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Original Article

"Shoulder-tip pain after carbon dioxide pneumoperitoneum – a reality or myth:" Role of subdiaphragmatic instillation of bupivacaine after laparoscopic cholecystectomy

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ABSTRACT

Objectives: Shoulder-tip pain associated with carbon dioxide pneumoperitoneum during laparoscopic procedures is regarded as an occurrence of concern, with the reported incidence being 30–50%. Multiple modalities have been employed for its relief, one such being the subdiaphragmatic instillation of bupivacaine. The efficacy of this modality was tested in this study.

Material and Methods: This prospective, double-blinded, randomized, controlled trial was carried out in a tertiary care hospital with a total of 83 patients divided into 2 parallel arms. In the study group, the 20 mL 0.25% bupivacaine was instilled sub-diaphragmatically, (n = 41), while in a control group, 20 mL normal saline was used (n = 42). Two separate Visual Analog Scores for abdominal (VA) and shoulder-tip pain (VS) were measured at various time points.

Results: Demographically, there was no significant difference between the two groups. While abdominal pain was present in all patients, the incidence of shoulder-tip pain was 16.8% across the entire cohort, with an identical distribution between the study and control groups (7 cases each). The severity of pain was mild (VA <3, VS <1). There was no difference in hemodynamic parameters, surgical time, and adverse effects between the two groups. The duration of post-operative analgesia was significantly longer in the bupivacaine group (P < 0.001).

Conclusion: This study demonstrates that the incidence and severity of shoulder-tip pain are significantly lower than that reported in the literature, raising a query whether "the incidence of shoulder-tip pain is overestimated?" Bupivacaine instillation is an easy, safe, and effective modality for reducing shoulder-tip pain, which was found to be significantly milder.

Keywords: Bupivacaine instillation, Gall-bladder fossa, Incidence, Shoulder-tip pain

INTRODUCTION

Laparoscopic cholecystectomy is one of the most widely performed surgeries worldwide. It has evolved into an advanced and more commonly performed procedure as compared to its open surgical counterpart, offering benefits such as lesser post-operative pain, faster recovery, shorter hospital stays, and early mobilization.[1,2]

The various components of pain that a patient feels post-laparoscopic cholecystectomy have been identified undoubtedly as incisional (somatic pain component), deep abdominal (visceral pain

component), and shoulder-tip (referred pain component), with a propensity for visceral component getting transformed into a chronic pain situation.[3]

The nature and intensity of pain may vary in factors such as duration, location and a pronounced subjective variability, thus making it largely unpredictable.[4] Several studies have sought to identify methods for reducing the incidence and severity of post-operative laparoscopic cholecystectomy pain.[2-4]

Besides other causes, such as sub-diaphragmatic fiber stretching, trauma to the abdominal wall nerves at the port site, biliary leakage, and high-pressure insufflation for the creation of pneumoperitoneum,[5-7] the most prominent cause leading to shoulder tip pain is based on the hypothesis of residual gas in the abdomen causing diaphragmatic distention and irritation causing referred pain at the C4 dermatome.[8]

Of all the types of pain mentioned above, the sole incidence of shoulder-tip pain has been reported to be frequently ranging from 30 to 50%.[9,10]

Multiple therapeutic strategies to manage post-operative shoulder-tip pain have been investigated. These include surgery with low-pressure pneumoperitoneum[11] and administration of prophylactic intraperitoneal analgesia.[12] It is likely that a combination of analgesic methods may be more effective in reducing post-operative pain.[13] One such approach is pre-emptive analgesia, involving the administration/instillation of local anesthetic agents (LAAs), such as bupivacaine, over the gallbladder fossa and subdiaphragmatic port site. The instillation and infiltration of LAAs are considered standard, safe, and cost-effective practices to tackle post-operative pain.[14,15]

Various studies have concluded that intraperitoneal administration of LAAs is more effective compared to wound site infiltration, although others have reported conflicting results.[16,17]

In light of this, we aimed to conduct a study to evaluate the effectiveness of bupivacaine instillation in alleviating shoulder-tip pain following laparoscopic cholecystectomy.

MATERIAL AND METHODS

The study was hospital-based and conducted under the department of anesthesiology and intensive care within the operation theater complex at a tertiary care teaching hospital in northern India. The study employed a prospective, double-blinded, parallel-arm, randomized, controlled trial design.

After receiving authorization from the institutional research and ethics committee vide registration No. ECR/1839/Inst/PB/2023 and registering with the clinical trials registry of India vide Ref No. CTRI/2024/08/072243, patient enrolment was initiated. Included participants presented were uncomplicated symptomatic gallstone disease patients (American Society of Anesthesiologists I-II) with ages ranging from 18 to 60 years, of either gender, intended for elective laparoscopic cholecystectomy under balanced general anesthesia.

Exclusion criteria consisted of pregnant patients, those requiring open cholecystectomy, or those with acute cholecystitis, choledocholithiasis, or cholangitis. In addition, patients with a history of known shoulder pain, shoulder trauma, or shoulder surgery, as well as those with opioid addiction, were excluded from the study.

After obtaining confirmed and written informed consent, patients were transported to the designated operating theater by trained personnel on a trolley.

All patients received the same anesthetic technique of pre-oxygenation, pre-medication, propofol induction, vecuronium-mediated muscle relaxation, endotracheal intubation, and isoflurane maintenance, after standard monitoring of electrocardiography, heart rate, pulse oximetry, non-invasive blood pressure was initiated. Minute ventilation was controlled, and adjustments were made to keep end-tidal carbon dioxide (CO_2) between 30 and 40 mmHg.

During the laparoscopy, abdominal insufflation was performed at a rate of 5 L/min, with the intra-abdominal pressure maintained at 12 mmHg using a CO_2 insufflator.

At the end of the procedure, before the removal of the ports, participants were randomly assigned using a computer-generated randomized numbered table into one of the two groups:

(I) Group bupivacaine (BUP) (case) – Patients receiving intraoperative intraperitoneal subdiaphragmatic instillation of 20 cc solution of 0.25% bupivacaine (10 mL of 0.5% bupivacaine (BUP) plain + 10 mL of normal saline (NS) = 20 mL of 0.25% total solution)

(II) Group NS (control) – Patients receiving intraoperative intraperitoneal subdiaphragmatic instillation of 20 cc normal saline solution without bupivacaine.

In all patients, port site infiltration with the injection of bupivacaine 0.5% was administrated at the time of wound closure.

A numerical Visual Analog Scale (VAS) was used to assess pain scores, ranging from 0 to 10.

Two site-specific VAS scores were measured:

(I) Abdomen site pain (VA)

(II) Shoulder tip pain (VS).

VAS for abdominal and shoulder site pain was measured preoperatively during pre-anesthetic check-ups (T0). Following surgery and immediately after shifting to post-anesthesia care unit (PACU) (T1), thereafter VA and VS were measured every 30 min. Hemodynamic changes were

monitored for 2 h (T2 – T5) in the PACU. After the patient was shifted to the ward, pain assessment of VA and VS was recorded every 6 h for the 1st 24 h postoperatively (T6–T9).

As part of the protocol, all patients recording VA and VS >3 post-time-point T2 were administered rescue analgesic, injection of ketorolac 30 mg in 100 mL normal saline over 10–15 min, intravenously. Any patient further complaining of persistent pain for any time point post T5 for a minimal duration of 2 h, labeled as breakthrough pain, provision was made to receive an injection of tramadol 75 mg in 100 mL normal saline + injection ondansetron 4 mg.

Statistical analysis was performed using a 2-tailed t-test and Chi-square analysis; $P < 0.05$ was considered statistically significant. Kaplan–Meier curves and Log Rank test were used for time-to-event analysis.

Microsoft Excel 2019 was used for data organization and standard calculations. Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS) version 13.0 (SPSS, Chicago, IL, USA).

RESULTS

Demographics

Figure 1 depicts the CONSORT diagram, showing the process of enrollment and final sample size accumulation. The study included a total of 83 patients undergoing laparoscopic cholecystectomy who were randomly assigned into two groups: Group BUP ($n = 41$) and Group NS ($n = 42$) as shown in Table 1.

Both groups had a similar mean age (around 44 years), with a predominance of female patients, which aligns with the known higher prevalence of cholelithiasis in women, particularly those in their 40s.[18]

The lack of significant differences between the groups in these demographic factors enhances the validity of the comparison, ensuring that any observed differences in pain outcomes can be attributed to the treatment intervention rather than baseline characteristics.

Hemodynamic parameters

The hemodynamic parameters, as seen in Table 2, remained stable in both groups throughout the study period. No clinically significant differences were observed between the groups at any time point ($P > 0.05$ for all comparisons).

Incidence and nature

As seen in Table 3, the incidence of shoulder-tip pain was found to be 16.8% across the entire cohort, with an identical distribution between the bupivacaine and NS groups (7 cases each). This suggests that the commonly reported incidence of shoulder-tip pain following laparoscopic cholecystectomy may be overestimated in some literature.[9,10] The results also suggest that factors other than the instillation of bupivacaine – such as the technique of surgery, use of CO_2 insufflation, and patient positioning – may play a significant role in the development of shoulder pain.

In contrast, abdominal pain was universally present in all patients but did not differ significantly between groups. This is consistent with the expectation that abdominal discomfort is common postoperatively after laparoscopic procedures, regardless of the type of local anesthetic used.[19]

The lack of statistically significant differences in abdominal pain scores when compared between both the groups may also be due to the relatively low severity of pain experienced by patients, which gradually diminished over time.

The findings support the idea that bupivacaine's effectiveness may be more pronounced for controlling localized, acute pain (such as shoulder-tip pain) rather than more diffuse abdominal pain.

Table 1: Demographic characteristics.

Characteristic	Group BUP (*n*=41)	Group NS (*n*=42)	*P*-value
Age (years, mean±SD)	44.2±11.3	43.8±10.9	0.867
Gender (M/F/O)	13/28/0	12/30/0	0.764
ASA Grade (I/II)	23/18	22/20	0.691

ASA: American Society of Anesthesiologists, SD: Standard deviation, BUP: Bupivacaine, NS: Normal saline, M/F/O: Male/Female/Other

Table 2: Mean hemodynamic parameters.

Parameter	Group BUP (*n*=41)	Group NS (*n*=42)	*P*-value
HR (bpm)	82.3±8.7	84.1±9.2	0.358
SBP (mmHg)	126.8±11.5	128.4±12.3	0.532
DBP (mmHg)	78.5±7.9	79.2±8.4	0.687
SpO_2 (%)	99.2±0.8	99.1±0.9	0.584

HR: Heart rate, SpO_2: Pulse oximetry, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, BUP: Bupivacaine, NS: Normal saline

Table 3: Incidence.

Parameter	Overall (*n*=83) (%)	Group BUP (*n*=41) (%)	Group NS (*n*=42) (%)
Shoulder pain incidence	14 (16.8)	7 (8.4)	7 (8.4)
Abdominal pain incidence	83 (100)	41 (100)	42 (100)

BUP: Bupivacaine, NS: Normal saline

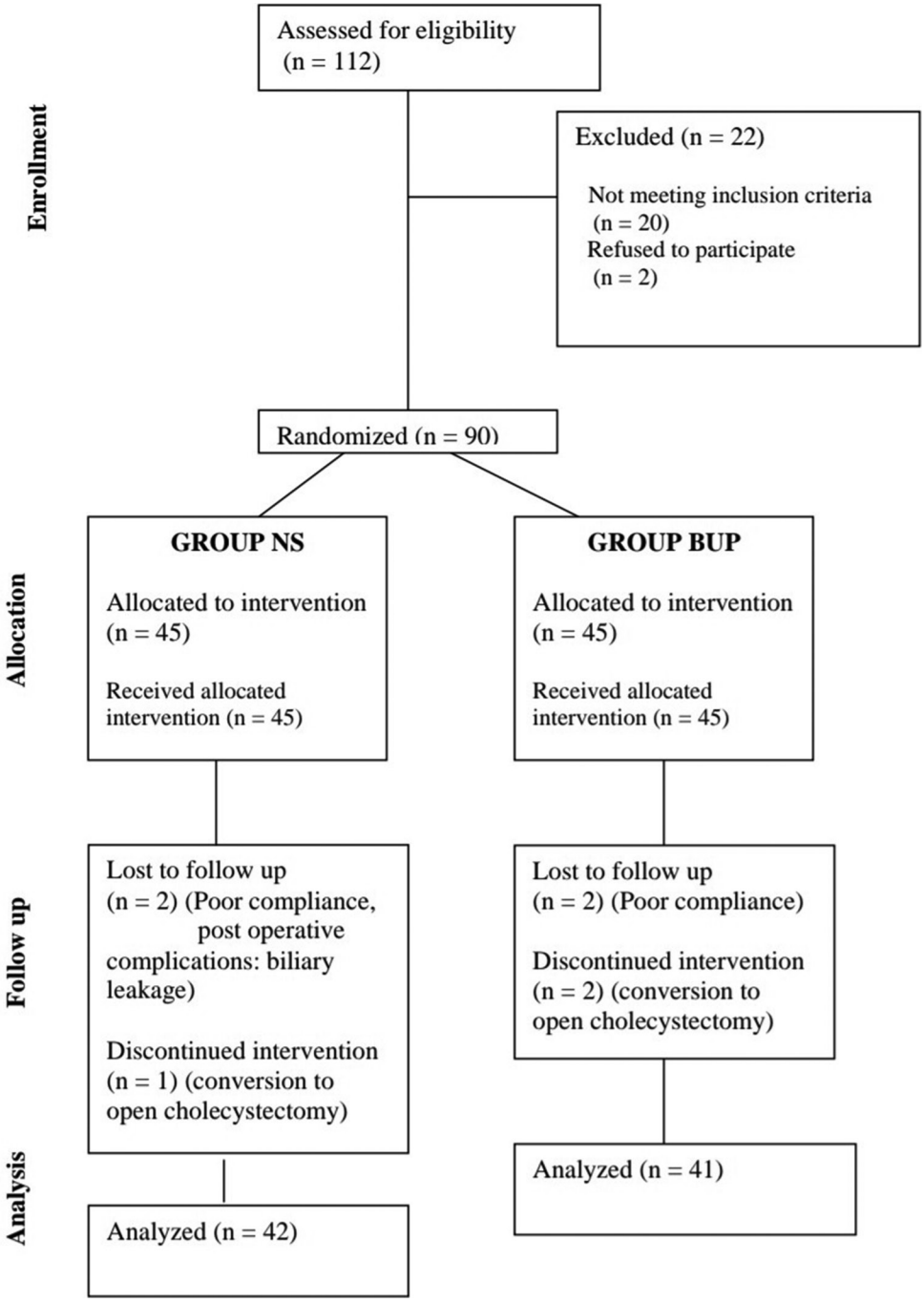

Figure 1: CONSORT diagram showing the distribution of patients according to arms. BUP: Bupivacaine, NS: Normal saline.

Pain score trends

The pain score trends across time (measured by the Numerical VAS) clearly indicated that bupivacaine was more effective than NS in controlling shoulder pain. At all post-operative time points, the shoulder-tip pain scores were significantly lower in the BUP group, suggesting that bupivacaine provided sustained pain relief.

Interestingly, while shoulder-tip pain score trends, as seen in Figure 2, were generally mild in both groups (none with average VAS >0.65), the difference between the case and control was consistently significant ($P < 0.001$). This highlights bupivacaine's role in minimizing shoulder-tip pain post-surgery, a phenomenon often attributed to diaphragmatic irritation due to CO_2 insufflation.[8]

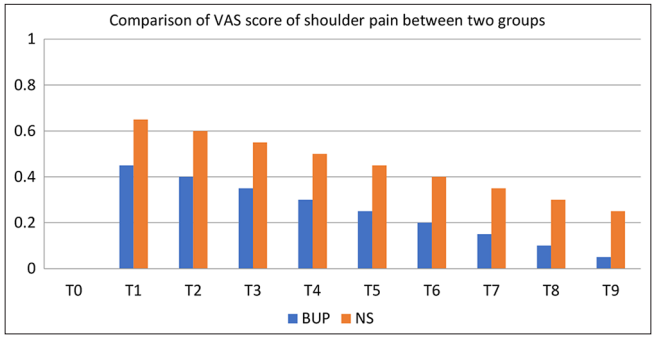

Figure 2: Pain score trends. BUP: Bupivacaine, NS: Normal saline, VAS: Visual analog score.

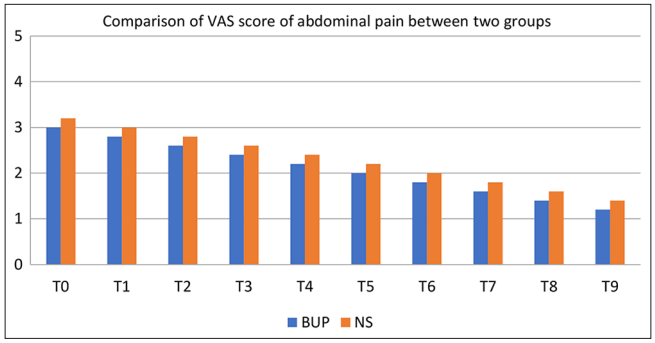

Figure 3: Pain score trends. BUP: Bupivacaine, NS: Normal saline, VAS: Visual analog score.

In contrast, abdominal pain score trends, as seen in Figure 3, showed a similar progression for both groups, with a gradual reduction over time. The lack of significant between-group differences in abdominal pain suggests that factors such as the smaller port-incision site or the effect of CO_2 on the peritoneum, rather than mere analgesic intervention, may be more influential in managing this type of pain.

The charts demonstrate that both abdominal (VA) and shoulder (VS) pain scores were consistently lower in the bupivacaine group compared to the normal saline group across all time points. The difference was more pronounced for shoulder-tip pain scores.

Rescue analgesia and duration of analgesia

An important finding of this study is the reduced need for rescue analgesia in the bupivacaine group. As seen in Table 4, only 22.0% of patients in the bupivacaine group required rescue analgesia, compared to 38.1% in the NS group, with a significant difference ($P = 0.032$). In addition, the time to the first analgesic request was significantly longer in Group BUP (8.2 ± 2.1 h) compared to Group NS (4.7 ± 1.8 h, $P < 0.001$). Out of 14 patients reporting shoulder pain, only 4 patients (2 in each group) required rescue analgesia.

The sustained relief observed in Group BUP may explain the reduced/no need for analgesia for breakthrough pain, making it a more effective strategy for post-operative pain management.

Furthermore, as seen in Table 5, Group BUP demonstrated a significantly longer duration of effective analgesia (12.5 h vs. 7.3 h in Group NS), highlighting bupivacaine's role in extending the post-operative pain relief window. This finding is consistent with previous studies that have shown that local anesthetics like bupivacaine not only provide superior pain control but also can effectively prolong the duration of analgesia following laparoscopic surgeries.[20]

Group BUP demonstrated a significantly longer duration of effective analgesia compared to the group NS ($P < 0.001$). This is evidenced by both a longer time to first analgesic request and a greater overall duration of effective pain relief.

Adverse effects and safety

Regarding adverse effects, both groups reported minor symptoms, such as nausea, vomiting, and dizziness, which were not significantly different between groups. This suggests that the use of bupivacaine was not associated with any notable increase in adverse outcomes, reinforcing its safety profile. Given that no serious adverse events were observed, the study supports the use of bupivacaine as a safe and effective adjunct for post-operative pain management.

DISCUSSION

Laparoscopic cholecystectomy is a minimally invasive surgery, offering less post-operative pain with early mobilization and shorter hospital stays compared to open cholecystectomy.[1,2] However, it is still not evidently pain-exempted, and so perioperative pain management holds considerable clinical importance.[21,22]

Local administration of LAAs may reduce the risk of sedation, gastrointestinal irritation, or injury, as well as complications such as paralysis, respiratory depression, and allergic reactions, in comparison to the systemic use of analgesics.[23]

One such LAA frequently employed is bupivacaine, used for both intrabdominal instillation and infiltration post-laparoscopy.[24,25] This is because of the most leading hypothesis that initiation of early post-surgical shoulder-tip pain, primarily due to the presence of residual gas in the abdomen causing stretching of the diaphragm and irritating the phrenic nerve, leads to referred pain at the C4 dermatome.[8] The application of bupivacaine may help alleviate this discomfort. This study shows that the instillation of subdiaphragmatic space with 20 mL of 0.25% bupivacaine reduces pain in patients undergoing laparoscopic cholecystectomy.

Table 4: Rescue analgesia requirements.

Parameter	Overall (*n*=83)	Group BUP (*n*=41)	Group NS (*n*=42)	*P*-value
Required rescue analgesia: (%)	20 (24.1)	9 (22.0)	11 (26.1)	0.032
VA	16 (19.2)	7 (17.1)	9 (21.4)	
VS	4 (4.8)	2 (4.8)	2 (4.7)	
Time to first rescue (hours): (%)	6.4±2.8	8.2±2.1	4.7±1.8	<0.001
VA		6.4±2.2	2.9±1.5	
VS		1.2±0.75	1.7±1.2	
Multiple	10 (12.0)	3 (7.3)	7 (16.7)	0.048

BUP: Bupivacaine, NS: Normal saline, VA: VAS for abdominal pain, VS: VAS for shoulder-tip pain.

Table 5: Duration of analgesia.

Parameter	Group (*n*=41)	BUP	Group (*n*=42)	NS	*P*-value
Time to first analgesic request (hours)	8.2±2.1		4.7±1.8		<0.001
Duration of effective analgesia (hours)	12.5±3.2		7.3±2.6		<0.001

BUP: Bupivacaine, NS: Normal saline

Over the years, various components of pain that a patient feels after laparoscopic cholecystectomy have been studied and can be identified as visceral, parietal, and shoulder-tip. Visceral pain arises at the site of gall bladder dissection due to inflammation of surrounding tissues and stretching of nerve endings, accounting for most of the discomfort experienced in the early post-operative period.[26] Parietal/somatic pain results from trauma to the abdominal wall nerves at the port site from incisions and trocar insertions during the procedure.[27]

Numerous studies have argued the origin of shoulder pain to be multifactorial, with proposed causes including neurapraxia of the phrenic nerve, subdiaphragmatic fiber stretching, biliary leakage, and high-pressure insufflation for the creation of pneumoperitoneum leading to nerve trauma and damage.[5-7]

Of all the types of pain mentioned, the sole incidence of shoulder-tip pain has been reported to be frequently ranging from 30 to 50%.[28,29] Contrary to this generalization, the incidence of shoulder tip pain as per our study was 16.8% which is practically minimal which is sufficiently self-evident.

In addition, even patients complaining about shoulder pain had it in very mild severity (mean VAS 0.35 ± 0.6) and did not require any specific active interventions, contrary to Park SJ. reporting shoulder pain VAS of >4[28] and Li and Li reporting persistent pain even after 24–48 h,[30] while our study recorded mean VAS of shoulder-tip pain at 0.2 ± 0.2 at 24 h. In addition, the significant shoulder-tip pain reduction in Group BUP during the first few hours postoperatively may be attributed to the localized effects of bupivacaine, which has a terminal half-life of 2–8 h,[31] providing effective analgesia in the immediate post-operative period but tend to fade away over time. This is to say that a more uniform trend of pain reduction was difficult to maintain.

Both abdominal (VA) and shoulder-tip (VS) pain were consistently lower in the study group compared to the control group at all time points. Some degree of abdominal pain was experienced by all patients over 24 h period; however, significant the incidence of VA was, the intensity of the pain was meager and hence required no urge to administer systemic analgesics like opioids, and manageable by few doses of rescue analgesic. The most common location for this pain was the right upper quadrant, followed by pain at the trocar insertion sites. The lack of significant between-group differences in abdominal pain suggests that factors such as the small incision site or the effect of CO_2 on the peritoneum, rather than mere analgesic intervention, may be more influential in managing this type of pain.

Interestingly, while shoulder-tip pain was generally mild in both groups (none with a VAS >0.65), the difference between the study and control was consistently significant ($P < 0.001$), highlighting bupivacaine's role in minimizing shoulder pain post-surgery.

A greater proportion of patients in the control group required rescue analgesia as compared to those in the study group. In actuality, rescue analgesia was predominantly sought for abdominal pain rather than shoulder-tip pain. Bhardwaj *et al.* also found patients from the control group requiring more number of rescue analgesics, mainly at 4–6 h.[32] Aside from intraperitoneal instillation, the analgesic methods employed were identical in both groups. This displays the fact that bupivacaine instillation is more effective than normal saline in alleviating abdominal pain and avoids the irrational need for opioids or non-steroidal anti-inflammatory drugs.

The most common post-operative symptom observed was nausea in 12 patients, leading to vomiting in three patients. Apart from this, tachycardia was observed during immediate to early post-operative hours in eight patients, presumably due to sudden anxiety and experience of pain.

The strengths of this study lie in its prospective and randomized design, which compares study and control groups. Furthermore, all surgeries were performed by the surgeons following a consistent technique and similar set of instruments. However, pain is subjective, with vast intellectual variability, largely influenced by each person's threshold and perception. The VAS simply relies on verbal reports from patients to assess pain. This study suggests that using this approach is a viable means of improving post-operative pain management in laparoscopic surgery.

CONCLUSION

Based on the findings and results from this study, we can safely suggest that the instillation of bupivacaine in the subdiaphragmatic space and gallbladder bed definitely minimizes, if not completely allays, the shoulder-tip and abdominal pain arising in post-operative laparoscopic cholecystectomy procedure and lowers analgesic consumption in the early post-operative period.

Bupivacaine administration through intraperitoneal instillation and infiltration to provide relief from post-operative shoulder-tip and visceral pain has been adopted by various surgeons during the modern era of laparoscopy with successful outcomes. This protocol could be implemented for laparoscopic cholecystectomies to promote faster recovery and shorter hospital stays.

Furthermore, our study reports the incidence of shoulder pain to be merely 16.8%, in contrast to some studies citing 30–60% to even as high as 80%. It may be presumed that these higher figures may be overestimated and exaggerated, suggesting that the projected incidence and severity of shoulder tip pain is more of a "myth than actual reality."

Ethical approval: The research/study was approved by the Institutional Review Board at Aresh University, Adesh Institute of Medical Sciences and Research, number AU/EC/FM/2024/26, dated 18th July 2024.
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Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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