

Impact of Sterilization Compliance on Frequency of Port Site Infection Following Laparoscopic Cholecystectomy

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ABSTRACT

Background: Laparoscopic cholecystectomy is the preferred surgical treatment for symptomatic gallstone disease; however, port site infection remains an important postoperative complication, especially in settings where sterilization practices and instrument reprocessing systems may vary. **Objective:** To assess sterilization compliance in the operating theatre, determine the frequency of port site infection, and evaluate the association between sterilization compliance and port site infection after elective laparoscopic cholecystectomy. **Methods:** This prospective observational analytical study was conducted at District Headquarter Hospital Batkhela over four months. Eighty-six adult patients undergoing elective standard four-port laparoscopic cholecystectomy were enrolled through consecutive sampling. Sterilization compliance was assessed perioperatively using a structured compliance score and categorized as low compliance (≤ 21) or high compliance (≥ 22). Patients were followed for seven postoperative days for clinical evidence of port site infection. Data were analyzed using descriptive statistics, chi-square testing, and exploratory binary logistic regression. **Results:** The mean age was 42.81 ± 15.37 years, and 50 patients (58.1%) were female. Overall, port site infection occurred in 10 patients (11.6%). Infection was observed in 9 of 41 low-compliance procedures (22.0%) compared with 1 of 45 high-compliance procedures (2.2%; $p = 0.004$). In exploratory regression, higher sterilization compliance score was associated with lower odds of infection (OR 0.63, 95% CI 0.42–0.95; $p = 0.028$). **Conclusion:** Lower sterilization compliance was associated with increased frequency of early port site infection after elective laparoscopic cholecystectomy. Strengthening sterilization protocols, staff training, and infection-control audits may improve postoperative safety. **Keywords:** Laparoscopic cholecystectomy; Port site infection; Sterilization compliance; Infection control; Patient safety.

INTRODUCTION

Gallstone disease is one of the most frequent hepatobiliary conditions requiring surgical management, and laparoscopic cholecystectomy has become the preferred operative treatment for symptomatic gallstones because it is associated with smaller incisions, reduced postoperative pain, shorter hospitalization, earlier mobilization, faster recovery, and improved cosmetic outcomes compared with open surgery (1). Although the laparoscopic approach has reduced many procedure-related complications, surgical site infection at trocar insertion sites remains a clinically relevant postoperative concern. Port site infection may present with localized erythema, pain, tenderness, swelling, purulent discharge, delayed wound healing, abscess formation, or systemic manifestations in more severe cases,

and even superficial infection can increase antibiotic use, follow-up visits, patient discomfort, treatment cost, and postoperative morbidity (2,3).

The frequency of port site infection after laparoscopic surgery varies across settings and is influenced by patient-related, procedure-related, and infection-control-related factors. Reported contributors include diabetes mellitus, obesity, smoking, prolonged operative duration, bile or stone spillage, tissue handling, local wound contamination, and deficiencies in instrument reprocessing or operating theatre asepsis (4,5). In laparoscopic cholecystectomy, the risk of infection is particularly relevant because reusable laparoscopic instruments are complex in structure, with long shafts, narrow lumens, joints, valves, and insulated surfaces that may retain blood, tissue debris, bile residue, or microbial contamination if cleaning and sterilization procedures are incomplete (6). Therefore, safe reprocessing of laparoscopic instruments requires systematic cleaning, disassembly where applicable, decontamination, sterilization, storage, and aseptic handling before reuse.

Sterilization compliance refers to consistent adherence to established procedures for cleaning, disinfection, sterilization, packaging, storage, and intraoperative handling of surgical instruments and operating room materials. Inadequate compliance at any stage of this process can compromise instrument sterility and increase the likelihood of postoperative infection, particularly where surgical workload is high and sterilization resources, trained personnel, monitoring systems, or routine audit mechanisms are limited (7,8). In resource-constrained healthcare settings, these challenges may be more pronounced because reusable instruments are frequently reprocessed under time pressure, and adherence to standardized infection prevention protocols may vary between operating lists, staff members, and sterilization cycles.

Although port site infection after laparoscopic cholecystectomy has been described in previous studies, there remains limited local evidence evaluating whether objectively assessed sterilization compliance during laparoscopic cholecystectomy is associated with subsequent port site infection in routine surgical practice. This gap is important because many infection-control interventions are feasible, low-cost, and modifiable, including staff training, standardized checklists, sterilization monitoring, proper documentation, and regular infection-control audits. Establishing the relationship between sterilization compliance and postoperative port site infection can help identify preventable weaknesses in operative practice and support quality improvement strategies aimed at improving patient safety.

Using a PICO framework, the population of interest in this study comprised adult patients undergoing elective four-port laparoscopic cholecystectomy; the exposure was lower sterilization compliance during instrument and operating theatre preparation; the comparison was higher sterilization compliance; and the outcome was clinically identified port site infection during early postoperative follow-up. The objective of this study was to assess sterilization compliance in the operating theatre, determine the frequency of port site infection after laparoscopic cholecystectomy, and evaluate whether sterilization compliance level was associated with the occurrence of port site infection among patients undergoing elective laparoscopic cholecystectomy.

MATERIAL AND METHODS

This prospective observational analytical study was conducted at District Headquarter Hospital Batkhela over a four-month period among adult patients undergoing elective laparoscopic cholecystectomy. The design was selected because sterilization compliance was assessed during the perioperative process and patients were subsequently followed during the early postoperative period for clinical evidence of port site infection. The study was conducted in the routine operating theatre setting of a tertiary care hospital where laparoscopic cholecystectomy procedures are performed as part of standard surgical care.

The study population included adult patients aged 18 to 75 years who were scheduled for elective standard four-port laparoscopic cholecystectomy and provided written informed consent for

participation. Patients were excluded if the procedure was converted from laparoscopic to open cholecystectomy, if they had acute cholecystitis, empyema gallbladder, bile spillage, stone spillage, pre-existing local skin infection at the anticipated port site, immunocompromised status, uncontrolled diabetes mellitus, morbid obesity with body mass index greater than 40 kg/m², refusal to participate, or inability to complete postoperative follow-up. These criteria were applied to reduce the influence of major clinical and procedural confounders that could independently increase the risk of postoperative port site infection.

The sample size was calculated using OpenEpi software on the basis of an expected port site infection prevalence of 5.9%, a 95% confidence level, and a 5% margin of error, resulting in a required sample size of 86 patients. Consecutive sampling was used, and all eligible patients undergoing elective laparoscopic cholecystectomy during the study period were enrolled until the calculated sample size was achieved. This recruitment method was used to include all accessible eligible cases during the data collection period and to reduce selective enrollment by the research team.

Data collection was performed using a structured data collection form consisting of patient characteristics, clinical variables, perioperative sterilization compliance assessment, and postoperative port site evaluation. Baseline variables included age, gender, body mass index, smoking status, diabetes mellitus, and hypertension. Sterilization compliance was assessed through direct perioperative observation of instrument cleaning and preparation, operating room preparation, and adherence to sterilization-related procedures before and during laparoscopic cholecystectomy. Each observed component contributed to a total compliance score, and procedures were categorized into low compliance and high compliance groups using the predefined study cutoff, with scores of 21 or less classified as low compliance and scores of 22 or higher classified as high compliance. Compliance score was also retained as a continuous variable for regression analysis.

The primary outcome was port site infection identified during the first seven postoperative days. Port sites were examined clinically during follow-up for features suggestive of infection, including localized redness, swelling, pain, tenderness, discharge, or delayed wound healing. Port site infection status was recorded as infection present or no infection. The assessment focused on early clinically evident infection after laparoscopic cholecystectomy and was documented using the postoperative section of the data collection form. Patients were followed through direct clinical assessment to ensure consistent outcome ascertainment within the defined follow-up period.

To improve internal validity, the study restricted enrollment to elective laparoscopic cholecystectomy cases and excluded patients with major operative contamination events or high-risk clinical conditions likely to confound the relationship between sterilization compliance and infection. Data collection forms were reviewed for completeness before entry, and anonymized data were entered into Microsoft Excel for cleaning and organization before statistical analysis. Patient identifiers were not used in the analytical dataset, and all study records were stored securely with access limited to the research team.

Statistical analysis was performed using SPSS version 27. Categorical variables, including gender, smoking status, diabetes mellitus, hypertension, compliance level, and port site infection status, were summarized as frequencies and percentages. Continuous variables, including age, body mass index, and sterilization compliance score, were summarized using mean, standard deviation, and range. The frequency of port site infection was calculated overall and compared between low-compliance and high-compliance groups. The association between sterilization compliance level and port site infection was assessed using the chi-square test, with Fisher's exact test considered appropriate where expected cell counts were small. Binary logistic regression was used to explore the association between sterilization compliance score and port site infection while accounting for selected patient-level variables, including smoking status, diabetes mellitus, hypertension, and gender. Results were expressed as odds ratios with 95% confidence intervals, and a p-value less than 0.05 was considered statistically significant. Because

the number of infection events was limited, adjusted regression findings were interpreted as exploratory rather than definitive evidence of independent prediction.

The study was conducted according to accepted ethical principles for biomedical research. Ethical approval was obtained before initiation of data collection, and written informed consent was obtained from all participants before enrollment. Participation was voluntary, and patients retained the right to withdraw from the study without any effect on their clinical care. Confidentiality and anonymity were maintained throughout data collection, analysis, and reporting, and the findings were reported in aggregate form only.

RESULTS

A total of 86 patients undergoing elective four-port laparoscopic cholecystectomy were included in the analysis. Females represented 50 participants (58.1%), while males represented 36 participants (41.9%). The mean age of the participants was 42.81 ± 15.37 years, with an age range of 19 to 69 years. The mean body mass index was 26.32 ± 4.40 kg/m², ranging from 15.5 to 36.1 kg/m². Diabetes mellitus was present in 25 patients (29.1%), and hypertension was present in 30 patients (34.9%). Regarding smoking status, 18 participants (20.9%) were current smokers, 18 (20.9%) were former smokers, and 50 (58.1%) had never smoked. The mean sterilization compliance score was 21.57 ± 1.88 , with observed scores ranging from 17 to 26. Port site infection was identified in 10 patients, giving an overall infection frequency of 11.6%.

Table 1. Demographic, Clinical, Sterilization Compliance, and Port Site Infection Characteristics of Study Participants (n = 86)

Variable	Category/Statistic	n	%	Mean ± SD	Range
Gender	Male	36	41.9	—	—
	Female	50	58.1	—	—
Smoking status	Current	18	20.9	—	—
	Former	18	20.9	—	—
	Never	50	58.1	—	—
Diabetes mellitus	Yes	25	29.1	—	—
	No	61	70.9	—	—
Hypertension	Yes	30	34.9	—	—
	No	56	65.1	—	—
Age	Years	—	—	42.81 ± 15.37	19–69
Body mass index	kg/m ²	—	—	26.32 ± 4.40	15.5–36.1
Sterilization compliance score	Score	—	—	21.57 ± 1.88	17–26
Port site infection	Present	10	11.6	—	—
	Absent	76	88.4	—	—

SD, standard deviation.

The study population was predominantly female and middle-aged, with a mean body mass index in the overweight range. Nearly one-third of participants had diabetes mellitus, and more than one-third had hypertension. The observed overall port site infection frequency was 11.6%, while the mean sterilization compliance score was 21.57 ± 1.88 , indicating moderate variation in compliance across procedures.

Sterilization compliance was categorized into low compliance and high compliance groups using the predefined cutoff. Low compliance was recorded in 41 procedures (47.7%), whereas high compliance was recorded in 45 procedures (52.3%). Port site infection occurred in 9 of 41 low-compliance procedures (22.0%) compared with 1 of 45 high-compliance procedures (2.2%). The absolute risk difference between the two compliance groups was 19.7 percentage points. The risk of port site infection was approximately 9.88 times higher in the low-compliance group compared with the high-compliance group, and the odds of infection were 12.38 times higher in low-compliance procedures.

Table 2. Association Between Sterilization Compliance Level and Port Site Infection (n = 86)

Sterilization Compliance Level	Port Site Infection Present, n (%)	Port Site Infection Absent, n (%)	Total, n	Risk Ratio	Odds Ratio	95% CI for Odds Ratio	p-value
Low compliance	9 (22.0)	32 (78.0)	41	9.88	12.38	1.49–102.65	0.004
High compliance	1 (2.2)	44 (97.8)	45	Reference	Reference	Reference	—

CI, confidence interval. The p-value corresponds to the reported chi-square comparison between compliance level and port site infection. Low compliance was defined as a compliance score ≤ 21 , and high compliance was defined as a compliance score ≥ 22 .

Port site infection was substantially more frequent following procedures with low sterilization compliance than those with high sterilization compliance. The difference was statistically significant, with infection observed in 22.0% of low-compliance procedures compared with 2.2% of high-compliance procedures. The wide confidence interval around the odds ratio reflects the small number of infection events, particularly the single infection recorded in the high-compliance group, but the direction and magnitude of association support a clinically important relationship between lower compliance and higher early postoperative infection frequency.

Exploratory binary logistic regression was performed to assess predictors of port site infection. Sterilization compliance score was the only variable significantly associated with port site infection in the adjusted model. Each one-point increase in compliance score was associated with lower odds of port site infection, with an odds ratio of 0.63. Smoking status, diabetes mellitus, hypertension, and gender were not statistically significant predictors in the model. Because only 10 port site infection events were observed, the adjusted regression findings should be interpreted cautiously as exploratory.

Table 3. Exploratory Binary Logistic Regression Analysis for Predictors of Port Site Infection

Variable	B	Wald	p-value	Odds Ratio	95% CI
Smoking status	0.386	0.61	0.436	1.47	0.56–3.88
Diabetes mellitus	0.658	0.77	0.382	1.93	0.44–8.42
Hypertension	-0.395	0.26	0.612	0.67	0.15–3.10
Sterilization compliance score	-0.464	4.82	0.028	0.63	0.42–0.95
Gender	-0.088	0.01	0.905	0.92	0.21–3.93

CI, confidence interval. The model included smoking status, diabetes mellitus, hypertension, sterilization compliance score, and gender. Regression results are presented as exploratory because of the limited number of port site infection events.

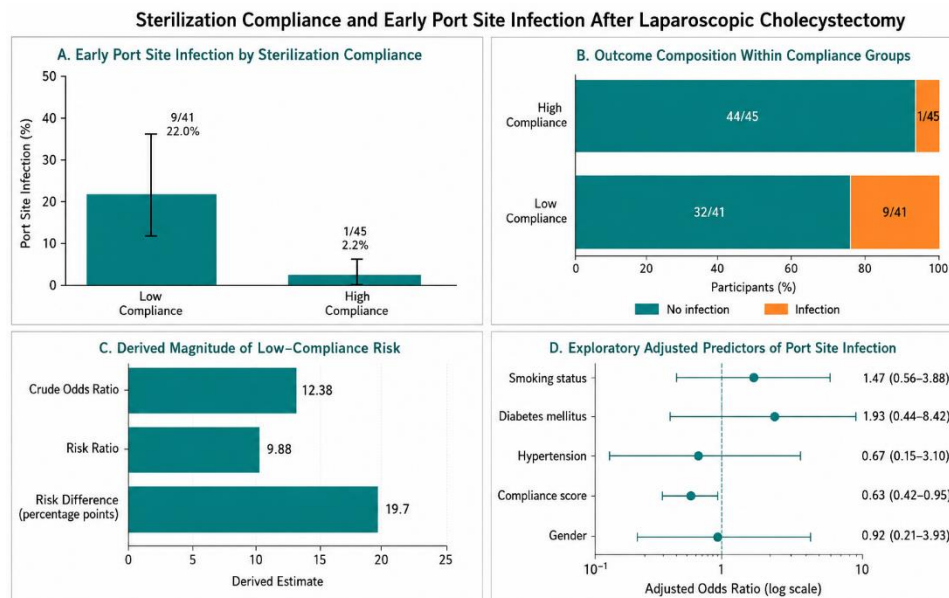


Figure 1 demonstrates the relationship between sterilization compliance and early port site infection after laparoscopic cholecystectomy. Infection occurred in 9 of 41 low-compliance procedures (22.0%) compared with 1 of 45 high-compliance procedures (2.2%), corresponding to an absolute risk difference of 19.7 percentage points. The crude risk of port site infection was approximately 9.88 times higher in the low-compliance group, while the crude odds of infection were 12.38 times higher, with a 95% confidence interval of 1.49 to 102.65. The outcome composition further shows that infection represented a markedly larger proportion of low-compliance procedures, whereas almost all high-compliance procedures remained infection-free. In the exploratory adjusted model, sterilization compliance score showed the clearest protective association with port site infection, with each one-point increase in compliance score associated with lower odds of infection (OR 0.63, 95% CI 0.42–0.95), while smoking status, diabetes mellitus, hypertension, and gender had confidence intervals crossing unity. These findings support a clinically meaningful association between lower sterilization compliance and increased early postoperative port site infection, although the wide interval estimates reflect the small number of infection events.

In the exploratory adjusted model, sterilization compliance score remained associated with port site infection after accounting for selected patient-level variables. The odds ratio of 0.63 indicates that higher compliance scores were associated with reduced odds of infection. Diabetes mellitus showed an odds ratio above 1.00, but the confidence interval was wide and crossed unity. Smoking status, hypertension, and gender also showed no statistically significant association with port site infection in this sample. These findings suggest that sterilization compliance was the dominant measured factor associated with early port site infection, although larger studies with more infection events are needed to confirm adjusted predictor estimates.

DISCUSSION

The present study evaluated the association between sterilization compliance and early port site infection among patients undergoing elective laparoscopic cholecystectomy. The overall frequency of port site infection was 11.6%, with infection observed in 22.0% of low-compliance procedures compared with 2.2% of high-compliance procedures. This difference indicates a clinically important association between lower adherence to sterilization procedures and higher early postoperative infection frequency. Although laparoscopic surgery is generally associated with reduced wound-related morbidity compared with open procedures, infection at trocar insertion sites remains a relevant complication, particularly when reusable instruments require repeated reprocessing and handling in routine operating theatre workflows (9,10).

The observed port site infection frequency was higher than rates commonly reported from well-resourced surgical environments, where laparoscopic cholecystectomy is generally associated with lower surgical site infection risk than open cholecystectomy (11,12). However, the finding is consistent with evidence from settings where infection control systems, operating theatre workload, sterilization resources, and adherence monitoring may vary. Port site infections after laparoscopy have been linked to multiple factors, including instrument contamination, umbilical microbial flora, inadequate reprocessing of reusable instruments, procedural contamination, and patient-related vulnerability (13,14). In the present study, the markedly higher infection frequency in low-compliance procedures supports the practical importance of consistent instrument cleaning, sterilization, storage, and aseptic handling as modifiable components of surgical safety.

The association between sterilization compliance and port site infection is biologically and clinically plausible. Laparoscopic instruments have complex designs, including narrow channels, joints, valves, and insulated surfaces, which can retain blood, tissue material, or microbial contamination if cleaning and sterilization are incomplete. When such instruments are reused without complete reprocessing, residual contamination may be transferred to the port site during trocar insertion, tissue manipulation, or instrument exchange. Previous studies have shown that port site complications and bacterial contamination remain important concerns after laparoscopic procedures, particularly when preventive practices are inconsistent (15,16). Therefore, the present findings reinforce the need for structured sterilization checklists, direct monitoring of reprocessing steps, staff training, and routine infection-control audits in laparoscopic surgical units.

In the exploratory adjusted regression model, sterilization compliance score remained associated with port site infection, with each one-point increase in compliance score corresponding to lower odds of infection. Smoking status, diabetes mellitus, hypertension, and gender did not show statistically significant associations with infection in this sample. These findings should not be interpreted as evidence that patient-related factors are unimportant, because the study included only 10 infection events and was therefore underpowered for stable multivariable prediction. Diabetes mellitus, smoking, obesity, and other clinical factors are well-recognized contributors to impaired wound healing and postoperative infection risk, but their effects may not have reached statistical significance because of

limited event numbers, exclusion of uncontrolled diabetes and morbid obesity, and restriction to elective cases (17,18).

The regression findings also require cautious interpretation because the number of infection events was small relative to the number of predictors included in the model. Although the direction of association for sterilization compliance was consistent with the unadjusted group comparison, the adjusted estimates should be considered exploratory. Overfitting is possible when several predictors are entered into a logistic regression model with few outcome events, and this can produce unstable estimates and wide confidence intervals. The wide confidence interval around the crude odds ratio for low compliance similarly reflects the low number of infections in the high-compliance group. Nevertheless, the consistency between the descriptive comparison and adjusted model suggests that sterilization compliance is a strong candidate factor for further evaluation in larger studies.

The study has direct implications for surgical infection prevention in resource-constrained settings. Nearly half of the procedures were categorized as low compliance, which indicates that sterilization-related practice gaps may exist despite the availability of routine operating theatre protocols. Improvement strategies should therefore focus not only on availability of sterilization equipment but also on compliance behavior, documentation, workflow design, accountability, and continuous training. Practical measures may include standardized instrument reprocessing protocols, preoperative sterilization verification checklists, periodic competency assessment of operating theatre staff, biological and chemical indicator monitoring where applicable, and routine surveillance of postoperative port site outcomes. Evidence from laparoscopic cholecystectomy and other abdominal surgical procedures suggests that structured preventive policies and risk-factor control can reduce infective complications and improve postoperative outcomes (19,20).

This study has several limitations. First, it was conducted at a single center with a relatively small sample size, which limits generalizability to other hospitals, surgical teams, and sterilization systems. Second, follow-up was limited to seven postoperative days, which may underestimate delayed port site infections, including infections presenting after suture removal or those caused by slow-growing organisms. Third, infection was assessed clinically without culture confirmation, so microbiological patterns, antimicrobial sensitivity, and organism-specific causes could not be evaluated. Fourth, sterilization compliance was categorized using a predefined score cutoff, but broader validation of the scoring system would strengthen future research. Finally, because high-risk surgical scenarios such as acute cholecystitis, bile spillage, stone spillage, uncontrolled diabetes, and morbid obesity were excluded, the findings apply mainly to elective laparoscopic cholecystectomy patients with lower procedural contamination risk.

Despite these limitations, the study provides useful local evidence that lower sterilization compliance is associated with a higher frequency of early port site infection after laparoscopic cholecystectomy. The findings support the need for larger multicenter prospective studies with standardized compliance tools, 30-day follow-up, culture-confirmed infection assessment, and adequately powered multivariable analysis. Future research should also evaluate barriers to sterilization compliance in operating theatre settings, including staff training, workload, equipment availability, documentation practices, and institutional audit systems. Such evidence would help translate the present findings into practical infection-control interventions that are feasible in routine surgical practice (21,22).

CONCLUSION

This study found that lower sterilization compliance was associated with a higher frequency of early port site infection following elective laparoscopic cholecystectomy. Port site infection occurred more frequently in low-compliance procedures than in high-compliance procedures, and sterilization compliance score showed an exploratory adjusted association with reduced odds of infection. These findings support the clinical importance of consistent instrument reprocessing, operating theatre

preparation, aseptic handling, staff training, standardized protocols, and regular infection-control audits. Because the study was single-center, included a limited number of infection events, and used short postoperative follow-up, the findings should be interpreted cautiously and confirmed through larger multicenter prospective studies with 30-day surveillance and culture-confirmed infection assessment.

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