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Original Research Article

Comparative analysis of analgesic consumption and pain relief in patients receiving 0.25% bupivacaine versus those without intervention

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ABSTRACT

Background: Laparoscopic cholecystectomy, now a standard for gall bladder surgery in symptomatic cholelithiasis, has significantly renovated our perspective on the postoperative recovery of patients undergoing cholecystectomy. However, pain stands out as a significant factor necessitating overnight stays after laparoscopic cholecystectomy. This study investigates the comparison of the analgesic and pain relief between groups who will receive 0.25% bupivacaine and group will not receive 0.25% bupivacaine.
Methods: A cross sectional study that was carried out in the department of surgery in Bangabandhu Sheikh Mujib Medical University, Dhaka over a period of six months and comprised 40 patients scheduled for laparoscopic cholecystectomy.
Results: At 12 hours after surgery, group I had a lower mean Numeric Rating Scale (NRS) score for pain (4.1±1.21) compared to group II (7.95±0.6). The difference between the groups was statistically significant ($p<0.05$). The mean NRS score for pain at 12 hours postoperatively was significantly lower in group I (4.72±0.61) compared to group II (6.08±0.64), suggesting a substantial reduction in pain intensity with the use of Bupivacaine during the initial 12 hours after surgery.
Conclusions: Considering the observed effectiveness of local administration of 0.25% bupivacaine at the port sites in reducing postoperative pain and the associated decrease in the need for conventional analgesics, patients undergoing laparoscopic cholecystectomy may benefit from discussing this pain management approach with their healthcare providers.

Keywords: Laparoscopic cholecystectomy, NRS score, Port-site 0.25% bupivacaine, Analgesia

INTRODUCTION

Laparoscopic cholecystectomy has evolved into a standard method for gall bladder surgery in cases of symptomatic cholelithiasis. The integration of laparoscopic techniques has significantly altered our perspective on the postoperative recovery of patients following cholecystectomy. Substantial progress has been achieved since the inception of laparoscopic cholecystectomy, and it is recognized that numerous unexplored possibilities remain for further exploration.[1] Laparoscopic cholecystectomy has proven effective in significantly reducing postoperative pain, enabling shorter hospital stays and quicker recovery times, leading to earlier resumption of normal activities.[2,3] While most patients are discharged on the first postoperative day, recent studies suggest the feasibility of outpatient procedures for appropriately selected patients.[4,5] Given the increasing importance of pain relief for timely discharge, infiltration of local anesthetics like bupivacaine into wound sites is a

simple, effective, and safe method to optimize postoperative pain.[6] Numerous researchers suggest that a combination of somatovisceral local anesthetic treatments effectively minimizes incisional site, intra-abdominal, and shoulder pain. These local agents induce antinociception by acting on nerve membranes, causing a reversible decrease in the rate of depolarization and repolarization of excitable membranes, including nociceptors.[7] Bupivacaine, with a half-life ranging from 2.5 to 3.5 hours, has demonstrated the ability to provide pain control for an average duration of 6 hours.[8] The safety margin of bupivacaine for anesthesia is substantial, with a maximum of 2.5 mg per kilogram body weight, allowing for the safe use of 100 mg in a patient with a lean body mass of 40 kgs.[8] The origin of pain after laparoscopic procedures is a subject of controversy among clinicians. Some attribute it to the placement of trocars through the abdominal wall, while others believe that most pain stems from intraperitoneal dissection or the creation of pneumoperitoneum.[9] Various analgesic effects have been reported for periportal infiltration of local anesthetics, intraperitoneal spraying above the gall bladder, and instillation into the sub-diaphragmatic and subhepatic spaces covering the hepatoduodenal ligament area. However, some studies failed to demonstrate any significant benefit.[10] Pandove et al, conducted a prospective study involving 60 patients undergoing laparoscopic cholecystectomy to investigate the impact of local infiltration of bupivacaine at trocar sites and the gall bladder fossa on postoperative pain relief.[11] The patients were divided into three groups: Group A received 20 ml of 0.25% bupivacaine subcutaneously at all trocar sites, Group B received 20 ml of 0.25% bupivacaine in the gallbladder fossa after gall bladder removal, and Group C received 20 ml bupivacaine at the gall bladder fossa and 20% at the trocar sites. This study aims to assess the impact of 0.25% bupivacaine infiltration at port sites following laparoscopic cholecystectomy in reducing early postoperative pain and analgesic consumption. The objective is to compare analgesic consumption and pain relief between groups receiving 0.25% bupivacaine and those not receiving this intervention.

METHODS

This cross-sectional study was conducted in the Department of General Surgery at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, over a period of six months, from March 2022 to September 2022. A total of 40 adult patients classified as American Society of Anesthesiologists (ASA) Class I and II, regardless of age or gender, scheduled for laparoscopic cholecystectomy were included after obtaining approval from the Institutional Review Board (IRB). Patients were excluded if they had allergies to bupivacaine, coagulation disorders, morbid obesity, major psychiatric illnesses, or kidney or liver failure that could interfere with pain score evaluation. Written informed consent was obtained from each patient, and they were informed about the study's purpose and their right to withdraw at any time. Patients were randomly allocated to groups. Preoperative assessments included history taking, physical examination, and laboratory evaluations conducted the day before surgery, during which patients were introduced to the numerical rating scale (NRS) for postoperative pain measurement. Patients receiving local infiltration were categorized as Group 1 (LA group), while those not receiving it were categorized as Group 2 (non-LA group). The drug preparation was as follows: Group 1 (LA Group): Received bupivacaine. Group 2 (Non-LA Group): Did not receive bupivacaine. Postoperative pain scores were assessed using the NRS, ranging from 0 to 10, with 0 indicating no pain and 10 representing the most severe pain.[1] Pneumoperitoneum was established by insufflating carbon dioxide, maintaining gas pressure between 12-14 mmHg. After cholecystectomy, a 0.25% bupivacaine solution was administered, with each milliliter containing 2.64 mg bupivacaine hydrochloride. The dose was calculated based on body weight, with a safety margin of 2 mg/kg. Local anesthetic (0.25% bupivacaine) was administered in all four ports, from the parietal peritoneum to the subcutaneous tissue. Calculated doses were distributed with 30% of the total volume administered to each 10 mm port and 20% to each 5 mm port, under aseptic precautions and direct visualization using sterile syringes. Pain intensity was assessed using the NRS at fixed intervals of 6 and 12 hours postoperatively. Patient pain was managed with opioid analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) intramuscularly as needed based on body weight, with the total number of doses recorded in a pre-designed form. Ethical implications of the study were addressed as follows: Prior to commencement, the research protocol was approved by the Institutional Review Board of Bangabandhu Sheikh Mujib Medical University. Patients were briefed on the study's aims, objectives, procedures, risks, and benefits in a language they could easily understand, followed by obtaining written informed consent. Patients were assured of confidentiality regarding their information and records, and that the study would aid physicians and patients in rational case management approaches.

RESULTS

The “Group 1 (LA group)” for the study includes 14 female and 6 male participants, while “Group 2 (non-LA group)” comprises 13 female and 7 male participants. In total, there are 40 participants, evenly distributed with 20 in each study group.

Table 1: Distribution of gender for different study groups.

Group name	Group 1 (LA)	Group 2 (non-LA)
Female	14	13
Male	6	7

Categorizing respondents into age groups, there are 7 females and 3 males from “Group 1 (LA group)” in the 21-30 age group. In the 31-40 age group, there are 2 females

and 9 males from "Group 1 (LA group)" and "Group 2 (non-LA group)," with 7 males from the latter. For the 41-50 age group, there are 3 females and 2 males from "Group 1 (LA group)." The 51-60 age group has 4 females from "Group 2 (non-LA group)." In the 61-70 age group, there are 2 females and 1 male from "Group 1 (LA group)."

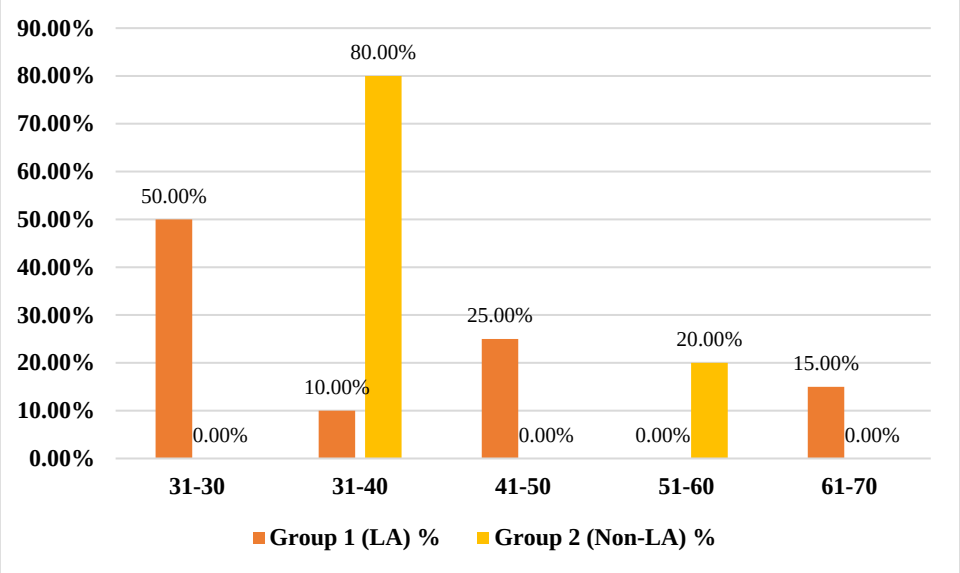

Figure 1: Age Distribution of the participants by groups

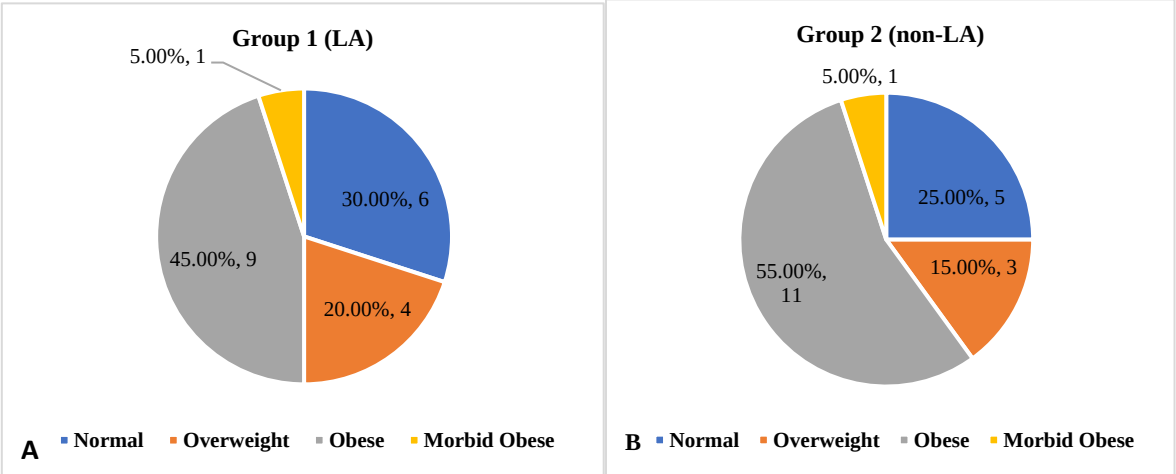

Figure 2 (A and B): BMI types for different study groups.

This study categorizes participants into five BMI (body mass index) classes: under-weight (below 18.5), normal (18.5-24.9), over-weight (25-29.9), obese (30-39.9), and morbid obese (more than 40). Notably, there is only 1 under-weight respondent in "Group 2 (non-LA group)." The Normal BMI category comprises a total of 11 respondents, with 5 in "Group 2 (non-LA group)" and 6 in "Group 1 (LA Group)." In the over-weight category, there are 7 respondents, with 4 in "Group 1 (LA group)" and 3 in "Group 2 (non-LA group)." The obese BMI class includes 20 respondents, distributed as 9 in "Group 1 (LA group)" and 11 in "Group 2 (non-LA group)." Finally, the morbid obese class has only 1 respondent in "Group 1 (LA group).

The mean NRS of pain at 6 hours was 2.55±0.6 (hours) with range from 2 to 4 (hours) in group I and 6.8±1.15 (hours) with range from 5 to 9 (hours) in group II. The mean NRS of pain at 12 hours was 4.7±1.21 (hours) with range from 3 to 6 (hours) in group I and 7.95±0.6 (hours) with range from 7 to 9 (hours) in group II. The difference was statistically significant ($p<0.05$) between two groups in both cases.

The mean time of 1st analgesic was 13.85±1.57 with range from 11 to 17 hours in group I and 2.75±0.72 hours with range from 2 to 4 hours in group II. The mean repeat dose of analgesic was 22±2.29 with range from 18 to 26 hours in group I and 9.5±1.15 with range from 7 to 11 hours in group II. The difference was statistically significant ($p<0.05$) between two groups in both cases. The

distribution of study patients by analgesic dose, it was observed that analgesic doses needed in group I in almost one third cases (30.0%) while in group II most of them needed analgesics (90%). Almost two third (60.0%) patients needed analgesics in 2nd 12 hours in group I and (70.0%) in group II. The difference was statistically significant (p<0.05) between two groups. The distribution of study patients by total dose 24 hours, it was observed that in group I, single dose of analgesics was needed in 20% patients, 2 doses needed in 75%, 3 doses needed in 5% while in group II at least 3 doses of analgesics were needed in 30% patients, 4 doses needed in 60% and 5 doses in 10% patients. The difference was statistically significant (p<0.05) between two groups. The distribution of study patients by analgesic in 1st 6 hours, it was observed that only one patient (5.0%) needed analgesic in 1st 6 hours in group I while 20 patients (100%) needed analgesics in group II. The difference was statistically significant (p<0.05) between two groups. Here all the information showed in the Table 2.

Table 2: Evaluating and comparing the results between two groups.

NRS of pain	Group I	Group II	P value
	Mean±SD	Mean±SD	
At 6 hours	2.55±0.6	6.8±1.15	0.001[s]
Range (min-max)	2-4	5-9	
At 12 hours	4.7±1.21	7.95±0.6	
Range (min-max)	3-6	7-9	
Analgesic dose			
Time of 1st analgesic	13.85±1.57	2.75±0.72	0.001[s]
Range (min-max)	11-17 hrs	2-4 hrs	
Repeat dose of analgesic	22±2.29	9.5±1.15	0.001[s]
Range (min-max)	18-26 hrs	7-11 hrs	
Analgesic dose in 1st 12 hours	Number of total patients (n=20)		
0	14	0	
1	6	0	0.001[s]
2	0	18	
3	0	2	
Analgesic dose in 2nd 12 hours	Number of total patients (n=20)		
0	1	0	
1	7	6	0.540[ns]
2	12	14	
Total dose 24 hours	Number of total patients (n=20)		
1	4	0	
2	15	0	0.001[s]
3	1	6	
4	0	12	
Analgesic in 1st 6 hours			
0	19	0	0.001[s]
1	1	20	

DISCUSSION

This comparative study was carried out with an aim to find out the effect of bupivacaine in relieving post-operative port site pain and also to compare the requirement of analgesics and pain relief between two groups. Bupivacaine exhibits a half-life of 2.5-3.5 hours and is known to offer pain control for an average duration of 6 hours. The safety margin for Bupivacaine in anesthesia is substantial, with 100 mg of the drug being safely applicable at the upper limit of 2.5 mg per kilogram of body weight in a patient with a lean body mass of 40 kgs.[12,13] In this study 45% obese patients are found in Group I on the other hand 55% found in Group II. In this current study the mean NRS of pain different in two groups. Where Group I show the higher scores than group II at 6 hours was 2.55±0.6 (hours) and 6.8±1.15 (hours) in group II. The mean difference of NRS of pain at 6 hours was significantly (p<0.05) higher between two groups. Similarly, Alam et al 2010 observed at 6 hours postoperatively the mean (±SD) pain score of groups I was found as compared to group II, it was found to be having significant (p<0.05). Therefore, Bupivacaine provided a substantial reduction of pain intensity during the first 6 hours postoperatively and this was found to be statistically highly significant. Pain at 12 hours was 4.1±1.21 (hours) with range from 2 to 6 (hours) in group I and 7.95±0.6 (hours) with ranged from 7 to 9 (hours) in group II. The difference was statistically significant (p<0.05) between two groups. it was found that at 12 hours postoperatively, although the mean was 4.72±0.61 of study group I in comparison to 6.08±0.64 of the group II, it was found to

be having significant (p<0.05). It is evident that bupivacaine did provide a substantial reduction of pain intensity during the first 12 hours postoperatively. A large variation in pain scores at each of the assessment times was found in different studies. They found the mean pain scores at 6 hours and 12 hours were found to be statistically significant. The main effect of bupivacaine seems to have been in amelioration of pain peak occurring during the initial 6 hours after the surgical procedure. An appreciable difference was found in total analgesics requirement between the control and bupivacaine group in study.[14] Pain relief and patient comfort during the early post-operative period becomes increasingly important, as the need for the 1st analgesic may delay in group I also obtained by.[15-18] In this present study the mean repeat dose of analgesic was 22±2.29 hours with range from 18 to 26 hours in group I and 9.5±1.15 hours with range from 7 to 11 hours in group II. The repeat dose of analgesic was also significantly (p<0.05) early in group II, which is similar with a study.[3] Noxious stimulation lead to alterations in CNS function which influence subsequent pain experience.[19] Local anesthetics successfully block the noxious inputs to CNS and thus alter the pain perception in the subsequent hours and thus result in reduced pain scores and reduced analgesic usage. In this present study the distribution of the overall doses in 24 hours shows the greatest different result between group I and Group II. Group I needed 1, 2 and 3 doses in 20%,75% and 5% of the patients. But in Group II 3 doses were needed in 30% patients, 4 doses needed in 60% and 10% of patients needed 5 doses of analgesics. Alam et al found the total analgesics requirement in study group was mean 1.91±0.61 while that in group II was 2.50±0.51.[14] In the group I, total doses requirement was significantly (p<0.05) less in comparison to group II. a relevant study also found a significant different intravenous dose between the two groups.[20] Between the groups in this study the patients those were not received bupivacaine in first six hours 20 patients means 100% needed analgesics. Whereover the 5% of bupivacaine received patients needed analgesics in 1st 6 hours. Szem et al reported that intraperitoneal bupivacaine 0.1% of 100 ml administered before surgery, offered advantages with respect to postoperative pain after laparoscopic cholecystectomy only for the first 6 hours without any reduction in the analgesic consumption, compared to the placebo group.[17] Chundrigar et al and Szem et al study showed modest overall analgesic effect where there was a statistically significant difference during the first 6 hours.[4,17]

This study was not without limitations. Patients with comorbid condition were not included in this study, pediatric patients were excluded and port related delayed complications were not evaluated.

CONCLUSION

Local administration of 0.25% bupivacaine at the port sites following laparoscopic cholecystectomy appears to be more effective than conventional analgesics in reducing post-operative port sites pain. It also reduces the dose and frequency of conventional analgesics consumption.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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