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Original Article

Nonsurgical Management of Partial Adhesive Small Bowel Obstruction with Bisacodyl Suppository Combine Intravenous Metoclopramide Therapy: A Randomized Control Trial

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Abstract

Background and Objective: Patients with clinical feature of small bowel obstruction and present of previous abdominal surgery should be suspected of adhesive small bowel obstruction especially midline incision. Previous study of oral laxative drug with digestive agent was a conservative treatment that this approach is associated with the hospital stays and risk of delayed surgery. The aims of the present randomized controlled trial study were to investigate a combining standard conservative treatment using Bisacodyl suppository with intravenous metoclopramide for partial adhesive small bowel obstruction comparing with the control group which nothing by mouth, intravenous hydration and nasogastric tube decompression.

Materials and Methods: 120 patients admitted between January 2019 - December 2020 with symptom and sign suggestive of partial adhesive small bowel obstruction were randomized to receive either the control group (nothing by mouth, intravenous hydration and nasogastric tube decompression) or treatment group (Bisacodyl suppository and intravenous metoclopramide). The primary outcome included time to first flatus and defecation, number of successfully treatment without surgery, and length of hospital stay were recorded.

Results: A total of 120 patients were included in this study, 60 patients in each treatment group and control group. The treatment group was more effective than the control group in the time of flatus and defecation ($p < 0.001$), and lower number surgical need than another group with statistic significantly ($p < 0.05$). Also, average length of hospital stay in the treatment group was shorter than the control group with statistically significant at $p < 0.001$. There were no statistically significant differences between patients in both groups in terms of age, gender, and type of previous surgical incision as baseline.

Conclusion: Bisacodyl suppository and metoclopramide intravenous injection was safe and effective without complication to use in patients. It was effective in hastening the resolution of conservatively treated partial adhesive small bowel obstruction and shortening the hospital stay.

Keywords: Adhesive small bowel obstruction, Bisacodyl suppository and metoclopramide, Randomized controlled trial, Nonsurgical management

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Introduction

About 95% after abdominal surgery in adult were develop small bowel obstruction and 65% to 75% are cause by adhesion.[1] Conservative management included intravenous hydration, nasogastric tube or long tube decompression and nothing by mouth were successes in 73-90% of case.[2,3] Midline surgical operation associate higher risk of adhesive small bowel obstruction.[4] Laparoscopic surgery may reduce incidence of adhesive small bowel adhesion and incisional herniation.[5] There are many studies to compare traditionally conservative management with gastrointestinal contrast study.[6-10] The study was significantly in management of small bowel obstruction leading to shorter hospital stayed but did not reduce the need for operation.

Few studies of cisapride a prokinetic agent have been in postoperative ileus trial and it has been advantage in reducing hospital stay but it must be used in caution because of cardiovascular adverse effect.[11-12] Metoclopramide is a prokinetic of stomach and small bowel, it acts at the level of acetylcholine and dopamine receptor for stimulating peristalsis but it is contraindication in patients with completed bowel obstruction. Metoclopramide has been very effective in patients of malignant incomplete small bowel obstruction.[13] Previous study of oral laxative drug, digestive agent and defoaming agent (magnesium oxide, Lactobacillus acidophilus and simethicone) it was effective in resolution of conservative treatment in partial adhesive small bowel obstruction and shortening of hospital stay.[14] Rectal suppository laxative was advantage of locally effort on patients. A small number of study of Bisacodyl suppository was used in post operative ileus patients.[15-16] One randomize controlled trial of bisacodyl suppository versus placebo for post operative ileus after elective Colectomy of colon cancer, it seem to be effective in resolving post operative ileus and may decrease the length of hospital stayed without increase risk of postoperative complications.[16] However no randomized studies have been published of both metoclopramide and Bisacodyl suppository in partial adhesive small bowel obstruction.

This study conducted a randomized controlled trial aimed to investigate the conservative treatment using bisacodyl suppository combined with intravenous metoclopramide for partial adhesive small bowel obstruction patients, this study hypothesized that the treatment group may be more effective than the control group in the aspect of the time of flatus and defecation, number of subsequent surgical interventions, the length of hospital stays.

Materials and Methods

Study design

A randomized controlled trial was used to investigate the effect of Bisacodyl suppository combine intravenous metoclopramide therapy for patients with partial adhesive small bowel obstruction. Participants were randomly assigned to one of two groups: Group I (control) received nothing by mouth, intravenous hydration and nasogastric tube decompression and Group II (treatment) received bisacodyl suppository and intravenous metoclopramide. After recruitment and screening of participants, baseline assessment was conducted before the intervention.

Patients and Methods

The inclusion criteria were as following: (1) History of midline surgical wound incision (2) Age > 18 years (3) Clinical symptom and sign compatible with cardinal sign of partial small bowel obstruction such as colicky abdominal pain, abdominal distension, vomiting and obstipation, and (4) Pain film acute abdomen series was shown the dilatation of small bowel loop (small bowel distention > 3 cm) with air fluid level and present of gas in rectum to confirm of partial small bowel obstruction. Exclusion criteria were: (1) Age below 18 years old (2) Clinical suggest of completed small bowel obstruction or strangulation (absence gas in large intestine or rectum, fever or peritonitis) (3) Previous treatment of radiation (4) Post operation within 4 weeks (5) Multiple surgery (more than 2 times) (6) Peritoneal carcinomatosis, and (7) None of midline skin incision such as appendectomy incision or cholecystectomy incision.

All patients arrived in emergency department; inclusion cases were enrolled in this study by emergency staff. Laboratory, plain film acute abdomen or CT scan was performed for evaluated closed loop obstruction or strangulation. At surgical ward the patients were randomized into two group by attending surgeon. Both groups are equal number of patients either control group (patients with intravenous fluid, nothing per oral and nasogastric tube decompression) or treatment group (patients with bisacodyl suppository once daily and intravenous metoclopramide every 8 hour) add to the conservative treatment.

All patients in both groups were followed clinical and repeat abdominal radiography after 24 hour and once daily until obstruction resolved by improved radiographic appearance or passage of flatus and defecation. Nasogastric tube was removed after clinical and radiographic showed resolution of partial adhesive small bowel obstruction was confirmed. Step oral liquid diet to solid soft diet was started. The attending surgeon were assessed discharge criteria as following: (1) Clinical abdominal pain was subsided and solid diet was tolerated (2) Flatus was pass and pain film abdomen showed absence of gas in small bowel and present gas in colon or rectum. If symptom of complications were developed such as fever, leukocytosis, peritonitis or obstruction did not resolve spontaneously after 3 days, then a laparotomy was performed by attending staff decision.

Ethical Considerations

The Ethics committee for medical research approved by IRB protocol and inform consent were written for all patients. Ethical considerations were taken from the ethical committee of Kratumbann Hospital (Registration No: 043/62). The protected samples were obtained as personal information and ethical concerns, which included informed-consent and maintaining confidentiality. The samples had the right to cancel participation in the study at any time without any impact.

Data Collection and Measurements

A randomize controlled clinical trial was performed for all patients who were admitted in Kratumbann Hospital during January 2019 - December 2020 with clinical of partial small bowel obstruction were consider. Baseline data included age, gender, diagnosis, symptom and previous surgery were recorded. The primary outcome was the days of the first passage to flatus and stool were observed. Secondary outcome measures were the length of hospital stayed and number of patients who need operative intervention.

Data Analysis

Data were double entered into the statistical program by research assistants. The outcome measures were presented as means and standard deviations. All analyses were performed on the basis of intention to-treat. Statistic comparative data were analyzed by Chi-square test, Fischer's exact test and independent t-test (p-value < 0.05).

Results

Total of 134 patients with adhesive small bowel obstruction during study period, there were 120 patients fulfilled the inclusion criteria for this study and all research consented were participated, 14 patients were excluded by exclusion criteria (Figure 1). Sixty patients were randomized into conservative group (control group) and sixty patients in the treatment group.

Baseline and demographic data were presented (Table 1). Patients in both groups had similar characteristic and did not differ significantly in gender ratio, age, and type of previous operative incision.

The overall outcome of patients in both groups were present in Table 2. The time of flatus and defecation are the most obvious differences. In the treatment group was higher successful of timing of flatus and defecation before day 3 than the control group with statistic significantly ($p < 0.001$). The average length of hospital stay was shorter in the treatment group (2.55 vs. 4.41 days) than the control group with statistic significantly ($p < 0.001$). The number of surgical needs was lower in the treatment than the control group. There were seven patients who need surgical operation in the treatment group which was lower than 19 patients in the control group with statistic significant difference between two group ($p = 0.047$).

The details of patients showed that 19 patients who required surgical operation in the control group, one patient had small bowel resection due to bowel ischemia. Most common indication for surgery was fail in the conservative treatment after 3 days (n = 18), seven patients in treatment group required operative treatment after failed 3 times of bisacodyl suppository and two patients were successful in Laparoscopic adhesiolysis procedure. During study period was found recurred in three patients after the first obstruction was resolved. Two patients were enrolled as new cases in the same group (conservative group) and one of two patient was failed for conservative treatment then the open adhesiolysis was performed. Other one patient was enrolled in the different group (treatment group) and patient's symptoms was improved before 3 days. The definition of patients with recurrence is the patient who discharge from the hospital more than 7 days and they will count as new cases. There was one patient was readmitted in 72 hours after discharge was excluded.

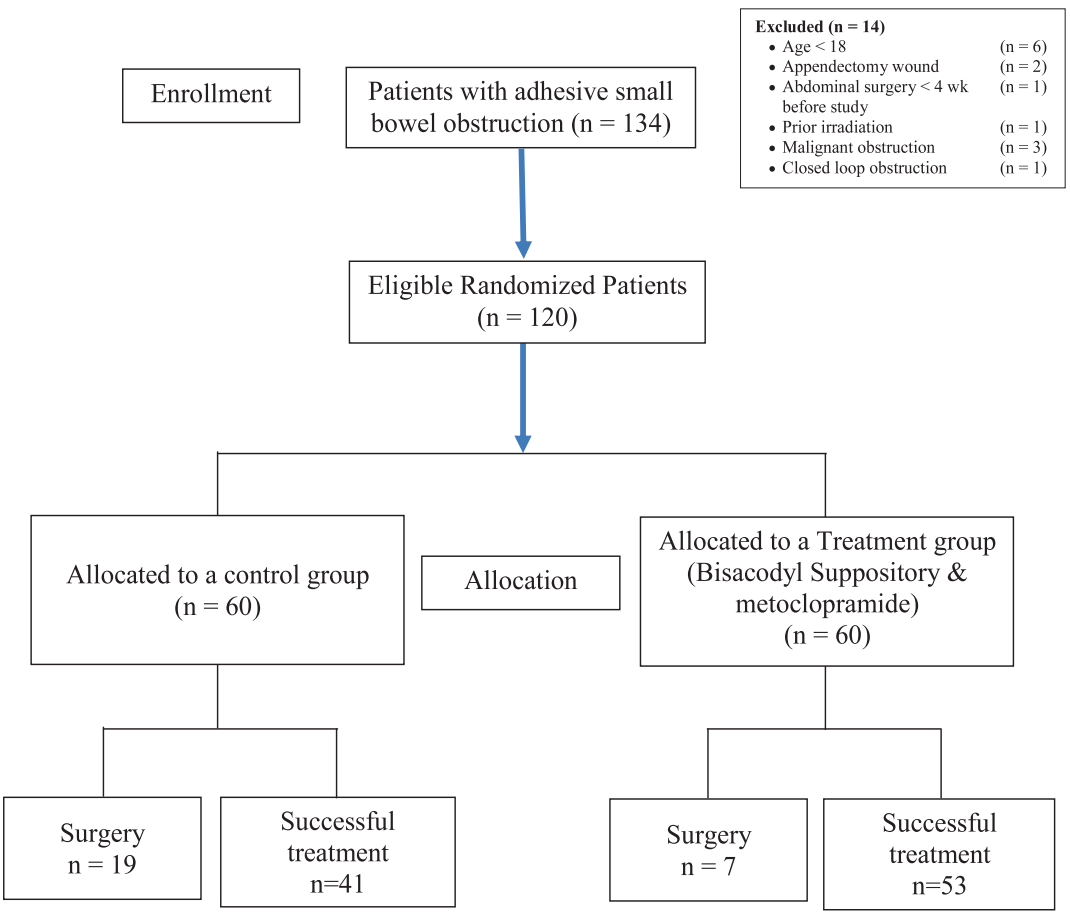

Figure 1 Flow chart of the progression of participants through the phases of the randomized controlled trial (RCT)

Table 1 Baseline and demographic of patient characteristics in the control group (n = 60) and treatment group (n = 60)

Characteristics	Control group (n = 60)	Treatment Group (n = 60)
Gender		
Male: Female	34: 26	32: 28
Age	($\bar{x}$ = 57.58, SD = 20.68, 18-92)	($\bar{x}$ = 52.83, SD = 18.70, 19-92)
Previous Surgery		
Lower line	13	11
Middle line	45	48
Upper line	2	1

Table 2 Comparison of outcomes between the control group and the treatment group

Outcomes	Control group (n = 60)	Treatment Group (n = 60)	*p*-value
Time of flatus			0.001[c*]
Day 3 or before	27	55	
After day 3	33	5	
Time of defecation			0.001[c*]
Day 3 or before	16	50	
After day 3	44	10	
Surgery needed			0.047[a*]
Open adhesiolysis	17	5	
Laparoscopic adhesiolysis	1	2	
Bowel resection	1	0	
Surgical indication			0.012[b*]
Failure of treatment	18	7	
Complication	1	0	0.05
Length of hospital stay	($\bar{x}$ = 7.07, SD = 4.41, 2-30)	($\bar{x}$ = 3.58, SD = 2.55, 2-12)	0.01[c*]

[a] Chi-square test, [b] Fisher's exact test, [c] Independent t-test (*p*-value < 0.05)

No patient was recurrence in same admission and patients was readmitted within 7 days were not count in the new case. No complication from Bisacodyl and metocloplamide used was seen.

Discussion

The results of this study showed the number of patients in the treatment group (Bisacodyl suppository with Metoclopramide injection) was statistically significant with higher successfully than the control group (conservative treatment) in reduce of length of hospital stay and number to surgery need. Additional therapy for non-operative management should be recommend without complications.

Various studies have been used other method of non-operative treatment to managed patients adhesive small bowel obstruction but controversy still remain.[17-20] Delayed operative treatment were increased mortality rate to about 30% in strangulate turn to necrosis or perforation.[21] Computed tomography may improve the accuracy of diagnosis especially completed closed loop obstruction or strangulation in small bowel obstruction.[22-24] This study used CT scan for excluded case of completed small bowel obstruction and malignant small bowel obstruction follow by exclusion criteria, not for all patients. Our study in the arm of treatment group had not seen complications from the delayed surgery (bowel resection) compared with the control group.

Previous randomized controlled trial studies for management of adhesive small bowel obstruction with oral magnesium oxide, lactobacillus acidophilus and simethicone were found that significant shorter hospital stayed than patients in the control group and number need to surgery was very low[14] because it had been effective to stimulation of bowel movement and subsequently cause the bowel empty. They did not used a prokinetic agent, which might have otherwise increase peristalsis.

Our study showing in a Randomized controlled trial that prokinetic agent and laxative drug which might have increased peristalsis to accelerated the passage of gas through the intestinal lumen and consequently reducing constipation and abdominal distension symptoms are effective and safe, no complication was seen. The use of suppository laxative to stimulated bowel movement should be quite safe and not effort on part of the patients unlike oral laxative. The laxative is almost entire locally. We used prokinetic drug to reduced gaseous symptom and promote spontaneous passage of stool and abdominal distension in intervention group. Patients given additional intravenous metoclopramide combine bisacodyl rectal suppository were more successfully spontaneous resolution than conservative treatment alone.

In systemic review study operative versus non operative management of adhesive small bowel obstruction and benefit of operative treatment is low risk of future recurrent but higher risk of mortality and complication.[25]

Laparoscopic adhesiolysis has been shown to be quickly recover in a experience hands, patients selection to laparoscopic adhesiolysis was consider and surgical judgment to be the most important factor for successful outcome.[26] In our study were 3 patients was performed laparoscopic adhesiolysis in both arm of study and post operative recovery was shorter than open exploratory adhesiolysis. Early laparoscopic adhesiolysis will be more successful and short recovery time in the intervention group than conservative group but surgeon experience is the most important consider.

Several limitations of our study were observed first, the study was prospective randomization but not double blind that cause attending bias in patients management. Second all surgical midline skin incision not excluded emergency or contamination case that potential present of severe adhesion cause some case not successfully treated. Third, this study didn't not conduct only one attending staff that cause of delayed decision making for time or type of surgical operation in case that fail conservative treatment, may cause prolong hospital stay.

Compared with conservative management, the additional of Bisacodyl suppository and prokinetic metoclopramide to be effective resolving in partial adhesive small bowel obstruction and may reduce surgical need and decrease the length of hospital stay without increase complication.

Conclusion and Recommendation

Bisacodyl suppository and prokinetic metoclopramide to be effective resolving in partial adhesive small bowel obstruction and may reduce surgical operation and decrease the length of hospital stay without complication. Further studies need to examine the early laparoscopic adhesiolysis compare to non-operative treatment with metoclopramides and Bisacodyl suppository for recurrent rate, return to work and hospital stay in prospective Randomized controlled trial.

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Ethical Considerations

Ethical considerations were taken from the ethical committee of Kratumbann Hospital (Registration No: 043/62). The protected samples were obtained as personal information and ethical concerns, which included informed-consent and maintaining confidentiality. The samples had the right to cancel participation in the study at any time without any impact.

Disclosure

The authors have no conflicts of interest.

Author Contributions

Conception and study design: SW; data collection and analysis: SW; manuscript preparation: SW & NS.

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บทคัดย่อ

การศึกษาเปรียบเทียบระหว่างการใช้ยาเหน็บถ่าย (Bisacodyl) ร่วมกับยาฉีดกระตุ้นการบีบตัวของลำไส้ (Metoclopramide) กับการไม่ได้รับยาในผู้ป่วยภาวะลำไส้อุดตันจากพังผืดในช่องท้อง

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ความเป็นมา: ผู้ป่วยที่มีอาการแสดงของภาวะลำไส้อุดตันและมีแผลผ่าตัดทางช่องท้อง ส่วนใหญ่ได้รับการรักษาโดยการงดน้ำงดอาหาร ให้สารน้ำ และใส่สายระบายทางกระเพาะอาหาร การศึกษาก่อนหน้านี้ได้มีการใช้ยาถ่ายชนิดกินทางปาก (Magnesium oxide) ร่วมกับยาช่วยย่อย พบว่าช่วยลดอัตราการผ่าตัดและลดระยะเวลาการนอนโรงพยาบาล ในการศึกษานี้มีจุดประสงค์เพื่อเปรียบเทียบการใช้ยาเหน็บถ่าย (Bisacodyl) และยาฉีดกระตุ้นลำไส้ (Metoclopramide) ร่วมกับการรักษาแบบเดิมกับกลุ่มที่ไม่ได้รับยา

วิธีการศึกษา: เป็นการเก็บข้อมูลผู้ป่วยที่มีอาการแสดงของภาวะลำไส้อุดตันจากพังผืดในช่องท้อง จำนวน 120 คน ตั้งแต่เดือนมกราคม พ.ศ.2562 ถึงเดือนธันวาคม พ.ศ.2563 โดยเปรียบเทียบระหว่างกลุ่มที่ได้รับยาเหน็บถ่ายและยาฉีดกระตุ้นลำไส้ร่วมกับการรักษาแบบเดิมกับกลุ่มที่ไม่ได้รับยา เพื่อดูผลการตอบสนองจากการผายลมและการถ่ายอุจจาระ รวมถึงอัตราการได้รับการผ่าตัดและระยะเวลาในการนอนโรงพยาบาล

ผลการศึกษา: ในผู้ป่วยจำนวน 120 คน แบ่งเป็น 2 กลุ่มในกลุ่มทดลองและกลุ่มควบคุม กลุ่มละ 60 คน ผลการเปรียบเทียบระหว่าง 2 กลุ่ม พบว่ากลุ่มที่ได้รับยาเหน็บถ่ายร่วมกับยาฉีดกระตุ้นการบีบตัวของลำไส้สามารถผายลมและถ่ายอุจจาระได้ก่อนวันที่ 3 เทียบกับกลุ่มที่ไม่ได้รับยาอย่างมีนัยสำคัญ ($p < 0.01$) มีระยะเวลานอนโรงพยาบาลสั้นกว่า (2.55 vs 4.4, $p < 0.01$) การได้รับการผ่าตัดในกลุ่มที่ได้รับยาน้อยกว่ากลุ่มที่ไม่ได้รับยา แต่ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติ อย่างไรก็ตามไม่พบความแตกต่างในกลุ่มอายุ เพศ และชนิดของแผลผ่าตัดในทั้ง 2 กลุ่ม

สรุปผลการศึกษา: การรักษาผู้ป่วยภาวะลำไส้อุดตันจากพังผืดในช่องท้องด้วยยาเหน็บถ่าย (Bisacodyl) และยาฉีดกระตุ้นการบีบตัวของลำไส้ (Metoclopramide) ได้ผลดีทั้งลดอัตราการผ่าตัดและลดระยะเวลาในการนอนโรงพยาบาล ปลอดภัย ไม่พบภาวะแทรกซ้อนและผลข้างเคียงจากการใช้ยา