

ROLE OF LEVOBUPIVACAINE IN POST-OPERATIVE PAIN MANAGEMENT AFTER OPEN CHOLECYSTECTOMY : A RANDOMISED CONTROL TRIAL

General Surgery

Dhirendra Nath Choudhury

Department Of General Surgery, Tezpur Medical College And Hospital, Assam, India

Bibhu Priyo Das

Department Of General Surgery, Tezpur Medical College And Hospital, Assam, India

Rajiv Mahato

Department Of General Surgery, Tezpur Medical College And Hospital, Assam, India

Eeshan

Department Of General Surgery, Tezpur Medical College And Hospital, Assam, India

Chakraborty*

*Corresponding Author

ABSTRACT

Objectives: To evaluate the effectiveness of long-acting local anesthetic (Levobupivacaine) at the incision site for post-operative pain management in patients undergoing open cholecystectomy. **Methods:** This randomized clinical trial was conducted at a tertiary care government hospital setting in Tezpur, Assam, India. All Patients undergoing open cholecystectomy who matched with the inclusion and exclusion criteria were randomly assigned to two groups; one group received a local infiltration of 10 ml of 0.25% w/v Levobupivacaine at the incision site during wound closure for open cholecystectomy, whereas the other group did not receive any intervention. Patients in both groups received analgesia with NSAIDs. Post-operative pain was assessed using the Visual Analog Scale (VAS) at 1, 6, 12, and 24 hours following the operation. Rescue analgesia was administered if the VAS score exceeded 7 or upon request. Demographic information, frequency of analgesic use, time of first rescue analgesic request, and total postoperative hospital stay were documented for each group, followed by appropriate statistical analysis of the collected data. **Results:** A total of 182 patients participated in this study, who were separated into two groups: the Levobupivacaine Group and the Standard Analgesia Group. Patients in the Levobupivacaine Group required their initial rescue analgesia dose after an average of 1.3 hours and the Standard Analgesia Group required it after 0.7 hours. The mean pain scores during the 1st and 6th postoperative hours were found to be statistically significant ($p < 0.001$) but insignificant at the 12th and 24th hour. The postoperative length of stay was 3.4 days for the Levobupivacaine Group and 3.6 days for the Standard Analgesia Group and was statistically insignificant. **Conclusion:** Administration of a Levobupivacaine at the incision site following open cholecystectomy significantly diminishes pain during the initial 6 hours postoperatively. This however, did not alter total length of hospital stay significantly.

KEYWORDS

Pain management, Open cholecystectomy, Post-operative management, Local anaesthesia

INTRODUCTION

Incisional pain is arguably one of the most prevalent complaints among all post-operative patients following open cholecystectomy. Pain frequently arises from substantial tissue dissection and tension during major surgical procedures. Post-operative pain, particularly in the initial days following surgery, results in delayed discharge and imposes a considerable strain on both patients and healthcare systems. Effective pain treatment is paramount for those treating patients undergoing open cholecystectomy. Consequently, the assessment of pain alleviation is progressively recognized as a postoperative quality metric. The objective of postoperative pain management is to alleviate or eradicate pain and discomfort while minimizing negative effects.

Post-operative pain is typically addressed with non-steroidal anti-inflammatory medications (NSAIDs). Tramadol is the most often utilized non-narcotic analgesic within the opioid category for managing post-operative pain. Opioid analgesics are occasionally linked to nausea, vomiting, and ileus. Nonsteroidal anti-inflammatory drugs reduce the necessity for using narcotic analgesics.[3] Nonetheless, NSAIDs have been documented to be linked with possible harmful effects such as cardiovascular incidents, surgical hemorrhage, and renal dysfunction. Levobupivacaine, a long-acting local anesthetic with a half-life of 2.5–3.5 hours, may effectively mitigate post-operative pain and decrease patients' post-operative analgesic use by up to 6 hours. Bupivacaine possesses a substantial safety margin and can be administered safely at a maximum dosage of 3 mg/kg of body weight.[4]

This study aimed to evaluate the effectiveness of long-acting local anesthetic (Levobupivacaine) at the incision site for post-operative pain management in patients undergoing open cholecystectomy in a tertiary care government hospital in Tezpur, Assam, India.

Aims And Objectives

1. To compare the frequency of analgesic consumption postoperatively.
2. To compare postoperative pain at 1st, 6th, 12th and 24 hours.
3. To compare length of stay post-operatively.

MATERIALS AND METHODS

This randomized clinical trial was conducted at a tertiary care government hospital setting in Tezpur, Assam, India between October 2023 and March 2024. Ethical approval for the study was obtained from the institutional review board of hospital on September 9, 2023. All individual participants who provided written informed consent were included in this study. There were a total of 190 patients eligible for our study and 182 of them were included for the same during this time period after matching with the inclusion and exclusion criteria.

Inclusion Criteria: Patients were eligible for enrolment if

1. They were at least 18 years of age
2. They agreed to provide written consent
3. They were in general good health

Exclusion Criteria: Patients were excluded from the study if

1. They were minors
2. They had some other pre-existing comorbid conditions or systemic disease that could lead to altered pain sensation.
3. They had allergy to bupivacaine or had liver or kidney disease
4. They had some other intra-abdominal pathology discovered intraoperatively or if incision was extended for some other reasons.
5. Patients who took any analgesics upto 24 hours before surgery

All procedures were conducted under general anesthesia. The mean incision length for each patient was maintained between 10 and 12 cm. Following the excision of the gallbladder and the achievement of hemostasis, the rectus sheath and subcutaneous layer were sutured closed with 2-0 vicryl sutures. In all instances, a normal ethilon 2-0 suture was employed for dermal closure. The patients were randomly assigned to two groups; one group received a local infiltration of 10 ml of 0.25% w/v Levobupivacaine at the incision site during wound closure for open cholecystectomy, whereas the other group did not receive any intervention. Patients in both groups received analgesia with the normal pain management protocol at our institution (NSAIDs [75 mg Diclofenac] administered intramuscularly every 12 hours). Post-operative pain was assessed using the Visual Analog Scale (VAS) at 1, 6, 12, and 24 hours following the operation. Rescue analgesia (100 mg Tramadol hydrochloride intramuscularly) was administered if the VAS score exceeded 7 or upon request, with the time documented.

Post-operative pain was evaluated with the Visual Analog Scale (VAS), a 10-point metric indicating pain intensity from 0 (absence of pain) to 10 (maximum pain severity). Scores of 1–3 were classified as mild, 4–7 as moderate, and those beyond 7 as severe. Demographic information, including age and sex, as well as operation details, frequency of analgesic use, time of initial analgesic request, and total postoperative hospital stay were documented for each group, followed by an analysis of the collected data.

Statistical Analysis

The statistical analysis of the data was conducted using SPSS version 22.0 software. The mean and standard deviation were computed for quantitative variables. The differences between the groups were assessed for statistical significance using a one-way analysis of variance. A p-value of less than 0.05 was deemed statistically significant.

RESULTS AND OBSERVATIONS

The research involved a total of 182 patients. The patients were separated into two groups: the Levobupivacaine Group and the Standard Analgesia Group. There were no differences in age, gender, or body weight between the two groups.

The mean operative time in the Levobupivacaine Group (48 ± 2.71) exceeded that of the Standard Analgesia Group (46 ± 3.01), although the difference was not statistically significant (Table 1).

Patients in the Levobupivacaine Group required their initial rescue analgesia dose after an average of 1.3 hours, whereas the Standard Analgesia Group required it after 0.7 hours, a difference that was statistically significant (Table 1).

Pain severity was assessed using the Visual Analog Scale at predetermined intervals of 1, 6, 12, and 24 hours postoperatively. The mean pain scores during the first and sixth postoperative hours were found to be statistically significant ($p < 0.001$). No substantial difference was observed at the 12th and 24th postoperative hours (Table 2 and Chart 1).

As NSAIDs and tramadol were not consistently utilized in either group, statistical data were not assessed in this context. The quantity of NSAIDs and tramadol dosages given within the initial 24 hours is specified in Table 1 and Chart 2.

The postoperative length of stay was 3.4 days for the Levobupivacaine Group and 3.6 days for the Standard Analgesia Group, a difference that was statistically insignificant (Table 1).

DISCUSSION

The issue of delivering sufficient postoperative analgesia continues to exist despite advancements in contemporary surgery and anesthesia [5]. The effective management of postoperative pain relies on patient demand, guidance from medical personnel, the disposition and accessibility of nursing staff, and the appropriate analgesic medication. The conventional administration of intramuscular injections of narcotic analgesics or NSAIDs presents numerous disadvantages. This leads to unnecessary suffering and exacerbates patient anxiety and stress.

Our study demonstrated that local infiltration of Levobupivacaine is efficacious and safe for managing pain after open cholecystectomy, with no adverse side effects or local complications seen [6]. This was also accompanied with better patient satisfaction. The employed approach delivers efficient and sustained local analgesia. The patient is both pain-free and awake, remaining cooperative without experiencing any adverse effects associated with opioid analgesia. Furthermore, local anesthesia promotes early mobilization, potentially diminishing the risk of deep vein thrombosis and muscular atrophy.

In our study, patients in the Levobupivacaine group experienced an extended pain-free phase postoperatively and delayed the use of rescue analgesics, if necessary. Prior research has demonstrated that local anesthetic infiltration at the incision site markedly decreases the requirement for analgesics and alleviates pain during the postoperative phase. [7, 8]

The VAS values provided by the patients demonstrated reduced pain intensity at the 1st and 6th hours postoperatively following local

infiltration of Levobupivacaine. Nevertheless, the pain assessments were comparable at the 12th and 24th hours postoperatively. Some studies have demonstrated an analgesic effect during the early postoperative phase (0–6 hours), whereas others have indicated a prolonged anesthetic effect (12–24 hours). [12, 13] Ali et al. [14] reported a reduction in hospitalization length in their study. According to Akbar et al., [15] the standard deviation was marginally elevated in the infiltration group, however the length of hospitalization was not statistically significant. Our analysis revealed no statistically significant difference in hospitalization duration between the two groups.

This approach of administering postoperative analgesia should be further expanded to supplant or, at the very least, augment the prevalent usage of narcotic medications. Pain is an unavoidable outcome of every surgical procedure, and adequate focus on its origins and management will yield substantial advantages for the patient and those responsible for their management.

CONCLUSION

In conclusion, the administration of a long-acting local anesthetic (Levobupivacaine) at the wound site following open cholecystectomy significantly diminishes pain during the initial 6 hours postoperatively, and we expect a reduced reliance on analgesics (NSAIDs, tramadol, etc.) for managing postoperative pain in these patients.

Conflict Of Interest

None declared.

Table 1

Patients characteristics	Levobupivacaine group (n=90)	Standard analgesia group (n=92)	p-value
Mean Age (Years)	49 ± 3.51	47 ± 3.66	0.47
Mean Weight (Kg)	68.5 ± 4.54	66.3 ± 4.71	0.387
Sex Ratio (F:M)	73:17	79:13	
Time of operation (minutes)	48 ± 2.71	46 ± 3.01	Not significant.
Time at which first rescue analgesia was given (hours)	1.3	0.7	<0.001
Number of NSAIDs doses administered in the first 24 hours	90	184	
Number of Tramadol doses administered in the first 24h	18	44	
Hospital stay (day)	3.4	3.6	Not significant.

Table 2

Postoperative assessment time (hours)	Levobupivacaine group	Standard analgesia group	p-value
1	3.6 ± 0.42	7.6 ± 0.52	<0.001
6	4.4 ± 0.24	6.9 ± 0.41	<0.001
12	2.1 ± 0.25	2.3 ± 0.6	0.786
24	1.9 ± 0.81	2.1 ± 0.54	0.698

VAS graph in groups intervals over time

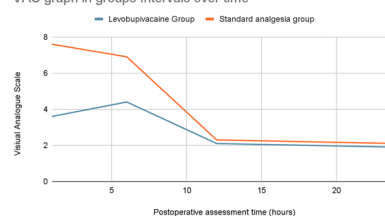


Chart 1

Number of doses of NSAIDs and tramadol administered in the first 24 hours

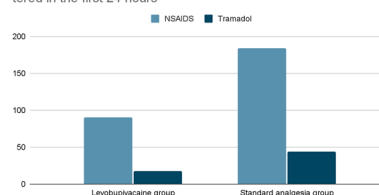


Chart 2

REFERENCES

1. Kokki H. Nonsteroidal anti-inflammatory drugs for postoperative pain: a focus on children. *Paediatr Drugs*. 2003;5(2):103-23. doi: 10.2165/00128072-200305020-00004. PMID: 12529163.
2. Porreca F, Ossipov MH. Nausea and vomiting side effects with opioid analgesics during treatment of chronic pain: mechanisms, implications, and management options. *Pain Med*. 2009 May-Jun;10(4):654-62. doi: 10.1111/j.1526-4637.2009.00583.x. Epub 2009 Mar 19. PMID: 19302436.
3. Newcomb W, Lincourt A, Hope W, Schmelzer T, Sing R, Kercher K, et al. Prospective, double-blinded, randomized, placebo-controlled comparison of local anesthetic and nonsteroidal anti-inflammatory drugs for postoperative pain management after laparoscopic surgery. *Am Surg* 2007;73:618-24; discussion 624-5.
4. Alam M S, Hoque H W, Saifullah M, Ali M O. Port-site and intraperitoneal infiltration of local anesthetics in reduction of postoperative pain after laparoscopic cholecystectomy. *Medicine Today* 2009;22:24-8.
5. Nayman J. Measurement and control of postoperative pain. *Ann R Coll Surg Engl* 1979;61:419-26.
6. Wallace WA, Milne DD. Intravenous regional analgesia. *Hospital Update* 1978;4:137-46.
7. Başgöl E, Kaynak Ş, Öcal T, Erçelen Ö, Şahin A. The effect of bupivacaine infiltration at the incision site on postoperative pain and narcotic analgesic requirement due to wide abdominal incision. *Ağrı* 1992;4:32-5.
8. Alessandri F, Lijoi D, Mistrangelo E, Nicoletti A, Ragni N. Effect of presurgical local infiltration of levobupivacaine in the surgical field on postsurgical wound pain in laparoscopic gynecological surgery. *Acta Obstet Gynecol Scand* 2006;85:844-9.
9. Liu YY, Yeh CN, Lee HL, Wang SY, Tsai CY, Lin CC, et al. Local anesthesia with ropivacaine for patients undergoing laparoscopic cholecystectomy. *World J Gastroenterol* 2009;15:2376-80.
10. Lee IO, Kim SH, Kong MH, Lee MK, Kim NS, Choi YS, et al. Pain after laparoscopic cholecystectomy: the effect and timing of incisional and intraperitoneal bupivacaine. *Can J Anaesth* 2001;48:545-50.
11. Pavlidis TE, Atmatzidis KS, Papaziogas BT, Makris JG, Lazaridis CN, Papaziogas TB. The effect of preincisional periportal infiltration with ropivacaine in pain relief after laparoscopic procedures: a prospective, randomized controlled trial. *JSLs* 2003;7:305-10.
12. Cha SM, Kang H, Baek CW, Jung YH, Koo GH, Kim BG, et al. Peritrocal and intraperitoneal ropivacaine for laparoscopic cholecystectomy: a prospective, randomized, double-blind controlled trial. *J Surg Res* 2012;175:251-8.
13. Altuntaş G, Akkaya ÖT, Özkan D, Sayın MM, Balas Ş, Özlü E. Comparison of intraabdominal and trocar site local anaesthetic infiltration on postoperative analgesia after laparoscopic cholecystectomy. *Türk J Anaesthesiol Reanim* 2016;44:306-11.
14. Ali S, Zarin M, Jan Z, Maroof A. Effect of bupivacaine on postoperative pain after laparoscopic cholecystectomy. *J Coll Physicians Surg Pak* 2018;28:663-6.
15. Akbar I, Bukhari S, Shoaib M. Effectiveness of local anaesthetic in reducing postoperative pain at port site after laparoscopic cholecystectomy. *J Ayub Med Coll Abbottabad* 2022;34:695-8.