ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

A Study Comparing Intra-Incisional And Intra-Peritoneal Bupivacaine Infiltration In Controlling Post Operative Pain Following Laparoscopic Cholecystectomy: A Single Tertiary Care Centre Experience.

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ABSTRACT

Postoperative pain is one of the most common adverse events after day surgery with most studies reporting the incidence of moderate-to-severe postoperative pain reaching 25–30%.[1] Laparoscopic cholecystectomy is one of the most frequently performed minimally invasive surgical procedures. To compare the efficacy of intra-incisional and intra-peritoneal infiltration bupivacaine on postoperative pain relief in laparoscopic cholecystectomy. A sample of 150 patients undergoing laparoscopic cholecystectomy were selected using simple random sampling technique. The patients were randomly assigned into three groups 1, 2 and 3. Group 1 was the control group who did not receive bupivacaine either intra peritoneally or intra-incisionally. Group 2 patients received intra-peritoneal infiltration of 20 ml solution of 0.25% bupivacaine and intra-incisional infiltration of 20 ml solution of 0.25% bupivacaine was given in Group 3. The study showed that Group 2 patients had better pain control as compared to group 3 patients. The VAS score at 30 minutes, 2 hours,4 hours ,12 hours and 24 hours was statistically significant in group 2 when compared with the group 1 (control group) and significant till 12hours when compared with group 3. The incidence of shoulder pain was higher in group 3 as compared to group 2. The demand for rescue analgesia was also higher (54%) in group 3 compared to group 2(44%). Intra-peritoneal infiltration of Bupivacaine provides better postoperative pain control following laparoscopic cholecystectomy and is associated with less requirement of analgesia in the postoperative period.

Keywords: intra-peritoneal bupivacaine infiltration, laparoscopic cholecystectomy.

https://doi.org/10.33887/rjpbcs/2023.14.1.27

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ISSN: 0975-8585

INTRODUCTION

Postoperative pain is one of the most common adverse events after day surgery with most studies reporting the incidence of moderate-to-severe postoperative pain reaching 25–30% [1]. Laparoscopic cholecystectomy is one of the most frequently performed minimally invasive surgical procedures [2, 3]. The procedure has many advantages like less postoperative pain [4], early mobility as well as early hospital discharge as compared to open cholecystectomy [5]. Despite these advantages the procedure is associated with varying degrees of postoperative pain. It is seen in early postoperative hours and then subsides slowly over 1 to 2 days. Pain is particularly more with coughing, movement and deep breathing. Postoperative pain has three components visceral pain, parietal pain and shoulder pain [6]. The inadequate treatment of postoperative pain in laparoscopic cholecystectomy (LC) can lead to negative consequences, such as late mobilization, with consequent delay in discharge, development of chronic pain and increased treatment costs [7]. Multimodal analgesia techniques are generally used to relieve pain caused by laparoscopic cholecystectomy. Non-steroidal anti-inflammatory drugs, epidural analgesia, opioids, incision site (port site) and intra-peritoneal local anaesthetic application are among the multimodal analgesia options [8].

The main reason for using multimodal analgesia techniques is to avoid possible side effects by limiting the utilisation of commonly used opioids to provide postoperative analgesia [9]. So far many studies have been done using intra-peritoneal or intra-incisional local anaesthetic infiltration, but the results have been conflicting [10-13].

In the present study, our aim was to compare the efficacy of intra-incisional vs intra-peritoneal infiltration of bupivacaine in the management of post-operative pain following laparoscopic cholecystectomy.

METHODS

The study was conducted in the departments of General Surgery and Anaesthesia at Government Medical College, Jammu, India. It was a randomised prospective case control study carried out between April 2021 to March 2022. A total of 150 patients with ASA I and II, belonging to the age group of 18-65yrs and posted for laparoscopic cholecystectomy under general anaesthesia were included. A written and informed consent was signed from all patients before enrolling them in the study.

Patients with uncontrolled co-existing systemic illness , BMI>30kg/m^2, known allergic reactions to local anaesthetics, acute cholecystitis and conversion to an open procedure were excluded from the study.

All necessary preoperative investigations were carried out. Pre-Anaesthetic checkup was done a day prior to surgery and included a detailed history and thorough physical as well as systemic examination. Basic demographic characteristics like age, gender, weight and height were noted.

Preoperatively, the patients were also introduced to the visual analogue scale (VAS) showing a 10cm straight line, where 0 meant no pain and 10 was worst possible pain. The patients were told to mark on the line to describe the intensity of pain. Lottery method was used for random distribution of patients into the groups 1, 2 and 3 comprising of 50 patients each.

Double blind technique was used for the study. Surgeon was responsible for patient randomization and site of local anaesthetic administration while resident doctor was responsible for data collection. The resident doctor as well as patient were blinded to the patient's status concerning local analgesia.

Tab Alprazolam 0.5 mg and Tab Pantoprazole 40 mg were given orally the night before surgery and all patients were kept nil per oral. In the operation theatre, intravenous line using appropriate sized cannula and ringer lactate infusion was started at the rate of 10ml/kg body weight. The patients were pre medicated with injection ondansetron 0.1 mg/kg for prevention of PONV.

Patients were pre-oxygenated and anaesthesia was induced using Propofol 2mg/kg. Tracheal intubation was achieved with the help of atracurium 0.5mg/kg. Anaesthesia was maintained with 1%

Isoflurane, nitrous oxide and oxygen in the ratio of 1:1. Intraoperative analgesia was given using paracetamol infusion. Additional doses of atracurium were given if required. Standard monitoring was performed using NIBP, heart rate, SpO2, ETCO2 and ECG. The pneumoperitoneum was established. Intra-abdominal pressure was maintained at 12mmHg. All operations were carried out using four ports, 10mm umbilical and 10mm subxiphoid in midline, 5mm in right subcostal area on midclavicular line and another 5mm in the anterior axillary line.

Group 1 was the control group and did not receive either intra-peritoneal or intra-incisional bupivacaine. Group 2 patients received intra-peritoneal instillation of 20 ml, 0.25% bupivacaine in the gall bladder fossa and right subhepatic space at the end of the laparoscopic procedure at the end of procedure while group 3 patients received port site(intra-incisional) infiltration into the fascia, muscle and pre-peritoneal space (20ml, 0.25% bupivacaine, 6ml for 10mm ports and 4ml for 5mm ports respectively). Residual muscle paralysis was reversed with neostigmine 0.04mg/kg and glycopyrrolate 0.01mg/ kg at the end of procedure. Abdominal drains were not used in any patient. After extubation patients were shifted to PACU.

After 30 minutes of monitoring, patients were shifted to parent ward. Our outcome variables were: Pain assessment by VAS, requirement of rescue analgesic and the occurrence of postoperative nausea and vomiting (PONV). The time of arrival in the post-operative recovery room was defined as zero hour post-operatively. Pain assessment was performed at 30 minutes, 2 hours, 4 hours, 12 hours and 24 hours postoperatively. Record of onset of pain and rescue analgesia was maintained by resident doctors. Diclofenac sodium 75mg was given as rescue analgesia when the VAS reported by the patient was 4 or more.

Statistical analysis

Descriptive statistics was done using mean with standard deviation (SD) for quantitative variables and categorical variables were presented in frequencies along with respective percentages. The statistical comparisons for quantitative variables were done using ANOVA & Student's 't' test while for categorical variables Chi-square was used as per the nature of data. All statistical analysis were performed by using MedCalc and SPSS software (Version 22, SPSS Inc, Chicago, IL, USA). The p value ≤0.05 was considered as statistically significant.

RESULTS

This study included 150 patients with 50 patients assigned in each group 1,2 and 3. The demographic characteristics of the studied patients has shown that all groups were matched as regarding age, gender and weight. Analysis of the demographic variables were not statistically significant between the three groups. Majority of the patients belonged to female gender(50% in group 1, 56% in group 2 and 54% in group 3).The difference in the mean duration of surgery between the groups was statistically insignificant.(Table 1)

Table 1: Demographic variables

Variables	Group 1 (n=50)	Group 2 (n=60)	Group 3 (n=50)	p-value
Gender				
Male (%)	25 (50.0)	22 (44.0)	23 (46.0)	0.6873
Female (%)	25 (50.0)	28 (56.0)	27 (54.0)	
Mean Age (years)	38.4 ± 10.28	39.5 ± 11.19	41.2 ± 9.77	0.403
Mean weight (Kg's)	65.1 ± 9.57	63.5 ± 9.13	64.7 ± 7.86	0.645
Mean duration of surgery (min.)	45.6 ± 7.22	47.3 ± 6.95	44.3 ± 6.14	0.089

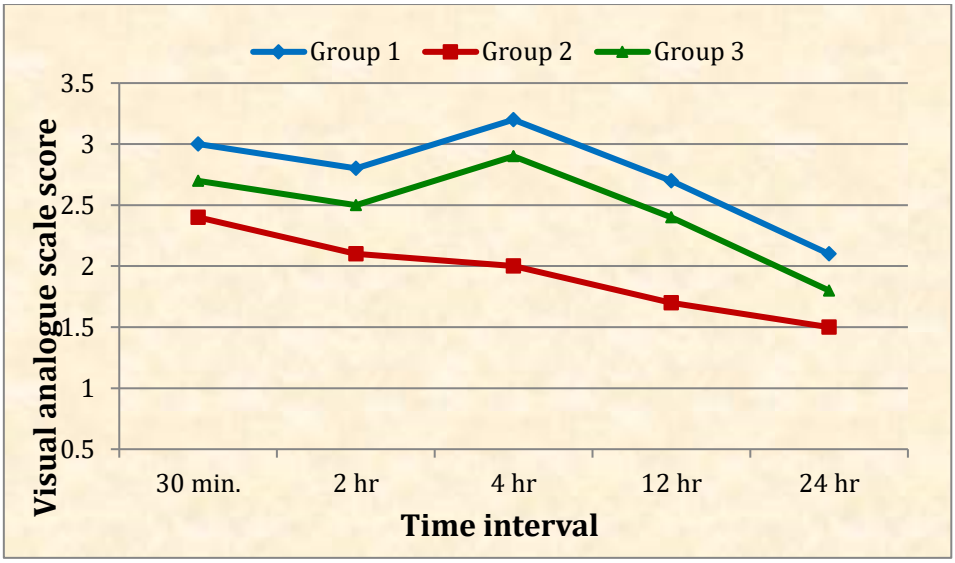
The VAS score at 30 minutes, 2 hours,4 hours ,12 hours and 24 hours was statistically significant in group 2 when compared with the group 1 (control group).The VAS score was statistically significant between groups 2 and 3 at 30 minutes, 2 hours,4 hours and 12 hours as shown in Table-2. As far as group 3 was concerned, there was a statistical difference in VAS scores, only at 30 minutes in comparison to group 1.

ISSN: 0975-8585

Table 2: Post operative pain using VAS

Time	Group 1 (n=50)	Group 2 (n=50)	Group 3 (n=50)	Group comparison (p-value)		
				1 vs 2	1 vs 3	2 vs 3
30 min.	3.1 ± 1.0	2.4 ± 0.8	2.7 ± 0.9	0.0013	0.0381	0.0208
2 hr	2.8 ± 1.2	2.1 ± 0.7	2.5 ± 1.1	0.0006	0.1956	0.0325
4 hr	3.2 ± 1.4	2.0 ± 0.8	2.9 ± 1.2	<0.0001	0.2528	<0.0001
12 hr	2.7 ± 1.2	1.7 ± 0.6	2.4 ± 0.8	<0.0001	0.1445	<0.0001
24 hr	2.1 ± 0.8	1.5 ± 0.5	1.7 ± 0.9	0.0011	0.0815	0.1727

Figure 1. Line diagram showing the trend of postoperative pain using VAS score.



The above line diagram shows the trend of postoperative pain using VAS score at 30 mins, 2 hours, 4 hours, 12 hours and 24 hours.

The incidence of right shoulder pain was statistically significant between groups 1 vs 2 and 1 vs 3 but the percentage of patients that reported pain was higher in group 3 in comparison to group 2. The requirement of rescue analgesia was also statistically significant in groups 2 and 3 compared to group 1 but the demand for rescue analgesia was higher (54%) in group 3 compared to group 2(44%). There was statistically insignificant difference between the incidence of PONV(Post-Operative Nausea Vomiting) in the 3 groups.(Table-3).

Table 3: Incidence of right shoulder pain, PONV and requirement of rescue analgesia.

Time	No. of patients (%)			Group comparison (p-value)		
	Group 1 (n=50)	Group 2 (n=50)	Group 3 (n=50)	1 vs 2	1 vs 3	2 vs 3
Right shoulder pain	41 (82.0)	19 (38.0)	23 (46.0)	<0.0001	<0.0001	0.3831
Rescue analgesia	46 (92.0)	22 (44.0)	27 (54.0)	<0.0001	<0.0001	0. 3191
PONV	28 (56.0)	19 (38.0)	24 (48.0)	0.0623	0.4322	0.2831

DISCUSSION

Laparoscopic cholecystectomy (LC) is a widely performed surgical procedure that achieves superior outcomes in postoperative pain, recovery time, cosmetic issues, and morbidity [14]. LC is associated with less postoperative pain than open cholecystectomy, but patients still experience significant pain. Pain after LC is characterized by body component, which is different from laparotomy [15]. This difference is roughly divided into abdominal and shoulder pain, according to location [16].

Abdominal pain consists of two components: visceral pain associated with tissue injury due to gallbladder dissection and the stretching of nerve endings in the peritoneal cavity; and parietal pain related to the incisional trauma at the port sites. Shoulder pain is referred by diaphragmatic stretching [17].

The pain following laparoscopic cholecystectomy remains a prevalent problem of the early post-operative period and may delay discharging the patient, especially in day-case departments. It reaches a peak within the first few hours following the operation but diminishes with time [18]. Various studies have been carried out to demonstrate postoperative pain control with local anaesthetics after laparoscopic surgery and proved the effective role of local anaesthetics in this regard [19-21]. In this study, we analysed the effectiveness of intra-peritoneal infiltration of bupivacaine injection in comparison to intra-incisional infiltration after laparoscopic cholecystectomy.

A significant number of trials have examined the intra-peritoneal administration of local anaesthetics in laparoscopic cholecystectomies as regards to post-operative pain and narcotic analgesic consumption, with promising results [10, 22-24], while others have noted only reduced shoulder pain with overall pain not affected [25]. However, other studies indicate that the postoperative analgesia and narcotic usage was not significantly different in the groups that received local anaesthesia [26-28].

Elhakim *et al.* [25] have shown that intra-peritoneal Lidocaine reduces effectively both shoulder pain and abdominal post-operative pain after laparoscopic cholecystectomy. A study by Geun Joo Choi *et al* [29]. concluded that intra-peritoneal administration of local anaesthetics is an effective method of postoperative pain relief including visceral, somatic and shoulder pain. In the present study the incidence of right shoulder pain was significantly lower in intra-peritoneal group compared to intra-incisional group.

Wei X *et al.* [30] demonstrated that intra-peritoneal levobupivacaine provides additional benefits for pain relief after laparoscopic cholecystectomy. Elhakim M *et al.* [25], concluded that intra-peritoneal lidocaine is simple to use and results in a long-lasting reduction of pain after a single administration. A study conducted by Mraović B *et al* [31] comparing intra-peritoneal infiltration of bupivacaine and saline demonstrated that pain was more intense in the saline group at each time point and the analgesic consumption was significantly lower in the bupivacaine group. In the present study, intra-peritoneal infiltration of bupivacaine turned out to be a statistically effective method of postoperative pain control after laparoscopic cholecystectomy as compared to port site infiltration of local anaesthetic.

Singh R R *et al.* [32] demonstrated effectiveness of port site instillation of bupivacaine at the beginning and end of laparoscopic procedures. A study carried out by Gouda M El- labban *et al.* [33] concluded that intra-incisional infiltration of levobupivacaine is more effective than intra-peritoneal infiltration for postoperative pain relief. Similarly, Lepner *et al.* [28] observed better postoperative pain relief with port site local anaesthetic infiltration Our results are consistent with that of Bano N *et al.* [34], who have compared both intra-incisional and intra-peritoneal infiltration of local anaesthetic. Their study has shown that intra-peritoneal infiltration of bupivacaine significantly reduces postoperative pain in laparoscopic cholecystectomy and there is less demand for rescue analgesia as compared to port site local anaesthesia infiltration. In the present study, post-operative right shoulder pain was less with patients assigned to intra-peritoneal infiltration of bupivacaine than those assigned to the intra-incisional group. There was also lesser requirement of rescue analgesia in the intra-peritoneal group. The incidence of PONV was lower in the intra-peritoneal group but the difference was statistically insignificant.

CONCLUSION

The present study showed that intra-peritoneal infiltration of bupivacaine is more effective than intra-incisional infiltration for the control of postoperative pain following laparoscopic cholecystectomy thereby decreasing the postoperative analgesic requirements.

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