**Оригінальна стаття** / *Original article*

Том 8, № 1–2 • 2023

PainMedicine Journal

**Медицина Болю // Медицина Боли**

www. painmedicine.org.ua

Міждисциплінарний • Науково-практичний журнал


DOI: 10.31636/pmjua.v8i1–2.4

# Assesment of postoperative analgesic effects of intramuscular tramadol administration and intraperitoneal bupivacaine following laparoscopic cholecystectomy

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**Abstract:**

**Background:** *for postoperative pain relief after laparoscopic surgeries, intramuscular or intravenous non-steroidal anti-inflammatory drugs and opioids, infiltration at the incision site with local anesthetics, intraperitoneal infiltration of local anesthetics with adjuvants, epidurals and nerve blocks were in use. The study was aimed to assess the efficacy of intramuscular Tramadol and intraperitoneal instillation of bupivacaine on postoperative analgesia, postoperative nausea, and vomiting following laparoscopic cholecystectomy.*

**Methods:** *this study included 60 American Society of Anesthesiologists (ASA) I and ASA II patients of aged 18–60 years who were scheduled for laparoscopic cholecystectomy under general anesthesia. 60 patients were classified randomly into two groups equally: Group-T received 100 Mg of intramuscular tramadol and Group-B received intraperitoneal instillation of 30 ml of plain bupivacaine. Time duration, postoperative pain, haemodynamics, nausea, vomiting, and time taken to rescue analgesia were noted.*

**Results:** *the time for onset of analgesia was 6.51 ± 2.41 min in Group-T and 7.61 ± 2.19 min in Group-B (P = 0.039). The duration of analgesia was 2.37 ± 0.67 hours in Group-T and 3.65 ± 0.79 hours in Group-B (P = 0.002). VAS Score was significantly lower in Group-T than Group-B at 1 hr, 2 hr, 4 hr and 6 hr (P < 0.05). Intraperitoneal bupivacaine showed a significant reduction in postoperative pain for the first 6 hours postoperatively (P < 0.05), and time taken to rescue analgesia requirement was prolonged (P < 0.05). The rescue analgesia consumption of Paracetamol was 1.5 grams in Group-B and 2.5 grams in Group-T (P < 0.05) in 24 hr post-surgery. Nausea and vomiting were observed in 2 cases, and shoulder pain in one case in Group-T.*

**Conclusion:** *bupivacaine is effective in reducing postoperative pain, and it prolongs the requirement time for rescue analgesia after LC surgery. It also required less consumption of rescue analgesic without fluctuations in hemodynamics.*

**Key words:** *bupivacaine, cholecystectomy, hemodynamics, tramadol, wound infection*

## Introduction

Laparoscopic Cholecystectomy (LC) is the gold standard for gallstone disease and is commonly performed in surgical settings.[1] Laparoscopic Cholecystectomy offered several advantages, including a short hospital stay, rapid return to regular activities, reduced postoperative discomfort, painkiller demand, rapid recovery of gastrointestinal function, lower postoperative wound infection, and enhanced cosmetic appearance.[2,3] Following laparoscopic cholecystectomy, pain radiates from the incision site to visceral regions,[4] and shoulder tip (sub-diaphragmatic region).[5] For postoperative pain relief, various methods such as intravenous or intramuscular NSAIDs[6] and opioids,[7] infiltration at the incision site with local anaesthetics [8], intraperitoneal infiltration of local anaesthetics,[8] local anaesthetics with adjuvants,[9] and regional anaesthesia techniques such as epidurals and nerve blocks are used. All of these have varying success rates.[10]

Tramadol has been reported to have local anaesthetic action in addition to its central action on opioid receptors, as well as noradrenergic and serotonergic actions.[11] It has 5–10th the analgesic efficacy of morphine. However, it can cause nausea, vomiting, urinary retention, and hypotension.

Bupivacaine inhibits the transmission of visceral pain from diaphragmatic irritation to the shoulder tip via the phrenic nerve (C3C4C5) and has a local analgesic effect. It has a long duration of effect of 180–300 minutes and a lower incidence of nausea, vomiting, and pruritis when compared to opioids. Bupivacaine, a long-acting amide local anesthetic, can be administered alone or in conjunction with tramadol to provide epidural post-operative analgesia.

There have been few studies comparing Tramadol with bupivacaine on postoperative analgesia in patients undergoing laparoscopic cholecystectomy.

Hence, the current study was carried out to evaluate the effects of Tramadol and bupivacaine on postoperative analgesia in patients who had had laparoscopic cholecystectomy.

## Patients and methods

### *Study type*

From March 2018 to March 2019, a randomized prospective study was carried out at the department of Anesthesia at Narayana Medical College and Hospital.

### *Patient randomization*

The study was carried out after the taking patient's informed consent. A computer-generated table randomly assigned patients to two groups. A total of 60 patients aged 18–60 years with ASA I and II physical status were scheduled for elective laparoscopic cholecystectomy under general anaesthesia. Based on the previous study results, a sample size of 30 patients per group was calculated for analysis of variance with a power of 80 % and a-level of 0.05.

Patients between the ages of 18 and 60 who were planned to have a laparoscopic cholecystectomy, ASA grades I and II, weight 30–80 kg, and who could give informed consent were included.

Patients who were allergic to the study drugs, patients who were unwilling to comply, a history of epilepsy, cardiovascular disease, or severe hepatic or renal disease were all eliminated.

### *Study groups*

Group-T received 100 mg intramuscular tramadol, whereas Group-B received 30 ml of 0.5 % bupivacaine (bupivacaine dose not to exceed 2.0 mg/kg body weight).

The primary outcome was to compare the analgesic efficacy of tramadol and bupivacaine, as well as the duration of pain alleviation. Secondary outcomes included a comparison of the hemodynamics and side effects of two medications.

General anaesthesia: after obtaining consent, administering a local anaesthetic test dosage, and confirming the lack of allergic responses, the patient was sent to the operating room. A non-invasive blood pressure monitor, an ECG, etco2 and spo2 were all attached. Premedication included inj. glycopyrrolate 0.2 mg IV, inj. ondansetron IV, and inj. fentanyl 2 μg/kg. After preoxygenation, induction was done with inj. Propofol 2 mg/kg and inj. succinylcholine 2mg per kg and intubated with appropriate size endotracheal tube. Inj. vecuronium 0.1 mg/kg loading dose given. Maintenance with $N_2O : O_2$ in 2 : 1 ratio and sevoflurane 1–2 % and inj. vecuronium 1mg was given.

### *Procedure*

Trained surgeons performed the surgeries. Following skin incision and umbilical port insertion, the abdomen was inflated with $CO_2$ and intraabdominal pressure was maintained at 12–14 mm of Hg. Following surgery, the patient groups were given inj. Bupivacaine 0.5 % 20 ml intraperitoneally or inj. Tramadol 100 mg intramuscular.

Following instillation of the research medicines, the Respiratory rate, Systolic blood pressure, Diastolic blood pressure, and Pulse rate were measured at various time intervals.

Post-operative pain is measured using a visual analogue scale. Intravenous Paracetamol (1 gr) was given as rescue analgesia when required / demanded or VAS > 4, up to a maximum of 4 gr in 24 hours.

The pain score is measured at 1, 2, 4, 6, 8, 10, and 12 hours after surgery, once the patient is fully awake and responding to verbal orders.

### *Statistical analysis*

S Data were expressed as mean, median, frequency, and percentage. To analyze quantitative data, the Statistical Package for the Social Sciences version 20 (IBM, Armonk, NY, USA) was used. The unpaired Student's t-test was used to examine demographic data. The Student t-test was used to determine whether there was a significant difference in mean pain score between the two groups. P<0.05 was considered statistically significant.

## Results

There was no difference between the two groups in terms of age, gender, body weight, ASA class, or duration of operation. Females outperformed males in both groups. (Table 1). There was a statistically significant difference between the two groups in terms of analgesia onset (P = 0.039) and duration of analgesia (P = 0.002). A statistically significant increase in analgesic duration was observed in Group-B cases as compared to Group-T. Individuals in Group-T had a statistically significant faster onset of analgesia than individuals in Group-B.

After medication infusion, mean SBP was measured at 1 hour intervals in both groups for the duration of the study and compared to baseline SBP; the difference was not statistically significant. Following the instillation of the study medicines, SBP was measured at 2 hour intervals in both groups during the observation period and compared to baseline SBP, which was shown to be statistically significant. After the study medicines were instilled, the mean DBP was collected at 2 hour intervals in both groups during our observation period and compared to baseline DBP; the difference was statistically significant (P > 0.05). The difference in mean heart rate at the 5-hour post-surgery period in Group-B participants was not statistically significant (P > 0.05). In Group-T, mean HR was collected at 1-hour intervals and compared to baseline HR; the difference was determined to be statistically significant (P < 0.05) (Table 2).

The mean DBP was measured at 1 hour intervals in both groups over the study period and compared to the baseline DBP; the difference was not statistically significant (P > 0.05).

The mean VAS score was examined one hour after surgery, as well as two, four, six, eight, ten, and twelve hours afterwards. The mean VAS score after 1, 2, 4, and 6 hours post-surgery was higher in Group-T than in Group-B, and the difference was statistically significant (Table 3).

The mean time interval of the first rescue analgesia (Paracetamol) demand was longer in Group-B compared to Group-T, which was statistically significant. In the first 24 hours after surgery, the majority of patients in Group-T experienced mild to moderate pain, while the

**Table 1. Demographic profile, duration of surgery and anesthesia in study groups**

| | Group-B | Group-T | P value |
|---|---|---|---|
| Age | 44.5 ± 9.65 | 42.6 ± 7.95 | 0.71 |
| Gender (male/female) | 13/17 | 12/18 | 0.5 |
| Body weight (kg) | 72.5 ± 10.8 | 72.8 ± 9.6 | 0.78 |
| Duration of surgery (min) | 53.9 ± 4.9 | 54.7 ± 5.18 | 0.69 |
| Onset of analgesia (minutes) | 7.61 ± 2.19 | 6.51 ± 2.41 | 0.039* |
| Duration of analgesia (hours) | 3.65 ± 0.79 | 2.37 ± 0.67 | 0.002* |

**significant*

**Table 2. Mean Systolic blood pressure, Diastolic blood pressure, Pulse rate, and Respiratory rate in study groups**

| | | Baseline | 5 min | 15 min | 30 min | 1 hour | 2 hour | 5 hour |
|---|---|---|---|---|---|---|---|---|
| SBP (mmHg) | Group-B | 115.65 ± 11.15 | 113.6 ± 11.6 | 115.4 ± 11.62 | 110.15 ± 11.6 | 108.9 ± 12.9 | 109.15 ± 12.55 | 111.25 ± 12.45 |
| | Group-T | 111.2 ± 10.5 | 116.5 ± 11.8 | 113.6 ± 11.5 | 116.14 ± 11.9 | 116.85 ± 11.85 | 117 ± 13.6 | 118.5 ± 9.12 |
| | P value | 0.035 | 0.04* | 0.41 | 0.049* | 0.003* | 0.003* | 0.21 |
| DBP (mmHg) | Group-B | 74.15 ± 11.5 | 72.7 ± 11.9 | 73.25 ± 10.35 | 72.6 ± 10.6 | 69.6 ± 9.18 | 69.2 ± 9.69 | 70.6 ± 9.5 |
| | Group-T | 72.55 ± 10.66 | 72.6 ± 11.6 | 72.4 ± 9.5 | 78.8 ± 9.12 | 75.6 ± 11.23 | 75.9 ± 10.8 | 84 ± 6.5 |
| | P value | 0.22 | 0.55 | 0.39 | 0.05* | 0.042* | 0.003* | 0.008* |
| Pulse rate (beats per minute) | Group-B | 78.12 ± 11.05 | 77.95 ± 7.95 | 78.5 ± 9.6 | 76.5 ± 9.8 | 77.85 ± 8.56 | 77.55 ± 11.15 | 81.12 ± 9.5 |
| | Group-T | 75.23 ± 6.5 | 75.6 ± 9.5 | 76.75 ± 8.4 | 75.2 ± 9.1 | 76.45 ± 7.85 | 77.25 ± 9.5 | 78.95 ± 10.78 |
| | P value | 0.079 | 0.085 | 0.25 | 0.072 | 0.32 | 0.45 | 0.35 |
| Respiratory rate (breaths per min) | Group-B | 18.85 ± 2.6 | 19.5 ± 2.7 | 18.62 ± 2.5 | 18.35 ± 2.3 | 18.25 ± 2.55 | 18.11 ± 2.4 | 18.6 ± 2.42 |
| | Group-T | 17.55 ± 2.35 | 18.3 ± 2.1 | 17.62 ± 2.32 | 19.15 ± 2.42 | 17.98 ± 2.17 | 18.98 ± 2.2 | 19.95 ± 2.4 |
| | P value | 0.02 | 0.039* | 0.071 | 0.69 | 0.45 | 0.04* | 0.07 |

**Table 3. Postoperative visual analog scale (VAS) in study groups**

| | Group-B | Group-T | P value |
|---|---|---|---|
| VAS score | | | |
| 1 hour | 1.12 ± 0.92 | 2.42 ± 1.52 | <0.0001* |
| 2 hours | 1.11 ± 0.09 | 2.52 ± 0.65 | <0.0001* |
| 4 hours | 2.02 ± 0.11 | 2.75 ± 0.96 | <0.0001* |
| 6 hours | 1.98 ± 1.11 | 2.86 ± 1.12 | 0.002* |
| 8 hours | 2.15 ± 1.25 | 2.42 ± 1.41 | 0.35 |
| 10 hours | 2.38 ± 3.75 | 2.69 ± 1.2 | 0.14 |
| 12 hours | 1.85 ± 5.11 | 1.85 ± 0.95 | 0.27 |
| Mean time interval of the first rescue analgesia | 7.62 ± 2.5 | 6.25 ± 2.45 | 0.04* |
| Postoperative nausea and vomiting | 0 | 2 | — |
| Postoperative shoulder pain | 0 | 1 | — |

majority of patients in Group-B experienced minor discomfort.

In 24 hours after surgery, the rescue analgesia intake of Paracetamol was 1.5 gr in Group-B and 2.5 gr in Group-T. There was no significant difference between the groups in terms of side effects at different time intervals after patients were transferred to the recovery room. Postoperative nausea and vomiting occurred in two patients in Group-T, and shoulder pain occurred in one. In Group-B, there was no postoperative nausea or vomiting.

## Discussion

Laparoscopic cholecystectomy is a part of day case surgery hence adequate analgesia and early recovery is of the highest importance. Postoperative discomfort is less severe following laparoscopic cholecystectomy than after open cholecystectomy, although it is still a significant cause of morbidity.[12] Parietal pain and visceral pain can occur during laparoscopic cholecystectomy. Referred shoulder tip discomfort is caused by the prolonged elevation of the diaphragm and leftover gas from pneumoperitoneum. Because of its great potency and prolonged duration of action, bupivacaine is administered intraperitoneally for postoperative pain management.

In this study, we examined the efficacy of intraperitoneal Tramadol and Bupivacaine in patients undergoing laparoscopic cholecystectomy. Instillation of anaesthetics intraperitoneally around the operative site is used as an analgesic technique on the assumption that conduction from visceral sites is obstructed and may lessen the intensity of referred pain to the shoulder, which results from irritation of diaphragm innervations, i.e., C3, C4, C5, and diaphragmatic shifting due to gaseous distension, in the post-operative period.[13] Absorption from the systemic circulation may also contribute to analgesia.[14]

According to current research, Bupivacaine reduces post-operative pain and analgesic intake in the first 24 hours following surgery, as well as provides a longer pain-free period when compared to patients who received tramadol after laparoscopic cholecystectomy.

The current study's findings were consistent with those of previous research.[15] The current study also found that individuals who received intraperitoneal bupivacaine experienced 2–5 hours of reasonably pain-free time.

Previous research has shown that tramadol administration generates superior post-operative analgesia in the early post-operative period after laparoscopic cholecystectomy than an identical intraperitoneal dose of tramadol in patients having laparoscopic cholecystectomy. During the first post-operative hour, tramadol patients had lower parietal and visceral pain scores.[16]

In our study, Group-T had a higher VAS score than Group-B. This was similar to other investigations.[9,15,17–19]

Raetzell et al. compared bupivacaine (0.125 % and 0.25 %) to normal saline and found no difference in pain scores between the groups,[20] which could be related to the lower concentration of bupivacaine utilised. Choi et al. reviewed 39 random control trial reviews and concluded that intraperitoneal local anaesthetics did not significantly diminish parietal pain but had a favourable analgesic impact on visceral pain and shoulder pain.[21]

In our study, the mean time for analgesia onset in Group-T patients was 6.51 ± 2.41 min, whereas the mean time for analgesia onset in Group-B was 7.61 ± 2.19 min. There was statistically significant quick onset of analgesia in patients of Group-T than patients of Group-B.

In our study, the mean duration of analgesia in Group-T cases was 2.37 ± 0.67 hrs and 3.65 ± 0.79 hrs in Group-B. There was a statistically significant increase in analgesic duration in Group-B patients when compared to Group-T cases. Yadava A et al found that the mean duration of analgesia was 71.62 ± 5.73 min in Group-T and 72.39 ± 4.8 min in Group-B.

In our investigation, the average time taken for the first analgesic dose was longer in Group-B than in Group-T. Another study found that patients who received normal saline had higher rates of rescue analgesia dose than those who got Bupivacaine.[22] Shalan et al observed that the pain score and necessary analgesic dose were lower in the bupivacaine group after laparoscopic pelvic surgery.[23]

Heart rate, systolic blood pressure, and diastolic blood pressure were measured at baseline, 15 minutes, 1 hour, 2 hours, and 5 hours in our study. At 5 hours, the mean heart rate of patients in groups T and B was not statistically significant. At 2 hours, the mean SBP of patients in groups T and B differed statistically (P = 0.003). The mean SBP of patients in groups T and B at 5 hours is not statistically significant (P = 0.22). The mean DBP of patients in groups T and B at 1 hour differed statistically significantly (P = 0.042). The mean DBP of patients in groups T and B at 2 hours was statistically significant (P = 0.003). At 5 hours, the mean DBP of patients in

groups T and B differed statistically (P = 0.008). When compared to patients who received Tramadol after laparoscopic cholecystectomy, Bupivacaine reduced the HR to a level that was somewhat lower than baseline and remained constant. This is consistent with other study findings. However, a considerable reduction in mean arterial pressure was also noted, which was not detected in our investigation.[24]

In our investigation, the mean difference in VAS score between patients in groups B and T at 1 hour, 2 hours, 4 hours, and 6 hours was statistically significant.

Yadava et al and Shukla et al found similar results.

Post-operative nausea and vomiting were noted in two patients in Group-T, but not in Group-B. These findings were consistent with those of other studies.[25]

In our study, no postoperative shoulder tip pain was seen in Group-B. Putta et al observed that the incidence of shoulder pain was lower in both groups receiving bupivacaine than in those getting normal saline.[26]

The current investigation used lower dosages of bupivacaine than those thought to produce systemic toxicity, and none of our patients showed signs of local anaesthetic toxicity. Several investigations have shown that the range of mean plasma concentration (0.92–1.14 g/ml) following simple intraperitoneal bupivacaine injection (100–150 mg) is much below the lethal threshold of 3 g/ml.[27] Bupivacaine use resulted in no adverse effects or toxicity. Similar findings were observed in a research by Hazinedarogle et al.[28] The Goldstein et al study found a decreased rate of PONV in patients who were given Bupivacaine.[29]

## Conclusion

Current study observed that Bupivacaine lowers the postoperative pain and increases the time needed for rescue analgesia. Although hemodynamic parameters and side effects were comparable in both groups, intraperitoneal instillation of Bupivacaine after laparoscopic surgery renders patients relatively pain-free in the first 24 hours after surgery, with a longer duration of pain-free period and less consumption of rescue analgesics in the post-operative period as compared to tramadol administration. We conclude that intraperitoneal Bupivacaine instillation is a safe and effective means of providing postoperative analgesia with no side effects.

## Ethics statement

Consent was obtained by all participants in this study.

## Acknowledgement

Authors acknowledges to the patients for their co-operation, and teaching and technical staff of the department.

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**Оцінка післяопераційних знеболюючих ефектів внутрішньом'язового введення трамадолу та внутрішньочеревного введення бупівакаїну після лапароскопічної холецистектомії**

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**Анотація**

**Мета:** *для післяопераційного знеболювання після лапароскопічних операцій використовували внутрішньом'язове або внутрішньовенне введення нестероїдних протизапальних препаратів та опіоїдів, інфільтрацію в місці розрізу місцевими анестетиками, внутрішньоочеревинну інфільтрацію місцевих анестетиків з ад'ювантами, епідуральні анестетики та блокади нервів. Метою дослідження було оцінити ефективність внутрішньом'язового введення трамадолу та внутрішньоочеревинної інстиляції бупівакаїну щодо післяопераційної анальгезії, післяопераційної нудоти та блювання після лапароскопічної холецистектомії.*

**Методи:** *це дослідження включало 60 пацієнтів Американського товариства анестезіологів (ASA) I та ASA II віком 18–60 років, яким була призначена лапароскопічна холецистектомія під загальною анестезією. 60 пацієнтів були розподілені випадковим чином на дві однакові групи: група T отримувала 100 мг трамадолу внутрішньом'язово, а група B отримувала внутрішньоочеревинну інстиляцію 30 мл простого бупівакаїну. Відзначали тривалість, післяопераційний біль, гемодинаміку, нудоту, блювання і час, витрачений на рятівну анальгезію.*

**Результати.** *Час початку анальгезії становив 6,51 ± 2,41 хв у групі T і 7,61 ± 2,19 хв у групі B (P = 0,039). Тривалість анальгезії становила 2,37 ± 0,67 години в групі T і 3,65 ± 0,79 години в групі B (P = 0,002). Показник VAS був значно нижчим у групі T, ніж у групі B, через 1 годину, 2 години, 4 години та 6 годин (P < 0,05). Внутрішньоочеревинне введення бупівакаїну продемонструвало значне зменшення післяопераційного болю протягом перших 6 годин після операції (P < 0,05), а час, необхідний для невідкладної анальгезії, був подовжений (P < 0,05). Споживання парацетамолу для екстреної анальгезії становило 1,5 грама в групі B і 2,5 грама в групі T (P < 0,05) через 24 години після операції. У групі T у 2 випадках спостерігалися нудота і блювання, в одному випадку – біль у плечі.*

**Висновок:** *Бупівакаїн є ефективним у зменшенні післяопераційного болю та подовжує час, необхідний для невідкладної анальгезії після лапароскопічної холецистектомії. Це також вимагало меншого споживання невідкладного анальгетика без коливань гемодинаміки.*

**Ключові слова:** *бупівакаїн, холецистектомія, гемодинаміка, трамадол, ранова інфекція.*