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Title

Author

Abstract
Background: *Gallstones are a common gastrointestinal disorder often requiring cholecystectomy. Laparoscopic cholecystectomy, the gold standard for gallbladder removal, involves pneumoperitoneum (PNP) using carbon dioxide (CO2) for better visibility and access. However, postoperative shoulder pain remains a frequent complication, largely attributed to CO2 insufflation. This study compares the incidence and severity of postoperative shoulder pain between low-pressure pneumoperitoneum (LPP) and standard-pressure pneumoperitoneum (SPP) during laparoscopic cholecystectomy.*
Materials and Methods: *A prospective interventional study was conducted at SMS Hospital, Jaipur, including 80 patients with gallstone disease undergoing elective laparoscopic cholecystectomy. Patients were divided into two groups: LPP (8–10 mm Hg) and SPP (12–14 mm Hg), each comprising 40 patients. Pain was assessed using the Verbal Rating Scale (VRS) at 2, 6, 12, 24, and 48 hours postoperatively. Data were analyzed using the unpaired two-tailed t-test, with a P value < 0.05 considered statistically significant.*
Results: *The incidence of shoulder pain was significantly lower in the LPP group (10%) compared to the SPP group (40%) (P = 0.00). Mean VAS scores at 2, 6,12,24, and 48 hours post-surgery were consistently lower in the LPP group, with significant differences noted at each time point. At 12 hours, the LPP group had a mean VAS score of 0.62 ± 0.34 compared to 2.92 ± 1.4 in the SPP group (P = 0.00). By 48 hours, no LPP patients reported shoulder pain, whereas the SPP group still reported a mean VAS score of 0.62 ± 0.21 (P = 0.00).*
Conclusion: *LPP is associated with significantly lower incidence and severity of postoperative shoulder pain compared to SPP in laparoscopic cholecystectomy. These findings suggest that LPP could be a better option for reducing patient discomfort and improving postoperative outcomes.*
Keywords: *Gallstones, laparoscopic cholecystectomy, low-pressure pneumoperitoneum, standard-pressure pneumoperitoneum, shoulder pain, postoperative pain, pneumoperitoneum.*

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I. Introduction

Gallstones are one of the most common gastrointestinal disorders, consisting of hardened bile that varies in size, shape, and composition. Some individuals with gallstones develop acute or chronic cholecystitis due to biliary obstruction, which may require cholecystectomy. Studies show that gallstones are more prevalent in women, accounting for 84.9% of cases, compared to 15.1% in men. (1)

Patients with acute cholecystitis typically present with symptoms such as colicky pain in the upper right abdomen, sometimes radiating to the shoulder, along with fever and elevated white blood cell counts. Gallbladder removal can be performed either via open cholecystectomy or laparoscopic cholecystectomy. The open technique involves making a single incision below the right rib or along the midline, while the laparoscopic approach uses four small incisions through which trocars are inserted into the peritoneal cavity to remove the gallbladder after the abdomen is inflated with carbon dioxide (CO2). Laparoscopic cholecystectomy is now regarded as the gold standard for treating gallstones. (1)

Laparoscopic surgery offers numerous advantages over open surgery, such as smaller incisions, shorter hospital stays, no need for drainage tubes or gastric tubes, reduced pain medication, fewer complications, and faster recovery, making it a widely preferred method. This procedure requires the expansion of the abdominal cavity for instrument insertion, typically achieved using gases like nitrogen, helium, or CO2, with CO2 being the most commonly used due to its non-flammability, high solubility in the blood, and rapid absorption and exhalation by the respiratory system. (1)

Pneumoperitoneum (PNP) is a crucial part of laparoscopic surgery. Surgeons must be aware of the physiological changes induced by PNP, recognize its clinical effects, and adjust intraoperative procedures to minimize risks. Maintaining controlled intra-abdominal pressure (IAP) is essential for safe surgery, as it lifts the anterior abdominal wall and compresses other abdominal organs and tissues. (2)

The concept of PNP was first introduced by Georg Kelling in 1901 during an examination technique then known as celioscopy, which evolved into laparoscopy. In 1924, Zollikofer is believed to have been the first to use CO2 for creating PNP. (2)

During laparoscopic surgery, PNP is created by insufflating CO2 into the peritoneal cavity. Despite efforts to remove excess CO2 after the procedure, a significant amount often remains as free gas in the cavity. (3) This gas typically accumulates beneath the diaphragm and around the liver and stomach due to its density and gravitational forces, potentially causing upper abdominal and shoulder pain by irritating the phrenic nerve. (3) However, the exact cause of postoperative shoulder pain remains uncertain, and its relationship to the volume of residual gas is not well understood.

Research shows that patients often begin to mobilize within 12 to 24 hours post-surgery, and shoulder pain tends to emerge once they become upright. This suggests that the gas position within the abdominal cavity may shift with body movement, potentially contributing to shoulder pain. (4) Although the precise mechanism of post-laparoscopic shoulder pain is unclear, residual gas in the abdominal cavity is thought to be a key factor. Methods to alleviate this pain include the use of suction drains or gradually increasing CO2 flow rates during pneumoperitoneum creation. (5)

Postoperative pain, particularly shoulder pain, remains one of the most common complications following cholecystectomy. Although laparoscopic surgery results in less pain than open surgery due to smaller incisions and avoidance of intercostal nerve and abdominal muscle disruption, postoperative discomfort is still frequent and can be localized at the surgical site or radiate to the shoulder. (6)

Factors contributing to shoulder pain during laparoscopic surgery include direct peritoneal irritation from CO2 and excessive diaphragmatic stretching due to rapid CO2 insufflation. Despite the high incidence of shoulder pain after laparoscopy, research on how CO2 insufflation rates affect pain is limited. This study aims to investigate the impact of different CO2 insufflation rates at the beginning of laparoscopic cholecystectomy. (6)

Recent advancements in minimally invasive surgery have led to the introduction of single-port laparoscopy, which offers cosmetic benefits by leaving only a single scar at the umbilicus. (7) However, despite its aesthetic advantages, patients undergoing single-port laparoscopy experience similar levels of postoperative shoulder pain as those who undergo conventional laparoscopy. (8) In our study, we aim to compare the effectiveness of low-pressure versus standard-pressure pneumoperitoneum during laparoscopic cholecystectomy in reducing both the frequency and severity of shoulder tip pain.

II. Materials And Methods

The study was conducted in the Department of Surgery at SMS Hospital, Jaipur, after obtaining approval from the institutional ethics committee. It was a hospital-based, prospective interventional study, with the study period extending from the approval of the review board and ethical committee to August 2024 or until the desired number of cases was achieved, whichever occurred earlier. The study population consisted of patients with cholelithiasis admitted to the Department of Surgery at SMS Medical College, Jaipur, who underwent laparoscopic cholecystectomy after providing written informed consent.

The sample size was calculated assuming that 24% of the subjects in the reference population would experience postoperative shoulder tip pain at 24 hours. After applying continuity correction, a sample size of 40 patients in each group (total sample size of 80) was required to achieve 80% power in detecting a difference in proportions of -0.16 between the two groups, at a two-sided p-value of 0.05.

Inclusion criteria for the study involved patients above 18 years of age, those undergoing elective surgery for gallstone disease, patients with a normal common bile duct on pre-operative ultrasound, and those who provided informed consent. Exclusion criteria included conversion to open cholecystectomy, acute inflammation or other complications of gallstone disease, choledocholithiasis, co-existent liver disease, diabetes mellitus, COPD, asthma, significant portal hypertension, uncorrectable coagulopathies, suspected gallbladder carcinoma, cirrhosis, and generalized peritonitis, as well as any intraoperative or postoperative complications like bile duct injury, obstruction, infection, or high fever.

Postoperative shoulder-tip pain was measured using a verbal rating scale (VRS), with scores ranging from 1 (no pain) to 10 (unbearable pain). Pain scores were recorded at 2, 6, 12, 24, and 48 hours postoperatively, and the mean operative time was noted. Data was collected using a pre-tested and pre-designed proforma that included sociodemographic factors like age and gender. Upon hospital admission, a detailed history and clinical examination were recorded, along with presenting complaints. The study population consisted of cases of cholelithiasis undergoing treatment in the upgraded Department of General Surgery at SMS Hospital, Jaipur, with evaluations based on their clinical profiles and management outcomes.

Statistical analysis was performed using an unpaired two-tailed t-test, with significance defined as $P < 0.05$. Follow-up assessments of shoulder-tip pain were conducted at 2, 6, 12, 24, and 48 hours postoperatively, evaluating both the frequency and intensity of pain.

III. Results

Baseline characteristics

Our study included 80 patients, equally divided in to LPP and SPP groups. The mean age was 40.42 years in the LPP and 40.77 years in the SPP Group. Other variables such as Gender, BMI, Mean duration of biliary colic, spillage, Mode of GB extraction, duration of surgery were comparable between the groups, with no significant differences ($p > 0.05$). (Table.1)

Prevalence of Shoulder pain

In the LPP group, 4 patients (10%) reported experiencing shoulder pain, whereas in the SPP group, a higher proportion of 16 patients (40%) reported shoulder pain. This totals to 20 patients (25%) across both groups who reported shoulder pain. The statistical analysis shows a significant difference with a P value of 0.00, indicating that the incidence of shoulder pain was significantly higher in the SPP group compared to the LPP group. (Table.2)

Comparison of Pain between both groups

At 2 hours post-surgery, no patients in the LPP group reported shoulder pain, while the SPP group had a mean VAS score of 0.15 ± 0.1, with a statistically significant P value of 0.02. By 6 hours, the LPP group reported a mean VAS score of 0.47 ± 0.46, compared to 1.15 ± 1.2 in the SPP group, with a P value of 0.04. The difference became more pronounced at 12 hours, where the LPP group had a mean VAS score of 0.62 ± 0.34, significantly lower than the SPP group's 2.92 ± 1.4 (P value = 0.00). This trend continued at 24 hours, with LPP reporting 0.27 ± 0.1 and SPP reporting 1.37 ± 1.1 (P value = 0.00), and at 48 hours, where LPP had no reported shoulder pain compared to SPP's 0.62 ± 0.21 (P value = 0.00). These findings indicate that patients undergoing SPP experience significantly higher levels of shoulder pain post-operatively compared to those undergoing LPP across all measured time points, suggesting a notable difference in post-operative pain management outcomes between the two groups.

IV. Discussion

Laparoscopic cholecystectomy, a preferred minimally invasive procedure for gallbladder removal, is generally associated with less postoperative pain and a quicker recovery compared to open cholecystectomy. However, the nature of postoperative pain varies between the two techniques. In open cholecystectomy, patients frequently experience parietal pain due to the larger incision and greater tissue manipulation. This pain arises from the abdominal wall and is more intense because of the trauma to muscles and skin. Conversely, laparoscopic cholecystectomy is more commonly associated with visceral pain, stemming from the internal organs due to the stretching and handling of structures like the gallbladder and liver. Additionally, around one-third of patients report shoulder tip pain lasting 2-3 days, caused by the irritation of the diaphragm and phrenic nerve due to carbon dioxide insufflation used to create the surgical workspace.

To address this discomfort, modern techniques aim to use lower intra-abdominal pressures during the procedure, minimizing diaphragm irritation while still providing sufficient space for the operation. Although laparoscopic cholecystectomy reduces overall pain and promotes faster recovery, targeted management of its specific pain profile, particularly shoulder tip pain, is important for improving patient outcomes. In our study In the LPP group, 11 male patients (27.5%) and 29 female patients (72.5%) were observed, while the SPP group had 13 male patients (32.5%) and 27 female patients (67.5%). Overall, this results in a total of 24 male patients and 56 female patients across both groups. The P value of 0.20 indicates no statistically significant difference in the sex distribution between the groups, suggesting similarity. **Abdallah et al.**[9] observed a total of 80 participants, with 9 (11%) men and 71 (89%) women. In another study by **Mahajan S et al.** [10] they compared two groups, HPP (n=60) and LPP (n=60), finding 15 males in the HPP group and 45 females, while the LPP group had 20 males and 40 females. This suggests a slight variation in gender distribution between the groups. Additionally, **Ram Chandra et al.**[11] noted that in their study on cholelithiasis involving 100 patients, 42% were male and 58% were female, indicating a higher prevalence of cholelithiasis among females.

In terms of age distribution, in the 18-35 age group, LPP comprised 13 patients (32.5%) and SPP had 15 patients (37.5%), totalling 28 patients (35%). For the 36-50 age group, LPP had 19 patients (47.5%) and SPP had 17 patients (42.5%), resulting in 36 patients (45%). In the over 50 age group, both LPP and SPP included 8 patients each (20%), totalling 16 patients (20%). The P value of 0.13 suggests no statistically significant difference in the age distribution between the LPP and SPP groups, indicating similarity. **Thapa et al.** [12]conducted a study comparing LPCP (n=50) and SPCP (n=50), with the LPCP group having a mean age of 38.20 years (±11.44 SD) and the SPCP group slightly younger at 37.10 years (±11.69 SD). **Ramesh Chandra et al.**[11] observed that the majority of participants were aged 36–50 years, followed by those aged 18–35 years, with mean ages of 39.82 years (±13.80) in the SPP group and 39.86 years (±1.58) in the LPP group. **Abdallah et al.** [9] reported that participants aged 36–50 years underwent LPLC in 65±10.6 minutes on average, while SPLC took 61±9.7 minutes

(P>0.05). In another study by **Mahajan S et al. [10]** participants in the HPP group had a mean age of 40.32 years (±9.89 SD), slightly higher than the LPP group's mean age of 38.32 years (±8.78 SD).

In our study in the LPP group, 4 patients (10%) reported experiencing shoulder pain, whereas in the SPP group, a higher proportion of 16 patients (40%) reported shoulder pain. This totals to 20 patients (25%) across both groups who reported shoulder pain. The statistical analysis shows a significant difference with a P value of 0.00, indicating that the incidence of shoulder pain was significantly higher in the SPP group compared to the LPP group. **Thapa P et al[12]** found that 28% of patients in the LPCP group and 64% in the SPCP group experienced shoulder tip pain (STP), supporting our study's results. **Abdallah HA et al. [9]** reported a significantly higher incidence of shoulder pain after surgery in patients who underwent SPLC (32.5%) compared to LPLC (7.5%) (P<0.05). Similarly, **Chandra R et al.[11]** noted post-operative shoulder pain in 15 patients in the SPP, with 11 patients in the LPP group experiencing discomfort. **Anup Shah et al.[13]** demonstrated that the frequency of shoulder tip pain was significantly lower after low-pressure LC (11.42%) compared to standard-pressure LC (31.42%) (p<0.05), consistent with findings from **Yasir M et al.[14], Barczynski M et al.[15], Sarli L et al.[16], Faisal Bilal Lodhi et al.[17], and Sandhu T et al.[18]**

In 2013 a meta-analysis was done by **Hua J et al.[19]** in 1263 patients to know the feasibility and safety of low-pressure pneumoperitoneum in LC. They found comparable operative time in low- and high-pressure group and LHS was shorter in the low-pressure group (P=0.01). A RCT conducted by Joshipura et al in 2019 showed that though surgeons experienced more difficulty in dissection during low pressure pneumoperitoneum, it was significantly beneficial in terms of postoperative pain, use of analgesics, and hospital stay.

The idea of low-pressure laparoscopic cholecystectomy with carbon dioxide has been developed to lessen these particular disadvantages. Compared to laparoscopic cholecystectomy performed under standard pressure pneumoperitoneum, numerous studies have shown that laparoscopic cholecystectomy performed under low pressure pneumoperitoneum is associated with improved postoperative recovery, improved quality of life following surgery, and lowered surgery pain intensity.[20]

In our research, we monitored post-operative pain at fixed intervals of 2, 6, 12, 24, and 48 hours. At 2 hours post-surgery, none of the patients in the LPP group reported shoulder pain, while the SPP group had a mean VRS score of 0.15 ± 0.1, with a statistically significant P value of 0.02. By 6 hours, the mean VRS score in the LPP group increased to 0.47 ± 0.46, compared to 1.15 ± 1.2 in the SPP group, with a P value of 0.04. This trend continued to 12 hours, where the LPP group reported a mean VRS score of 0.62 ± 0.34, significantly lower than the SPP group's 2.92 ± 1.4 (P value = 0.00). The difference persisted at 24 hours, with LPP reporting 0.27 ± 0.1 and SPP reporting 1.37 ± 1.1 (P value = 0.00), and at 48 hours, where LPP had no reported shoulder pain compared to SPP's 0.62 ± 0.21 (P value = 0.00). These findings indicate that patients undergoing SPP experience significantly higher levels of shoulder pain post-operatively compared to those undergoing LPP across all measured time points, suggesting a notable difference in post-operative pain management outcomes between the two groups.

Our study's results are consistent with **Thapa P et al.[12]** who found significant differences in VAS scores between LPCP and SPCP groups at 8 hours (p=0.006) and 12 hours (p=0.008). Similarly, Goel et al. reported significant STP differences at 8 and 12 hours but not at 4 and 24 hours. Additionally, **Agarwal et al.[21]** in 2021 showed that 14% of patients in the low-pressure group versus 38% in the standard-pressure group experienced STP, with significant differences at 6 hours (p=0.002) and 12 hours (p=0.002). **Ali et al.[22]** also reported lower mean VAS pain scores in the LPCP group compared to the SPCP group (p=0.001). **Chandra R et al.[11] similarly** noted higher VAS pain scores in the SPP group compared to the LPP group, reflecting significant differences in post-operative shoulder pain incidence. Similarly, **Meena J et al.[23]** did a study in 2019 where they found mean VAS score at four hours in low pressure was 6.2 ± 0.82 and 6.8 ± 0.98 in standard pressure (p value<0.001). **Chandra R et al.[11]** observed that post-operative shoulder pain was noted in 15 patients in the standard-pressure pneumoperitoneum (SPP) group compared to 11 patients in the low-pressure pneumoperitoneum (LPP) group, with significantly higher VAS pain scores in the SPP group. This finding aligns with **Sarli et al**.[16] who also reported a lower incidence of shoulder pain in the LPP group. **Abdallah et al.[9]** similarly found that the low-pressure group experienced less postoperative shoulder pain, with statistically significant differences consistent with previous research (references 17–20). In contrast, **Sandhu T et al.[18]** found no statistically significant variation in shoulder pain frequency between low-pressure and standard-pressure groups. **Shaha A et al.[13]** demonstrated that the mean intensity of shoulder tip pain was higher after standard-pressure LC compared to low-pressure LC at 4 hours, 8 hours, and 24 hours post-operatively, suggesting better pain management outcomes with low-pressure pneumoperitoneum. **Agarwal V et al.[24]** the average magnitude of post operative shoulder tip pain at 4, 8 and 24 hours was more after standard pressure laparoscopic cholecystectomy as compared to low pressure laparoscopic cholecystectomy.

V. Conclusion

This study provides compelling evidence that reducing the pressure of pneumoperitoneum to 8 to 10 mm Hg leads to a significant decrease in both the intensity and frequency of postoperative shoulder tip pain. The

findings strongly support the widespread adoption of low-pressure pneumoperitoneum in laparoscopic cholecystectomy procedures. By lowering intra-abdominal pressure, surgeons can effectively mitigate the discomfort experienced by patients post-operatively, thereby enhancing overall patient satisfaction and improving recovery outcomes.

Source of Funding
Nil.

Conflict of Interests
None.

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Table.1 Baseline characteristics

Variables	No. of patients, % LPP (n=40)	No. of patients, % SPP (n=40)	P-value
Age Years (Mean± SD)	40.42 ±12.02	40.77 ±13.0	0.13
Gender			
Male	11 (27.5)	13 (32.5)	0.20

Female	29 (72.5)	27 (67.5)	
BMI kg/m2 (Mean± SD)	37.30 ±6.2	38.47 ±6.67	0.41
History of Biliary Colic (Mean± SD)	3.60± 1.19	3.2 ±1.32	0.18
Bile or stone spillage			
Yes	2(5)	5(12.5)	0.34
No	38 (95)	35(87.5)	
Mode of GB extraction	40	40	0.34
Duration of surgery(min) (Mean± SD)	50 ± 3.34	47.87 ± 3.44	.06

Table. 2 Prevalence of Shoulder pain

Shoulder pain	**No. of patients, % LPP (n=40)**	**No. of patients, % SPP (n=40)**	**Total**
Yes	4(10)	16(40)	20(25)
No	36 (90)	24(60)	60(75)
P value	.00		

Fig.1 Comparison of Pain between both groups