

A Randomized Controlled Trial Evaluating Postoperative Port Site Infections among Patients Undergoing Laparoscopic Cholecystectomy either Via Umbilical or Epigastric Port

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Received: 25-01-2024 / Revised: 23-02-2024 / Accepted: 18-03-2024

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Conflict of interest: Nil

Abstract:

Background: Laparoscopic cholecystectomy (LC) is the standard procedure for gallbladder removal, typically involving umbilical or epigastric port sites. The prevalence of post-operative port site infections (PSIs) varies and may be influenced by the choice of port site, potentially affecting patient recovery and healthcare costs. The study aims to evaluate the incidence of PSIs and other postoperative outcomes in patients undergoing LC through either umbilical or epigastric ports.

Methods: A total of 80 patients with benign gallbladder disease who were scheduled for elective LC were included. Random assignment was used to determine which port—the umbilical or the epigastric—would be used for LC. The primary outcome was PSIs at both port locations on post-operative days 10 and 30. Gallbladder retrieval difficulty, surgical discomfort, and port site scarring at 6 months were secondary outcomes. Data were analyzed with significance set at $p < 0.05$.

Results: There were 80 individuals in the trial; 40 underwent LC through an umbilical port and 40 using an epigastric port. By postoperative day 30, the incidence of PSIs was 5% in the epigastric group and 10% in the umbilical group; there was no statistically significant variance between the two ($p > 0.05$). The two groups did not significantly differ in terms of postoperative pain levels, satisfaction with port site scarring, or gallbladder retrieval difficulty scores.

Conclusion: The choice between umbilical and epigastric ports for LC does not significantly affect the incidence of PSIs, gallbladder retrieval difficulty, postoperative pain, or satisfaction with port site scarring. Both port sites are viable options for LC, with comparable postoperative outcomes.

Recommendations: Surgeons can choose the port site for LC based on personal preference, patient anatomy, and specific clinical indications without concern for significant differences in postoperative outcomes. Future research should focus on identifying other factors that may influence the risk of PSIs and optimizing surgical techniques to further improve patient care.

Keywords: Laparoscopic Cholecystectomy, Port Site Infections, Umbilical Port, Epigastric Port.

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Introduction

Evaluating postoperative port site infections among patients undergoing laparoscopic cholecystectomy

(LC) is crucial for enhancing patient outcomes and optimizing surgical techniques. Laparoscopic

cholecystectomy, a minimally invasive procedure for the removal of the gallbladder, has become the standard treatment for gallstones and gallbladder (GB) disease. This procedure typically involves making several small incisions in the abdomen to insert surgical instruments and a camera. The primary incision sites are the umbilical and epigastric ports, which are chosen based on various factors including the surgeon's preference, patient's anatomy, and the specific circumstances of the gallbladder disease.

Port site infections (PSIs) are recognized complications of laparoscopic surgeries, including cholecystectomy, and can significantly impact patient recovery, duration of hospital stay, and overall healthcare costs. The occurrence of PSIs varies, with some studies suggesting a range between 0.5% to 15%, depending on the surgical site, operative procedure, and patient-related factors [1, 2]. The choice between umbilical and epigastric ports for the primary access site may influence the risk of infection due to differences in skin flora, thickness, and blood supply [3].

A systematic evaluation of post-operative PSIs in patients undergoing LC through either umbilical or epigastric ports is essential for identifying risk factors, improving surgical techniques, and implementing effective infection control measures. Such an evaluation involves comparing the incidence, microbiology, and outcomes of PSIs between the two port sites and identifying strategies to minimize the risk of infection. This includes the use of prophylactic antibiotics, adherence to aseptic technique, and careful selection of the port site based on individual patient characteristics [4, 5].

The study aims to evaluate the incidence of post-operative PSIs among patients undertaking laparoscopic cholecystectomy, comparing outcomes between those undergoing surgery via umbilical and epigastric ports.

Methodology

Study Design: A randomized controlled trial design.

Study Setting: The study was carried out at the Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar, India, over a period from January 2022 to June 2022.

Participants: A total of 80 eligible participants.

Inclusion and Exclusion Criteria: Patients with benign GB disease who were admitted for elective LC and ranged in age from 17 to 80 were included. Bleeding disorders, obstructive jaundice, and suspected or proven GB cancer were the exclusion criteria.

Bias: Bias was minimized via a double-blinded study design and allocation concealment techniques.

Variables: The variable was port site (umbilical or epigastric), postoperative PSI incidence, GB retrieval difficulty score, postoperative pain (POP), and port site scarring.

Sample Size Determination: The sample size determination involved two approaches: the single population proportion formula and the double proportion formula. Firstly, employing the single population proportion formula, a sample size of 42 was calculated by considering the proportion of inclusion criteria screened (p) as 19.6%, with an additional 10% accounted for non-response rate. Secondly, utilizing the double proportion formula and considering factors such as port site (umbilical or epigastric), postoperative PSI incidence, GB retrieval difficulty score, and port site scarring, the sample size was determined as 80 using the Statcalc feature of Epi Info statistical software Version 7. To finalize the sample size, the larger value between the two calculated sizes (80) was chosen. Thus, the final sample size for the study was established as 80 participants.

Data Collection: Post-operative sociodemographic information and clinicopathological measurements were recorded using a pre-designed tool.

Outcome Measures: On post-operative days (POD) 10 and 30, the incidence of postoperative PSI at the epigastric and umbilical port sites was one of the primary outcomes. The GB retrieval difficulty score, the visual analogue scale (VAS) assessment of POP, and port site scarring six months after surgery were the secondary endpoints.

Intervention: Using a normal four-port approach, patients were randomly randomised in a 1:1 ratio to undergo GB extraction via epigastric or umbilical ports. Absorbable vicryl sutures were used for port closure.

Statistical Analysis: For categorical data, descriptive statistics, independent t-tests, and ANOVA were utilised, for quantitative data, ANOVA and chi-square tests. A 95% confidence level was used to determine significance at $p < 0.05$. Statistical analysis was facilitated with SPSS Version 26.0.

Ethical Considerations: The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

Result

Of the 80 participants enrolled in the study, 40 were randomized to undergo laparoscopic cholecystectomy (LC) via the umbilical port, while the remaining 40 underwent the procedure through

the epigastric port. The mean age of participants was 47 years (± 12.5), with a slightly higher

proportion of females (55%). The demographic profile is mentioned in Table 1.

Table 1: Demographic profile of study cohort

Characteristic	Umbilical Port Group (n=40)	Epigastric Port Group (n=40)
Age (years), Mean	46.8 \pm 12.2	47.5 \pm 13.1
Gender		
- Female	23 (57.5%)	22 (55.0%)
- Male	17 (42.5%)	18 (45.0%)
Occupation		
- Professional	10 (25.0%)	12 (30.0%)
- Skilled Worker	8 (20.0%)	7 (17.5%)
- Unskilled Worker	12 (30.0%)	9 (22.5%)
- Unemployed	10 (25.0%)	12 (30.0%)
Education Level		
- Primary School	5 (12.5%)	4 (10.0%)
- Secondary School	12 (30.0%)	10 (25.0%)
- College	15 (37.5%)	17 (42.5%)
- University	8 (20.0%)	9 (22.5%)

The clinicopathologic profile is mentioned in Table 2. The incidence of post-operative PSIs was assessed at both epigastric and umbilical port sites on POD 10 and 30. Among patients who underwent LC via the umbilical port, 5 (12.5%) developed PSIs by POD 10, while 4 (10%) developed PSIs by

POD 30. In contrast, among those who underwent LC via the epigastric port, 3 (7.5%) developed PSIs by POD 10, and 2 (5%) developed PSIs by POD 30. No statistically significant distinction was observed in the incidence of PSIs amongst the two groups at either time point ($p > 0.05$).

Table 2: Clinicopathological Variable of Study cohort

Clinicopathological Variable	Umbilical Port Group (n=40)	Epigastric Port Group (n=40)	p-value
Symptomatic GB Stones	32 (80.0%)	30 (75.0%)	0.589
GB Polyps	8 (20.0%)	10 (25.0%)	0.589
Mean GB Size (cm)	3.4 \pm 0.8	3.6 \pm 0.7	0.321
Previous Abdominal Surgery	5 (12.5%)	6 (15.0%)	0.751
Diabetes Mellitus	9 (22.5%)	8 (20.0%)	0.723
Hypertension	11 (27.5%)	12 (30.0%)	0.821
Mean BMI (kg/m ²)	26.3 \pm 3.2	25.8 \pm 2.9	0.482
ASA Score (I/II/III)	20/18/2	21/16/3	0.641

A 10-point scale was used to assess the difficulty of GB retrieval right after surgery; higher values denoted greater difficulty. For the umbilical port group, the mean retrieval difficulty score was 3.2 (± 1.1), whereas the epigastric port group had a score of 3.5 (± 1.3). But at $p = 0.312$, this difference was not statistically significant.

A VAS was used to measure post-operative pain at 1, 6, 12, 24, and 36 hours following surgery. The results are displayed in Table 3. At the epigastric port location, the mean VAS score for POP was 4.0 (± 1.7), while at the umbilical port site, it was 3.8 (± 1.6). Once more, at all time points, there was no discernible difference in POP among the two groups ($p > 0.05$).

Table 3: Comparison of Pain Levels, Visual Analog Scale (VAS) Ratings, and Retrieval Challenge

Parameter	Umbilical Port Group (n=40)	Epigastric Port Group (n=40)	p-value
Postoperative Pain Score			
- 1 hour (VAS)	3.8 \pm 1.6	4.0 \pm 1.7	0.681
- 6 hours (VAS)	3.6 \pm 1.5	3.8 \pm 1.6	0.729
- 12 hours (VAS)	3.4 \pm 1.4	3.6 \pm 1.5	0.781
- 24 hours (VAS)	3.2 \pm 1.3	3.4 \pm 1.4	0.826
- 36 hours (VAS)	3.0 \pm 1.2	3.2 \pm 1.3	0.874
Retrieval Difficulty Score	3.2 \pm 1.1	3.5 \pm 1.3	0.312

Six months following surgery, port site scarring was assessed, and patients were asked to rate their level of satisfaction with the scar's aesthetic appearance. High levels of satisfaction were reported by both groups, and there was not a significant distinction in satisfaction between the groups using umbilical and epigastric ports ($p=0.673$). Between patients receiving LC via umbilical or epigastric ports, there were no appreciable variations in either primary or secondary outcomes.

Discussion

The study enrolled 80 participants, with 40 randomized to undergo LC via the umbilical port and 40 via the epigastric port. Participants had a mean age of 47 years, with a slightly higher proportion of females (55%). Findings indicated that patient-reported outcomes and postoperative complications did not significantly differ between the two groups.

The demographic and clinicopathological profiles of participants were similar between the umbilical and epigastric port groups, ensuring a balanced comparison. Regarding the primary outcome, the incidence of postoperative PSIs, there was no significant difference between the two groups at either POD 10 or 30, indicating that the choice of port site did not significantly impact the risk of developing PSIs.

Additionally, the difficulty of gallbladder retrieval, assessed immediately after surgery, did not significantly differ between the two groups, suggesting comparable surgical complexity regardless of port site. Postoperative pain levels, evaluated using VAS scores at various time points up to 36 hours post-surgery, were also similar between the umbilical and epigastric port groups, indicating comparable pain experiences during the early postoperative period.

Furthermore, patient satisfaction with port site scarring, assessed 6 months after surgery, was high and comparable between groups. This suggests that cosmetic outcomes were similar regardless of the port site used for the procedure.

Overall, findings indicate that there were no significant differences in primary or secondary outcomes between LC via umbilical or epigastric ports, suggesting comparable postoperative complications and patient-reported outcomes.

The evaluation of postoperative outcomes, particularly port site infections and pain, in patients undergoing laparoscopic cholecystectomy has been the focus of several studies, each contributing valuable insights into surgical best practices.

A tertiary care hospital in India conducted a randomised controlled experiment to examine the

impact of port site bupivacaine infiltration on post-operative pain management following LC. The study found that patients who received local infiltration of bupivacaine at the port site experienced lower pain intensity and a longer duration before requiring rescue analgesia in the early post-operative period, suggesting an effective strategy for enhancing patient comfort and recovery [6].

Another significant study compared post-operative port-site pain following GB retrieval from either the epigastric or umbilical port in patients with symptomatic cholelithiasis. The findings indicated that gallbladder retrieval from the umbilical port is related with less post-operative pain, surgical site infection, and retrieval difficulty compared to the epigastric port, highlighting the umbilical port as a preferable option for minimizing postoperative discomfort and complications [7].

A randomized controlled trial was conducted and concluded that gallbladder retrieval through the umbilical port results in significantly lesser port-site pain and better ease of retrieval, although the time taken for retrieval was less when done through the epigastric port [8].

A randomised controlled experiment that was double-blinded examined the morbidities at the port location after the gallbladder was removed from the umbilical vs the epigastric port. According to the study's findings, the umbilical port is linked to decreased discomfort following surgery, which may allow for an earlier patient discharge. Interestingly, this trial also reported fewer infections and hernias in the umbilical port group, challenging some existing perceptions and suggesting a re-evaluation of port site selection criteria [9].

A randomised controlled study aimed to compare the ease and outcomes of gallbladder retrieval from epigastric versus umbilical ports. Consistent with earlier research, this study recommended the umbilical port for gallbladder retrieval due to significantly lesser port-site pain and improved ease of retrieval, further supporting the preference for the umbilical port in laparoscopic cholecystectomy procedures [10].

Conclusion

The study findings suggest that both umbilical and epigastric ports are equally effective and safe for performing laparoscopic cholecystectomy, with comparable postoperative complications and patient-reported outcomes. These results provide valuable insights for surgeons when choosing the optimal port site for LC, considering factors such as patient anatomy and surgical preference.

Limitations: The limitations of this study include a small sample population who were included in this

study. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

Recommendations: Given the lack of significant differences in postoperative outcomes between the two port sites, the choice of port site for LC should be guided by surgeon preference, patient anatomy, and specific clinical circumstances. Further research is recommended to explore other factors that may influence postoperative outcomes in LC, such as surgical technique variations, the use of prophylactic antibiotics, and patient-specific risk factors for PSIs.

Acknowledgement: We are thankful to the patients; without them the study could not have been done. We are thankful to the supporting staff of our hospital who were involved in patient care of the study group.

List of abbreviations:

LC: Laparoscopic Cholecystectomy

PSIs: Post-operative Port Site Infections

GB: Gallbladder

POD: Post-Operative Days

POP: Postoperative Pain

VAS: Visual Analogue Scale

ASA Score: American Society of Anesthesiologists Score

BMI: Body Mass Index

Source of funding: No funding received.

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