https://doi.org/10.48047/AFJBS.6.11.2024. .447-457

African Journal of Biological Sciences

Effect of Port-Site Local Anesthetic Application on Immediate Postoperative Pain Management in Laparoscopic Cholecystectomy: A Prospective, Randomized Controlled study

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Article History
Volume 6, Issue 11, 2024
Received: 02 Jun 2024
Accepted: 15 Jun 2024
doi: ***10.48047/AFJBS.6.11.2024. .447-457***

Abstract

Background: Parietal pain is often associated with the port site entry used during laparoscopic cholecystectomy. **Objectives:** To determine the effects of bupivacaine infiltration to the port sites after laparoscopic cholecystectomy on postoperative pain intensity (assessed using visual analogue scale) and need for rescue analgesia. Materials and Methods: This was a hospital based, prospective, triple blinded, randomized controlled trial conducted in the Department of General Surgery, Chettinad Academy of Research and Education, Chennai, India between January, and April 2024 among patients undergoing elective laparoscopic cholecystectomy. **Results:** A total of 60 patients were included – 30 in Group A receiving 10ml solution of 0.25% bupivacaine through the port site (local infiltration) at the end of the surgery before sound closure, using 2.5ml at each port site, and 30 in Group B, the control group not receiving local infiltration (or intra-incisional; port site) of bupivacaine. The baseline characteristics of the two study groups (including age, gender, body mass index (BMI), and duration of surgery) were comparable. Comparing the need for rescue analgesia, 13.3% patients in Group A and 46.7% patients in Group B required rescue analgesia – the difference in need for rescue analgesia between was found to be statistically significant ($p<0.05$). The mean (SD) duration of hospital stay in Group A was 1.6 days (0.3) and that in Group B was 2.3 days (0.5) – the difference in duration of hospital stay was found to be statistically significant ($p<0.05$). The mean (SD) visual analogue scale scores were significantly ($p<0.05$) lower in Group A in comparison with Group B at 1 hour (8.8 (0.7) vs 9.6 (0.9)), 2 hours (6.4 (0.4) vs 6.9 (0.5)), 4 hours (4.9 (0.7) vs 5.4 (0.3)), 6 hours (3.1 (0.6) vs 3.4 (0.4)), and at 8 hours (2.3 (0.5) vs 3.3 (0.8)). **Conclusion:** Implementing bupivacaine infiltration at port sites can be a simple, effective, and low-cost strategy to enhance postoperative pain management.

Keywords: Local anesthesia, Postoperative pain management, Laparoscopic cholecystectomy, Bupivacaine

Introduction

Laparoscopic cholecystectomy is a highly effective procedure for treating benign gallbladder diseases and has established itself as the gold standard for managing symptomatic gallstones.(1) This minimally invasive technique offers several advantages over open cholecystectomy, including reduced postoperative pain, quicker recovery times, superior cosmetic results, lower morbidity rates, and greater patient satisfaction.(2) However, it is not entirely free of pain. Despite its minimally invasive nature, many patients experience varying degrees of pain during the early postoperative period. This pain manifests primarily in two forms: visceral pain and parietal pain, both of which can be exacerbated by activities such as coughing and deep breathing, thus hindering early patient mobilization.(3)

Parietal pain, in particular, is often associated with the port site entry used during laparoscopic cholecystectomy, presenting a persistent clinical challenge to minimize.(4) The intensity of postoperative pain typically peaks within six hours following the surgery. This pain is a significant factor in early postoperative complications and directly affects the quality of life of surgical patients.(5) To manage postoperative pain following laparoscopic cholecystectomy, various pain relief methods are employed, including systemic opioids, intravenous or intramuscular nonsteroidal anti-inflammatory drugs (NSAIDs), intraperitoneal local anesthesia, epidural or intrathecal opioids, local anesthetic infiltration at the surgical site, intraperitoneal saline, adequate removal of insufflation gas, as well as the use of heated and low-pressure gas.(6) Each of these methods has specific benefits and limitations. Bupivacaine, known for its long half-life of 2.5 to 3.5 hours, is commonly used as a local anesthetic due to its ability to reduce pain for an average duration of six hours. It boasts a wide safety margin, allowing it to be safely administered up to an upper limit of 2.5 mg/kg body weight.(7)

Against this background, the objective of the present study was to determine the effects of bupivacaine infiltration to the port sites after laparoscopic cholecystectomy on postoperative pain intensity (assessed using visual analogue scale) and need for rescue analgesia.

Materials and Methods

This was a hospital based, prospective, triple blinded, randomized controlled trial conducted in the Department of General Surgery, Chettinad Academy of Research and Education, a tertiary healthcare facility in Chennai, India between January, and April 2024. The study was approved by the Institutional Human Ethics Committee (IHEC). The Participant Information Sheet (PIS) was made available in the local language for participants and their attendants. The contents were read aloud to them in their native language until they were satisfied with

the information. Participants were then enrolled in the study after providing written informed consent. All patients presenting to the outpatient department and/or inpatient wards of the Department of General Surgery, between 18 and 65 years of age, of both gender, and undergoing elective laparoscopic cholecystectomy were enrolled in the present study However, patients allergic to local anesthetics, patients undergoing surgery for acute cholecystitis, and procedures with intraoperative complications requiring conversion to an open procedure, choledocholithiasis, previous upper abdominal surgery, chronic medical diseases, and patients on chronic opioid treatment were excluded from the study. Also, patients not willing to provide informed written consent were excluded from the present study.

The present study included a total of 60 patients based on the results shown by Baskent et al.(8) – 30 patients in Group A receiving 10ml solution of 0.25% bupivacaine through the port site (local infiltration) at the end of the surgery before sound closure, using 2.5ml at each port site, and 30 patients in Group B, the control group not receiving local infiltration (or intra-incisional; port site) of bupivacaine. We used probability sampling – simple random sampling to enroll study participants. However, to allot patients randomly into groups A and B, simple randomization was done – computer generated random numbers (with the help of an independent statistician, not aware of the research hypothesis) were used. The patients were assessed for pain using visual analogue scale (VAS) scores – on a scale of 0 to 10 – at 1, 2, 4, 6 and 8 hours after the surgery (postoperatively). On patients request/perception of pain, analgesics were provided (considered rescue analgesia) – analgesic consumption along with time of provision was noted. We used a predesigned questionnaire to document the sociodemographic characteristics (age (in years), gender), anthropometry (weight in kilograms and height in meters), American Society of Anesthesiologists (ASA) physical status classification system,(9) total duration of surgery, number of NSAIDS/Tramadol administered in the first 24 hours, duration of hospital stay (in days), and visual analogue scale (VAS) scores.(10)

The data was manually inputted into Microsoft Excel and analyzed with SPSS v23. Categorical variables were summarized using frequencies and percentages, while continuous variables were summarized using the mean (standard deviation) and/or median (interquartile range), depending on data normality, which was tested using the Kolmogorov–Smirnov test and the Shapiro–Wilk test. Statistical significance was assessed using the Chi-square test or Fisher exact test for categorical variables, and the independent t-test or Mann-Whitney U test for continuous variables. A p-value of less than 0.05 was considered statistically significant.

Results

The present study included a total of 60 patients undergoing laparoscopic cholecystectomy – 30 patients in Group A receiving 10ml solution of 0.25% bupivacaine through the port site (local infiltration) at the end of the surgery before sound closure, using 2.5ml at each port site, and 30 patients in Group B, the control group not receiving local infiltration (or intra-incisional; port site) of bupivacaine.

Baseline characteristics of study groups: The baseline characteristics of the study groups showed that the mean (SD) age of patients in Group A was 48.9 years (4.5) and that in Group B was 48.2 years (4.1). The proportion of patients more than 50 years of age in Group A was 46.7% and that in Group B was 50.0% Importantly, the study groups did not vary significantly by age of the patients ($p>0.05$). Majority (81.7%) of the patients enrolled were females – 80.0% in Group A and 83.3% in Group B – the study groups did not vary significantly by gender ($p>0.05$). The mean (SD) body mass index of patients in group A was 25.7 kg/m2 (4.7) and that in Group B was 26.7 kg/m2 (5.1). The proportion of overweight/obese patients in Group A was 56.7% and that in Group B was 63.3%. Also, 3.3% patients in Group A and 6.7% patients in Group B were underweight. However, it was found that the study groups did not vary significantly by body mass index ($p>0.05$). The mean (SD) duration of surgery among patients in Group A was 49.2 minutes (3.4) and that among patients in Group B was 48.9 minutes (3.7) – the study groups did not vary significantly by duration of surgery ($p>0.05$).

Comparison of study groups by outcomes of interest: The results showed that overall, a total of 92 doses of NSAIDs were administered in the first 24 hours – 30 doses among patients in Group A, and 62 doses among patients in Group B. Similarly, the overall total number of Tramadol doses administered in the present study in the first 24 hours was 16 – 4 among patients in Group A and 12 among patients in Group B. Comparing the need for rescue analgesia, it was found that 13.3% patients in Group A required rescue analgesia and 46.7% patients in Group B required rescue analgesia – the difference in need for rescue analgesia between the study groups was found to be statistically significant ($p<0.05$).

The mean (SD) duration of hospital stay among patients in Group A was 1.6 days (0.3) and that among patients in Group B was 2.3 days (0.5) – the difference in duration of hospital stay observed between the study groups was found to be statistically significant ($p<0.05$).

The mean (SD) visual analogue scale scores were significantly ($p<0.05$) lower in Group A in comparison with Group B at 1 hour (8.8 (0.7) vs 9.6 (0.9)), 2 hours (6.4 (0.4) vs 6.9 (0.5)), 4 hours (4.9 (0.7) vs 5.4 (0.3)), 6 hours (3.1 (0.6) vs 3.4 (0.4)), and at 8 hours (2.3 (0.5) vs 3.3 (0.8)).

Discussion

This study aimed to evaluate the effect of bupivacaine infiltration at the port sites on postoperative pain intensity and the need for rescue analgesia in patients undergoing laparoscopic cholecystectomy. The results indicated that the baseline characteristics of the two study groups were comparable, ensuring that any differences observed in postoperative outcomes could be attributed to the intervention rather than confounding variables. The baseline characteristics, including age, gender, body mass index (BMI), and duration of surgery, did not show significant differences between the two groups, which is crucial for the internal validity of the study. The mean age of patients in both groups was similar, with a mean (SD) age of 48.9 years (4.5) in Group A and 48.2 years (4.1) in Group B. The gender distribution also did not differ significantly, with a high proportion of female patients in both groups (80.0% in Group A and 83.3% in Group B). The BMI of the patients was also comparable, with Group A having a mean (SD) BMI of 25.7 kg/m² (4.7) and Group B having a mean (SD) BMI of 26.7 kg/m² (5.1). The proportion of overweight/obese patients was slightly higher in Group B, but the difference was not statistically significant. The duration of surgery was almost identical between the groups, further supporting the homogeneity of the study population.

The administration of analgesics in the first 24 hours post-surgery was markedly different between the groups. Group A, which received bupivacaine infiltration, required significantly fewer doses of both NSAIDs and Tramadol compared to Group B. Specifically, Group A had 30 doses of NSAIDs and 4 doses of Tramadol, while Group B had 62 doses of NSAIDs and 12 doses of Tramadol. This reduction in analgesic requirement in Group A highlights the efficacy of bupivacaine in providing sufficient local pain relief.(11) The need for rescue analgesia was significantly lower in Group A, with only 13.3% of patients requiring additional pain relief compared to 46.7% in Group B ($p<0.05$). This finding aligns with prior research, such as the study by Lee et al. (2001),(12) which demonstrated the effectiveness of bupivacaine in reducing the need for postoperative analgesics in laparoscopic cholecystectomy patients.(13)

The Visual Analogue Scale (VAS) scores, which measure pain intensity, were significantly lower in Group A at all postoperative time points (1, 2, 4, 6, and 8 hours) compared to Group B. Specifically, the mean (SD) VAS scores at 1 hour were 8.8 (0.7) in Group A versus 9.6 (0.9) in Group B. At 8 hours, the scores were 2.3 (0.5) in Group A versus 3.3 (0.8) in Group B. These results indicate that bupivacaine infiltration provides a substantial and sustained reduction in postoperative pain. This outcome supports the findings of El-labban et al.(14) (2011), who reported that patients receiving bupivacaine infiltration experienced significantly lower pain scores postoperatively compared to those who did not receive the infiltration. The consistent

pain relief observed in Group A underscores the potential of bupivacaine to improve patient comfort and reduce the reliance on systemic analgesics.(15, 16)

The duration of the hospital stay was another important outcome. The mean (SD) hospital stay was significantly shorter for Group A (1.6 days (0.3)) compared to Group B (2.3 days (0.5)), with a p-value of less than 0.05. This reduction in hospital stay can be attributed to the better pain management in Group A, which likely facilitated quicker mobilization and recovery. Studies have shown that effective pain management is a critical factor in reducing hospital stay and improving overall recovery after surgery.(17, 18)

The findings of this study have significant implications for clinical practice. Implementing bupivacaine infiltration at port sites can be a simple, effective, and low-cost strategy to enhance postoperative pain management.(19) This intervention not only improves patient comfort but also reduces the need for systemic analgesics, which can have various side effects. Additionally, the shorter hospital stay associated with better pain management can contribute to reduced healthcare costs and resource utilization.(20, 21)

Despite the positive findings, this study has some limitations. The sample size of 60 patients, though adequate for detecting significant differences, limits the generalizability of the results. Future studies with larger sample sizes and multi-center designs could provide more robust evidence. Additionally, the study focused on short-term pain outcomes within the first 8 hours postoperatively. Long-term follow-up could offer a more comprehensive understanding of the analgesic effects of bupivacaine infiltration. Future research should also explore different concentrations and volumes of bupivacaine, as well as comparisons with other local anesthetics. Investigating the impact of bupivacaine infiltration on other postoperative outcomes, such as nausea, vomiting, and recovery of gastrointestinal function, could provide a more holistic view of its benefits.

Conclusion

The present study demonstrates that bupivacaine infiltration at port sites significantly reduces postoperative pain intensity and the need for rescue analgesia in patients undergoing laparoscopic cholecystectomy. Patients receiving bupivacaine experienced lower pain scores at all measured postoperative intervals and required fewer doses of NSAIDs and Tramadol compared to the control group. Additionally, the use of bupivacaine was associated with a shorter duration of hospital stay, highlighting its effectiveness in enhancing postoperative recovery. Given these findings, bupivacaine infiltration should be considered a valuable and effective component of postoperative pain management protocols for laparoscopic

cholecystectomy. Future studies with larger sample sizes and longer follow-up periods are recommended to further validate these results and explore additional benefits.

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Table 1: Baseline characteristics of study participants

		Group A N = 30	**Group B N = 30**	**Total N = 60**	**P value**
		n (%)	**n (%)**	**n (%)**	
Age (in years) *Mean (SD)*		48.9 (4.5)	48.2 (4.1)	48.6 (4.3)	0.531
Age (in years)	Less than 50	16 (53.3)	15 (50.0)	31 (51.7)	0.796
	More than 50	14 (46.7)	15 (50.0)	29 (48.3)	
Gender	Male	6 (20.0)	5 (16.7)	11 (18.3)	0.739
	Female	24 (80.0)	25 (83.3)	49 (81.7)	
Body mass index (in kg/m2) *Mean (SD)*		25.7 (4.7)	26.7 (5.1)	26.2 (4.9)	0.433
Body mass index	Normal	12 (40.0)	9 (30.0)	21 (35.0)	0.646
	Underweight	1 (3.3)	2 (6.7)	3 (5.0)	
	Overweight/Obese	17 (56.7)	19 (63.3)	36 (60.0)	
Duration of surgery (in minutes) *Mean (SD)*		49.2 (3.4)	48.9 (3.7)	49.1 (3.6)	0.745
*Statistically significant at p<0.05					

Table 2: Comparison of study groups, by need for rescue analgesia and duration of hospital stay

	Group A N = 30	**Group B N = 30**	**Total N = 60**	**P value**
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	
Number of NSAIDs doses administered in the first 24 hours	30	62	92	_
Number of Tramadol doses administered in the first 24 hours	4	12	16	_

Rescue analgesia	Yes	4 (13.3)	14 (46.7)	18 (30.0)	0.005*
	No	26 (86.7)	16 (53.3)	42 (70.0)	
Duration of hospital stay (in days)		1.6 (0.3)	2.3 (0.5)	1.9 (0.4)	<0.001*
*Statistically significant at p<0.05					

Table 3: Comparison of study groups, by visual analogue scale (VAS) scores

	Group A N = 30	**Group B N = 30**	**Total N = 60**	**P value**
	n (%)	**n (%)**	**n (%)**	
At 1 hour	8.8 (0.7)	9.6 (0.9)	9.2 (0.8)	<0.001*
At 2 hours	6.4 (0.4)	6.9 (0.5)	6.7 (0.5)	<0.001*
At 4 hours	4.9 (0.7)	5.4 (0.3)	5.2 (0.5)	0.001*
At 6 hours	3.1 (0.6)	3.4 (0.4)	3.3 (0.5)	0.026*
At 8 hours	2.3 (0.5)	3.3 (0.8)	2.8 (0.7)	<0.001*
*Statistically significant at p<0.05				

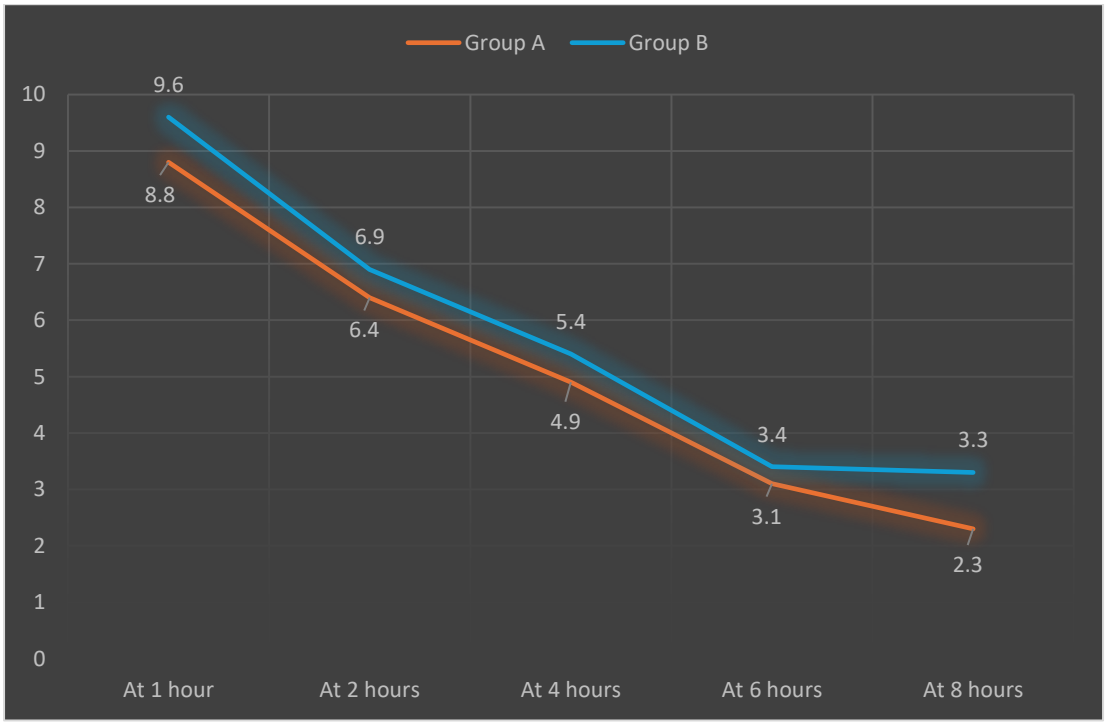

Figure 1: Comparison of study groups, by visual analogue scale (VAS) scores