



## Article

# A Comparative Study on Frequency of Port Site Infection Rates After Gallbladder Retrieval with and Without the Sterile Glove Bag Technique in Laparoscopic Cholecystectomy

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**ABSTRACT**

**Background:** Gallbladder retrieval during laparoscopic cholecystectomy can result in port site infections, especially in patients with comorbidities; however, evidence supporting the sterile glove bag technique remains limited in local populations. **Objective:** To compare the incidence of port site surgical site infections (SSI) after laparoscopic cholecystectomy using the sterile glove bag technique versus standard retrieval, and to evaluate the association of demographic and clinical risk factors with infection rates. **Methods:** This randomized controlled trial included 280 adult patients (n = 140 per group) scheduled for elective laparoscopic cholecystectomy at a tertiary care hospital. Inclusion criteria were adults aged 18–75 years; key exclusions were immunodeficiency, active infection, or conversion to open surgery. Patients were randomly assigned to gallbladder retrieval with or without the sterile glove bag. Demographics, BMI, diabetes, hypertension, and SSI occurrence (within 7 postoperative days) were recorded. Diagnosis of SSI was clinical, with microbiological confirmation where indicated. Ethical approval was obtained from the hospital review board in accordance with the Helsinki Declaration. Data were analyzed using SPSS version 25, with chi-square tests for categorical data and a significance threshold of  $p \leq 0.05$ . **Results:** The mean age was  $43.21 \pm 3.12$  years; females predominated (76.8%). Port site SSI occurred exclusively in the standard retrieval group (7.9% vs. 0%,  $p < 0.01$ ). All SSIs were associated with diabetes and hypertension ( $p = 0.01$  each). Overweight and obese patients showed a trend toward increased SSI risk. **Conclusion:** The sterile glove bag technique significantly reduces port site infection rates in laparoscopic cholecystectomy, particularly benefitting patients with comorbidities. Routine adoption can enhance patient safety and reduce postoperative complications in clinical practice.

**Keywords:** Laparoscopic Cholecystectomy, Surgical Site Infection, Sterile Glove Bag Technique, Gallbladder Disease, Obesity, Diabetes Mellitus, Minimally Invasive Surgery.

**INTRODUCTION**

Gallstones are a prevalent health concern affecting 10–15% of adults worldwide, with a substantial burden also observed in Pakistan, where 3–6% of the adult population is impacted (1). Laparoscopic cholecystectomy has emerged as the gold standard for the surgical management of gallbladder pathologies such as cholecystitis, cholelithiasis, and pancreatitis due to its minimally invasive nature and association with reduced tissue trauma, postoperative pain, hospital costs, and recovery times compared to open surgery (2). In developed nations, this approach is adopted in up to 90% of

cholecystectomy cases, further highlighting its global acceptance and advantages (1). Despite these benefits, laparoscopic cholecystectomy is not without complications, with surgical site infections (SSI) representing a significant postoperative challenge that can undermine the advantages of minimally invasive techniques (3).

The occurrence of SSI is influenced by several factors, including advanced age, male gender, comorbidities such as diabetes mellitus and hypertension, and prolonged surgical duration (4,5).

These infections not only result in patient morbidity but also contribute to increased healthcare costs and workload and can negatively affect institutional and surgeon reputations (6). A frequent technical challenge during laparoscopic cholecystectomy is the retrieval of an inflamed or stone-laden gallbladder, which is prone to perforation and spillage of bile or stones at the port site, reported in up to 25% of cases (7). To mitigate these risks, retrieval bags—including commercially available endo-bags or improvised sterile glove bags—are often utilized to prevent contamination of the abdominal wall and reduce the incidence of port site infections (8).

Existing literature supports the utility of such measures, with studies demonstrating a lower rate of port site wound infection when retrieval bags are used, compared to direct extraction without such protective devices (1,8). For instance, Rehman *et al.* reported a marked reduction in wound infection rates (0.4% vs. 5.5%) with the use of a retrieval bag during gallbladder extraction (8). Nevertheless, the adoption of the sterile glove bag technique remains inconsistent due to concerns about technical difficulty, the need for larger incisions, or potential injury to abdominal organs during bag manipulation (9).

The controversy surrounding the routine use of retrieval bags is further complicated by limited local data, especially in resource-constrained healthcare settings where cost and availability may restrict their use.

Port site infections remain a persistent problem after laparoscopic cholecystectomy, particularly in patients with obesity, diabetes, or hypertension—comorbidities known to impair wound healing and increase susceptibility to infection (2,10,11). Obesity has been repeatedly identified as an independent risk factor for SSI, as increased adipose tissue may compromise immune response and surgical site perfusion, leading to poor healing outcomes (12,13).

Similarly, diabetes mellitus and hypertension have been implicated in delayed wound healing and increased postoperative infection rates, underscoring the importance of preoperative optimization of these conditions (5,14). While the relationship between these risk factors and SSI has been established in international studies, there remains a paucity of region-specific research addressing the effectiveness of preventive strategies, such as the sterile glove bag technique, in the Pakistani population.

Given these considerations, the current study seeks to address the knowledge gap regarding the efficacy of the sterile glove bag technique in reducing port site infections following laparoscopic cholecystectomy in a local clinical context. By comparing infection rates in patients with and without the use of this technique, while also examining the influence of demographic and clinical risk factors such as age, gender, BMI, diabetes, and hypertension, this study aims to provide evidence to inform best practices in gallbladder retrieval and infection prevention (15,16). The research question guiding this investigation is: Does the use of the sterile glove bag technique during gallbladder retrieval in laparoscopic cholecystectomy significantly reduce the incidence of port site infections compared to standard practice

without the bag, particularly among patients with established risk factors

## MATERIALS AND METHODS

This study was conducted as a randomized controlled trial at the Department of General Surgery, Capital Hospital, Islamabad, over a period of six months. The aim was to compare the incidence of port site infections following laparoscopic cholecystectomy with and without the use of the sterile glove bag technique. Participants included patients aged 18 to 75 years of either gender who were scheduled for elective laparoscopic cholecystectomy. Exclusion criteria comprised individuals with known allergies to surgical gloves or any materials used in the glove bag technique, pregnant or breastfeeding women, patients with immunodeficiencies or on immunosuppressive therapy, those with chronic liver disease or severe systemic illnesses, individuals with active infections, and patients who required conversion from laparoscopic to open cholecystectomy. Recruitment was performed in the outpatient department using a non-probability consecutive sampling method, where eligible candidates were informed about the study's objectives and procedures. Written informed consent was obtained from all participants prior to their inclusion in the trial, and the study protocol received approval from the hospital's review board and ethical committee in accordance with the Declaration of Helsinki.

Upon enrollment, participants were randomly assigned in equal numbers to two groups through blocked randomization: Group A underwent gallbladder retrieval with the sterile glove bag technique, while Group B underwent retrieval without the use of the glove bag. Both groups received identical preoperative antiseptic preparation, anesthesia, and perioperative care protocols. Laparoscopic cholecystectomy was performed using the standardized four-port technique, with a 10 mm epigastric port dedicated to gallbladder extraction. Closure of fascial sheaths was performed using absorbable sutures (Vicryl), and skin closure employed non-absorbable sutures (Prolene). Standardized postoperative antiseptic dressings and an identical antibiotic regimen were administered to all patients, with both groups receiving the same duration and choice of antibiotics.

The primary outcome was the incidence of port site surgical site infection (SSI) within the first postoperative week. Secondary data collected included demographic information (age, gender), clinical characteristics (weight, height, BMI), comorbidities (diabetes mellitus and hypertension), and surgery duration. Diagnosis of SSI was based on the presence of clinical signs such as pain, redness, swelling, or purulent discharge at the port site. Where infection was suspected, swabs were collected for microbiological culture and antibiotic sensitivity testing. All patients were followed up for seven days postoperatively to monitor the occurrence of SSI and assess wound healing outcomes. Confidentiality was maintained by assigning anonymized codes to all collected data and restricting access to study investigators only.

All collected data were analyzed using SPSS version 25. Continuous variables, including age, weight, height, BMI, and

surgery duration, were summarized as means with standard deviations, while categorical variables such as gender, comorbidities, surgical technique, and SSI occurrence were presented as frequencies and percentages. The chi-square test was used for categorical variables to evaluate differences in SSI rates between groups and to perform post-stratification analysis for potential effect modifiers, with statistical significance defined as a  $p$ -value  $\leq 0.05$ . Missing data were minimized by rigorous follow-up and were excluded from analysis if present. The methodology adhered to recognized ethical standards and best practices in surgical research, ensuring transparency and reproducibility in accordance with CONSORT guidelines (1).

## RESULTS

A total of 280 patients who underwent laparoscopic cholecystectomy were included in the study, with equal distribution across Group A (sterile glove bag technique;  $n=140$ ) and Group B (no sterile glove bag technique;  $n=140$ ). The mean age for the overall cohort was  $43.21 \pm 3.12$  years (range: 18–75 years), with comparable age distributions between the groups. The largest proportion of patients in both groups was found within the 46–55 years age category (Group A: 25.0%; Group B: 27.1%). The distribution of gender was predominantly female in both groups (Group A: 78.6%; Group B: 75.0%).

Body mass index (BMI) analysis revealed a higher prevalence of normal weight among Group A participants (50.0%), while overweight status was notably more frequent in Group B (63.6%). Obesity rates were somewhat higher in Group A (15.7% vs. 10.7%), and the underweight category was minimally represented in both arms. The prevalence of diabetes mellitus was comparable (Group A: 21.4%; Group B: 25.0%), whereas hypertension was more common in Group B (42.9%) than Group A (24.3%).

Crucially, the incidence of surgical site infection (SSI) at the port site was significantly different between groups: no cases were recorded in Group A (0.0%), while 11 cases were observed in Group B (7.9%). This difference suggests a substantial protective

effect of the sterile glove bag technique. Table 1 summarizes the demographic and clinical characteristics of the study population.

No SSIs were recorded in Group A, while all 11 cases occurred in Group B. In Group B, stratification revealed the highest SSI frequency among patients aged 46–55 years (36.4%), followed by 56–65 years (27.3%), 66–75 years (18.1%), and 26–45 years (each 9.1%); no SSIs occurred in those aged 18–25. Gender-wise, most SSI cases were observed among females (72.7%) compared to males (27.3%). Notably, overweight individuals represented the largest proportion of SSIs (45.4%), followed by obese (27.3%) and normal-weight (27.3%) patients, with no SSIs among the underweight.

Crucially, all SSI cases in Group B were associated with both diabetes mellitus and hypertension, with both comorbidities demonstrating strong statistical significance ( $p = 0.01$ ). Overweight status and gender also approached significance with  $p$ -values of 0.05, suggesting a clinically meaningful association that warrants further investigation. There were no significant associations between age categories and SSI occurrence (all  $p > 0.05$ ), though a trend towards higher SSI in older groups was observed.

No post hoc testing or effect size calculation was possible due to the absence of SSI events in Group A. However, the chi-square analysis demonstrates a statistically significant association between SSI and the presence of diabetes mellitus and hypertension in Group B ( $p = 0.01$  for both), highlighting the substantial risk these comorbidities pose for infection. The association between overweight/obesity and SSI approached statistical significance ( $p = 0.05$  for overweight and  $p = 0.08$  for obese), suggesting a potentially important clinical trend that may warrant further study with larger sample sizes. The distribution of SSI by age and gender did not reach conventional statistical significance but indicated possible clinically relevant patterns, with older age and female gender showing higher rates of SSI in Group B.

**Table 1. Demographic and Clinical Characteristics of Study Participants (N = 280)**

Variable	Categories	Group A (n=140), n (%)	Group B (n=140), n (%)
Age (years)	18–25	5 (3.57)	4 (2.85)
	26–35	21 (15.00)	22 (15.71)
	36–45	28 (20.00)	26 (18.57)
	46–55	35 (25.00)	38 (27.14)
	56–65	30 (21.42)	28 (20.00)
	66–75	21 (15.00)	22 (15.71)
Gender	Male	30 (21.43)	35 (25.00)
	Female	110 (78.57)	105 (75.00)
BMI	Underweight	8 (5.71)	6 (4.29)
	Normal	70 (50.00)	30 (21.43)
	Overweight	40 (28.57)	89 (63.57)
	Obese	22 (15.71)	15 (10.71)
Diabetes Mellitus	Yes	30 (21.43)	35 (25.00)
	No	110 (78.57)	105 (75.00)
Hypertension	Yes	34 (24.29)	60 (42.86)
	No	106 (75.71)	80 (57.14)
SSI	Yes	0 (0.00)	11 (7.86)
	No	140 (100.0)	129 (92.14)

Table 2. Stratification of Surgical Site Infection (SSI) by Demographic and Clinical Characteristics in Group A and Group B

Variable	Category	Group A SSI Yes n (%)	Group A SSI No n (%)	Group B SSI Yes n (%)	Group B SSI No n (%)	p-value
Age (years)	18-25	0 (0.00)	5 (3.57)	0 (0.00)	4 (3.10)	0.15
	26-35	0 (0.00)	21 (15.00)	1 (9.1)	21 (16.30)	0.12
	36-45	0 (0.00)	28 (20.00)	1 (9.1)	25 (19.40)	0.08
	46-55	0 (0.00)	35 (25.00)	4 (36.4)	34 (26.40)	0.20
	56-65	0 (0.00)	30 (21.42)	3 (27.3)	25 (19.40)	0.05
	66-75	0 (0.00)	21 (15.00)	2 (18.1)	20 (15.50)	0.25
Gender	Male	0 (0.00)	30 (21.43)	3 (27.3)	32 (24.80)	0.05
	Female	0 (0.00)	110 (78.57)	8 (72.7)	97 (75.20)	
BMI	Underweight	0 (0.00)	8 (5.71)	0 (0.00)	6 (4.65)	0.45
	Normal	0 (0.00)	70 (50.00)	3 (27.3)	27 (20.90)	0.15
	Overweight	0 (0.00)	40 (28.57)	5 (45.4)	84 (65.10)	0.05
	Obese	0 (0.00)	22 (15.71)	3 (27.3)	12 (9.30)	0.08
Diabetes	Yes	0 (0.00)	30 (21.43)	11 (100.0)	24 (18.60)	0.01*
	No	0 (0.00)	110 (78.57)	0 (0.00)	105 (81.40)	
Hypertension	Yes	0 (0.00)	34 (24.29)	11 (100.0)	49 (37.90)	0.01*
	No	0 (0.00)	106 (75.71)	0 (0.00)	80 (62.10)	

In summary, the results of this trial demonstrate a clear protective benefit of the sterile glove bag technique in preventing surgical site infections following laparoscopic cholecystectomy, especially among patients with additional risk

DISCUSSION

The present study provides robust evidence supporting the effectiveness of the sterile glove bag technique in reducing the incidence of surgical site infections (SSI) following laparoscopic cholecystectomy. The absence of SSI in the group utilizing the sterile glove bag stands in marked contrast to the 7.9% infection rate observed in the group where the technique was not employed. This substantial difference reinforces the theoretical and practical benefits of physical barriers in minimizing the contamination of port sites, particularly during the extraction of inflamed or stone-filled gallbladders. These findings align with previous reports that have demonstrated lower SSI rates with the use of retrieval bags, including studies by Rehman et al. and Ahmed et al., which reported reductions in infection rates to as low as 0.4% with protective extraction methods compared to higher rates without such techniques (1,8). The data presented here thus advances the evidence base by providing high-quality, locally relevant results that strongly support the routine adoption of the sterile glove bag technique during laparoscopic cholecystectomy, especially in populations with a high burden of comorbidities.

The comparative analysis of demographic and clinical risk factors for SSI in this study corroborates established associations described in the literature. In particular, the observed relationships between increased BMI, diabetes mellitus, hypertension, and heightened SSI risk are consistent with numerous prior studies, which have identified these variables as key predictors of poor postoperative wound healing and increased susceptibility to infection (2,5,12,14). While obesity has been theorized to compromise immune response and microcirculation, resulting in suboptimal healing environments, diabetes and hypertension further exacerbate these effects through impaired leukocyte function and vascular compromise(5,13). Notably, all patients who developed SSI in this

factors such as diabetes, hypertension, and elevated BMI. These findings underscore the importance of targeted preventive strategies and comorbidity management in surgical practice.

study's control group had both diabetes and hypertension, underlining the synergistic risk imposed by multiple comorbidities. Although older age and female gender were associated with a higher proportion of SSIs in Group B, these trends did not achieve statistical significance, mirroring mixed results reported in other investigations (3,4). Some studies suggest male gender as a risk factor, while others have found higher rates among females, likely reflecting population-specific variations and the influence of additional confounding variables (3,10).

Mechanistically, the findings reinforce the clinical rationale for using a protective barrier at the time of gallbladder retrieval. Spillage of bile or gallstones during extraction has long been recognized as a direct cause of postoperative wound contamination and subsequent infection (7). By employing a sterile glove bag, the risk of such contamination is mitigated, theoretically interrupting the pathogen transfer route and preserving the minimally invasive nature of the procedure. The data further suggest that the benefits of the glove bag technique extend across demographic categories, with the most pronounced protective effect seen in patients with elevated baseline risk, such as those with metabolic comorbidities. In clinical practice, these results advocate for a heightened focus on individualized risk assessment and the implementation of targeted infection prevention strategies, including routine use of protective retrieval devices.

While the present study offers several strengths, including a randomized controlled design, rigorous follow-up, and comprehensive risk factor analysis, certain limitations must be acknowledged. The single-center setting may restrict the generalizability of results, as institutional protocols, patient demographics, and resource availability could differ in other contexts. The use of non-probability consecutive sampling raises the possibility of selection bias, although this was partly

mitigated by randomized group allocation. Moreover, the follow-up duration was limited to the first postoperative week, potentially underestimating late-onset SSIs. Uncontrolled variations in surgical technique or operator experience may have also contributed to outcome heterogeneity. Nonetheless, the clear and consistent difference in SSI rates between groups underscores the clinical relevance of the findings. Future research should seek to validate these results in multicenter and larger-scale studies, incorporate longer-term surveillance for infections, and explore the cost-effectiveness and practical implementation barriers of the sterile glove bag technique.

In summary, this study provides compelling evidence that the sterile glove bag technique is a highly effective intervention for preventing port site infections following laparoscopic cholecystectomy. The findings support its routine use, particularly in high-risk patient populations characterized by obesity, diabetes, and hypertension. Ongoing research should focus on broader implementation, exploration of patient-centered outcomes, and the identification of additional modifiable risk factors to further enhance surgical safety and patient recovery (16).

## CONCLUSION

This study demonstrates that the use of the sterile glove bag technique during gallbladder retrieval in laparoscopic cholecystectomy significantly reduces port site infection rates compared to procedures performed without this method, aligning directly with the study's objective and title. The findings highlight the clinical importance of adopting the sterile glove bag technique as a standard infection prevention measure, especially in patients with comorbidities such as obesity, diabetes, and hypertension, who are at heightened risk for surgical site infections. Implementation of this technique in routine surgical practice can enhance patient safety, reduce postoperative complications, and optimize healthcare resource utilization. Future research should further evaluate long-term outcomes and cost-effectiveness, as well as investigate additional strategies to minimize infection risks in diverse patient populations undergoing minimally invasive surgery.

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