

EFFECTIVENESS OF SEPRAFILM AS ADHESION BARRIER FOLLOWING ABDOMINOPELVIC SURGERY- AN EXPERIMENTAL STUDY

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ABSTRACT

BACKGROUND

Postoperative adhesions form one of the most common complication following abdominopelvic surgeries. The consequence of adhesion leads to lifelong morbidity and form major burden in surgeons operating for the second time. Few complications of adhesions include postoperative adhesive colic, bowel obstruction and female infertility. The aim of this study is to evaluate the effectiveness of Seprafilm as adhesion barrier among patients undergoing elective laparotomy.

MATERIALS AND METHODS

All surgical inpatients of Government Rajaji Hospital during the study period who are more than 18 years admitted in surgical wards and planned for elective/emergency laparotomy will be recruited for the study after obtaining valid consent. Patients will be randomly allotted into study and control groups. Patients under the study group will be subjected to placement of Seprafilm. Contrast-enhanced computerised tomogram will be performed for all the patients (both study and control) during 20th postoperative day to evaluate the presence of intraperitoneal adhesions.

RESULTS

30 cases in study group were subjected to the placement of Seprafilm after obtaining prior written informed consent explaining the possible complications in detail. Out of 30 patients, only 4 patients developed minimal adhesions as compared to 16 patients who developed adhesions in the control group as evident by the 20th day CT.

CONCLUSION

Formation of adhesions has been attributed to the morbidity of patients in terms of hospital stay and frequent readmissions along with development of complications like bowel obstruction, chronic pain and certain times vascular compromise. This study conducted in the Department of General Surgery in Government Rajaji Hospital, Madurai, explains the usefulness and effectiveness of Seprafilm as an adhesive barrier in abdominopelvic surgery.

KEYWORDS

Postoperative Adhesions, Seprafilm, Adhesion Barrier, Intraperitoneal Adhesions.

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BACKGROUND

Postoperative adhesions form one of the most common complication following abdominopelvic surgeries. The consequence of adhesion leads to lifelong morbidity and form major burden in surgeons operating for the second time. Few complications of adhesions include postoperative adhesive colic, bowel obstruction and female infertility.

Frequent readmissions leads to mobility of patients. Difficulty in resurgery on opening the abdomen for the second time comprises an important outcome of adhesions. Adhesiolysis stays a temporary mainstay treatment to remove adhesions as they tend to recur following

subsequent surgeries. There is need for thorough understanding of the formation adhesions, which is mainly due to reaction of the peritoneum with the intestinal loops, which comes in contact with it, the complication of peritonitis, the pathology of bowel obstruction and the evolution of the adhesion barrier.

RESEARCH PROPOSAL

Aims and Objectives of the Study

Effectiveness of Seprafilm as adhesion barrier among patients undergoing elective laparotomy.

Inclusion Criteria

1. All patients more than 18 years admitted in surgical wards.
2. Planned for elective laparotomy.

Exclusion Criteria

1. Patients who are planned for/undergoing intestinal anastomosis at the time of laparotomy.
2. Immunocompromised patients.

Financial or Other, Competing Interest: None.

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Source of Data- All surgical inpatients of Government Rajaji Hospital during the study period satisfying the inclusion criteria planned for elective/emergency laparotomy will be recruited for the study after obtaining valid consent. Patients will be randomly allotted into study and control groups.

MATERIALS AND METHODS

- a. Patients under the study group will be subjected to placement of Seprafilm.
- b. Contrast-Enhanced Computerised Tomogram will be performed for all the patients (both study and control) during 20th postoperative day to evaluate the presence of intraperitoneal adhesions.

OBSERVATION AND RESULTS

Study Design- A prospective study with a sample size of 60 patients was conducted at Department of General Surgery, Madurai Medical College, Madurai. 30 patients under the study group under the inclusion criteria were subjected to the placement of Seprafilm and were monitored for the presence of any postoperative complications and observed for the formation of adhesions in the 20th postoperative day. 30 control who have undergone abdominopelvic surgeries under the same inclusion criteria are observed for the presence of adhesions in the 20th postoperative day. Results were discussed at the end of the study.

Age	Cases	Control
<40	10	11
41-50	9	9
51-60	10	10
Total	29	30
Mean	46.2	46.367
SD	14.423	13.187
'P' value	0.963	Not sig.

Table 1. Distribution of Cases According to Age

Patients were randomly designated to the study and control groups. The mean age of both the control and study was found to be 46.36 and 46.2, respectively. The 'p' value is 0.963, thus making it not significant.

Thus, the distribution of cases according to age does not influence the placement of Seprafilm or the formation of adhesions.

Sex	Cases	Control
Male	11	12
Female	19	18
Total	30	30
'P' value	0.946	Not Sig.

Table 2. Distribution of Cases According to Sex

In the study conducted, 11 patients in the study group and 12 cases in control group were males and 19 cases in the study group and 18 cases in the control group were females. The 'p' value of sex distribution is 0.946.

Thus, the placement of Seprafilm and its outcome is influenced by sex distribution as the 'p' value is not significant.

Previous Surgery	Cases	Control
Yes	17	15
No	13	15
Total	30	30

Table 3. Previous Surgery

Previous history of surgery is an important factor in formation of adhesions as surgery done early allows the contact of peritoneum to the previous scar tissue leading to fibrin formation. Out the 30 cases in study group, 17 cases had history of surgery and 15 cases in control groups.

Preoperative Diagnosis	Cases	Control
Cholelithiasis	3	2
Epigastric hernia	1	2
Fatty hernia of linea alba	0	1
Fistula post hydatid excision	0	1
Incisional hernia	12	11
Irreducible epigastric hernia	1	0
Irreducible umbilical hernia	0	1
Obstructed incisional hernia	0	1
Paraumbilical hernia	1	0
Post appendectomy fistula	0	1
Port site incisional hernia	1	0
Recurrent incisional hernia	1	0
Subacute intestinal obstruction	2	0
Umbilical hernia	7	10
Ventral hernia	1	0
Total	30	30

Table 4. Preoperative Diagnosis

A wide variety of cases were subjected to the placement of Seprafilm meeting the exclusion criteria of no history of patients with intestinal anastomosis or in procedures requiring intestinal anastomosis along with immune compromised patients.

Procedure	Cases	Control
Adhesiolysis	2	0
Fistulous tract excision	0	2
Open cholecystectomy	2	2
Open cholecystectomy with umbilical hernia	1	0
Open mesh repair	25	26
Total	30	30

Table 5. Procedure

Out of the 60 patients under study 25 patients in the study group and 26 patients in the control group underwent open mesh repair.

2 of the cases in the study group underwent adhesiolysis with previous history of surgery. The placement of Seprafilm in these patients showed no evidence of adhesions in the 20th day CT in the subsequent surgery performed.

Postoperative Complications	Cases	Control
Nil	26	15
Fever	3	9
Pain	0	4
Wound infection	1	2
Total	30	30
P' Value	0.048	Significant

Table 6. Postoperative Complications

In this study, immediate postoperative fever occurred in 3 patients in the study group and 9 cases in the control group. 4 patients in the control group experienced postoperative pain in 3rd to 7th day while nil pain in patients using Seprafilm.

This pain maybe contributed due to the presence of adhesions in the postoperative period in the control group. The 'p' value is 0.048, which is significant indicates pain is more common in postoperative patients with adhesions.

CT (20 th Day)	Cases	Control
Extensive	0	1
Minimal	4	15
No adhesions	26	14
Total	30	30
P' Value	0.037	Significant

Table 7. CT 20th Day- Adhesions

MATERIALS AND METHODS

In this study, 30 cases in the study group were subjected to the placement of Seprafilm. Out of the 30 patients in the study group, only 4 patients' developed minimal adhesions in the 20th postoperative day CT, while compared to 16 patients out of the 30 in the control group.

The 'p' value is 0.037, which is significant. Thus, this study proves the effectiveness of Seprafilm as an adhesion barrier in abdominopelvic surgeries.

DISCUSSION

Results of the study has been discussed in detail in the following section.

Age Distribution and Adhesion- In two large surveys conducted, postsurgical adhesion formation did not show any dependence to age. There is no prospective evaluation of the effect of age with adhesion.

Weibel¹ and Majno reported increased frequency of spontaneous adhesions after the age of 60.

In our study, distribution of age is categorised into age <40, 41-50 and 51-60. The mean age in cases is 46.2 and in control group was 46.36. The 'p' value is 0.963, which is not significant. Thus, in our study, age does not contribute in formation of adhesions for the placement of Seprafilm.

Sex Distribution and Adhesion- There is no sex bias in the development of postoperative adhesions. Weibel² and Majno reported very slight increase in frequency in formation of adhesions in male patients. Raf² in his study reported the incidence of adhesions to be 48% in males and 52% in female patients.

In this study, male:female ratio in the study group is 11:19 and in the control group is 12:18. The 'p' value is 0.946, which is not significant. Thus, male and female have equal preponderance in formation of postoperative adhesions, thus favouring application of Seprafilm in both sexes.

Previous History of Laparotomy- The omentum is the primary organ to be involved in adhesion formation. According to Weibel¹ and Majno, 100% of the 128 patients under spontaneous adhesion revealed involvement of omentum. Previous history of surgery, which involves peritoneal suturing does not alter the formation of adhesion in allowing the peritoneum to heal or reapproximation with sutures. There is no difference in adhesion relating to previous laparotomy.

In this study, 17 cases in the study group and 15 cases in the control group had previous history of surgery. There is no specific difference in the changes in adhesions in previous history of laparotomy done.

Incision in Procedure Performed- Brill et al³ correlated location and frequency of skin incision in the formation of adhesion. Adhesion to bowel and omentum were found in 27% of patients in the Pfannenstiel group, 58% in midline incision above the umbilicus and in 67% of patients in incisions below the umbilicus.

In our study, except for 4 patients who underwent open cholecystectomy with roof top incisions, the remaining patients had conventional midline scars. So, the incidence of adhesion due to incidence in this study is not significant.

Postoperative Complications- Minor complications noted in studies after placement of Seprafilm include anastomotic leak, peritonitis, abdominal abscess and very few cases reporting foreign body reaction. Patients who need procedures involving intestinal anastomosis are excluded from the group under study.

No such complications occurred in patients under study group. Three patients developed postoperative fever, which settled before third postoperative day. One case developed wound infection, which was managed conservatively. In the control group, 9 cases developed fever, which settled within third postoperative day. Four patients developed postoperative pain till seventh day, which may attribute to formation of adhesions as all developed adhesions in the 20th day CT.

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