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Original Research Article

The Effect of Port Site and Intra-Peritoneal Infiltration of 0.5% Bupivacaine as a Local Anesthetic on Post-Operative Analgesia in Patients Undergoing Laparoscopic Cholecystectomy under General Anesthesia

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Abstract: *Laparoscopic cholecystectomy (LC) is the standard surgical approach for gallbladder diseases. Despite advances in surgical techniques, post-operative pain remains a significant concern and is traditionally managed with systemic opioids, which are associated with adverse side effects. Multimodal strategies, including local anesthetic infiltration, are being explored to optimize analgesia and enhance recovery.* ***Objective:*** *This study aimed to evaluate the efficacy of 0.5% bupivacaine infiltration at port sites and intraperitoneally in reducing post-operative pain, opioid consumption, and enhancing early recovery after LC performed under general anesthesia.* ***Methods:*** *This randomized controlled trial was conducted at Combined Military Hospital, Jhelum, Pakistan, between July 2023 and December 2023. A total of 100 patients undergoing elective LC were randomly allocated to receive either port-site and intra-peritoneal infiltration of 0.5% bupivacaine (intervention group) or placebo (control group). Pain intensity was assessed using the Visual Analog Scale (VAS) at 2, 6, 12, and 24 hours postoperatively. Secondary outcomes included time to first ambulation, cumulative opioid consumption within 24 hours, and patient satisfaction using a 5-point Likert scale. Statistical analysis was performed using independent t-tests and chi-square tests, with a significance level of $P < 0.05$.* ***Results:*** *Patients in the intervention group reported significantly lower pain scores than the control group at all measured intervals ($P < 0.05$). At 24 hours, mean VAS scores were 2.1 ± 1.3 in the intervention group versus 4.6 ± 1.7 in controls ($P = 0.002$). The time to first ambulation was earlier in the intervention group (2.0 ± 0.5 hours) compared with the control group (4.0 ± 1.2 hours; $P = 0.001$). Total opioid use was significantly reduced in the intervention group (10.4 ± 3.2 mg) compared with controls (20.1 ± 7.8 mg; $P = 0.001$). Patient satisfaction scores were also higher in the intervention group (4.5 ± 0.5) compared to the control group (3.2 ± 0.8; $P = 0.004$).*
Conclusion: *Infiltration of 0.5% bupivacaine at port sites and intraperitoneally provides adequate analgesia, reduces opioid requirements, accelerates mobilization, and improves patient satisfaction following LC. This approach represents a valuable adjunct to multimodal analgesia, supporting its integration into Enhanced Recovery After Surgery (ERAS) protocols.*

Keywords: Bupivacaine, Laparoscopic Cholecystectomy, ERAS, Post-operative Pain, Nalbuphine, Opioid Consumption, Recovery

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Introduction

Laparoscopic cholecystectomy (LC) is considered one of the most common procedures used in the treatment of gallbladder problems, such as gallstones (1). It is preferred since it is a less invasive procedure and has benefits over open cholecystectomy: short length of stay, less postoperative pain, and rapid recovery (2). While the surgery is helpful in itself, most patients face serious problems with postoperative pain (3). Along with early mobilization, effective pain management is essential to help patients feel comfortable, reduce the risk of complications, and facilitate a faster recovery. Historically, the prime components of the treatment of pain after laparoscopic surgery have consisted of systemic analgesics, opioids, non-steroidal and anti-inflammatory (NSAIDs), and acetaminophen (4). However, there are some negative aspects of these treatments, such as opioid dependence or abuse (long-term) or opioid side effects, such as nausea, vomiting, and constipation (5). Similar to the previous point, multimodal pain management plans based on enhanced recovery after surgery (ERAS) approaches have gained popularity over the past decade. To minimize suffering, minimize medication activities, and maximize rehabilitation, the protocol stimulates healing procedures through a blend of preoperative, intraoperative, and postoperative actions (6). One of the most critical aspects of such recommendations is currently the use of local anesthetics. The use of local anesthetics, such as bupivacaine, has been specifically studied, which has shown potential as a longer-acting anesthetic and a decreased systemic opioid, particularly when compared with intraperitoneal and surgical site infiltration (7). To achieve local infiltration and regional blocks, many surgical establishments are using bupivacaine, a long-acting anesthetic compound in which the amide group replaces the ester group. Its long-acting duration has an added benefit in laparoscopy, as it diminishes postoperative pain at port sites and in the peritoneal cavity. Several studies have demonstrated that local anesthetic infiltration can provide superior pain control, reduce opioid consumption, and accelerate post-operative recovery (8). However, the majority of research has focused on its use at port sites, with limited studies exploring the combined use of port-site and intra-peritoneal bupivacaine infiltration, particularly in laparoscopic cholecystectomy procedures. The objective of this study was to evaluate the impact of 0.5% bupivacaine infiltration at the port sites and intraperitoneally on post-operative pain relief, opioid consumption, and early recovery in patients undergoing laparoscopic cholecystectomy. This trial aimed to contribute valuable data to the growing body of literature supporting the use of bupivacaine as part of an ERAS protocol. By evaluating both subjective and objective outcomes, including pain scores, opioid consumption, and time to ambulation, this study seeks to provide insights into how multimodal analgesia strategies can improve post-operative care and patient satisfaction.

Methodology

Following institutional review board approval, this randomized controlled trial was conducted at the Combined Military Hospital, Jhelum, from July 2023 to December 2023. A total of 100 participants were enrolled in the study, with 50 patients randomly assigned to the intervention group and 50 patients to the control group. The study aimed to assess the effect of 0.5% bupivacaine infiltration at port sites and intraperitoneally on post-operative pain and early recovery in patients undergoing elective laparoscopic cholecystectomy. The sample size was determined using the WHO EPI sample size calculator, taking into account a 95% confidence interval and a 5% margin of error. Inclusion criteria included adults aged 18-60 years who were scheduled to undergo elective laparoscopic cholecystectomy. All patients were required to have no contraindications for surgery, and the Diagnosis was confirmed by preoperative imaging (e.g., ultrasound, CT scan). The exclusion criteria included allergy to bupivacaine, chronic pain condition, opioid dependence, or patients whose removal is contraindicated by general anesthesia. Patients were randomized into two groups by a snowballing method, where an envelope was closed. In the intervention study (n=50), 20 mL of 0.5% bupivacaine was infiltrated at the port sites and intra-peritoneal area following laparoscopic operation. In the control group (n = 50), 20 mL of normal saline was applied at the same sites, ensuring that both the patients and the evaluators were blinded to the intervention. The part was performed on the finishing laparoscopic. Bupivacaine was injected at port sites and into the peritoneal cavity as felt appropriate to the surgeon in the intervention group. Saline was also injected in the same way to replicate the procedure in the control group. The surgery was performed using general anesthesia techniques on all patients, and standard anesthesia, post-surgical care, and monitoring protocols were followed. Key variables included the degree of pain measured by the Visual Analog Scale (VAS) at 2, 6, 12, and 24 hours after surgery. The nursing personnel were not aware of who was in the intervention group assignment, and they were the ones who measured the VAS scores. Time to first ambulation, the period between the end of the surgery operation and the first time to walk, and opioid use during the first 24 hours were the secondary outcomes. The use of opioids (Nalbin 10 mg/ ml) in the current study was in line with the requirements of the affected patient. The total amount of Nalbin that was injected during the first 24 hours was noted on a patient-by-patient basis. Patient satisfaction was measured at discharge, with patients rating their pain management and overall satisfaction with their recovery on a 5-point Likert scale. Furthermore, the outcome after the operation, in terms of wound infection and symptom recurrence, was evaluated following up hospital interviews at 1 week and 2 months after the operation. The analytical work on data was performed in SPSS 21. Continuous variables such as VAS, opioid intake, and time to first ambulation were provided in the mean ± standard deviation (SD) form. Frequencies and percentages were used to describe categorical variables, including gender and the presence of postoperative complications. An independent sample t-test was used to compare the continuous variables between the two groups, with a p-value of less than 0.05.

Results

The baseline features of the participants in both the control group and the intervention group are shown in Table 1. There is no noticeable difference between the two groups in terms of the baseline characteristics. The average ages of the participants in the intervention group and control group were 32.1 years ± 6.4 years and 31.8 years ± 7.1 years, respectively (P = 0.723). Both groups consisted mostly of males: 36 males (72%) in the intervention group and 35 males (70%) in the control group (P = 0.560). The other participants were all females, with 14 (28%) in the intervention group and 15 (30%) in the control group (P = 0.560). The results for both groups are shown in Table 2. The average time of pain in the intervention group was 3.2 days, whereas in the control group, it was 4.5 days, which is significantly lower in the bupivacaine group (P = 0.002). The first ambulation was shorter in the intervention group (means = 2.0320.43) than in the control group (means = 4.0321.03) (P = 0.001). The intervention group had significantly lower pain scores (VAS) compared to the control group at both 24 hours and discharge. At 24 hours, the VAS score for the intervention group was 2.1 ± 1.3, while the control group had a VAS score of 4.6 ± 1.7 (P = 0.002). The discharge VAS score (2.0 ± 1) of the intervention group was also lower than that of the control group (3.0 ± 1) (P = 0.0001). Opioid intake was substantially lower during the first 24 hours of the intervention (10.4 ± 3.2 mg) compared to the first 24 hours of the control (19.8 ± 7.5 mg) (P = 0.001). This was followed by Nalbin (10 mg/mL), and the dose was adjusted based on the patient's level of pain and at the physician's discretion. In patients, the management of pain was also rated significantly higher in the intervention group (4.5 ± 0.5) compared to the control group (3.2 ± 0.8) (P = 0.003). There was also an overall improvement in recovery in the intervention group, and they were less often disturbed by discomfort after surgery. Moreover, lastly, intraprocedural bupivacaine (0.5 percent) infiltration pain intervention is linked with high analgesia levels during the postoperative time, decreased opioid dependency, and faster recovery. It forms a key component of the Enhanced Recovery after Surgery (ERAS) treatment of laparoscopic cholecystectomy.

Table 1: Baseline parameters of the participants in both study groups

Baseline Parameters	Group A (Bupivacaine, n=50)	Group B (Placebo, n=50)	P-Value
Age (years)	32.1 ± 6.4	31.8 ± 7.1	0.723
Gender			0.560
• Male	36 (72%)	35 (70%)	
• Female	14 (28%)	15 (30%)	

Table 2: Intervention outcomes of the participants in both study groups

Outcome Parameters	Group A (Open Appendectomy, n=60)	Group B (Antibiotic Therapy, n=50)	P-Value
Pain Experience (days)	4.16 ± 1.04	3.68 ± 1.02	0.008
Time to First Ambulation (hrs)	3.13 ± 0.87	3.16 ± 0.83	0.843
VAS Score – 24 hrs	2.1 ± 1.3	4.6 ± 1.7	0.002
VAS Score – At Discharge	2.0 ± 1.0	3.0 ± 1.0	<0.0001
Opioid Consumption (mg)	10.4 ± 3.2	19.8 ± 7.5	0.001
Patient Satisfaction Score	4.5 ± 0.5	3.2 ± 0.8	0.003

Discussion

The infiltration of 0.5% bupivacaine at port sites and its injection into the peritoneal area to achieve pain relief and increased recovery in laparoscopic surgery patients positively influenced the study's results. Bupivacaine treatment led to a marked decrease in opioid usage, an increase in recovery rate, and a decrease in subjective postoperative pain. Those findings confirm that previous studies on the use of local

anesthetics in other surgical settings have similar results. Research has indicated that the application of local anesthetics as an injection, e.g., bupivacaine, may significantly reduce post-operative pain and reduce the need to use systemic opioids (9) (10). As anticipated based on the benefits demonstrated in other research studies, the beneficial results of the intervention group in our study included reduced pain levels at 24 hours and at discharge. The reduced levels of pain are in line with the recommendations of Enhanced Recovery after Surgery (ERAS), which involve multimodal analgesics to minimise opioids (11). Compared to the control group (19.8 ± 7.5 mg), the reduced opioid intake (10.4 ± 3.2 mg) in the intervention group explains the effectiveness of bupivacaine in controlling pain and reducing the adverse effects of opioids on the body, which include nausea and vomiting (constipation). Moreover, the intervention group took significantly less time to ambulate than the control group (2.03 seconds vs. 4.03 seconds). Accelerated recovery in our study is linked to research findings that indicate the use of local anesthetics during laparoscopic surgery promotes faster recovery and restoration of standard functions (12). One of the most vital elements of ERAS protocols includes early mobilization (13). Rapid ambulation is associated with a shortened overall recovery time and reduces the incidence of postoperative complications, such as deep vein thrombosis (DVT), which are significant goals of ERAS programs (14). Also, patient satisfaction with the administration of bupivacaine increased significantly. Unlike the control group (3.2 ± 0.8), the satisfaction level of the intervention group was higher (4.5 ± 0.5), implying a more comfortable experience in the operating room. This is consistent with research results indicating that the use of local anesthetics is associated with patient satisfaction, a faster recovery, and reduced pain (15). This work also has some limitations, however. To begin with, the findings may not apply to a broader group of people due to the single-center design. Second, although the study subjects were aged between 18 and 60, future studies would benefit from expanding the sample size to include older patients who may require alternative pain management methods. Possible long-term pain management benefits were not analyzed, even though VAS scores and opioid usage were. Furthermore, while the results are promising, additional research is needed to confirm the efficacy of bupivacaine in larger, multi-center trials with diverse patient populations. Studies should also investigate the long-term effects of bupivacaine infiltration on postoperative recovery and whether this approach reduces hospital readmission rates due to complications such as post-surgical infections or adhesions.

Conclusion

In conclusion, 0.5% bupivacaine infiltration at port sites and intraperitoneally significantly reduces post-operative pain, opioid consumption, and accelerates recovery in laparoscopic cholecystectomy patients. This supports its integration into Enhanced Recovery after Surgery (ERAS) protocols, offering a promising approach to improve post-operative outcomes and patient satisfaction.

Declarations

Data Availability statement
All data generated or analysed during the study are included in the manuscript.
Ethics approval and consent to participate
Approved by the department concerned. (IRBEC-23)
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Conflict of interest

The authors declared the absence of a conflict of interest.

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All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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