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Evaluation of a water-soluble contrast protocol for small bowel obstruction: A southwestern surgical congress multicenter trial

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ABSTRACT

Differentiation between SBO that will resolve with supportive measures and those requiring surgery remains challenging. WSC administration may be diagnostic and therapeutic. The purpose of this study was to evaluate use of a SBO protocol using WSC challenge.

A protocol was implemented at five tertiary care centers. Demographics, prior surgical history, time to operation, complications, and LOS were analyzed.

283 patients were admitted with SBO; 13% underwent immediate laparotomy; these patients had a median LOS of 7.5 days. The remaining 245 were candidates for WSC challenge. Of those, 80% received contrast. 139 (71%) had contrast passage to the colon. LOS in these patients was 4 days. Sixty-five patients (29%) failed contrast passage within 24 h and underwent surgery. LOS was 9 days. 8% of patients in whom contrast passage was observed at 24 h nevertheless subsequently underwent surgery. 4% of patients who failed WSC challenge did not proceed to surgery.

Our multicenter trial revealed that implementation of a WSC protocol may facilitate early recognition of partial from complete obstruction.

Background

In North America, there are more than 300,000 annual hospital admissions for SBO which accounts for 850,000 days of inpatient care and $2.7 billion in medical expenditures.[1] Of these, adhesive related obstructions are the most common.[2] The ability to discern between adhesive SBOs likely to resolve with conservative management versus those that will require surgical intervention remains challenging.[2,3] Imaging with the use of water soluble contrast (WSC) is utilized for both diagnostic and therapeutic reasons. Hypertonic WSC agents may be therapeutic, as they draw fluid into the lumen of the bowel, thereby decreasing intestinal wall edema and stimulating peristalsis.[4] Abdominal radiographs can evaluate for contrast passage to the colon following administration; hence WSC may also be diagnostic. Contrast passage combined with pain abatement are indications that the patient's diet can be advanced and disposition plans can be considered. However, failure of WSC to reach the colon within 24 h of ingestion suggests an obstruction likely necessitating operative intervention.[5] Numerous centers report successful implementation of standardized protocols for the management of SBO using contrast challenges.[4,6,7]

Previous groups have demonstrated the utility of a WSC protocol in the diagnosis and treatment of SBO in a single center study. They found that implementation of WSC protocols helped to facilitate early recognition of SBO, contrast administration had both diagnostic and therapeutic value, and that protocol implementation did not increase length of stay, morbidity, or mortality.[6] The

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purpose of this multicenter trial was to evaluate the efficacy of and any complications associated with our institutions' use of a standard SBO protocol using WSC challenge. We hypothesized that use of a WSC protocol would facilitate differentiation between an SBO requiring surgical intervention from obstructions which can be managed conservatively.

Methods

This is a retrospective review of all patients with SBO from five tertiary care centers from July 1, 2017–June 30, 2018. Inclusion criteria were patients admitted to the Acute Care Surgery (ACS) or Emergency General Surgery (EGS) services with SBO between July 1, 2017–June 30. All patients underwent computed tomography (CT) of their abdomen and pelvis on admission. Patients were taken immediately to the operating room if, on presentation, they demonstrated features of peritonitis, if there was a high clinical suspicion of bowel compromise, or CT scan demonstrated concern for bowel compromise or perforation. For CT findings of mesenteric edema, pneumatosis, free fluid, suspicion for closed-loop obstruction, or "whirlpool" or swirl sign, the decision to proceed to surgery versus administration of WSC protocol was determined by the attending surgeon based on clinical findings.

WSC Protocol: For patients who were not taken to the operating room immediately, a WSC was employed. **Following at least 6 h of nasogastric tube decompression, patients received a dose of 80 ml of undiluted Gastrografin (Diatriazole) via nasogastric tube (NGT), followed by 40 mL of sterile water.** The NGT was subsequently clamped. If the patient developed nausea or increasing abdominal pain, the NGT was unclamped and the patient re-assessed by the surgical team. Plain radiographs were taken at 12 and 24 h after contrast administration to evaluate for contrast passage to the colon. Failure of contrast passage to the colon after 24 h was considered a relative indication for surgery. Increased abdominal pain and worsening leukocytosis during protocol administration were considered relative indications for surgery. Development of peritonitis during protocol was considered an absolute indication for surgery.

After institutional review board approval, we collected data from all patients presenting with SBO admitted to the aforementioned services. Demographics, CT findings, time to operation, postoperative complications (categorized as cardiac, pulmonary, infectious and renal), and hospital length of stay were reviewed. Statistical analysis was performed using Chi Squared or Fischer's exact test where appropriate for categorical variables and the Kruskal-Wallace nonparametric test for continuous variables. A p value ≤ 0.05 was considered significant. Data were collected and managed with Microsoft Excel 8.0 (Microsoft, Redmond, WA). All statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

Results

During the one year study, 366 patients were admitted with SBO to 5 institutions. Of these, 77% (n = 283) were admitted to the Acute Care or Emergency General Surgery Services and are included in this study (Fig. 1). The median age of patients admitted with SBO was 56 years (IRQ 44–67). The median BMI was 27 (IQR 23–32). 54% of patients were female (Table 1). Median number of comorbidities was 2 (IQR 1–3).

Baseline covariates were predictive of failure of contrast to pass to the colon. These included the presence of bowel wall thickening on CT (72% of those who failed to pass contrast had showed bowel wall thickening vs 26% of those who passed contrast, $P < 0.01$), older age (median 57 years vs 54 years, $p = 0.05$), and number of comorbidities (median 4 vs 2, $p < 0.01$). There was also a statistically significant difference in the Serum WBC (p=<0.01), Lactic Acid (p=<0.01), and Bicarbonate (p=<0.01) levels at admission when comparing those who successfully cleared contrast to those who did not (Table 1).

Of the 283 patients included in the study (Fig. 1), 13% (n = 38) underwent immediate laparotomy because of concern for bowel compromise. Of these, 55% underwent adhesiolysis (LOA) alone, while the remaining 45% underwent small bowel resection. Patients needing immediate surgery had a median LOS of 7.5 days and an overall complication rate of 21%. Mortality rate in this cohort of patients was 2.6% (Table 3).

Of the remaining 245 patients who were candidates for WSC protocol, 80% (n = 197) received contrast. Contrast successfully passed to the colon in 144 of those patients (73%). Contrast passage was observed at 0–12 h in 107 patients and between 12 and 24 h in 37 patients. Of patients who cleared contrast in under 24 h, 92% were managed non-operatively; 8% of patients in whom contrast passage was observed at 24 h underwent surgery, with the decision to proceed to surgery despite passage of contrast to the colon ultimately having been at discretion of the Attending Surgeon based on clinical findings consistent with failure of resolution of obstruction. 47 patients (24%) had failure of contrast to progress to the colon within 24 h; of these, 96% underwent surgery. Of patients undergoing surgery, 40% underwent open LOA, 3% underwent laparoscopic LOA, and 52% required SBR (Fig. 1).

Among the 144 patients who had contrast passage to the colon successfully by 24 h, median LOS was 4 days (IQR 2–6). Complication rate was 3% (Table 2). Complication rate and LOS did not differ significantly between subjects who passed contrast in 12 h vs. those who cleared by 24 h. In the 47 patients who failed WSC, median LOS was 9 days (Table 2). Their complication rate was 49%.

Of the patients who were candidates for WSC protocol, 20% (n = 48) did not receive contrast, per discretion of the surgical team. Bivariate analysis shows that these patients differed from those who received the contrast in terms of initial lactate and WBC values, and swirl/whirlpool signs and wall thickening on initial CT, but were similar in other respects (age, sex, BMI, number of comorbidities) (Table 1). Of these, 73% were managed non operatively, while 27% underwent ultimately underwent SBR or LOA. In this cohort, 62% of patients underwent SBR, while 23% of patients underwent LOA alone.

Overall complication rate among patients receiving water soluble contrast was 14.2%, with the most common complication subtype being infectious. Among patients who underwent the protocol and had contrast passage, complication rate was 2.8%. Among patients who received contrast but failed to demonstrate contrast passage at 24 h, complication rate was 48.9%, with a majority of these complications again being infectious (either superficial or deep surgical site infections (SSI)). Among patients who were immediately taken to the OR, complication rate was 21%. Mortality rate amongst patients who underwent the protocol was 1.5%.

Discussion

The results of the present multicenter study demonstrate that implementation of a water-soluble contrast protocol can facilitate early differentiation between an SBO requiring surgical intervention from obstructions which can be managed conservatively. We previously performed a retrospective review of the outcomes of patients admitted to **a single** institution with SBO after WSC protocol implementation.[7] We chose to perform a multicenter trial following performance of said review for multiple reasons. Firstly, our results were found to be valid. Second, they can be repeated,

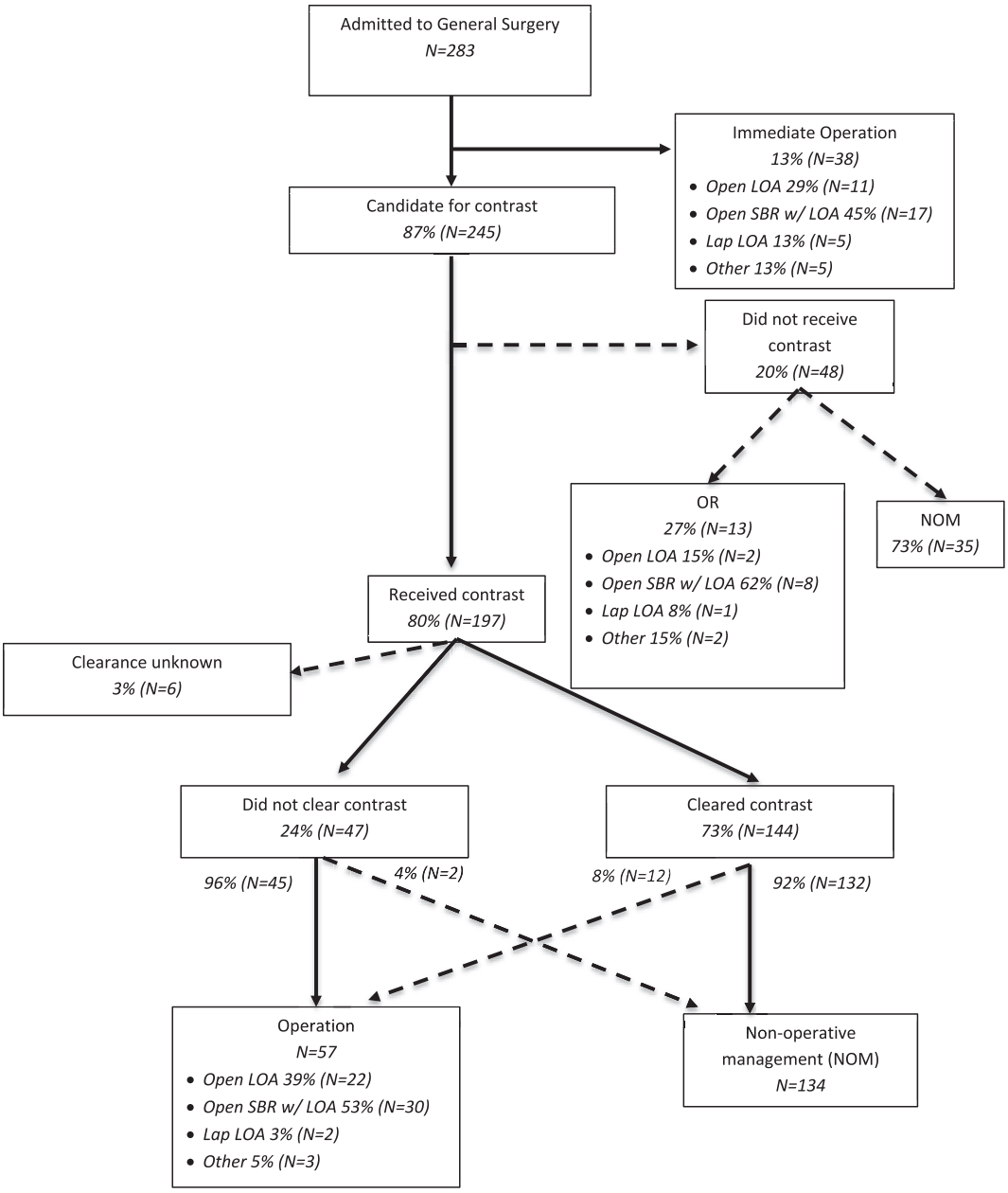

Fig. 1. Patient flow diagram.

and third the protocol was easily implementable at multiple centers, with different patient populations, making this protocol easily portable to other centers. This was a retrospective study of patients with SBO admitted to surgical services at five tertiary care centers that adopted a uniform protocol for management of SBO using WSC. This protocol was modified and adapted from prior published work.[6,7] The ability to differentiate which SBO patients can be managed non-operatively from those who require an operation promptly and accurately is paramount. Our study demonstrated that admission lab and CT imaging findings in this patient cohort can help identify patients for whom administration of water soluble contrast is unlikely to result in successful NOM. Using these data together with a standardized WSC protocol is safe and effective.

Other recent multicenter trials of similar protocols have demonstrated similarly promising results, one reporting that those patients who received WSC with gastrografin had lower rates of operative exploration, and had a shorter LOS as compared to those managed without WSC.[8] An earlier meta-analysis of eight studies demonstrated that not only did administration of WSC reduce need for operation and shorten LOS, but it also was effective in predicting the need for operation in patients with adhesive SBO, with 98% specificity and 96% sensitivity.[9] World Society of Emergency Surgery Guidelines (Bologna Guidelines) for the management of SBO suggest waiting 3 days before administration of contrast, and consideration of exploration for patients without presence of contrast within the colon 8 h after administration.[10] EAST guidelines recommend consideration of WSC in patients who do not demonstrate clinical resolution after 48 h.[11] Our current protocol called for 6 h of NGT decompression, followed by films at 12 and 24 h. In doing so earlier, we potentially decreased decision to operation as well as LOS in patients who are successful with NOM. In our study, 19% of patients (37/191) underwent WSC protocol

Table 1
Patient Demographics and Characteristics. Numbers represented as median (interquartile range) or % (n).

	All patients (N = 283)	Among all patients (n = 283)			Among all patients eligible for contrast (n = 245)			Among all patients receiving contrast with 24-h clearance status known (n = 191)		
		Straight to OR n = 38	Eligible for contrast n = 245	p-value	Received contrast n = 197	Did not receive contrast n = 48	P-value	Failure to pass contrast within 24 h n = 47	Contrast passed within 24 h n = 144	P-value
Age	56.0 (44.0–67.0)	56.0 (41.0–69.0)	56.0 (44.0–67.0)	0.78	55.0 (44.0–67.0)	62.0 (45.0–70.5)	0.17	57.0 (51.0–72.0)	54.0 (43.0–66.0)	0.05
BMI	27.0 (22.7–32.0)	27.5 (23.0–32.0)	27.0 (22.5–32.0)	0.78	27.0 (23.0–32.0)	27.0 (22.1–38.0)	0.58	26.0 (23.0–31.0)	27.1 (23.0–32.0)	0.50
Number of comorbidity categories	2.0 (1.0–3.0)	1.5 (0.0–3.0)	2.0 (1.0–4.0)	<0.01	2.0 (1.0–4.0)	2.0 (1.0–3.0)	0.07	4.0 (3.0–4.0)	2.0 (1.0–3.0)	<0.01
Number of CT findings	1.0 (0.0–2.0)	2.0 (1.0–3.0)	1.0 (0.0–1.0)	<0.01	1.0 (0.0–1.0)	1.0 (0.0–2.0)	0.45	1.0 (1.0–2.0)	0.0 (0.0–1.0)	<0.01
Initial WBC	12.2 (8.6–16.6)	10.8 (7.3–13.7)	12.5 (8.9–17.0)	0.02	13.2 (9.4–17.0)	10.6 (7.6–14.5)	0.02	18.0 (16.0–21.0)	12.0 (8.7–15.7)	<0.01
Initial Lactate	1.6 (1.1–2.1)	1.8 (1.0–4.8)	1.6 (1.1–2.1)	0.07	1.5 (1.1–2.0)	1.9 (1.3–2.8)	<0.01	2.0 (1.7–2.3)	1.4 (0.9–1.8)	<0.01
Initial Bicarbonate	24.0 (21.0–27.0)	26.0 (22.0–28.0)	24.0 (21.0–26.5)	0.09	24.0 (21.0–26.5)	24.0 (20.0–27.0)	0.65	20.0 (17.0–22.0)	25.0 (23.0–27.0)	<0.01
Sex (female)	54.4% (154)	63.2% (24)	53.1% (130)	0.24	52.8% (104)	54.2% (26)	0.86	42.6% (20)	54.2% (78)	0.17
CT: fecalization	16.8% (47)	13.2% (5)	17.4% (42)	0.52	15.9% (31)	23.4% (11)	0.22	12.8% (6)	15.5% (22)	0.65
CT: free fluid	32.1% (90)	52.6% (20)	28.9% (70)	<0.01	27.2% (53)	36.2% (17)	0.22	34.0% (16)	24.6% (35)	0.21
CT: wall thickening	35.0% (98)	42.1% (16)	33.9% (82)	0.32	36.9% (72)	21.3% (10)	0.04	72.3% (34)	26.1% (37)	<0.01
CT: closed loop	10.0% (28)	47.4% (18)	4.1% (10)	<0.01	3.6% (7)	6.4% (3)	0.41	8.5% (4)	2.1% (3)	0.07
CT: swirl/whirlpool	5.0% (14)	26.3% (10)	1.7% (4)	<0.01	0.5% (1)	6.4% (3)	0.02	0.0% (0)	0.7% (1)	>0.99

Note: No patients were missing data on age, sex, comorbidities, or WBC. Among all patients, 29 (10%) were missing an initial lactate measurement, 2 (1%) were missing initial bicarbonate, 30 (11%) were missing BMI, and 3 were missing all CT variables (1%).

without demonstration of contrast clearance by 12 h, but with clear demonstration of contrast clearance by 24 h. The complication rate in this cohort was only 2.7%.

In our current study, we evaluated patients with abdominal radiograph (AXR) at 12 and 24 h. In comparing the patients in whom contrast passage was demonstrated at 12 h to those in whom contrast passage was demonstrated between 12 and 24 h, we did not find a difference in LOS, complication rate, or mortality rate. Other groups obtained AXR at more frequent intervals – one group at 4, 8, 12, and 24 h for example.[6] We attempted to maximize efficiency and hospital throughput by obtaining less imaging, as we felt films at 4 and 8 h, would add little diagnostic value. While previous studies found no diagnostic advantage in waiting longer than 8 h for contrast to reach the colon,[9] **we identified that waiting up to 24 h identifies a significant number of patients that will pass contrast to their colon and do not need operative intervention. As such, doing so may prevent unnecessary operations and decrease hospital cost.**

Delay in appropriate and expeditious operative management of patients with small bowel obstruction may cause a profound increase in morbidity and mortality.[10] Adoption of a WSC protocol can help distinguish partial from complete SBO without increasing LOS, morbidity, or mortality, as has been previously reported.[4,6,9,12] Moreover, some investigators have found that administration of WSC reduces operative rates and success of conservative treatment,[10,13] and decreases postoperative complication, as well as subsequent risk of future SBO.[14] We found a 71% rate of successful non-operative management using our WSC protocol. Our successful use of a WSC protocol to differentiate those patients who require urgent surgical intervention from those who can be managed non-operatively, is consistent with previously reported success rates with WSC administration in patients with SBO.[6,9,10] In patients who underwent WSC protocol, median LOS was 5 days. This is comparable to the LOS observed in other studies after protocol implementation, with one study having observed decreased LOS to 3 days following implementation of WSC protocol, as compared to 11 days prior to protocol implementation.[6,10,15] This has tremendous implications in terms of health care utilization and hospital costs, as previously addressed in this manuscript.[3] **It is imperative to bear in mind that when managing patients with SBO with a WSC protocol, performance of serial abdominal exams and close monitoring of hemodynamics and laboratory values is key in differentiating those patients who may require prompt surgical intervention.**

We observed high complication rates in patients who underwent SBFT protocol and subsequently required an operation. In those that had a WSC challenge and did not clear contrast within 24 h, a significant proportion had complications that were secondary to surgical site infections (40.4%; Table 3). Surgical site infections are unlikely to be directly attributable to the administration of contrast. Other complications observed in this group (though not as frequently as infectious complications) included pneumonia, pulmonary embolism, atrial fibrillation, and myocardial infarction. It would be difficult to plausibly attribute the aforementioned complications directly, to the administration of Gastrografin contrast. The sole exception to this being, the possibility of pneumonia being caused secondary to an aspiration event related to gastrografin administration, however, we did not observe this on chart review in our cohort. This cohort of patients (those who failed to pass contrast) overall were older (57 vs 54), had more comorbidities at baseline and (4 vs 2; p=<0.01) (Table 1). The risk of postoperative complications is strongly predicted by the presence of preoperative comorbidities[16–18]; there is evidence that the presence of 3 or more comorbidities is the strongest preoperative risk factor in some populations.[18] While we observed high

Table 2
Outcomes. Values are shown as median (IQR) (n) or % (n).

	Underwent WSC Protocol (n = 197)	Underwent WSC Protocol; contrast passage by 12 h (n = 107)	Underwent WSC Protocol; contrast passage by 24 h (n = 37)	Underwent WSC Protocol; NO contrast passage at 24 h (n = 47)	Immediate operation (n = 38)	P (Immediate operation vs not clear in 24 h)	P (contrast passage by 12 or 24 h v, vs NO contrast passage)
Hospital LOS	5 (3–8) (197)	4 (2–5) (107)	4 (3–8) (37)	9 (7–11) (47)	7.5 (5–13) (38)	0.21	<0.0001
Surgery rate	29.4% (58/197)	6.5% (7/107)	13.5% (5/37)	95.6% (45/47)	100% (38/38)	0.50	<0.0001
Nights to Surgery	2 (1–3) (58)	1 (1–4) (7)	2 (2-2) (5)	2 (1–3) (45)	1 (0–1) (38)	0.02	0.77
Death Rate	1.5% (3/197)	0.0% (0/107)	0.0% (0/37)	6.4% (3/47)	2.6% (1/38)	0.62	0.01
30-day Readmission rate	10.2% (14/137[a])	10.1% (8/79[a])	9.5% (2/21[a])	12.9% (4/31[a])	8.8% (3/34[a])	0.70	0.74
Complication Rate	14.2% (28/197)	2.8% (3/107)	2.7% (1/37)	48.9% (23/47)	21.0% (8/38)	0.01	<0.0001

[a] 30-day readmission was unknown for some patients.

Table 3
Complication rates by protocol group and complication type, values shown as % (n).

	Underwent WSC Protocol (n = 197)	Underwent WSC Protocol; contrast passage by 12 h (n = 107)	Underwent WSC Protocol; contrast passage by 24 h (n = 37)	Underwent WSC Protocol; NO contrast passage at 24 h (n = 47)	Immediate operation (n = 38)
Overall Complication Rate	14.2% (28/197)	2.8% (3/107)	2.7% (1/37)	48.9% (23/47)	21.0% (8/38)
Cardiac	2.5% (5/197)	0.0% (0/107)	0.0% (1/37)	10.6% (5/47)	7.9% (3/38)
Pulmonary	6.1% (12/197)	2.8% (3/107)	0.0% (0/37)	17.0% (8/47)	13.2% (5/38)
Infectious	10.2% (20/197)	0.0% (0/107)	2.7% (1/37)	40.4% (19/47)	10.5% (4/38)
Renal	0.5% (1/197)	0.0% (0/107)	0.0% (0/37)	2.1% (1/47)	2.6% (1/38)
Death	1.5% (3/197)	0.0% (0/107)	0.0% (0/37)	6.4% (3/47)	2.6% (1/38)

complication rates in all operative groups, the complication rate in the group who failed contrast challenge and subsequently underwent surgery was higher than that in the group who went to the OR immediately. This may suggest that patients who meet certain criteria (a certain number of comorbidities, for instance), should be observed even more closely during the WSC challenge period, as they are at a significantly higher risk of developing complications following surgical intervention. Without a direct comparison group, we cannot rule out that earlier surgical intervention might have prevented some of these surgical infection. However, earlier surgical intervention would also likely have exposed a number of patients to operative risk unnecessarily as 32 of the 84 patients that did not have contrast passage at 12 h had contrast passage by 24 h and avoided surgery. Unfortunately, we did not collect data on perioperative antibiotic use or other measures during surgery to prevent SSI. This will be important in future studies now that we have identified that patients requiring surgery after contrast administration for SBO are a high risk group for SSI.

There are several limitations of our study. First, our analysis was performed as a retrospective review. As such, we are limited to the prospective recording of clinical findings, patient management, and subsequent **retrospective** data collection. Second as a **observational** study, we are unable to determine if this would have occurred with NGT decompression alone. Third, "time to surgery" was defined as "nights to surgery" in our dataset, and hours to surgery were not quantified. Fourth, this multicenter retrospective study only reviewed admissions during a one year time frame. No data as to long term follow-up or recurrence are known in this cohort. **We identified high rates of surgical site infection but did not have data on perioperative antibiotic use or intraoperative measures to reduce SSI. Additionally, patients admitted to medical services with SBO were notably excluded from this study, as the management of said patients did not always include consultation throughout their admission by the surgical service, and their management was not uniform. Comparison of management of SBO on surgical versus medical services is a possible topic for future study. Additionally, we did not have information on the underlying indication for bowel resection and are unable to determine what percentage of bowel resections were for ischemia.**

In summary, implementation of a WSC protocol facilitates early recognition of partial from complete small bowel obstruction. The popular adage "never let the sun set on a small bowel obstruction" still holds true in that these patients should be closely observed. However, rethinking which patients can safely be managed, overnight or longer, with NOM, as compared to those who need immediate operative intervention, is warranted **given the high complication rates in patients that are taken to the operating room in a delayed fashion. We believe that the use of enteric contrast aids in the identification of patients in whom non-operative management is unlikely to succeed. However, further work needs to be performed to identify which patients are best served going directly to the operating room and to identify factors to prevent surgical site infections.**

Declaration of competing interest

The authors have no conflicts and no reported funding.

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