and mesenteric edema (Fig. 1). Of these 29 patients, 22 required exploration, resulting in a sensitivity of 43% (22 of 51 patients requiring operative intervention) and a specificity of 86% (22 of 29 patients) for this combination of features. Patients with this combination of features were 4.6 times more likely to need an operation compared with patients having some other combination of these features (OR: 4.6, 95% CI: 1.7 to 12.1,  $p = 0.002$ ). Despite this difference, when patients with all 4 features were evaluated according to whether they underwent operative exploration within 12 hours of admission compared with greater than 12 hours, mortality (23% versus 29%;  $p = 1.0$ ), morbidity (50% versus 57%;  $p = 1.0$ ), and mean duration of stay (12 versus 11 days;  $p = 0.75$ ) were similar. Specificity decreased with fewer features. When 3 or more features were present ( $n = 63$ ), there was a sensitivity of 84% and a specificity of 59%, whereas 2 or fewer features ( $n = 91$ ) decreased the specificity to 14% with a corresponding increase in sensitivity to 96%.

**Table 1.** Overall Incidence of Clinical and CT Features Comparing Retrospective and Prospective Cohorts

Feature	Retrospective (N = 100)	Prospective (N = 100)	p Value
Median age at admission, y (range)	66 (18–96)	67 (21–93)	0.485
Median no. of prior abdominal operations (range)	2 (0–9)	2 (0–10)	0.473
Median serum lactate, mg/dL (range)	1.2 (0–5.8)	1.2 (0.6–10.3)	0.727
Median duration of stay, d (range)	8 (1–65)	8 (0–65)	0.711
Males, n	48	50	0.777
Prior small bowel obstruction, n	38	43	0.471
Prior abdominal operation, n	88	88	1.0
History of hernia, n	17	23	0.289
Diabetes mellitus, n	18	17	0.852
Cardiac comorbidities, n	31	36	0.454
Vascular comorbidities, n	8	25	0.001
Prior abdominal radiation, n	9	14	0.268
History of Crohn disease, n	4	5	1.0
History of malignancy, n	20	36	0.012
Abdominal distension, n	67	68	0.880
Peritonitis, n	5	3	0.721
Vomiting, n	74	81	0.236
Fever, n	4	3	1.0
Tachycardia, n	21	26	0.339
Leukocytosis, n	36	36	0.869
Obstipation, n	N/A	22	1.0
CT features, n			
Small-bowel dilation	87	94	0.091
Small-bowel feces sign	20	41	0.001
Thickened small-bowel wall	34	41	0.307
Free intraperitoneal fluid	48	61	0.065
Mesenteric edema	51	81	<0.001
Mesenteric engorgement	76	91	0.004
Transition point	63	81	0.005
Closed-loop obstruction	5	11	0.118
Small-bowel air fluid level	99	99	1.0
Mesenteric swirling	0	5	0.059
Pneumatosis intestinalis	2	3	1.0
Portal venous gas	2	1	1.0
Free intraperitoneal air	1	1	1.0
Colonic gas	N/A	98	1.0
Overall morbidity, n	36	37	0.883
Mortality, n	9	8	0.800

There were 7 patients of the 29 with all 4 features present who did not require operative intervention. Patient 1 was a 25-year-old man with cognitive delay and a preoperative diagnostic of dysmotility disorder. Despite bowel function within the 24 hours before operation, laparoscopic exploration was pursued after 2 weeks of nasogastric decompression to ensure there was no mechanical component to his functional bowel disorder; this operation was a nontherapeutic intervention. Patient 2 was a 92-year-old woman with prior hysterectomy, cholecystectomy, appendectomy,

and esophageal perforation repair who refused exploration despite the recommendation to proceed. She was managed successfully by nonoperative means after 10 days. Patient 3 was a 92-year-old man with prior partial gastrectomy who presented to an outside hospital with SBO and acute renal failure. He was transferred to our institution for operative exploration 1 week after admission, still underresuscitated. After aggressive rehydration, the patient improved, and it was decided not to perform an operation. After a total of 12 days of nonoperative management, he was dismissed. Pa-

**Table 2.** Univariate Associations of Clinical and CT Features with the Need for Exploration

Feature	Odds ratio (95% CI)	p Value
Age	1.01 (0.98–1.03)*	0.552
Male sex	0.57 (0.26–1.26)	0.163
Obstipation (n = 96)	2.84 (1.24–6.55)	0.014
Vomiting	1.20 (0.44–3.25)	0.725
Prior small-bowel obstruction	0.37 (0.17–0.84)	0.018
No. of prior abdominal operations	0.69 (0.53–0.90)*	0.006
Prior abdominal operation	0.30 (0.08–1.20)	0.089
History of hernia	0.33 (0.12–0.89)	0.028
Diabetes mellitus	0.46 (0.16–1.36)	0.161
Cardiac comorbidities	0.66 (0.29–1.51)	0.326
Vascular comorbidities	0.85 (0.34–2.11)	0.729
Prior abdominal radiation	1.33 (0.43–4.17)	0.621
History of Crohn disease	0.63 (0.10–3.92)	0.617
History of malignancy	3.32 (1.40–7.91)	0.007
Abdominal distension	1.54 (0.66–3.58)	0.321
Peritonitis	3.82 (0.40–infinity) <sup>†</sup>	0.258
Fever (n = 97)	1.92 (0.17–21.86)	0.601
Tachycardia (n = 97)	2.18 (0.86–5.53)	0.103
Serum lactate (n = 77)	0.84 (0.56–1.26)*	0.397
Leukocytosis (n = 96)	1.60 (0.70–3.69)	0.270
CT features		
Small-bowel dilation	2.18 (0.38–12.47)	0.382
Lack of small-bowel feces sign	3.24 (1.41–7.47)	0.006
Thickened small-bowel wall	2.81 (1.23–6.44)	0.014
Free intraperitoneal fluid	3.99 (1.69–9.40)	0.002
Mesenteric edema	5.18 (1.58–17.00)	0.007
Mesenteric engorgement	2.23 (0.53–9.48)	0.276
Transition point	7.76 (2.09–28.75)	0.002
Closed-loop obstruction	5.04 (1.03–24.63)	0.046
Small-bowel air fluid level	1.04 (0.03–infinity) <sup>†</sup>	0.980
Pneumatosis intestinalis	1.96 (0.17–22.32)	0.588
Portal venous gas	0.96 (0.03–infinity) <sup>†</sup>	1.0
Free intraperitoneal air	0.96 (0–37.47) <sup>†</sup>	0.980
Absent/colonic fecalization	1.0 (reference)	
Gaseous distension	0.61 (0.21–1.72)	0.346

\*Odds ratio represents a 1-unit increase in the feature.

<sup>†</sup>Odds ratio, 95% CI, and p value estimated using exact logistic regression.

tient 4 was a 63-year-old man with a distant ileoileostomy who was having bowel function at the time of admission but had substantial nausea and vomiting with evidence of obstruction at the anastomosis. Supportive management was successful after 4 days. Patient 5 was a 72-year-old woman with spina bifida who had undergone end ileostomy and ileal conduit for neurogenic bowel and bladder. Nonoperative management was successful after 3 days. Patient 6 presented 7 days after stem cell transplant with

**Table 3.** Univariate Associations of Clinical and CT Features with Strangulation Obstruction

Feature	Odds ratio (95% CI)	p Value
Age	1.01 (0.98–1.05)*	0.503
Male sex	1.00 (0.32–3.10)	1.0
Obstipation (n = 96)	2.19 (0.66–7.28)	0.199
Vomiting	1.48 (0.30–7.24)	0.630
Prior small-bowel obstruction	0.08 (0.01–0.64)	0.018
No. of prior abdominal operations	0.56 (0.32–0.97)*	0.038
Prior abdominal operation	0.43 (0.10–1.83)	0.253
History of hernia	1.41 (0.40–5.01)	0.594
Diabetes mellitus	0.21 (0.00–1.39) <sup>†</sup>	0.120
Cardiac comorbidities	0.68 (0.20–2.33)	0.534
Vascular comorbidities	0.46 (0.10–2.20)	0.328
Prior abdominal radiation	0.43 (0.05–3.59)	0.437
History of Crohn disease	0.89 (0.00–6.99) <sup>†</sup>	0.925
History of malignancy	0.26 (0.05–1.21)	0.086
Abdominal distension	0.82 (0.25–2.69)	0.748
Peritonitis	3.23 (0.27–38.22)	0.352
Fever (n = 97)	1.67 (0.00–16.30) <sup>‡</sup>	1.0
Tachycardia (n = 97)	2.74 (0.83–9.11)	0.100
Serum lactate (n = 77)	1.06 (0.69–1.63)*	0.787
Leukocytosis (n = 96)	3.14 (0.94–10.50)	0.063
CT features		
Small-bowel dilation	0.80 (0.09–7.43)	0.846
Lack of small-bowel feces sign	2.90 (0.76–11.15)	0.121
Thickened small-bowel wall	3.04 (0.94–9.86)	0.064
Free intraperitoneal fluid	4.53 (0.96–21.49)	0.057
Mesenteric edema	5.39 (0.84–infinity) <sup>‡</sup>	0.083
Mesenteric engorgement	2.19 (0.32–infinity) <sup>‡</sup>	0.484
Transition point	3.44 (0.42–28.08)	0.249
Closed-loop obstruction	4.51 (1.12–18.19)	0.034
Small-bowel air fluid level	0.16 (0.00–infinity) <sup>‡</sup>	1.0
Pneumatosis intestinalis	14.17 (1.19–168.38)	0.036
Portal venous gas	6.14 (0.16–infinity) <sup>‡</sup>	0.280
Free intraperitoneal air	6.14 (0.00–239.57) <sup>‡</sup>	1.0
Absent/colonic fecalization		
Gaseous distension	3.20 (0.39–26.21)	0.28

\*Odds ratio represents a 1-unit increase in the feature.

<sup>†</sup>Odds ratio, 95% CI, and p-value estimated using exact logistic regression.

<sup>‡</sup>Odds ratio, 95% CI, and p value estimated using exact logistic regression.

pancytopenia, sepsis, abdominal distension, and diarrhea requiring significant fluid resuscitation and pressor support. The CT imaging of the abdomen demonstrated a proximal transition point with dilated loops of small bowel along with the 4 features. The patient had no history of prior abdominal procedures but had known B-cell lymphoma within his small-bowel mesentery. After treatment of the sepsis, evidence of obstruction resolved on serial

**Table 4.** Validation Data of the 4 Clinical Features of the Old Model and the New, Prospectively Developed Model's Data Using Multivariate Associations of Clinical and CT Features with the Need for Exploration

Feature	Odds ratio (95% CI)	p Value
Old model		
Emesis	1.46 (0.47–4.53)	0.510
Lack of small-bowel feces sign	3.53 (1.42–8.77)	0.007
Free intraperitoneal fluid	2.61 (0.99–6.86)	0.052
Mesenteric edema	4.17 (1.10–15.80)	0.036
c-index: 0.75		
New model		
Lack of small-bowel feces sign	5.12 (1.92–13.62)	0.001
Mesenteric edema	5.62 (1.52–20.70)	0.010
Obstipation	3.21 (1.24–8.32)	0.016
c-index: 0.77		

c-index, concordance index.

abdominal x-ray imaging. Patient 7 was a 44-year-old man with Crohn disease admitted for SBO after a remote ileoileostomy for his Crohn disease. He was dismissed tolerating a diet, but the symptoms recurred; he underwent exploration with revision of his anastomosis 2 weeks after dismissal.

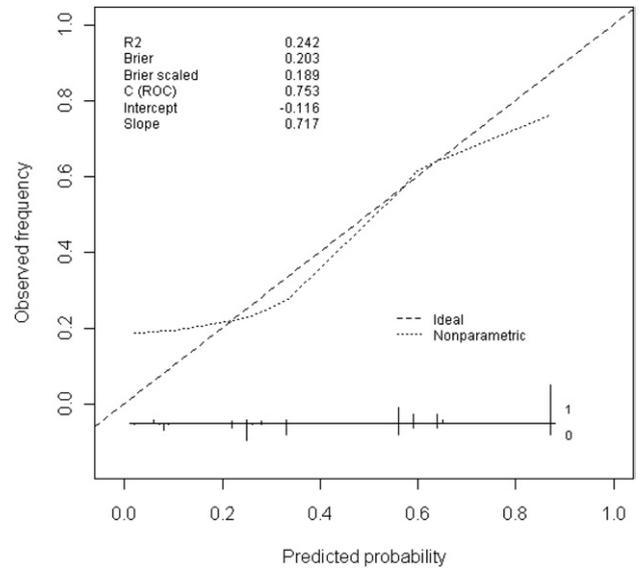
**Model refinement**

One new clinical feature and 1 new radiographic feature were investigated for predictive value in the prospective cohort: obstipation and lack of colonic gas by CT imaging. Only 2 patients had complete absence of colonic gas on axial CT imaging, whereas 16 patients had gas associated with stool only (colonic fecalization). The remaining 82 patients had gross gas without obvious intercoloculated stool of at least one area of the colon (Table 1), but this was not associated with the need for exploration or strangulation (Tables 2, 3). Obstipation, present in 43 patients, was associated with the need for operative intervention (OR: 2.84, 95% CI: 1.24 to 6.55).

Two features from the original model, vomiting and free intraperitoneal fluid, were not predictive in the prospective

**Table 5.** Breakdown of Number of New Model Features in Regard to Need for Exploration and the Presence of Strangulation Obstruction

No. of new model features	n	Need for exploration, n (%)	Strangulation obstruction, n (%)
0	5	0 (0)	0 (0)
1	28	8 (29)	1 (4)
2	46	25 (54)	7 (15)
3	21	18 (86)	6 (29)



**Figure 1.** Predicted probability of the need for operative intervention versus observed frequency of the 4 clinical features. Actual versus predicted outcome was plotted for the validation sample. ROC, receiver operating characteristic.

cohort and were consequently eliminated from the new model. Mesenteric edema, lack of the small-bowel feces sign, and obstipation, however, were predictive of the need for operation in the prospective cohort. These 3 predictive features were present in 21 patients and retained in the final model. The c-index for the new model was 0.77 (Table 4). Exploration within 12 hours of evaluation compared with delayed exploration greater than 12 hours did not affect mortality (15% versus 13%; p = 1.0), morbidity (46% versus 63%; p = 0.66), or duration of stay (15 versus 13 days; p = 0.94). The breakdown of positive features in the new model are presented in Table 5.

There were 3 patients of the 21 who presented with all 3 of the new model features. Two of these 3 were patients 2 and 5 described earlier. Patient 8, an 85-year-old woman, also presented with the 3 features in the new model. She was diagnosed with SBO secondary to presumed severe constipation. She was dismissed from the hospital after 18 days with a hospital course complicated by staphylococcus bacteremia secondary to a catheter for parenteral nutrition. She died 6 days after dismissal from aspiration from recurrent SBO. Autopsy revealed an obstructing sigmoid adenocarcinoma.

The sensitivity and specificity to predict the need for exploration when all 3 features were present concurrently were 37% and 94% of the time, respectively. The positive and negative predictive values were 86% and 59%, respectively, with an accuracy of 65%. The sensitivity and specificity of the 3 features for the presence of a strangulation

obstruction were 46% and 82%, respectively, whereas the positive and negative predictive values were 29% and 91%, respectively, giving an accuracy of 77%.

## DISCUSSION

The traditional criterion for operative intervention in SBO has been the presence of a complete obstruction, defined as a lack of gas in the distal small bowel or colon on a plain abdominal radiograph.<sup>13</sup> Before the advent of CT, early exploration was the appropriate treatment paradigm to prevent complications from unrecognized strangulation obstructions.<sup>3,14</sup> Current CT resolution has reached a point that allows clinicians to visualize details never before imagined.<sup>10</sup> These details, when combined with the patient's history and physical examination, can appropriately direct the clinical course of a patient with SBO and should be incorporated into a treatment algorithm.<sup>4-11,15,16</sup> The current use of the term and concept of "complete bowel obstruction" appears to be outdated and in need of refinement.

The primary goal of any treatment algorithm for SBO must be first the elimination of unrecognized strangulation obstructions and second decrease in duration of hospitalization. If none of the traditional signs indicative of intestinal ischemia are present, a nonoperative approach consisting of nasogastric decompression; fluid resuscitation; and close, frequent clinical reassessment can be successful, but the potential consequences of this approach are a greater rate of missed strangulation obstructions and poorer outcomes with prolonged hospitalization before definitive operative treatment.<sup>17,18</sup> We published previously a model based on clinical and CT features that decreased the rate of unrecognized strangulation obstructions by identifying with good accuracy those patients at the time of admission who would require exploration before dismissal.<sup>3</sup> This model was able to outline an appropriate and accurate treatment plan for those patients who presented with SBO based on the retrospective cohort of 100 patients. We recommended that those patients presenting with SBO and signs of strangulation should undergo emergent operative exploration. The remaining patients, however, should undergo CT examination. Based on this information, an appropriate clinical plan could be devised. Before widespread clinical adoption, however, validation in a separate patient population was necessary. The prospective cohort in the current study confirmed the validity of the model. The model was able to identify with good accuracy (65%) those patients who would require operative intervention before dismissal and therefore was also predictive of those patients who may be managed safely by nonoperative methods. Most importantly, the model reduced the rate of unrecog-

nized strangulation obstructions. Despite this success, the model was developed further based on 2 more clinical features.

Performance improvement is a mainstay of any practice management guideline. Because of the retrospective design of our prior study, we were unable to gather all the information deemed necessary. In addition, with the new knowledge gained, we wanted to apply the original definition of complete bowel obstruction to the modern day and determine whether the absence of colonic gas on CT was able to further discriminate the need for operative exploration. As demonstrated, some form of colonic gas was present in the overwhelming majority of patients, thereby eliminating any discriminating ability it might have been presumed to confer. Even with further qualification of the type of pattern of colonic gas, this CT feature is not useful in determining whether the patient should undergo exploration; CT appears to be too sensitive regarding this radiographic feature. Comparing CT axial imaging with a plain abdominal radiograph may be useful for future study. In contrast, obstipation was associated strongly with the need for exploration (OR: 3.2) when analyzed in a multivariate setting. In addition, a history of vomiting was not confirmed to be predictive of the need for operative intervention in our current, prospectively collected patient cohort. With these features in mind, we improved the model. Our new model, built originally on the previous 4-feature model, eliminated a history of vomiting and the presence of free intraperitoneal fluid, which were not predictive in our prospective cohort, and added the presence of obstipation. This new prospective model composed of 3 features—history of obstipation, mesenteric edema, and lack of small-bowel fecalization—maintained the same degree of discrimination (c-index of 0.77 versus 0.75 for the original model) while simplifying the model to these 3 features.

There were important, substantive, and clinically relevant differences within the retrospective and prospective cohorts in our 2 studies that affected our original model. Likely, the prospectively collected data were more accurate. There were substantially more patients with a history of malignancy in the prospective cohort (36 versus 20 patients). Because many had malignant SBO secondary to extensive peritoneal disease, the mortality postoperatively was greater. This difference may explain the elimination of free intraperitoneal fluid in the new model owing to the lack of discriminating ability of this feature; intraperitoneal disease may increase the incidence of intraperitoneal fluid. Moreover, a substantial proportion of these patients died of their malignancy during hospitalization, which may have confounded the ostensible lack of difference in mortality, morbidity, and hospital stay using the model; whether the

new model would have decreased these parameters in patients with benign SBO is suggestive but, as of yet, unproven. Additionally, several of the CT features of interest might also be expected to be different with more patients with malignancy. Because of patient diversity, a third cohort would likely have differences as well. Nevertheless, we believe that the new model is valid owing to the incorporation of features that are consistent between the 2 patient populations.

The model presented can and should be used when evaluating patients with SBO. The first step in management should be resuscitation, which continues during the work-up. The initial step in developing the appropriate treatment is the determination of the presence of a strangulation obstruction. This step is based on known risk factors for bowel ischemia (peritonitis, strangulated hernia, and hypotension). When these factors are present, these patients should forgo further diagnostic work-up and proceed to emergent exploration. Within this series, only 3 patients had peritonitis on physical examination, likely as a result of patients with this finding proceeding straight to emergent operation without any CT imaging; indeed, this approach is standard practice at our institution unless there are extenuating circumstances. Although not statistically significant because of the low number in this study, all 3 of these patients required operation. It is imperative to realize that patients without these overt signs of ischemia are still at risk for strangulation. The CT imaging should be performed, therefore, to elucidate the presence of other signs of ischemia (closed-loop obstructions, pneumatosis intestinalis, or portal venous gas) and to determine the number of new model features present. Those patients with 3 features should undergo urgent (<12 hours) operative exploration owing to their high risk of ischemia (29%) and the 90% chance of requiring exploration before dismissal. Those patients with 2 or fewer risk factors can be treated initially nonoperatively with close, frequent reassessments. Those patients with 1 or fewer features can generally be managed by nonoperative means. Their risk of strangulation, although present, is extremely low. Following these guidelines based on our model may lessen morbidity and mortality.

Other algorithms have been developed in an attempt to predict the need for operative intervention in patients with SBO.<sup>7,19,20</sup> The advantage our model offers is its use of data collated from 2 separate patient cohorts and its use of information from both clinical and imaging features of the initial patient evaluation. In addition, our model allows for an informed decision to be made not only about the presence of strangulation but also about the eventual need for operative exploration rather than days later. The water-soluble contrast (diatrizoate meglumine) challenge (ie,

“Gastrografin challenge”) has also been used as a predictor for the need for operative exploration in SBO.<sup>21-29</sup> This test has been used in several prospective, randomized trials with variable success. Strangulation obstructions not recognized by this test were present in these studies; nevertheless, use of this test was able to predict the need for operative intervention. The greatest benefit that our model appears to offer over many other algorithms is the ability at admission to predict the need for eventual operative intervention during the hospitalization. Operative delay may result in greater mortality, especially in the setting of unrecognized strangulation obstruction.<sup>3,17,18</sup> Additionally, the ability to identify those patients who may not have strangulation obstruction but who will require operative intervention before dismissal for failure of the SBO to resolve can prevent delays of operative management and should decrease total hospitalization by eliminating the preoperative days of nonoperative, expectant management. A clinical trial comparing this model with the “Gastrografin challenge” or combining the 2 approaches would be appropriate.

Small-bowel obstruction is a common surgical dilemma, the management of which is dealt with on a daily basis by surgeons and nonsurgeons alike. We believe that the new model presented in this report is easy to use and clinically applicable. In addition, its use throughout a region may identify those patients in need of early exploration who may require transfer versus those who may be safely managed in an outlying facility. Because of the results of this study, we currently use the presented model in the treatment of our patients with SBO and are introducing it to our affiliated centers. With widespread implementation, this model has the potential for improving patient outcomes and reducing resource consumption.

#### Author Contributions

Study conception and design: Zielinski, Heller, Sarr, Bannon

Acquisition of data: Zielinski, Eiken

Analysis and interpretation of data: Zielinski, Lohse, Huebner, Sarr, Bannon

Drafting of manuscript: Zielinski, Eiken, Lohse

Critical revision: Zielinski, Eiken, Heller, Lohse, Huebner, Sarr, Bannon

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# **EAST Multi-institutional, Prospective, Observational Study in Small Bowel Obstruction**

Supported by the Eastern Association for the Surgery of Trauma's Multi-institutional and Acute Care Surgery Sections

## **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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> Several predictive models have been developed.<sup>4,5,6,7</sup> Of these, a model exists which incorporates the Gastrografin (GG) Challenge.<sup>8</sup> 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.<sup>9</sup>

Originally studied via a randomized, controlled clinical trial (RCT), the GG Challenge has subsequently undergone several further attempts at RCTs with mixed results.<sup>10,11,12,13,14,15</sup> A recent meta-analysis of these trials, however, demonstrated that the GG Challenge provided both a therapeutic and diagnostic effect.<sup>9</sup> 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) Sections. In addition to the question of GG, there are other multiple questions in the treatment of SBO which require answers. Using a multi-institutional SBO Registry, we can provide these answers.

### **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).

3. To determine if a daily NG volume output predicts successful removal.

*Primary Outcome:* Daily volumes of NG output compared to successful removal (i.e. lack of NG re-insertion)

4. To determine the risk factors for operative intervention in SBO

*Primary Outcome:* Multivariable analysis of the features which were associated with SBO operative management

5. To determine the standard treatments for malignant SBO treatment.

*Primary outcome:* Rates of treatment for patients with malignant SBO

### **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 REDCap web-based portal will be utilized for data collection.

### Statistics:

Continuous variables will be presented as medians and interquartile range and compared using the Wilcoxon two-sample test. Categorical variables will be presented as percentages and analyzed with the Fisher's exact test. Statistical significance will be defined as  $p$  value  $\leq 0.05$ . To study the predictive ability of the model, we will use the a concordance index (c-index), which is equivalent to the area under the receiver operating characteristic curve (AUROC). A c-index of 0.5 indicates no predictive ability, while a value of 1.0 indicates a perfect predictive ability.

Power Statement: Assuming an alpha of 0.05 and a power of 0.80 as well as an exploration rate of 25% in the Gastrografin institution's versus 42% in non-Gastrografin institutions, 132 patients will be required in each arm.

### *Inclusion Criteria*

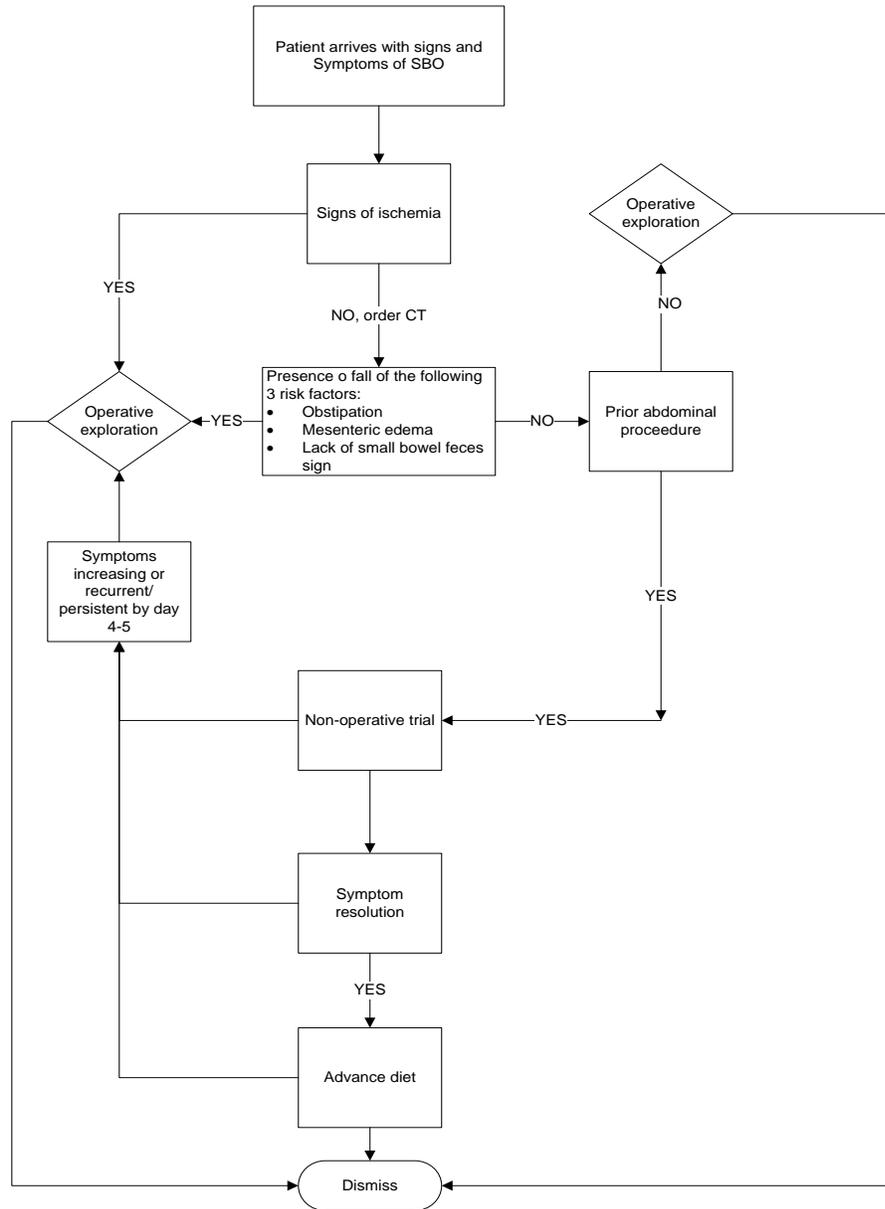
- 1) Age  $\geq 18$  years of age
- 2) Small bowel obstruction

### *Exclusion Criteria*

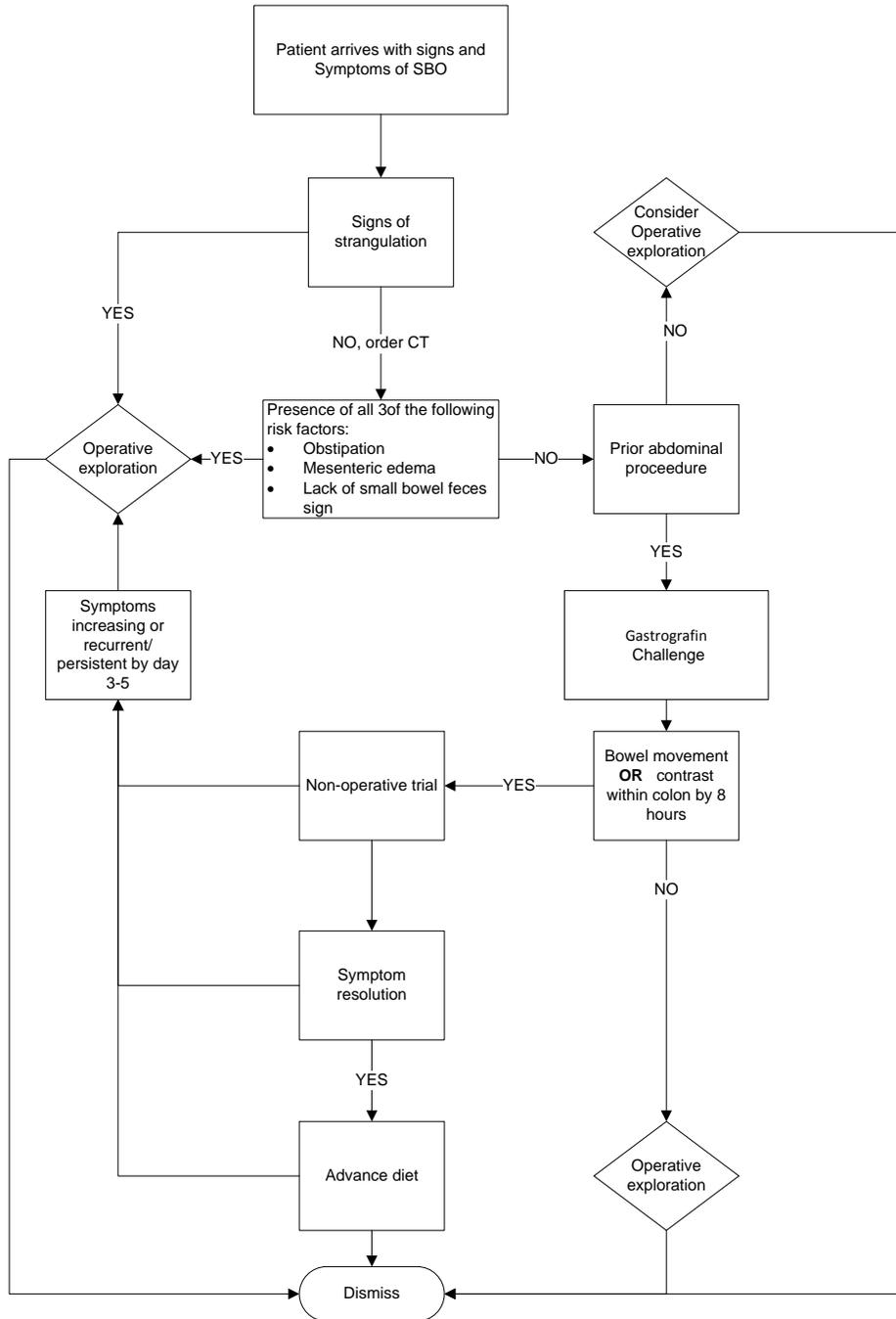
- 1) Prisoners

## 2) SBO Treatment Algorithms

### **Adhesive Small Bowel Obstruction (SBO) Protocol – Non-Gastrografin Challenge Institutions**



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



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- <sup>14</sup> Feigin E, Seror D, Szold A et al (1996) Water-soluble contrast material has no therapeutic effect on postoperative small bowel obstruction: results of a prospective randomized clinical trial. *Am J Surg* 171:227–229.
- <sup>15</sup> Kumar P, Kaman L, Singh G et al (2009) Therapeutic role of oral water soluble iodinated contrast agent in postoperative small bowel obstruction. *Singap Med J* 50:360–364.



## IRB Minimal Risk Protocol Template

**Note: If this study establishes a human specimen repository (biobank) for research purposes, do not use this template. Use the Mayo Clinic Human Specimen Repository Protocol Template found on the IRB home page under Forms and Procedures at <http://intranet.mayo.edu/charlie/irb/>**

**First-time Use:** Use this template to describe your study for a new IRB submission.

1. Complete the questions that apply to your study.
2. Save an electronic copy of this protocol for future revisions.
3. When completing your IRBe application, you will be asked to upload this template to the protocol section.

**Modification:** To modify this template after your study has been approved:

1. Open your study in IRBe. Click on the study 'Documents' tab and select the most recent version of the protocol. Save it to your files.
2. Open the saved document and activate "Track Changes".
3. Revise the protocol template to reflect the modification points, save the template to your files
4. Create an IRBe Modification for the study and upload the revised protocol template.

## General Study Information

Principal Investigator: Martin D. Zielinski, MD

Study Title: **EAST Multi-institutional, Prospective, Observational Study in Small Bowel Obstruction**

Protocol version number and date: #1; 1/23/15

## Purpose

Hypothesis: Institutions which use the Gastrografin Challenge will have a lower rate of operative exploration in the setting of small bowel obstruction

Aims, purpose, or objectives:

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).

3. To determine if a daily NG volume output predicts successful removal.

Primary Outcome: Daily volumes of NG output compared to successful removal (i.e. lack of NG re-insertion)

4. To determine the risk factors for operative intervention in SBO

Primary Outcome: Multivariable analysis of the features which were associated with SBO operative management

5. To determine the standard treatments for malignant SBO treatment.

Primary outcome: Rates of treatment for patients with malignant SBO

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc.*):

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.<sup>i</sup> 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.<sup>ii</sup> 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.<sup>iii</sup> Several predictive models have been developed.<sup>iv,v,vi,vii</sup> Of these, a model exists which incorporates the Gastrografin (GG) Challenge.<sup>viii</sup> 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.<sup>ix</sup>



Originally studied via a randomized, controlled clinical trial (RCT), the GG Challenge has subsequently undergone several further attempts at RCTs with mixed results.<sup>x,xi,xii,xiii,xiv,xv</sup> A recent meta-analysis of these trials, however, demonstrated that the GG Challenge provided both a therapeutic and diagnostic effect.<sup>ix</sup> 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) Sections.

### **Subject Information** – charts, records, images, or specimens are considered 'subjects'

*Target accrual is the proposed number of subjects to be included in your study at your site. "Subjects" may include Mayo Clinic charts, records, or specimens, **and/or** charts, records, or specimens received at Mayo Clinic from external sources for collaborating analysis by the investigator under this IRB application:*

Target accrual: 500

#### Inclusion Criteria:

Age ≥ 18 years of age

Small bowel obstruction secondary to adhesions

#### Exclusion Criteria

prisoners

Yes  No Will a Certificate of Confidentiality (COC) be obtained from NIH? If yes,  
Who is obtaining the COC: Mayo Clinic investigator, study sponsor, other:  
Explain why a COC is needed:



## Study Design

Methods: *Describe, in detail, the research activities that will be conducted under this protocol:*

Resources: *Describe the available resources to conduct the research (personnel, time, facilities, mentor commitment, etc.):*

**Check all that apply. If none apply, leave blank:**

- This is a multisite study involving Mayo Clinic and non-Mayo Clinic sites.  
When checked, describe the research procedures/activities being conducted **only** at Mayo Clinic:
- Mayo Clinic staff will be engaged in research activity at a non-Mayo Clinic site. *When checked, provide the location and a detailed description of the Mayo Clinic research staff involvement.*
- This study is to establish and/or maintain an ongoing database or registry for research purposes only.
- The research involves contact or interaction with subjects, for example, surveys, questionnaires, observation, blood draw.
- The study involves photographing, audiotaping or videotaping subjects (and guests).

## Blood Collection

If this study involves prospective blood collection by finger, heel, ear stick or venipuncture, complete the following:

- From healthy, non pregnant, adult subjects who weigh at least 110 pounds.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.

Volume per blood draw: \_\_\_\_\_ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) \_\_\_\_\_

- From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.

Volume per blood draw: \_\_\_\_\_ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) \_\_\_\_\_



**Review of Chart, Images, Specimens**

Provide the date range for collection of data and/or specimens that will be included in your research dataset.

*Example: 01/01/2000 to 12/31/2013 or all records through mm/dd/yyyy.*

For a retrospective chart review, enter the date range:

**Check all that apply:**

This study involves only data and/or specimens that exist at the time this application is submitted to the IRB (IRB submission date). No data or specimens will be collected beyond this date.

This study involves only data and/or specimens that will be collected after submission to the IRB.

The study involves data and/or specimens that exist at the time of submission to the IRB **and** data and/or specimens that will be collected after submission to the IRB, for example a study that includes collection of existing data and prospective collection of specimens.

Data and/or specimens used in this study are collected under another IRB protocol. *When checked, provide the IRB number(s) from which the research material will be obtained. When appropriate, check the box below to attest that subjects have provided consent for future use of their data and/or specimens, as described in this protocol.*

IRB Number/s - Data Only: \_\_\_\_\_

IRB Number/s - Specimens Only: \_\_\_\_\_

IRB Number/s - Data and Specimens: \_\_\_\_\_

Note: When subjects provided consent for use of their data and/or specimens, as described in this protocol.

Other data sources will be utilized in this study, e.g. receiving data/specimens from an external party. When checked, provide all data sources:





**Data Confidentiality, HIPAA Subject Identifiers**

Review the list of subject identifiers below and, if applicable, check the box next to each subject identifier being recorded at the time you are collecting/abstracting data/specimens for use in this study.

**Subject Identifiers:** Individually identifiable information, including demographic data, that identifies the individual or for which there is reasonable basis to believe it can be used to identify the individual. **NOTE:** Identifiers apply to subjects enrolled in your study and to the subject’s relatives, household members, employers, etc.

**Internal** refers to subject identifiers that will be included in the dataset maintained by the study team. **External** refers to subject identifiers that will be shared with persons outside of the immediate study team, for example, sent to an external collaborator or shared with a national registry.

<b>SUBJECT IDENTIFIERS</b> Check all that apply	INTERNAL IDENTIFIER	EXTERNAL IDENTIFIER
Name	X	
Social Security number		
Medical record/patient registration number, lab accession, specimen or radiologic image number	X	
Study number, subject ID, or any other unique identifying number, characteristic or code that can be used to link the identity of the subject to the data	X	X
Dates: All elements of dates [month, day, and year] directly related to an individual. Their birth date, date of death, date of diagnosis, etc. <b>Note:</b> Recording a year only is not a unique identifier.	X	
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images		
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address		
Street address, city, county, precinct, zip code, and their equivalent geocodes		
Phone or fax numbers		
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
<b>If None of the above identifiers will be recorded or maintained in the dataset and/or sent outside of the study team, please check “None”.</b>	<input type="checkbox"/> None	<input type="checkbox"/> None



## Statistical Information

*Note: Power analyses and study endpoints are not needed for a pilot or feasibility studies.*

No statistical information. *If checked, please explain:*

### Statistical Considerations

#### Power Statement:

Assuming an alpha of 0.05 and a power of 0.80 as well as an exploration rate of 25% in the Gastrografin institution's versus 42% in non-Gastrografin institutions, 132 patients will be required in each arm.

#### Data Analysis Plan:

Continuous variables will be presented as medians and interquartile range and compared using the Wilcoxon two-sample test. Categorical variables will be presented as percentages and analyzed with the Fisher's exact test. Statistical significance will be defined as p value  $\leq 0.05$ . To study the predictive ability of the model, we will use the a concordance index (c-index), which is equivalent to the area under the receiver operating characteristic curve (AUROC). A c-index of 0.5 indicates no predictive ability, while a value of 1.0 indicates a perfect predictive ability.

### Endpoints

#### **Aim 1:**

*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).

#### **Aim 2:**

*Primary Outcome:* Ability of the scoring system to predict mortality as measure by the area under the receiver operating characteristic curve (AUROC).

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- <sup>xii</sup> Zhang Y, Gao Y, Ma Q et al (2006) Randomised clinical trial investigating the effects of combined administration of octreotide and methylglucamine diatrizoate in the older persons with adhesive small bowel obstruction. *Dig Liver Dis* 38:188–194.
- <sup>xiii</sup> Chen SC, Lin FY, Lee PH et al (1998) Water-soluble contrast study predicts the need for early surgery in adhesive small bowel obstruction. *Br J Surg* 85:1692–1694.
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- <sup>xv</sup> Kumar P, Kaman L, Singh G et al (2009) Therapeutic role of oral water soluble iodinated contrast agent in postoperative small bowel obstruction. *Singap Med J* 50:360–364.

# EAST Multi-institutional, Prospective, Observational Study in Small Bowel Obstruction

## 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):

Myocardial infarct.	CHF	Periph. Vasc. Dz.	Cerberovasc. Dz.
Dementia	COPD	Connect. Tissue Dz.	Peptic Ulcer Dz.
AIDS	Mod to Severe CKD	Hemiplegia	Leukemia
DM without end organ damage	DM with end organ damage	Mild Liver Disease	Moderate-Severe Liver Disease

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** Active Pregnancy? **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**  
 Prior Open Abdomen? **YES / NO** Prior EC Fistula **YES / NO**

### Pre-op History, Physical Exam, Lab, Vitals

Duration of Obstipation \_\_\_\_\_ Peritonitis? **YES / NO**  
 Temperature \_\_\_\_\_ Heart Rate \_\_\_\_\_  
 Systolic Blood Pressure \_\_\_\_\_ Lactate (mmol/L) \_\_\_\_\_  
 Hemoglobin (g/dL) \_\_\_\_\_ PaCO<sub>2</sub> \_\_\_\_\_  
 Respiratory Rate \_\_\_\_\_ pH \_\_\_\_\_  
 White Blood Cell (x10<sup>9</sup>/L) \_\_\_\_\_ Base Deficit \_\_\_\_\_  
 Serum Creatinine (mg/dL) \_\_\_\_\_ Albumin (g/dL) \_\_\_\_\_  
 Blood Urea Nitrogen (mg/dL) \_\_\_\_\_ Severe Sepsis **YES / NO**  
 Sepsis **YES / NO** ≥ 2 organ system failure **YES / NO**  
 Septic Shock **YES / NO**

### Admission Radiographic Data

Abdominal radiograph? **YES / NO**  
 Gas present in the colon **YES / NO**

<i>Computed Tomography?</i>	<b>YES / NO</b>		
Small bowel feces sign	<b>YES / NO</b>	CT Gastrografen?	<b>YES / NO</b>
Free intra-peritoneal fluid	<b>YES / NO</b>	Mesenteric edema	<b>YES / NO</b>
Closed Loop Obstruction	<b>YES / NO</b>	Transition Point	<b>YES / NO</b>

**GG Challenge Results**

Hours from GG to Abd Xray:_____		Contrast in Colon:	<b>YES / NO</b>
BM prior to Xray	<b>YES / NO</b>	Exploration prior to GG results	<b>YES / NO</b>
Transition Point?	<b>YES / NO</b>	Location of Transition Point_____	
Bowel Wall Edema	<b>YES / NO</b>	Maximum Distension (cm)_____	

**Operative Data**

Exploration:	<b>YES / NO</b>	Operative Indication_____	
Type of Exploration:	<b>LAPAROTOMY / LAPAROSCOPY</b>		
	<b>OTHER:</b> _____		
Convert from Laparoscopy to Open?	<b>YES / NO</b>	Date of Exploration:_____	
Hours from Admission to OR_____			
Strangulation Obstruction:	<b>YES / NO</b>	Perforation:	<b>YES / NO</b>
Small Bowel resection:	<b>YES / NO</b>	Anastomosis:	<b>YES / NO</b>
Stoma Creation:	<b>YES / NO</b>	Open abdomen:	<b>YES / NO</b>
Non-therapeutic Exploration:	<b>YES / NO</b>	Unrecognized Malignant SBO	<b>YES / NO</b>
Frozen Abdomen	<b>YES / NO</b>	Operative time (mins)_____	
Cecostomy tube	<b>YES / NO</b>	Diffuse peritoneal contamination	<b>YES / NO</b>

**Outcomes** (see protocol for definitions)

ICU Admission	<b>YES / NO</b>		
Date of ICU Admission_____		Date of ICU Dismissal_____	
Acute Renal Failure	<b>YES / NO</b>	Pneumonia	<b>YES / NO</b>
GG Pneumonitis	<b>YES / NO</b>		
Deep Wound Infection	<b>YES / NO</b>	Superficial SSI	<b>YES / NO</b>
Deep Incisional SSI	<b>YES / NO</b>	Organ Space SSI	<b>YES / NO</b>
Anastomotic leak	<b>YES / NO</b>	PEG	<b>YES / NO</b>
Date of first flatus_____		Date of Tolerating Clears_____	
Date of tolerating soft diet_____		Total Parenteral Nutrition use	<b>YES / NO</b>
Readmission within 30 days	<b>YES / NO</b>	Date of Readmission_____	

**Volumes of NG effluent**

Day 1_____		Day 2_____	
Day 3_____		Day 4_____	
Day 5_____		Day 6_____	
Day 7_____		Day 8_____	
Day 9_____		Day 10_____	
Date of NG insertion_____		Date of NG removal_____	
Was NG replaced?	<b>YES / NO</b>		

## **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

Complete Small Bowel Obstruction: a lack of gas in the distal small bowel or colon on a plain abdominal radiograph.

Systemic Inflammatory Response Syndrome (SIRS): ≥ 2 of the following

1. Temperature > 38 °C or < 36°C
2. Heart Rate > 90 beats per minute
3. Respiratory Rate > 20 breaths per minute or PaCO<sub>2</sub> < 32 mm Hg
4. White Blood Cell Count > 12,000 or less than 4,000 or ?10% bands

Sepsis Criteria: SIRS plus a source of infection (i.e. suspected SBO)

Severe Sepsis: Sepsis Criteria plus lactic Acidosis, Systolic Blood Pressure < 90 or > 40 drop from normal

Septic Shock: Severe Sepsis plus hypotension despite adequate fluid resuscitation

Multiple Organ Dysfunction Syndrome: Septic Shock plus 2 or more organ failures

## **EAST Multi-institutional, Prospective, Observational Study in Small Bowel Obstruction IRB Documentation**

1. All participating institutions will send documentation of their respective institution's IRB approval.
2. The lead PI (Zielinski) will send updates to the protocol to ensure all centers have the most current version via email to the addresses listed below.
3. The REDCap web based data module will be utilized for data collection and management. Patient data will be deidentified prior to uploading to the REDCAP site. Data analysis will be performed at the Mayo Clinic on the de-identified data.

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