



To evaluate the effect of intraperitoneal instillation with 0.5% ropivacaine as pre insufflation and at the time of closure in patients undergoing laparoscopic cholecystectomy

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Abstract

Background: Postoperative pain management remains a major challenge after laparoscopic procedures. Effective pain control encourages early ambulation, which significantly reduces the risk of deep vein thrombosis and to decrease the other risk of complications.

Aims & Objectives: The present study is designed to evaluate the effect of intraperitoneal instillation with 0.5% ropivacaine as pre insufflation and at the time of closure in patients undergoing laparoscopic cholecystectomy.

Materials and Methods: In this observational study, seventy patients belonging to ASA I and ASA II aged between 18 to 65 years were randomly allocated to two groups Group A (n=35) and Group B (n=35), undergoing laparoscopic cholecystectomy. Patients belonging to group A received 2 mg/kg of 0.5% ropivacaine before insufflation of gas and patients belonging to Group B received the same as wound infiltration at the time of closure. Injection diclofenac sodium intravenous was given as a rescue analgesia when required. We observed pain intensity with Visual Analogue Scale VAS score at 0.5, 1, 2, 4, 6, 12, 24 h after surgery and over all VAS score (mean of all VAS scores), time for first analgesic requirement, total diclofenac sodium consumption and incidence of nausea and vomiting.

Results: Mean VAS score immediately after the surgery for group A was (2.5±1.2) significantly lower than group B (5.2±2.9, P=0.0001). First analgesic dose requirement time was longer in group A (6.25 hours) than group B(4.50 hours ,P=0.0003). Total amount of diclofenac sodium required in group A(75±4.3mg) was less than group B(160±5.9mg,P=0.054) Incidence of post operative complications were equal in both the groups.

Conclusion: Infiltration with 0.5% Ropivacaine significantly decreases post-operative pain intensity and diclofenac sodium consumption in patients undergoing laparoscopic cholecystectomy. Infiltration has better effect when given pre insufflation.

Keywords: pre insufflation, Post-operative analgesia, laparoscopic cholecystectomy, Ropivacaine.

Introduction

Postoperative pain results in multiple undesirable physiologic and psychological outcomes, and it should be managed in a multimodal approach.¹ Postoperative pain management remains a major challenge after laparoscopic procedures.

Currently, the standard treatment for acute post-operative pain is the use of systemic opioids. Opioids bind to specific receptors located throughout the central nervous system and other tissues. Unfortunately, opioids are not without complications. Drowsiness, nausea, vomiting, ileus, urinary retention and pruritus, are all side effects of opioids. These side effects can lead to longer lengths of stays and poor patient outcomes.^{2,3}

Thus to adequately manage post-operative pain and reduce side effects of current therapies other courses of treatment must be considered. One approach to control post-operative pain and limit post-operative opioid usage is local anesthetic wound infiltration. There are two main approaches to local anesthetic wound infiltration. The first is a preemptive model which applies the anesthetic prior to surgical incision. The second model applies the anesthetic immediately prior to surgical closure at the end of the surgical case. Several studies have applied both models and administered local anesthetic both prior to and at closure.⁴

Methods

The present study was conducted in the department of anesthesiology in Govt; medical collage Srinagar from September 2016 to September 2017 for seventy patients of (ASA) physical status I-II of both sexes, aged between 20 to 60 years, equally divided in to two groups, Group A (n=35) and Group B (n=35), undergoing laparoscopic cholecystectomies were included in this prospective, randomized, observational study. Patient who were allergic to local anesthetic and study drugs, patients with acute cholecystitis, patients with severe cardiac, pulmonary, and neurological diseases, those in whom procedure

had to be converted to open cholecystectomy, in whom abdominal drain was put were excluded from the study. After getting approval from Institutional Ethical Committee, written informed consent was obtained from all the patients before surgery.

All patients were transported to the operating room without premedication. On arrival to operating room, an 18-gauge intravenous (IV) catheter was inserted and 6ml/kg/h crystalloid was infused intraoperatively, monitoring of electrocardiography, non-invasive blood pressure, oxygen saturation (SpO₂) was started and baseline values were recorded. Pre-oxygenation with 100% oxygen (O₂) was done for 3 min. General anesthesia was induced with IV propofol 2.0–2.5 mg/kg followed by succinyl choline 2 mg/kg to facilitate orotracheal intubation. The trachea was intubated with a cuffed orotracheal tube of appropriate size. Anesthesia was maintained with 60% N₂O in oxygen with 0.5–1% isoflurane. Intermittent boluses of atracurium bromide were used to achieve muscle relaxation. Minute ventilation was adjusted to maintain normocapnia (end tidal carbon-dioxide [EtCO₂] between 34 and 38 mm Hg) and EtCO₂ was monitored. Nasogastric tube of appropriate size was inserted. Hypotension/hypertension was defined as fall/rise in systolic blood pressure of >20% from the baseline values and bradycardia/tachycardia was defined as fall/rise in pulse rate of >20% from the baseline values. Haemodynamic fluctuations were to be managed accordingly. Patients were placed in neutral position. During laparoscopy, intra-abdominal pressure was maintained 12-14 mm Hg. The CO₂ was removed carefully by manual compression of the abdomen at the end of the procedure with open trocar.

Patients and Groups

Patients were randomly allocated to one of the groups using table of randomization. Each group consists of 35 patients. Groups were as follows:

Group A (Ropivacaine 0.5%): Received Ropivacaine 0.5 % (2 mg/kg) dose locally at the incision sites before insufflation.

Group B (Ropivacaine 0.5%): Received Ropivacaine 0.5 % (2mg/kg) dose intraperitoneally at the end of surgery.

Study drugs were prepared by an anesthesiologist not involved in the study. Anesthesiologist who observed the patient and surgeon were unaware of the study group until the end of the study. The neuro-muscular blockade was antagonized with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg and trachea was extubated. The nasogastric tube was removed, and the patient was shifted to post-anesthesia care unit (PACU).

Postoperative management and pain control

All patients stayed in PACU for 24 h after the end of surgery. The primary outcome variable was to compare pain (visual analogue scale [VAS]) score. The Secondary outcome included time to the first request of analgesia in the post-operative period 24 hrs and any adverse/side effects.

The intensity of post-operative pain was recorded for all the patients using VAS score at 0.5, 1, 2, 4, 6, 12, 24 h after surgery and over all VAS score (mean of all VAS scores). All the study patients were instructed about the use of the VAS score before induction of anesthesia (VAS score 0 - no pain, VAS score 10- worst possible pain). Patients who reported VAS >3 were given diclofenac 75 mg intramuscularly as rescue analgesia. The shoulder pain was also included in the VAS score. Patients were also observed for post-operative nausea and vomiting. Patients who suffered nausea or vomiting were given ondansetron 4 mg IV. Time to the first request of analgesia

(considering the extubation as time 0), total dose of analgesia and adverse or side effects over 24 h postoperatively were noted.

Statistical Analysis

A total sample size of 70 patients (n= 35) for each group was calculated using PASSE (power and sample estimation) for study design and analysis. Assuming 30% improvement in pain score with error of 0.05 (i.e. 5% of DOF (degree of freedom) and power of 80%.

Statistical analysis was performed using Microsoft (MS) Office Excel Software (Microsoft Microsoft Excel, Redmond, Washington: Microsoft 2003, Computer software). Results were expressed as mean \pm standard deviation, number and percentage (%). Data were analyzed using *post hoc* analysis method. Normally distributed data were assessed using unpaired Student's *t*-test (for comparison of parameters among groups). Comparison was carried out using Chi-square test with a *P* value reported at 95% confidence level. Level of significance used was *P* = 0.05.

Result

Demographic data of two groups of patients as shown in table 1 were without significant difference. Mean VAS score immediately after the surgery for group A was (2.5 \pm 1.2) significantly lower than group B (5.2 \pm 2.9, *P*=0.0001) Fig 1. First analgesic dose requirement time was longer in group A (6.25 hours) than group B(4.50 hours ,*P*=0.0003) table 2. Total amount of diclofenac sodium required in group A(75 \pm 4.3mg) was less than group B(160 \pm 5.9mg, *P*=0.054) fig2

Table: 1 Demographic data of patients.

Variables	Group A N=35	GROUP B N=35	P VALUE
Age (years)	36.45 \pm 14.65	35.54 \pm 13.37	0.80
Sex (M/F)	12/23	15/20	1.0
Weight (kg)	62.56 \pm 9.50	64.45 \pm 10.50	0.81
Height (cm)	167.4 \pm 5.50	168.30 \pm 6.45	0.265
ASA class (I/II)	24/11	25/10	0.421
Duration of surgery	48.50 \pm 11.50	50.90 \pm 10.92	0.452

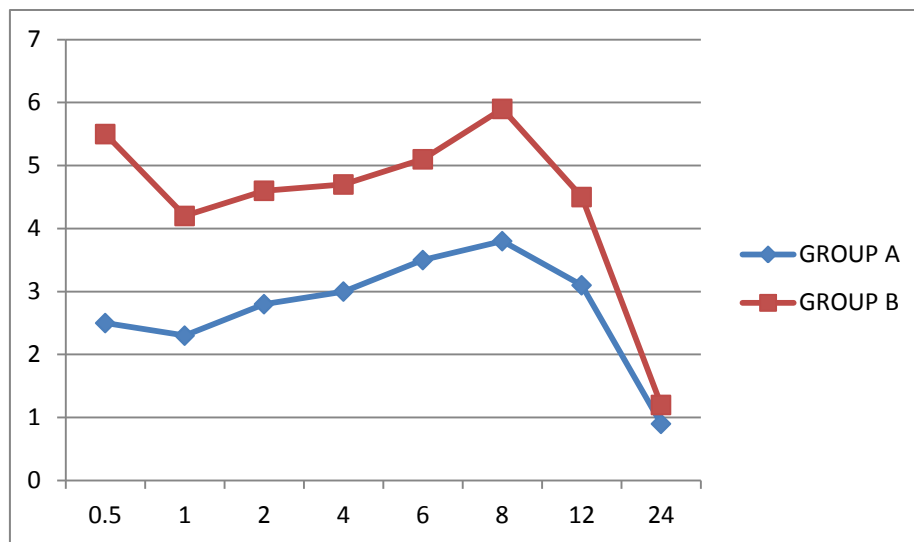


Fig 1. Post operative VAS score (mean±SD) in studied groups:

Table 2: Time to first request of analgesic in postoperative period (hours)

Group	N	Mean	SD	Range	p-value	Remarks
Group A	35	6.25	1.20	4-12	0.003	Sig
Group B	35	4.50	0.80	3-4		

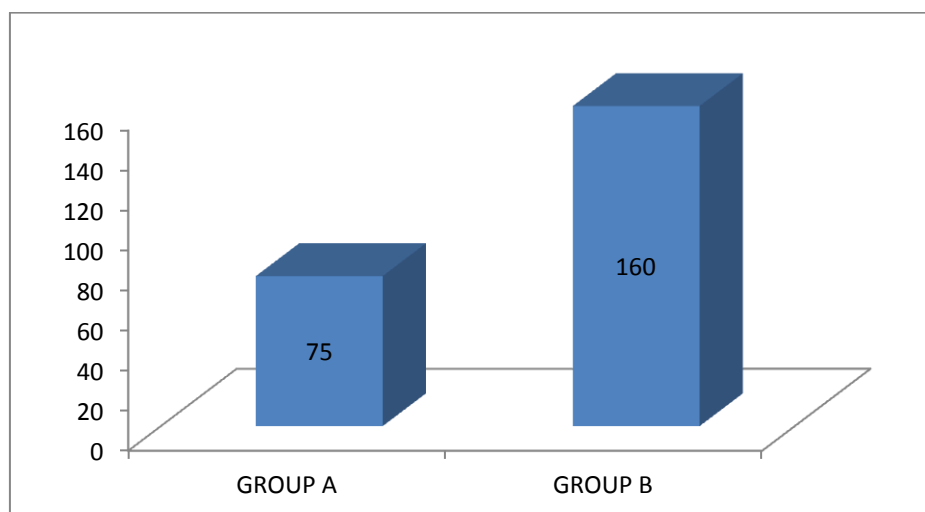


Fig 2.

Discussion

Laparoscopic cholecystectomy results in less postoperative pain as compared with open cholecystectomy and pain may be mild or moderate or even severe for some patients. After laparoscopic cholecystectomy patients complain more of visceral pain as a result of stretching of the intraabdominal cavity, peritoneal inflammation and phrenic nerve irritation caused by residual carbon dioxide in the peritoneal cavity, whereas after open cholecystectomy the type of pain results mostly in parietal pain.⁵

In our study the time for first analgesic requirement was longer with lowest pain intensity in pre-incisional group. Andre Laranjeira et al⁶ studied 2mg/kg 0.75% ropivacaine before incision and after incision. The data of the study shows that morphine consumption was significantly lower in pre-incisional group (1.5mg) as compared to the pre-closure group (5.5mg) or the control group (17mg). Similar to this our data also shows ropivacaine infiltration before incision has decreased post-operative pain intensity, rescue analgesic consumption as compared to after

incision group. The time for first analgesic dose requirement was significantly longer in pre insufflation infiltration group (group A) 6.25 ± 1.20 than at wound closure (group B) 4.50 ± 0.80 . This shows that the application of peritoneal instillation with ropivacaine before the creation of pneumoperitoneum is superior to its use after the completion of surgery. The results were comparable to Barczynski *et al.*⁷ in which latency time in patients who received intraperitoneal bupivacaine before creation of pneumoperitoneum was (426 ± 57 min), whereas it was (307 ± 39 min) in patients who received Intraperitoneal instillation of bupivacaine after the completion of surgery.

Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate myelinated motor fiber, resulting in a reduced motor blockade, and also the reduced potential for central nervous system toxicity and cardio toxicity. Thus it has greater degree of motor sensory differentiation and greater degree of safety margin.⁸ In vitro studies shows that ropivacaine induces vessel contractility there by induces vasoconstriction.⁹ These finding suggests that the vaso-constrictive property of ropivacaine makes it an ideal agent for infiltration.

The recommended dose of ropivacaine used for infiltration is 2-225 mg. one study has demonstrated 300 mg of ropivacaine ($\sim 5\text{mg/kg}$) was well tolerated by 37 patients and significantly reduced post-operative pain after inguinal hernia repair till 7th post-operative day.¹⁰ We used 2mg/kg of 0.5% ropivacaine and found significantly lower VAS score in pre-emptive infiltration group as compared to group B. A study by Horn et al, found infiltration followed by drain lavage with 30 ml of 0.75% ropivacaine significantly decreased post-operative pain and did not observed toxic effects.¹¹

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