# **Original Research Article**

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# A prospective observational study: combined irrigation of bupivacaine at the gallbladder fossa with infiltration at port site for postoperative pain relief after laparoscopic cholecystectomy

Palak Paliwal<sup>1</sup>, Tanweerul Huda<sup>1</sup>, Krishnanand Anand<sup>1</sup>, Manish Shivani<sup>2</sup>, Navneet Mishra<sup>1\*</sup>

<sup>1</sup>Department of General Surgery, <sup>2</sup>Department of Anaesthesia, Lakshmi Narain Medical College, Bhopal, India

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# \*Correspondence:

Dr. Navneet Mishra,

E-mail: drnavneetmishra@yahoo.com

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#### **ABSTRACT**

**Background:** Laparoscopic cholecystectomy is a well-established procedure for gallbladder disease. Pain in laparoscopic cholecystectomy is associated with multiple factors: somatic, visceral, and phrenic nerve irritation. Effective analgesic support should, therefore, be a multimodal approach following laparoscopic surgery for better patient compliance.

**Methods:** A prospective, randomized observational study was undertaken at a tertiary research center for a period of two years (2018-2020). 160 patients undergoing laparoscopic cholecystectomy were chosen and randomized using a computer program into 2 groups. No infiltration was given in the control population. The study group was irrigated with a 0.5% bupivacaine solution (20cc in 30 ml normal saline).

**Results:** The bupivacaine group required fewer analgesics in comparison to the control faction, with less pain at 6 hrs. The timing of oral intake and ambulation were comparable in both factions.

**Conclusions:** Combined bupivacaine use led to a considerable decrease in postoperative pain thereby leading to decreased analgesic use.

**Keywords:** Laparoscopic cholecystectomy, Bupivacaine, Analgesia, Port site infiltration, Gall bladder, fossa infiltration

## **INTRODUCTION**

Laparoscopic cholecystectomy is a well-established procedure for gallbladder disease. The morbidity associated with conventional cholecystectomy has reduced significantly with laparoscopic cholecystectomy. In the era of laparoscopic cholecystectomy, early discharge and return to routine activity have become feasible owing to minimal invasion. The post-operative compliance from the patient and the satisfaction level has significantly improved with this technique. The management of pain in the postoperative period is crucial in aiding the recovery of the patient.

The pain in laparoscopic cholecystectomy is mainly parietal somatic pain which tends to conceal the deep visceral pain experienced by the patient. Pain is associated with multiple factors in laparoscopic cholecystectomy: somatic, visceral, and phrenic nerve irritation.<sup>2,3</sup>

With the advancement in pain management, the postoperative stay has been reduced significantly. Therefore, it is done in various centers as a daycare procedure. However, pain is the main cause of an overnight hospital stay and a longer convalescence in around 17-41% of patients.<sup>4</sup> Effective analgesic support should, therefore, be a multimodal approach as post-operative pain following laparoscopic surgery is considered as a complex entity in itself.<sup>5</sup> The support consists of making the patient feel comfortable, explaining the procedure to the patient and its complication, and administration of a non-steroidal anti-inflammatory analgesic agent an hour before surgery. It should additionally include local anesthetic infiltration at the incision site, perioperatively administration of an opioid, infiltrating the peritoneal cavity with a local anesthetic, along with fluids, electrolytes, and nutrition.<sup>5-9</sup>

With our study, we are assessing the use of the irrigation of a local anesthetic, such as bupivacaine, at gall bladder fossa combined with local infiltration at the incision site for postoperative analgesia and its effect on patient's comfort. We have tried to determine whether this analgesic approach decreases the postoperative use of non-steroidal anti-inflammatory drugs.<sup>7,8</sup>

#### **METHODS**

It is a randomized prospective, observational study undertaken at a tertiary research hospital from a period of 2018-2020. Eligible candidates from age 18 to 65 years and both sexes were selected and were explained the procedure. Exclusion criteria were pregnancy, cholecystectomy in acute cholecystitis, complicated cases requiring a drain, and bodyweight below 50 kgs. Patients undergoing chronic treatment with any analgesic or anti-inflammatory agents for some other conditions were also excluded. Well, informed consent was taken from all participants.

160 patients undergoing laparoscopic cholecystectomy were chosen using simple random sampling and randomized by a computer program into 2 groups. No infiltration was given in the control population. The study group was irrigated with a 0.5% bupivacaine solution (20cc in 30 ml normal saline).<sup>10</sup>

Before surgery, all the patients underwent routine preoperative investigations including upper abdominal sonography. All patients received iv ceftriaxone 1gm one hour before the surgery, and the induction was performed using cisatracurium or vecuronium, propofol, and fentanyl.

A standard 4 port trocar technique was used in all patients. Pneumoperitoneum was created using either a closed verses needle technique or an open technique. Laparoscopic cholecystectomy was performed and after assuring hemostasis surgical bed was irrigated with an irrigation cannula. No patients had any complications. After irrigating the gallbladder bed and deflating the abdomen, instruments, and trocars were removed. All the port site was also infiltrated with 10cc of 0.5% bupi vacaine. <sup>11</sup>

Using a visual analog scale (VAS) postoperative pain was assessed. It was done postoperatively in the recuperation room at 0 hours, 6 hours, 12 hours, and 24 hours. All patients received analgesics (i.e., iv acetaminophen) postoperatively if needed, and this requirement was duly noted. Post-operative symptoms like vomiting, nausea, and fever were additionally noted during the hospital stay. The initiation of the oral intake as well as ambulation of the patient was noted.

## **RESULTS**

160 participants were recruited in this study where 95 were women, and 65 were men ranging in age from 18 to 54 years. The result was statistically significant for the age in both study groups (Table 1).

Table 1: Demographic data.

Characteristics	Bupivacaine (processing group)	Placebo group	P value
Female/Male	50/30	45/35	0.135
Age (SD)	29.7(9.2)	36.7(9.5)	0.001

A substantial difference in the average pain rates between the experimental and control groups was observed postoperatively at 6 hours (Table 2). There was no need for any analgesia in the combined bupivacaine faction until the 4th postoperative hour, and also a decreased requirement in the later hours. Thus, a decreased total analgesic requirement in comparison to the control faction.

Table 2: VAS pain comparison between the two groups.

Visual analog scale	Bupivacaine (processing group) (n=80)	Placebo (control group) (n=80)	P value
Pain T0 p50 (p25–p75)	2.5 (2-3.5)	3.4(3-5)	0.0001
Pain T6 p50 (p25–p75)	4.78 (4.5-5.5)	6(6-7.5)	0.0237
Pain T12 p50 (p25–p75)	5 (3-4)	4.5(4-6)	0.0371
Pain T24 p50 (p25-p75)	2.25 (2-3)	3(3-5)	0.0449

The most commonly identified postoperative symptom was nausea, with a 13 percent incidence in the bupivacaine faction and 18 percent in the control faction. No significant statistical difference was observed. 10 patients overall experienced vomiting, 2 from the bupivacaine group, and 4 from the placebo group. Only a single patient in the combined bupivacaine faction and 2 patients in the control faction experienced fever. These patients received 500 mg of acetaminophen per oral every

6 hours and were discharged the second day after surgery (Table 3).

**Table 3: Comparison of post-operative symptoms.** 

Postsurgical Symptoms (n%)	Bupivacaine (processing group) (n=80)	Placebo (control group) (n=80)	P value
Nausea	13 (16.5)	18 (22.5)	0.002
Vomiting	4 (5.0)	6 (7.5)	0.12
Fever N	1 (0.25)	2 (2.5)	0.65

The timing of oral intake and ambulation were comparable in both groups (Table 4).

Table 4: Comparison of recovery indices.

Variables	Bupivacaine (processing group) (n=80)	Placebo (control group) (n=80)	P value
Time to start eating hr p50 (p25-p75)	14.5 (13-15)	18 (14-19)	0.004
Time to walk hr p50 (p25-p75)	10 (9-12)	13 (10.5-14.5)	0.035

Of the 160 patients recruited in the study, 124 required intravenous postoperative analgesics; 48 patients were in the bupivacaine community and 76 from the control faction. A significant statistical difference was found (P~0.004) (Table 5). This variation was found mainly postoperatively at the 6-hour interval.

Table 5: Comparison of the analgesia requirement in the two groups.

Variables	Bupivacaine (processing group) (n=80)	Placebo (control group) (n=80)	P value
Analgesia required	48 (60%)	76 (95%)	0.004

# **DISCUSSION**

Laparoscopic cholecystectomy is a well-established procedure for gallbladder disease due to the patient's comfort, early discharge, and reduced morbidity associated with this procedure. As the stay has been reduced, management of pain in the post-operative period is of considerable importance, therefore, making anaesthetic irrigation ideal for such patients. Post-operative pain in such patients is observed at a peak immediately after surgery and decreases after 24 postoperative hours. This study demonstrates the use of 0.5% bupivacaine infiltration at the surgical site to reduce post-operative pain in laparoscopic cholecystectomy.

160 participants were recruited in this study where 95 were women, and 65 were men ranging in age from 18 to 54 years. The result was statistically significant for the age in both study groups. This was comparable with the earlier studies.<sup>1</sup> a substantial difference in the average pain rates between the experimental and control groups was observed postoperatively at 6 hours. This was comparable with previous studies.<sup>1,2</sup> thus, a decreased total analgesic requirement in comparison to the control faction as seen with previous studies.<sup>1,2</sup> with our findings, early post-surgical pain is believed to have been caused by peritoneum and diaphragm irritation, and bupivacaine application would reduce post-operative pain.

The most commonly identified postoperative symptom was nausea, with a 13 percent incidence in the bupivacaine faction and 18 percent in the control faction. No significant statistical difference was observed as compared with the previous studies. 1,2 the timing of oral intake and ambulation were comparable in both groups in relation to previous studies. 1,2

Of the 160 patients recruited in the study, 124 required intravenous postoperative analgesics; 48 patients were in the bupivacaine community and 76 from the control faction. A significant statistical difference was found (p~0.004). This was comparable with the previous studies.<sup>1,2</sup> no immediate analgesia was required in 32 patients of the bupivacaine group. While, in the control faction, 4 patients didn't require any analgesia. The pain experienced by both the groups was mild to moderate intensity and mostly located in the right upper quadrant followed by pain experienced at trocar sites.

A noteworthy difference was witnessed in the vas score in both the groups for the decrease in pain in patients irrigated with bupivacaine at 6th postoperative hours. To conclude, there was greater visceral pain management within the bupivacaine community during the immediate postoperative hours.

It is noteworthy that pain manifestation varies from person to person which depends largely on the pain threshold of each person, so the tool utilized to measure pain is subjective. Thus, postoperative analgesia is better with combined bupivacaine infiltration. But this does not cause a decrease in other symptoms such as nausea.

# **CONCLUSION**

With this research, it is safe to conclude that postoperative analgesia is better with combined bupivacaine infiltration leading to fewer analgesic requirements. Combined bupivacaine use during laparoscopic cholecystectomy ensured a swifter recovery, ambulation, more patient compliance, and shorter hospital stay. In conclusion, the dosage of bupivacaine was remarkably safe and caused no significant side effects. Therefore, pain management is considerably better with combined bupivacaine use in patients who

undergo laparoscopic cholecystectomy in ambulatory centers. However due to the limited size of the sample, a larger study is warranted to better correlate the findings.

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Institutional Ethics Committee

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