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Research Article

Intraperitoneal and Port-Site Bupivacaine for Postoperative Analgesia After Laparoscopic Cholecystectomy: A Placebo-Controlled Study.

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Abstract:*Background*: Postoperative pain following laparoscopic cholecystectomy remains a significant concern despite the minimally invasive nature of the procedure. Intraperitoneal and port-site administration of local anesthetics has emerged as a promising strategy for improving postoperative analgesia. ***Objective*:** To evaluate the analgesic efficacy of intraperitoneal instillation and port-site infiltration of 0.25% bupivacaine in patients undergoing laparoscopic cholecystectomy. ***Methods*:** This prospective, randomized, placebo-controlled study included 100 patients (ASA I–II) undergoing elective laparoscopic cholecystectomy. Patients were randomized into two groups: Group B received 20 mL of 0.25% bupivacaine intraperitoneally plus 10 mL for port-site infiltration, while Group A received an equivalent volume of normal saline. Postoperative pain was assessed using the Visual Analogue Scale (VAS) at predefined intervals up to 24 hours. Secondary outcomes included total analgesic consumption, time to first rescue analgesia, postoperative nausea and vomiting (PONV), shoulder tip pain, and hemodynamic parameters. ***Results*:** VAS scores were significantly lower in the bupivacaine group during the early postoperative period (0–6 hours). Total analgesic consumption was reduced, and time to first rescue analgesia was significantly prolonged in Group B ($p < 0.05$). Hemodynamic parameters remained comparable between groups. The incidence of PONV and shoulder tip pain was lower in the bupivacaine group, although not statistically significant. ***Conclusion*:** Intraperitoneal instillation and port-site infiltration of 0.25% bupivacaine provide effective early postoperative analgesia, reduce analgesic requirements, and improve patient comfort following laparoscopic cholecystectomy.

Keywords: Laparoscopic cholecystectomy; Postoperative pain; Bupivacaine; Intraperitoneal instillation; Port-site infiltration; Postoperative analgesia.

INTRODUCTION

Laparoscopic cholecystectomy has become a standard technique for gall bladder surgery.[1] Intraperitoneal insufflation of gas like carbon dioxide stretches the abdominal tissues, causes traumatic vessel tear, nerve traction and release of inflammatory mediators causing perioperative pain. Pain may be visceral or somatic, upper abdominal, lower abdominal or in shoulders as well.[2,3] Immediately after surgery, the intensity of pain is more in the first 24 hours and then decreases gradually.[4] The reason for marked variation of pain between individuals remains unclear but could be due to multiple factors including duration of surgery, the degree of invasiveness of the procedure, the experience of surgeon and the amount of peri operative bleeding.[5] It could also be influenced by the size of the trocars, the use of suction to remove any blood and insufflated gas at the end of surgery.[6]

This post operative pain management involves the use of opioids, non- steroidal anti-inflammatory drugs (NSAIDs), paracetamol and local anaesthetics. The main advantage of using local anaesthetics is that they do not have the adverse effects of opioids, which may delay recovery and discharge from hospital. The adverse effects of opioids is obviated by administering local anaesthetics. In addition, NSAIDs have the disadvantage that they may cause gastric irritation in addition to impairing platelet and renal function.[7]

Bupivacaine is one such local anaesthetic which, is long acting and free of side effects like gastritis due to NSAIDs or nausea and vomiting and fear of drug dependence as in opioids. [8] Intraperitoneal instillation of local anaesthetic is an easy, cheap, and non- invasive method which provides good analgesia in the immediate postoperative period after laparoscopic surgery.[1]

Hence we undertook this clinical study: Evaluation of intra peritoneal and port sites administration of bupivacaine for post operative analgesia following laparoscopic cholecystectomy.

MATERIALS AND METHODS

This prospective, randomized, placebo-controlled study was conducted at Bapuji Hospital attached to J.J.M. Medical College, Davangere, between November 2016 and August 2018, after obtaining approval from the Institutional Ethics Committee. Written informed consent

was obtained from all participants or their legally authorized representatives.

STUDY POPULATION

A total of 100 adult patients aged 20–70 years, of either sex, belonging to American Society of Anesthesiologists (ASA) physical status I or II, and scheduled for elective laparoscopic cholecystectomy under general anesthesia were enrolled.

INCLUSION CRITERIA: comprised patients willing to participate and able to provide informed consent.

EXCLUSION CRITERIA: included patient refusal, inability to comprehend the Visual Analogue Scale (VAS), and known allergy to bupivacaine.

RANDOMIZATION AND STUDY GROUPS

Participants were randomly allocated into two equal groups (n=50 each):

- **Group B (Bupivacaine group):** Received 20 mL of 0.25% bupivacaine intraperitoneally and 10 mL for port-site infiltration
- **Group A (Control group):** Received an equivalent volume of 0.9% normal saline

The study drug was administered at the end of surgery by instillation over the gallbladder bed, subdiaphragmatic region, and by infiltration at port sites.

ANAESTHETIC TECHNIQUE

All patients underwent a standardized anesthetic protocol. Premedication included oral alprazolam 0.5 mg and ranitidine 150 mg on the night prior to surgery. In the operating room, patients received intravenous glycopyrrolate (0.02 mg/kg), midazolam (0.03 mg/kg), and pentazocine (0.5 mg/kg). Anesthesia was induced with propofol (2 mg/kg) and succinylcholine (2 mg/kg) to facilitate endotracheal intubation.

Anesthesia was maintained with isoflurane in a mixture of oxygen and nitrous oxide, along with vecuronium bromide (0.05 mg/kg) for muscle relaxation. Standard intraoperative monitoring included electrocardiography, non-invasive blood pressure, pulse oximetry, and end-tidal carbon dioxide.

At the conclusion of surgery, neuromuscular blockade was reversed with neostigmine (0.05 mg/kg) and glycopyrrolate (0.02 mg/kg), and patients were extubated after adequate recovery.

POSTOPERATIVE ASSESSMENT AND OUTCOMES

Postoperative pain was assessed using the Visual Analogue Scale (VAS) at 0, 30 minutes, 1, 2, 4, 8, 12, and 24 hours following surgery.

Rescue analgesia consisted of intravenous diclofenac 75 mg diluted in 100 mL normal saline, administered on patient demand. The **primary outcome** was postoperative pain intensity (VAS score), while **secondary outcomes** included total analgesic consumption over 24 hours, time to first rescue analgesia, incidence of postoperative nausea and vomiting (PONV), shoulder tip pain, and hemodynamic parameters (heart rate, blood pressure, and oxygen saturation).

SAMPLE SIZE CALCULATION

Sample size was calculated using the formula n=4pq/d2n = 4pq/d^2n=4pq/d2, yielding a minimum requirement of 64 patients, which was increased to 100 to improve study power.

STATISTICAL ANALYSIS

Data were entered into Microsoft Excel and analyzed using SPSS version 16. Continuous variables were expressed as mean ± standard deviation and compared using Student's t-test (between groups) and paired t-test (within groups). Categorical variables were expressed as proportions or percentages and analyzed using Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 100 patients were randomized into two groups of 50 each: Group A (normal saline) and Group B (0.25% bupivacaine). All patients completed the study and were analyzed.

BASELINE CHARACTERISTICS

The two groups were comparable in terms of age, gender distribution, and body weight, with no statistically significant differences ($p > 0.05$). This is shown in Table 1.

Table 1: Baseline Demographic Characteristics

Variable	Group A (Normal Saline)	Group B (Bupivacaine)	p-value
Age (years)	43.2 ± SD	46.6 ± SD	NS
Gender (F/M)	28 / 22	31 / 19	NS
Weight (kg)	Comparable	Comparable	NS

PRIMARY OUTCOME: Postoperative Pain (VAS Scores)

Patients in the bupivacaine group demonstrated **significantly lower VAS scores in the early postoperative period (0–6 hours)** compared to the control group. Pain scores between groups became comparable by 24 hours. Line graph comparing postoperative pain scores (VAS) between Group A and Group B at predefined intervals (0, 30 min, 1, 2, 4, 8, 12, and 24 hours). Group B shows significantly lower pain scores during the early postoperative period. This is shown in Figure 1.

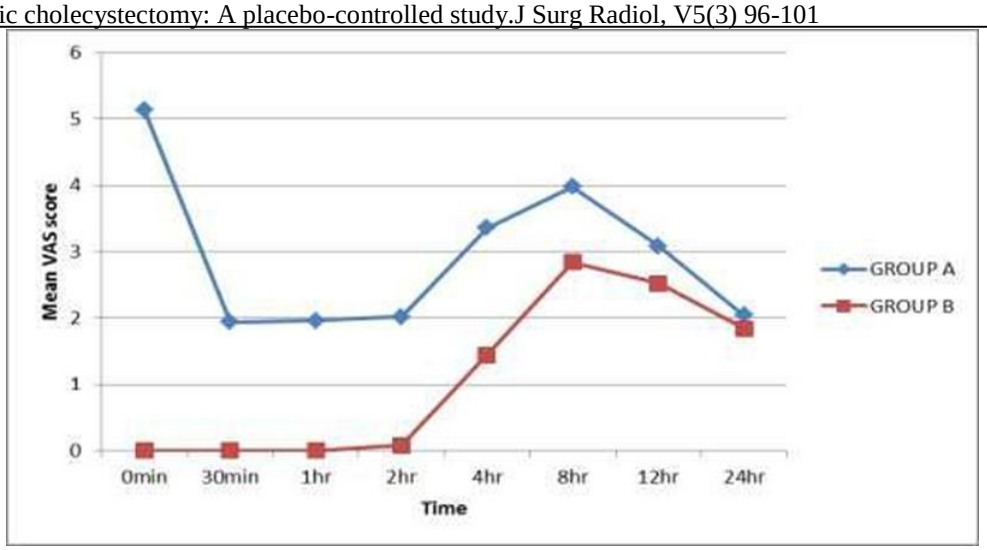

Figure 1: Mean VAS Scores Over 24 Hours

SECONDARY OUTCOMES

1. RESCUE ANALGESIC REQUIREMENT

Total diclofenac consumption over 24 hours was **significantly lower in Group B**. Time to first rescue analgesia was **prolonged** in the bupivacaine group. This is shown in Table 2.

Table 2: Analgesic Requirement

Parameter	Group A	Group B	p-value
Total diclofenac (mg/24h)	Higher	Lower	<0.05
Time to first analgesia (min)	Shorter	Longer	<0.05

2. HEMODYNAMIC PARAMETERS

No statistically significant differences were observed in heart rate, blood pressure, or oxygen saturation between groups at any time point. This is shown in Table 3.

Table 3: Hemodynamic Parameters

Parameter	Group A	Group B	p-value
Heart Rate	Stable	Stable	NS
Systolic BP	Stable	Stable	NS
Diastolic BP	Stable	Stable	NS
SpO_2	Stable	Stable	NS

3. POSTOPERATIVE NAUSEA AND VOMITING

The incidence of PONV was lower in the bupivacaine group, although the difference was not statistically significant. Bar chart comparing the proportion of patients experiencing postoperative nausea and vomiting in both groups.
This is shown in Figure 2.

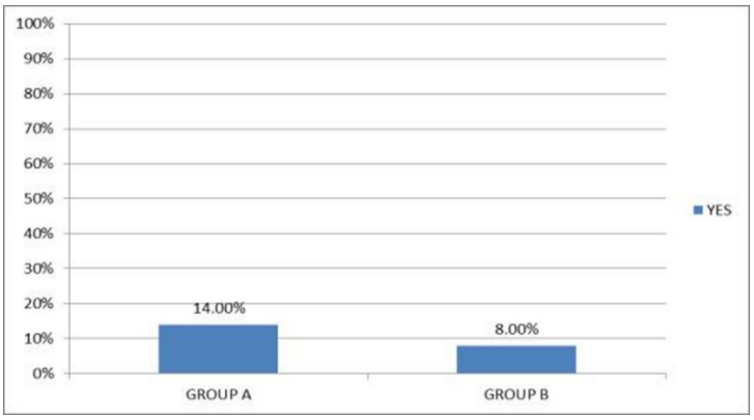

Figure 2: Incidence of PONV

4. SHOULDER TIP PAIN

Shoulder tip pain was less frequent in the bupivacaine group compared to the control group. Bar chart showing reduced incidence of shoulder tip pain in Group B

compared to Group A. This is shown in Figure 3.

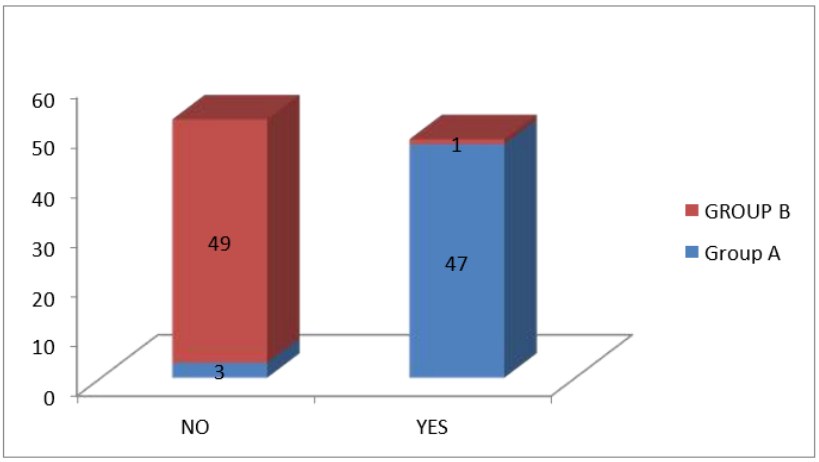

Figure 3: Incidence of Shoulder Tip Pain

DISCUSSION

Laparoscopic cholecystectomy, although minimally invasive, is frequently associated with postoperative pain, particularly in the first 24 hours. This pain is multifactorial, arising from peritoneal stretching due to pneumoperitoneum, tissue trauma, and inflammatory mediator release.[1-4] ki International Association for Study of Pain de□nes pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."[9]

Visceral pain predominates in the early postoperative period, while shoulder tip pain may develop later due to diaphragmatic irritation from residual carbon dioxide.[10]

Effective postoperative pain control is essential not only for patient comfort but also for reducing postoperative morbidity, improving early mobilization, and shortening hospital stay.[11] Traditionally, opioids and NSAIDs have been used for pain relief; however, opioids are associated with adverse effects such as respiratory depression, nausea, vomiting, and delayed recovery.[12] NSAIDs, although effective, may cause gastrointestinal irritation and renal impairment.[13] This has led to increasing interest in multimodal analgesia strategies, including the use of local anesthetics.

In the present study, intraperitoneal instillation combined with port-site infiltration of 0.25% bupivacaine significantly reduced postoperative pain scores, particularly in the early postoperative period (0–6 hours). This finding is consistent with previous studies demonstrating that intraperitoneal local anesthetic administration provides effective early postoperative analgesia following laparoscopic procedures.[1,2,14]

Sulekha et al. reported that intraperitoneal bupivacaine significantly reduces postoperative pain and analgesic requirement following laparoscopic cholecystectomy.[1] Similarly, Deepali Valecha et al. observed improved postoperative pain control with 0.25% bupivacaine compared to normal saline.[2] Maharjan et al. also demonstrated that combined intraperitoneal and periportal administration of bupivacaine effectively reduces postoperative pain.[3] These findings support the results of the present study, where both intraperitoneal and port-site administration contributed to improved analgesia.

The reduction in total analgesic consumption observed in this study further reinforces the efficacy of bupivacaine as part of multimodal analgesia. Similar findings have been reported in previous studies, where intraperitoneal local anesthetic use was associated with decreased opioid or NSAID requirements.[7,15] The prolonged time to first rescue analgesia in the bupivacaine group also indicates sustained analgesic action, likely due to the high protein binding and long duration of action of bupivacaine.

Hemodynamic parameters remained stable in both groups, indicating that intraperitoneal and port-site administration of bupivacaine is a safe technique without significant systemic effects. This observation is in agreement with previous studies, which have reported minimal systemic absorption and negligible hemodynamic impact of intraperitoneal local anesthetics.[16,17]

The incidence of postoperative nausea and vomiting (PONV) was lower in the bupivacaine group, although not statistically significant. This may be attributed to reduced analgesic (particularly opioid) requirement, as opioids are a known risk factor for PONV.[11] Similar trends have been reported in earlier studies evaluating local anesthetic use in laparoscopic surgery.

Shoulder tip pain, a common complaint after laparoscopic cholecystectomy due to phrenic nerve irritation, was also reduced in the bupivacaine group. This supports the hypothesis that intraperitoneal local anesthetic reduces diaphragmatic irritation and peritoneal inflammation.[10] Previous studies have also demonstrated a reduction in shoulder tip pain with intraperitoneal local anesthetic administration.[17]

Despite these positive findings, some studies have reported variable results regarding the efficacy of intraperitoneal local anesthetics. Joris et al. found no significant reduction in postoperative pain with intraperitoneal bupivacaine.[5] Similarly, meta-analyses have shown mixed outcomes, with some trials demonstrating benefit while others show minimal or no effect.[11] These variations may be attributed to differences

in drug concentration, volume, timing, and site of administration, as well as surgical and patient-related factors. The present study supports the growing body of evidence favoring the use of intraperitoneal and port-site local anesthetic administration as an effective component of multimodal analgesia in laparoscopic cholecystectomy. The technique is simple, cost-effective, minimally invasive, and associated with minimal adverse effects.

LIMITATIONS

This study has several limitations. First, it was conducted at a single center with a relatively small sample size, which may limit the generalizability of the findings. Second, although randomization was performed, the absence of clearly defined blinding methods may introduce observer bias. Third, pain assessment using the Visual Analogue Scale (VAS) is subjective and may vary between individuals. Additionally, the study evaluated outcomes only up to 24 hours postoperatively, and long-term pain outcomes were not assessed.

FUTURE DIRECTIONS

Future studies should focus on larger, multicentric randomized controlled trials to validate these findings across diverse populations. Comparative studies evaluating different concentrations, volumes, and timing of bupivacaine administration may help optimize analgesic protocols. Further research should also explore the role of combining intraperitoneal local anesthetics with other multimodal analgesic strategies, including regional blocks and non-opioid pharmacological agents. Additionally, evaluation of long-term outcomes such as chronic pain, patient satisfaction, and early discharge metrics would provide a more comprehensive understanding of the clinical benefits.

CONCLUSION

Intraperitoneal instillation combined with port-site infiltration of 0.25% bupivacaine is a simple, safe, and effective technique for postoperative pain management following laparoscopic cholecystectomy. It significantly reduces early postoperative pain, decreases total analgesic consumption, and prolongs the duration before the first requirement of rescue analgesia without causing adverse hemodynamic effects. Given its ease of administration, cost-effectiveness, and minimal side-effect profile, this technique can be recommended as a routine component of multimodal analgesia in laparoscopic cholecystectomy.

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