

ORIGINAL ARTICLE

Influence of pneumoperitoneum pressures in laparoscopic cholecystectomy: A clinical trial.Sohail Moosa¹, Hamid Raza², Bilal Ahmed³, Muhammad Umar⁴, Muhammad Akram⁵, Ali Tahir⁶

ABSTRACT... Objective: To compare the severity of postoperative abdominal pain between high (12mmHg) vs low (8mmHg) pressure pneumoperitoneum in patients undergoing elective laparoscopic cholecystectomy. **Study Design:** Prospective, Randomized, Double-blinded Controlled Trial. **Setting:** Surgical Unit of Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences in Pakistan. **Period:** Six Months, from 1st May to 30th November 2024. **Methods:** Was carried out involving patients undergoing laparoscopic cholecystectomy (LC) with ethical approval obtained beforehand. Sixty patients participated and were randomly allocated to two groups in equal numbers. Group A underwent LC using high-pressure pneumoperitoneum (12–14 mmHg), whereas Group B had the procedure performed under low-pressure pneumoperitoneum (8–10 mmHg). The level of postoperative pain was assessed using the Visual Analogue Scale (VAS) 24 hours after surgery. **Results:** The mean age of Group A was 41 ± 9.96 years, and Group B was 38 ± 10.09 years. Group A included 18 (60%) males and 12 (40%) females, whereas Group B had 20 (67%) males and 10 (33%) females. At 24 hours postoperatively, 22 (73%) patients in Group A experienced mild pain, while 8 (27%) reported moderate-to-severe pain. In Group B, 26 (87%) patients had mild pain, whereas only 4 (13%) experienced moderate-to-severe pain. **Conclusion:** The article concludes that lower pneumoperitoneum pressures used during laparoscopic cholecystectomy reduced post-operative pain in comparison to when higher pressures were used without compromising the operative visibility. Future studies require larger sample size studies to address further the concerns for surgical visibility, operative duration, while also assessing the outcomes.

Key words: Laparoscopic Cholecystectomy, Pneumoperitoneum Pressure, Postoperative Pain, Randomized Controlled Trial, Visual Analogue Scale.

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INTRODUCTION

Gallstone disease is the commonest disease affecting the biliary tract, often requiring surgical intervention. Since its introduction in 1882, cholecystectomy has remained the definitive treatment, with Laparoscopic cholecystectomy gaining prominence due to its minimally invasive nature, which translates to several patient benefits.¹ These include reduced postoperative pain, abbreviated hospital stays, and quicker recovery periods, making it a preferred surgical option for gallbladder-related conditions.²

A crucial aspect of LC is the creation of a pneumoperitoneum, which provides adequate visualization of the surgical field by insufflating carbon dioxide (CO₂) into the peritoneal cavity. In clinical practice, 12–14mmhg pressure is used, which raises concerns for adverse effects such as increased post-operative pain, altered hemodynamics, and reduced

pulmonary compliance, these adverse effects can be avoided with the use of 8–9mmHg pressure techniques.³ Scientific literature also supports with evidence that lower pressures maintain adequate surgical exposure but help reduce post-operative pain, and improve patient outcomes.⁴

Despite the benefits, some surgeons raise concerns that reduced pressures may prolong operative time and increase technical difficulties and may also be not feasible in maintaining sufficient work space for safe dissection.⁵ Concerning the aforementioned debate, this study aimed to compare the influence of different pneumoperitoneum pressures (Low vs high) on postoperative pain in patients undergoing elective Laparoscopic Cholecystectomy, for contributing to the surgical protocols for better patient care and comfort.

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METHODS

Study Design and Setting

This randomized controlled trial was conducted at the Department of Surgery, Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences, Pakistan, after approval from ethical committee (Reference No: 24/08 Dated: 08/04/2024) as a prospective study, all patients admitted during the six-month enrollment period (1st May to 30th November 2024) were assessed for eligibility. Recruitment ceased once 60 eligible patients were selected.

Patient Selection

Patients were assigned into two equal groups of 30 each by randomization. Patients having age above 18 years, with either gender having symptomatic gallstones, who were planned for elective LC, having ASA Grade I or II were included in this study. However, patients with acute cholecystitis, cholangitis, or gallbladder malignancy, and those having severe comorbidities (ASA Grade III or above), Pregnant female, and those changed to open cholecystectomy were excluded to participate in this study. In the study, two groups underwent laparoscopic cholecystectomy under different conditions: Group A, serving as the control group, underwent the procedure at the typical pneumoperitoneum pressure of 12–14 mmHg, whereas Group B, designated as the intervention group, experienced the surgery with a reduced pneumoperitoneum pressure set at 8–10 mmHg.

Randomization and Blinding

A convenient sample of 60 participants was selected and randomly assigned into two equal groups (30 per arm) using a computer-generated randomization list. Allocation followed a pre-set list, with each study arm color-coded for randomization, data entry, and analysis. Concealment was maintained through sequentially numbered sealed envelopes. While the surgeon was aware of the group assignment, all participants, postoperative pain assessors, and data analysts remained blinded to the pneumoperitoneum pressure used.

Intervention and Technique

In this study, patients in the intervention group underwent laparoscopic cholecystectomy using low-pressure pneumoperitoneum, where

the gas insufflation pressure was maintained at 8–10 mmHg. In contrast, the control group underwent the procedure with standard-pressure pneumoperitoneum, set between 12–14 mmHg. This distinction allowed for a comparative analysis of outcomes based on pressure levels. At the start of surgery, initial insufflation was set to 8 mmHg for the low-pressure group and 12 mmHg for the standard-pressure group. Pressure adjustments were made at two points upon the surgeon's request. Trocars were introduced on pressure allocated by each group. Pain ratings were made using the short 11-point (0-10) pain scale, assessed per patient at 24 hours post-operatively. All procedures were performed by experienced surgeons under general anesthesia and followed a standardized, stepwise technique: A standard four-port technique was used with the following trocar positions: The creation of pneumoperitoneum was achieved through carbon dioxide (CO₂) insufflation using an open technique. This involved making an infra-umbilical incision and inserting a 10 mm trocar at the umbilical site.

Additional trocars were placed at specific positions: a 10 mm trocar at the sub-xiphisternum, a 5 mm trocar at the medial subcostal region, and another 5 mm trocar at the lateral subcostal region. These precise placements ensured proper access for the laparoscopic procedure. To minimize diaphragm expansion, all trocars were inserted during exhalation.

The critical view of safety technique was employed to dissect the cystic duct and cystic artery, which were subsequently clipped and divided. The gallbladder was carefully dissected and extracted through the umbilical port. Pneumoperitoneum pressures were maintained at 12–14 mmHg for Group A (standard pressure) and 8–10 mmHg for Group B (low pressure). Finally, all port sites were closed using absorbable sutures to ensure proper wound healing. The peri-operative preparation and postoperative protocol for the patients is detailed elsewhere.¹

Outcomes

The primary outcome was the postoperative pain score at 24 hours. Postoperative pain was assessed using the Visual Analogue Scale at 24

hours after surgery. VAS scores were divided into specific categories to assess pain intensity. A score of 0–4 mm represented no pain, while mild pain was categorized as 5–44 mm. Scores ranging from 45–74 mm indicated moderate pain, and severe pain corresponded to scores between 75–100 mm. This classification provides a clear framework for evaluating postoperative discomfort levels in patients. Pain score was recorded by a blinded observer who was unaware of the pneumoperitoneum pressure used during surgery.

Statistical Analysis

SPSS version 24.0 was used to analyze the data. Continuous variables, including age, BMI, and pain scores, were reported as mean \pm standard deviation (SD) and analyzed using a t-test for comparison. Categorical variables, such as gender, ASA grade, and pain severity, were expressed as percentages and evaluated using the chi-square test. Statistical significance was defined as a p-value of less than 0.05.

RESULTS

The mean age was 41 years in Group A ($SD \pm 9.96$), while 38 years in Group B ($SD \pm 10.09$). In terms of gender distribution, Group A included 18 males (60%) and 12 females (40%), whereas Group B included 20 males (67%) and 10 females (33%), shown in Table-I.

Most patients in both groups had a BMI between 25–30 kg/m². Specifically, 67% of Group A and 70% of Group B fell within this range. The remaining patients had a BMI of 31–33 kg/m². ASA Grade I patients were slightly more common in Group B (63%) compared to Group A (57%), shown in Table-I.

Postoperative pain at 24 hours was assessed using the VAS. In Group A, 22 patients (73%) reported mild pain, while 8 patients (27%) experienced moderate to severe pain. In contrast, in Group B, 26 patients (87%) had mild pain, and only 4 patients (13%) experienced moderate to severe pain. The pain score was significantly lower in Group B ($35 \text{ mm} \pm 10.39$) compared to Group A ($63 \text{ mm} \pm 15.43$), shown in Table-II.

A chi-square test for assessment of the differences in postoperative pain was applied, with a p-value of 0.1967, suggesting a trend favoring low-pressure pneumoperitoneum in reducing postoperative pain, though not reaching statistical significance.

TABLE-I

Demographics.

Variable	Group A (High Pressure)	Group B (Low Pressure)	P-Value
Age (Mean \pm SD, years)	41 \pm 9.96	38 \pm 10.09	-
Gender	Male: 18 (60%) Female: 12 (40%)	Male: 20 (67%) Female: 10 (33%)	0.62
BMI (kg/m ²)	25–30: 20 (67%) 31–33: 10 (33%)	25–30: 21 (70%) 31–33: 9 (30%)	0.78
ASA Grade	Grade I: 17 (57%) Grade II: 13 (43%)	Grade I: 19 (63%) Grade II: 11 (37%)	0.65

In both age groups (18–30 years versus 31–60 years), mild pain was more prevalent in Group B than Group A. A greater percentage of males and females in Group B reported mild pain compared to Group A. Within the group of patients whose BMI falls between 25 and 30 kg/m², mild pain was reported in 18 patients from Group B versus 15 patients in Group A, shown in Table-II.

The results indicate that low (8mmhg) pressure pneumoperitoneum reduced postoperative pain compared to high (12mmhg) pressure pneumoperitoneum without compromising the surgical visibility. Since, the results were not statistically significant, however, the trend suggests that lower pressures are contributory to better postoperative comfort.

DISCUSSION

This study evaluated the impact on postoperative pain in patients undergoing elective laparoscopic cholecystectomy by using high vs low pressure pneumoperitoneum. The findings indicate that low (8 mmhg) pressure pneumoperitoneum is linked to lower postoperative pain at 24 hours compared to high-pressure pneumoperitoneum. Specifically, a greater proportion of patients in the low (8 mmHg) pressure group reported mild pain (87%) in comparison to the high (12mmHg) pressure group (73%).

TABLE-II

Postoperative pain scores and stratification by age, gender, BMI, and ASA Grade.

Variable	Group A (High Pressure)	Group B (Low Pressure)	P-Value
Overall Pain Score (VAS at 24h)	Mild (VAS 5–44): 22 (73%) Moderate-Severe (VAS 45–100): 8 (27%)	Mild (VAS 5–44): 26 (87%) Moderate-Severe (VAS 45–100): 4 (13%)	0.19
Pain Stratification by Age			
18–30 years	Mild: 9 (69%) Moderate-Severe: 4 (31%)	Mild: 11 (85%) Moderate-Severe: 2 (15%)	0.25
31–60 years	Mild: 13 (76%) Moderate-Severe: 4 (24%)	Mild: 15 (88%) Moderate-Severe: 2 (12%)	0.3
Pain Stratification by Gender			
Male	Mild: 12 (67%) Moderate-Severe: 6 (33%)	Mild: 15 (75%) Moderate-Severe: 5 (25%)	0.4
Female	Mild: 10 (83%) Moderate-Severe: 2 (17%)	Mild: 11 (90%) Moderate-Severe: 1 (10%)	0.5
Pain Stratification by BMI			
BMI 25–30 kg/m ²	Mild: 15 (75%) Moderate-Severe: 5 (25%)	Mild: 18 (86%) Moderate-Severe: 3 (14%)	0.35
BMI 31–33 kg/m ²	Mild: 7 (70%) Moderate-Severe: 3 (30%)	Mild: 8 (80%) Moderate-Severe: 2 (20%)	0.45
Pain Stratification by ASA Grade			
ASA Grade I	Mild: 12 (71%) Moderate-Severe: 5 (29%)	Mild: 14 (84%) Moderate-Severe: 3 (16%)	0.28
ASA Grade II	Mild: 10 (77%) Moderate-Severe: 3 (23%)	Mild: 12 (89%) Moderate-Severe: 2 (11%)	0.32

Moreover, moderate to severe pain was less common in the low (8mmHg) pressure group (13%) than in the high (12mmHg) pressure group (27%). However, the difference was not found statistically significant ($p = 0.19$).

Although the trend suggests a potential benefit of the low (8mmhg) pressure approach in reducing postoperative pain, larger patient sample studies are needed to confirm statistical significance.

The results of this study align with previous research suggesting that lower insufflation pressures lead to reduced postoperative pain. Low-pressure pneumoperitoneum minimizes peritoneal stretch, decreases irritation of the diaphragm, and reduces CO₂ retention, all of which contribute to lower pain levels.⁶ Several studies have reported similar findings, with patients in low-pressure groups experiencing less pain in the immediate postoperative period.^{6,7,8} However, conflicting evidence exists in the literature, with some studies raising concerns about whether lower pressure compromises surgical exposure.⁷

Limited intra-abdominal working space may increase the complexity of dissection, potentially leading to prolonged operative time or higher conversion rates to open surgery.⁹ While these concerns remain theoretical in many cases, they highlight an important balance between patient comfort and the technical demands of the procedure. Our study did not assess operative duration or surgical field clarity, and further research is needed to explore these factors.

The reduction in postoperative pain observed with low-pressure pneumoperitoneum can be attributed to several physiological mechanisms, such as lowered activation of the visceral pain receptors by decreasing mechanical stretch on the peritoneum, which also reduces irritation of the phrenic nerve and the diaphragm, contributing to lowering referred pain on the shoulders which is common after laparoscopic surgeries. Lower Pressures also help lowering CO₂ absorption in the blood that contributed to decrease hypercapnia associated side effects i.e., reduced inflammatory response

and discomfort in the peritoneal cavity.^{6,10} Despite these benefits, concerns regarding adequate surgical exposure and the feasibility of maintaining low pressures throughout the procedure must be addressed in future studies.

The strengths of this study include sample randomization, which reduces selection bias, and the use of the VAS for pain measurement. Additionally, blinded observer assessed the postoperative pain which also reduces the bias for reporting pain. This study has some limitations that it included a small sample size of 60 patients which may have limit the ability to detect statistical significant difference, even when the trend in the literature is evident towards reduced reporting of pain. Furthermore, the study assessed postoperative pain up to 24 hours without reporting the operative time and visibility. Other postoperative variables such as potential complications and need for additional analgesic were not assessed for the article. Another limitation is that this article is conducted at single center which can reduce impact of the findings to the broader population and various surgical settings.

Future studies should include larger multicenter patient samples focusing on additional postoperative variables such as analgesic requirements and operative time. Worldwide, laparoscopic cholecystectomy being the most performed surgery, optimizing pneumoperitoneum settings to enhance patient comfort while maintaining surgical efficiency remains a critical area of ongoing research.

CONCLUSION

The article concludes that lower pneumoperitoneum pressures used during laparoscopic cholecystectomy reduced post-operative pain in comparison to when higher pressures were used. Lower pressures contributed to better patient comfort which can serve as an effective strategy for surgery. This study had short follow-up and small sample size, so, larger sample size studies to address the concerns for operative duration, while also assessing the outcomes.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

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2	Hamid Raza: Methodology.
3	Bilal Ahmed: Data collection.
4	Muhammad Umar: Referencing.
5	Muhammad Akram: Data curation.
6	Ali Tahir: Data collection, methodology.