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Original Research Article

Postoperative pain relief after laparoscopic cholecystectomy: a comparison between intraperitoneal instillation of ropivacaine and bupivacaine

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ABSTRACT

Background: Although some studies have reported a significant reduction in postoperative pain after the use of intraperitoneal local anaesthetic in laparoscopic cholecystectomy (LC), others have reported no benefit or reduction in analgesic requirement. The present randomized controlled study compares the analgesic efficacy of intraperitoneally instilled local anaesthetic ropivacaine and bupivacaine after LC.
Methods: Sixty patients aged between 18 and 65 years, scheduled to undergo LC and American Society of Anesthesiologist grades I-II were randomly divided into two groups by computer-generated tables. Group A patients received an intraperitoneal instillation of 20 ml of 0.50% ropivacaine and group B patients received an intraperitoneal instillation of 20 ml of 0.50% bupivacaine after completion of the surgery. The primary objective was to compare the presence of post-operative shoulder-tip pain, whereas the secondary objectives were to compare adverse effects and hemodynamic changes. The visual analogue scale (VAS) score and hemodynamic parameters were recorded up to 24 hours postoperatively.
Results: The mean VAS score, heart rate and systolic blood pressure were significantly higher in Group B than in Group A (p value=0.001). The mean diastolic blood pressure was comparable between the two groups (p-value=0.215). The requirement for rescue analgesia was significantly higher in Group B than in Group A (p-value=0.001). The incidence of nausea and shoulder tip pain were comparable between the two groups (p values=0.612).
Conclusions: Intraperitoneal instillation of ropivacaine provides an excellent alternative for intraperitoneal analgesia in laparoscopic cholecystectomy cases.

Keywords: Bupivacaine, Intraperitoneal instillation, Laparoscopic cholecystectomy, Ropivacaine, Visual analogue scale score

INTRODUCTION

Cholecystectomy is the most common surgery of the biliary tract and the second most common operation performed today.[1] Laparoscopic cholecystectomy (LC) has now substituted open cholecystectomy as the first choice of treatment for gallstones and inflammation of the gallbladder except there are contraindications to the laparoscopic approach, since open cholecystectomy may cause post-operative infection.[2] Although it is the belief of patients that laparoscopy has ushered in a pain-free era, the fact remains that patients complain more of visceral pain after LC in contrast to parietal pain experienced in open cholecystectomy.[3] Providing adequate postoperative pain relief is of considerable importance to enhance recovery. Pain after LC is generally less than open cholecystectomy; however, postoperative shoulder and abdominal pain still cause considerable distress.[4] Patients often suffer from visceral pain during coughing, respiration and mobilization. This can lengthen hospital stay and increase

morbidity and costs. The pain after LC may be generated by stretching of the abdominal wall during the pneumoperitoneum and release of inflammatory mediators, local dissection and irritation of the peritoneum produced by blood, bile spillage or CO2 used for pneumoperitoneum.[5]

Various multimodal approaches have, therefore, been tried to ameliorate postoperative pain. These include parenteral analgesics such as nonsteroidal anti-inflammatory drugs, local infiltrations with local anaesthetic, epidural and intrathecal opioids and local anaesthetic, interpleural and intercostal nerve blocks as well as intraperitoneal routes that in turn have been explored with local anaesthetic and opioids.[6,7] The local anaesthetic can be instilled into the peritoneal cavity. This can block visceral afferent signals and possibly alter visceral nociception and downstream illness responses.[8]

Many surgeons administer intraperitoneal local anaesthetic during operation or post-operatively to reduce postoperative pain. This procedure was first used in patients undergoing gynecological laparoscopic surgery.[9] Its application in LC was initially examined in a randomized trial in 1993.[10] Since then, several trials evaluating the efficacy of intraperitoneal local anaesthetic in LC have been published worldwide.[11] Instillation of intraperitoneal lignocaine, bupivacaine, levobupivacaine and ropivacaine has been used following laparoscopic gynecological and general surgical procedures to reduce postoperative pain.[5] Although a number of these studies have reported a significant reduction in postoperative pain after the use of intraperitoneal LA, others have reported no benefit or reduction in analgesic requirement.[11]

Not many studies are available in the literature comparing intraperitoneal instillation of different local anaesthetic solutions for post-operative pain relief in laparoscopic cholecystectomy cases. Hence, the present randomized controlled study was conducted to compare the analgesic efficacy of intraperitoneally instilled local anaesthetic ropivacaine and bupivacaine after LC.

METHODS

The present randomized controlled study was conducted between December 2022 and June 2024 in the major and minor operation theatres of Poona Hospital and Research Centre, a tertiary care hospital, in India. An institutional ethics committee approval (Letter # RECH/ECBHR/2022-23/282 dated 18th November 2022) was obtained before the commencement of the study. The risks and benefits of the procedure were explained to the patients. A written informed consent was obtained from all the patients.

The patients aged between 18 and 65 years, scheduled to undergo LC and American Society of Anesthesiologist (ASA) grades I-II were included. Patients using regular analgesic medications for chronic pain, a history of allergy to drugs or drug components, any contraindication to non-steroid anti-inflammatory drugs and local anaesthetic drugs and patients converted to open cholecystectomy were excluded. In all 70 patients were assessed for eligibility. Ten patients were excluded. Sixty patients were randomly divided into two groups by computer-generated tables. Group A patients received an intraperitoneal instillation of 20 ml of 0.50% ropivacaine after completion of the surgery and group B patients received an intraperitoneal instillation of 20 ml of 0.50% bupivacaine.

The sample size was calculated from a previous similar study conducted 12 by the formula $N^{13}=(2SD^2 (Z\alpha+Z\beta)^2)/\Delta^2$, N is the number of subjects in each group, whereas standard deviation (SD) was taken from previous study and Δ is the difference between means of previous study. The term $(Z\alpha+Z\beta)^2$ is sometimes referred to as power index. The required sample size was 25 in each group. Thirty patients were included in each group to authenticate the results. The primary objective was to compare the presence of post-operative shoulder-tip pain, whereas the secondary objectives were to compare adverse effects and hemodynamic changes.

Written informed consent for participation in the study was taken. A detailed pre-anesthesia check-up was conducted for anaesthesia fitness. In the operation theatre, adequate intravenous (IV) access was confirmed. Heart rate, non-invasive blood pressure (NIBP), mean arterial blood pressure, pulse oximeter, electrocardiogram, SpO2 and end-tidal carbon dioxide ($EtCO_2$) were monitored after intubation. Anesthesia was induced with fentanyl 2 mcg/kg IV, Inj. propofol 2-2.5 mg/Kg IV and Inj. atracurium 0.5 mg / Kg IV. As per the anaesthesia protocol Inj. Ondansetron 4 mg was given to all the patients as an antiemetic.

Intubation with an appropriate-sized cuffed oral endotracheal tube was done and placement was confirmed by auscultation over the chest. The orogastric tube was placed for deflating the stomach. The tube was removed at the end of the surgery.

The anaesthesia was maintained with Oxygen: air 50:50, sevoflurane 1–2.5 % (adjusted according to hemodynamic parameters) with controlled ventilation. EtCO2 was maintained between 30-35 mm of Hg. Inj. Atracurium in supplemental doses of 0.1 mg/Kg was used. After the surgery was over, intraperitoneally instillation of 0.50% ropivacaine and bupivacaine 20 ml was given in Group A and Group B respectively. When the patient's spontaneous respiratory efforts appeared, muscle relaxation was reversed with Inj. neostigmine 50 mcg/Kg and Inj. glycopyrrolate 4 mcg/kg.

During the pre-operative visit, all patients were explained the visual analogue scale (VAS) method of reporting pain. Patients were asked to mark the severity of their pain with the help of a VAS score devised by Yale University.[14] The pain was measured in the recovery room and wards, as soon as the patient was alert enough to use VAS thereafter,

at 0, 2, 4, 8, 16 and 24 hours. Shoulder pain was also assessed. Hemodynamic parameters such as heart rate and blood pressure were measured. At any time, if the pain was more than or equal to 5 on VAS, rescue analgesia in the form of Inj paracetamol 1gm IV was given.

Statistical analysis

The data on categorical variables is shown as n (% of cases) and the data on normally distributed continuous variables is presented as mean and SD. The inter-group comparison of the distribution of categorical variables was tested using the Chi-Square test or Fisher's exact probability test. The inter-group comparison of means of normally distributed continuous variables was done using an independent sample t-test. The underlying normality assumption was tested before subjecting the study variables to a t-test. A p value less than 0.05 was considered statistically significant. The data was analyzed using Statistical Package for Social Sciences (SPSS version 24.0, IBM Corporation, USA) for MS Windows.

RESULTS

Of 70 patients assessed for eligibility, 10 were excluded (Patients using regular analgesic medications for chronic pain 7 and converted to open cholecystectomy 3). Sixty patients were randomized into two groups (Figure 1).

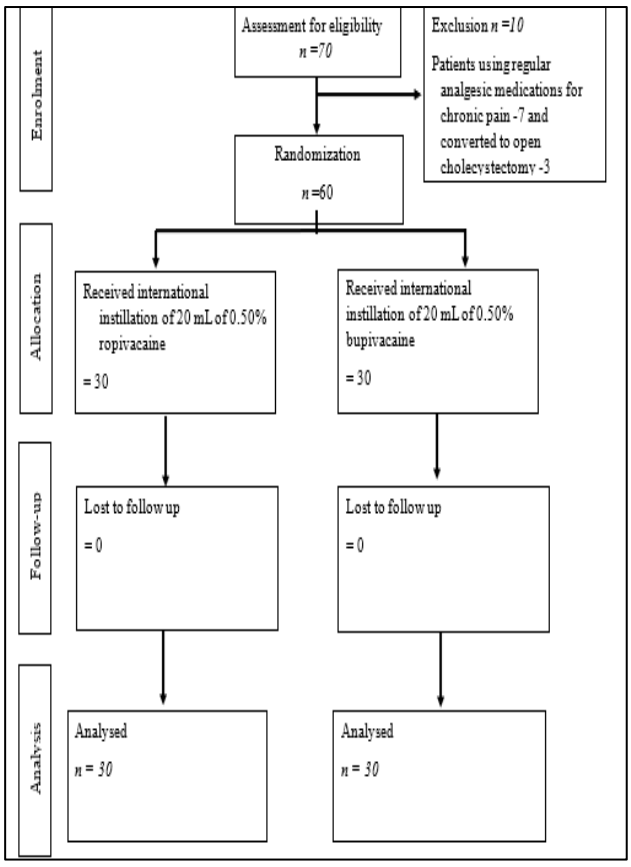

Figure 1: Consolidated standards of reporting trials (CONSORT) flow diagram.

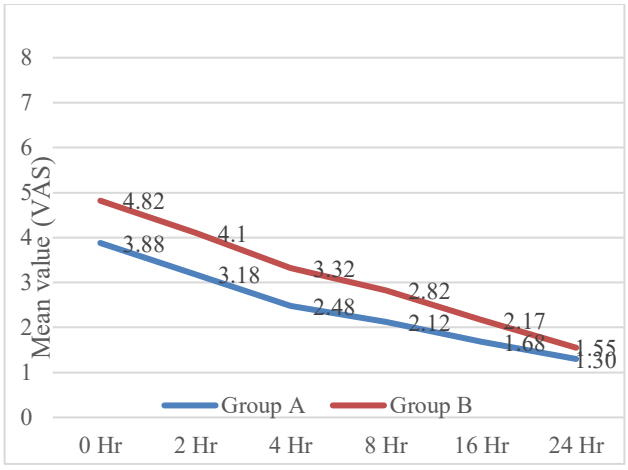

Figure 2: Comparison of mean visual analogue scale score at different postoperative time intervals.

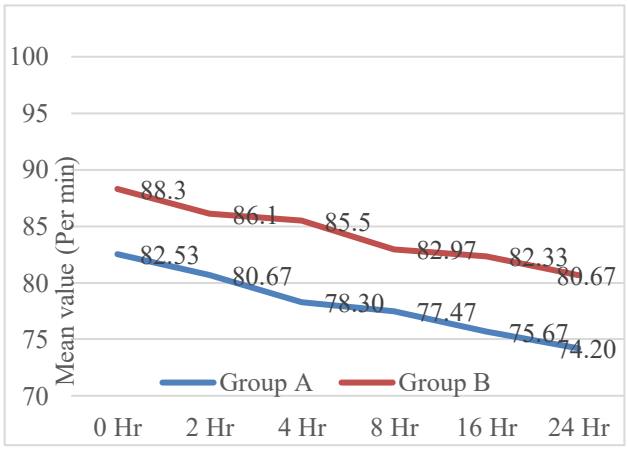

Figure 3: Comparison of mean heart rate at different postoperative time intervals.

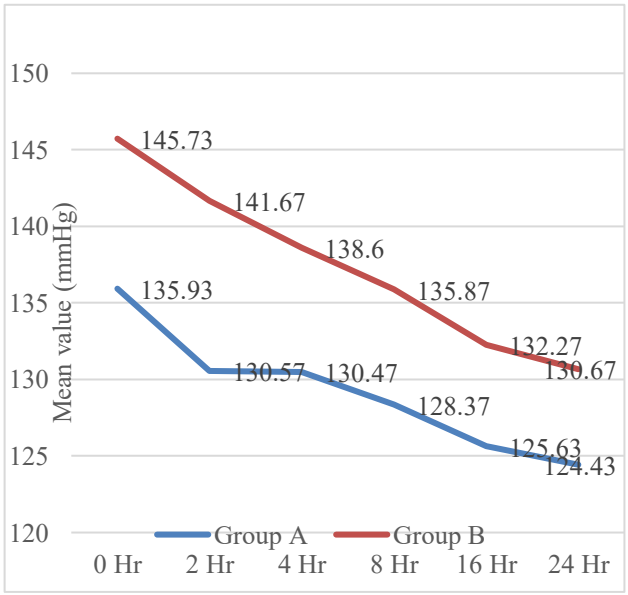

Figure 4: Comparison of mean systolic blood pressure at different post-operative time intervals.

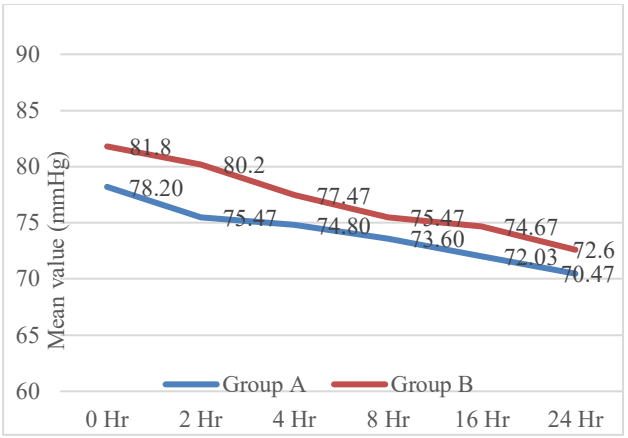

Figure 5: Comparison of mean diastolic blood pressure at different post-operative time intervals.

Group A and Group B patients received an intraperitoneal instillation of 20 ml of 0.50% ropivacaine and 20 ml of 0.50% bupivacaine respectively after completion of the surgery.

The mean age, gender, mean weight and ASA grades were comparable between the two groups (Table 1). The mean VAS score was significantly higher in Group B than in Group A (Figure 2). The mean heart rate, mean systolic blood pressure (BP) and diastolic BP were significantly higher in Group B than in Group A (Figure 3-5).

The incidence of nausea and shoulder tip pain were comparable between the two groups, whereas the requirement of rescue analgesia was significantly higher in Group B than in Group A (Table 2).

Table 1: Comparison of baseline characteristics between the two groups.

	Group A	Group B	P value
Age±SD in years	50.9±9.5	48.1±10.2	0.269*
Gender (%)			
Male	16 (53.3)	14 (46.7)	0.606**
Female	14 (46.7)	16 (53.3)	
Mean weight±SD in Kg	68.5±8.2	70.1±8.6	0.454*
ASA grades (%)			
I	12 (40.0)	13 (43.3)	0.793**
II	18 (60.0)	17 (56.7)	

*An unpaired t-test was used, **The Chi-square test was used, SD–Standard deviation, ASA–American Society of Anaesthesiologists.

Table 2: Comparison of outcome variables between the two groups.

	Group A N (%)	Group B N (%)	P value
Incidence of nausea			
Present	1 (3.3)	3 (10.0)	0.612
Absent	29 (96.7)	27 (90.0)	
Requirement of rescue analgesia			
Required	12 (40.0)	29 (96.7)	0.001
Not required	18 (60.0)	1 (3.3)	
Shoulder tip pain			
Present	1 (3.3)	3 (10.0)	0.612
Absent	29 (96.7)	27 (90.0)	

*The Fisher's exact test was used.

DISCUSSION

Postoperative pain is multifactorial in origin and therefore, multimodal therapy may be needed to optimize pain relief. Improved postoperative pain management using opioid-sparing regimens may facilitate a high success rate of LC. The accurate assessment of pain is difficult because of its individual threshold, subjectivity and difficulty in measurement. The local anaesthetic does not cause the adverse effects of opioids such as post-operative nausea, sedation, impairment of return of gastrointestinal motility and pruritus. Also, the return of post-operative bowel function may be earlier by administering local anaesthetic. In the present study, the mean VAS score, the mean heart rate and the mean systolic and diastolic BP at post-operative time intervals such as 0 h, 2 h, 4 h, 8 h, 16 h and 24 h were significantly higher in Group B compared to Group A. In the present study, the incidence of nausea and shoulder tip pain were comparable between the two groups, whereas the requirement of rescue analgesia was significantly higher in group B than in group A.

The volume of drug we used (20 ml) was with reference to the previous studies conducted by Gupta et al and Bhardwaj et al.[4,15] We used the same volume of drugs but with a lower concentration. Gupta et al, used ropivacaine 0.5% as an intermittent injection through the catheter and they concluded that the early postoperative pain after

ambulatory LC could be relieved using intermittent injections of ropivacaine 0.5% into the bed of the gall bladder. Bhardwaj et al, gave one group normal saline and the other group bupivacaine which showed intraperitoneal instillation of bupivacaine causes good pain relief.[4] A study conducted by Meena et al, observed that heart rate, systolic BP and diastolic BP were comparatively lower in group R (Patients received 0.75% ropivacaine in a dose of 2 mg/Kg diluted in normal saline to make a solution of 50 ml) than in group B (Patients received 0.5% bupivacaine in a dose of 2 mg/Kg diluted in normal saline to make a solution of 50 mL), but the VAS score was significantly lower in Group-R from postoperative 5th to 12th hours.[12] The study further stated that the rescue analgesia requirement was also less in Group R. The study conducted by Chundrigar et al, could not elicit any statistically significant difference in the incidence of shoulder-tip pain in their respective study groups. These results are comparable to our study findings.[10]

A study conducted by Sharan et al, reported that there was no statistically significant difference in the mean pulse rate, systolic BP and diastolic BP, but were comparatively lower in group B (patients received 20 ml of 0.5% ropivacaine intraperitoneally after cholecystectomy) than in group A (patients received 20 ml of 0.5% bupivacaine intraperitoneally after cholecystectomy).[8] The study further stated that the VAS score was significantly lower in Group B at 4, 6 and 8 h (p values 0.03, 0.02 and 0.04 respectively) and the rescue analgesic requirement was also less in Group B but was not statistically significant.

A study conducted by Das et al, observed that trocar site infiltration and intraperitoneal instillation in the gallbladder fossa and subdiaphragmatic hepatic surface using ropivacaine (35 ml of 0.375%) and bupivacaine (35 ml of 0.25%) at the end of surgery as a part of multimodal analgesia provide safe and effective somato-visceral analgesia in patients undergoing LC.[5] The study concluded that ropivacaine provides more profound and prolonged analgesia as compared to bupivacaine. A study conducted by Kucuk et al, reported that the intraperitoneal instillation of 100 mg bupivacaine, 100 mg ropivacaine or 150 mg ropivacaine at the end of an LC significantly reduced the morphine consumption during the first 24 hours.[16] The study further stated that by using 150 mg of ropivacaine prevented postoperative pain more effectively than either 100 mg bupivacaine or 100 mg ropivacaine.

Limitations

The duration of surgery was not noted. The duration of the study was only 24 hours. The VAS requires more concentration and coordination on the part of the patient and may be prone to some error in the immediate postoperative period. We did not measure the plasma concentration of either drug. During general anaesthesia, signs of neurological toxicity are masked, which calls for caution in dosing. The study population was from a single institution and the research was conducted by the same investigator, hence, a multicentric study with a larger sample size should be conducted for the generalizability of these results and to substantiate the findings reported in this paper.

CONCLUSION

Our study showed that intraperitoneal instillation of 20 mL of 0.50% ropivacaine, a local anaesthetic solution, in laparoscopic cholecystectomy provided effective postoperative analgesia. The analgesia provided by ropivacaine was of longer duration and the requirement for rescue analgesia was less than that of bupivacaine. The post-operative haemodynamic parameters were better in the ropivacaine group.

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

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