



EFFECTS OF INTRAPERITONEAL BUPIVACAINE VERSUS PLACEBO ON POSTOPERATIVE PAIN AFTER LAPAROSCOPIC CHOLECYSTECTOMY: A RANDOMISED DOUBLE BLIND STUDY

Anaesthesiology

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ABSTRACT

Background & Aims: Postoperative abdominal and visceral pain after elective Laparoscopic Cholecystectomy (LC) is of prime concern to patients as it causes significant distress. (1)(2) The aim of our study was to evaluate the benefit of intraperitoneal bupivacaine irrigation on the surgical bed versus placebo.

Methods: 50 patients undergoing elective laparoscopic cholecystectomy were included in the study. They were prospectively randomised into 2 groups. The placebo group (Group P, n = 25) received 35 cc saline without bupivacaine, installed into the gallbladder bed. The bupivacaine group (Group B, n=25) were given 35 cc of 0.25% bupivacaine at the same location. Pain was evaluated at regular intervals of 0, 5, 10, and 24 hours using the visual analogue scale (VAS).

Result: A significant difference (P=) was seen on VAS to evaluate post-operative pain between two groups at 5 hours post operatively.

Conclusion: Irrigation of local anaesthetic bupivacaine at the gall bladder bed can be an effective method for decreasing post-operative pain in the first 5 hours after laparoscopic surgery.

KEYWORDS

Intraperitoneal, bupivacaine, local anaesthetic

INTRODUCTION:

Laparoscopic Cholecystectomy (LC) is one of the most frequently performed elective day care procedures.

Provision of adequate postoperative pain relief is of considerable importance to enhance recovery.

Pain after LC is generally lesser than open cholecystectomy; however postoperative shoulder and abdominal pain still cause considerable distress (1)

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

Postoperative abdominal & visceral pain after elective LC is of prime concern to patients as it causes significant distress.(1,2)

Instillation of intraperitoneal lignocaine, bupivacaine, levobupivacaine and ropivacaine has been used following laparoscopic gynaecological and general surgical procedures to reduce postoperative pain through randomized trials for many years (3-10)

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

This study was conducted to ascertain the analgesic efficacy of intraperitoneally instilled local anaesthetic's after LC.

The **Aim of our study** was to evaluate the benefit of intraperitoneal irrigation of local anaesthetic bupivacaine versus placebo on postoperative pain after LC when used as a part of multi modal analgesia.

MATERIALS AND METHODOLOGY:

After ethical committee approval of the university and written informed consent, a double blind randomized, prospective clinical study was carried out in Saraswathi Institute of Medical Sciences, Anwarpur, Hapur(U.P.), in patients undergoing elective Laproscopic Cholecystectomy under General Anesthesia.

Study Duration: Two years (September 2019 to August 2021)

Sample Collection: 50 cases were included in the study (25 cases in each group)

Study Design: Randomized, double-blind, prospective, clinical study. Patients were divided by using Slips in the box method into one of the two groups:

Group Placebo (P): received 35 cc of 0.9% normal saline instilled into the gallbladder bed.

Group Bupivacaine (B): received 35 cc of 0.25% bupivacaine (87.5 mg) instilled into the gallbladder bed.

All the study drugs were prepared and coded by an anaesthetist who was not part of the study and the anaesthetist conducting the study was unaware of the drug being injected. The patient was blind to the drug injected as well

Inclusion Criteria:

- Written & informed consent from all the patients.
- Aged 18- 60 years,
- undergoing elective laparoscopic cholecystectomy
- (ASA) physical status I & II patients of either sex

Exclusion Criteria:

- ASA grade III-IV
- allergy to local anesthetics
- chronic pain syndromes
- prolonged opioid medication
- Patients needing bile duct exploration, insertion of a T-drain or patients with acute cholecystitis
- surgery related complication eg., bile spillage or conversion to open cholecystectomy or if the surgery exceeded 200 minutes

METHODOLOGY

All patients underwent thorough medical evaluation and investigations.

Intraoperative monitoring included five lead ECG with standard lead II, NIBP monitor, pulse oximeter, ETCO₂ monitor and temperature monitor.

All patients received standard premedication and general endotracheal anaesthesia.

All surgical procedures were performed by an experienced surgeon.

Standard 10 mm trocar umbilical port and epigastric ports were used.

Intraperitoneal pressure was maintained at 10 mmHg using a flow rate of 3 l/min and the operative table placed in the reverse Trendelenberg with left side down tilting position.

After removal of the gallbladder and haemostasis, residual blood, fluid and CO₂ were thoroughly suctioned.

The surgeon instilled 20 ml of test drug in the subdiaphragmatic suprahepatic surface of liver and 5 ml in the gallbladder fossa.

The patient was maintained in the right lateral Trendelenberg position for 10-15 minutes. Further, 10 ml was used for port-site infiltration.

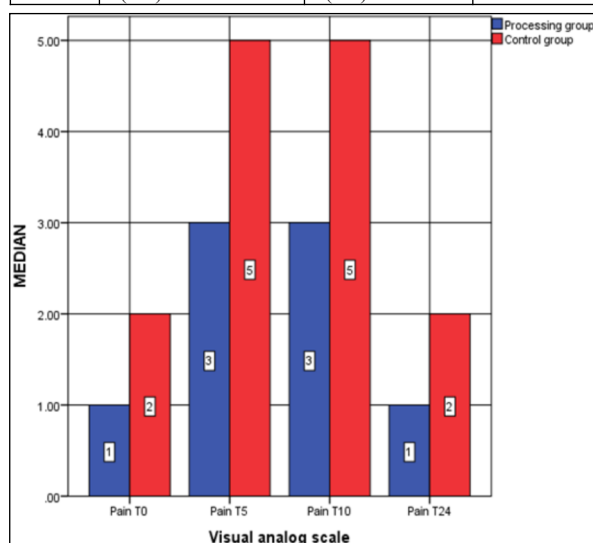
Pain scores were recorded immediately on arrival in Post Anaesthesia Care Unit (PACU), at 0, 5th hour, 10th hour and 24th hour after surgery using **Visual Analogue Scale [VAS]**.

For breakthrough pain, inj paracetamol 1gm intravenous infusion was given as first line rescue analgesia & injection tramadol 1 mg/kg intravenous or diclofenac 1 mg/kg intravenous infusion was given as the second line rescue analgesia.

RESULTS:

Time taken for first analgesic requirement is longer in group B when compared to P group. It is statistically significant in 0 and 5th hour with P value—0.0023 & 0.0001 respectively.

Visual analogue scale	Group B[Processing group] (n=25) Median (range)	Group P[Control group] (n=25) Median (range)	P-value
Pain T0	1 (1-2)	2 (1-5)	0.0023
Pain T5	3 (2-5)	5 (4-6)	0.0001
Pain T10	3 (4-2)	5 (2-5)	0.8230
Pain T24	1 (1-2)	2 (1-2)	0.6273



DISCUSSION:

Many clinical trials have been carried out to assess analgesic effects of local anaesthetics instilled intraperitoneally into the gallbladder bed and right subdiaphragmatic space [10].

The rationale for this route is that the peritoneum is exposed to block the visceral nociceptive conduction from the area of tissue damage and the peritoneum, thereby providing an additional mechanism of analgesia.

However, absorption from the large peritoneal surface may be a further mechanism of analgesia. Intraperitoneal administration of local anaesthetic has also been shown to reduce nausea and vomiting [11].

Ahmed BH et al., in their study concluded that normal saline instillation also provides analgesia [12]. **Donatsky AM et al.**, conducted a systematic review to study the role of intraperitoneal saline in prevention of postoperative pain in LC [13]. Their findings also support the analgesic action of normal saline in the form of intraperitoneal instillation. Thus, we compared the effect of intraperitoneal local anaesthetic drugs with normal saline.

Narchi P et al., compared 0.5% lignocaine and 0.125% bupivacaine intraperitoneal infiltration with normal saline and control in day-case laparoscopic surgeries [14]. Local anaesthetics were found to be more effective in reducing postoperative shoulder pain and analgesic requirements were lesser in the local anaesthetic groups. Our study also found that intraperitoneal local anaesthetics provide better analgesia as compared to that of saline.

Roberts KJ et al., compared 0.25% bupivacaine and normal saline

given subcutaneously in trocar sites, subdiaphragmatically and intraperitoneally as a topical wash [15]. VAS scores were lowest for the longest period in the subdiaphragmatic & intraperitoneal wash technique group with local anesthetic rather than with normal saline group. In our study also, VAS scores were lowest for the longest period in the bupivacaine group as compared to saline

Kim TH et al., instilled ropivacaine (2 mg/kg) intraperitoneally at the beginning of laparoscopy. VAS scores were significantly lower in the ropivacaine group as compared to the normal saline group [16].

Our finding of a more efficacious pain relief by intraperitoneal local anaesthetic instillation over that of normal saline (control) is in keeping with the findings of above studies

The bupivacaine group had stable haemodynamics and this can be attributed to the better analgesia provided by the local anaesthetics over that of normal saline.

Adverse effects associated with the use of local anaesthetic, such as allergic reactions and local tissue, cardiovascular, central nervous system and systemic toxicity were not observed in our study with the use of local anaesthesia. No patient from the entire study population had any complications. This shows that intraperitoneal instillation of bupivacaine in the volume and dose used in our study is not associated with any adverse effects

CONCLUSION:

- Irrigation of local anaesthetic 0.25% bupivacaine at the gallbladder bed can be an effective method for decreasing postoperative pain in the first 5 hours after laparoscopic cholecystectomy
- This technique of providing postoperative analgesia is simple, effective and will help in improving the postoperative recovery profile of the patient and help in making it a truly out-patient based surgery.

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