Surgery Section

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Direct Gallbladder Extraction versus

Cholecystectomy: A Prospective

Endobag Extraction during Laparoscopic

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ABSTRACT

Introduction: The most effective treatment for gallstone disease symptoms is Laparoscopic Cholecystectomy (LC). Gallbladder retrieval is a crucial step, with direct extraction and endobagassisted extraction being commonly used techniques. Direct extraction may lead to increased bile spillage and port-site infections, whereas the endobag provides protection against contamination but may increase operative time.

Observational Study

Aim: To compare the outcomes of direct gallbladder extraction versus endobag-assisted extraction in LC, focusing on bile spillage, port-site infections, operative time, postoperative pain and hospital stay duration.

Materials and Methods: This prospective observational study was conducted in the Department of General Surgery, SRM Medical College Hospital and Research Institute, Kattankulathur, Chengalpattu, Tamil Nadu, India, from December 2024 to March 2025. A total of 60 patients undergoing elective LC were randomised into two groups: Group A (direct extraction) and Group B (endobag extraction). Primary outcomes included intraoperative complications (gallbladder perforation and bile spillage) and postoperative complications (port-site infections and pain levels). Secondary outcomes assessed operative time and hospital stay duration. Continuous variables were expressed

as means with standard deviations, and categorical variables as frequency counts and percentages. An independent t-test was used for comparing continuous variables and the Chi-square test for categorical data. A p-value <0.05 was considered statistically significant.

Results: The mean age of subjects in Group A was 38.1 ± 13.9 years {males: 16 (53.3%), females: 14 (46.7%)}, and in Group B, it was 44.3 ± 12.5 years {males: 13 (43.3%), females: 17 (56.7%)}. The endobag group (Group B) had significantly lower rates of bile spillage (6.7% vs. 23.3%, p-value=0.036) and port-site infections (3.3% vs. 16.7%, p-value=0.019) compared to direct extraction (Group A). Group B also demonstrated significantly shorter operative times (32.2 ±3.7 minutes vs. 39.1 ± 5.4 minutes, p-value <0.001) and hospital stay durations (1.5 ±0.5 days vs. 2.2 ±0.8 days, p-value <0.001). Postoperative pain scores on the 1st day (5.4 ±1.3) and 3rd day (2.2 ±0.8) were significantly lower in Group B (p-value <0.001).

Conclusion: Endobag-assisted gallbladder extraction significantly reduces bile spillage, port-site infections, and postoperative pain while decreasing the duration of hospital stay. It is a safer alternative to direct extraction, particularly in high-risk patients.

INTRODUCTION

The most popular minimally invasive surgical technique for treating gallstone disease symptoms is LC [1]. Its benefits over open surgery, which include less postoperative pain, quicker recovery, shorter hospital stays and improved outcomes, have established it as the gold standard technique [2,3]. Despite its widespread success, certain intraoperative challenges, particularly during gallbladder retrieval, remain a concern. Gallbladder retrieval is a critical step in LC, influencing postoperative outcomes and patient recovery [4]. Conventionally, the gallbladder is extracted through either the umbilical or epigastric port, depending on surgeon preference [5]. However, this step is associated with potential complications such as gallbladder perforation, bile spillage and portsite contamination. Studies report that gallbladder perforation occurs in 10-40% of cases, while bile and stone spillage ranges from 6-30%, potentially leading to intra-abdominal infections, abscess formation and port-site complications [6-14].

To ensure a clean and safe surgery, various types of retrieval bags have been developed and have gained widespread popularity [15]. Among these alternative retrieval methods, the use of an endobag has attracted attention as a protective measure against bile and stone spillage, particularly in cases of acute cholecystitis, empyema, and suspected malignancy [16,17].

Keywords: Bile spillage, Gallbladder perforation, Port-site infection

The endobag offers benefits by minimising port-site infections, reducing the risk of tumour cell seeding in suspected malignancies, and preventing surgical site contamination [18]. However, its routine use remains a topic of debate, primarily due to cost considerations and concerns regarding increased operative time and port-site enlargement, which may contribute to hernia formation [19,20]. While endobags have demonstrated value in specific high-risk cases, their necessity in routine LC is still uncertain, particularly in resource-limited settings where healthcare costs play a significant role in decision-making.

This study seeks to address this gap in outcomes by assessing and comparing the rates of intraoperative complications, such as gallbladder perforation and bile spillage, as well as postoperative outcomes, including port-site infections, operative duration, hospital stays, and postoperative pain levels related to both techniques.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of General Surgery, SRM Medical College Hospital and Research Institute, Kattankulathur, Chengalpattu, Tamil Nadu, India, from December 2024 to March 2025. With ethics clearance number

SRMIEC-571124-1740, the Institutional Ethics Committee granted ethical approval for this investigation.

Inclusion criteria: Individuals between the ages of 18 and 65 years who had an ultrasonography-confirmed diagnosis of symptomatic gallstone disease were included in the study.

Exclusion criteria: Patients with Common Bile Duct (CBD) stones, acute calculous cholecystitis, empyema of the gallbladder, coagulopathies, patients not fit for general anesthesia, those not consenting for surgery, and individuals with severe co-morbidities that could impact surgical risk and recovery were excluded from the study.

Sample size and randomisation: Consecutive sampling of eligible patients meeting the inclusion criteria during the study period was conducted. With a significance level of 5% and a power of 90%, the expected non spillage rate in group A was 99%, and in group B, it was 77%. These rates were taken from a similar study by Vergadia A et al., [21]. The 60 patients were randomly split into two groups, each with 30 patients, following the acquisition of written informed consent for the study. Computer-generated random numbers were used for the randomisation process; patients assigned odd numbers were placed in group A (direct extraction), while those assigned even numbers were placed in group B (endobag extraction).

Surgical techniques: All patients underwent preoperative preparation and were administered general anaesthesia. A traditional four-port approach for LC was utilised, involving a 10-mm epigastric port, a 10-mm umbilical port and two 5-mm ports located at the midclavicular and anterior axillary lines. After securing the Cystic Artery (CA) and Cystic Duct (CD) and identifying the triangle of safety and Calot's triangle, the gallbladder was removed from the liver bed and extracted directly through the 10-mm epigastric or umbilical port in group A (Direct Extraction) without the need for an endobag.

In group B (Endobag Extraction), after identifying Calot's triangle and the triangle of safety, and securing the CA and CD, the gallbladder was removed from the liver bed. A sterile surgical glove was used as a cost-effective endobag [Table/Fig-1]. The abdominal cavity was then filled with the sterile endobag, which served as a substitute for standard retrieval bags. The gallbladder, free of spilled stones, was placed into the endobag and extracted via the 10-mm epigastric or umbilical port. For larger gallbladder specimens, fragmentation was performed within the endobag before removal through the same port. In both groups, the gallbladder was extracted through the 10-mm port. At the end of the operation, the abdominal skin was closed at the ports with 0-2 nylon sutures.



[Table/Fig-1]: Intraoperative view of economical endobag technique for gallbladder extraction using sterile surgical gloves.

Postoperative Care and Follow-Up

Postoperative recovery was facilitated by early mobilisation and resumption of oral intake. Pain levels were evaluated using the Visual Analog Scale (VAS), with pain management initiated in a stepwise manner, starting with intravenous paracetamol, followed by Non Steroidal Anti-Inflammatory Drugs (NSAIDs), and opioids as needed. Venous thromboembolism prophylaxis was maintained unless contraindicated. Hospital discharge was planned once the patient achieved haemodynamic stability and had no significant blood abnormalities. Follow-up assessments were scheduled at one week and one month postoperatively to monitor recovery and detect complications.

Outcome Measures

The primary outcome was the prevalence of postoperative complications, including bile spillage, wound contamination and port-site infections. Secondary outcomes included operative time, postoperative pain scores, intraoperative blood loss and duration of hospital stay. Potential confounding factors such as age, Body Mass Index (BMI), co-morbidities and surgeon expertise were considered to ensure valid comparisons. To minimise surgeon-related bias, all procedures were performed by a team of experienced laparoscopic surgeons. Cases were evenly randomised among the surgeons, with each performing an equal number of direct extraction and endobag-assisted extraction procedures. A standardised operative protocol was followed throughout and outcome assessors were blinded to the method of gallbladder retrieval.

Operational Definitions

- **Operative time:** Defined as the amount of time between skin incision and its closure.
- **Hospital stay:** Measured as the time from surgery to hospital discharge.
- **Spillage:** Refers to the unintentional escape of bile or stones from the gallbladder during retrieval.
- Wound contamination: Refers to the presence of bile, blood, or infected material at the surgical site, particularly at the portsites, due to intraoperative spillage or improper specimen retrieval technique.

STATISTICAL ANALYSIS

The Statistical Package for the Social Sciences (SPSS) version 29.0 was used for statistical analysis. Continuous variables were represented as mean±standard deviations, while categorical data were represented as: i) frequency counts; ii) percentages. The Independent t-test was employed for continuous data analysis, while the Chi-square test was used for categorical data comparison. Statistical significance was defined as a p-value <0.05.

RESULTS

The mean age in group A was 38.1 ± 13.9 years, while that in group B was 44.3 ± 12.5 years. There were 16 men (53.3%) and 14 women (46.7%) in group A, whereas group B included 13 males (43.3%) and 17 females (56.7%) [Table/Fig-2]. Chronic cholecystitis was the most frequent indication: group A had 46.7% (14 patients), and group B had 56.7% (17 patients). There was no significant difference in the distribution of indications between the two groups (p-value=0.734) [Table/Fig-3].

Demographic characteristics		Group A	Group B	p-value	
Age ^a (years)		38.1±13.9	44.3±12.5	0.073	
Gender ^ь n (%)	Male	16 (53.3)	13 (43.3)	0.438	
	Female	14 (46.7)	17 (56.7)		
Co-morbidities ^b n (%)	DM	3 (10)	5 (16.7)		
	HTN	5 (16.7)	6 (20)	0.667	
	None	22 (73.3)	19 63.3)		
[Table/Fig-2]: Demographic characteristics of study participants.					

a- independent t-test; b- Chi-square test

Group A's average operating duration was 39.1 ± 5.4 minutes, whereas group B's was 32.2 ± 3.7 minutes, and the difference was statistically significant (p-value <0.001) [Table/Fig-4]. The baseline pain scores in the two groups did not differ significantly (p=0.836). However, group B reported considerably lower pain scores than group A on the first and third postoperative days (p-value <0.001)

	Group			
Indication for	А	В	Total	
cholecystectomy	n (%)	n (%)	n (%)	p-value
Chronic cholecystitis	14 (46.7)	17 (56.7)	31 (51.7)	
Gallbladder polyp	7 (23.3)	6 (20.0)	13 (21.7)	0.734
Symptomatic gallstones	9 (30.0)	7 (23.3)	16 (26.7)	

[Table/Fig-3]: Distribution of study participants according to indication for cholecystectomy. Chi-square test

Characteristics	Group A	Group B	p-value		
Blood loss (mL)	291.3±5.9	270±5.6	<0.001*		
Operative time (minutes)	39.1±5.4	32.2±3.7	<0.001*		
Duration of hospital stay (days)	2.2±0.8	1.5±0.5	<0.001*		
[Table/Fig_4]: Comparison of blood loss, procedure time and bespital stay					

[table/Fig-4]: Comparison of blood loss, procedure time and nospital stay between groups. Independent t-test

for both days) [Table/Fig-5]. Statistically significant differences (p-value <0.05) were noted: p-value=0.036 for intraoperative and p-value=0.019 for postoperative complications between the groups [Table/Fig-6].

VAS score	Group A	Group B	p-value	
Baseline	9.7±0.8	9.2±0.9	0.836	
Day 1	6.7±0.8	5.4±1.3	<0.001*	
Day 3	4.7±1.3	2.2±0.8	<0.001*	
[Table/Fig-5]: Comparison of VAS scores between groups. Independent t-test				

reported a lengthier hospital stay [26]. On the other hand, the direct extraction group had a shorter hospital stay (p-value=0.001), according to Qassem MG et al., [23]. These differences imply that the length of hospitalisation may be affected by perioperative care guidelines and institutional discharge policies.

Postoperative pain was significantly lower in the endobag group on days 1 and 3 postoperatively (p-value <0.001). This aligns with Inayat K et al., who observed significant pain reduction with endobag use by day 3 (p-value=0.05) [27]. Makhsosi BR et al., reported a marginally lower VAS score in the endobag group, though not statistically significant [22]. Conversely, Qassem MG et al., found higher pain levels in the endobag group at 12 and 24 hours (p-value=0.001) [23]. These variations may be attributed to differences in pain management strategies and surgical expertise.

The retrieval technique may have a direct impact on bile and stone spillage, but it is unlikely to affect parameters such as intraoperative blood loss. While using an endobag offers containment and minimises manipulation-induced rupture, direct extraction through a restricted port site may raise the risk of gallbladder wall disruption and bile leakage. Qassem MG et al., observed a higher port-site spillage in cases where endobags were not used [23]. Similarly, Memon MA et al., reported the absence of bile spillage when endobags were employed, showcasing their protective effect [11]. On the other hand, studies by Sood I et al., and Vergadia A et al., did not note any major intraoperative complications, indicating that the surgeon's skill and experience may also contribute significantly to reducing such risks [15,21]. The incidence of port-site infections was higher in patients who underwent direct specimen extraction (p-value=0.019), which was also associated with increased wound

		Group			
		А	В	Total	
Complications		n (%)	n (%)	n (%)	p-value
Intraoperative	Gallbladder perforation	6 (20.0)	2 (6.7)	8 (13.3)	0.036*
	Stone spillage	7 (23.3)	2 (6.7)	9 (15.0)	
	None	17 (56.7)	26 (86.7)	43 (71.7)	
Postoperative	None	21 (70.0)	29 (96.7)	50 (83.3)	0.019*
	Port-site infection	5 (16.7)	1 (3.3)	6 (10.0)	
	Wound contamination	4 (13.3)	0	4 (6.7)	
[Table/Fig-6]: Comparison of intra and postoperative complications between groups.					

DISCUSSION

Chi-square test

The present study observed that the operative time was significantly shorter in the endobag group compared to the direct extraction group (p-value <0.001). These findings align with the results of Makhsosi BR et al., who reported a shorter operative duration in the endobag group (37.68±11.36 minutes) compared to the non endobag group (43.85±12.79 minutes), with a statistically significant difference (p-value <0.005) [22]. However, other studies, including those by Qassem MG et al., and Singh K et al., did not demonstrate significant differences in operative time between the techniques [23,24]. Qassem MG et al., reported mean operative times of 38.22±9.31 minutes for the endobag group and 39.74±7.63 minutes for the direct extraction group (p-value=0.374), while Singh K et al., observed operative times of 53.4 minutes and 57.9 minutes for the endobag and direct extraction groups, respectively (p-value=0.125) [23,24]. These contrasting results suggest that variations in surgical technique, patient characteristics and endobag design may contribute to differing outcomes across studies.

Compared to the direct extraction group, patients in the endobag group spent considerably less time in the hospital (p-value <0.001). Singh K et al., and Mumtaz N et al., observed no significant differences between groups [24,25]; however, Stevens KA et al.,

contamination. Consistent findings were reported by Mumtaz N et al., who found a significantly lower rate of port-site infections in the endobag group [25]. This protective trend was further supported by studies from Singh K et al., Narayanswamy T and Prajwal RK; and Rehman H et al., all of whom noted reduced infection rates when endobags were used [24,28,29].

This study reinforces the benefits of endobag-assisted gallbladder extraction in minimising bile spillage, port-site infections and postoperative pain while also reducing the duration of hospital stay. While direct extraction remains a viable option, careful patient selection and surgical judgment are important. The validity and usefulness of these findings need to be confirmed by a larger, multicentric, randomised clinical trial.

Limitation(s)

This study was conducted at a single tertiary care centre, which may limit the generalisability of its findings to the broader population. A short follow-up period is another drawback, as it prevents the evaluation of long-term issues such as port-site recurrence or incisional hernia. Lastly, the subjective nature of postoperative pain evaluation using the VAS may have introduced some degree of measurement bias.

CONCLUSION(S)

The outcomes of the study demonstrated that endobag-assisted extraction was associated with a significantly lower incidence of portsite infections, bile spillage and wound contamination, showcasing its protective effect against intra-abdominal contamination. This suggests that, particularly in resource-limited settings, using a sterilised surgical glove can be a viable alternative to standard retrieval bags while maintaining the advantages of reduced contamination risk.

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