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EFFICACY OF POWDER-FREE SURGICAL GLOVE BAG VERSUS NO GLOVE BAG FOR RETRIEVAL OF THE GALLBLADDER DURING LAPAROSCOPIC CHOLECYSTECTOMY: A ONE YEAR RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Economical sterile surgical gloves or sterile endobag can be used instead of expensive commercial ones to retrieve the gallbladder specimen and also intraabdominal spilt stones safely without complications in laparoscopic cholecystectomy. But the evidence available on the subject is still conflicting. Study was done with the objective of comparing the duration of surgery with the use of powder-free glove bag versus without glove bag for extraction of gallbladder specimen to determine the ease and efficacy of the use of glove bag.This was a 1 year randomized controlled trial, conducted in the Department of general surgery, Dr Prabhakar Kore hospital, KLE, Belgavi between January 2017 to January 2018. The patients were divided into group A (use of powder-free glove bag for extraction of gallbladder specimen) and group B (without the use of glove bag for extraction of gallbladder specimen). The intra-op time taken for withdrawal of the specimen in both groups was measured and compared. A total of 60 people were included in the analysis, with 30 participants each in study and control group. Among the control group, the median time taken for removal specimen was 2.05 minutes; it was 4.25 minutes was a study group. The difference in the median time taken for removal specimen between the group was statistically significant (P value <0.001).The post-operative infective complications were significantly lower in the study group, as compared to controls. But the duration and the occurrence of intraoperative bile leak were higher among study group. Hence the choice procedure needs to make with caution, considering all the risks and benefits involved.

KEYWORDS: Laparoscopic cholecystectomy, Specimen retrieval, Low cost, Powder-free glove bag.

INTRODUCTION

Laparoscopic cholecystectomy (LC) is considered worldwide the "gold standard" in the surgical treatment of symptomatic cholelithiasis and acute cholecystitis because it offers well-known and more definite advantages in comparison with open cholecystectomy (1). LC, introduced in the late 1980s, has replaced the open technique, although the former is less invasive, requires shorter hospitalizations, and is associated with faster recovery than open cholecystectomy, gall bladder perforation and spillage are the common complications encountered during dissection and removal of gall bladder (25%) (2). However there has been increasing report of infectious complications due to un-retrieved stones and spillage of bile. Economical sterile surgical gloves or sterile endobag can be used instead of expensive commercial ones to retrieve the gallbladder specimen and also intraabdominal spilled stones safely without complications (3).

In the developed world 90 % of cholecystectomies are completed laparoscopically. Since the introduction of laparoscopic surgery for gallbladder disease different types of retrieval devices have been used to extract the gallbladder from the peritoneal cavity. These ranged from simple non-powdered gloves to several types of commercially produced bags (4-5). The use of retrieval devices have been advocated for several reasons, including prevention of wound infection and avoidance of port site metastasis.6-8 In LC, their use is thought to provide the further benefit of reducing the risk of stone spillage into the peritoneal cavity. However, the use of retrieval bags can make removal of the specimen more difficult, requiring enlargement of the port site incision and potential risk of abdominal organ damage during bag insertion and retrieval (9-10).

Intraperitoneal spillage of bile and gallstones and later implantation of gallstones, during dissection of the gallbladder off its liver bed and it's retrieval without endobag, are documented complications (11-12). In order to prevent above complications, gallbladder specimen and the spilled gallstones are retrieved in an endobag, usually through umbilical port. Distended

gallbladders that are packed with stones always create a problem during their retrieval from the abdomen. Gallbladder removal in these cases required a needle decompression, stone fragmentation and stone removal from the gallbladder near the port site or enlargement of the one of the fascial incision to facilitate gallbladder retrieval, which causes more postoperative port site pain.

After laparoscopic cholecystectomy, extraction of the gallbladder is a time consuming and difficult job. So proper positioning of instruments (railroading) and orientation are required for retrieval of gallbladder specimen (13). Although, several techniques and methods are suggested to facilitate the retrieval of gallbladder safely, problems occurring during retraction have not been completely remedied and generally widening of the port site is required. This increases the risk of bleeding, haematoma and infection as well as leaving a risky area for incisional hernia (14).The present study intended to ascertain the safety, ease of retrieval and septic complications of using powder-free surgical glove bag for retrieval of gallbladder specimens and the spilled gallstones during laparoscopic cholecystectomy.

OBJECTIVE: To compare the duration of surgery with the use of powder-free glove bag versus without glove bag for extraction of gall bladder specimen to determine the ease and efficacy of the use of glove bag.

MATERIALS AND METHODS

Study Site: This study was conducted in the Department of general surgery, Dr. Prabhaker Kore hospital, KLE, Belgavi

Study Population: All the patients who are admitted and undergoing laparoscopic cholecystectomy in the department OF GENERAL SURGERY at Dr. Prabhakar Kore hospital.

Study Design: The current study was a randomised control trial.

Sample Size: 60

Sampling Method: All the eligible subjects were recruited into the study consecutively till the sample size is reached.

Study duration: The data collection for the study was done between January 2017 to January 2018 for a period of 1 year.

Inclusion Criteria

- Patients who were admitted and undergoing laparoscopic cholecystectomy in in the department of general surgery at Dr. Prabhakar Kore hospital
- Patients who gave written and informed consent for participation in the study.

Exclusion Criteria

- Patients with known latex allergy.
- Patients with deranged coagulopathy
- Patients with significant other co-morbities, in whom ejection fraction is 20% or less, or with copd
- Patients diagnosed with peritonitis

Ethical Considerations: Study was approved by institutional human ethics committee. Informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and voluntary nature of participation were explained to the participants before obtaining consent. Confidentiality of the study participants was maintained.

Data Collection Tools: All the relevant parameters were documented in a structured study proforma.

Methodology: Data collection was done from KLE Dr Prabhakar Kore Hospital and MRC, Belgavi surgery wards. Computer generated random numbers by SPSS programme were used to assign the type of intervention chosen for the patients that is, group A (use of powder free glove bag for extraction of gall bladder specimen) and group B (without the use of glove bag for extraction of gall bladder specimen) The intra-op time taken for withdrawal of the specimen in both groups was measured and compared.

Surgery

Initial procedure of the conventional laparoscopic cholecystectomy is done. A powder-free glove bag is introduced into the peritoneal cavity through the umbilical port, with the help of the instruments, the specimen is carefully placed into the glove bag and retrieved through the umbilical port.

Investigations

- Routine blood investigations including coagulation profile, USG abdomen and pelvis, CT abdomen wherever applicable.

Intervention

- Powder-free glove bag was used to retrieve the gall bladder specimen after laparoscopic cholecystectomy.

Statistical Methods

Gender, history of complaints, comorbidities, diagnosis, were considered as primary outcome variables. Group was considered as primary explanatory variable.

All Quantitative variables were checked for normal

distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro- wilk test was also conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution.

For non-normally distributed time taken for removal of specimen (minutes) the median values were compared between study groups using Mann-Whitney U test. (2 groups).

The association between group and Gender, history of complaints, comorbidities, associated complications was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis (15).

RESULTS

A total 60 people were included in the analysis with 30 participants in each group. 12(40%) were males and 18 (60%) were females. The gender matching was done for control groups.

Diagnosis	Frequency	Percentages
Cholecystitis	21	35.59%
Cholelithiasis	12	20.33%
Carcinoma of gall bladder (incidental finding)	4	6.76%
Gangrenous Gall bladder	3	5.08%
Empyema gall bladder	3	5.08%
Gall bladder polyp	2	3.38%
Gall stone pancreatitis	1	1.69%
Mucocele of gall bladder	1	1.69%

Table 1: Descriptive analysis Of Diagnosis In The Study Population

The majority of 35.59% participants hadCholecystitis, followed by Cholelithiasis, Carcinoma of gall bladder, gangrenous gall bladder, empyema gall bladder and gall bladder polyp was 20.33%, 6.76%, 5.08%, 5.08% and 3.38% respectively.

The majority of 86.44% participants underwent laparoscopic cholecystectomy, followed by laparoscopic subtotal cholecystectomy and ERCP followed by laparoscopic cholecystectomy was 6.67% and 3.38% respectively.

Procedure done	Frequency	Percent
laparoscopic cholecystectomy	51	86.44%
laparoscopic cholecystectomy subtotal cholecystectomy	4	6.67%
ERCP followed by laparoscopic chole cystectomy	2	3.38%
ERCP-Basketting of stone, CBD stent Laparoscopic cholecystectomy	1	1.69%
lap cholecystectomy with laparo-scopic hernia repair, mesh plasty	1	1.69%
Laparoscopic Cholecystectomy with anatomical repair of paraumilicalhermia	1	1.69%
Laparoscopic cholecystectomy with adhesiolysis	1	1.69%
Laparoscopic cholecystectomy with biopsy of liver nodute	1	1.69%
Laparoscopic cholecystectomy with Choledochotomy	1	1.69%
Laparoscopic cholecystectomy with tubectomy, mesh repair	1	1.69%

Table 2: Descriptive Analysis Of Procedure Done In The Study Population

Among the control, the median time taken for removal specimen was 2.05 minutes, it was 4.25 minutes was study group. The difference in the median time taken for removal specimen between group was statistically significant (P value <0.001).

Parameter	Group		Mann Whitney U Test (P value)
	Control group (N=30)	Study group (N=30)	
Time taken for removal specimen (minutes) Median(IQR)	2.05 (1.69, 3.56)	4.25 (3, 7.20)	*<0.001*

Table 3: Comparison of Median Time Taken For Removal Specimen Between The Two Groups (N=60)

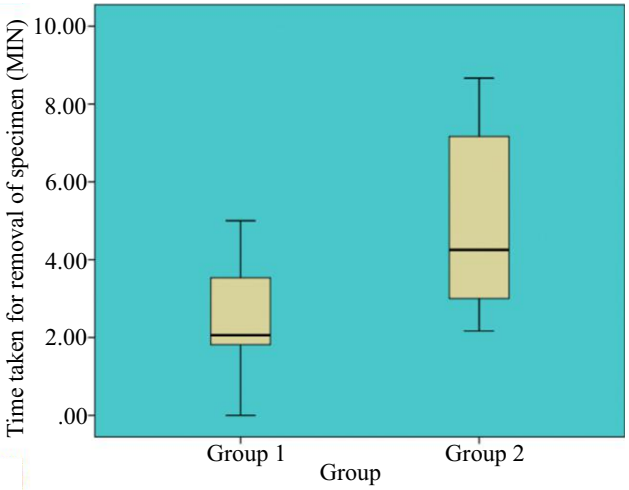

Fig 1: Comparative Box Plots of Comparison of Median Time Taken For Removal Specimen Between The Two Groups (N=60)

Among the control, 13 (68.4%) participants had associated complications. Among the study group, 7 (31.8%) participants had associated complications. The difference in the proportion of associated complications between groups was statistically significant (P value 0.019).

Among the control, 11 (57.9%) participants had extended incision. Among the study group, 2 (9.1%) participants had extended incision. The difference in the proportion of extended incision between groups was statistically significant (P value 0.001). Among the control, 5 (26.3%) participants had infection. Among the study group, 1 (4.5%) participants had infections. The difference in the proportion of infection between group was statistically significant (P value 0.049). Among the control, 2 (10.5%) participants had intra op bile leak. Among the study group, 4 (18.2%) participants had intra op bile leak. The difference in the proportion of intra op bile leak between group was statistically not significant (P value 0.489). Among the study group, only 1 (4.5%) participants had bile drained from GB in glove.

DISCUSSION

Laparoscopic cholecystectomy has been established as the most preferred approach in the management of symptomatic gallbladder diseases due to short hospital stay, early recovery, less postoperative pain, good cosmetic results and early return to work. Spilled or implanted gallstones and spillage of infected bile in the peritoneal cavity are common events during LC without using endobag. Spillage of infected bile and gallstones in the peritoneal cavity and retrieval port site with implantation of the gallstones in the subcutaneous tissues of the abdominal wall causing discharging sinus or abscess are reported complications (16).

The present study demonstrates an easy, safe and cheap method for removal of the gallbladder in LC, which is in agreement with a study by Yano et al (17). and Holme et al (4).

On the whole 60 subjects were included with equal proportion in control group (50%) and study group (50%). In the current study 12(40%) were males and

Associated complications	**Group**		**Chi square**	**P-value**
	Control group (N=19)	**Study group (N=22)**		
Extended incision				
Yes	11 (57.9%)	2 (9.1%)	11.21	0.001
No	8 (42.1%)	20 (90.9%)		
Infection				
Yes	5 (26.3%)	1 (4.5%)	3.868	0.049
No	14 (73.7%)	21 (95.5%)		
Intra op bile leak				
Yes	2 (10.5%)	4 (18.2%)	0.478	0.489
No	17 (89.5%)	18 (81.8%)		
Bile drained from GB in glove				
Yes	0 (0%)	1 (4.5%)	**	*
No	19 (100%)	21 (95.5%)		
Total				
Yes	13 (68.4%)	7 (31.8%)	5.467	***0.019***
No	6 (31.6%)	15 (68.2%)		

Table 4: Comparison of Group With Associated Types Of Complications (N=41)

***Chi square test not applicable.*

**No statistical test was applied- due to 0 subjects in the cells.*

(18) (60%) were females. Gender wise the Iraqi study18 had most of its subjects being females (91.2%) with 8.8% males, so are those reported by Sajid M et al (19). (Females-92%: 8% males). Though, the present had relatively lesser proportion of female participants, still a higher proportion of females (60%) were noted in relation to males (40%) both in control and study groups. These findings corroborate that the prevalence of cholelithiasis is more common among females.

Among the participants, cholecystitis (35.59%) was the commonest diagnostic conditionfollowed by cholelithiasis (20.33%), gangrenous gall bladder (5.08%) and gall bladder polyp (3.38%). AL-Dhahiry 18 reported that chronic calculous cholecystitis (88.6%) as the most common condition among the subjects, followed by mucocele of gallbladder (5.9%) and acute episode of chronic calculous cholecystitis (3.9%).

Cholelithiasis can be either asymptomatic or symptomatic. Symptoms can be specific including intermittent pains in the right upper quadrant of abdomen or can be nonspecific as nausea and vomiting (20).

The majority of participants (86.44%)underwent laparoscopic cholecystectomy, followed by laparoscopic subtotal cholecystectomy (6.67%) and ERCP followed by laparoscopic cholecystectomy (3.38%). Similar to our findings, Sajid M et al.19 performed laparoscopic cholecystectomy in 92% patients. Currently, more than 80% of cholecystectomies globally are laparoscopically performed (21).

Regarding the complications during or after surgery, AL-Dhahiry18 noted post-operative bile leak among 2% of their cases, while no port site infection, intra peritoneal infection was present in the patients. However, bleeding from the cystic artery was noted in 4.2% of patients, accidental spillage of gallbladder with/without spillage of stones was seen in 3.6% patients and perforation of condom endobag during the retrieval of specimens occurred in 3.8% cases. Sajid M et al.19noted post-operative bile leak in 2% patients which was due to minor injury of CBD, which required re-exploration & suturing of defect and 6% patients developed wound infection.

Of the 41 participants having surgical complications, a significantly higher (P = 0.019)proportion of them were present in the control group (68.4%) in relation to the study group (31.8%).

A significantly higher (P = 0.001) proportion of controls (57.9%) had extended incision than the study group (9.1%) participants. Contrastingly, Majid et al. 22 noted that among 9.7% (36) patients who required extended incision, 75% (27) of them belonged those in whom retrieval bag was used.

Among the control, 26.3% participants had infection while in the study group only one participant (4.5%) had infection and the difference was statistically significant (P = 0.049). Concurring this are the findings from Majid et al (22) who found that among those post LC surgery patients with superficial wound infections, 57% patients were in the group in whom retrieval bag was not used compared with those in whom retrieval bag was used (43%). Wound infections can be prevented by; appropriate administration of antibiotic prophylaxis, sterile techniques and the use of specimen endobags for specimen extraction (23).

Bile leakage and choleperitonitis after open cholecystectomy is rare but its rate increases in Machado et al (24). reported that nearly 50% of the cases with complications had bile leakage, while Amir D et al.25 reported in 1.4% of patients. However, in our study a higher proportion of bile leak was noted during the operation. This was more participants of the study group (18.2%) than the control group (10.5%).

Bile duct injuries are the most serious complication of LC. Although no significant difference has been reported in the rate of bile duct injury between open and laparoscopic cholecystectomy, injuries are more frequent in LC than open surgery and this rate is variable from almost 1% in LC to 0.5% in open cholecystectomy. However, special attention must be paid to high rate of bile duct injuries. For preventing these injuries knowledge on local anatomy during surgery is mandatory (25).

Unlike primary reports that indicated an increase in the complications rate of LC in comparison to open surgery, recent data shows that LC accounts for less morbidity and mortality compared to open surgery. Mounting evidence suggests that laparoscopic cholecystectomy is an effective and safe technique of treating symptomatic gallstones even in cases of acute cholecystitis because of accelerated recovery couple with less postoperative pain and short hospital stay (18, 24-25).

The study findings reveal that post-operative pain was not significantly different among patients of either group. Concurring with these findings Majid et al (22). reported that the post-operative pain was not significantly different between the group undergoing LC using a retrieval bag and the group where no bag was used.

The mean time taken for specimen removal among the study group was significantly (P value <0.001) higher (4.25 minutes) than that of the control group (2.05 minutes). Kirshtein et al (26). reported similar increase in overall operative time in the drain (endobag) group (42.5 minutes) than the non-drain group (37 minutes)

It could be possibly due to delay in using the glove bag, which in turn influenced by the surgeon's inexperience in manoeuvring the glove bag, the need to crush the gall stones before retrieval, the need to drain bile before retrieval, the necessity to remove the specimens without increasing the incision size or combination of all these factors.

It is easier to place the gallbladder and any spilled stones in the glove bag than in an ordinary endo- bag occupying a trocar. The glove bag allows the surgeon to work with 2 hands because the bag lies free in the abdominal cavity and does not, like an ordinary endobag, occupy a trocar 2. Third, gallbladder cancers that are incidentally discovered after LC have the potential for tumor seedings at the port sites (27). It has therefore become the standard practice in many institutions to excise laparoscopic port sites in these patients after the primary operation. Routine use of the glove bag is expected to prevent port site implantation of tumor cells.

The Study Had Some Limitations

Firstly, investigator blinding was not possible due to the nature of the intervention, hence the role of ascertainment bias cannot be ruled out from study.

Secondly, generalizability of the study findings is limited as the study was conducted in a single center. Hence, there is a need for further large scale studies on the subject to enhance the quality of available evidence on the subject.

CONCLUSION

The study has compared the post-operative outcomes between powder free surgical glove bag and no bag groups, in patients undergoing gall bladder retrieval during laparoscopic cholecystectomy. The most common etiology in the study was Cholecystitis, followed by Cholelithiasis. The other conditions were metastatic adenocarcinoma of gall bladder, gangrenous gall bladder and gall bladder polyp. Laparoscopic cholecystectomy was the most common surgical procedure. A minor portion had prior ERCP and very few patients had undergone, laparoscopic subtotal cholecystectomy. The etiology and surgical procedures were comparable between two groups.

The median time taken for removal among control group was significantly shorter, compared to intervention group. The incidence of complications was significantly lower in intervention groups, as compared to control group (31.8% Vs 68.4%, P value = 0.019). The proportion of participants, which needed extended incision, was quite higher among controls, as compared to cases (57.9%) Vs 9.1%, P value 0.001).The proportion of people with infection was significantly higher among controls as compared to cases (26.3% Vs 4.5%, P value 0.049). Intra operative bile leak was higher among the intervention group, as compared to controls (18.2% vs 10.5%, P value 0.489). But the difference was statistically not significant. Among the study group, only 1 (4.5%) participants had bile drained from GB in glove.

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