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A Comparative Study of Standard Versus Low-Pressure Pneumoperitoneum on Patients Outcome Following Laparoscopic Cholecystectomy at Khyber Teaching Hospital Peshawar a Randomized Controlled Trial

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ABSTRACT

Laparoscopic cholecystectomy (LC) is the gold-standard treatment for gallstone disease, typically performed under standard-pressure pneumoperitoneum (SPP, 12–14 mmHg). High intra-abdominal pressure, however, has been associated with increased postoperative pain and shoulder-tip discomfort, leading to the proposal of low-pressure pneumoperitoneum (LPP, 8–10 mmHg) as a safer alternative. This randomized controlled trial, conducted at Khyber Teaching Hospital, Peshawar, enrolled 60 patients undergoing elective LC to compare postoperative outcomes between LPP and SPP. Patients were randomized into two equal groups (n=30 each). Postoperative outcomes included requirement for additional analgesia, incidence of shoulder-tip pain, and 24-hour postoperative abdominal pain measured on the Visual Analog Scale (VAS). Baseline demographics were comparable across groups (mean age 37.0 ± 9.9 years; mean BMI 25.6 ± 1.7 kg/m^2; 61.7% female; most ASA I–II). The analysis demonstrated no significant differences between groups in 24-hour VAS scores (p = 0.32), requirement for additional analgesia (93.3% vs. 96.7%), or incidence of shoulder-tip pain (66.7% vs. 73.3%, p = 0.58). Subgroup analyses also failed to demonstrate statistically significant differences, though trends suggested a possible benefit of LPP among patients with normal BMI, lower socio-economic background, and rural residence. The findings indicate that LPP does not provide a significant advantage over SPP in reducing postoperative pain, shoulder-tip discomfort, or analgesic requirement within 24 hours. Larger, multicenter trials with extended follow-up and standardized analgesic regimens are warranted to further evaluate potential subgroup benefits.

INTRODUCTION

One of the most frequent gastrointestinal issues that is seen in surgical practice is that of gallstone disease, and cholecystectomy is the definitive treatment for the same[1, 2, 3]. Historically, the standard procedure was open cholecystectomy; however, with the introduction of minimally invasive surgery, laparoscopic cholecystectomy (LC) has replaced open cholecystectomy as the gold standard because of its benefits of lower postoperative pain, early mobilization, short hospitalization, and better cosmetic results[4]. The critical process of LC is the development of pneumoperitoneum through carbon dioxide (CO2) to ensure that the intra-abdominal environment has enough space to see and move instruments around[5,6,7]. Normal LC pneumoperitoneum pressure is typically maintained to 12-14 mmHg, which provides adequate operative field exposure[8,9,10]. Nevertheless, research has pointed to these increased pressures as potentially being the cause of negative physiological responses, such as changes in hemodynamics, escalated systemic CO2 uptake, decreased pulmonary compliance, and postoperative shoulder-tip pain[11].

To reduce these negative effects, low-pressure pneumoperitoneum (LPP), which is usually determined as 8-10 mmHg, is proposed as an alternative method[12,13]. Recent international trials and meta-analyses have indicated that LPP can have considerable advantages, including lower pain measures, smaller analgesic dosage, lower incidence of shoulder-tip pain, higher quality of

recovery, and lesser change in hepatic functioning, without jeopardizing the safety of the procedure[14,15,16]. The majority of the evidence available is, however, of international populations with differences in patient characteristics, surgical environments, and resources[17,18]. In Pakistan, there is a dearth of local data on the effect of LPP on postoperative outcomes[19,20]. It is essential to establish locally relevant evidence to inform surgeons of practices that maximize patient comfort, safety, and cost-effectiveness.

Objective: To make a comparison between the postoperative outcomes of standard- and low-pressure pneumoperitoneum in laparoscopic cholecystectomy patients at Khyber Teaching Hospital, Peshawar.

METHODOLOGY

Design of the study: Randomized Controlled Trial.

Setting/Duration: The trial was conducted in the Department of Surgery at Khyber Teaching Hospital, Peshawar, from 6 February 2025 to 6 June 2025 over a period of four months following approval of the study synopsis.

Sample: 60 patients who underwent elective laparoscopic cholecystectomy were used as the sample. The inclusion criteria included adults between 18-80 years of both sexes with ASA physical status I-II. Patients with acute cholecystitis and severe cardiopulmonary disease, uncontrolled cardiac or respiratory comorbidity, prior upper abdominal operation, or confirmed pregnancy were excluded.

Sample Size: The sample was 60 patients (30 in each group), calculated through the WHO sample size calculator with 5% level of significance and a power of 80% at a previously reported mean postoperative pain score of 5.2 +- 0.8 with standard-pressure pneumoperitoneum (SPP) and 4.6 +- 0.81 with low-pressure pneumoperitoneum (LPP).

Randomization: Blocked randomization of patients who met the selection criteria was done into two equal groups (n = 30 each). LC with SPP (12-14 mmHg) occurred in Group A and LC with LPP (8-10 mmHg) in Group B.

Interventions/Exposures: All surgeries were under general anesthesia by a consultant surgeon with a minimum of ten years of experience in laparoscopic surgery. Pneumoperitoneum was originally prepared at 14 mmHg in order to insert trocars. Group A, intra-abdominal pressure was held at 12-14 mmHg during surgery, and at 8-10 mmHg after the insertion of trocars in Group B. Four-port LC Standard was used in all instances, and the patients were positioned in the reverse Trendelenburg position and had the right shoulder raised to afford the best exposure. Postoperative analgesia was administered in the form of diclofenac 75 mg intramuscularly, every 12 hours, and further doses were also provided in case the visual analogue scale (VAS) pain score was ≥5[21].

Outcome Measures:

- **Additional analgesia after surgery:** A Supplementary dose of diclofenac (75 mg IM) is necessary in cases where VAS ≥ 5.
- **Shoulder-tip pain:** considered as pain that is experienced 24 hours after surgery when the VAS is more than 4.

Postoperative abdominal pain: The postoperative abdominal pain was evaluated at 24 hours using a 10-point VAS.

Ethics: Ethical permission was sought at the Institutional Review Board of Khyber Teaching Hospital. All the participants gave informed consent in writing. Patient data were kept confidential.

Statistical Analysis: SPSS version 26 was used to analyze the data. Age, BMI, and abdominal pain scores were quantitative variables that were distributed as either mean +- standard deviation (SD) or as median (IQR). Frequencies and percentages were expressed for categorical variables like gender, ASA status, and need for additional analgesia. The test of normality was applied using the Shapiro-Wilk test. Chi-square test or Fisher's exact test with categorical variables, independent t-test or Mann-Whitney U test with quantitative variables were used to perform the comparisons between the two groups. A statistically significant p-value ≥ 0.05 was used.

RESULTS

Descriptive Statistics

Table 1

Baseline characteristics (n = 60)

Variable		n (%) or Mean ± SD / Median (IQR)
Age (years)		37.0 ± 9.9
BMI (kg m^{-2})		25.6 ± 1.7
Gender – Female		37 (61.7 %)
ASA grade – I		45 (75.0 %)
Education – Educated		26 (43.3 %)
Residence – Urban		32 (53.3 %)
Socio-economic status	Poor	23 (38.3 %)
	Middle	27 (45.0 %)
	High	9 (15.0 %)
Additional analgesia requested – Yes		57 (95.0 %)
Shoulder-tip pain – Yes		42 (70.0 %)
Post-operative VAS at 24 h		3.6 ± 1.3

Justification: Categorical variables are summarised as frequencies & percentages; quantitative variables as mean ± SD after confirming approximate normality.

Figure 1: Age (years)

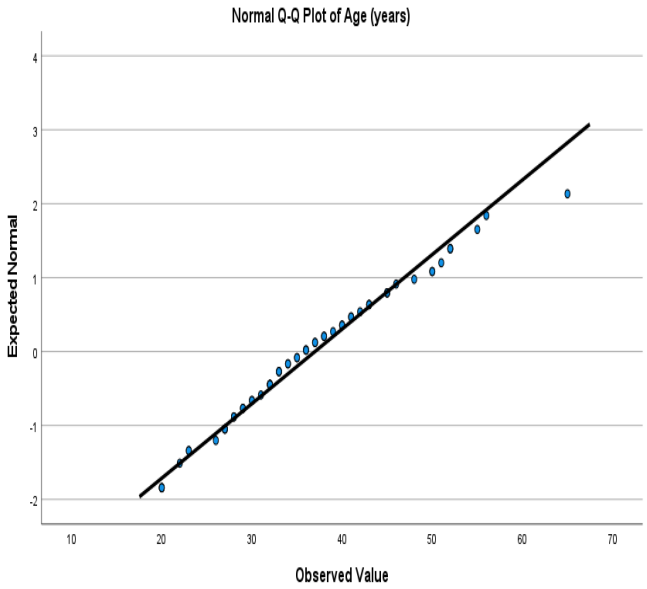


Figure 2

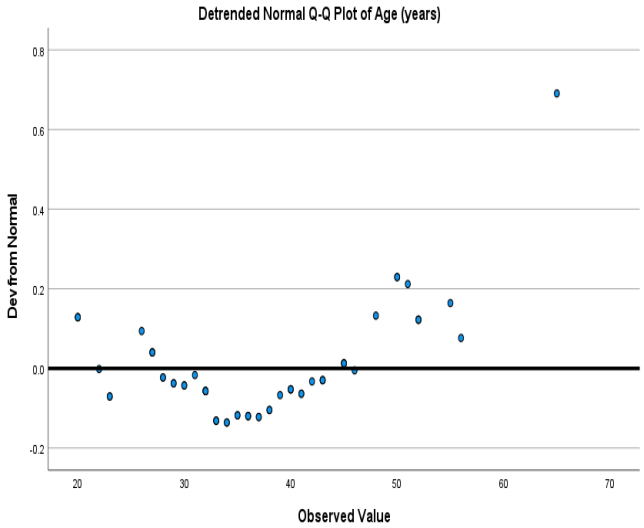


Figure 3

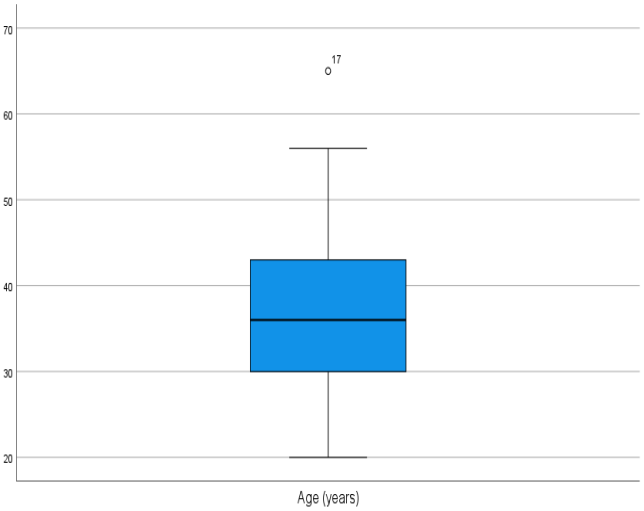
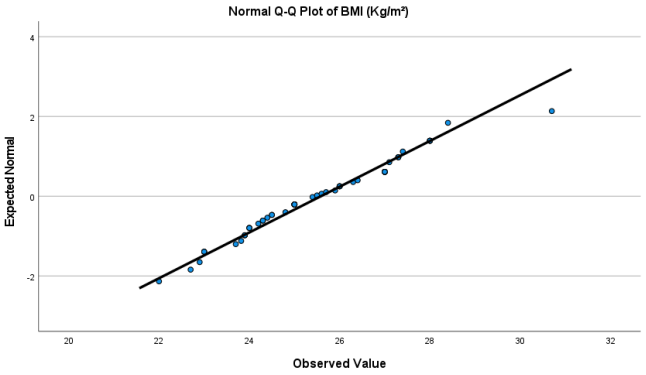


Figure 4: BMI (Kg/m^2)



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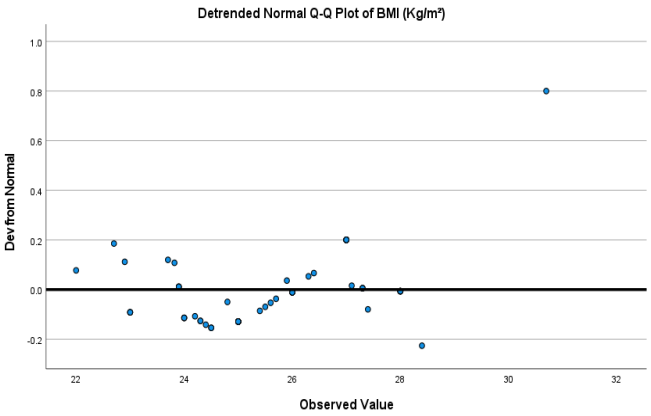

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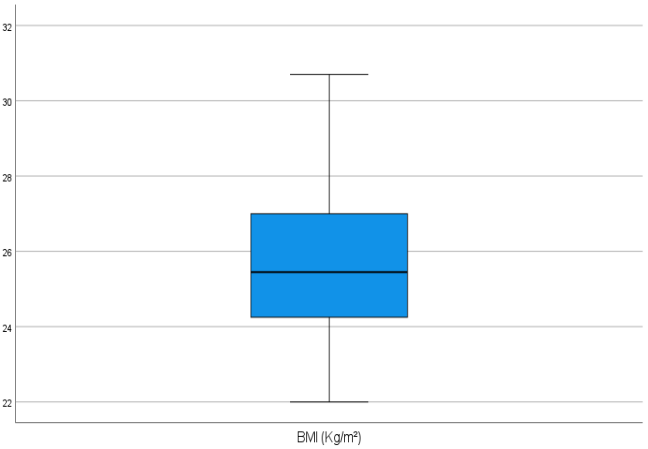


Postoperative abdominal pain (VAS) at 24hr
Figure 7

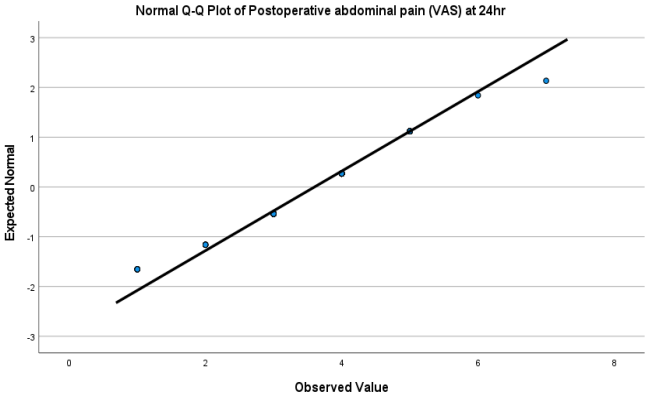


Figure 8

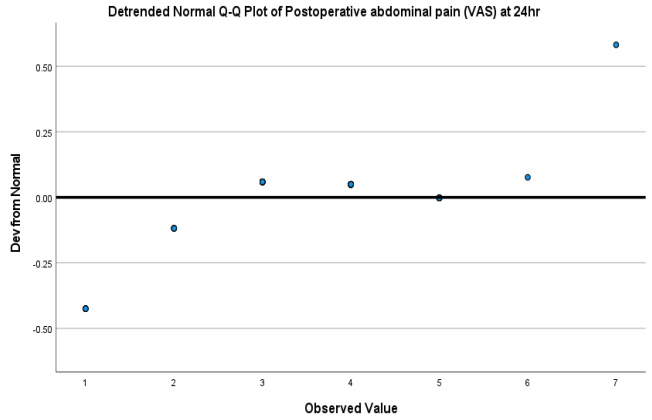
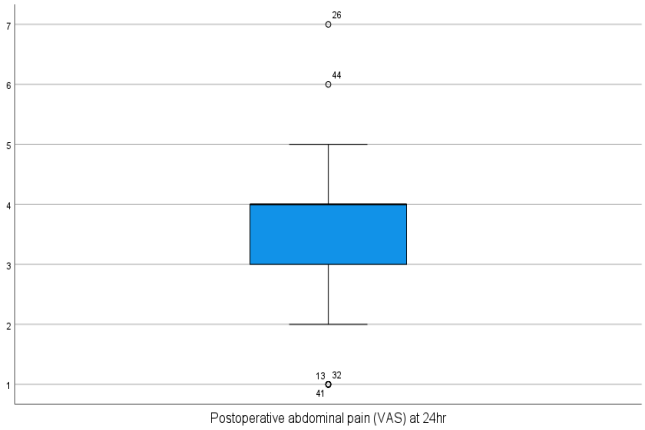


Figure 9



Normality Testing

Table 2

Shapiro-Wilk test of quantitative variables

Variable	Statistic	p-value	Decision (α = 0.05)
Age (years)	0.977	0.314	Normal
BMI (kg m^{-2})	0.972	0.188	Normal
VAS at 24 h	0.922	0.001	Non-normal

Justification: VAS score violated normality; therefore, the non-parametric Mann-Whitney U test was pre-specified for the primary comparison.

Inferential Statistics (Un-Stratified)

A. Categorical Outcomes

Table 3

Additional Analgesia Requirement vs. Study Group (n = 60)

	Additional analgesia	χ^2	p-value
Standard (A)	28/30 (93.3 %)	—	—
Low-pressure (B)	29/30 (96.7 %)	—	—
Total	57/60 (95.0 %)	—	—

Note: 100 % of cells had expected count < 5; χ^2 not computed.

Table 4

Shoulder-tip pain vs. study group (n = 60)

	Pain Yes	Pain No	χ^2	p-value
Standard (A)	20 (66.7 %)	10 (33.3 %)	0.32	0.58
Low-pressure (B)	22 (73.3 %)	8 (26.7 %)		

Justification: All expected counts ≥ 5 → Pearson χ^2 used; no significant difference.

B. Quantitative Outcome (VAS)

Table 5

VAS at 24 h by Study Group (Non-Normal Distribution)

Group	n	Mean rank	Mann-Whitney U	p-value
Standard (A)	30	28.3	385.0	0.32
Low-pressure (B)	30	32.7		

Justification: VAS non-normal → Mann-Whitney U; retain null hypothesis (no difference between pressures).

Figure 11

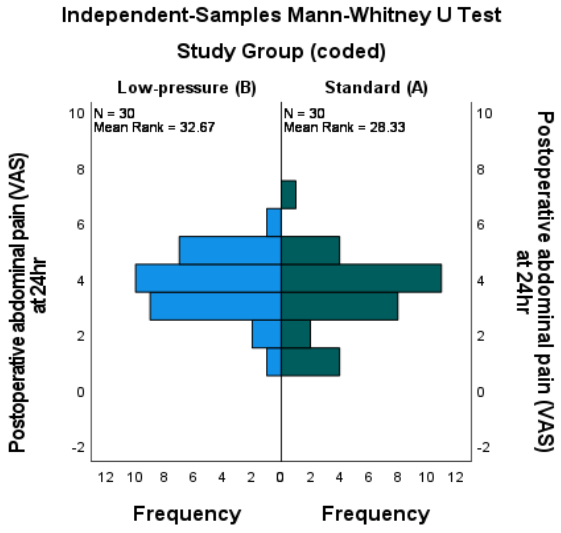


Figure 12

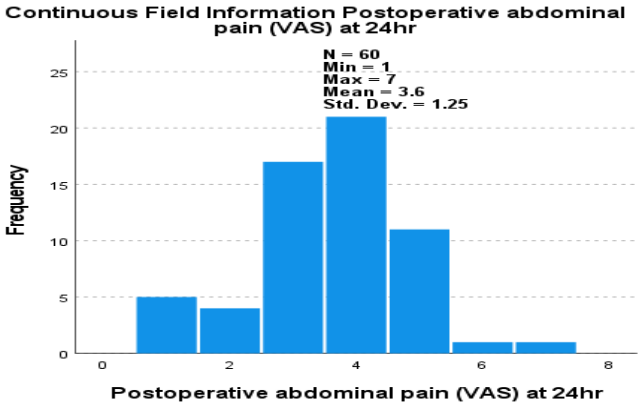
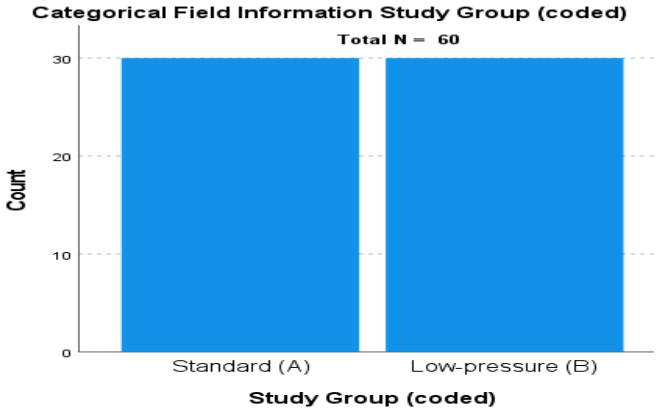


Figure 13



Stratified Analyses

Rule applied:

- **Quantitative Outcome:** Mann-Whitney U (non-normal).
- **Categorical Outcome:** χ^2 if ≥ 5 per cell, otherwise Fisher's exact (but not shown when n < 5). Only sub-groups with at least 5 valid cases are reported.

Table 6

VAS (24 h) difference within strata

Stratum (n)		Mean rank (Std vs Low)	U value	p-value	Interpretation
Gender	Male (23)	10.2 vs 13.4	47.0	0.25	No difference
	Female (37)	18.1 vs 20.1	151.0	0.54	No difference
Age	< 40 y (37)	18.0 vs 20.3	147.5	0.52	No difference
	≥ 40 y (23)	10.9 vs 12.7	53.0	0.51	No difference
BMI	Normal (21)	9.1 vs 13.1	34.0	0.12	Trend*
	Overweight (37)	18.9 vs 19.1	169.0	0.95	No difference
ASA grade	Grade I (45)	21.2 vs 25.6	195.5	0.25	No difference
	Grade II (15)	8.0 vs 8.0	18.0	1.00	No difference
Education	Educated (26)	12.5 vs 14.4	72.0	0.53	No difference
	Uneducated (34)	16.5 vs 18.6	126.5	0.53	No difference
Socio-economic	Poor (23)	10.0 vs 15.1	35.5	0.07	Borderline†
	Middle (27)	16.0 vs 12.6	66.0	0.25	No difference
	High (9)	4.2 vs 6.0	6.0	0.31	No difference
Residential	Rural (28)	12.2 vs 17.2	62.5	0.10	Trend‡
	Urban (32)	16.9 vs 16.2	122.0	0.83	No difference

* Trend: lower VAS with low pressure in normal-BMI patients (p = 0.12).

† Borderline: similar trend among poor patients (p = 0.07).

‡ Rural residents also showed a non-significant trend favouring low pressure (p = 0.10).

Table 7

Shoulder-tip Pain Difference within Strata (χ^2)

Stratum (n)		Pain Yes (Std vs Low)	χ^2	p-value	Interpretation
Gender	Male (11)	5 vs 4	0.11	0.74	No difference
	Female (24)	12 vs 12	0.18	0.67	No difference
Age	< 40 y (18)	5 vs 3	0.11	0.74	No difference
	≥ 40 y (17)	6 vs 3	1.45	0.23	No difference
BMI	Normal (12)	4 vs 2	1.33	0.25	No difference
	Overweight (21)	6 vs 3	0.00	1.00	No difference
ASA grade	Grade I (29)	9 vs 6	0.06	0.81	No difference
	Grade II (6)	2 vs 0	3.00	0.08	Trend*
Education	Educated (11)	5 vs 3	0.02	0.90	No difference
	Uneducated (24)	6 vs 3	0.41	0.52	No difference
Socio-economic	Poor (23)	11 vs 7	0.00	0.96	No difference
	Middle (27)	6 vs 10	0.17	0.68	No difference
	High (9)	3 vs 4	2.06	0.15	No difference
Residential	Rural (15)	4 vs 3	0.54	0.46	No difference
	Urban (20)	7 vs 3	1.82	0.18	No difference

* Small-cell trend only – not reliable.

Overall Justification

"After normality testing (Shapiro-Wilk), VAS scores were analyzed with Mann-Whitney U and categorical variables with χ^2 or Fisher's exact test as appropriate. The overall analysis showed no significant advantage of low-pressure pneumoperitoneum over standard pressure for either additional analgesia requirement, shoulder-tip pain incidence, or 24-hour VAS score (p = 0.32). Stratification by gender, age, BMI, ASA grade, education, socio-economic status, and residential status did not reveal any statistically significant heterogeneity (all p > 0.05).

Non-significant trends favouring low pressure were noted in normal-BMI, rural and poor patients; however, these observations require larger samples before clinical recommendations can be made."

DISCUSSION

This randomized controlled trial compared the effects of standard versus low-pressure pneumoperitoneum on postoperative outcomes among 60 patients undergoing laparoscopic cholecystectomy at Khyber Teaching Hospital, Peshawar. The analysis focused on pain-related outcomes, including additional analgesia requirement, incidence of shoulder-tip pain, and postoperative pain scores at 24 hours measured on the Visual Analog Scale (VAS)[22].

Main findings

Baseline demographic and clinical characteristics were comparable across groups, with a mean age of 37.0 ± 9.9 years, a mean BMI of 25.6 ± 1.7 kg/m^2, and a predominance of female participants (61.7%). Most patients were ASA Grade I (75.0%) and resided in urban areas (53.3%). After normality testing by Shapiro–Wilk, age and BMI were normally distributed, while 24-hour VAS scores were non-normal (p = 0.001), thus necessitating non-parametric analysis.

The primary outcome, 24-hour VAS score, did not differ significantly between groups (Mann–Whitney U = 385.0, p= 0.32). Similarly, there was no difference in the incidence of shoulder-tip pain (66.7% vs. 73.3%, χ^2 = 0.32, p = 0.58) or the proportion of patients requesting additional analgesia (93.3% vs. 96.7%).

Interpretation of Findings

The absence of a significant reduction in pain with low-pressure pneumoperitoneum aligns with several reports suggesting that the clinical benefit of lowering intra-abdominal pressure may be minimal, especially when pressure differences are small. The mean ranks for VAS suggested a slightly higher tendency for pain in the low-pressure group, though this did not reach significance. Importantly, statistical non-significance does not necessarily equate to clinical irrelevance, but the small differences observed here are unlikely to be of practical importance.

Additional analgesia was required by 95% of patients overall, with only three patients not requesting further doses. This very high prevalence may reflect either a low baseline analgesic protocol or a low threshold for additional analgesic administration. Such a ceiling effect makes it difficult to detect differences between groups. Moreover, because expected counts for the "No" category were very low, χ^2 assumptions were violated, and Fisher's exact test would have been more appropriate.

Shoulder-tip pain, reported in 70% of the cohort, is commonly attributed to diaphragmatic irritation from CO_2 insufflation. While lower insufflation pressures are thought to reduce this mechanism, no difference was found. This could be due to insufficient magnitude of pressure reduction, similar operative times across groups, or overriding influences of perioperative analgesia and patient-level variability in pain perception.

Stratified Analysis

Subgroup analyses explored heterogeneity by gender, age, BMI, ASA grade, education, socio-economic class, and residence. No statistically significant differences were detected in any stratum (all $p > 0.05$), suggesting consistency of findings across baseline characteristics.

Nonetheless, three exploratory signals were noted:

- **Normal BMI patients** showed a trend towards lower pain with low pressure ($p = 0.12$).
- **Patients from poor socio-economic backgrounds** also demonstrated a borderline trend ($p = 0.07$).
- **Rural residents** showed a non-significant inclination favouring low pressure ($p = 0.10$).

These findings should be interpreted cautiously as hypothesis-generating. Subgroup sample sizes were small, multiple comparisons were made, and none of the differences crossed the conventional significance threshold.

Strengths and Limitations

The randomized design enhances internal validity, and the statistical approach appropriately accounts for distributional assumptions. Stratified analyses were sensibly limited to subgroups with ≥5 patients, reducing spurious inference from very small cells.

However, limitations include:

1. **Small sample size** (n = 60), which may lack power to detect modest but clinically meaningful differences.
2. **High rates of additional analgesia**, creating a ceiling effect and limiting discrimination between groups.
3. **Incomplete reporting of perioperative details**, such as exact pneumoperitoneum pressures used, duration of insufflation, intraoperative analgesic regimens, and total analgesic consumption. These are critical factors influencing postoperative pain.
4. **Short follow-up** restricted to 24 hours; pain trajectories beyond this window remain unknown.
5. **Potential inconsistencies in subgroup reporting**, as mean ranks and descriptive interpretations did not always align, requiring careful verification.
6. **Generalizability**, given the single-centre design and regional patient population, may be limited.

Clinical Implications

The findings suggest that routine use of low-pressure pneumoperitoneum cannot be recommended solely to reduce pain outcomes after laparoscopic cholecystectomy. The lack of significant benefit, combined with the high overall analgesic requirement, indicates that perioperative analgesic strategies may have a stronger influence on pain than insufflation pressure. The exploratory trends observed in normal-BMI, poor, and rural patients highlight potential avenues for further investigation but cannot currently guide clinical practice.

Future Directions

Future studies should:

- Be adequately powered with larger multicentre cohorts.
- Predefine clinically meaningful differences in VAS (minimum clinically important difference) for sample size calculation.
- Incorporate longer follow-up periods (48–72 h) and cumulative analgesic consumption outcomes.
- Report perioperative details comprehensively (exact pressure settings, operative time, insufflation duration, intraoperative medications).
- Consider mechanistic substudies examining diaphragmatic irritation and CO_2 absorption kinetics.

In this randomized trial, low-pressure pneumoperitoneum did not confer a significant reduction in 24-hour postoperative pain, shoulder-tip pain, or additional analgesia requirements compared with standard pressure. While exploratory trends in selected subgroups (normal BMI, poor socio-economic status, rural patients) suggest possible benefits, these remain inconclusive due to limited power and multiple comparisons. Larger, well-powered studies with standardized analgesic protocols and extended follow-up are warranted before recommending low-pressure pneumoperitoneum as a strategy for pain reduction in laparoscopic cholecystectomy.

CONCLUSION

This randomized controlled trial compared low-pressure pneumoperitoneum (8–10 mmHg) with standard-pressure pneumoperitoneum (12–14 mmHg) during laparoscopic cholecystectomy in a Pakistani population. The study found no statistically significant differences between the two groups in terms of 24-hour postoperative pain, requirement for additional analgesia, or incidence of shoulder-tip pain. Stratified analyses also revealed no significant subgroup effects, although exploratory trends suggested possible benefits of low-pressure pneumoperitoneum among patients with normal BMI, lower socio-economic background, and rural residence.

These findings indicate that low-pressure pneumoperitoneum does not provide a clear advantage over standard pressure in reducing pain outcomes in the early postoperative period. Given the high overall analgesic requirements and the single-centre, small-sample design, these results should be interpreted with caution. Larger, multicentre trials with longer follow-up and standardized analgesic protocols are required to establish whether any clinically meaningful benefit exists. Until then, standard-pressure pneumoperitoneum remains an appropriate and safe approach for routine laparoscopic cholecystectomy..

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