



EFFECT OF INTRA-PERITONEAL LEVO-BUPIVACAINE ON POST LAPAROSCOPIC PAIN - A TRIPLE BLINDED RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Laparoscopic cholecystectomy offers benefits like reduced pain and faster recovery, but postoperative pain persists, mainly due to peritoneal irritation and CO₂ effects. This study assessed intraperitoneal levobupivacaine's effectiveness in managing pain compared to 0.9% sodium chloride. In a randomized, triple-blinded, placebo-controlled study, 118 women undergoing diagnostic laparoscopic surgery were divided into two groups: Group 1 received 0.25% levobupivacaine, while Group 2 received 0.9% sodium chloride. Pain levels were assessed at 0, 12, 24, and 48 hours postoperatively using the visual analogue scale. The results indicated that Group 1 experienced significantly lower pain levels at all time points ($p < 0.05$) and required less analgesia than Group 2. Moreover, Group 1 reported higher satisfaction with postoperative management. The study concluded that intraperitoneal levobupivacaine provides superior pain relief, reduces the need for additional analgesics, and enhances patient satisfaction compared to sodium chloride, making it a more effective strategy for postoperative pain management following laparoscopic surgery.

KEYWORDS :

INTRODUCTION

Laparoscopic cholecystectomy (LC) is among the most commonly performed elective surgeries. Compared to open surgery, LC offers advantages such as less postoperative pain, reduced need for analgesics, and a quicker return to normal activities. However, postoperative pain remains the most common complaint following this procedure.[1]

The pain experienced after laparoscopic surgery is caused by multiple factors, including visceral pain from the stretching of the abdominal cavity and peritoneal irritation due to trapped CO₂. Shoulder tip pain occurs due to phrenic nerve irritation caused by CO₂ trapped under the diaphragm.[2] Less commonly, parietal pain may occur at the site of the surgical incision.[3] Patients often report severe pain within the first 24 hours following laparoscopic surgery.[4] Various methods have been explored to reduce this immediate postoperative pain, including different analgesic regimens and the type of gas used for abdominal insufflation.[5]

Intraperitoneal administration of local anesthetic (LA) is a multimodal analgesic approach used to provide effective postoperative pain relief after LC. Among various LAs, intraperitoneal bupivacaine is the most commonly used due to its long-lasting analgesic effect and high potency. However, there is limited evidence on the effectiveness of other LAs, as most studies have focused on bupivacaine.[6] Levobupivacaine, an isomer of racemic bupivacaine, has been proposed as a safer alternative with a lower risk of systemic toxicity and prolonged action.[7] Nonetheless, there is limited data on the intraperitoneal use of levobupivacaine. Therefore, the present study was undertaken to compare post-laparoscopic pain in women treated with Levobupivacaine with those treated with 0.9% sodium chloride over 48 hrs.

MATERIALS AND METHOD

This single-center, prospective, randomized, triple-blinded, placebo-controlled study was conducted at the Department of Obstetrics and Gynaecology, Rohilkhand Medical College and Hospital, Bareilly, from November 2022 to October 2023. A total of 118 women classified as ASA 1-2 were included, while those with ASA > 2, weighing less than 50 kg, or having contraindications to bupivacaine were excluded.

Participants were randomly assigned to two groups: Group 1 received 100 ml of intraperitoneal 0.25% levobupivacaine, while Group 2 received 100 ml of intraperitoneal 0.9% sodium

chloride as a placebo. The randomization was done using a computer-generated number, and patient assignments were determined by a lottery method.

Preoperative preparations included fasting (NPO) for 8 hours, with systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) recorded before surgery. Anesthesia was maintained with a mixture of 50% nitrous oxide in oxygen and isoflurane. Mechanical ventilation was finely regulated to maintain normocapnia (Et.CO₂ between 35- and 40-mm Hg), with vecuronium (0.02 mg/kg) used as an additional neuromuscular blocker to sustain relaxation.

During the laparoscopic procedure, pneumoperitoneum was established and maintained, and the assigned solution (levobupivacaine or sodium chloride) was instilled into the abdomen post-intervention. Pain was assessed using the visual analogue scale (VAS) at multiple intervals—1, 3-, 6-, 12-, and 24-hours post-surgery, and later as needed.

The primary outcome was pain levels at specific postoperative time points. Secondary outcomes included analgesic consumption within the first 24 hours and the incidence of postoperative complications, such as nausea, vomiting, sedation, and urinary retention.

Statistical analysis

Descriptive data are presented as mean \pm SD for continuous variables and as a frequency and percentage for categorical variables. T-tests were employed to compare continuous data, Mann-Whitney tests were used for ordinal data, and Chi-square tests were applied for categorical data. A p-value less than 0.05 was considered statistically significant.

RESULTS

The mean age of group 1 subjects was 34.46 ± 5.81 years, while group 2 had a mean age of 31.22 ± 4.92 years ($p < 0.05$). The duration of procedure was comparable between groups (Group 1: 1.96 ± 0.51 hours vs Group 2: 1.78 ± 0.32 hours, $p < 0.05$).

A significant difference was found in the pain intensity at various time intervals when compared between groups ($P < 0.05$) (Table 1).

Table 1. Comparison of postoperative pain between Group 1 and Group 2 at different time intervals

Time intervals (hrs)	Group 1				Group 2			
	No pain (%)	Mild (%)	Miserable (%)	Intense (%)	No pain (%)	Mild (%)	Miserable (%)	Intense (%)
0	84.75	6.78	3.38	5.08	6.78	37.29	38.98	16.95
12	91.53	0	8.47	0	27.12	35.59	37.29	0
24	91.53	6.78	1.69	0	40.68	32.2	27.12	0
48	91.53	6.78	1.69	0	45.76	32.2	22.03	0
P value	<0.05							

Table 2. illustrates the need for analgesia in group 1 and group 2. These results indicate that Group 1 experienced less need for analgesia overall, suggesting more effective pain management compared to Group 2. A significant difference was observed between group 1 and group (p<0.05).

Table 2. Comparison of Need of analgesia between Group 1 and Group 2 at different time intervals

Time intervals (hrs)	Group 1		Group 2	
	No (%)	Yes (%)	No (%)	Yes (%)
0	84.75	15.25	6.78	93.22
12	76.27	23.73	8.47	91.53
24	89.83	10.19	27.12	72.88
48	88.14	11.86	33.90	66.10
P value	<0.05			

Table 3. illustrates the overall quality in post-op management in Group 1 and Group 2. The statistically significant p-value of <0.05 indicates that Group 1 patients generally had a more favorable perception of postoperative management quality compared to Group 2 patients.

Table 3. Comparison of Overall quality post-op management in between Group 1 and Group 2

Overall quality post-op management	Group 1 (%)	Group 2 (%)	P-Value
Excellent	3.39	0.0	0.000
Very good	57.63	6.8	
Good	8.47	3.4	
Satisfactory	22.03	47.5	
Unsatisfactory	0.00	1.7	
Poor	5.08	28.8	
Very poor	3.39	11.9	

DISCUSSION

Laparoscopic surgery benefits gynecological procedures with faster recovery and shorter hospital stays. However, early postoperative pain, caused by abdominal trauma, distension, and CO2-induced peritoneal irritation, is common. Visceral and shoulder tip pain, which peaks shortly after surgery and worsens with movement, can be particularly troublesome. Intraperitoneal infiltration effectively alleviates both visceral and shoulder tip pain, enhancing postoperative comfort and recovery.[8]

In this study, the mean age of the study group was 34.46 years, which is comparable to the mean ages reported in studies by Shaw et al,[9] Keita H et al,[10] Butala BP et al,[11] and Sharma CS et al. [12]

The mean operating time in the present study was 1.96 hours in the study group and 1.78 hours in the control group, this difference in operating time may be attributed to varying surgical techniques or complexities, which could influence pain management outcomes. These findings are consistent with the findings from studies by Keita H et al [10], Butala BP [11], and Sharma CS et al.[12]

Pain assessment revealed significant differences between the two groups at all postoperative time points (0, 12, 24, and 48 hours). Group 1 consistently reported higher percentages of patients with no pain and lower percentages of patients experiencing mild, miserable, or intense pain. At 0 hours,

84.75% of Group 1 reported no pain compared to only 6.78% in Group 2. This trend continued at subsequent time points, with Group 1 maintaining better pain control. These results suggest that Group 1 experienced more effective pain management throughout the postoperative period indicating that levo-bupivacaine is more effective in reducing postoperative pain. These outcomes are similar to the findings of Shaw IC et al [9], Keita H et al [10], and Goldstein et al.[13]

The need for analgesia further supports the efficacy of pain management in Group 1. A significantly higher proportion of patients in Group 2 required analgesia at all postoperative intervals (0, 12, 24, and 48 hours) compared to Group 1 such as at 0 hours, 93.22% of Group 2 patients required analgesia versus 15.25% in Group 1. This is consistent with the studies conducted by Cunningham TK et al [5] and Butala BP et al.[11] This trend indicates that intraperitoneal levo-bupivacaine reduced the need for additional pain relief. Finally, the overall quality of postoperative management was significantly better in Group 1. A higher percentage of patients in Group 1 rated the management as "Excellent" or "Very good" compared to Group 2, with 57.63% of Group 1 patients rating it as "Very good" versus only 6.8% in Group 2. In contrast, Group 2 had higher percentages of patients rating the management as "Satisfactory," "Poor," or "Very poor." The statistically significant p-value (p < 0.05) underscores that Group 1 had a more favorable perception of their postoperative care. These results suggest that intraperitoneal levobupivacaine is effective in reducing postoperative pain and quality of postoperative management.

CONCLUSION

The study found that intraperitoneal levobupivacaine improved pain management, reduced analgesic use, and increased patient satisfaction compared to normal saline, despite a slightly longer operating time, ultimately enhancing overall patient recovery.

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