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ORIGINAL: The Effect of Endo-bag on Postoperative Complications in Laparoscopic Cholecystectomy Surgery

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ABSTRACT

Introduction: Laparoscopic cholecystectomy is the standard treatment for cholecystitis, which has different advantages and disadvantages. This study was aimed to determine the effect of endo-bag on postoperative complications in laparoscopic cholecystectomy surgery.

Material and Methods: This double-blind clinical trial was conducted in Imam Khomeini Hospital affiliated with Kermanshah University of medical science (KUMS), Kermanshah, Iran. 160 eligible patients (127 females and 33 males) were randomly located in two groups: without endo-bag (104 patients) and with endo-bag (56 patients). The data were collected by experienced nurses. The intensity of pain was assessed by Visual Analogue Scale (VAS). The data was analyzed using independent samples t-test for quantitative variables and chi-square for qualitative variables in SPSS-22 with significance level of 0.05.

Results: Mean duration of surgery with and without endo-bag was 37.68 and 43.85 minutes, respectively ($p<0.05$). The pain intensity in recovery and 12 hours after surgery as well as the incidence of infection in the first two weeks after surgery were lower in endo-bag group than the group without it; however, the association was not significant.

Conclusion: overall, the use of endo-bag to remove the surgical specimen in laparoscopic cholecystectomy surgery can be effective in reducing the duration of surgery and the postoperative infection.

Introduction

With the advancement of technology, surgical techniques tend to be less invasive than non-traditional methods. Laparoscopic cholecystectomy surgery is among these methods, which has replaced open surgery from early 1990s (1). Considering the increasing use of video in surgical techniques, there was a need for new methods and initiatives to remove large samples or contaminants and lumps.

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There are several bags and methods to remove gallbladder, including the use of gloves, condoms and plastic bags; however, the disadvantage of these handmade bags is that they are not subject to quality control and that they may rupture when leaving the abdominal wall (2). In fact, the use of a device called endo-bag is a standard method that was introduced by David et al. in 1993 (3). The use of an extraction bag is meant to reduce the amount of bile or stones shed into the peritoneal cavity and is also beneficial in preventing known metastases in malignancies (4). Nevertheless, extraction bags can complicate the sample removal process and increase the potential risk of abdominal organ damage during bag placement and recovery (5). Therefore, the aim of this study was to evaluate the effect of endo-bag on Postoperative complications of laparoscopic cholecystectomy surgery.

Methods

Study design and population

This double-blind clinical trial was conducted in Imam Khomeini Hospital affiliated with Kermanshah University of medical science (KUMS), Kermanshah, Iran. 160 Patients who referred to surgery unit of Imam Khomeini Hospital for laparoscopic cholecystectomy were included to the study after obtaining written consent. Before performing surgery, the patients were ensured to understand the risks, complications, and changes. The inclusion criterion was patients who diagnosed with gallstones, biliary colic or chronic cholecystitis and subsequently underwent the elective laparoscopic cholecystectomy and age range of 18-65 years. the exclusion criteria were as follows: hepatic cirrhosis, chronic treatment with narcotic drugs or NSAIDS, change of anesthetization method, severe bleeding during surgery leading to laparotomy, patients with obstructive jaundice, pregnancy, malignancy .

160 patients selected to participate in this study. We chose this number because similar study had reported 30% unwanted consequences in the group without endo-bag and 10% in the group with it and, using a confidence level of 95% and a marginal error of 5%, the computed sample size was 72 per group. On the other hand, based on a Cochrane table for determining sample size, the minimum was 70. However, considering a possible 5-10% non-response rate, a sample size of 80 per group was considered appropriate.

Patients were assigned to each group as random blocks to control the effect of age and sex, in such a way that the sex (male and female) and age (<40 years, >40 years, and over) were relatively the same in the two groups. Patients were randomly divided into two groups: A without endo-bag and B with endo-bag to remove the cholecystitis specimen.

Surgical Procedures

In both groups, surgery was performed by routine laparoscopic cholecystectomy with four ports (two 10-mm ports in umbilical and epigastria regions as well as two 5-mm lateral ports for technologist). In group A (without endo-bag), the samples were removed from the epigastric port by laparoscopic graspers. But in group B (with endo-bag), the endo-bag was first inserted into abdominal cavity and opened in the liver bed, the isolated cholecystitis specimen was placed inside it and was then extracted from the epigastric port after closing it. For large samples in both groups, the incision was widened at epigastric port and the samples were subsequently removed. At the end of the operation, in both procedures, the abdominal skin was closed at the ports with 0-2 nylon. The participants were subject to the same anesthetization method, and a nasogastric tube was used for all of them. Following surgery, patients received oral acetaminophen (500-mg tablet) three times per day for wound pain during the first 3 days and were advised with early oral intake and off-bed activity. Narcotic drugs were injected if the patient's pain scale was >5.

Data collection

In Surgery Department and before transfer of

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patients to the operating room, the interviewer presented the necessary training to participants in both groups for responding to the questionnaires. In this study, the patients and the group who measured the variables were unaware of patient's assignment to endo-bag or non-endo-bag group. Instead of patient's name, a special code was used and patient information was kept confidential. Only the surgeon was aware of the group to which the patients were assigned, and based on the coding system, he placed each subject on a checklist after the measurements were completed. The degree of pain was assessed using Visual Analog Scale for pain that was performed by recovery and ward nurses who were unaware of the groups. Pain was also evaluated in the recovery room as well as 4 hours after the operation. For this purpose, a ruler divided into ten equal parts is used. A score of 0 equals no pain and a score of 10 is equal to maximum pain intensity. Finally, the patient was asked to rate the pain between zero and 10 (6).

Statistical Methods

Data were analysed using descriptive statistics including mean ± standard deviation (SD), median, frequencies and percentages wherever applicable. Differences between subgroups were assessed using independent t-test for continuous and normally-distributed variables and chi-square test (or Fisher's exact test) for categorical variables. A test was considered statistically significant if the probability value (P-value) was less than 0.05. All analyses were carried out using Stata software (version 14.1) (Stata Corp, College Station, TX, USA).

Ethics

The Research Ethics Committee at the Deputy of Research of KUMS approved the study protocol in January 2019 (IR.KUMS.REC.1397.200). Also, this Research has been registered by Iranian Registry of Clinical Trials (IRCT20100609004141N3). In addition, the participants were given a participant information statement and signed a written consent form. Individual personal information was kept confidential.

Results

The total number of subjects was 160, of which 104 were in group A and 56 in group B. 127 patients (79.4%) were female and 33 (20.6%) were male; mean age of subjects was 46.08 with SD of 14.05 years and minimum and maximum age of 21 and 84 years, respectively. There were 68 people (42.5%) <40 years and 92 (57.5%) >40 years. The results showed that there was no significant difference between the studied groups in terms of quantitative and qualitative characteristics (p>0.05); in other words, the two groups were matched (**Table 1**).

Mean duration of surgery in the group with and without endo-bag was 37.68 and 43.85 minutes, respectively, and there was a significant difference between using and not using endo-bag during surgery (p<0.005) (**Table 2**).

Table 1. Relationship and frequency distribution of variables by study groups

		With endo-bag N(%)	Without endo-bag N(%)	P
Sex	Female	(80.4%) 45	(78.8%) 82	0.842
	Male	(19.6%)11	22) 21.2%(	
Age		(46.38)56	104)45.91%(	0.844

Chi-square test, *p < 0.05

Table 2. Mean and standard deviation of quantitative variables by study groups and the relationship between them

	With endo-bag Mean(SD)	Without endo-bag Mean(SD)	P
pain intensity in recovery	4.84 (1.125)	5.15 (1.095)	0.088
pain intensity in 4 hours after surgery	5.59 (1.005)	5.87 (1.533)	0.227
pain intensity in 12 hours after surgery	6.25 0.879)	6.32 (1.017)	0.676

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Table 2 Continue			
duration of surgery	37.6 (11.360)	43.85 (12.795)	0.003*
duration of anesthesia	57.32(11.118)	56.97(15.351)	0.880
Duration of hospitalization	26.89(10.861)	24.92(3.077)	0.086

t-test, *p < 0.05

During the first 24 hours after surgery, 17 people had defecation, of which 3 were in without endo-bag (17.6%) and 14 in endo-bag group (82.4%), and none of the subjects had postoperative ileus (POI). According to the results of the first defecation after surgery, there was no significant difference between the endo-bag and without endo-bag groups (p>0.05) (**Table 3**).

Wound infection after laparoscopic cholecystectomy over the first and second weeks in endo-bag group was less than the group without endo-bag, but the difference was not significant and was not observed in any of the samples in the third week (**Table 4**).

Table 3. Relationship between use and non-use of endo-bag on frequency of first defecation during 24 hours after surgery

		With endo-bag (%)N	Without endo-bag (%)N	P
First defection during 24 hours after surgery	Yes	(82.4%) 14	(17.6%) 3	0.090
	No	(62.9%) 90	(37.1%) 53	

Chi-square test, *p < 0.05

Table 4. Relationship between use and non-use of endo-bag on the frequency of wound infection after surgery

		With endo-bag N(%)	Without endo-bag N(%)	P
Wound infection after surgery (First week)	Yes	1(16.7%)	5(83.3%)	0.315
	No	55(35.7%)	99(64.3%)	
Wound infection after surgery (Second week)	Yes	0(0.0%)	2(100.0%)	0.421
	No	56(35.4%)	102(64.6%)	

Chi-square test, *p < 0.05

Discussion

Laparoscopic cholecystectomy is currently the gold standard in the treatment of symptomatic gallbladder disease and chronic cholecystitis. Laparoscopic cholecystectomy is safe and it is associated with less pain, fewer complications and faster recovery compared to open cholecystectomy, which was the previous gold standard (7). On the other hand, Laparoscopic cholecystectomy has a number of problems during and after surgery. The frequency of complications varies between 0.5 and 6%. The most common complications are bleeding, bile duct leakage and surgical wound infection (8). Extraction bags are used to reduce the mentioned complications. Although several studies have investigated the effect of using endo-bags in laparoscopic surgeries (9-11), few researchers have specifically addressed the role of endo-bag and several consequences of it in laparoscopic cholecystectomy surgery. In the present study, we evaluated the role of endo-bags on pain intensity, duration of surgery, wound infection, and POI.

In this study, the intensity of patient's pain was assessed in three stages: during recovery, 4 and 12 hours after surgery. Based on results, the pain intensity in cholecystectomy without endo-bag group was higher than that with endo-bag; however, this finding was not statistically significant. Our study was not consistent with the study of Majid et al. in Ireland, which aimed to assess the safety of gallbladder without using a bag and found that not using a bag was associated with less need to increase the size of incision site and hence reduced postoperative pain and risk of hernia (5). In explanation of this finding, we can state that gallbladder resection was

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performed by two surgeons with different styles in their study, which may have caused the difference in the results of the two studies because one surgeon routinely performed all operations using endo-bags and the other extracted all gallbladders that were not likely to rupture on preoperative ultrasound without the use of an endo-bag and excluded them from the study if ruptured; therefore, 75% of increases in incision cases were observed when using endo-bag.

In the present study, mean duration of surgery in surgery with and without endo-bag was 37.68 and 43.85 minutes, respectively, and there was a significant difference between use and non-use of endo-bag during surgery and the use of endo-bag reduced surgical duration. These findings were not in line with Narayanswamy & Prajwal study because they reported average duration of surgery with and without endo-bag to be equal to 17 and 6 minutes, respectively (12). This may be due to differences in the types of endo-bags as some endo-bags open automatically after entering the abdomen, while others require manual opening by graspers (2). Since we used the automatic type in our study but Narayanswamy & Prajwal applied the manual type in their research, it seems that the difference in type of endo-bags caused a time difference between the two studies. Consistent with our study, in the investigation by Campo and Garcea, the duration of laparoscopic ovarian cyst removal surgery was significantly reduced using endo-bag compared to not using it (63 vs. 81 minutes) (9). Based on the findings of their research, Campo and Campo have recommended the use of endo-bags to remove dermoid cysts laparoscopically to reduce the duration of surgery (11).

In this research, wound infection after laparoscopic cholecystectomy surgery in the first and second weeks after surgery was less in the group with endo-bag than that without it; however, this relationship was not significant and none of the samples (with and without endo-bag) showed infection in the third week, which was in line with previous studies. Kadhim et al. used a sterile male condom to remove a surgical sample during laparoscopic cholecystectomy surgery and reported no cases of intraperitoneal and surgical wound infection (13). In the study of J Comajuncosas et al., there were 8 cases of wound infection in the group using endo-bags to remove gallbladder sample and 7 cases of it in the control group (without using endo-bags) but the reduction was not significant (14). In the study of Girgin et al., the rate of surgical wound infection was lower in the endo-bag group (0 patients) than in the control group (3 patients) (15). In the study of Ahmed Khan et al. who used sterile surgical gloves as a bag to remove the gallbladder, the rate of infection at surgical site was lower in the group using bag than in the other group (2% compared to 6%) (16). Taj et al. also reported a lower rate of wound infection in the group using surgical gloves as endo-bag than the other group among patients with laparoscopic cholecystectomy (0.2% relative to 5.28%) (17). Yano et al. also reported 0.72% rate of surgical wound infection using gloves without surgical powder as an endo-bag (18) and the rate of infection in the study of Narayanswamy & Prajwal was 7.2% in all patients, 80% of whom (16 patients) were in the group without endo-bag (12). In the study of Rehman et al., the prevalence of wound infection was 5.9% (15 out of 254 patients), and 14 patients (5%) were in the group without endo-bag and 1 patient (0.4%) in that with endo-bag (19). A review study by La Regina et al. found that there was a lower rate of infection in samples in which gallbladders were extracted with the help of endo-bag relative to those without endo-bag, but this reduction was not significant and they suggested further extensive studies (20). Also, Bhagavan et al. reported in their retrospective study that the overall rate of superficial wound infection in site of laparoscopic cholecystectomy was 7.2% and that 80% of the patients were in the group without endo-bag (21).

In this study, the first postoperative defecation was investigated in connection with POI. 82.4% of patients who had defecation in the first 24 hours were cholecystectomy patients

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with endo-bag. However, no case of POI was observed in any of the groups and as a result no significant difference was observed between the group with and without endo-bag, which was in line with the study by Garcia and Vara who had no case of POI in the laparoscopic cholecystectomy patients that was attributed to the prevention of intra-abdominal manipulation (22).

Strengths and Limitations

The strengths of this study comprise its double-blind randomized controlled design, blinding of both patients and surgeons, and single-center recruitment, that guarantees homogeneity of the surgical procedure and postoperative management. Another strength of this study is the investigation of the effect of using an endo-bag on several complications of laparoscopic cystectomy surgery at the same time. Our study faced several limitations: first, this study did not report any long-term complications after surgery, such as herniorrhaphy. Second, our data were derived from a single center; hence, our participants may not be representative of the whole population.

Conclusion

Overall, it can be inferred that the use of endo-bag to remove the surgical sample in laparoscopic cholecystitis surgery can be effective in reducing pain, infection after surgery and the duration of surgery.

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Conflicts of interest

Authors have no conflict of interests.

Authors' contributions

All authors were involved in the conception and design, analysis and interpretation of the data, drafting of the manuscript and revising it critically for intellectual content, approved the final version for submission, and agreed to be accountable for all aspects of the work.

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