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ORIGINAL ARTICLE

The Efficacy of Using a Sterile Glove Technique for Retrieval of the Gall Bladder Through the Epigastric Port in Preventing Post-Operative Infections During Laparoscopic Cholecystectomy

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ABSTRACT

Objectives: To compare the efficacy of using sterile surgical gloves to retrieve the gall bladder through the epigastric port in laparoscopic cholecystectomy as compared to the direct retrieval technique in terms of surgical port site infections.
Study Design: Randomized Controlled Trial
Setting: Department of Surgery, Khyber Teaching Hospital, Peshawar.
Duration: From 1st August, 2022, to 31st January, 2023.
Methodology: After attaining approval from the Hospital ethical committee all patients meeting the inclusion criteria were included in the study. The patients were allocated in two groups through blocked randomization: Group A (use of sterile glove for extraction) and Group B (direct removal of gall bladder). Results were analyzed on Statistical Package for Social Sciences (SPSS) Version 23 and depicted in the form of description and statistical tables.
Results: The mean age was 39.64 years ± 3.22 in group A and 38.25 years ±13.3 in group B and most patients were females in both groups, group A (n=40, 80%) and group B (n= 69, 86.3%).In group, A ,11 patients were diabetic (22%) and 5(10%) of the patients developedPSI at the epigastric port, 3(27.3%) in diabetics and 2(5.1%) in non-diabetics, p-value 0.031. In group B, 19 patients were diabetic (23.8%) and10 (12.5%) patients developed PSI, seen on 7th day follow up, 8 in diabetics (80%) and 2 non-diabetics(20%), p-value <0.01. The correlation between diabetes mellites and PSIs showed significant correlation p-value <0. 001.However,no significant correlation was seen between both groups in terms of PSIs, p-value 0.530.
Conclusion: Even though it was observed that using retrieval bags relatively decreases the incidence of port site infections in laparoscopic cholecystectomy, the percentage is not notable enough to justify for its impact on operative time.
Keywords: Laparoscopic Cholecystectomy, Epigastric Port,Glove Technique, Direct Removal, Port Site Infections.

INTRODUCTION

The first laparoscopic cholecystectomy was performed in the late 1980s[1] and, since then, it has become the method of choice for various gall bladder related diseases such as acute and chronic cholecystitis, cholelithiasis, gall stone induced pancreatitis, cancers and polyps. Its main benefit lies in significantly reducing the post-operative complications and adverse effects related to surgical site infections, post-surgery pain[2,3] and the incidence of incisional hernias. In addition, this procedure is also reported to be superior to open cholecystectomy in terms hospital expenses and quick recovery of the patient[4].

Common complications of laparoscopic cholecystectomies include postoperative pain, bleeding, infection, and damage to the surrounding structure. Many factors have been deemed responsible for surgical site infections following cholecystectomies such as old age[5], male gender[6], a longer duration of surgery[7] and underlying comorbid medical conditions[8]. One drastic complication, often induced by the surgeon himself, is injury to the common bile duct/hepatic duct[9]. There are circumstances where the surgery is converted to the open technique, however, the frequency has reduced courtesy of growing experience of the surgeons[10].

Even though they are infrequent, port site infection (PSI) is one of the inconvenient side effects that negates the advantages of laparoscopic/endoscopic surgery. Studies have compared various surgeries in terms of PSIs that develop at different laparoscopic ports: e.g., about 8% following laparoscopic cholecystectomy and 11% after laparoscopic appendectomy[11] at the umbilical port. Despite the fact that numerous aseptic techniques and antibacterial chemicals have been designed to counteract this problem, PSIs continue to be prevalent[12]. The main reason behind occurrence of PSIs is the vulnerability of the skin to be infected with multiple microorganisms derived from extrinsic as well as intrinsic sources[13].

Removal of the gall bladder at the end of laparoscopic cholecystectomy is a significant final step in this procedure having an effect on the rate of PSIs in the post-operative period. GB withdrawal is achieved either through the epigastric port or the umbilical port in laparoscopic cholecystectomy[14-16] and both ports have been utilized over the years, greatly dependent upon the personal preference of the surgeon himself rather than decisions based on studies[17]. Data on the umbilical port is available however studies on epigastric port are limited. This study will test the hypothesis that the use of the endo bag seems to decrease the risk of infection with microbes, bile, and gallstones following retrieval through the epigastric port[18]

MATERIALS AND METHODS

This randomized controlled trial was conducted in a tertiary care Hospital in Peshawar from 1st August, 2022, to 31stJanuary, 2023. The sample size was 130 (50 patients in group A and 80 patients in group B) using percent of unexposed with outcome 1% and percent of exposed with outcome as 14%[19],95% confidence interval, and 80% power of the test. Non-probability consecutive sampling technique was used.

Data Collection: The institution's ethical and research council gave its approval before the study could begin. All patients who met the requirements for inclusion in the study underwent screening in the OPD before being admitted to the ward for further assessment. They were made aware of the aim and purpose of the study and reassured that it was being carried out solely for research. If they agreed, informed consent was obtained.

The patients were allocated in two groups through blocked randomization. Group A (use of sterile glove for extraction) and Group B (sterile glove not used for extraction). All patients were given standard anesthesia and pre-operative antiseptic techniques were the same for both groups of patients. Under general anesthesia, the same general surgeon performed the procedure using the four ports method. At the infra-umbilical port (open technique) and epigastric regions(closed technique), 10 mm ports were placed. Following dissection, GB was removed via the epigastric port using both retrieval methods.

Fascial sheath following both techniques was closed with absorbable suture (Vicryl) and skin with non-absorbable sutures (prolene) followed by same antiseptic dressing at port sites for both groups of patients. It was made sure that all patients received the same antibiotic per operatively and after surgery in the ward. Post

operatively, all patients in both the group were kept under observations for 3 days to be discharged. The final outcome was measured on day of discharge and on the 7th post-operative day after follow up. Signs of infection were defined as erythema, tenderness, palpable swelling and wound dehiscence at the surgical site. All the above-mentioned information including name, age, and gender were recorded in a pre-designed proforma.

Data Analysis: Data was analyzed by using a statistical software SPSS version 23.0. Continuous variables i.e., age, duration of surgery was calculated as Means ± Standard deviation. Categorical variables i.e., gender, technique of GB retrieval and post-operative port site infection were analyzed as proportions. Outcome i.e., port site infection was compared in both groups by student's T-test if assumptions are fulfilled. P value of < 0.05 was considered significant. All the results were presented in the form of graphs and tables.

RESULTS

The mean age was 39.64 years ± 3.22 in group A and 38.25 years ±13.3 in group B and most patients were females in both groups, group A (n=40, 80%) and group B (n= 69, 86.3%). There were 10 males in group A (10%) and 11 in group B(11%). Most patients fell in the age category of 20 to 39 for both groups. Pearsonchi square test was appliedamong age, gender, diabetes mellites and PSIs. In group Athe relationship of gender with PSIs gives us a p-value of 0.018 showing that more females are prone to develop PSIs compared to males, age categories had no correlation, p-value 0.520. Out of 50 cases ,11 patients were diabetic (22%), no patient developed any evidence of port site infections from the first till the third postop day however on 7th post op day follow up in the OPD it was observed that 5 (10%) of the patients appeared to have surgical site infection at the epigastric port, 3(27.3%) in diabetics and 2(5.1%) in non-diabetics. The correlation among diabetes mellites and PSIs on follow up was statistically significant, p-value 0.031 rejecting the null hypothesis that more patients with diabetes mellites are at risk for having PSIs on follow up.Similarly, in group B, Pearson chi square test was applied between age, gender, diabetes mellites and PSIs. The relationship of gender with PSIs gives us a p-value of <0.01 again showing that more females are prone to develop PSIs compared to males, age categories also had correlation, p-value 0.017 showing that most patients fell in the age group of 20-39. Out of 50 cases ,19 patients were diabetic (23,8%), no patient developed any evidence of port site infections from the first till the third postop day Out of total 80 candidates, none of the patients had any wound site infections from 1st to 3rd post op day and in the 7th postop day follow up it was observed that 10 (12.5%) of the patients had developed port site infection, 8 in diabetics (80%) and 2 non-diabetics (20%), and the same management strategy was used to benefit the patient.Diabetes mellites and PSIs on follow up showed very significant correlation, p-value of<0.01 however no significant correlation was seen between both groups in terms of incidence of PSIs, p-value 0.530.

Table 1: Variables with frequencies and percentages (N = 130)

Variable	Groups			
	A		B	
Age Mean ± SD	39.64 ± 3.22		38.25 ± 13.3	
Gender	Females	Males	Female	Male
	40(80%)	10(20%)	69(86.3%)	11(13.7%)
Diabetes Mellites	11 (22%)		19 (23.8%)	
PSIs	5 (10%)		10 (12.5%)	

Table 2: Group A Gender Portsiteinfectiononfollowup Crosstabulation

Variables		Portsite Infection on Follow Up		Total	p-value
		none	yes		
Gender	female	38(84.4%)	2(40%)	40(80%)	0.018
	male	7(15.6%)	3(60%)	10(20%)	
Age categories	20 to 39	29(64.4%)	2(40%)	31(62%)	0.520
	40 to 59	9(20%)	2(40%)	11(22%)	
	60 to 80	7(15.6%)	1(10%)	8(16%)	
Diabetes Mellites		2(40%)	3(60%)	5(100%)	0.031

Table 3: Group B Gender Port Site Infection on Followup Crosstabulation

Variables		Portsite Infection On Follow Up		Total	p-value
		none	yes		
Gender	female	65(92.8%)	4(40%)	69(86.3%)	<0.001
	male	5(7.2%)	6(60%)	11(13.7%)	
Age categories	20 to 39	46(65.7%)	3(30%)	49(61.3%)	0.017
	40 to 59	20(28.6%)	4(40%)	24(30%)	
	60 to 80	4(5.7%)	3(30%)	7(8.6%)	
Diabetes Mellites		2(20%)	8(80%)	10(100%)	<0.001

Table 4: Group B Ports iteinfections on follow up Ports iteinfection on follow up groupa Crosstabulation

		Ports iteinfection on follow up group a						Total		p-value
		none				yes				
Port Site Infections On Follow Up Group B	none	27	90%	38	84.4%	5	100%	70	87.5%	0.530
	yes	3	10%	7	15.6%	0	0%	10	12.5%	
Total		30	100%	45	100%	5	100%	80	100%	

DISCUSSION

Laparoscopic surgery comes with its own sets of post-operative adverse events. Even though it happens rarely, port site infections (PSIs) are one of the inconvenient side effects that negates the advantages of minimally invasive surgery. Surgical site infections are to blame for rising hospital costs and lengthened hospital stays.

In our study the mean age was 38.78 years ± 14.25 SD and the population was predominantly female (n=109, 83.8%) compared to males (n=21, 16.2%) These findings are consistent with the results of Raj PK et al and other analysis as well[20-22]. There was no noticeable difference in the septicemia percentage between the two methods of GB retrieval. Research has shown an average percentage of 2.4-3.2% port site surgical site infections following elective laparoscopic cholecystectomy[23-24].The findings in our study are consistent with these previous researches as PSIs were observed in only 5% of the group A study population and zero cases had PSIs in the immediate post-op period.

According to Taj MN et al20, postsurgical dermal contamination was found in 26 (5.28%) patients where the gallbladder was extracted without the use of removal bag, whereas 1 (0.20%) patient had port site infections (PSIs) with the use of Endo gloves out of 492 patients. In the present study group, A had 11 (22%) while group B had 19 (23.8%) diabetic patients and both groups showed significant correlation with developing PSIs on follow up. Out of all medical diseases, highest abundance was seen among diabetic patients (44%)[20]. The risk of SSIs increases in patients with a history of nicotine or steroid usage, diabetes[25-26].

However, despite higher costs and a lack of reliable evidence, endoscopic bags are frequently used in elective cholecystectomy[27-29]. In a study by Harling et al. which correlated categories receiving an antibiotic in a constant dose (750 mg i.e.) and where the gallbladder was retrieved with a standardized bag[30]: in total 76 patients undergoing laparoscopic cholecystectomy only 3 presented with wound infections. Patients were randomly assigned by Comajuncosas et al. to receive a retrieval bag during gallbladder removal or not[31]. It was observed there were 8 cases in the research group and 7 in the control group totaling 15 (9.6%) diagnosed wound infections. No statistically purposeful variations were found. In previous studies, similar results were obtained[32-38].

The results in this study depicted only 12.5% cases of PSIs seen on follow up in patients where retrieval bag was not used. Unexpectedly, there is a risk of abdominal organ damage during bag insertion and retrieval, which renders the procedure unnecessary and occasionally harmful[39].Retained gallbladder remnants and gallstones, can occur secondary to retrieval bag rupture[40].

There were some limitations in the study. In addition to its finite sample size and minimum duration, there was some selection bias as well among the study participants. Instead of using a custom-made endoscopic retrieval bag we used sterile surgical gloves as an alternative. The findings of the study should provide a basis for larger-scale studies. Measuring the average time, it takes to assemble the endo bag and its per-operative manipulation to retrieve the gall bladder would have made the study more well-grounded.

CONCLUSION AND RECOMMENDATION STATEMENT

Even though it was observed that using retrieval bags relatively decreases the incidence of port site infections in laparoscopic cholecystectomy, the percentage is not notable enough to justify for its impact on operative time. According to international literature, the use of an endo bag is dependent uponsurgeons'personal preference. We recommend the retrieval of gall bladder directly through the epigastric port to save operating time and hospital resources.

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