Original Article

To Evaluate The Efficacy Of Bioresorbable Seprafilm Membrane In Avoiding Abdominal Adhesions

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Abstract

Aim: To evaluate the efficacy of bioresorbable Seprafilm membrane in avoiding abdominal adhesions.
Material and methods: After obtaining approval from the appropriate institutional review board, this research was conducted within the department of General Surgery. Patients who needed a Hartmann procedure for diverticulitis or rectosigmoid blockage were randomly assigned to receive Seprafilm or to act as a control patient.
Results: This research covered 100 patients in total. 50 patients were randomly assigned to receive Seprafilm while the other 50 served as controls. There were no significant variations in medical history or preoperative physical examination. At the midline incision, five patients got three Seprafilm membranes, 35 patients received two membranes, and ten patients received one membrane. In 40 patients, additional surgical operations were performed during the Hartmann procedure. In the Seprafilm group, 8 patients had appendectomy, 6 had surgical decompression of the small intestine, 3 had his peritoneal dialysis catheter removed, and 3 had ovarian cyst resection and partial small intestinal resection for unintentional bowel perforation. In the control group, 8 patients had further appendectomy, 6 patients had splenectomy, 3 patients had suturing for an iatrogenic bladder damage, and 3 patients had partial small bowel resection for a mesentery abscess. The median blood loss in the Seprafilm group was 352mL and 420mL in the control group. Postoperative wound healing was abnormal in 18 of the Seprafilm patients and 14 of the control patients. The time between the original operation and the follow-up surgery was not statistically different across groups. The median interval in the Seprafilm group was 6 months (range 2-17) and 4 months in the control group (range 1–31).
Conclusion: we concluded a decrease in the degree of adhesion development following the application of Seprafilm in Hartmann procedure patients compared to controls.

Keywords: Efficacy, bioresorbable Seprafilm membrane, abdominal adhesions

Introduction

Adhesions are aberrant connections between tissues or organs, and they may occur after abdominal surgery. Adhesions may occur in the abdominal cavity due to trauma to the peritoneum, ischemia inside the abdominal cavity, or the presence of foreign substances including powdered gloves, bacteria, lint from gauze, sutures, or prosthetic mesh. Sixty-eight percent to one hundred percent of individuals who have had one or more laparotomies develop 1-3 adhesions.[1-4]

Most individuals with intraabdominal adhesions do not experience any symptoms; nonetheless, adhesions may lead to issues such as intestinal blockage, persistent abdominal discomfort, infertility, and more. In the Western world, adhesions are the leading cause of intestinal blockages. [4,5] Adhesions may also be the root of another clinical issue, recurrent abdominal discomfort. Intraabdominal adhesions have been linked to infertility.[6,7]

Extended operating times, postoperative bleeding, and the possibility of intestinal perforations are all contributors to the greater complication rate.[8,9] The frequency of prior laparotomies or laparoscopic procedures performed is correlated with an increased risk of severe problems.[10,11] Adhesion-related clinical issues carry significant financial burdens. [12-15]

Adhesions may be prevented by minimising surgical stress and keeping the abdominal cavity free of extraneous substances. Alternative strategies for decreasing postoperative adhesions have been investigated. The production of adhesions between tissues and organs may be reduced, in theory, by placing a mechanical barrier between them. After 7 days, the peritoneum that has been injured by surgery has fully healed. [16] To achieve the desired result without having to deal with the constant presence of foreign material inside the abdominal cavity, a temporary barrier that does not dissolve within 7 days is desirable. HAL-F As a mechanical barrier between medically injured tissues, bioresorbable membrane (Seprafilm; Genzyme Corp., Cambridge, MA) was created. This biodegradable membrane begins to resorb after 7 days. Seprafilm has been demonstrated to lessen the number, intensity, and duration of postoperative adhesions in animal tests and a single randomised human study. [17] Due to the high rate of adhesion formation after (partial) colectomy, this technique may serve as a useful model for research into adhesion avoidance strategies. [18,19] To evaluate the efficacy of the Seprafilm membrane, we will use a Hartmann operation that involves a second-stage restoration of the continuity of the colon as a case study.

Material and methods

After obtaining approval from the appropriate institutional review board, this research was conducted within the Genral Surgery. Patients who needed a Hartmann procedure for diverticulitis or rectosigmoid blockage were randomly assigned to receive Seprafilm or to act as a control patient. Patients who were pregnant, had carcinosis peritonei, were using any other experimental medicine, or who had povidone-iodine, corticosteroids, heparin, salicylates, nonsteroidal anti-inflammatory medications, dextran, or antibiotics used in abdominal irrigation were excluded. Patients gave their verbal and written permission after being fully informed of the trial's nature.

Temporarily dividing tissues that have been mechanically injured following surgery is the goal of the membrane Seprafilm. Sodium hyaluronate, a glycosaminoglycan, and carboxymethyl cellulose are its main components. The usage of these compounds has not been reported to be harmful or hazardous. The standard retail size for Seprafilm is 12.7 by 15.2 cm. It was decided to use a two-stage abdominal surgical technique to assess the efficacy of Seprafilm, with the antiadhesions material being applied during the first stage of surgery and the development of adhesions being evaluated during the second. After the Hartmann technique, we determined how well Seprafilm worked. At admission, we recorded demographic information such as age, sex, body mass index (BMI), height, list of current medicines, and list of prior abdominal surgeries. A BMI of 30 or above was considered clinically obese. Physical examination abnormalities were recorded. The sigmoid colon was removed, a colostomy was made, and the rectal stump was closed in accordance with Hartmann's surgical technique. The length of the midline incision, the kind and length of the colon segment resection, the technique used to close the rectal stump, the presence or absence of the omentum, and the suturing of the peritoneum should all be recorded. During the procedure to reanastomose the rectal stump and close the colostomy, an assessment of adhesions was made. The surgeon evaluating adhesions did not know which group each patient belonged to. Midline adhesions were examined through laparoscopy for prevalence, severity, and kind.

Table 1. Macroscopic classification of abdominal adhesions

Type	Characteristics
1	Filmy adhesion, easy to separate by blunt dissection
2	Stronger adhesion; blunt dissection possible, partly sharp dissection necessary; beginning of Vascularization
3	Strong adhesion; lysis possible by sharp dissection only; clear vascularization
4	Very strong adhesion; lysis possible by sharp dissection only; organs strongly attached with severe adhesions; damage of organs hardly preventable

Results

This research covered 100 patients in total. 50 patients were randomly assigned to receive Seprafilm while the other 50 served as controls. An intention-to-treat analysis was carried out. In terms of preoperative data, the groups were similar (Table 2). There were no significant variations in medical history or preoperative physical examination. There were no variations in medication use across groups. There was no history of prior abdominal surgery in 35 of the Seprafilm patients and 36 of the control patients. There were no significant differences between the groups in terms of the frequency and kind of prior abdominal surgery. Data from intraoperative procedures did not vary substantially (Table 3). In the Seprafilm group, the resected colon segment designated as "other" was an ileocecal resection. A subtotal colectomy, a left hemicolectomy, and a colostomy for a rectovaginal fistula that formed following a low anterior resection for a villous adenoma of the rectum were the surgeries categorised as "other" in the control group. Preexisting adhesions were found in nine individuals in the Seprafilm group, with 15 of these patients having adhesions to the locations being evaluated in the future. Ten individuals in the control group had preexisting adhesions; seven of these patients had adhesions to the sites implicated in future examination. These differences were not statistically significant.

Table 2. Basic profile

	Seprafilm	Control
Age	58.85±12.36	59.15±11.69
Gender		
Male	48	47
Female	52	53
Obesity		
Present	5	5
Absent	45	45
Diagnosis		
Diverticulitis	40	41
Others	10	9

Table 3. Intraoperative data

	Seprafilm	**Control**
Length of midline incision (cm; mean ± SD)	20.52±3.58	20.69±4.8
Resected colon segment		
Sigmoid	48	45
Other	2	5
Length of resected segment	18.2	15.2
Closure rectal stump		
Sutured	12	15
Stapled	38	35
Drain placed		
Yes	24	24
No	26	26
Peritoneum sutured		
Yes	6	0
No	44	50
Duration of surgery (min;	104±6	101±5
Adhesions present		
Yes	15	10
No	35	40
Peritonitis		
No	9	13
Local	17	15

Locoregional	15	12
Diffuse	9	10

At the midline incision, five patients got three Seprafilm membranes, 35 patients received two membranes, and ten patients received one membrane. The last nine patients had initial incision lengths of 15, 15, 25, and 30 cm, suggesting that the region beneath the midline incision had only been partly covered with Seprafilm. Two membranes were placed in the pelvic region in 21 patients, one membrane was placed in 21 patients, and no membrane was placed in 8 patients. Three inadvertent intestinal perforations occurred in five patients in the Seprafilm group and three patients in the control group. Two patients in the control group were injured by accident to the bladder.

Table 4. Incidence of postoperative adhesions assessed during evaluation at laparoscopy

Adhesions to the midline incision Superior segment	**Seprafilm**	**Control**	**P value**
Yes	35	40	0.39
No	15	10	
Middle segment			0.07
Yes	30	46	
No	20	4	
Inferior segment			0.31
Yes	32	44	
No	18	6	
Total midline incision			
Yes	45	50	0.38
No	5	0	
Adhesions to the pelvic area			0.33
Yes	39	45	
No	11	5	

In 40 patients, additional surgical operations were performed during the Hartmann procedure. In the Seprafilm group, 8 patients had appendectomy, 6 had surgical decompression of the small intestine, 3 had his peritoneal dialysis catheter removed, and 3 had ovarian cyst resection and partial small intestinal resection for unintentional bowel perforation. In the control group, 8 patients had further appendectomy, 6 patients had splenectomy, 3 patients had suturing for an iatrogenic bladder damage, and 3 patients had partial small bowel resection for a mesentery abscess. The median blood loss in the Seprafilm group was 352mL and 420mL in the control group. Postoperative wound healing was abnormal in 18 of the Seprafilm patients and 14 of the control patients. The time between the original operation and the follow-up surgery was not statistically different across groups. The median interval in the Seprafilm group was 6 months (range 2-17) and 4 months in the control group (range 1–31). Both groups had a substantial increase in the severity of adhesions after second-stage surgery compared to first surgery, in terms of both the whole midline incision (P =.006) and the pelvic region (P =.017). The prevalence of adhesions discovered during the examination did not vary substantially across groups (Table 4).

Discussion

Adhesions form in the overwhelming majority of individuals after abdominal surgery[1,3,4] and may cause problems. Because there is no noninvasive approach for assessing the postoperative incidence, severity, and location of adhesions, it is seldom documented. The present randomised clinical study's design allowed for the assessment of adhesion formation after the insertion of Seprafilm during a Hartmann operation. Only one additional randomised trial on adhesion prevention has been conducted. [17]

Filmy adhesions are thought to cause fewer complaints and difficulties than thick adhesions. However, there is no data on this topic.

The severity of adhesions was considerably lower in patients who received Seprafilm compared to the control group. This finding is consistent with the findings of Becker et al.[17], who conducted a randomised clinical trial to evaluate the efficacy of Seprafilm in reducing the incidence and severity of adhesions in patients undergoing colectomy and ileal pouch-anal anastomosis with diverting-loop ileostomy and subsequent ileostomy closure with laparoscopic evaluation of formed adhesions. However, Becker et al reported a considerable reduction in the occurrence of adhesions, which our findings did not support. One probable reason for this disparity is because in the current trial, 78% of 100 patients had peritonitis requiring emergency surgery, while in the previous study, no patient had peritonitis. Peritonitis has been characterised as disrupting naturally occurring systems involved in adhesion development, and hence potentially enhances adhesion formation.[20,21] As a result, interventions aimed at reducing postoperative adhesions may be less successful if peritonitis is present.

Blood loss was said to reduce the effectiveness of a cellulose barrier in minimising postoperative adhesions. Becker et al[17] discovered no relationship between blood loss and Seprafilm's antiadhesion impact, and since blood loss was equivalent between that trial and the current one, blood loss is not a possible reason for the membrane's decreased efficacy.

In theory, the relatively high prevalence of preexisting adhesions might explain the lack of adhesion formation decrease in the Seprafilm group. The rate of adhesion reformation after adhesiolysis has been characterised as high, with the recurrence rate presumably dependent on the technique of adhesiolysis, antiadhesions treatments used, and time between original surgery and examination of reformation. [8,9,23]

Seprafilm is difficult to work with, and considerable skill is required to use it well. Application in more difficult-to-reach places than those utilised in this research may provide challenges. Dislocation is theoretically conceivable after application, which may interfere with the membrane's antiadhesion action. The colon was not pushed aside when closing the fascia to avoid membrane displacement; theoretically, this might result in poor fascia closure and dehiscence, but no significant difference in the incidence of dehiscence was identified between the groups. Devices that are easy to use are likely to be more successful in reducing postoperative adhesions.

Conclusion

In conclusion, we discovered a decrease in the degree of adhesion development following the application of Seprafilm in Hartmann procedure patients compared to controls. In the event of planned relaparotomy, such as with a Hartmann operation, the use of Seprafilm will enable reexploration and may reduce the risk of bowel damage during surgery. As a result, if a relaparotomy is planned, it is recommended that Seprafilm be used as an antiadhesions barrier following colorectal surgery.

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