



COMPARISON OF INTRA-PERITONEAL BUPIVACAINE AND INTRAVENOUS PARACETAMOL FOR POSTOPERATIVE PAIN RELIEF AFTER LAPAROSCOPIC CHOLECYSTECTOMY

Anaesthesiology

Dr. Vaaraada Mallika

Post Graduate, Department of Anesthesiology, Siddhartha Medical College, Vijayawada.

Dr. Noorulla. KAS*

M.D, Associate Professor Department of Emergency Medicine, Siddhartha Medical College, Vijayawada. *Corresponding Author

Dr. K. Samson Dev Sundar

Assistant Professor, Dept. of Anesthesia, Siddhartha medical College, Vijayawada.

ABSTRACT

Introduction: Non-steroidal anti-inflammatory drugs (NSAIDs) used for postoperative analgesia have significant side effects, with paracetamol having a different mechanism of action, a better side effect profile, and intravenous (IV) availability. **Aims And Objectives:** Aim of the study was to compare intra-peritoneal bupivacaine to intravenous paracetamol for postoperative analgesia after laparoscopic cholecystectomy. **Materials And Methods:** It is a prospective randomized clinical trial. After ethics committee approval and written informed consent. This study was undertaken in the Government General Hospital, affiliated to Siddhartha Medical College, Vijayawada, Andhra Pradesh. The study included 60 patients with American Society of Anesthesiologists physical status I and II who were scheduled for laparoscopic cholecystectomy. Group I patients were given 2 mg/kg of 0.5% bupivacaine as a local intra-peritoneal application, Group II patients were given IV 1 g paracetamol every 6 hours. Postoperative pain was assessed using the Visual Analog Scale (VAS), Visual Rating Prince Henry Scale (VRS), and shoulder pain. The total number of patients who required rescue analgesia, as well as any side effects, were recorded. The data was analysed using the Students unpaired t-test. $P < 0.05$ was considered statistically significant. **Results:** At the 8th, 12th, and 24th postoperative hours, the VAS scores in Group I were significantly higher than in Group II ($p = 0.001$). Although VRS in Group I was higher than VRS in Group II at the 12th and 24th postoperative hours, the difference was statistically significant only at the 24th postoperative hour 1.53 ± 0.50 vs 1.23 ± 0.43 ($p = 0.016$). Up to 8 hours postoperatively, none of the patients in either group experienced shoulder pain. The total number of patients requiring analgesics was higher in Group II than in Group I. **Conclusion:** Although local anaesthetic infiltration and intra-peritoneal administration of 0.5% bupivacaine reduce the severity of incisional, visceral, and shoulder pain in the early postoperative period, IV paracetamol provides long-term pain relief after elective laparoscopic cholecystectomy for 24 hours.

KEYWORDS

Laparoscopic cholecystectomy, intra-peritoneal bupivacaine, intravenous paracetamol, postoperative analgesia.

INTRODUCTION

- Laparoscopic cholecystectomy was introduced by Phillippe Mouret in 1987 is now the gold standard for the treatment of gallstones disease.[1]
- Pain after laparoscopic cholecystectomy is usually an acute pain, sharp in character.
- Although it is less when compared with open cholecystectomy, some patients still experience considerable discomfort in the (24–72hrs) postoperative period, which may lead to delayed discharge from hospital.
- The origin of pain after laparoscopic cholecystectomy is multifactorial.
- Pain from incision sites is somatic pain, pain from the gallbladder bed is visceral in origin and shoulder pain is mainly due to the residual CO₂ irritating the diaphragm.
- Postoperative pain causes hemodynamic changes such as tachycardia, hypertension increased cardiac work, nausea, vomiting, and ileus. Thus, pain relief and patient comfort during the early postoperative period becomes increasingly important.
- Adequate postoperative pain relief is one of the most important factors in determining when a patient can be discharged from a surgical facility and important factor to determine when patient can resume their normal activities of daily living [7]
- Perioperative analgesia has been traditionally provided by opioid analgesics. However, extensive use of opioids is associated with perioperative side effects.
- Multimodal or balanced analgesic techniques in which smaller doses of opioids in combination with nonopioid analgesic drugs
- This study was undertaken to compare efficacy of intra-peritoneal bupivacaine and IV paracetamol for postoperative analgesia following laparoscopic cholecystectomy.

AIMS AND OBJECTIVES

The aim of the study was to compare intraperitoneal bupivacaine to intravenous paracetamol for postoperative analgesia after laparoscopic cholecystectomy.

Objective of the study is to compare the following parameters in the study groups.

- Intensity of pain by VRS and VAS.

- Duration of post operative pain relief
- 24 hour post operative analgesic requirement

MATERIALS AND METHODS

Study Design:

A Prospective Randomized double blind clinical study.

Place Of Study:

Government General Hospital, Siddhartha Medical college, Vijayawada.

Duration Of Study: January 2022 – August 2022.

Study Subjects:

Patients Admitted to General surgery unit, GGH/Siddhartha Medical College, Vijayawada undergoing elective Laparoscopic cholecystectomy under General Anaesthesia.

After obtaining approval by the ethical's committee and getting written informed consent from all patients, 60 patients belonging to American Society of Anesthesiologists (ASA) physical Status I or II aged between 18 and 60 years scheduled for elective laparoscopic cholecystectomy were included in this study.

Inclusion Criteria

- Age 18 – 60 years
- Both sex
- American society of Anaesthesiologist (ASA) grade I-II.

Exclusion Criteria

- Patient refusal,
- Acute cholecystitis,
- Inability to understand and use the VAS
- History of allergy to NSAIDs and local anesthetics,
- ASA Grade III and IV,
- Patients with choledocholithiasis, and drain in situ.
- Pregnancy

Sample size:

Sample size estimated based on the findings of pilot study where the

primary outcome being visual analogue score for post operative pain using $\alpha=0.05$ and $\beta=0.02$ and power of study 80% sample size of 30 patients in each group was calculated.

Preoperative Preparation:

- A thorough preoperative evaluation was done.
- All necessary investigations were done.
- Complete haemogram, bleeding time, clotting time, RFTS, LFTS, urine analysis, RBS, ECG, 2DECHO, chest x-ray.

Randomization:

60 Patients were randomly allocated with the help of computer generated random number tables into two groups of 30 each.

Study Groups:

The study consists of two groups as follows

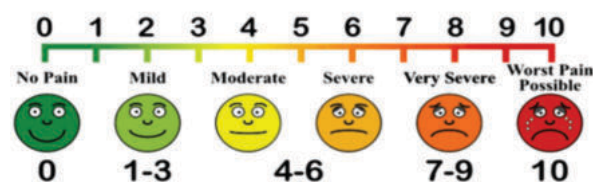
Group I patients received inj. 0.5% bupivacaine 10 ml which is instilled in the right sub diaphragmatic space via suction port in trendelenburg position after deflation of pneumo peritoneum by direct visualization and another 10 ml was infiltrated into the port sites. A volume of 6 ml was infiltrated through the abdominal wall around midline port site and 4 ml at the lateral port sites.

Group II patients received inj. Paracetamol 1g IV - 8th hourly 1st dose was given over a period of 15 min after intubation, before the creation of pneumo-peritoneum

Blinding

- Medications were prepared and covered according to the random number list by an anaesthesia assistant who was blinded to the study.
- Post operative pain is assessed and recorded by an anaesthesiologist who was blinded to the study.
- After getting the informed consent, patients were shifted into the theatre. Basal vitals (parameters) were noted.
- Patients were premedicated with inj. Glycopyrrolate 0.2mg IV, inj. midazolam 0.05mg/kg IV, inj. Fentanyl 2-3 mcg/Kg IV, NG tubes was inserted, position confirmed and secured
- Pre oxygenated with 100% O₂ for 3min with bag and mask. Induction was carried out with inj. Propofol 2.5mg/kg IV and inj. Suxamethonium 1-1.5 mg/kg IV. Trachea was intubated with an appropriate size endotracheal tube.
- Maintenance of anaesthesia was with N₂O:O₂ 2:1, sevoflurane 1-2%. inj. Vecuronium 0.08-0.1 mg/kg IV was used for relaxation. Ventilation controlled using closed circuit with tidal volume 8-10 ml/Kg and respiratory rate 12-16/min with minimal PEEP. EtCO₂ was maintained between 35-45mm of Hg.
- Patients received study drugs as mentioned according to the allocation of groups.

Visual Analog Scale (VAS)/Visual Rating Prince Henry Scale Visual Analog Scale (VAS)



Visual Rating Prince Henry Scale

0	-	No pain on cough,
1	-	Pain on cough, but not on deep breathing,
2	-	Pain on deep breathing but not on rest,
3	-	Slight pain at rest and
4	-	Severe pain at rest.

Primary outcomes :

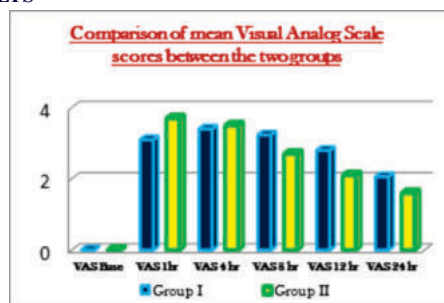
- Postoperative pain was assessed using the Visual Analog Scale (VAS), Visual Rating Prince Henry Scale (VRS)
- Requirement of analgesia.

Statistical Analysis

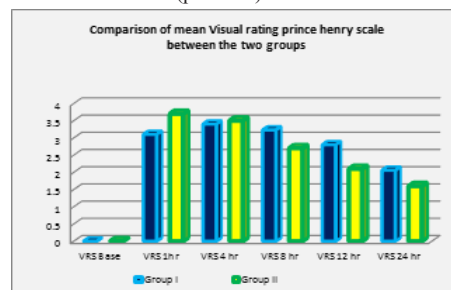
- Statistical analysis was performed using Graph Pad.com software.
- The data was analysed using the Students unpaired t-test, Fishers exact test and Chi- square test.
- Data were represented as a mean and standard deviation . $P<0.05$

was considered statistically significant and P value <0.001 is considered highly significant.

RESULTS



The difference between the Groups is Statistically significant at 8 hours, 12 hours and 24 hours ($p<0.05$)



	Group I Mean $\pm$ SD	Group II Mean $\pm$ SD	p= value
VRS Base	0	00	0.0
VRS 1 Hr	2 ± 0.371	2.03 ± 0.49	0.768
VRS 4 Hr	2.23 ± 0.504	2 ± 0.455	0.065
VRS 8 Hr	1.80 ± 0.365	2 ± 0.555	0.186
VRS 12 Hr	1.93 ± 0.365	2 ± 0.455	0.320
VRS 24 Hr	1.533 ± 0.507	1.23 ± 0.430	0.010*

The difference between the Groups is significant at 24th hour ($p<0.05$)

Comparison of requirement of analgesia between the groups at various time points.

Time Interval	Requirement of analgesia	Group I (N= 30)	Group I (N= 30)	P= value
At 1 Hr	YES	0	02	0.492
	NO	25	23	
At 4 Hr	YES	0	0	--
	NO	0	0	
At 8 Hr	YES	0	0	--
	NO	0	0	
At 12 Hr	YES	5	4	0.989
	NO	20	2	
At 24 Hr	YES	12	0	0.001*
	NO	13	25	

The difference between the Groups is Statistically significant at 24 hours ($p<0.05$)

DISCUSSION

- Pain is the most predominant complaint following laparoscopic procedures, in the early postoperative period.
- In an attempt to decrease the severity of pain following laparoscopic procedures, many techniques have been adopted for adult patients such as using low inflation pressure, local anesthetic infiltration of port sites, intraperitoneal instillation.
- The use of parenteral opioids provided adequate analgesia, but the amount of drug required was higher, resulting in complications thereby increasing the hospital stay.
- Although paracetamol is commonly used for postoperative pain management, its slow onset of analgesia and the non availability of the oral route immediately after surgery makes oral paracetamol of limited value in the treatment of immediate postoperative pain.
- Therefore, a parenteral formulation of paracetamol is an attractive option for the treatment of postsurgical pain.
- IV paracetamol has been evaluated for postoperative analgesia by

many studies in recent years as a single dose of 1 g IV or 1 g IV 6th hourly for 24 h. In our study we used 1 g paracetamol IV over a period of 15 min immediately after intubation before the creation of pnetmo peritoneum similar to the study conducted by Salihoglu et al.

- and also 1 gram paracetamol was given IV 6th hourly for 24 h similar to study conducted by Tippanna et al.
- In comparison to a study conducted by Gregoire et al. where 5 g of paracetamol was given over a period of 24 h, in our study maximum dose of paracetamol administered was limited to 4 g in 24 h, that was well below the toxic dose.
- Thus sustained pain relief up to 24 h in the paracetamol group is due to the repeated administration of IV paracetamol every 6 h and in the bupivacaine group, good pain relief was achieved in the initial 4 postoperative hours.

CONCLUSION

Although local anesthetic infiltration and intra-peritoneal administration of 0.5% bupivacaine decreases the severity of incisional, visceral and shoulder pain in the early postoperative period, IV paracetamol provides sustained pain relief for 24 postoperative hours after elective laparoscopic cholecystectomy.

REFERENCES

1. Vecchio R, MacFayden BV, Palazzo F. History of laparoscopic surgery. *Panminerva Med.* 2000;42:87–90. [PubMed] [Google Scholar]
2. M. Upadya, S. H. Pushpavathi I, Kaushik Rao Seetharam, Comparison of intraperitoneal bupivacaine and intravenous paracetamol for postoperative pain relief after laparoscopic cholecystectomy, "Anesthesia: Essays and Researches; 9(1); Jan Apr 2015".
3. Holmér Pettersson P, Owall A, Jakobsson J. Early bioavailability of paracetamol after oral or intravenous administration. *Acta Anaesthesiol Scand* 2004;48:867-70.
4. Salihoglu Z, Yildirim M, Demiroglu S, Kaya G, Karatas A, Ertem M, et al. Evaluation of intravenous paracetamol administration on postoperative pain and recovery characteristics in patients undergoing laparoscopic cholecystectomy. *Surg Laparosc Endosc Percutan Tech* 2009;19:321-3
5. Tippanna E, Bachmann M, Kalso E, Pere P. Effect of paracetamol and coxib with or without dexamethasone after laparoscopic cholecystectomy. *Acta Anaesthesiol Scand* 2008;52:673-80.
6. Gregoire N, Hovsepian L, Gualano V, Evenc E, Dufour G, Gendron A. Safety and pharmacokinetics of paracetamol following intravenous administration of 5 g during the first 24 h with a 2-g starting dose. *Clin Pharmacol Ther* 2007;81:401-5.
7. Gayatri P. Post-operative pain services. *Indian J Anesth.* 2005;49:17–9. [Google Scholar]