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## **Direct Gall Bladder Retrieval Versus Endo-bag Technique: A Comparison of Postoperative-Operative Outcomes Following Laparoscopic Cholecystectomy**

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### **Abstract**

#### **Objectives**

To compare the effectiveness of using sterile surgical gloves as an endo-bag to remove the gall bladder through the epigastric port in laparoscopic cholecystectomy as compared to the direct removal in terms of rate of bile spillage and post-operative pain.

#### **Study Design**

Prospective Cohort Study.

#### **Setting**

Department of Surgery, Khyber Teaching Hospital, Peshawar.

#### **Duration**

From 1st January 2023 to 31<sup>st</sup> Decembers, 2023.

#### **Methodology**

After attaining approval from the Hospital ethical committee, 100 patients meeting the inclusion criteria were included in the study. The patients were equally allocated in

two groups. Group A (direct removal of gall bladder) and Group B (removal of gall bladder using a sterile glove as an endo bag). Results were analyzed on Statistical Package for Social Sciences (SPSS) Version 23 and depicted in the form of description and statistical tables and charts.

#### **Results**

Out of our population sample, 83 (83%) patients were females and 17 (17%) were males with a mean age of 38.3 and a SD  $\pm$  1.46. Overall, gall bladder spillage was observed in 15 patients with 11 cases in group A and 4 in group B. Association of group of the patients with rate of gall bladder spillage (p-value 0.012) and post-operative pain at day 3 on VAS (p-value 0.05) was statistically significant.

#### **Conclusion**

Therefore, gallbladder removal, with the help of a sterile endo-bag is a safer technique compared to direct extraction as far as post-operative outcomes are concerned.

**Keywords:** Laparoscopic Cholecystectomy, Epigastric Port, Glove Technique, Direct Removal, Port Site Infections

### **Introduction**

Compared to open cholecystectomy, laparoscopic cholecystectomy has become the standard of care for various pathologies related to the gall bladder after its introduction back in the 1980s<sup>[1]</sup>. Phillippe Mouret performed the first video-laparoscopic cholecystectomy in France in 1987. After that, the procedure has gained worldwide global recognition for its minimally invasive approach which leads to decreased post-operative pain<sup>[2]</sup>, reduced risk of surgical site infection<sup>[3]</sup> shorter hospital stays, better cosmesis and saving hospital funds<sup>[4]</sup>. Some of the indications for which laparoscopic technique can be employed include gallstones, acute and chronic cholecystitis, gallbladder polyps, biliary dyskinesia and other related diseases<sup>[5]</sup>.

Retrieval of the gall bladder is the terminal event in this procedure and probably the most important step in terms of defining the post-operative outcomes<sup>[6]</sup>. Retrieval is done through the umbilical port or the epigastric port, depending upon surgeon preference<sup>[7]</sup>. During the procedure, there is always a risk of gall bladder rupture either intrabdominal or on the skin hence

resulting in spillage and gross contamination of the surgical site. Complications may range from intra-abdominal and subcutaneous abscesses and fistulas to liver abscesses and staphylococcal bacteremia, bronchiectasis and empyema [8]. To prevent this, the gall bladder is usually removed directly while grasped with a blunt laparoscopic instrument using an endo-bag [9]. An improvised endo bag made from the cuff of surgical glove has been used for this purpose [10].

While laparoscopic surgery has significantly reduced port-site related morbidity, gall bladder removal through any of the ports can result in varying degrees of post-operative pain [11]. It has been postulated that due to widening of the port site due to decreased space, gall bladder extraction with an endo-bag causes more pain in comparison to direct removal [12]. Pain following extraction of the gallbladder with an endo-bag is mostly related to traumatic rupture of the subcutaneous blood vessels, traction on the sensory nerves and pressure on the abdominal wall from the pneumoperitoneum [13]. Therefore, to test this hypothesis, the following study has been undertaken to compare endo-bag removal with direct removal of the gall bladder following laparoscopic cholecystectomy in terms of determining the difference in post-operative pain and rate of bile soilage.

### Materials and Methods

This Prospective Cohort study was conducted in a tertiary care Hospital in Peshawar from 1<sup>st</sup> January 2023 to 31<sup>st</sup> December, 2023. The sample size was 100 (50 patients in group A and 50 patients in group B) using percent of unexposed with an outcome 1% and percent of exposed with an outcome as 14%<sup>28</sup>, 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. Group A (direct removal with a blunt laparoscopic instrument) and Group B (using an endo-bag for extraction). All patients were given standard analgesia (in the pre-operative and post-operative period) as per WHO step ladder protocol. Under general anesthesia, the same general surgeon performed the procedure using the four ports method. At the infra-umbilical and epigastric sites, 10 mm ports were placed. Following dissection, GB was removed via the epigastric port using both retrieval methods.

Any evidence of biliary spillage in the form of bile and stones with or without rupture of the endo-bag was monitored and recorded. All patients were given local injection of 2% plain bupivacaine for pain relief at the port sites. The fascial sheath, when required, was expanded with blunt artery forceps and following both techniques it was closed with absorbable suture (Vicryl) and skin with non-absorbable sutures (proline) followed by same antiseptic dressing at port sites for both groups of patients. Post operatively, all patients in the groups were kept under observation for 3 days to be discharged. Outcome i.e.

postoperative port site pain was assessed with Visual Analog Scale (VAS) ranging from 0 to 10. Pain was assessed in every patient at both port sites on the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> post-operative date by a registered and trained nurse. All the above-mentioned information including name, age, and gender were recorded in a pre-designed proforma.

### Data Analysis

Data was analyzed by using statistical software SPSS version 23.0. Continuous variables i.e., age was calculated as Means  $\pm$  Standard deviation. Categorical variables i.e., gender, comorbidities, technique of GB retrieval, post-operative port site pain and biliary spillage were analyzed as proportions. Outcome i.e., port site pain and biliary spillage was compared in both groups by student's *T*-test if assumptions were fulfilled. P value of  $\leq 0.05$  was considered significant. All the results were presented in the form of graphs, tables and charts.

### Results

Out of our population sample, 83 (83%) patients were females and 17 (17%) were males with a mean age of 38.3 and a SD  $\pm$  1.46. Equal numbers of patients were divided into group A and B, 50 each. In terms of co-morbidities, it was discovered that 23 (23%) patients had type 2 diabetes mellitus, 17 (17%) had a history of ischemic heart disease and 60 (60%) of them had no associated medical conditions. Overall, gall bladder spillage was observed in 15 patients with 11 cases in group A and 4 in group B. Statistics for post-operative pain in terms of VAS scale were observed in the following order as shown in tables 1 and 2:

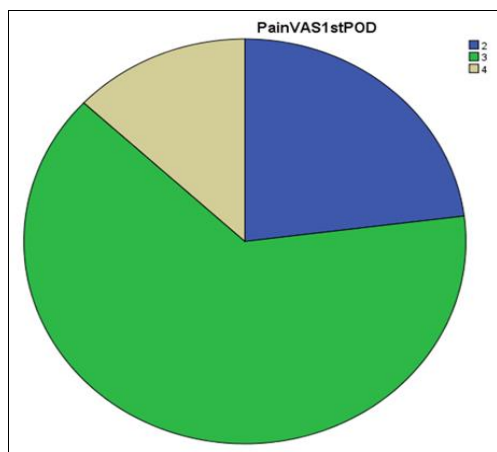
- **Postoperative day 1:** VAS score 1(0 patients), 2 (23 patients), 3 (64 patients) and 4 (13 Patients).
- **Post Operative day 3:** VAS score 1 (32 patients), 2 (61 patients), 3(7 patients) and 4(0 patients).

Post stratification chi square test was applied to test the correlation between all the confounding variables and their association with the risk of gall bladder rupture resulting in soilage and chances of having post-operative pain. The following results were obtained:

- Age with post-operative pain on 1<sup>st</sup> POD: P value (0.362).
- Age with post-operative pain on 3<sup>rd</sup> POD: P value (0.531).
- Gender with post-operative pain on 1<sup>st</sup> POD: P value (0.986).
- Gender with post-operative pain on 3<sup>rd</sup> POD: P value (0.697).
- Group with post-operative pain on 1<sup>st</sup> POD: P value (0.085).
- Gender with post-operative pain on 3<sup>rd</sup> POD: P value (0.05).
- Age with chances of Gall bladder spillage: P- value (0.593).
- Gender with chances of Gall bladder spillage: P- value (0.280).
- Group with chances of Gall bladder spillage: P- value (0.012).

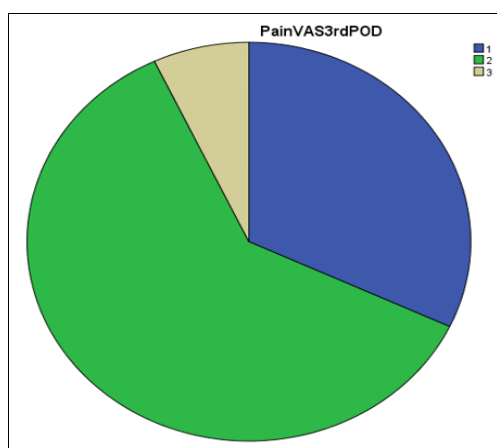
**Table 1:** Pain VAS 1<sup>st</sup> POD

VAS	Frequency (N)	Percentage (%)
1	0	0
2	23	23
3	64	64
4	13	13



**Table 2:** Pain on 3<sup>rd</sup> POD VAS scale

VAS	Frequency	Percentage
0	0	0
1	32	32
2	61	61
3	7	7
4	0	0



**Table 3:** Frequencies and percentages of various variables

Variable	Frequency (N)	Percentage (%)
Age less than 40	33	33
Age greater than 40	67	67
Gender (male)	17	17
Gender (Female)	83	83
Group A	50	50
Group B	50	50
Diabetes mellites	23	23
Cardiac diseases	60	60
Bile spillage Group A	11	22
Bile spillage Group B	4	8

**Table 4:** Stratification between variables and post-operative outcome

Variable	Post-operative outcome	P-value
Age	Bile Spillage	(0.593)
Gender	Bile spillage	(0.280)
Group	Bile spillage	(0.012)
Age	Post-operative pain day 1 VAS	(0.362)
Age	Post operative pain day 3 VAS	(0.531)
Group	Post-operative pain day 1 VAS	(0.085)
Group	Post-operative pain day 3 VAS	(0.05)
Gender	Post-operative pain day 1 VAS	(0.986)
Gender	Post-operative pain day 3 VAS	(0.697)

VAS: Visual Analogue Scale

**Discussion**

Gall stone disease, being a global health issue, is either treated with open cholecystectomy, laparoscopic cholecystectomy and the recently introduced robotic cholecystectomy [14]. Laparoscopic cholecystectomy (LC) is performed in over 90% elective and 70% emergency cholecystectomies making LC the most frequently performed procedure in the world [15]. Though LC is associated with less pain, better recovery and a decreased hospital stay, still there are various known complications ranging in frequency from 0.5% to 6%. The most important complications include bleeding, post-operative pain, bile duct leakage and surgical site infections [16]. Endo bags are employed to control these post-operative events as supported by various studies [17-18].

The commercial standard endo- bag as shown in Fig 1 is unfortunately not available in our set-up and it's quite costly as well, therefore a sterile surgical glove as shown in Fig 2 was used as an alternative as per common practice. Different types of retrieval bags have been introduced to the markets and become widely popular to provide nice and clean surgery not just in LC but also in appendectomy, splenectomy, and adrenalectomy [19]. Not only does it decrease the mean operative time [20-21], but it is also regarded as safe and easy to use. The bag is introduced with the help of a trocar and once retracted the surgeon can easily puncture the gall bladder and remove the bile and stones with suction [22]. One common drawback usually mentioned in literature is the need to expand the facial layer at times during retrieval [23].

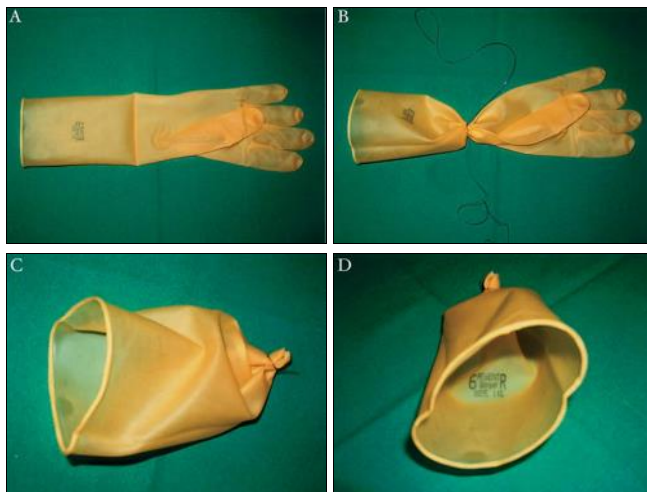
In our study, gall bladder puncture resulting in spillage was recorded in 4 patients (8%) in group B as compared to group A, 11 patients (22%). The spillage through endo bag technique was noticed due to 2 reasons: Unnecessary haste during extraction and a distended gallbladder. Nonetheless, the figures are in favor of using the endo bag as far as prevention of spillage is concerned. These findings have been supported through many papers in literature. A study by Dr. Satharaj P and colleagues in India reported no spillage in any of the cases related to endo-bag retrieval [24]. Dr Agha Nadeem and co-workers in Pakistan advise endo-bag utilization citing reasons that it decreases the risk of perforation hence preventing contamination with bile, bacteria and stones [25]. In another study [20] endo bag extraction showed no spillage of stones and bile but in direct removal group, 3 (6%) patients had spillage of stones and bile. Scha'fer *et al* found 581 cases of spillage (6%) following 10,714 LCs which led to the formation of intra-abdominal abscess in 8 cases that subsequently required intervention thus favoring endo bag technique.

As previously pointed out, at times it gets tedious to remove the gall bladder along with the endo-bag in one go and for that reason surgeons are often forced to expand the subcutaneous fascial layers at the trocar site. This maneuver results in relatively more post-operative pain in the endo-bag group [24, 26]. Similar findings were noticed in our study as well, as shown in the tables and charts above, with endo-bag group having a slightly higher VAS scale on 3<sup>rd</sup> post-operative day as compared to the direct retrieval group though the difference is not much significant. However, some authors have a different opinion. Kuldip Singh and his colleagues illustrated Port site pain in endo-bag group present in 2 (4%) patients, while 4 (8%) of the patients in the other group. The pain was related to port site infection

and spillage<sup>[20]</sup>. In support to these statistics, a study showed mean pain on VRS using the endo bag technique as 4.84 compared to 5.15 with direct removal, again a negligible difference<sup>[21]</sup>. A study by Nadeem Ahmad Siddique and co-workers advocated the use of pethidine and ketorolac to control the rate of post-operative pain following direct extraction of the gall bladder.



**Fig 1:**



**Fig 2:**

### Conclusion and Recommendation Statement

The following prospective cohort analyzed and evaluated the two methods used for retrieval of the gallbladder following laparoscopic cholecystectomy. The findings are in favor of employing a sterile endo-bag for gall bladder extraction as its utility is associated with better outcomes in terms of bile spillage and post-operative pain. Though in few patients, we had to expand the facial planes but to remove the bag however it didn't affect the pain scores on a significant scale. We recommend doing further multicentric trials and studies using other variables to further augment and support our conclusion in terms of deciding the optimum technique to remove the gall bladder.

### Fundings

The whole project was self-funded by the authors.

### Conflict of Interest

In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial

relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

### Authors Contribution

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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