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Original Research Article

COMPARATIVE EVALUATION OF ULTRASOUND GUIDED ERECTOR SPINAE PLANE BLOCK AND INTRAPERITONEAL INSTILLATION WITH PERIPORTAL INFILTRATION FOR POSTOPERATIVE ANALGESIA IN LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE RANDOMISED STUDY

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ABSTRACT

Background: Laparoscopic cholecystectomy (LC) is associated with both visceral and somatic pain. Ultrasound (USG)-guided erector spinae plane block (ESPB) and intraperitoneal instillation (IPI) with periportal infiltration (PPI) are widely used for postoperative analgesia. This study compared the effectiveness of ESPB versus IPI with PPI using injection (inj.) ropivacaine and inj. nalbuphine. **Materials and Methods:** One hundred patients undergoing elective LC were randomized into two groups (n=50 each). Group ESPB received USG-guided ESPB using 29 ml (72.5 mg) of inj. ropivacaine 0.25% and 1 ml (10 mg) of inj. nalbuphine making a total of 30 ml and Group IPI received IPI with PPI of same dose and volume of the drug. Postoperative pain was assessed using the visual analogue scale (VAS) at 2, 4, 6, 8, 10, 12, 14, 16, and 24 hours. Time to first rescue analgesia and total consumption of analgesics were recorded. **Result:** VAS scores were significantly lower in Group IPI at 8 hours ($p<0.05$). Scores were comparable at 12–16 hours, but at 24 hours, Group ESPB had significantly lower VAS scores ($p<0.05$). The first analgesic request occurred at ~8 h in Group ESPB, while none in Group IPI required analgesia at that point. Between 10–16 hours, requirements were similar, but at 24 hours, no patient in Group ESPB required rescue analgesia, indicating sustained analgesia with ESPB. No major adverse effects were noted. **Conclusion:** Both ESPB and IPI with PPI provided comparable and effective analgesia after LC.

INTRODUCTION

Laparoscopic cholecystectomy (LC), a minimally invasive surgical treatment for gallbladder removal, has become more popular as a result of its many benefits over open surgery, including less postoperative discomfort, shorter hospital stays, and a quicker recovery.[1] However, despite being minimal invasive procedure, patients often experience significant postoperative pain particularly from abdominal wall incision, peritoneal stretching and diaphragmatic irritation caused by pneumoperitoneum.[2] Adequate postoperative analgesia that is both effective and well tolerated is still essential for patient satisfaction and the speedy recovery which is necessary for early discharge.[3]

Several analgesic techniques have been explored for pain relief after LC which includes systemic opioids, local anesthetic infiltrations, or regional nerve blocks. Recently, Ultrasound (USG)- guided erector spinae plane block (ESPB) has emerged as a promising regional Anaesthesia (RA) technique for thoraco abdominial surgeries by depositing local anesthetics (LA) deep to erector spinae muscle.[4] This technique specifically targets the ventral rami, dorsal rami and rami-communicantes of the spinal nerves. Following the administration of ESPB, the LA extents both cranially and caudally, covering

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multiple dermatomes with a favorable safety profile.[5,6] Studies have demonstrated its efficacy in providing postoperative analgesia after various laparoscopic and open abdominal surgeries.[7]

Intraperitoneal instillation (IPI) with periportal infiltration (PPI) of the LA agent into gall bladder bed has been proved to be an effective method of postoperative analgesia in LC. It is an easy, non-invasive method associated with low pain scores, less opioid consumption, shoulder pain and emetic symptoms.[8] However, duration of analgesia may be limited for few hours. Hence, the addition of adjuvants has been proposed to prolong the duration and quality of LA action, thereby improving analgesic outcomes.[9,10] The addition of nalbuphine, a mixed kappa-agonist and mu-antagonist opioid, has been shown to enhance the quality and duration of local anesthetic analgesia when used as an adjuvant.[11,12] Nalbuphine not only prolongs the analgesic effect but also reduces opioid-related side effects, making it an attractive adjuvant.[13]

Individual studies evaluating the efficacy and safety of USG-guided ESPB and IPI with PPI for postoperative analgesia after LC have shown promising results; however, comparative studies are lacking. Therefore, the purpose of this prospective randomized study is to compare USG-guided ESPB and IPI with PPI of injection (inj.) ropivacaine 0.25% with inj. nalbuphine 10 mgs in terms of efficacy, duration of analgesia, opioid consumption, or patient satisfaction in patients undergoing LC.[14]

MATERIALS AND METHODS

This comparative, prospective, randomized controlled double blind hospital based study was conducted in the department of anesthesiology, after taking informed consent from patient and their close relatives.

Inclusion Criteria

A total of 100 patients in the age group of 18 to 60 years, of both sexes, belonging to American Society of Anesthesiologists (ASA) grade I or II, and scheduled to undergo LC under general Anaesthesia (GA) were included in the study.

Exclusion Criteria

Patients with any chronic medical illness, allergy to study drug, previous abdominal surgery, or patients in whom surgery had to be converted to open cholecystectomy or with complications which could increase postoperative pain such as biliary spillage owing to puncture of the gall bladder or extensive dissection owing to adhesions were excluded from the study.

The patients were randomly allocated into two groups having 50 patients each, according to computer-generated numbers.

In group –ESPB: patients received ESPB using 29 ml (72.5 mg) of inj. ropivacaine 0.25% and 1 ml (10 mg) of inj. nalbuphine making a total of 30 ml.

In group -IPI: patients received IPI and periportal infiltration of 29 ml (72.5 mg) of inj. ropivacaine 0.25% and 1 ml (10 mg) of inj. nalbuphine making a total of 30 ml.

For double blinding, the anaesthesiologist performing the block and preparing the drug solution was aware of the group allocation but took no further part in postoperative assessments. The investigator responsible for postoperative pain assessment and data collection was blinded to the group assignments. Patients were also blinded to their assigned group. A detailed preoperative assessment was done for the patients which included taking medical history and performing general physical and systemic examination. The relevant laboratory investigations were done. Visual analog scale (VAS) was explained in great detail to every patient. VAS consists of a straight vertical 10 cm line where the bottom point (0 cm) represents no pain and the top (10 cm) represents the worst imaginable pain. Patients were kept fasting for 6 h for solids and 2 h for clear liquids before surgery. Anaesthesia technique was same in all the patients. Tablet alprazolam 0.5 mg was administered the night before the surgery. The patients were shifted to operation theatre and routine physiological monitoring was commenced including baseline heart rate (HR), pulse oximetry (SpO2), noninvasive blood pressure (NIBP), and three-lead electrocardiogram (ECG). Then peripheral intravascular (iv) access was obtained. Patients were premedicated with iv administration of glycopyrrolate 0.2 mg and midazolam 1 mg. Patients were preoxygenated with 100% O2 for 3-5 min and induction of Anaesthesia was done with iv fentanyl 1-2 µg/kg and propofol 1-2 mg/kg till loss of verbal response. Endotracheal intubation with an appropriate size cuffed tube was facilitated using atracurium 0.5 mg/kg. Maintenance of Anaesthesia was done with isoflurane (1%-1.5%) along with O2 and N2O and atracurium. Ventilation was adjusted to keep end-tidal CO2 at 35–40 mmHg. Nasogastric tube was inserted after intubation and removed at the end of surgery. Intraoperative analgesia was supplemented with iv infusion of acetaminophen (15 mg/kg). Patients were placed in reverse trendelenberg position of around 15° to 20°. Pneumoperitoneum was created by insufflating CO2 at rate of 5 L/min and intra-abdominal pressure was kept between 12-15 mmHg throughout the surgery. After dissecting the gall bladder from liver bed, hemostasis, washing of the peritoneal cavity, and suctioning of the irrigating fluid were done. At the end of surgery CO2 was carefully evacuated by manual compression of abdomen with open trocar.

Study drug (30 ml) according to group was instilled IPI with PPI under direct vision into the right hepatodiaphragmatic space, on the gall bladder bed, above and near hepatoduodenal ligament and sprayed on upper surface of liver. Patients were kept in trendelenberg's position of 15-20º for 10 min. After removal of trocar, 10 ml of the study drug was infiltrated at all port sites.

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In ESPB group after the completion of surgery, patients were placed in a lateral decubitus position. The anesthesiologist positioned the ultrasound probe longitudinally at the level of the T7 spinous process. Thereafter, the anaesthesiologist moved the probe to 3cm laterally from the midline. Ultrasonic landmarks were identified, including the T7 transverse process and the erector spinae muscle overlaying it. To reach the T7 transverse process, a 21G (80mm) block needle was inserted at 30-40 degrees angle from cranial to caudal within same plane. After hydrodissection with 2-3 ml of isotonic saline solution, we confirm the needle's correct position, and the anaesthesiologist administered 15 ml injection of 0.25% ropivacaine with nalbuphine bilaterally on each side.

At the end of surgery, reversal of residual neuromuscular blockade was done with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. Then, patients were extubated and shifted to the recovery room, where HR, NIBP, and SpO2 were monitored. Severity of pain was assessed using VAS ranging from 0 to 10.VAS score was recorded immediately after recovery (regarded as 0 h) and at 1, 2, 4, 6, 8, 10.12,16 and 24 h postoperatively. For patients with VAS score ≥ 4, rescue analgesia was given, using intramuscular Inj. diclofenac (75 mg). The time to first analgesic request and the total analgesic consumption in 24 h postoperatively were recorded. Adverse effects such as hypotension (> 20% decrease of MAP from baseline), bradycardia (HR< 60 bpm), postoperative nausea and vomiting (PONV), pruritis, respiratory depression (SpO2< 90% on room air or respiratory rate< 10 breaths/min), shoulder tip pain or sedation.

Statistical Analysis: The data was analyzed using SPSS 16.0. In order to ensure that the data were normally distributed, the Kolmogorov-Smirnov test was carried out. It was common practice to use the median or mean when discussing continuous variables. When analyzing continuous variables with the same variance, a 2-sample, independent t-test was used for the analysis. For this reason, we employed the Mann-Whitney U test to examine our non-normally distributed data. Chi-square analysis was used to compare the ratios. To evaluate differences across groups, we used the Fisher exact test. The p-value was less than 0.05, indicating statistical significance. We used Bonferroni correction for the NRS scores, and the threshold of statistical significance was chosen at p 0.01.

RESULTS

A total of 100 patients were screened and enrolled for the study, divided into two groups that is ESPB group receiving USG-guided ESPB block after LC before extubation of the patient and IPI group receiving IPI with PPI after completion of the surgery.

Table 1: Group comparison for demographic variables

Demographic Variables	ESPB (n=50)	IPI (n=50)	p-value
Age (Years), Mean ± SD	45.86± 4.81	44.98±3.92	0.318
Sex (Number, %)			
Male	28 (56.0)	34 (68.0)	0.084
Female	22 (44.0)	16 (32.0)	
Weight (kgs), Mean ±SD	68.38± 7.33	68.74± 4.77	0.772
Height (m), Mean ±SD	1.71± 0.09	1.73± 0.10	0.404
ASA I	29 (58.0)	26 (52.0)	0.691
ASA II	12 (24.0)	14 (28.0)	
ASA III	9 (18.0)	10 (20.0)	

Demographic variables are comparable in both the groups (p>0.05) (Table 1).

Table 2: Group comparison for heart rate (HR) (beats/minutes)

Heart Rate (beat/min.)	Mean ± Standard Deviation		p-value
	ESPB (n=50)	IPI (n=50)	
1 hr	91.24± 8.86	90.86± 7.62	0.818
2 hr	91.58± 7.10	90.58± 6.08	0.451
4 hr	94.52± 7.07	92.76± 5.83	0.178
6 hr	91.22± 8.60	90.20± 7.77	0.535
8 hr	86.78± 7.21	85.26± 6.37	0.267
10 hr	84.84± 6.69	84.34± 3.68	0.644
12 hr	82.68± 4.00	81.30± 3.53	0.070
14 hr	81.48± 3.74	82.18± 3.51	0.337
16 hr	81.00± 4.34	82.04± 4.77	0.209
24 hr	80.20± 4.22	80.14± 4.46	0.945

As far as comparison of HR at different time-intervals was concerned, it was found to be statistically insignificant (p>0.05) [Table 2].

Table 3: Group comparison for MAP (mm-Hg)

MAP (mmHg)	Mean ± Standard Deviation		p-value
	ESPB (n=50)	IPI (n=50)	
1 hr	97.18± 4.66	96.50± 5.30	0.497
2 hr	97.62± 4.17	97.18± 4.08	0.595

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4 hr	99.28± 5.30	98.18± 5.31	0.302
6 hr	96.64± 6.75	95.46± 5.22	0.331
8 hr	95.06± 4.65	94.44± 4.79	0.513
10 hr	92.70± 6.42	94.72± 3.99	0.062
12 hr	93.50± 6.62	92.04± 6.32	0.262
14 hr	91.74± 6.75	91.96± 6.11	0.864
16 hr	92.48± 3.14	91.92± 3.49	0.401
24 hr	91.06± 3.65	90.28± 3.72	0.293

MAP was comparable at different time-intervals between the two groups (p>0.05) [Table 3].

Table 4: Group comparison for VAS Score

VAS Score	Mean ± Standard Deviation		p-value
	ESPB (n=50)	IPI (n=50)	
1 hr	1.60± 0.49	1.64± 0.83	0.769
2 hr	1.22± 0.42	1.34± 0.52	0.207
4 hr	1.44± 0.50	1.52± 0.50	0.426
6 hr	2.14± 0.35	2.06± 0.24	0.186
8 hr	2.28± 1.70	2.02± 0.32	0.018
10 hr	2.62± 0.95	2.40± 0.86	0.228
12 hr	2.92± 1.17	2.56± 1.26	0.110
14 hr	2.60± 0.49	2.64± 0.83	0.769
16 hr	1.30± 0.74	1.40± 1.11	0.597
24 hr	2.70± 0.95	3.22± 0.68	0.002

[Table 4] depicts VAS scores between two groups at different time intervals. At 8th hour, VAS score was significantly high (p<0.05). After this, VAS score was high but was comparable in both the groups till 16th hour (p>0.05). Once again, VAS score was significantly higher in IPI group (p<0.05).

Table 5: Group comparison for first analgesics dose

Analgesics doses	Number of patients (%)	
	ESPB (n=50)	IPI (n=50)
6 hr	0 (0.0)	0 (0)
8 hr	5 (10.0)	0 (0.0)
10 hr	10 (20.0)	10 (20.0)
12 hr	15 (30.0)	15 (30.0)
14 hr	15 (30.0)	15 (30.0)
16 hr	5 (10.0)	5 (10.0)
24 hr	0 (0.0)	5 (10.0)
p-value	<s 0.0001	

[Table 5] demonstrates first analgesic doses requirement. 5 patients at 8th hour, 10 patients at 10th hour, 15 patients each at 12th hour and 14th hour and 5 patients at 16th hour in ESPB group required analgesic doses whereas in IPI group, none of the patients required analgesic doses before 10th hour. Till 16th hour, same number of patients as in ESPB group required analgesic doses and further at 24th hour, 5 patients required analgesia in IPI group.

Table 6: Group comparison for requirement of analgesics doses

Analgesics doses	Number of patients (%)	
	ESPB (n=50)	IPI (n=50)
1 dose	45 (90)	50 (100)
2 doses	5 (10)	0 (0.0)
p-value	<0.0001	

45 patients in ESPB group required first analgesic dose and 5 required second analgesic dose whereas 50 patients in IPI group required first analgesic dose and none of the patients required second analgesic dose in IPI group which was statistically significant (p<0.05) [Table 6].

DISCUSSION

Present study compared the effectiveness of USG-guided ESPB and IPI with PPI of inj. ropivacaine combined with inj. nalbuphine for postoperative analgesia following LC. A total of 100 patients were screened for the study and divided into 2 groups. Our findings demonstrated that VAS scores was significantly higher in ESPB group at 8 hours. Between 12-16 hours, it was comparable among the two groups and at 24 hours, it was significantly higher in the IPI group compared to ESPB group indicating more sustained analgesia at 24 hours. In terms of first analgesic request, patients in the ESPB group requested first analgesia at around 8 hours while none in the IPI group did at that time whereas the requirement pattern was very similar in both the groups between 10-16 hours and at 24 hours, no patient in ESPB required analgesia showing a longer

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lasting analgesic effect of ESPB compared to IPI with PPI. Parallel to our research, Kumar et al. in their study compared the analgesic efficacy of IPI of ropivacaine with dexmedetomidine and USG-guided ESPB undergoing LC and concluded that though there was significant increased consumption of analgesics in first 24 hours in IPI group, but either of the procedures can be used as multimodal analgesia in LC.[15] In contrast, studies focusing on IPI and PPI have reported effective analgesia in the immediate postoperative period. Bhati et al. compared IPI with PPI of ropivacaine with dexmedetomidine and found that higher concentration of ropivacaine (0.75%) with dexmedetomidine provides superior and prolonged postoperative analgesia after LC.[16] Similarly, Pramatha Nath Dutta reported IPI with bupivacaine 0.5% as a simple and effective approach to reduce early postoperative pain.[17] Radhe sharan et al observed that both bupivacaine and ropivacaine provided satisfactory analgesia with ropivacaine offering a slightly longer duration of action.[18] Likewise Devalkar Priti S & Salgaonkar Sweta V studied the efficacy and safety of analgesic effect of postoperative intraperitoneal instillation of 0.25% of Bupivacaine or 0.9% normal saline in patients undergoing laparoscopic cholecystectomy and found intraperitoneal instillation of 30ml of 0.25% Bupivacaine provides postoperative pain relief for first 8 hrs, reduces need of rescue analgesic drugs and decreases side effects.[19] These findings support the efficacy of intraperitoneal techniques, particularly for immediate postoperative pain relief, which corresponds with our observation of lower VAS scores at 8 hours in the IPI group. Our findings suggest that while IPI with PPI provides better early analgesia, ESPB offers a more prolonged analgesic effect upto 24 hours, which is helpful in minimizing delayed postoperative pain and reducing the need for opioids. Furthermore, ESPB provides consistent visceral and somatic coverage, whereas IPI primarily addresses visceral and port-site pain, which may explain the sustained superiority of ESPB at later time points.

Limitation

Limitations of this study include the relatively small sample size and short follow-up period. Long-term outcomes, including the prevention of chronic post-laparoscopic pain, were not assessed. Further large-scale randomized controlled trials are warranted to confirm these findings and to better define the role of nalbuphine as an adjuvant in both techniques.

CONCLUSION

In conclusion, both ESPB and IPI with PPI of ropivacaine combined with nalbuphine provided effective postoperative analgesia following LC. IPI with periportal infiltration was superior in the immediate postoperative period, while ESPB demonstrated more sustained analgesic efficacy at 24 hours, reducing late postoperative pain and the requirement for rescue analgesia. Hence our study indicates that both ESPB and IPI with PPI provided comparable postoperative analgesia after LC and can be used as a multimodal pain control strategies.

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