

Feasibility and Safety of Low Pressure Pneumoperitoneum in Laparoscopic Cholecystectomy

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Authors Contribution	ABSTRACT
^{1,2} Substantial contributions to the conception or design of the work; or the acquisition, ^{4,6} Active participation in active methodology, ^{2,3} analysis, or interpretation of data for the work, ⁵ Drafting the work or revising it critically for important intellectual content	Objective: To observe the feasibility and safety of low pressure pneumoperitoneum in laparoscopic cholecystectomy in terms of changes in liver enzymes, operative time, post-operative pain and postoperative hospital stay.
Funding Source: None	Methods: This comparative Cross Sectional Study was conducted at department of Surgery, LUMHS/Jamshoro from November 2020 to October 2021. Patients with gallstones planned for laparoscopic cholecystectomy were included. Patients were randomly assigned to either the low-pressure or standard-pressure pneumoperitoneum groups. During surgery, patients in the low-pressure group were have pneumoperitoneum established and maintained at <10 mmHg, while those in the standard-pressure group was have it maintained at 14-15 mmHg. The operative time, from the first incision to the closure of the last port site, was recorded. Postoperatively, liver enzyme levels were measured at 6, 24, and 48 hours to monitor changes in liver function. Postoperative pain and duration of the hospital stay were recorded. The safety of low-pressure pneumoperitoneum was evaluated by comparing complication rates between the two groups. Data was analyzed using SPSS software version 26.
Conflict of Interest: None	Results: Patient's mean age was 40.74 +12.37 years with female predominance 83.9%. Findings showed that patients in the low-pressure group had better outcomes as, none of them had changes in liver function tests, while 11.3% in the standard-pressure group did ($p = 0.006$). The surgery time was shorter in the low-pressure group (33.79 minutes vs. 44.93 minutes, $p = 0.001$). They also felt less pain (average score 2.72 vs. 4.38, $p = 0.001$), had less drain output (23.73 ml vs. 46.96 ml, $p = 0.001$), and stayed in the hospital for a shorter time (1.47 days vs. 2.08 days, $p = 0.001$).
Received: Sept 05, 2024	Conclusion: Study revealed that the low-pressure pneumoperitoneum observed to be the feasible and safe alternative to standard pressure pneumoperitoneum, with certain potential benefits including reduced operative time, lower postoperative pain, and shorter hospital stays, while maintaining safety with no significant impact on liver enzyme levels.
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Introduction

Gallstone disease is one of the most common conditions encountered in surgical practice, affecting a significant proportion of the global population. It is estimated that approximately 15% of adults develop gallstones, a condition that can lead to a variety of symptoms and complications, including pain, inflammation, and infection of the gallbladder, commonly known as cholecystitis.^{1,2} When symptomatic, these gallstones often necessitate surgical intervention, with cholecystectomy the surgical removal of the gallbladder being the definitive treatment. Cholecystectomy has long been a cornerstone of general surgery, particularly in the treatment of symptomatic gallstones, and remains one of the most frequently performed procedures by general surgeons worldwide. Indeed, it is reported that 93% of patients with gallbladder disease are referred to surgeons for evaluation and management.³ The advent of laparoscopic surgery revolutionized the approach to cholecystectomy. Introduced in the late 20th century, laparoscopic cholecystectomy (LC) has rapidly become the gold standard for the treatment of gallstone disease. This minimally invasive technique offers numerous advantages over the traditional open cholecystectomy, including smaller incisions, reduced postoperative pain, shorter hospital stays, quicker recovery times, and a faster return to normal activities. As a result, laparoscopic cholecystectomy is now widely practiced as a day-care surgery, where patients can be admitted, operated on, and discharged within the same day, thereby optimizing healthcare resources and enhancing patient convenience.

The success of laparoscopic surgery, including LC, is closely linked to the surgeon's ability to create a working space within the abdominal cavity, known as pneumoperitoneum. This is typically achieved by insufflating carbon dioxide (CO₂) gas into the peritoneal cavity, thereby lifting the abdominal wall away from the internal organs and providing the surgeon with the necessary visibility and room to operate. The pressure at which CO₂ is maintained within the abdomen is critical, as it directly influences the safety and efficacy of the procedure.^{4,5} Standard pressure pneumoperitoneum for laparoscopic cholecystectomy is typically set at 12-14 mmHg, a range that has been widely adopted in surgical practice.⁶⁻⁹

However, the creation and maintenance of pneumoperitoneum at these standard pressures are not

without potential complications. The introduction of CO₂ under pressure into the peritoneal cavity can lead to a variety of physiological alterations, some of which may have adverse effects on the patient. For instance, increased intra-abdominal pressure can decrease pulmonary compliance, making it more difficult for the patient to breathe postoperatively. Additionally, elevated pressure within the abdomen can impair blood gas exchange, alter circulatory dynamics, and increase the risk of venous thromboembolism. There is also evidence to suggest that standard pressure pneumoperitoneum may contribute to elevated liver enzymes postoperatively, indicating a potential impact on hepatic function. Furthermore, the increased intra-abdominal pressure has been associated with higher levels of postoperative pain, which can delay recovery and prolong hospitalization. In light of these concerns, there has been growing interest in the use of low-pressure pneumoperitoneum as an alternative to the standard approach. Low-pressure pneumoperitoneum, typically set at 8-10 mmHg, aims to minimize the physiological disturbances associated with higher pressures while still providing an adequate working space for the surgeon.¹⁰ Preliminary studies suggest that low-pressure pneumoperitoneum may be associated with a reduced incidence of postoperative pain, with reported rates of 27.9% in low-pressure cases compared to 44.3% in those undergoing standard pressure pneumoperitoneum.¹¹⁻¹³ These findings have created a debate within the surgical community regarding the optimal pressure settings for pneumoperitoneum in laparoscopic cholecystectomy.

Despite the potential benefits of low-pressure pneumoperitoneum, its feasibility and safety remain subjects of ongoing research. The reduced pressure may, in some cases, compromise the surgeon's ability to adequately visualize and access the surgical field, particularly in patients with complex anatomy or significant inflammation. Moreover, the lower pressure may increase the duration of the surgery or require additional technical adjustments, which could offset the potential advantages.

This prospective study aims to address these uncertainties by directly comparing the outcomes of low-pressure pneumoperitoneum (<10 mmHg) with those of standard pressure pneumoperitoneum (14-15 mmHg) in patients undergoing laparoscopic cholecystectomy. By assessing a range of parameters including operative time, intraoperative complications, postoperative pain,

recovery time, and patient satisfaction this study seeks to determine whether low-pressure pneumoperitoneum can be safely and effectively implemented as a standard practice in laparoscopic cholecystectomy. The findings of this study will have important implications for surgical practice, particularly in refining the techniques used in laparoscopic cholecystectomy to enhance patient outcomes while minimizing risks.

Methodology

This Cross Sectional comparative study was done at department of surgery, LUMHS, Jamshoro during one year from November 2020 to October 2021 after ethical approval. Patients with gallstones planned for laparoscopic cholecystectomy were included. Patients who were not willing to participate in study, history of previous abdominal surgery, patients with co-morbidities and unfit for anesthesia, patients with deranged liver profile prior to surgery and patients with deranged bleeding profile prior to surgery were excluded. Patients were randomly assigned to either the low-pressure or standard-pressure pneumoperitoneum groups using a computer-generated randomization sequence, with allocation concealed in sealed envelopes until the time of surgery. Study was done after taking ethical approval from LUMHS. Prior to enrollment, all eligible participants were thoroughly informed about the study's objectives, procedures, potential risks, and benefits, and were assured that their participation is voluntary, with the option to withdraw at any time without affecting their medical care. Written informed consent was obtained from each participant before inclusion in the study. Data collection was begin with a preoperative assessment, where baseline demographic data, medical history, and relevant laboratory results, including liver function tests were recorded. During surgery, patients in the low-pressure group were have pneumoperitoneum established and maintained at <10 mmHg, while those in the standard-pressure group was have it maintained at 14-15 mmHg. The operative time, from the first incision to the closure of the last port site, was recorded. Postoperatively, liver enzyme levels were measured at 6, 24, and 48 hours to monitor changes in liver function. Postoperative pain was assessed using a Visual Analog Scale (VAS). The duration of the hospital stay, defined as the time from the end of surgery until discharge, was also be recorded. Safety monitoring was involved documenting any intraoperative or postoperative complications, categorizing them as minor or major, and

assessing their potential relation to pneumoperitoneum pressure. The safety of low-pressure pneumoperitoneum was evaluated by comparing complication rates between the two groups. Data was analyzed using SPSS software version 26.

Results

According to the descriptive statistics of age for a sample of 124 individuals shows that the average age was 40.74 years, with a standard deviation of 12.37 years. There were 16.1% males and 83.9% females. In the low-pressure group, 43.5% of patients (27 out of 62) had three ports applied, while 56.5% (35 out of 62) had four ports. In the standard pressure group, 41.9% of patients (26 out of 62) had three ports, and 58.1% (36 out of 62) had four ports. Overall, 42.7% of the total sample had three ports applied, and 57.3% had four ports ($p=0.856$). **Table: 1**

Table 1: Frequency of ports applied in surgery in both groups n=124

Number of port applied	PRESSURE		p-value
	PNEUMOPERITONEUM Low pressure	Standard pressure	
III	27	26	53
	43.5%	41.9%	42.7%
IV	35	36	71
	56.5%	58.1%	57.3%
Total	62	62	124
	100.0%	100.0%	100.0%

According to the comparison of mean operative time between the low-pressure and standard-pressure groups, the low-pressure group had a shorter mean operative time of 33.79 ± 5.98 minutes, while the standard-pressure group had a longer mean operative time of 44.93 ± 9.08 minutes ($p = 0.001$). The low-pressure group also reported a lower mean pain score of 2.72 ± 0.90 compared to 4.38 ± 1.47 in the standard-pressure group ($p = 0.001$). Additionally, the mean drain output was significantly lower in the low-pressure group (23.73 ± 19.59 mL) than in the standard-pressure group (46.96 ± 32.29 mL) ($p = 0.001$). The average hospital stay was also shorter in the low-pressure group (1.47 ± 0.64 days) compared to the standard-pressure group (2.08 ± 0.75 days) ($p = 0.001$). **Table: 2**

Table 2: Comparison of LFTs changes in both groups n=124

Variables	PRESSURE		p-value
	PNEUMOPERITONEUM Low pressure	Standard pressure	

Mean operative time (minutes)	Mean	33.79	44.93	
	Std.	5.98	9.08	0.001
Deviation				
Mean pain (VAS) score	Mean	2.72	0.90	
	Std.	4.38	1.47	0.001
Deviation				
Mean drain output (ml)	Mean	23.73	46.96	
	Std.	19.59	32.29	0.001
Deviation				
Mean Hospital stay (days)	Mean	1.47	2.08	
	Std.	0.64	0.75	0.001
Deviation				

In the comparison of liver function test (LFT) changes, none of the patients in the low-pressure group showed any changes, while 11.3% (7 out of 62) in the standard-pressure group did. Overall, 5.6% of all patients had LFT changes. This difference was statistically significant ($p = 0.006$), showing that LFT alterations were more common in the standard-pressure group as shown in **table.3**

Table 3: Comparison of LFTs changes in both groups n=124

LFT	PRESSURE		Total	P-value
	PNEUMOPERITONEUM	Low pressure		
Yes	0	7	7	0.006
	0.0%	11.3%	5.6%	
No	62	55	117	
	100.0%	88.7%	94.4%	
Total	62	62	124	
	100.0%	100.0%	100.0%	

Discussion

Laparoscopic cholecystectomy, the minimally invasive removal of the gallbladder, has become the gold standard for treating symptomatic cholelithiasis, performed under standard-pressure pneumoperitoneum, where the intra-abdominal pressure is maintained between 12-15 mmHg. However, concerns about the potential adverse effects of higher intra-abdominal pressures. This study was conducted to observe the feasibility and safety of low-pressure pneumoperitoneum in laparoscopic cholecystectomy in terms of changes in liver enzymes, operative time, postoperative pain, and postoperative hospital stay, with the overall mean age of the patients being 40.74 years, with a standard deviation of 12.37 years, with gender distribution as 16.1% were male (20 patients), and 83.9% were female (104 patients). In aligns to this study Chandio A et al¹⁴ reported that the among total of 335 patients underwent cholecystectomy, with a female to male ratio of 5:2 (245 females and 90 males) and the overall mean age of the patients was 51 years, ranging from 15 to 90 years. In the study by Amin A et al¹⁵ also reported that the average age of the patients was

41 years, with a standard deviation of 15.6 years. In the study by Sohu KM et al¹⁶ also reported that the average age among the 1100 patients was 47.63 years, with a male to female ratio of 1:4.6. The predominance of females in cholelithiasis, leading to a higher rate of laparoscopic cholecystectomy among women, is well-documented and can be attributed to several factors. Hormonal influences play a significant role, as elevated estrogen levels—common during pregnancy, from oral contraceptives, or hormone replacement therapy—increase cholesterol saturation in bile, promoting gallstone formation. Additionally, progesterone, which slows gallbladder emptying, contributes to bile stasis and further increases the risk of gallstone development. Women are also more prone to obesity, a major risk factor for cholelithiasis due to its association with higher cholesterol levels in bile. These factors, combined with dietary patterns more common among women, such as higher intake of refined carbohydrates, contribute to the increased incidence of gallstones in females. Consequently, women are more likely to undergo laparoscopic cholecystectomy, as reflected in the consistently higher female-to-male ratios observed in clinical studies and surgical cases.

In this study based on the comparison of liver function test (LFT) changes between the low-pressure and standard-pressure groups, there was in the low-pressure group, no patients (0.0%) showed alterations in LFTs, while in the standard-pressure group, 11.3% of patients (7 out of 62) experienced changes. Overall, 5.6% of the total sample had LFT alterations. A significant difference was observed between the two groups, with a p-value of 0.006, indicating that alterations in LFTs were more common in the standard-pressure group. In line with this study, Praveen G et al¹⁷ reported pre-operative Alanine transaminase (ALT/SGPT) levels of 44.27 ± 21.14 units/liter in the low-pressure pneumoperitoneum group and 57.97 ± 21.14 units/liter in the standard-pressure group. On the first postoperative day, ALT (SGPT) levels rose to 56.23 ± 23.33 units/liter in the low-pressure group and 77.67 ± 51.38 units/liter in the standard-pressure pneumoperitoneum group. Although Aggarwal M et al¹⁸ found inconsistent findings as there was no notable difference in bilirubin and ALP levels between the two groups; however, serum Aspartate Aminotransferase (AST) and Alkaline Phosphatase (ALP) levels showed a significant postoperative increase in group II patients. Although group I patients had shorter operative times, hospital stays, and quicker returns to normal routines

postoperatively, these differences were not statistically significant.¹⁸

In this study according to the comparison of mean operative time between the low-pressure and standard-pressure groups, the mean operative time for the low-pressure group was 33.79 minutes, with a standard deviation of 5.98 minutes. In contrast, the standard-pressure group had a longer mean operative time of 44.93 minutes, with a standard deviation of 9.08 minutes. This difference in operative duration between the two groups was statistically significant, with a p-value of 0.001, indicating that surgeries in the low-pressure group were performed more shortly. In the comparison of this study other studies reported that the LPP, usually set at 8–10 mmHg, has no discernible effect on intraoperative time; mean durations for LPP and SPP have been reported to be 65–10.6 and 61–9.7 minutes, respectively.¹⁹ Furthermore, the incidence of intraoperative problems and conversion to open surgery were comparable for both techniques.^{20,21} On the other hand, LPP improves patient comfort by lowering the need for extra analgesics and reducing postoperative shoulder pain.^{19,21} LPP may also result in decreased inflammatory markers, albeit this was not shown to be statistically significant.¹⁴³ All things considered, LPP seems to be a secure and reliable substitute for SPP, providing advantages in the control of postoperative pain without sacrificing surgical effectiveness.^{22,23}

When the mean pain scores, using the Visual Analog Scale (VAS) was compared between the low-pressure and standard-pressure groups, the low-pressure group reported a mean pain score of 2.72 with a standard deviation of 0.90, while the standard-pressure group had a higher mean pain score of 4.38 with a standard deviation of 1.47. This difference in pain levels between the two groups was statistically significant, with a p-value of 0.001, showing that patients in the low-pressure group experienced less pain postoperatively. Furthermore, the low-pressure group had an average hospital stay of 1.47 days, with a standard deviation of 0.64 days. In comparison, the standard-pressure group experienced a longer mean hospital stay of 2.08 days, with a standard deviation of 0.75 days. This difference was statistically significant, with a p-value of 0.001, suggesting that patients in the low-pressure group were discharged earlier than those in the standard-pressure group. In the comparison of this study just 11.42% of individuals in the LPP group and 31.42% in the SPP

group, respectively, experienced shoulder pain in a randomized controlled study, indicating that the differences were statistically significant ($P=0.0414$).²⁴ Furthermore, a different study discovered that while LPP had no discernible effect on intraoperative hemodynamics or surgical time, it did reduce postoperative shoulder discomfort and narcotic consumption.^{20,21} Moreover, a comparison analysis revealed that LPP was linked to lower CO₂ usage and shorter stays in the hospital, even if the length of the procedure and the field accessibility were not much different.²⁰ When everything is considered, LPP seems to be a secure and reliable substitute, providing advantages in pain relief without sacrificing surgical results.^{20,21}

An important factor to take into account during laparoscopic cholecystectomy is the safety of low-pressure pneumoperitoneum. It is crucial to make sure that lower pressure does not result in higher surgical risks, even though it may lessen the chance of hemodynamic and respiratory issues. Studies have indicated that the majority of individuals can successfully undergo low-pressure pneumoperitoneum without experiencing a notable increase in the incidence of intraoperative problems such as bleeding or damage to the bile duct. Furthermore, a quicker return to normal activities, a decrease in shoulder tip pain, and less postoperative pain could result from the lower intra-abdominal pressure, all of which would improve patient satisfaction.

Emerging data increasingly supports the safety and viability of low-pressure pneumoperitoneum during laparoscopic cholecystectomy. The available findings indicate that low-pressure pneumoperitoneum offers a viable option to standard-pressure procedures, especially in patients at risk of pressure-related problems. However, more extensive randomized controlled studies are required to develop clear guidelines. When using this strategy, surgeons must take into account the unique characteristics of each patient and make sure that sufficient surgical knowledge and resources are available.

Conclusion

Study revealed that the low-pressure pneumoperitoneum observed to be the feasible and safe alternative to standard pressure pneumoperitoneum, with certain potential benefits in laparoscopic cholecystectomy for the patients with cholelithiasis. Particularly it was observed

with a shorter operative time and reduced post-operative pain compared to standard pressure pneumoperitoneum. Additionally, patients in the low-pressure group had a significantly shorter hospital stay and lower drain output. Importantly, there were no significant changes in liver enzymes, suggesting that low-pressure pneumoperitoneum does not adversely affect liver function.

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