ORIGINAL ARTICLE ASIAN JOURNAL OF MEDICAL SCIENCES

Effect of pulmonary recruitment maneuver and intraperitoneal bupivacaine on post-operative shoulder pain after laparoscopic cholecystectomy: A randomized comparative study

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Submission: 23-12-2024 Revision: 30-01-2025 Publication: 01-03-2025

ABSTRACT

Background: Laparoscopic cholecystectomy nowadays is the preferable approach over open cholecystectomy because of early recovery and lower rate of complications. However, some undesirable effects, such as shoulder pain, which has an incidence of about 12–60% after laparoscopic cholecystectomy, can affect the early recovery of patients. **Aims and Objectives:** To study the efficacy of a pulmonary recruitment maneuver and intraperitoneal bupivacaine in combination for reducing shoulder pain following laparoscopic cholecystectomy. **Materials and Methods:** This randomized comparative study was conducted in patients undergoing elective laparoscopic cholecystectomy in a tertiary care center. A total of 46 patients were randomly assigned to two groups: group A, intraperitoneal bupivacaine instillation was done; and group B, a combination of intraperitoneal bupivacaine and a pulmonary recruitment maneuver was done. The interventions were carried out at the end of the surgery. At 1, 6, 12, 18, 24, and 48 h postoperatively, shoulder pain and abdominal were measured on a Visual Analog Scale (VAS). **Results:** The incidence of shoulder pain was higher in group A in comparison to group B and difference between two was statistically significant. In group A 34.78 % patients required rescue analgesia whereas in group B 13.6% patients needed rescue analgesia in postoperative period for shoulder pain. A significant difference in VAS scores for shoulder pain in the post-operative period was observed till 12 h. For abdominal pain, no significant difference in VAS scores and consumption of rescue analgesia was observed in the post-operative period. **Conclusion:** When intraperitoneal bupivacaine is used in conjunction with a pulmonary recruitment maneuver, shoulder pain is significantly reduced in comparison to intraperitoneal bupivacaine alone in the post-operative period after laparoscopic cholecystectomy.

Key words: Laparoscopic cholecystectomy; Shoulder pain; Pulmonary recruitment maneuver; Intraperitoneal bupivacaine; Visual analog scale

Access this article online

Website: https://ajmsjournal.info/index.php/AJMS/index

DOI: 10.71152/ajms.v16i3.4373

E-ISSN: 2091-0576

P-ISSN: 2467-9100

INTRODUCTION

Up to 20% of the population in affluent countries suffers from cholelithiasis, for which laparoscopic cholecystectomy is the preferred surgical therapy of choice because of reduced post-operative pain, smaller incisions, less blood loss, a shorter hospital stay, and a faster recovery.[1,2] However, shoulder pain, as well as discomfort at the

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incision site, is the major cause of extended hospitalization following laparoscopic cholecystectomy.[3,4] Shoulder and sub-diaphragmatic discomfort affect between 12 and 60% of people. The level of pain often peaks within the first few post-operative hours and reduces after 2 or 3 days.[5,6]

Pain in laparoscopic cholecystectomy is composed of three clinically different components: incisional pain (somatic pain), visceral pain (deep intraabdominal pain), and shoulder discomfort (presumably transferred visceral pain).[7]

Various multimodal strategies are being used to reduce post-operative pain after laparoscopic cholecystectomy. Parenteral analgesics (including opioids and non-steroidal anti-inflammatory medications), local infiltration with local anesthetics, and intraperitoneal instillation of local anesthetics are examples. Intraperitoneal injection of bupivacaine is one of the most effective pain control treatments following laparoscopic cholecystectomy.[8] Other effective methods include lung recruitment maneuvers that increase intraperitoneal pressure and enable the elimination of leftover carbon dioxide. It is performed through opening trocars at the conclusion of the surgery.[9]

In 2020, Cho et al. conducted a randomized controlled trial and studied the combination of pulmonary recruitment maneuver with intraperitoneal bupivacaine for the reduction of post-operative shoulder pain in gynecologic laparoscopy. This study concluded that the combination significantly decreases shoulder pain after gynecologic laparoscopy.[10]

The purpose of this randomized comparative study was to evaluate the efficacy of the pulmonary recruitment maneuver in the supplementation of intraperitoneal bupivacaine in reducing pain following laparoscopic cholecystectomy.

Aims and objectives

The aim of the study was to study the efficacy of pulmonary recruitment manoeuvre and intraperitoneal bupivacaine in combination for reducing shoulder pain following laparoscopic cholecystectomy. The primary objective of this study was to compare the intensity of shoulder pain by VAS score. The secondary objectives were to compare the postoperative incidence of shoulder pain, intensity of abdominal pain by VAS score, and requirement of rescue analgesic in both groups.

MATERIALS AND METHODS

The current randomized comparative study was carried out after obtaining ethical and CTRI approval at King George Medical University, Lucknow (India), from August 2022 to August 2023 in patients undergoing laparoscopic cholecystectomy. A written informed consent was obtained from patients.

Inclusion criteria: All patients who were planned for laparoscopic cholecystectomy between 18 and 65 years of age with ASA grades 1 and 2 were included in the study.

Exclusion criteria were as follows: (1) refusal to consent to participate; (2) an operative time of more than 2 h; (3) patients with pre-existing frozen shoulder; (4) patients on chronic NSAIDs; (5) chronic obstructive pulmonary disease; and (6) atelectasis.

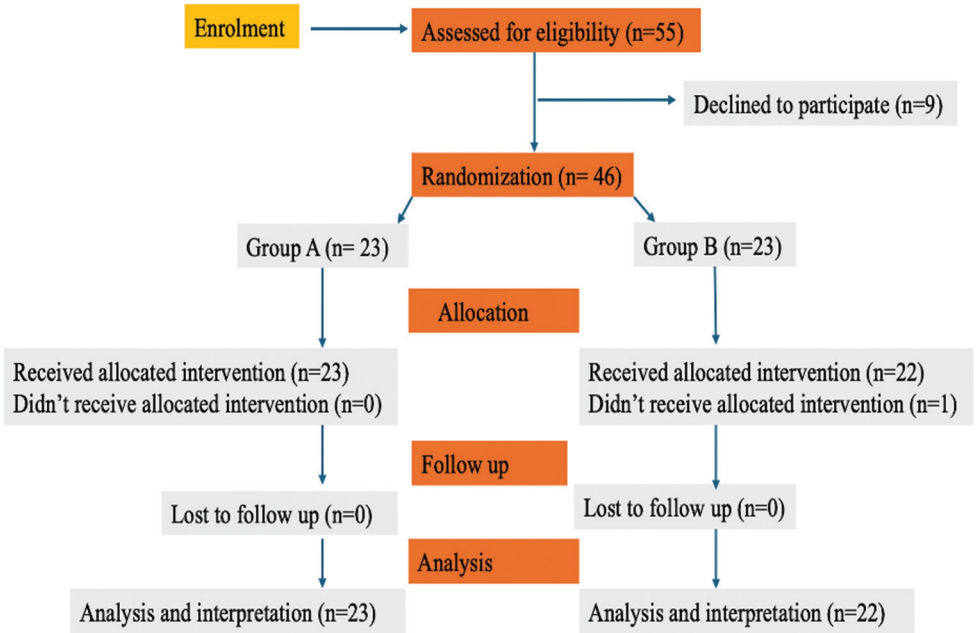

Figure 1: Consolidated standards of reporting trials chart

Patients were randomly assigned to groups A and B (Figure 1) using the computer-generated randomization sequence method. Allocation concealment was done using a sequentially numbered sealed opaque envelope method. The observer and patients were blinded to the group allocation.

On arrival of the patient in the operation theater all standard monitors were attached. Intravenous cannulation was done, an intravenous drip was attached, and an injection of fentanyl 1.5 μg/kg was given. After 3 min of pre-oxygenation with 100% oxygen, the patient was induced with an injection of propofol 1.5–2.5 mg/kg and an injection of vecuronium 0.01 mg/kg. After 3–4 min of the bag and mask ventilation, either a supraglottic airway device or endotracheal tube was inserted. Maintenance of anesthesia was done with O_2 with FiO_2 40%, sevoflurane 1–2%, and vecuronium as per requirement. In the intraoperative period, $EtCO_2$ was kept between 30 and 40 mm of Hg and intraabdominal pressure below 15 mm of Hg. After completion of the surgery, the surgeon was asked to keep the trocar *in situ*.

According to the group allocation by computer-generated randomization sequence, one of two procedures was performed. The patients in group A had 0.5% bupivacaine (20 mL) instilled under the diaphragm. Bupivacaine was sprayed subdiaphragmatically by the surgeon through a trocar kept *in situ*. In group B, along with subdiaphragmatic instillation of 0.5% bupivacaine (20 mL), a pulmonary recruitment maneuver was done. The pulmonary recruitment maneuver procedure consists of five manual lung inflations in which the peak pressure is <30 cm H_2O. The fifth positive pressure inflation lasted for approximately 5 s. While the anesthesiologist was performing the pulmonary recruitment maneuver, the surgeon was instructed to open the trocar valve fully to remove intraperitoneal CO_2 gas. After the completion of the surgery, periportal wound infiltration with bupivacaine was also performed in every patient, and 1 g of intravenous paracetamol was also given to all patients in both groups. Post-operative analgesia was provided with intravenous paracetamol (1 g) every 6 h until 24 h.

If any patient complained of shoulder pain (VAS >3) or abdominal pain (VAS>3) rescue analgesia (intravenous tramadol 100 mg) was given. Postoperatively, the frequency and severity of shoulder pain and abdominal pain in terms of VAS score were measured at 0, 1, 6, 12, 18, 24, and 48 h.

Sample size and statistical analysis

Sample size is calculated based on a previous study in which SD of VAS at 24 h in studied groups were 1.33 and 1.03, and if the difference of 1 in VAS scores at 24 h would be clinically significant, the sample size of 23 was calculated for each group.[10] The power of the study was set at 80% with a 95% confidence level. Data were entered in Microsoft Excel and analyzed using the statistical software SPSS version 26 (SPSS Inc., Chicago, IL, USA). The continuous variables were evaluated by mean (standard deviation) or range value when required. The dichotomous variables were presented in number or frequency and were analyzed using Chi-square. Analysis of variance and Kruskall–Wallis H tests were used to compare the means between the two groups. A $P<0.05$ was regarded as significant.

RESULTS

The patients' demographic profiles were comparable in terms of age, sex, and body weight (Table 1).

The incidence of shoulder tip pain in 1st 24 h was significantly higher in group A compared to group B. For shoulder pain, 10 (34.78%) patients required rescue analgesia in group A, and in group B only 3 (13.6%) patients demanded rescue analgesia. The post-operative pain scores for shoulder pain were lesser in group B compared to group A but a significant difference was observed till 12 h (Table 2).

For abdominal pain, no significant difference in VAS scores was observed in the post-operative period, and the requirement of rescue analgesia was also comparable in both groups (Table 3).

For abdominal pain, in group A, 22 patients (95.65%) required rescue analgesia, whereas in group B, all 22 (100%) patients required rescue analgesics in post-operative period (Table 4).

Table 1: Demographic data of patients with duration of surgery

Variable	Group A (n=23) Mean±SD	Group B (n=22) Mean±SD	P-value
Age (years)	44.30±14.31	39.17±13.90	0.22#
Sex (Female: Male)	17:6	15:8	0.52#
Height (cm)	160.91±5.99	163.95±4.71	0.06#
Weight (kg)	56.35±5.69	54.57±6.60	0.33#
Duration of surgery (min)	51.09±6.56	51.52±7.90	0.84#

#Non-significant

Table 2: Intensity of shoulder pain recorded on a Visual Analog Scale (VAS) at each post-operative time interval

Shoulder tip pain (VAS)	Group A (n=23) Mean±SD	Group B (n=22) Mean±SD	P-value
0 h	0.00±0.00	0.00±0.00	-
1 h	1.65±1.67	0.45±1.47	0.0144*
6 h	2.57±1.34	1.05±1.43	0.0007*
12 h	1.87±1.01	1.14±0.47	0.0035*
18 h	1.013±0.69	0.91±0.29	0.1745#
24 h	0.96±0.56	0.91±0.29	0.7265#
48 h	0.39±0.50	0.36±0.49	0.8524#

*Significant, #Non-significant

Table 3: Intensity of abdominal pain recorded on a Visual Analog Scale (VAS) at each post-operative time interval

Abdominal pain (VAS)	Group A (n=23) Mean±SD	Group B (n=22) Mean±SD	P-value
0 h	0.48±0.90	0.55±1.01	0.81#
1 h	2.09±1.38	2.73±1.08	0.09#
6 h	2.65±0.98	2.36±1.09	0.36#
12 h	2.43±1.20	1.82±1.33	0.11#
18 h	1.87±1.63	1.36±1.43	0.28#
24 h	0.43±0.90	0.32±0.48	0.59#
48 h	0.09±0.29	0.00±0.00	0.16#

#Non-significant

Table 4: Distribution of rescue analgesia doses

Rescue analgesia	Group A (n=23)		Group B (n=22)		P-value
	No.	%	No.	%	
Shoulder pain					<0.03*
Nil	13	82.6	19	100.0	
100 mg	10	17.4	3	0.0	
Abdominal pain					0.32#
Nil	1	4.3	0	0.0	
100 mg	5	21.7	8	39.1	
200 mg	14	60.9	12	52.2	
300 mg	3	13.0	2	8.7	

*Significant, #Non-significant

Both groups were similar in terms of the incidence of nausea and vomiting after surgery. In group A, 34.8% of patients and in group B, 52.2% of patients observed nausea, and the difference between the two was not significant (P=0.18). The difference between the incidence of vomiting between the two groups was also not statistically significant (P=0.73). In group A, 17.4% of patients and in group B, 13% of patients complained of vomiting. Cardiovascular or pulmonary complications were not found as a result of the maneuver.

DISCUSSION

Pain after laparoscopic cholecystectomy has multiple components: visceral pain from gallbladder dissection, somatic pain from stretching of the peritoneal cavity, and shoulder pain because of retention of carbon dioxide irritating the phenic nerve. Intraperitoneal instillation of local anesthetic is a commonly used modality along with intravenous analgesia to reduce the pain after laparoscopic cholecystectomy. The pulmonary recruitment maneuver at the end of surgery aims to remove the residual CO_2 which is one of the main causes of post-operative shoulder pain. The use of pulmonary recruitment maneuvers has been found to decrease the incidence of shoulder pain.[11-15] Hence, we hypothesized that the combination of intraperitoneal bupivacaine and pulmonary recruitment maneuver can bring the incidence of shoulder pain further low. This study was performed to compare the efficacy of the combination of a pulmonary recruitment maneuver and intraperitoneal bupivacaine for the reduction of post-operative shoulder pain after laparoscopic cholecystectomy. Intraperitoneal bupivacaine has exhibited beneficial effects in reducing post-operative abdominal and shoulder pain after laparoscopic cholecystectomy surgery.[5,6,8]

In our study, we observed that the incidence of shoulder tip pain and the intensity of shoulder pain (based on VAS score) were lower in the group in which a combination of intraperitoneal bupivacaine plus a pulmonary recruitment maneuver was used, which is consistent with Cho et al.,[10] conducted research on four groups of women who had laparoscopic gynecologic surgery. Group A received a placebo; Group B received intraperitoneal bupivacaine; Group C received CO_2 removal through a pulmonary recruitment maneuver; and Group D received a combination of intraperitoneal bupivacaine plus a pulmonary recruitment maneuver. The total incidence of shoulder pain was 49.8%, with a decreasing trend from group A to group D (59.0% in group A, 54.8% in group B, 44.4% in group C, and 41.5% in group D; (P=0.026). In their study, the incidence of shoulder discomfort was higher than in our study. It might be due to the length of the procedure and the type of surgery, as the duration of surgery increases the incidence of shoulder pain. Similarly, Feroj et al. observed that the pulmonary recruitment maneuver decreases the incidence as well as the intensity of post-operative shoulder pain in comparison to the control group. In the control group, the authors kept the surgical ports open and allowed the decompression of the abdomen by passive evacuation of residual CO_2 gas. In Feroj et al., study the number of patients (38.3%) experiencing shoulder pain in the pulmonary recruitment group was considerably lower than the proportion in the control group (68.3%).[12] Furthermore, Kihlstedt Pasquier et al. discovered that a 1-min ventilator-piloted pulmonary recruitment maneuver (PRM) minimizes the occurrence of shoulder

pain following laparoscopic cholecystectomy. There was a substantial difference in the incidence of shoulder pain, favoring the PRM group. In their study, 44.7% of the PRM group experienced shoulder pain 48 h after surgery, compared to 63.4% of the control group.[13] Similarly, Khanna et al. and Gungorduk et al. also observed that the pulmonary recruitment maneuver decreases the incidence of shoulder pain.[14,15]

Kumari et al. found in their study that the combination of a pulmonary recruitment maneuver with intraperitoneal normal saline infusion significantly reduced shoulder pain after gynecological laparoscopy. VAS scores for shoulder pain were also significantly lower in the combination group.[16]

Regarding abdominal pain, we did not observe any statistical difference in the requirement of rescue analgesia for abdominal pain. VAS score (abdominal pain) was also comparable between the two groups. As in both groups, intraperitoneal instillation of bupivacaine and local anesthetic infiltration of the periportal wound were done, so that may be a reason for comparable abdominal pain scores.

No significant difference was observed in the incidence of nausea and vomiting in both groups. Similarly, Cho et al. found no significant difference in post-operative nausea or vomiting between the control and intervention groups.[10] However, Kihlstedt Pasquier and Andersson observed a lower incidence of nausea and vomiting in the pulmonary recruitment technique group compared to the control group.[13]

Limitations of the study

This study has some limitations, such as no control group was included, and follow-up of the patients was done till only 48 h after surgery.

CONCLUSION

This study demonstrates that a combination of PRM and intraperitoneal bupivacaine is more effective in reducing the incidence as well as the intensity of post-operative shoulder pain in comparison to intraperitoneal bupivacaine alone in patients undergoing laparoscopic cholecystectomy.

ACKNOWLEDGMENT

The authors would like to thank operation theatre staff and faculty of Department of General Surgery, KGMU, Lucknow.

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https://doi.org/10.1007/s13224-019-01224-4

Authors Contribution:
SN- Prepared first draft of the manuscript, data collection, data analysis, and manuscript preparation; **RV-** Implementation of the study protocol, design of the study, concept design, clinical protocol, manuscript preparation, editing, statistical analysis, and interpretation and submission of the article; **H-** Design of study, concept design, and review of the manuscript; **AS-** Design of study, concept design, and review of the manuscript; **RG-** Editing and manuscript revision.

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Source of Support: Nil, **Conflicts of Interest:** None declared.