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Use of the laparoscopic protective drape mechanism: A prospective comparative study of 60 patients

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ABSTRACT

Introduction: This study aims to reveal the use and advantages of the laparoscopic protective drape mechanism, designed to prevent contamination in minimally invasive surgeries.

Materials and Methods: The laparoscopic protective drape is formed by passing a surgical thread around the circular transparent polyurethane material. It prevents intra-abdominal contamination by laying on the operation area from the trocar; then, it is taken out of the abdomen by pulling the thread. The findings were evaluated by comparing two groups. According to G*Power (v3.1.7) analysis, a total of 60 laparoscopic cholecystectomy-appendectomy cases were examined. IBM SPSS Statistics 26 (IBM SPSS, Türkiye) was used. Significance was evaluated at the $p<0.05$ level.

Results: The material was found useful in 76.67% (n=23) of the cases in which it was used. Preoperative and perioperative findings were similar ($p>0.05$). In the group in which the material was used, peristalsis was more frequent, drain usage was lower, and the hospital stay was shorter ($p=0.001$, $p=0.001$). The decrease in temperature and CRP, and an increase in CRP for those who didn't use the material, were significant ($p=0.001$; $p=0.013$).

Conclusion: The laparoscopic protective drape, designed to prevent contamination in minimally invasive surgeries, is expected to reduce intra-abdominal infectious complications, drain use, postoperative ileus, and shorten hospital stays. It is predicted that it will reduce outcomes such as tumor implantation.

Keywords: Intra-abdominal contamination, laparoscopic protective drape, minimally invasive surgery, postoperative complications

Introduction

Although surgical site infections have decreased due to today's technical developments and treatment modalities, they remain an important postoperative complication that can cause serious morbidity and mortality. Intra-abdominal contamination with materials such as intestinal content and bile is known to cause peritoneal irritation and infectious complications. Perioperative contamination is attempted to be controlled through irrigation and drains.[1-3] In open surgeries, when there is a possibility of contamination with luminal content, contamination in the surrounding tissues is prevented by covering the proce-

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dure floor with sterile compresses. In minimally invasive surgeries, no barrier material or method is known to prevent contamination before it occurs. It appears that some equipment, such as organ extraction bags and wound protection rings, are insufficient to prevent intra-abdominal contamination.[4] As a matter of fact, it is important to avoid rupture and contamination in order to prevent consequences such as biliary peritonitis, which has a mortality rate of up to 26%, chemical peritonitis due to mature cystic teratoma rupture, seeding, and anaphylactic shock due to hydatid cyst rupture.[5-7] However, intra-abdominal contamination isn't only caused by microbial factors but also includes malignant cells, and many surgeons prefer laparotomy in such cases. To eliminate this deficiency, the Laparoscopic Protective Drape Mechanism was designed.[8] In this study, benefits such as preventing postoperative intra-abdominal infectious complications, reducing the need for drains, reducing postoperative ileus, and shortening the operation time and hospital stay have been identified; goals such as preventing tumoral implantation in the long term have been described.[4,8-11]

Materials and Methods

Laparoscopic Protective Drape Mechanism, Preparation, and Usage

The laparoscopic protective drape mechanism, which prevents contamination and seeding in cases where there is a possibility of contamination in minimally invasive surgeries, was patented and received ethics committee approval.

The material consists of a transparent polyurethane surface and a surrounding rope (choosing a transparent material is important for safe viewing). It can be prepared just before the operation with a piece from the last part of the laparoscopic camera cover (we did it this way, and it prevents extra costs), or it can be prepared in advance for routine use and undergo packaging-sterilization processes. A piece is taken from the end of the laparoscopic camera cover and turned into a circle (we have found that a circle with a radius of 6-7 cm is suitable for manipulation). The circle is wrapped around the circumference with a surgical thread in the form of a purse-string suture (we preferred No: 0 silk-sharp, as it is easily obtained, used relatively little, to avoid any extra financial burden, and because it has less memory and more durability). The ends of the thread are left long for later use. The prepared material is rolled into a roll and made ready to be passed through the trocar (Fig. 1a). It is used by inserting the trocar into the abdomen and laying it on a suitable surface, leaving the ends of the thread outside (Fig. 1b). After the surgery is completed, the ends of the thread outside the trocar are pulled, and the material shrinks all around to form a chamber, preventing contamination. Then, it is taken out through the trocar (Fig. 1c). Although its primary purpose isn't as an organ extraction bag, it can be used to remove resected small-sized tissues (for larger tissues, a larger radius may be prepared, or standard organ removal bags may be used while this material lies on the ground) (Fig. 1d).

Study Method

The study was conducted to prospectively evaluate the effects of using the laparoscopic protective drape mechanism in minimally invasive abdominal surgeries in a tertiary healthcare institution. For standardization, laparoscopic cholecystectomies, representing surgeries where irritant luminal content may spread, and laparoscopic appendectomies, representing intestinal resections with high microbial load, were included in the study. Patients with intra-abdominal contamination due to reasons such as intra-abdominal abscesses, collections, and organ perforations before the operation were excluded from the study. The cases in which a laparoscopic protective drape would be used were randomly determined by the operator on the operating table just before the surgery.

The cases were examined in two groups: those in which the laparoscopic protective drape mechanism was used and those in which it wasn't used. The following data were recorded: age, gender, diseases, medications, surgical history, and operation diagnosis; preoperative body temperatures (°C), physical examination findings, leukocyte (µl) and CRP (mg/l) values; and for the perioperative period, whether a laparoscopic protective drape was used, operation duration (min), antibiotic prophylaxis, perforation-contamination status during surgery, and whether abdominal irrigation and/or drain usage occurred. In the postoperative period, body temperatures, physical examination, leukocyte-CRP values just before discharge, drain usage and duration, peristalsis onset time, and postoperative hospitalization time were recorded. Additionally, all cases were called after 1 month and were evaluated and recorded for infectious complications. The operator's comments were also included for the cases in which the equipment was used. The data are presented comparatively between both groups.

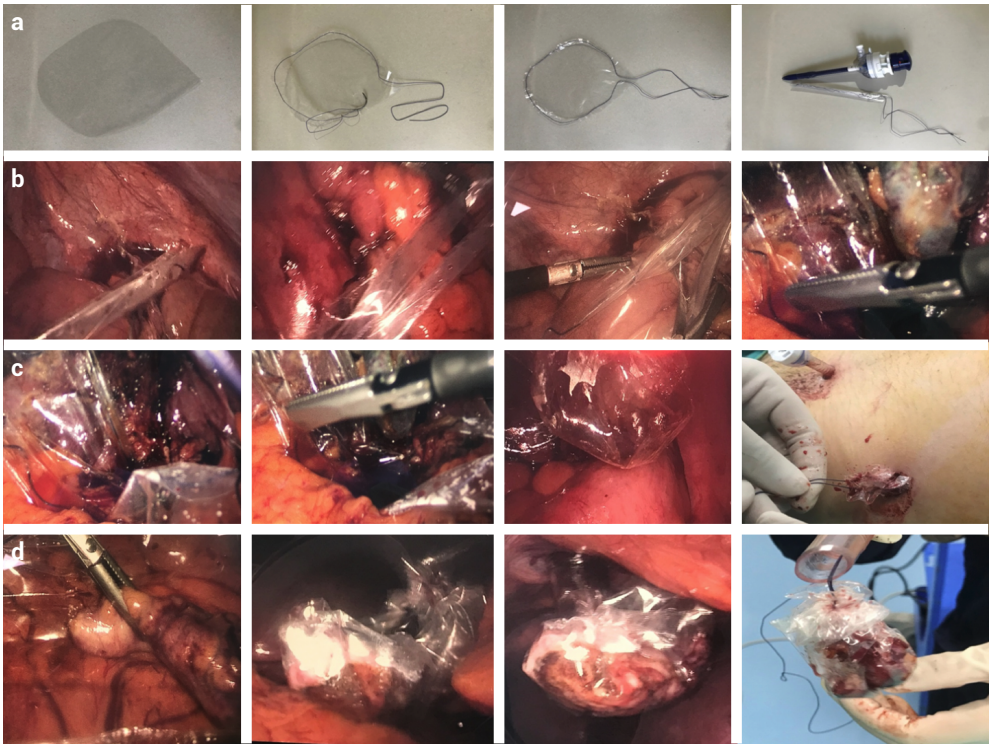

Figure 1. (a) Preparation stages of the laparoscopic protective drape, with a piece taken from the last part of the laparoscopic camera cover. **(b)** Placing the laparoscopic protective drape onto the abdomen through the trocar and laying it on the operating area, ready for use. **(c)** Stages of use of the laparoscopic protective drape by pulling the string when needed and taking it out of the abdomen at the end of the procedure. **(d)** The stages of placing the specimen (appendectomy is shown here) on the laparoscopic protective drape and taking it out of the abdomen through the trocar incision.

Statistical Method

The G*Power (v3.1.7) program was used to determine the number of samples. It was calculated that there should be at least 26 people in each group for 80% power. IBM SPSS Statistics 26 (IBM SPSS, Turkey) was used. Descriptive methods (mean, standard deviation, median, frequency, ratio, minimum, maximum) were applied. The suitability of the quantitative data for normal distribution was tested with the Kolmogorov-Smirnov, Shapiro-Wilk, and Skewness-Kurtosis tests. Independent Samples t-Test was used for two-group comparisons of normally distributed quantitative data, and the Mann-Whitney U test was used for non-normally distributed data. Pearson Chi-Square, Fisher Freeman Halton Exact, and Fisher's Exact tests were used to compare qualitative data. Paired Sample t-Test was used for intragroup (preoperative-postoperative) comparisons of parameters with normal distribution, and the Wilcoxon Signed Ranks test was used for those with non-normal distribution. Significance was evaluated at the $p<0.05$ level.

Results

The study was conducted with a total of 60 cases, 30 in each group. Of these, 60.0% (n=36) were female, and 40.0% (n=24) were male. The mean age was 46.63±16.88. There was a history of comorbidities in 16.7% (n=10) of the cases, a history of medication in 15.0% (n=9), and a history of surgery in 15.0% (n=9). When we look at the subtypes of comorbidities that may affect our evaluation parameters, such as malignancy and infection, none were found in any patient. Similarly, in terms of medications, no antibiotics or immunosuppressants were used in any case. In surgical history, all cases had non-abdominal surgeries.

63.3% (n=38) of the cases underwent cholecystectomy, and 36.7% (n=22) underwent appendectomy. Antibiotic prophylaxis was administered to all of them (n=60). The average operation time was 69.00±25.27 minutes. Perioperative contamination or perforation occurred in 33.3% (n=20) of the cases, and the abdomen was irrigated in 73.3% (n=44). No drain was used in 18.3% (n=11) of the cases, 1 day in 21.7% (n=13), 2 days in 30.0% (n=18), and

3 days or more in 30.0% (n=18); the median drain usage time was 2 days. Abdominal tenderness was present in 46.7% (n=28) of the cases in the preoperative period and in 3.3% (n=2) postoperatively. Postoperative peristalsis occurred in less than 1 day in 53.3% (n=32), 1-2 days in 38.3% (n=23), and longer than 2 days in 8.3% (n=5) of the cases. Postoperative hospital stay was 1 day in 28.3% (n=17), 2 days in 35.0% (n=21), and 3 days or more in 36.7% (n=22); the median hospital stay was 2 days. In the postoperative evaluation 1 month later, intra-abdominal loculated fluid was detected in 1.7% (n=1) of the cases.

Laparoscopic protective drape was used in the operation in 50% (n=30) of the cases. The demographic findings of the cases, their medical history, and preoperative findings were similar between both groups (p>0.05). Considering the perioperative findings, operation times, contamination-perforation rates, irrigation, and drain use rates were similar (p>0.05). However, nearly significant differences were detected in the rates of irrigation and drain use; irrigation and drain use were lower in the group using the material (p=0.080, p=0.053). In postoperative findings, in cases where the material was used, peristalsis was more likely to occur in less than 1 day, and drain usage time and hospital stay were shorter (p=0.001, p=0.001, p=0.001). The results were not significant in the evaluation of complications 1 month postoperatively (p=1.000) (Table 1).

Considering the preoperative-postoperative changes according to the use of the laparoscopic protective drape, WBC and physical examination findings were similar (p=0.225, p=0.6), but postoperative body temperatures were lower in those using the material (p=0.010). In addition, the postoperative decrease in the values was significant in the group where the material was used (p=0.001). Similarly, postoperative CRP values of the materials used were found to be lower, and there was an increase in those not using the material (p=0.043, p=0.002). The decrease in values in the group where the material was used was not significant, but the increase in the group where it wasn't used was significant (p=0.237, p=0.002). In the postoperative period, abdominal tenderness decreased in both groups (p=0.001, p=0.001), but the rates were similar (p=0.602) (Table 2).

According to the operator's evaluation, the material prevented intra-abdominal contamination in 86.67% (n=26) of the cases, eliminated the need for irrigation in 63.33% (n=19), and eliminated the need for a drain in 70% (n=21). It was stated in 53.33% (n=16) of the cases that it made it easier to take the specimen. It was found to be beneficial in shortening the operation time in 50% (n=15) and had a positive effect on early mobilization and discharge in 53.33% (n=16). In 76.67% (n=23) of the cases, the material was found to be generally useful (Fig. 2).

Discussion

Although the rates are lower in minimally invasive surgeries, surgical site infections continue to be a serious cause of morbidity. Paralytic ileus, biliary peritonitis, anaphylaxis, and tumoral implantation may occur.[3] Practices such as the use of perioperative abdominal compresses to prevent contamination in open surgeries suggest that there is no mechanism fully corresponding to minimally invasive surgeries.[12] A material that performs the same function should not only reduce contamination and complications but also be harmless. For this reason, the laparoscopic protective drape mechanism is designed to be of a size that doesn't hinder the surgeon's manipulation, and is transparent to avoid obstructing vision. This material was found to be generally useful in 76.67% (n=23) of the cases.

The use of the laparoscopic protective drape reduces contamination, thus reducing postoperative ileus and drain use; this is expected to shorten the length of hospital stay.[9,13] In order to clearly demonstrate these benefits, our study was conducted with cases in which factors that would affect evaluation parameters were minimized. It is evident that the case selection in such studies is similar.[14] Although we didn't select cases before including them in the study, the fact that the age, gender, comorbidities, medication, surgery and allergy histories of the cases, and the surgeries were similar in both groups contributed to standardization and helped reveal the effects of the material more clearly.

Considering the postoperative findings, peristalsis time was shorter in those using the laparoscopic protective drape (p=0.001); this is consistent with studies mentioning that contamination can cause intra-abdominal abscess and intestinal obstruction.[10] Although contamination-perforation rates were similar, irrigation and drain use were lower in the group where the material was used (p=0.080, p=0.053). Although there are studies showing that irrigation and drainage of infected effusions are beneficial in treatment, there are also studies stating that they don't affect the rates of intra-abdominal abscess, bowel obstruction findings, or hospital read-

Table 1. Evaluation of demographic, preoperative, perioperative and postoperative characteristics according to the use of laparoscopic protective drape mechanism

	Use of Laparoscopic Protective Drape Mechanism			p
	Total (n=60)	Yes (n=30)	No (n=30)	
Age (year)				
Median (Min/Max)	50 (20/ 79)	51 (20/ 72)	49.5 (20/ 79)	[a]0.916
Mean±SD	46.63±16.88	46.40±15.54	46.87±18.38	
Gender				
Female	36 (60.0)	16 (53.3)	20 (66.7)	[b]0.292
Male	24 (40.0)	14 (46.7)	10 (33.3)	
Comorbidities				
Yes	10 (16.7)	5 (16.7)	5 (16.7)	[b]1.000
No	50 (83.3)	25 (83.3)	25 (83.3)	
Medications				
Yes	9 (15.0)	5 (16.7)	4 (13.3)	[c]1.000
No	51 (85.0)	25 (83.3)	26 (86.7)	
Previous surgeries				
Yes	9 (15.0)	5 (16.7)	4 (13.3)	[c]1.000
No	51 (85.0)	25 (83.3)	26 (86.7)	
Allergy				
No	60 (100)	30 (100)	30 (100)	-
Diagnosis				
Acute appendicitis	22 (36.7)	11 (36.7)	11 (36.7)	[d]1.000
Biliary pancreatitis	3 (5)	1 (3.3)	2 (6.7)	
Cholelithiasis	26 (43.3)	13 (43.3)	13 (43.3)	
Acute cholecystitis	9 (15)	5 (16.7)	4 (13.3)	
Operation				
Lap. cholecystectomy	38 (63.3)	19 (63.3)	19 (63.3)	[b]1.000
Lap. appendectomy	22 (36.7)	11 (36.7)	11 (36.7)	
Intraabdominal Contamination/Effusion/Drain				
Yes	0	0	0	-
No	60 (100)	30 (100)	30 (100)	
Start of peristaltism (day)				
<1 day	32 (53.3)	24 (80.0)	8 (26.7)	[d]0.001**
1-2 day	23 (38.3)	5 (16.7)	18 (60.0)	
>2 day	5 (8.3)	1 (3.3)	4 (13.3)	
Time of drain use (day)				
Median (Min/Max)	2 (0/ 8)	1 (0/ 3)	2,5 (0/ 8)	[e]0.001**
Mean±SD	1.98±1.68	1.23±0.97	2.73±1.91	
0 day	11 (18.3)	8 (26.7)	3 (10.0)	[b]0.003**
1 day	13 (21.7)	10 (33.3)	3 (10.0)	
2 day	18 (30.0)	9 (30.0)	9 (30.0)	
≥ 3 day	18 (30.0)	3 (10.0)	15 (50.0)	

Table 1. Cont.

	Use of Laparoscopic Protective Drape Mechanism			p
	Total (n=60)	Yes (n=30)	No (n=30)	
Hospitalization time (day)				
Median (Min/Max)	2 (1/ 8)	2 (1/ 4)	3 (1/ 8)	[e]0.001**
Mean±SD	2.38±1.51	1.77±0.82	3.00±1.78	
1 day	17 (28.3)	13 (43.3)	4 (13.3)	[b]0.003**
2 day	21 (35.0)	12 (40.0)	9 (30.0)	
≥ 3 day	22 (36.7)	5 (16.7)	17 (56.7)	
Postoperative intraabdominal abscess/loculated fluid				
Yes	1 (1.7)	0 (0)	1 (3.3)	[c]1.000
No	59 (98.3)	30 (100)	29 (96.7)	
Postoperative trocar site infection etc.				
Yes	0	0	0	-
No	60 (100)	30 (100)	30 (100)	
Operation time (min)				
Median (Min/Max)	65 (30/ 160)	65 (30/ 120)	65 (40/ 160)	[e]0.635
Mean±SD	69.00±25.27	66.33±22.32	71.67±28.05	
Antibiotic prophylaxis				
Yes	60 (100)	30 (100)	30 (100)	-
No	0	0	0	
Perioperative perforation/contamination				
Yes	20 (33.3)	10 (33.3)	10 (33.3)	[b]1.000
No	40 (66.7)	20 (66.7)	20 (66.7)	
Irrigation of the abdomen				
Yes	44 (73.3)	19 (63.3)	25 (83.3)	[b]0.080
No	16 (26.7)	11 (36.7)	5 (16.7)	
Placement of drain				
Yes	48 (80.0)	21 (70.0)	27 (90.0)	[b]0.053
No	12 (20.0)	9 (30.0)	3 (10.0)	

[a]Independent Samples t Test; [b]Pearson Chi-Square Test; [c]Fisher's Exact Test; [d]Fisher Freeman Halton Exact Test; [e]Mann Whitney U Test; **p<0.01.

mission.[15,16] A meta-analysis comparing peritoneal irrigation and aspiration with aspiration alone in cases of acute appendicitis also showed that irrigation wasn't superior in reducing complications such as intra-abdominal abscess.[17] On the contrary, there are studies showing that irrigation with hypertonic saline increases adhesion in the dissection area.[18] In our study, the rate of irrigation was lower in the group where the material was used (p=0.080), the rate of peristalsis occurring in less than 1 day was higher (p=0.001), and the duration of drain use was shorter (p=0.053), indicating a causal relationship between these results.

Studies have shown that, in addition to perioperative abdominal irrigation and drain use, measures such as antibiotic prophylaxis may be useful in reducing postoperative infections.[19] In our study, where no preoperative antibiotic history was found, antibiotic prophylaxis was administered to all cases. This has contributed to a clearer examination of the effects and consequences of changes in body temperature and leukocytes, which are responses to infection and inflammation.[20] A decrease of 0.24±3.88 µl in WBC value in the group where laparoscopic protective drape was used and an increase of 0.94±3.68 µl in the other group (p=0.225) support the conclusion that this ma-

Table 2. Evaluation of follow-up variables according to the use of laparoscopic protective drape mechanism

	Use of Laparoscopic Protective Drape Mechanism		p
	Yes (n=30)	No (n=30)	
Body temperature (°C)			
Preoperative period			
Median (Min/Max)	36.6 (36/ 37.4)	36.5 (36/ 37.4)	[a]1.000
Mean±Sd	36.61±0.38	36.61±0.45	
Postoperative period			
Median (Min/Max)	36.4 (36/ 36.7)	36.6 (36/ 37.2)	[a]0.010*
Mean±SD	36.32±0.21	36.51±0.32	
p	[f]0.001**	[f]0.236	
Preop-Postop difference			
Median (Min/Max)	-0.2 (-1.3/ 0.6)	-0.1 (-1.2/ 0.8)	[e]0.213
Mean±SD	-0.29±0.45	-0.10±0.47	
WBC (µl)			
Preoperative period			
Median (Min/Max)	9 (5/ 19.7)	8.7 (4/ 23.9)	[e]0.801
Mean±SD	9.63±3.74	9.48±4.36	
Postoperative period			
Median (Min/Max)	9 (4.3/ 16.6)	10 (4.4/ 17.2)	[e]0.169
Mean±SD	9.38±2.89	10.42±3.12	
p	[g]0,713	[g]0,139	
Preop-Postop difference			
Median (Min/Max)	0.3 (-10.7/ 10.1)	0.9 (-6.7/ 7.5)	[e]0.225
Mean±SD	-0.24±3.88	+0.94±3.68	
CRP (mg/l)			
Preoperative period			
Median (Min/Max)	10 (0.3/ 300)	9.8 (0.3/ 185.5)	[e]0.544
Mean±SD	44.57±71.38	38.18±57.61	
Postoperative period			
Median (Min/Max)	22 (4.1/ 360)	40.5 (4/ 269)	[e]0.043*
Mean±SD	43.78±66.11	72.11±70.91	
p	[g]0.237	[g]0.002**	
Preop-Postop difference			
Median (Min/Max)	8.4 (-253.4/180)	23.8 (-97/207.4)	[e]0.013*
Mean±SD	-0.79±71.47	+33.92±59.69	
Sensitivity in physical examination			
Preoperative period			
Yes	15 (50.0)	13 (43.3)	[b]0.605
No	15 (50.0)	17 (56.7)	
Postoperative period			
Yes	1 (3.3)	1 (3.3)	[c]1.000
No	29 (96.7)	29 (96.7)	
p	[g]0.001**	[g]0.001**	
Preop-Postop difference			
Decreasing (yes → no)	14 (46.7)	12 (40.0)	[b]0.602
Unchanging	16 (53.3)	18 (60.0)	

[a]Independent Samples t Test; [b]Pearson Chi-Square Test; [c]Fisher's Exact Test; [e]Mann Whitney U Test; [f]Paired Samples t Test; [g]Wilcoxon Signed Ranks Test **p<0.01; *p<0.05.

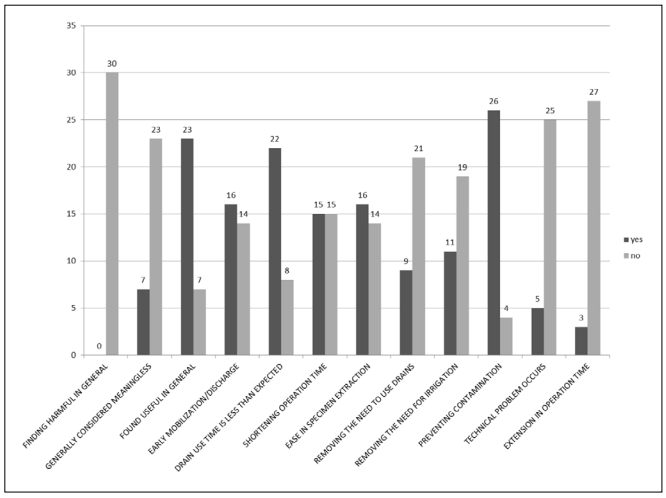

Figure 2. Questions and answers asked to the operator in the group where the laparoscopic protective drape mechanism was used.

terial is useful. However, CRP, which is known to increase in case of infection or inflammation, is generally used as a marker in conditions such as malignancy, trauma, and infection. The values may be affected by some factors. In studies evaluating the use of endobags, it was observed that cases were studied without factors that would impact the CRP value.[13] In our study, cases that could impact the CRP value due to comorbidities and medications weren't included. In addition, the similarity of CRP values in both groups in the preoperative period was a positive factor in examining the results (p=0.544). Postoperative CRP values were found to be lower in the group where laparoscopic protective drape was used (p=0.043). Additionally, when looking at the preoperative-postoperative CRP change, it was observed that the decrease was more evident in the group where the material was used, and the increase was more evident in the group where the material wasn't used (p=0.013), which strengthens the causality of this result with the use of laparoscopic protective drape.

Abdominal pain, whose causes range from conditions requiring emergency surgery to chronic conditions without an underlying pathology, is a very common reason for hospital admission. Gallbladder and appendix pathologies, which are known to be among the basic symptoms of abdominal pain and are extremely important in diagnosis, constitute the patient group examined in our study. The first approach to diagnosis should be clinical evaluation, starting with a physical examination.[21,22] In our study, 46.7% (n=28) of the cases had abdominal sensitivity on preoperative physical examination, and the distribution was similar in both groups (p=0.605). Sensitivity decreased in both groups in the postoperative period (p=0.001, p=0.001); however, the decrease was similar in both groups (p=0.602). This result is consistent with the fact that surgery itself forms the basis of treatment. However, it isn't correct to infer from this result that the laparoscopic protective drape is a useful material.

The main limitation of the study is that it is not possible to examine its effects, such as preventing tumor seeding, in the short term.

Conclusion

Infections acquired in healthcare settings and the resulting prolonged hospital stays both increase the workload and constitute approximately 90% of the total costs. We designed the laparoscopic protective drape mechanism after noticing some correctable shortcomings in minimally invasive surgeries, which are advantageous compared to open surgeries, especially with the shorter hospital stay. We have seen that it prevents intra-abdominal contamination, thereby reducing the use of irrigation and drains, and ultimately provides advantages such as early peristalsis by reducing postoperative infection and inflammation.

When all these factors are evaluated together, the postoperative hospital stay was shorter in the group where the laparoscopic protective drape was used (p=0.001). This shows that the use of the laparoscopic protective drape mechanism in minimally invasive surgeries will be extremely beneficial in the short and long term, both on a patient basis and in terms of general healthcare.

Disclosures

Ethichs Committee Approval: The study was approved by Istanbul University-Cerrhapasa Clinical Research Ethics Committee. (No: E-83045809-604.01.01-419058, Date 30/06/2022).

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Informed Consent: All patients singed an informed consent before the surgery.

Authorship Contributions: Concept – B.G.; Design – B.G.; Supervision – M.F.O.; Materials – B.G.; Data Collection – E.H., E.O., S.E., S.S.U.; Analysis and/ or interpretation – B.G.; Literature Search – B.G.; Writing – B.G.; Critical Review – B.G.

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