

## Effect of Tricholine Citrate and Sorbitol Solution in Post-Gastrointestinal Surgical Patients

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### ABSTRACT

**Background:** Postoperative subacute intestinal obstruction (SAIO) is a clinically important complication following gastrointestinal surgery. Conservative management remains an important component of treatment. This study evaluated the clinical effectiveness and safety of tricholine citrate and sorbitol solution as an adjunct to conservative management in postoperative SAIO. **Aim and Objective:** To evaluate the clinical effectiveness and safety of tricholine citrate and sorbitol solution in patients with postoperative gastrointestinal surgical SAIO, with particular emphasis on symptom relief, restoration of bowel function, oral diet tolerance, and requirement for further intervention. **Materials and Methods:** A prospective cohort study was conducted in the Department of General Surgery, Government Medical College, Kota. The field/experimental work was conducted over 18 months within the approved project period. The approved project period was from 01 May 2023 to 30 April 2025. Adult patients with postoperative SAIO who met the predefined eligibility criteria were included. Patients with acute intestinal obstruction, severe hepatic or renal disease, allergy to the medication, unwillingness to participate, and age below 18 years were excluded. Patients received tricholine citrate plus sorbitol solution in addition to conservative management, including intravenous fluids, bowel rest, and electrolyte correction. Clinical symptoms, bowel function, oral diet tolerance, laboratory parameters, and treatment-related adverse events were assessed during follow-up. **Results:** A total of 100 patients were included in the detailed study analysis. The mean age was  $44.1 \pm 7.6$  years, with males comprising 59% and females 41% of the study population. Vomiting was present in 84% of patients and showed statistically significant improvement ( $\chi^2 = 6.25$ ,  $p = 0.012$ ). Abdominal tenderness was present in 12% of patients and demonstrated a statistically significant association with clinical improvement ( $\chi^2 = 42.38$ ,  $p < 0.00001$ ). Bowel sounds were present in 100% of patients by Day 3 ( $\chi^2 = 37.63$ ,  $p < 0.00001$ ). The mean pulse rate was  $82.4 \pm 6.3$  beats/min and the mean serum lactate level was 1.49 mmol/L. ROC analysis demonstrated an AUC of 0.91. Overall, 72% of patients showed significant symptom improvement within 48–72 hours. The reported time to first passage of flatus was approximately 36 hours, compared with a reported average of 72 hours before improvement, and oral diet was tolerated at an average of 2.5 days. Mild bloating was reported in 5% of patients, with no major adverse effects recorded. **Conclusion:** Tricholine citrate and sorbitol solution, when used along with conservative management, was associated with improvement in clinical symptoms and bowel function in postoperative SAIO patients. The treatment was well tolerated, with no major adverse effects reported. Larger controlled studies are required to confirm these findings.

**Keywords:** Tricholine Citrate; Sorbitol; Subacute Intestinal Obstruction; SAIO; Gastrointestinal Surgery; Postoperative Intestinal Obstruction; Bowel Motility; Conservative Management; Serum Lactate.

### INTRODUCTION

Intestinal obstruction is one of the most commonly encountered surgical entities in all age groups, which accounts for approximately 15 percent of patients

visiting the emergency department with complaints of acute pain in the abdomen.<sup>1</sup> Even Ebers Papyrus (1550 BC) and Hippocrates have documented cases of bowel obstruction.

SAIO implies incomplete obstruction.<sup>2</sup> It has been defined in a number of ways and there are many confusions in the treatment protocols. It is characterized by onset of symptoms like colicky abdominal pain, vomiting, and abdominal distension along with continued passage of flatus and/or faeces beyond 6-12 hrs. The patient usually presents with recurrent and intermittent intestinal obstruction, the patient being well in between.<sup>2</sup> SAIO may get relieved within few hours spontaneously/after conservative management or may progress to acute obstruction. Intermittent nature of symptoms and signs delays diagnosis as well as definitive treatment and the patients often suffer for weeks and months before appropriate treatment is instituted. The intestinal obstruction can be of small intestine or large intestine. Tricholene Citrate and Sorbitol solution is a combination of two drugs used primarily for liver diseases and constipation. Tricholene Citrate is a bile acid binding agent that reduces the level of bile acid present for enterohepatic circulation thereby forcing the liver to produce more bile acid consuming cholesterol present in blood. This reduces the S. Cholesterol level and improves the excretory function of liver. Sorbitol Solution is the Syrup base used in the solution which acts as osmotic laxative in the gut forcing water to shift from intestinal wall into the bowel cavity thereby improving the bulk of the stool and easing the passage of the stool. The combined pharmacological effects of tricholine citrate and sorbitol may support gastrointestinal function and bowel evacuation and may therefore contribute to improvement in symptoms in selected patients with SAIO.

## AIMS AND OBJECTIVES

The primary aim of the study was to evaluate the clinical effectiveness of tricholine citrate and sorbitol solution in postoperative gastrointestinal surgical patients with subacute intestinal obstruction (SAIO).

### Specific objectives were:

- To evaluate relief of abdominal pain and abdominal distension.
- To assess improvement in vomiting, constipation, and passage of flatus/stool.
- To assess return of bowel sounds and tolerance to oral liquids/soft diet.
- To assess the requirement for nasogastric tube reinsertion and re-exploration surgery.
- To evaluate treatment-related adverse drug reactions and overall tolerability.
- To assess relevant clinical and biochemical parameters during follow-up.

## REVIEW OF LITERATURE

Although tricholine citrate and sorbitol are used in gastrointestinal and hepatobiliary-related clinical settings, evidence regarding their use as an adjunct in postoperative SAIO remains limited. This provided the rationale for evaluating their potential role in symptom relief, restoration of bowel function, oral diet tolerance, and reduction in the need for further intervention in selected postoperative patients.

### Pathophysiology

Small-bowel obstruction (SBO) leads to proximal dilatation of the intestine due to accumulation of gastrointestinal (GI) secretions and swallowed air. Bowel dilatation stimulates cell secretory activity, resulting in more fluid accumulation. This, in turn, leads to increased peristalsis above and below the obstruction, with frequent loose stools and flatus early in its course.

Vomiting occurs if the level of obstruction is proximal. Increasing small-bowel distention leads to increased intraluminal pressures. This can cause compression of mucosal lymphatics, leading to bowel wall lymphedema. With even higher intraluminal hydrostatic pressures, increased hydrostatic pressure in the capillary beds results in massive third spacing of fluid, electrolytes, and proteins into the intestinal lumen. The fluid loss and dehydration that ensue may be severe and contribute to increased morbidity and mortality.

Strangulated SBOs are most commonly associated with adhesions and occur when a loop of distended bowel twists on its mesenteric pedicle. The arterial occlusion leads to bowel ischemia and necrosis. If left untreated, this progresses to perforation, peritonitis, and death.

Bacteria in the gut proliferate proximal to the obstruction. Microvascular changes in the bowel wall allow translocation to the mesenteric lymph nodes. This is associated with an increase in the incidence of bacteraemia due to *Escherichia coli*, but the clinical significance is unclear.

### Causes

#### Small bowel obstruction

Causes of small bowel obstruction include:<sup>[3]</sup>

- Adhesions from previous abdominal surgery (most common cause)
- Barbed sutures<sup>[6]</sup>
- Pseudo obstruction
- Hernias containing bowel
- Crohn's disease-causing adhesions or inflammatory strictures
- Neoplasms, benign or malignant
- Intussusception
- Volvulus

- Superior mesenteric artery syndrome, a compression of the duodenum by the superior mesenteric artery and the abdominal aorta
- Ischemic strictures
- Foreign bodies (e.g., gallstones in gallstone ileus, swallowed objects such as expandable water toys)
- Intestinal atresia

After abdominal surgery, the incidence of small bowel obstruction from any cause is 9%. In those where the cause of the obstruction was clear, adhesions are the single most common cause (more than half).<sup>[7]</sup>

### Large bowel obstruction

Causes of large bowel obstruction include:<sup>[8]</sup>

- Neoplasms / cancer
- Diverticulitis / Diverticulosis
- Hernias
- Inflammatory bowel disease
- Colonic volvulus (sigmoid, caecal, transverse colon)
- Adhesions
- Constipation
- Fecal impaction
- Fecaloma
- Colon atresia
- Intestinal pseudoobstruction
- Endometriosis
- Narcotic induced (especially with the large doses given to cancer or palliative care patients)

### Signs and Symptoms

Depending on the level of obstruction, bowel obstruction can present with abdominal pain, swollen abdomen, abdominal distension, and constipation. Bowel obstruction may be complicated by dehydration and electrolyte abnormalities due to vomiting; respiratory compromise from pressure on the diaphragm by a distended abdomen, or aspiration of vomitus; bowel ischemia or perforation from prolonged distension or pressure from a foreign body.<sup>[9]</sup>

In small bowel obstruction, the pain tends to be colicky (cramping and intermittent) in nature, with spasms lasting a few minutes. The pain tends to be central and mid-abdominal. Vomiting may occur before constipation.<sup>[9]</sup>

In large bowel obstruction, the pain is felt lower in the abdomen and the spasms last longer. Constipation occurs earlier and vomiting may be less prominent. Proximal obstruction of the large bowel may present as small bowel obstruction.<sup>[9]</sup>

### Diagnosis

The main diagnostic tools are blood tests, X-rays of the abdomen, CT scanning, and ultrasound. If a mass is identified, biopsy may determine the nature of the mass.

Radiological signs of bowel obstruction include bowel distension and the presence of multiple (more than six) gas-fluid levels on supine and erect abdominal radiographs. Ultrasounds may be as useful as CT scanning to make the diagnosis.<sup>[10]</sup>

Contrast enema or small bowel series or CT scan can be used to define the level of obstruction, whether the obstruction is partial or complete, and to help define the cause of the obstruction. The appearance of water-soluble contrast in the cecum on an abdominal radiograph within 24 hours of it being given by mouth predicts resolution of an adhesive small bowel obstruction with sensitivity of 97% and specificity of 96%.<sup>[11]</sup>

Colonoscopy, small bowel investigation with ingested camera or push endoscopy, and laparoscopy are other diagnostic options.

### TRICHOLINE CITRATE + SORBITOL SOLUTION

The formulation is a mixture of two medicines: Tricholine citrate and sorbitol. Tricholine citrate binds to bile in GIT and removes bile acids from the body. The liver in return produces more bile acids using cholesterol as a substrate. Ultimately, the level of cholesterol in the body is lowered. Sorbitol acts a syrup base and also as an osmotic laxative to relieve constipation.

### Indications

Sorbitol and tricholine citrate is prescribed for the management of constipation in adults and children. It is also prescribed to enhance appetite, digestion and liver functions. Combination also normalizes intestinal peristalsis, prevents fatty liver diseases and hepatotoxicity.

### Mechanism

Tricholine citrate contains three molecules of choline. Choline shows fat breakdown action, it is useful in the treatment of fatty infiltration and improper functioning of liver due to long term damage. Choline converts fat into phospholipids like, lecithin, which is essential to biomembrane structure and its function. Lecithin is also a major component of high density lipoprotein (HDL) and is used to mobilize cholesterol from cell membrane. In patients suffering from fatty liver, increased rate of phospholipid turnover has been observed following administration of choline.

Sorbitol is hydrolysed in the colon to short chain fatty acids which stimulates colonic propulsive motility by drawing water into the lumen due to its osmotic action.

## MATERIAL AND METHODS

### Study Design

This was a prospective cohort study conducted in the Department of General Surgery, Government Medical College, Kota, Rajasthan, India. The study evaluated the clinical effectiveness and safety of tricholine citrate and sorbitol solution as an adjunct to conservative management in adult patients with postoperative subacute intestinal obstruction (SAIO).

### Study Setting and Duration

The study was conducted at Government Medical College, Kota. The project commenced on 01 May 2023 and was completed on 30 April 2025. The field/experimental work was conducted over 18 months as reported in the final closure report.

### Sample Size

A total of 100 eligible patients were included in the study based on the available study population during the predefined study period.

### Ethical Approval

The study was conducted after obtaining approval from the Institutional Ethics Committee of Government Medical College, Kota. Written informed consent was obtained from all eligible participants before enrollment. The study was conducted in accordance with applicable ethical principles for research involving human participants.

### Primary and Secondary Outcomes

#### Primary Outcome:

The primary outcome was improvement in gastrointestinal symptoms, particularly abdominal distension and passage of flatus or stool, following administration of tricholine citrate and sorbitol solution.

#### Secondary Outcomes:

Secondary outcomes included improvement in dyspepsia and appetite and changes in inflammatory, ischemic, hepatic, and renal biochemical parameters during follow-up.

### Safety Assessment

All enrolled patients were monitored for treatment-related adverse events during the study period. Any gastrointestinal symptoms, allergic reactions, electrolyte abnormalities, or other clinically significant adverse events occurring during treatment were recorded and appropriately managed.

### Source of data

Patients admitted to the surgical ward of Government Medical College, Kota, with postoperative subacute intestinal obstruction and patients who had undergone

gastrointestinal surgery and met the predefined eligibility criteria were evaluated for inclusion in the study.

### Inclusion Criteria

- Male and female patients aged 18 years or above.
- Patients who had undergone gastrointestinal surgery and were permitted oral feeding.
- Patients with subacute intestinal obstruction (SAIO) and associated symptoms such as dyspepsia, constipation, and loss of appetite.

### Exclusion Criteria

- Patients with acute intestinal obstruction.
- Patients with severe hepatic or renal disorders.
- Patients with known allergy to the components of the medication.
- Patients unwilling to participate in the study.
- Patients younger than 18 years.

### Clinical Evaluation

A detailed clinical history was obtained for each patient, including abdominal pain, abdominal distension, vomiting, failure to pass flatus or feces, and history of recent gastrointestinal surgery. Clinical examination included systemic examination and abdominal examination. Appropriate clinical and radiological assessment was performed to exclude acute intestinal obstruction.

## METHOD

### Patient examination

A detailed history of each patient will be taken along with personal history, family history and dietary history with systemic examination of respiratory, cardiovascular system and abdominal examination. Local examination including proctoscopy to rule out acute intestinal obstruction will be done.

The patients will be told in detail about their disease and the various modalities available for treatment will be explained with the advantages and disadvantages of each.

All patients who will be enrolled in the study will be asked to sign the consent form.

Once the patient starts oral feeding, a dose of 10 ml of Tricholene citrate + sorbitol solution will be administered twice a day half an hour before the meal. Patients will be followed up for 3 months and examined for improvement in symptoms monthly after initial treatment using various markers as follows:

### Subjective Markers

1. Dyspepsia
2. Improvement in appetite

3. Relief in abdominal distension
4. Passing of Flatus / motion

### Objective markers

1. Inflammatory markers: - TLC, CRP, ESR, IL – 6
2. Ischemic markers: - ABG, S. electrolytes, S. lactate
3. Liver Function Test: - S. Bilirubin, SGOT, SGPT, Lipid Profile
4. Renal Function Test: - B. Urea, S. Creatinine

A decreasing trend in objective markers and subjective improvement in patient's well be considered as a positive prognostic factor.

### STATISTICAL ANALYSIS

Statistical analysis will be performed with the SPSS software (ANOVA 3.0) for Windows statistical software package (SPSS Inc., Chicago, IL, USA). Result will be expressed as mean and standard deviation. Unpaired Independent T – test, independent Chi square test and other statistical test was applied to compare various objective parameters. A p-value of <0.05 was considered statistically significant.

### EXPECTED OUTCOME

Tricholene citrate is bile acid binding agent that helps in improving G.I. function with hepatic, cardio vascular and renal function as it binds to bile acids and prevent there reabsorption and therefore body has to produce new bile acid using cholesterol and thereby reducing its level.

Sorbitol Solution is osmotic laxative and shifts fluid from intestinal walls and improves the bulk of stool and increase the peristaltic activity.

Therefore use of this medication is considered to improve the gut motility and relieve the symptoms of SAIO, prevent abdominal adhesions in post operative periods and also improves constipation, dyspepsia , loss of appetite.

## RESULTS

### Baseline Characteristics

A total of 100 patients were included in the detailed study analysis. The mean age of the study population was  $44.1 \pm 7.6$  years. Males constituted 59% of the study population, while females constituted 41%.

**Table 1. Baseline Characteristics**

| Variable       | Result               |
|----------------|----------------------|
| Total patients | 100                  |
| Mean age       | $44.1 \pm 7.6$ years |
| Male           | 59%                  |
| Female         | 41%                  |

### Clinical Outcomes

Vomiting was reported in 84% of the study population. A statistically significant improvement in vomiting was observed ( $\chi^2 = 6.25$ ,  $p = 0.012$ ). Abdominal tenderness was reported in 12% of patients and showed a statistically significant association with clinical improvement ( $\chi^2 = 42.38$ ,  $p < 0.00001$ ). Bowel sounds were present in 100% of patients by Day 3, with a statistically significant improvement ( $\chi^2 = 37.63$ ,  $p < 0.00001$ ). Overall, 72% of patients demonstrated significant symptom improvement within 48–72 hours. The mean time to first passage of flatus was approximately 36 hours, compared with approximately 72 hours before improvement, and oral diet was tolerated at an average of 2.5 days.

**Table 2. Clinical Outcomes**

| Clinical parameter                  | Result                           |
|-------------------------------------|----------------------------------|
| Vomiting                            | 84%                              |
| Improvement in vomiting             | $\chi^2 = 6.25$ ; $p = 0.012$    |
| Abdominal tenderness                | 12%                              |
| Improvement in abdominal tenderness | $\chi^2 = 42.38$ ; $p < 0.00001$ |
| Bowel sounds by Day 3               | 100%                             |
| Bowel sound improvement             | $\chi^2 = 37.63$ ; $p < 0.00001$ |
| Symptom improvement within 48–72 h  | 72%                              |
| First passage of flatus             | ~36 h                            |
| Oral diet tolerance                 | 2.5 days                         |

### Laboratory and Objective Outcomes

The mean pulse rate was  $82.4 \pm 6.3$  beats/min and the mean serum lactate level was 1.49 mmol/L. The study also demonstrated faster normalization trends in CRP and WBC counts. ROC analysis showed an area under the curve (AUC) of 0.91.

**Table 3. Laboratory and Objective Findings**

| Parameter          | Result                     |
|--------------------|----------------------------|
| Mean pulse rate    | $82.4 \pm 6.3$ beats/min   |
| Mean serum lactate | 1.49 mmol/L                |
| CRP                | Faster normalization trend |
| WBC count          | Faster normalization trend |
| ROC AUC            | 0.91                       |

### Safety Outcomes

The intervention was generally well tolerated. Mild bloating was reported in 5% of patients, while no major adverse effects were reported during the study period.

**Table 4. Safety Outcomes**

| Safety parameter      | Result         |
|-----------------------|----------------|
| Mild bloating         | 5%             |
| Major adverse effects | None reported  |
| Overall tolerability  | Well tolerated |

## DISCUSSION

The present study evaluated the clinical effectiveness and safety of tricholine citrate and sorbitol solution as an adjunct to conservative management in patients with postoperative subacute intestinal obstruction. The findings demonstrated improvement in several clinically relevant parameters, including vomiting, abdominal tenderness, bowel sounds, passage of flatus, symptom relief, and oral diet tolerance.

In the present study, 84% of patients experienced vomiting, with statistically significant improvement following treatment. Similarly, abdominal tenderness showed significant improvement. Restoration of bowel sounds by Day 3 was observed in all patients, suggesting recovery of intestinal activity during the clinical follow-up period.

A clinically important finding was that 72% of patients demonstrated significant symptom improvement within 48–72 hours. The reported reduction in time to first passage of flatus to approximately 36 hours and oral diet tolerance at an average of 2.5 days further indicate improvement in bowel function and clinical recovery.

The mean serum lactate level was 1.49 mmol/L, while ROC analysis demonstrated an AUC of 0.91. These findings suggest that objective biochemical assessment may have a role in monitoring patients with postoperative intestinal obstruction. However, the ROC finding should be interpreted cautiously because the precise ROC outcome definition and comparator are not fully detailed in the available study report.

The intervention was generally well tolerated. Mild bloating was reported in 5% of patients, and no major adverse effects were recorded.

Overall, the findings suggest that tricholine citrate and sorbitol solution may be a useful adjunct to conservative management in selected postoperative SAIO patients. However, the observational nature of the study and the absence of a clearly defined contemporaneous control group limit definitive conclusions regarding treatment efficacy.

The findings of the present study should be interpreted in the context of the limited available evidence regarding the use of tricholine citrate and sorbitol in postoperative SAIO. As direct comparative studies are limited, the observed clinical improvements cannot be conclusively attributed to the intervention alone. The findings therefore provide preliminary evidence that warrants confirmation through controlled studies.

## STRENGTHS OF THE STUDY

The strengths of this study include its prospective design, predefined eligibility criteria, systematic clinical follow-up, and assessment of both clinical and laboratory parameters. The study also evaluated treatment tolerability and adverse events, providing preliminary evidence regarding the potential role of tricholine citrate and sorbitol solution as an adjunct to conservative management in postoperative SAIO.

## FUTURE RECOMMENDATIONS

Future studies should include larger multicentric populations and a clearly defined control or comparison group. Randomized controlled trials with standardized outcome measures and longer follow-up are recommended to confirm the effectiveness and safety of tricholine citrate and sorbitol solution in postoperative SAIO.

## LIMITATIONS

This study was conducted at a single center and included a relatively limited study population. The prospective cohort design and absence of a clearly defined contemporaneous control group limit the ability to establish a direct causal relationship between the intervention and the observed clinical improvements. The reported reduction in re-operation from 18% to 7% was based on a historical comparison and therefore should not be interpreted as a randomized comparative outcome. Further multicentric randomized controlled studies with larger sample sizes are required to confirm the findings.

## CONCLUSION

Tricholine citrate and sorbitol solution, when used as an adjunct to conservative management, was associated with improvement in clinical symptoms and bowel function in patients with postoperative SAIO. In the reported study population, 72% of patients demonstrated significant symptom improvement within 48–72 hours, bowel sounds were restored by Day 3, and the reported average time to first passage of flatus was approximately 36 hours. The intervention was generally well tolerated, with mild bloating reported in 5% of cases and no major adverse effects. These findings suggest a potential role for tricholine citrate and sorbitol as an adjunct in the conservative management of selected postoperative SAIO patients. Larger multicentric controlled studies are required for confirmation.

## DECLARATIONS

### Funding

The study was conducted under the Multidisciplinary Research Unit, Government Medical College, Kota.

### Conflict of Interest

The authors declare that they have no conflict of interest related to this study.

### Data Availability

The data generated and analyzed during the present study are available from the corresponding author upon reasonable request, subject to institutional and ethical restrictions.

### Author Contributions

All authors contributed to the conception and design of the study, data collection and/or clinical management, interpretation of findings, manuscript preparation, and critical revision of the manuscript. All authors approved the final version of the manuscript.

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### Clinical Trial Registration:

Not applicable.

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