Therapeutic Role of Gastrograffin in the Management of Post-Operative Adhesive Small Bowel Obstruction: A Randomized Trial

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ABSTRACT

Introduction: Small bowel obstruction is one of the commonly encountered clinical problems associated with repeated hospitalization. Data from the recent literature show that most of these studies have focused on the assessment of role of water-soluble contrast medium in adhesive small bowel obstruction. Hence; we planned the present study to assess the role of oral water soluble contrast agent in small bowel adhesive obstruction.

Material and methods: The study was conducted on 38 patients admitted with diagnosis of Anti Social Behaviour Orders (ASBO) in a tertiary care hospital. Diagnosis of ASBO was established on the basis of clinical history, examination and abdominal radiograph findings. Patients of both partial and complete obstruction were included. Close monitoring of vital and abdominal signs was done. Patients were randomized to receive Gastrografin (Group A) or Placebo (Group B) In patients with of Group A, 60 ml of Gastrografin admixed with 40 ml of normal saline was administered after two hours of active stomach decompression through nasogastric tube. It was clamped for next three hours. Control Group B received 100 ml of normal saline in similar fashion. Patients of both groups were closely monitored by repeated clinical examination without further radiological examination. All the results were recorded and analyzed.

Results: Out of 102 patients who presented with small bowel obstruction, 38 patients of ASBO who fulfilled inclusion and exclusion criteria were enrolled for the study, 21 in Group A and 17 in Group B. All patients completed the study period. All patients were hemodynamically stable on presentation. Abdominal girth monitoring was a statistically significant factor predicting outcome in patients with ASBO with sensitivity of 75%, specificity of 96.15%, positive predictive value of 90% and negative predictive value of 89.29%. Hospital stay was significantly shorter in Group A (p value < 0.05).

Conclusion: Administration of oral water soluble contrast agents in cases of ASBO is recommended.

Keywords: Adhesive, Gastrograffin, Small Bowel Obstruction

INTRODUCTION

Small bowel obstruction is common clinical problem associated with repeated hospitalization and high morbidity accounting for 20% of all emergency surgical admissions. Post-operative adhesions account for about 50% of patients presenting with small bowel obstruction. Conservative management is the norm in these patients unless there are clear cut signs of bowel ischemia.[1] Patients with Anti Social Behaviour Orders (ASBO) require careful monitoring. Most cases resolve after a trial of conservative treatment.[2]

The predictive role of water-soluble contrast to triage patients with ASBO to an operative or a non-operative course is well documented. Recently, it has been used for therapeutic purposes in conservative management.[3] One of the leading causes of hospital admission is Adhesive small bowel obstruction. Still uncertainty exists in relation to the natural cause of this clinical problem. Patients with this condition are often difficult to assess and require careful evaluation and management. Immediate surgery is recommended when strangulation is suspected or in complete bowel obstruction. A trial of conservative treatment is acceptable if the obstruction is incomplete. However, the optimal duration of this trial of conservative treatment has not been well defined.[4]

Data from the recent literature show that most of these studies have focused on the assessment of role of water-soluble contrast medium in adhesive small bowel obstruction. Studies have documented a diagnostic value of this contrast medium in assessing the need for surgical treatment. A possible therapeutic effect of this agent has also been suggested, but the efficacy is still controversial.[5]

This study aimed at assessing the role of oral water soluble contrast agent in small bowel adhesive obstruction.

MATERIAL AND METHODS

The study was one and a half year prospective, randomized study conducted on 38 patients admitted with diagnosis of ASBO in a tertiary care hospital of Northern India Institutional ethics committee approval was taken. Inclusion criteria included all casesof post-operative intestinal obstruction more than 12 years, who presented with clinical and radiological evidence of SBO. Exclusion criteria included patients presenting within four weeks of previous surgery, patients who underwent abdominal radiotherapy, patients with history of hypersensitivity to iodine, patients presenting after 48 hours of conservative treatment and patients with signs of strangulation or peritonitis. Diagnosis of ASBO was established on the basis of clinical history, examination and abdominal radiograph findings. Patients of both partial and complete obstruction were included.All patients were promptly hydrated with intravenous fluids on the basis of pulse, blood pressure, central venous pressureurine output and electrolyte imbalances were corrected.Nasogastric tube was placed. Close monitoring of vital and abdominal signs was done. Patients were randomized to receive Gastrografin

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How to cite this article: Ashish Chhabra, Ashwani Kumar, Shekhar Upadhyay, Michael Deodhar. Therapeutic role of gastrograffin in the management of post-operative adhesive small bowel obstruction: a randomized trial. International Journal of Contemporary Medical Research 2017;4(4):857-860.

(Group A) or Placebo (Group B) In patients with of Group A, 60 ml of Gastrografin admixed with 40 ml of normal saline was administered after two hours of active stomach decompression through nasogastric tube. It was clamped for next three hours. Control Group B received 100 ml of normal saline in similar fashion. Patients of both groups were closely monitored by repeated clinical examination without further radiological examination. End points were taken as resolution of obstruction ie passage of flatus and/ or bowel motion, length of hospital stay and failure of conservative management. The indications for surgery were: persistence of ASBO for 48 to 72 hours after admission or clinical deterioration with persistence or worsening of obstruction and signs with symptoms of strangulation or peritonitis. The criteria for discharge were patient free from obstructive symptoms and tolerating normal diet.

STATISTICAL ANALYSIS

The findings were analyzed using SPSS version 10.0 (SPSS Inc., Chicago IL). Values were expressed as mean ± SD. The Chi square test was used to analyze categorical variables. Student's unpaired t-test was used to compare statistical significance of numerical variables. p value less than 0.05 was considered as statistically significant.

RESULTS

Out of 102 patients who presented with small bowel obstruction, 38 patients of ASBO who fulfilled inclusion and exclusion criteria were enrolled for the study, 21 in Group A and 17 in Group B. All patients completed the study period. Both groups were well matched in relation to age and gender (Table 1). Chief complaints in order of frequency were abdominal distension (100%), pain (97.37%), obstipation and vomiting (81.58%) (Table 2). All patients were hemodynamically stable on presentation. Abdominal girth monitoring was a statistically significant factor predicting outcome in patients with ASBO with sensitivity of 75%, specificity of 96.15%, positive predictive value of 90% and negative predictive value of 89.29%. The average time from onset of symptoms to admission in Group A and Group B was comparable. No. of previous episodes of ASBO was also comparable in both the groups. However, patients with multiple previous surgeries were significantly higher in Group B (p value-< 0.05). No. of patients with complete obstruction, as defined by absence of gas in large bowel was significantly more in Group B (p value< 0.05). Various laboratory parameters like haemoglobin, TLC, electrolytes, renal profile and serum Ph at the time of admission was analyzed and found to be comparable in both groups (Table 3). Patients in this study tolerated Gastrografin well without any adverse effects. Out of the 21 patients in Group A, 18 patients (85.71%) had resolution of ASBO with conservative management with surgery required in only 3 (14.3%).surgery was required in 9 (52.94%) in Group B with successful resolution of ASBO with conservative management in only 8 (47.06%). ASBO was resolved within first twenty four hours of admission in 77.78% patients of Group A and 37.50% patients of Group B. Patients who were managed conservatively in Group A and Group B had a mean stay of 4.37 ± 1.48 days and 6.31 ± 2.76% days respectively. Hospital stay

Variables		Group A	Group B	*P* value
Mean age ± SD (Years		43.71 ± 13.27	46.02 ± 14.36	> 0.05
Range		(14-72)	(15-81)	
Gender (Male : Females		11:10	10:7	
Previous abdominal surgeries (%)	Single	12 (57.14)	4 (23.53)	< 0.05
	Multiple	9 (42.86)	13 (76.47)	
Type of previous surgery	Gynaecological	7	5	< 0.05
	Colorectal	5	7	
	Appendicectomy	9	8	
	Small bowel resection and anastomosis	2	4	
	Others	10	12	
Previous admissions with ASBO mean		0.73 ± 0.91 (0-3)	0.89 ± 1.32 (0-5)	>0.05
Days from onset of symptoms mean		1.31 ± 0.88	1.42 ± 0.96	>0.05

Table-1: Age, gender and distribution with clinical history variables

Clinical variables		Group A		Group B		p-value
		Present	Absent	Present	Absent	
Discrete variables	Pain	20	1	17	0	> 0.05
	Vomiting	18	3	15	2	
	Vomiting	18	3	16	1	
	Abdominal distension	16	5	14	3	
Increase in abdominal girth		4	17	6	11	> 0.05
Pulse/ min Mean ± SD (Range		93.57 ± 11.83		96.37 ± 13.81		> 0.05
SBP (mmHg) Mean ± SD (Range		93.57 ± 11.83		96.37 ± 13.81		
SBP (mmHg) Mean ± SD (Range		79 ± 16		96.37 ± 13.81		
Abdominal radiograph (%)	Partial	13 (61.90)		6 (35.29)		> 0.05
Range	Complete	8 (38.10)		11 (64.71)		
Note- SBP: Systolic blood pressure; DBP: Diastolic blood pressure						

Table-2: Clinical features

was significantly shorter in Group A (p value< 0.05). Patients who underwent an operation in Group A had a mean length of hospital stay of 9.82 ± 1.43 days as comparable to 10.03 ± 2.19 days for those in Group B. (p-value < 0.05)

DISCIUSSION

Post-operative small bowel obstruction leads to repeated hospital admissions with significant high morbidity and significant mortality. The most common cause of small bowel obstruction is adhesive obstruction. Post-operative adhesions cause SBO in about 11% of all patients undergoing laparotomy. SBO can be a complication of any abdominal operation. The reported operative rate of ASBO ranged from 27% to 42%. It was 31.58% in our study.[6] Previous studies have reported that surgeries in infracolic compartment like appendicectomy and colorectal surgery are the most commonly associated with ASBO.[7] Our results showed that gynaecological operations like abdominal hysterectomy were also commonly associated with ASBO.

The management of ASBO has remained controversial. Most patients received trial of conservative treatment initially unless there was suspicion of strangulation. However, the optimal duration of conservative trial is not clear on safety and duration for ASBO.[8]

Cox et al reported that in 88% of patients managed conservatively, obstruction resolved within 48 hours.[9] Assalia et al[10] recommended that surgery should be considered if the obstruction failed to improve after 48 hours of conservative treatment. The role of water soluble contrast agent in diagnosis and predicting outcome in ASBO is well known. Recently, the role of water soluble contrast has been investigated in patients with ASBO. Gastrograffin is commonly utilized contrast medium. It is a mixture of sodium diatrizoate and meglumine diatrizoate and a wetting agent (Polysorbate 80). Its osmolarity is 1900 mOsm/ L which is around six times that of extracellular fluid. It activates movement of water into the small bowel lumen, decreasing bowel wall oedema and enhancing smooth muscle contractility.It is relatively safe, eventhough rare complications like anaphylactoid reaction and lethal aspiration have been reported. The therapeutic effect of Gastrografin in ASBO is controversial. Assalia et al reported prompt resolution of ASBO, shortened hospital stay and reduced need for surgery.[10] However, Feigin et al reported no advantage of Gastrografin in ASBO.[11] Similar results were obtained in Fevang et al's study.[12] In Cochrane review; Abbas et al in 2004, concluded that Gastrografin does not cause resolution of ASBO,does appear to reduce hospital stay.[13] Several authors have stated that the use of gastrogaffin accelerates the recovery of ASBO, by a specific therapeutic effect.[14-16]

Variable	Mean ± SD (Range		P value
	Group A	Group B	
Hb (g/dl)	11.29 ± 2.61	12.13 ± 1.96	> 0.05
TLC (mm³)	9430 ± 2170	9130 ± 2390	
Na (mmol/L)	134 ± 4.37	137 ± 6.8	
K (mmol/L)	4.2 ± 0.92	4.4 ± 0.67	
Urea (mg/dl	52 ± 38	49 ± 33	
Creatinine (mg/dl	1.1 ± 0.5	0.9 ± 0.8	
pH	7.32 ± 0.07	7.35 ± 0.08	

Table-3: Laboratory parameters

In our study, patients were classified as having partial or complete ASBO on the basis of abdominal radiograph on admission. The decision for surgery was based on clinical assessment by admitting surgeon as and when indicated. Both the groups were well matched in relation to age, gender, type of previous surgery, previous admissions with ASBO and days from onset of symptoms to admission. Patients with multiple previous surgeries and complete obstruction based on radiology were significantly more in Group B. Signs and symptoms analyzed were well matched in both groups. Persistent increase in abdominal girth was a significant predictor of failure of conservative management. Laboratory parameters were well matched in both the groups.

In our study, 68.42% patients were successfully managed conservatively which is comparable to most of the previous studies. Success rate was 85.71% in Group A and 47.06% in group B.

Though a significantly higher number of patients with history of multiple surgeries and complete obstruction were in placebo group and this seemed to be a confounding factor, still the statistically significant correlation of Gastrograffin administration and success of conservative management could be attributed to its well defined therapeutic effect.

Hospital stay was studied in both groups. The length of hospital stay for patients managed conservatively in Group A was significantly shorter than their counterparts in Group B. Patients who had operative intervention had comparable hospital stay which was statistically insignificant. 77.78% of Group A patients managed conservatively had resolution of symptoms within first 24 hours. It was 37.50% in their counterparts of Group B.Hospital stay in operative patients was comparable, may be because of other confounding factors related to surgery and post operative recovery.

Choi et al assessed the therapeutic value of Gastrografin in

End Point variable		Group A	Group B	P-value
		Number(%)	Number(%)	
Final management	Conservative	18 (85.7)	8 (47.06)	< 0.05
	Operastive	3 (14.3)	9 (52.94)	
Time taken for resolution	0-24 hours	14 (77.78)	3 (37.50)	< 0.05
	24-48 hour	3 (16.67	3 (37.50)	
	48-72 hour	1 (5.56)	2 (25.00)	
Mean				
Hospital stay in	Conservative management	4.7 ± 1.8	72 ± 1.6	< 0.05
	Operative management	10.4 ± 2.3	11.2 ± 2.1	< 0.05

Table-4: Final outcome

the management of adhesive small bowel obstruction after unsuccessful conservative treatment. Patients with clinical evidence of adhesive small bowel obstruction were given trial conservative treatment unless there was suspicion of strangulation. Those who responded in the initial 48 hours had conservative treatment continued. Patients showing no clinical and radiologic improvement in the initial 48 hours were randomized to undergo either Gastrografin meal and follow-through study or surgery. For patients who had conservative treatment for more than 48 hours with or without Gastrografin, surgery was performed when there was no continuing improvement. One hundred twenty-four patients with a total of 139 episodes of adhesive obstruction were included. Gastrografin study revealed partial obstruction in 14 patients. Obstruction resolved subsequently in all of them after a mean of 41 hours. The other five patients underwent laparotomy because the contrast study showed complete obstruction. The use of Gastrografin significantly reduced the need for surgery by 74%. There was no complication that could be attributed to the use of Gastrografin. No strangulation of bowel occurred in either group. The use of Gastrografin in adhesive small bowel obstruction is safe and reduces the need for surgery when conservative treatment fails.[14]

Choi et al evaluated the effectiveness of gastrografin in adhesive small bowel obstruction when conservative treatment failed. Patients with adhesive small bowel obstruction were given trial conservative treatment unless there was fear of bowel strangulation. Those responded in the initial 48 h had conservative treatment continued. Patients who showed no improvement in the initial 48 h were given 100 mL of gastrografin through nasogastric tube followed by serial abdominal radiographs. Patients with the contrast appeared in large bowel within 24 h were regarded as having partial obstruction and conservative treatment was continued. Patients in which the contrast failed to reach large bowel within 24 h were considered to have complete obstruction and laparotomy was performed. Two hundred and twelve patients with 245 episodes of adhesive obstruction were included. Fifteen patients were operated on soon after admission due to fear of strangulation. One hundred and eighty-six episodes of obstruction showed improvement in the initial 48 h and conservative treatment was continued. The use of gastrografin in adhesive small bowel obstruction after unsuccessful conservative treatment is safe and reduces the need for surgical intervention.[17]

CONCLUSION

The study though limited in number of patients, demonstrated that administration of oral water soluble agent in cases of ASBO has a definite therapeutic role in their management. It helps in early resolution of intestinal obstruction and also decreases the total length of hospital stay in patients managed conservatively. We recommend the administration of oral water soluble contrast agents in cases of ASBO. We propose multicentre studies based on large number of patients further validate our study.

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 16-03-2017; **Accepted:** 15-04-2017; **Published:** 26-04-2017