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Long-term outcomes of gastrografin in small bowel obstruction

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Abstract

Background—The gastrografin (GG) challenge is a diagnostic and therapeutic tool used to treat patients with small bowel obstruction (SBO); however, long-term data on SBO recurrence after the GG challenge remain limited. We hypothesized that patients treated with GG would have the same long-term recurrence as those treated before the implementation of the GG challenge protocol.

Methods—Patients 18 years who were treated for SBO between July 2009 and December 2012 were identified. We excluded patients with contraindications to the GG challenge (i.e., signs of strangulation), patients having SBO within 6-wk of previous abdominal or pelvic surgery and patients with malignant SBO. All patients had been followed a minimum of 1 y or until death. Kaplan–Meier method and Cox regression models were used to describe the time-dependent outcomes.

Results—A total of 202 patients were identified of whom 114 (56%) received the challenge. Mean patients age was 66 y (range, 19–99 y) with 110 being female (54%). A total of 184 patients (91%) were followed minimum of 1 year or death (18 patients lost to follow-up). Median follow-up of living patients was 3 y (range, 1–5 y). During follow-up, 50 patients (25%) experienced SBO recurrences, and 24 (12%) had exploration for SBO recurrence. The 3-year cumulative rate of SBO recurrence in patients who received the GG was 30% (95% confidence interval [CI], 21%–42%) compared to 27% (95% CI, 18%–38%) for those who did not ($P = 0.4$). The 3-year cumulative rate of exploration for SBO recurrence in patients who received the GG was 15% (95% CI, 8%–26%) compared to 12% (95% CI, 6%–22%) for those who did not ($P = 0.6$).

Conclusions—The GG challenge is a clinically useful tool in treating SBO patients with comparable long-term recurrence rates compared to traditional management of SBO.

Keywords

Gastrografin; Outcomes; Recurrence; Small bowel obstruction

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1. Background

Small bowel obstructions (SBOs) are one of the most common acute surgical problems which cause a significant burden on health care in the United States [1]. Although SBO can frequently be treated with nonoperative measures by nasogastric tube decompression, fluid resuscitation, and bowel rest, immediate surgical treatment is indicated in those with risks of bowel strangulation and/or perforation [2–5]. The goal of surgical treatment is to alleviate the obstruction, generally with adhesiolysis, but exploration is associated with further adhesion formation, which, in turn, can result in SBO recurrence [6–13]. Conversely, whereas nonoperative management offers a less invasive approach for decompression and bowel rest, it is associated with more frequent SBO recurrences compared with surgical treatment [6,13].

The gastrografen (GG) challenge has been promoted as a diagnostic and therapeutic tool for SBO patients that is associated with a reduction in the need of operative intervention as well as the number of hospital days in the short term [14–17]. Long-term recurrence rates, however, are unknown. The objective of the present study was to determine whether the recurrence of SBO differs between patients who did and did not receive the GG challenge. We performed a study with the hypothesis that patients treated with the GG challenge will have comparable SBO recurrence rates as those treated before the implementation of the GG challenge protocol.

2. Methods

Approval from the institutional review board was obtained to study patients who were admitted to our institution for SBO between July 2009 and December 2012. Exclusion criteria included patients younger than 18 y, SBO within 6 wk of prior abdominal or pelvic surgery, malignant SBO, incarcerated hernia, traditional signs of strangulation, or three of three clinical criteria predicting the need for urgent operative exploration [2,5,18].

In November 2010, the SBO management protocol at our institution was modified to include the GG challenge [16]. We compared the outcomes of interest obtained during follow-up for patients who were treated with the GG challenge to patients from before November 2010 who did not receive the GG challenge. Some of these patients have been previously reported to demonstrate the efficacy of the GG challenge compared to the historic group in the short term [16].

2.1. GG challenge protocol

All patients included in this study underwent NG tube decompression, intravenous fluid resuscitation, and abdomen and pelvic computed tomography (CT) imaging to establish the SBO diagnosis and confirm the absence of strangulation, and the features predicting the need of immediate operative exploration (the lack of the small bowel feces sign and mesenteric edema) [2,5]. CT images were consecutive 5-mm thickness or less obtained with the use of different multi-detector CT scanners (Siemens Sensation 64, Sensation Open, and Sensation 16 [Siemens Medical Solutions] and GE Light-Speed Pro 16, LightSpeed 16, and LightSpeed Ultra [GEMedical Systems]) [2,5,16]. The imaging was performed using

intravenous contrast material in 158 patients (89 received GG later and 69 did not) and/or oral contrast (diatrizoate meglumine, Bracco Diagnostics Inc) in 47 patients (12 received GG later and 35 did not).

The GG challenge has previously been described [16]. Briefly, those patients who had no signs of strangulation underwent NG decompression for 2 hours. After this, they were administered 100 mL of GG diluted in 50 mL of water through the NG tube. Subsequently, the NG tube was clamped and then a plain abdominal radiograph was obtained 8 hours later. The presence of contrast within the colon or having a bowel movement was considered as successful result and patient continued to be managed nonoperatively. Operative exploration was recommended to those patients who failed the GG challenge. SBO resolution was defined as hospital dismissal while tolerating an oral diet.

The medical records of all eligible patients were reviewed to obtain details about patients' characteristics, preexisting medical conditions, previous surgical procedures, presenting vital parameters, laboratory investigations with imaging studies performed at presentation, and interventions with treatments carried out. Details regarding complications, reoperations, and mortality during the index hospital stay or after the hospital discharge during study follow-up were also recorded. The follow-up was conducted until death, loss to follow-up, or the latest clinical evaluation of record. The follow-up duration was calculated from the index hospitalization for the treatment of SBO until the most recent assessment at our institution. The most recent assessment was obtained from patients through medical records (197 patients) and questionnaires inquiring about recurrences (five patients).

Categorical variables were shown as numbers with proportions and continuous variables as means with standard deviations, medians with interquartile ranges, or medians with ranges. The χ^2 tests, 2-sample *t* tests, and Wilcoxon rank sum tests were appropriately used to compare patients groups. The Kaplan–Meier method was used to analyze time-dependent outcomes and determine the cumulative rates with 95% confidence intervals (CIs) using the first event of SBO recurrence, operative exploration for SBO recurrence, and operative exploration for any cause as end points [19]. The log-rank test was used to compare Kaplan–Meier estimates between groups. Univariate Cox regression models were also created to determine the risks of SBO recurrence, operative exploration for SBO recurrence, and operative exploration for any cause during the study period. All statistical tests were two sided with statistical significance considered at $P < 0.05$.

3. Results

3.1. Cohort characteristics, treatment, morbidity, and mortality

A total of 202 patients met inclusion criteria with a mean age of 66 y (range, 19–99 y). The GG challenge was performed in 114 patients (56%) and compared to 88 patients (44%) treated similarly but without the GG challenge. There was no observed statistical difference between cohorts for patients' characteristics obtained before treatment except for the rate of underlying inflammatory bowel disease (Table 1). Fourteen percent (16 of 114) of the patients treated with the GG challenge at the index hospitalization underwent operative exploration compared to 33% (29 of 88) treated without the GG challenge ($P < 0.001$). In

addition, GG challenge patients had a shorter duration of hospital stay (4 d *versus* 5 d; $P=0.02$; Table 2). In-hospital morbidity and mortality were comparable (Table 2).

3.2. Follow-up

Of the total 202 patients, 184 patients (91%) were followed for a minimum of 1 y or through death. Twelve patients died before reaching a minimum of 1-y follow-up (range, 0.03–9 mo) and 20 died after 1 y of follow-up (range, 1–4.7 y). The median follow-up of the 172 patients (85%) who were alive at the 1-y after index was 3 y (range, 1–5 y); of those, 98 were treated with the GG challenge and 74 were not.

3.3. SBO recurrence analysis

After the index hospitalization, 50 patients (25%) experienced SBO recurrence; 28 (25%) treated with the GG Challenge and 22 (25%) not treated with GG. Thirty-one patients had one recurrence, 10 patients had two recurrences, and nine patients had three or more recurrences. Hospitalization for the first SBO recurrence occurred after a median of 8 months from the index hospitalization (range, 0.2 mo–5 y). Of the 50 patients with SBO recurrence, 29 (58%) underwent treatment with the GG Challenge at the time of recurrence. The cumulative rate of SBO recurrence at 3 years was 29% (95% confidence interval [CI], 22%–36%) based on Kaplan Meier analysis. The cumulative rate of SBO recurrence at 3 years for patients who received the GG challenge was 30% (95% CI, 21%–42%) compared to 27% (95% CI, 18%–38%) for the patients not treated with the GG challenge at index hospitalization ($P=0.4$; Fig. 1).

Thirteen of the 114 patients (11%) treated with the GG challenge underwent operative exploration for SBO during follow-up compared to 11 of the 88 (13%) treated without the GG challenge ($P=0.8$). Based on Kaplan–Meier analysis, the rate of operative exploration for SBO recurrence at 3 years for patients treated with the GG challenge was 15% (95% CI, 8%–26%) compared to 12% (95% CI, 6%–22%) for the patients not treated with GG at index hospitalization ($P=0.6$). Cumulatively over the short and long-term (combining index hospitalization with long-term follow-up), fewer patients underwent exploration for SBO at 3-year when treated with the GG challenge at index hospitalization (28% *versus* 43%, $P=0.004$). The rate of SBO recurrence at 3 years for patients undergoing exploration at index was 27% (95% CI = 16%–43%) compared to 29% (95% CI = 22%–39%) for the patients not undergoing exploration at index hospitalization ($P=0.9$).

Thirty-six patients (18%) underwent surgical exploration for any cause; 18 patients treated with GG and 18 without (Fig. 2). Overall, the cumulative rate for operative exploration for any cause at 3 years was 21% (95% CI, 16%–29%). There was also no observed difference between patients groups ($P=1.0$; Table 3).

Cox regression analysis demonstrated that patients with prior SBO history had a nearly 3 times greater risk for SBO recurrence (HR, 2.76, 95% CI, 1.54–5.21) and 2 times greater risk for operative exploration for SBO recurrence (HR, 2.29, 95% CI, 1.01–5.65) compared to those without a history of prior SBO. Patients with previous surgery for SBO also showed significantly greater risk for SBO recurrence compared to those without (HR, 2.11, 95% CI, 1.17–3.72). None of the remaining clinical features were significantly associated with SBO

recurrence, operative exploration for SBO recurrence, or operative exploration for any indication during the study follow-up.

4. Discussion

In the present study, we compared the cumulative recurrence rate in patients treated with the GG challenge to those treated before the implementation of the GG challenge protocol at our institution. The present study finds that patients who did and did not receive the GG challenge developed comparable estimates of cumulative recurrence rates at the long term (cumulative rates at 3-year time point: 30% *versus* 27%, respectively). Additionally, a history of prior SBO and a surgical exploration for SBO before index hospitalization are risk factors associated with these recurrences (Table 3).

Numerous studies address the question on the difference in SBO recurrence during follow-up between patients treated surgically or nonoperatively [6,7,9,13]. Some authors suggest that the type of SBO treatment significantly influenced the risk of recurrence during follow-up with patients treated non-operatively having the greatest recurrence rate [6,13]. None of these studies, however, included patients treated with the GG challenge. Meier *et al.* [13] concluded that patients managed surgically for SBO had lower risks for SBO recurrence and hospitalizations compared to patients treated nonoperatively with bowel rest, nasogastric tube decompression, and fluid resuscitation (14% *versus* 29.4%). Likewise, Landercasper *et al.* [6] reported that surgical treatment was associated with lower recurrence rates compared to nonoperative treatment (29% *versus* 53%). Miller *et al.* [7] noted, however, comparable rates of SBO recurrence (32% *versus* 34%) and reoperations (11% *versus* 14%) between surgically and nonoperatively managed SBO patients. They found that the risk of SBO recurrence was significantly associated with the number of prior admissions for SBO treatment.

SBO recurrence rates vary widely and can exceed 50% [6–11,13,20,21]. In a prospective multi-institutional study including patients who underwent operation for an adhesive postoperative SBO (286 patients; median follow-up, 3.42 years), Duron *et al.* [10] reported approximately 16% cumulative incidence for overall recurrence; age <40 y and presence of adhesions were independent risk factors for recurrence. Fevang *et al.* [8] reported that recurrence rates for surgically treated SBO patients were increased with increasing number of prior SBO episodes. They reported a cumulative recurrence rate of 81% for those having 4 prior SBO admissions [8]. In our cohort study, the cumulative estimates were lower at 3-y follow-up with 29% for overall SBO recurrence and 14% for operative exploration for SBO recurrence. The unadjusted Cox analyses agree with a prior SBO and operative explorations for SBO as risk factors resulting in SBO recurrence during follow-up. There were several patients who received another GG challenge with SBO recurrence. These patients went through the same protocol as at index hospitalization. Consideration for operative exploration for frequent SBO recurrences was done on a case by case basis. This discussion, however, occurs after the results of the repeat GG challenge. This allows us to frame the discussion as a need exploration for acute SBO resolution *versus* the prevention of SBO recurrence in the long term.

There is a paucity of long-term outcomes data about using the GG challenge for the treatment of SBO patients. Chen *et al.* [22] reported no difference in SBO recurrence rate during the 6-mo follow-up duration in a randomized controlled trial; three of the 65 patients who received GG developed recurrences compared to four of the 63 patients who did not receive GG. The limited power and duration of follow-up, however, precludes major conclusions to be drawn. We have reported on the SBO recurrences among patients having the GG challenge with a history of abdominal and/or pelvic malignancy [17]. Although the emphasis was on survival given the patients' usual poor prognosis, there were comparable rates of SBO recurrence at the 1-y time point between patients with malignant SBO receiving the GG challenge and those who did not (28% *versus* 26%). In the current investigation, we opted to evaluate SBO recurrence among patients who received or did not receive the GG for SBO resulting from causes other than abdominal and/or pelvic malignancy at a longer follow-up period.

The results of this study can be presented in light of a number of limitations. As a retrospective review study, there is a potential variability in recording clinical findings, managing patients, and subsequent data gathering. Second, the review represents a single institution experience potentially not being generalizable to other settings or outside other major academic institutions with extensive experience with the use of the GG challenge. Only a multi-institutional study will be able to discern the difference in recurrence over the long term. Furthermore, as we compared follow-up outcomes in patients who were treated for SBO using protocols implemented at different times, the follow-up was relatively shorter in those who had GG that was introduced later during the study period. The use of Kaplan–Meier estimates of recurrence, however, should control for these discrepancies.

In conclusion, the use of the GG challenge in managing SBO patients is beneficial in the short term with similar rates of SBO recurrence in the long term. Although the GG challenge did not influence the rate SBO recurrence and exploration for SBO recurrence during the follow-up period, its usage has beneficial effects in the acute phase with lower rates of operative exploration at the index presentation. Our institution routinely continues to use the GG challenge for our SBO patients.

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Fig. 1.

Kaplan–Meier cumulative estimates for SBO recurrence (solid lines) and 95% confidence intervals (shaded area) in patients who received the GG challenge (blue font) and patients who did not using (red font). SBO indicates small bowel obstruction. (Color version of figure is available online.)

Fig. 2.

Kaplan–Meier cumulative estimates for operation due to any cause (solid lines) and 95% confidence intervals (shaded area) in patients who received the GG challenge (blue font) and patients who did not (red font). SBO indicates small bowel obstruction. (Color version of figure is available online.)

Table 1

Patient characteristics.

Variables	No GG	GG	<i>P</i> value
Patients	88	114	
Mean age (SD)	64 (18)	68 (16)	0.09
Male, <i>n</i> (%)	42 (48)	50 (44)	0.6
Female, <i>n</i> (%)	46 (52)	64 (56)	
Prior SBO, <i>n</i> (%)	39 (44)	57 (50)	0.4
Prior surgery for SBO, <i>n</i> (%)	20 (23)	30 (26)	0.6
Prior abdomen surgery, <i>n</i> (%)	87 (99)	112 (98)	0.7
Prior gastric bypass surgery, <i>n</i> (%)	12 (14)	7 (6)	0.07
Prior hernia (internal/external), <i>n</i> (%)	26 (30)	34 (30)	1.0
Inflammatory bowel disease, <i>n</i> (%)	11 (13)	4 (4)	0.02
Prior radiotherapy, <i>n</i> (%)	11 (13)	10 (9)	0.4
Diabetes mellitus, <i>n</i> (%)	19 (22)	34 (30)	0.2
Liver disease, <i>n</i> (%)	5 (6)	2 (2)	0.1
Age-Charlson's comorbidity score (SD)	6 (3)	6 (4)	0.4

SBO = Small bowel obstruction; SD = standard deviation.

Bold font P-value indicates statistical significance with $P < 0.05$.

Table 2

Patient treatments details at presentation.

Variables	No GG	GG	P value
Etiology [*]			
Adhesions, <i>n</i> (%)	77 (88)	106 (93)	0.2
Radiation enteritis, <i>n</i> (%)	1 (1)	2 (2)	0.7
Stricture/stenosis, <i>n</i> (%)	6 (7)	3 (3)	0.2
Fecal/mucous impaction, <i>n</i> (%)	2 (2)	3 (3)	0.9
Intussusception, <i>n</i> (%)	2 (2)	0 (0)	0.1
Diverticular lesion, <i>n</i> (%)	1 (1)	1 (1)	0.9
Inflammatory bowel disease, <i>n</i> (%)	0 (0)	1 (1)	0.4
Initial 24 hrs. Nasogastric tube output in cc's, median (IQR)	425 (150–850) [‡]	500 (230–1000) [‡]	0.07
SIRS [23] at presentation, <i>n</i> (%)	37 (42)	43 (38)	0.5
WBC count (x 10 ⁹ /L), mean (SD)	10.0 (4.1)	10.9 (4.2) [‡]	0.1
Any exploration, <i>n</i> (%)	29 (33)	16 (14)	0.001
Approach			
Laparoscopic	11	1	
Laparotomy	18	15	
Total number of explorations on admission	30	16	
Primary procedure performed [§]			
Lysis of adhesions, <i>n</i> (%)	20 (23)	13 (11)	0.03
Bowel resection and/or anastomosis, <i>n</i> (%)	10 (11)	3 (3)	0.01
Bowel resection/stoma, <i>n</i> (%)	1 (1)	1 (1)	0.85
Nonoperable, <i>n</i> (%)	1 (1)	1 (1)	0.85
Absent pathology, <i>n</i> (%)	1 (1)	0 (0)	0.25
Days of hospital stay, median (IQR)	5 (3–9)	4 (2–8)	0.02
In-hospital morbidity, <i>n</i> (%)	14 (16)	16 (14)	0.7
In-hospital mortality, <i>n</i> (%)	2 (2)	2 (2)	0.8
Death within 30 d, <i>n</i> (%)	2 (2)	4 (4)	0.6

IQR = interquartile range; SIRS = systemic inflammatory response syndrome [23]; WBC = white blood cell.

Bold font P-value indicates statistical significance with $P < 0.05$.^{*} More than one etiology can be present.[‡] Data were not available in 17 patients for the nasogastric tube output.[‡] Data were not available in 11 patients for the nasogastric tube output and one patient for the WBC count.[§] More than one procedure performed during the same operation.

Table 3

Kaplan–Meier failure estimates* for various end points among patients who received the GG challenge and those who did not.

End points	SBO recurrence, % (95% CI)		Operative exploration for SBO recurrence, % (95% CI)		Operative exploration for any cause, % (95% CI)	
	GG (n = 28)	No GG (n = 22)	GG (n = 13)	No GG (n = 11)	GG (n = 18)	No GG (n = 18)
1 y	20 (13–28)	13 (7–22)	10 (5–17)	5 (2–13)	14 (8–22)	9 (4–18)
2 y	25 (18–35)	21 (13–31)	12 (7–20)	9 (4–18)	16 (10–25)	17 (10–28)
3 y	30 (21–42)	27 (18–38)	15 (8–26)	12 (6–22)	22 (13–34)	22 (14–33)

SBO = small bowel obstruction.

* The values are given as the Kaplan–Meier failure estimates. These values were not significant with $P > 0.05$.