ORIGINAL RESEARCH PAPER

Volume-8 | Issue-8 | August - 2019 | PRINT ISSN No. 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

# THERAPEUTIC VALUE OF LIQUID PARAFFIN IN THE TREATMENT OF ADHESIVE SMALL BOWEL OBSTRUCTION

General Surgery

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## ABSTRACT

**BACKGROUND:** Treatment of partial adhesive small bowel obstruction (SBO) is still controversial. The purpose of this study was to determine the effects of oral administration of liquid paraffin to the standard of conservative treatment in this disease.
**METHODS:** 160 cases of partial adhesive SBO were prospectively allocated into either, and clinical results were compared.
**RESULTS:** Of the 160 patients, 80 were in the control group and 80 in the intervention group. 62 patients (77.5%) in control group responded to conservative management while 72 patients (90.0%) responded to conservative management in liquid paraffin group. A shorter hospital stay (2.86 ± 1.51 days vs 5.44 ± 1.84 days, P = 0.029) were observed in the interventional group.
**CONCLUSIONS:** Our study showed that liquid paraffin was a safe and effective adjunct to the standard treatment of partial adhesive SBO.

## KEYWORDS

Adhesive small bowel obstruction; liquid paraffin; intestinal obstruction; randomized; oral liquid paraffin

## INTRODUCTION

Adhesive Bowel obstruction is a mechanical obstruction of the intestines, preventing the normal transit of the products of digestion.

Mechanical small-bowel obstruction (SBO) is a common surgical emergency and is a frequently encountered problem in abdominal surgery. It constitutes a major cause of morbidity and financial expenditure in hospitals around the world [1].

Intestinal obstruction is responsible for approximately 20% of surgical admissions for acute abdominal conditions[5]. The small bowel is involved in 60-80% of cases of intestinal obstructions [2].

When peritoneal cavity is opened, in whatever type of surgery, bowel obstruction may develop due to bands or adhesions [3,4]. Obstruction due to minimal adhesions resolve with conservative management. However, obstruction with gross distension due to adhesions may need laparotomy for correction. The release of such adhesions results in serosal injury to the bowel and is a potential threat for re-adhesion and obstruction [5,6].

Intestinal obstruction requires a quick diagnosis as well as an immediate rational and effective therapy. Accurate and early recognition of intestinal strangulation in patients with mechanical adhesive SBO is important to decide between emergency surgery or safe non-operative management of carefully selected patients [7].

In spite of advances in imaging and better understanding of pathophysiology of small bowel, its obstruction is still misdiagnosed. Despite advances in the treatment of this condition, the attendant mortality is still high and remains in the range of 5-11%. The most important complication which has been constantly bothering the surgeons in intestinal obstruction is strangulation, where surgical intervention becomes mandatory [1].

The "classic signs" of strangulation obstruction have been variously cited to include continuous (verses colicky) abdominal pain, a fever, tachycardia, peritoneal signs, leukocytosis, acidosis, the presence of a painful mass, the absence of bowel sounds, and blood in the stool[4,8].

Many authors have mentioned of the successful use of oral therapy for adhesive intestinal obstruction [9,10,11,12], and they reported that the hospital stay of these patients and hospital costs has been significantly reduced by speeding up the conservative management by oral therapy. Patients with subacute intestinal obstruction managed conservatively have a long hospital stay which is associated with increased hospital costs [13,14]. Speeding up the nonsurgical management by oral therapy may decrease the frequency of these problems. We performed a prospective, randomized, un-blinded, study comparing the administration of oral liquid paraffin to standard care in patients judged to have partial adhesive intestinal obstruction.

Liquid paraffin is a transparent, colourless, odourless, or almost odourless, oily liquid composed of saturated hydrocarbons obtained from petroleum. Liquid paraffin appears to work primarily as a stool lubricant. Therefore, liquid paraffin is not associated with abdominal cramps, diarrhoea, flatulence, electrolyte disturbances, or emergence of tolerance with long term usage[17].

## AIMS AND OBJECTIVES

1. To evaluate the effectiveness of oral liquid paraffin in increasing the spontaneous (non-operative) resolution of SBO compared to standard care.

## MATERIALS AND METHODS

This prospective comparative study was conducted in the Department of Surgery, Holy Family Hospital, Okhla Road, New Delhi. The study comprised of 80 patients in study group and 80 patients in control group aged 12 years or more.

All of the patients provided their informed consent before inclusion in the study. Upon admission to surgery department, each patient was evaluated by a surgical resident. After taking a detailed history and performing a physical examination, the staff member drew a venous blood sample for complete blood cell count and took a plain abdominal radiograph with the patient in an upright position. Ultrasound abdomen was done. If the consultant in charge confirmed that it was a case of partial adhesive SBO based on clinical findings, abdomen radiograph showing gas in large bowel and, ultrasound findings, the patient was considered for inclusion in the study. In case of any doubt in clinical picture of patient, CECT abdomen is done.

The study included the patients with the history of abdominal pain, abdominal distension, vomiting and constipation, after applying following selection and exclusion criteria.

**Selection criteria:**

- Previous abdominal surgery conducted more than 4 weeks before enrolment
- One of the following radiological criteria:

1. A plain abdominal radiograph taken with the patient upright that showed dilated loops of the small intestine, air fluid levels and gas in the colon, indicating a partial SBO.
2. Ultrasound abdomen and/or CECT abdomen shows dilated bowel loops with hyper peristalsis without any free fluid or any other pathology.

**Exclusion criteria:**

- Pregnancy.
- No clear evidence of air in the large bowel on abdominal radiographs indicating complete obstruction.
- One or more signs suggestive of intestinal strangulation or peritonitis such as rigidity, fever, leukocytosis, absent bowel sound, gas under diaphragm, intractable pain, and tachycardia.

- Patients with documented/suspected intra-abdominal malignancy.
- Hemodynamically unstable patients.
- Patients with irreducible abdominal hernia.
- Patients with previous history of OR active abdominal tuberculosis
- Patients of Crohn's disease
- Palpable intra-abdominal lump.
- Ultrasound abdomen and/or CECT abdomen suggestive of any other abdominal pathology
- Prior abdominal irradiation
- The abdominal radiograph showed no gas in the colon

A total of 170 patients were identified with adhesive bowel obstruction, meeting our inclusion criteria, out of which 10 patients were excluded as either they were discharged otherwise or did not followed up. Patients in the 2 groups had similar characteristics, including age, sex and clinical presentation. We are very eager to assume that samples come from normal populations.

Participants are randomised to one of two groups. The randomization was performed by drawing a card from a box containing an equal number of cards labelled either C (control) or L (liquid paraffin). Patient is accordingly allocated liquid paraffin or control group based on random allocation.

Control group: Participants receive standard conservative management, in which patients are given nothing by mouth, besides nasogastric tube aspiration. Electrolyte imbalance (if any) is corrected accordingly.

Intervention group: Participants receive 30ml liquid paraffin orally/via nasogastric tube twice a day for 5 days in addition to standard care. The nasogastric tube was clamped for one hour after the administration of the medications, to prevent reflux of the medications through the tube.
Primary outcome Measures:

1. Ability to tolerate diet,
2. Return of normal bowel function. Time to passage of flatus or stool is recorded via patient interviews at baseline and every 12 hours until resolution of symptoms or decision of surgery is taken (whichever is earlier).

**Secondary outcomes Measures:**

1. Abdominal distension is measured via abdominal examination and
2. Air-fluid levels are measured using an abdominal radiograph at baseline and 24, 48, 72, 96 and 120 hours or until resolution of symptoms (whichever is earlier).

Surgical intervention in both groups was determined by the attending surgeon based on the presence of one or more toxic signs (e.g., fever, tachycardia, leukocytosis, intractable pain and peritonitis) or if the obstruction did not resolve spontaneously after 5 days.

The nasogastric tube was removed when distension decreased and bowel sounds became normal, after resolution of the adhesive SBO was confirmed radiographically, the abdominal pain subsided or the patient passed stools or flatus. Oral intake was initiated with a liquid diet followed by a soft diet after resolution of the obstruction. Which was confirmed by clinical examination, and abdominal radiography.

Termination of conservative treatment was done when clinical examination was suggestive of strangulation or perforation.

Patients were discharged from the hospital when the following criteria were met:
(a) The abdominal pain subsided and a solid diet was tolerated, and
(b) A plain abdominal radiograph showed the normal colonic gas and the absence of air-fluid levels in the small bowel.

The patients who responded were discharged without surgery and followed in outpatient department weekly over a period of first month and every two weekly in next two months while un-responded patients and those with clinical features of complications like strangulation and perforation were managed operatively.

**Follow up involves:**

1. Clinical examination and,
2. Abdominal radiograph if history suggestive of recurrent symptoms.

Follow up takes place at outpatient department of holy family hospital, New Delhi.

The data was collected and tabulated, and subjected to standard statistical analysis. Statistical analysis was performed by the SPSS program for Windows, version 17.0. Continuous variables are presented as mean± SD, and categorical variables are presented as absolute numbers and percentage. Data were checked for normality before statistical analysis. Normally distributed continuous variables were compared using the unpaired t test, whereas the Mann-Whitney U test was used for those variables that were not normally distributed. Categorical variables were analysed using either the chi square test or Fisher's exact test.

For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

## RESULTS

In our series of 160 patients, 71 (44.37%) presented in the age group of 21-40 years and the incidence decreased with increase in age. Mean age was 40.85 ± 18.63 years in control group while 39.12 ± 18.53 years in liquid paraffin group.

Sex distribution was almost similar in our study in both the groups, with 37 patients (46.2%) being males in control group and 40 patients (50.0%) were males in liquid paraffin group.

In our study the most common clinical feature observed was abdominal pain in 74 patients (92.5%) in control group and 77 patients (96.2%) in liquid paraffin group, followed by abdominal distension in 71 patients (88.8%) in control group and 72 patients (90.0%) in liquid paraffin group. Constipation was a symptom in 43 patients (53.8%) in control group and 40 patients (50.0%) in liquid paraffin group while vomiting was observed in 60 patients (75.0%) in the control group and 57 patients (71.2%) in the liquid paraffin group

In our study plain abdominal X-Ray of 121 patients (75.62%) showed air-fluid levels. Ultrasound abdomen was diagnostic in 118 patients (73.75%). Computed tomographic scan was done in selected patients. It was done in a total no of 43 patients (26.87%) and was found to be diagnostic in all of the cases.

***Table 1. Demographic characteristics, initial clinical examination and radiographic findings of patients with partial adhesive SBO receiving nothing by mouth (control) or liquid paraffin.***

| | Controls | | Liquid Paraffin | | P Value |
|---|---|---|---|---|---|
| | Frequency | % | Frequency | % | |
| **Age Groups** | | | | | 0.674 |
| <=20 yrs | 10 | 12.50% | 11 | 13.80% | |
| 21 - 40 Yrs | 32 | 40.00% | 39 | 48.80% | |
| 41 - 60 yrs | 24 | 30.00% | 16 | 20.00% | |
| 61 - 80 yrs | 13 | 16.20% | 13 | 16.20% | |
| >80 yrs | 1 | 1.20% | 1 | 1.20% | |
| **Mean ± SD** | 40.85 ± 18.63 | 39.12 ± 18.53 | 0.558 | | |
| **Gender** | | | | | 0.635 |
| F | 43 | 53.80% | 40 | 50.00% | |
| M | 37 | 46.20% | 40 | 50.00% | |
| **Symptoms** | | | | | |
| Pain abd | 74 | 92.50% | 77 | 96.20% | 0.495 |
| Vomiting | 60 | 75.00% | 57 | 71.20% | 0.593 |
| Obstipation | 43 | 53.80% | 40 | 50.00% | 0.635 |
| Abd distension | 71 | 88.80% | 72 | 90.00% | 0.798 |
| **Prev. abd surg.** | | | | | |
| Upper abdominal | 36 | 45.00% | 33 | 41.20% | 0.632 |
| Lower abdmonial | 44 | 55.00% | 47 | 58.80% | |
| **H/O Recurrent symptoms** | 41 | 51.20% | 39 | 48.80% | 0.752 |

| | | | | | |
|---|---|---|---|---|---|
| **Physical examination** | | | | | |
| Mild Tenderness | 18 | 22.50% | 29 | 36.20% | 0.056 |
| Exaggerated Bowel sounds | 34 | 42.50% | 26 | 32.50% | 0.087 |
| **Ballooning in digital rectal examination** | | | | | 0.837 |
| N | 15 | 18.80% | 14 | 17.50% | |
| Y | 65 | 81.20% | 66 | 82.50% | |
| **Abdominal X-Ray AF LEVELS** | | | | | 0.581 |
| N | 18 | 22.50% | 21 | 26.20% | |
| Y | 62 | 77.50% | 59 | 73.80% | |
| **Ultrasound findings** | | | | | |
| fluid filled loops | 62 | 77.50% | 56 | 70.00% | 0.286 |
| hyperperastal asis | 43 | 53.80% | 44 | 55.00% | 0.603 |

A total number of 134 patients (83.75%) responded with conservative means with one death (1.2%) in liquid paraffin group. In our study the number of patients who responded to conservative measures are higher in liquid paraffin group (72 patients, 90.0%) than in control group (62 patients, 77.5%), (p=0.032, Significant). Hospital stay was 3 to 9 days in control group with the mean of 5.44 ± 1.84 days while in liquid paraffin group it was 1 to 8 days with the mean of 2.86 ± 1.51 days (p=0.029, significant).

***Table 2: Comparison of day to passing flatus in study population***

| Day to passing flatus | Controls | | Liquid Paraffin | | P Value |
|---|---|---|---|---|---|
| | Frequency | % | Frequency | % | |
| operated | 18 | 22.50% | 8 | 10.00% | |
| | | | | | <0.001 |
| 1 | 13 | 16.30% | 54 | 67.50% | |
| 2 | 20 | 25.00% | 14 | 17.50% | |
| 3 | 14 | 17.50% | 1 | 1.30% | |
| 4 | 8 | 10.00% | 3 | 3.80% | |
| 5 | 6 | 7.50% | 0 | 0.00% | |
| 6 | 1 | 1.30% | 0 | 0.00% | |
| Total | 80 | 100% | 80 | 100% | |

Most of the patients in control group passed flatus on day 2 of admission (20 patients, 25.0%) while in liquid paraffin group most of the patients passed flatus on day 1 (54 patients, 67.5%). (p=<0.001, significant)

***Table 3: Comparison of day to bowel movements in study population***

| Day to bowel movement | Controls | | Liquid Paraffin | | P Value |
|---|---|---|---|---|---|
| | Frequency | % | Frequency | % | |
| operated | 18 | 22.50% | 8 | 10.00% | |
| | | | | | <0.001 |
| 1 | 1 | 1.30% | 26 | 32.50% | |
| 2 | 3 | 3.80% | 17 | 21.30% | |
| 3 | 10 | 12.50% | 15 | 18.80% | |
| 4 | 13 | 16.30% | 8 | 10.00% | |
| 5 | 15 | 18.80% | 2 | 2.50% | |
| 6 | 9 | 11.30% | 3 | 3.80% | |
| 7 | 5 | 6.30% | 0 | 0.00% | |
| 8 | 6 | 7.50% | 1 | 1.30% | |
| Total | 80 | 100% | 80 | 100% | |

Most of the patients in control group passed stools on day 5 of admission (15 patients, 18.8%) while in liquid paraffin group most of the patients passed stools on day 1 (26 patients, 32.5%). (p=<0.001, significant)

***Table 4: Comparison of day to tolerating liquids in study population***

| Day to tolerating liquids | Controls | | Liquid Paraffin | | P Value |
|---|---|---|---|---|---|
| | Frequency | % | Frequency | % | |
| operated | 18 | 22.50% | 8 | 10.00% | |
| | | | | | <0.001 |
| 1 | 2 | 2.50% | 34 | 42.50% | |
| 2 | 17 | 21.30% | 21 | 26.30% | |
| 3 | 15 | 18.80% | 12 | 15.00% | |
| 4 | 13 | 16.30% | 3 | 3.80% | |
| 5 | 8 | 10.00% | 2 | 2.50% | |
| 6 | 6 | 7.50% | 0 | 0.00% | |
| 7 | 1 | 1.30% | 0 | 0.00% | |
| Total | 80 | 100% | 80 | 100% | |

Most of the patients in control group accepted liquids on day 2 of admission (17 patients, 21.3%) while in liquid paraffin group most of the patients accepted liquids on day 1 (34 patients, 42.5%). (p=<0.001, significant)

***Table 5: Comparison of day to tolerating solids in study population***

| Day to tolerating solids | Controls | | Liquid Paraffin | | P Value |
|---|---|---|---|---|---|
| | Frequency | % | Frequency | % | |
| **operated** | **18** | **22.50%** | **8** | **10.00%** | |
| | | | | | <0.001 |
| 1 | 0 | 0.00% | 20 | 25.00% | |
| 2 | 3 | 3.80% | 21 | 26.30% | |
| 3 | 12 | 15.00% | 12 | 15.00% | |
| 4 | 15 | 18.80% | 12 | 15.00% | |
| 5 | 10 | 12.50% | 5 | 6.30% | |
| 6 | 10 | 12.50% | 0 | 0.00% | |
| 7 | 7 | 8.80% | 2 | 2.50% | |
| 8 | 3 | 3.80% | 0 | 0.00% | |
| 9 | 2 | 2.50% | 0 | 0.00% | |
| Total | 80 | 100% | 80 | 100% | |

| | Controls | | Liquid Paraffin | | P Value |
|---|---|---|---|---|---|
| | Mean ± SD | Min - Max | Mean ± SD | Min - Max | |
| Day to passing flatus | 2.63 ± 1.31 | one - six | 1.35 ± 0.71 | one - four | <0.001 |
| Day to bowel movements | 4.87 ± 1.67 | one - eight | 2.40 ± 1.52 | one - eight | <0.001 |
| Day to tolerating liquids | 3.48 ± 1.43 | one - seven | 1.86 ± 1.02 | one - five | <0.001 |
| Day to tolerating solids | 4.89 ± 1.77 | two - nine | 2.57 ± 1.46 | one - seven | <0.001 |

| Response | Controls | | Liquid Paraffin | | P Value |
|---|---|---|---|---|---|
| | Frequency | % | Frequency | % | |
| Death | 0 | 0.00% | 1 | 1.20% | 0.032 |
| N | 18 | 22.50% | 7 | 8.80% | |
| R | 62 | 77.50% | 72 | 90.00% | |
| Total | 80 | 100% | 80 | 100% | |

| hospital stay(days) | Mean ± SD | Min - Max | P Value |
|---|---|---|---|
| Controls | 5.44 ± 1.84 | 9-Mar | 0.029 |
| Liquid Paraffin | 2.86 ± 1.51 | 8-Jan | |

Most of the patients in control group accepted solids on day 4 of admission (15 patients, 18.8%) while in liquid paraffin group most of the patients accepted solids on day 2 (21 patients, 26.3%). (p=<0.001, significant)

62 patients (77.5%) in control group responded to conservative management while 72 patients (90.0%) responded to conservative management in liquid paraffin group. One patient in liquid paraffin group died after being operated for perforation. (p=0.032, Significant). Patients not responded in above table were subjected to operative intervention.

One death in liquid paraffin group was of a mentally retarded 14 years old male with the previous history of abdominal surgery for intestinal obstruction due to malrotation 9 years back. After all routine investigations, patient was included in study. CECT abdomen was

done on day 1 of the admission, which was suggestive of dilated small bowel loops, no features suggestive of acute obstruction, strangulations, free fluid, close loop obstruction. On Day 2 of admission patient has tachycardia, on exploration, he was having gangrenous cecum. Patient was being treated in ICU, cardiologists consultation was taken as the patient was having congenital ventricular septal defect with eisenmenger syndrome. Patient expired on post-operative day 3 due to cardiac arrest.

In our study 1.25% patients develop strangulation while 2.5 % patients develop perforation. Use of liquid paraffin did not alter the rate of complications (p is insignificant). A total number of 26 patients (16.25%) require surgery following a failed conservative management, out of which 18 patients (22.5%) in control group and 8 patients (10.0%) in liquid paraffin group required surgery, with a significant p value of 0.032.

Hospital stay of patients in control group is 5.44 ± 1.84 days while in liquid paraffin group is 2.86 ± 1.51 days with significant p value of 0.029

During the follow-up in the study period, partial adhesive small bowel obstruction recurred in 4 patients (5.0%) in the control group and 4 patients (5.0%) in the intervention group with one patient of control group lost follow up with insignificant p value of 0.605, and none of them required surgery.

## DISCUSSION

Intestinal obstruction describes failure of aboral progression of intestinal contents. Intestinal obstruction is one of the common life threatening emergencies all over the world. There is a global change in the spectrum of aetiology of intestinal obstruction over the past few years. The diagnosis of intestinal obstruction is usually delayed and several patients continue to suffer from symptoms for weeks and months due to the waxing and waning nature of the disease.

The management of adhesive obstruction has remained controversial. Most patients received trial conservative treatment in the initial period unless there was suspicion of bowel strangulation. However, the optimal duration of this trial of conservative treatment was never clear. There has been no definite answer as to when conservative treatment should be considered unsuccessful and the patient should undergo surgery. Cox et al [15] reported that of patients who were cured by conservative treatment, 88% had obstruction resolved within 48 hours. While Schraufnagel D, et al [14] concluded that patients of small bowel obstruction can be observed safely for 5 days. Shih SC, et al [16] described in their study that an average of 6.9 days was required for spontaneous resolution.

Standard conservative management for intestinal obstruction of keeping patients' nil by mouth, with nasogastric tube aspiration has been challenged by many authors. Ji Z-L, et al [11] has concluded in their study that oral administration on sesame oil was a safe and effective adjunct to the standard conservative management in intestinal obstruction. Shyr-Chyr Chen, et al [10] have concluded that oral therapy with a laxative was effective in hastening the resolution of conservatively treated partial adhesive SBO and shortening the hospital stay. Hok-Kwok Choi, et al [9] have proved the effectiveness of oral gastrografin in the management of intestinal obstruction. We have given liquid paraffin as an adjuvant to conservative management of intestinal obstruction in our study.

## CONCLUSIONS:

We found that therapy with liquid paraffin orally/via nasogastric tube, in addition to the standard nonsurgical treatment of partial adhesive SBO resulted in a marked reduction in the need for surgical intervention. It also resulted in marked reduction in the resolution time to bowel obstruction and the length of hospital stay compared with the standard nonsurgical treatment alone. Liquid paraffin does not increase the risk of complications. Thus we conclude that liquid paraffin is a safe and effective adjunct to standard treatment for adhesive small bowel obstruction.

### Recommendations:

Patients of adhesive intestinal obstruction with no signs of strangulation can be managed conservatively, and these patients should be given a trial of conservative management. Oral therapy with liquid paraffin appears to be helpful in the management of patients with partial adhesive SBO, and should be considered as a management option.

### Acknowledgments

This study was funded by Holy Family Hospital, New Delhi.

### Compliance with ethical standards

### Conflicts of interest

None.

### Ethical approval

Ethical approval was granted by Holy Family Hospital Ethics Committee 2012 (Ref: 01/HFH2012).

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