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Evaluation of efficacy of ultrasound guided erector spinae plane block (ESPB) for post-operative analgesia in patients undergoing laparoscopic cholecystectomy

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ABSTRACT

Objective: The objective is to assess the clinical efficacy of erector spinae plane block (ESPB) for post-operative analgesia in patients undergoing laparoscopic cholecystectomies.

Material and Methods: This prospective, interventional, quasi-randomized single-blind study was approved by institutional ethical committee. Total 82 patients undergoing laparoscopic cholecystectomy were allocated into two groups, ESPB and control group. Postoperatively, the total tramadol consumption in 24 hours, the visual analogue scale (VAS) at various time intervals and time to rescue analgesia in both groups were monitored.

Results: The requirement of tramadol in first 24 hours was significantly more in controls as compared to cases (p=0.005). The mean VAS at rest, coughing and at movement was significantly lower in the immediate period, at 2nd hour and 4th hour after being shifted to post-operative area, in case group as compared to control. The time to rescue analgesia was statistically significantly more in ESPB group (p=0.002).

Conclusion: ESPB for laparoscopic cholecystectomy is a safe and effective technique of multimodal analgesia which provides better pain relief, reduced opioid requirement, lower post-operative pain scores, reduced total post-operative analgesic consumption along with prolonged time to rescue analgesia.

Keywords: Erector spinae plane block, multimodal analgesia, post-operative analgesia, rescue analgesia, visual analogue scale

INTRODUCTION

Laparoscopic cholecystectomy is now considered the gold standard for treatment of Gall stone disease, as it has been proven to cause less surgical trauma, better tissue healing, and faster recovery. Even though laparoscopic cholecystectomy is a minimally invasive procedure, post-operative pain, especially at port sites, remains a problem to be solved. Post-operative pain after laparoscopic surgeries is related to surgical manipulations, diaphragmatic irritation and indwelling abdominal trocars. Visceral pain after laparoscopic surgery may be due to stretching of the peritoneum, insufflation of gases intraoperatively, or post-operative residual pneumoperitoneum (1).

Various analgesic strategies, as a part of multimodal analgesia, exist for the management of post-operative pain. Regional anaesthetic techniques are prevalent in clinical practice and have a promising role in the management of post-operative analgesia after laparoscopic abdominal surgeries (2). Several techniques such as transversus abdominis plane block (3), serratus anterior plane block (4), and intraperitoneal insufflation of local anaesthetic (5) have been proven to reduce the post-operative analgesic requirement after abdominal surgeries.

The erector spinae plane block (ESPB) was first described by Forero et al. (6) for neuropathic pain resulting from metastatic lesions to the ribs and from the malunion of multiple rib fractures. The ultrasound-guided ESPB, effective for both somatic and visceral pain, is a recent interfascial block described for post-operative analgesia (6).

The role of ESPB as a better analgesic modality in reducing 24-hour opioid consumption has recently been established for post-operative analgesia in breast surgeries (7), video-assisted thoracoscopic surgery (8), and cardiothoracic

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surgeries (9). The use of this modality for post-operative analgesia in abdominal surgeries are few and are mostly case-reports and case series (10-12).

The purpose of this study was to assess the efficacy of ESPB versus conventional analgesia in post-operative pain relief after laparoscopic cholecystectomy. Recently, few studies with small sample sizes have been conducted to evaluate the role of ESPB in laparoscopic cholecystectomies, with administration of 0.25-0.5% bupivacaine. A reduction in post-operative analgesic score and 24-hour opioid usage was found by Aksu et al. (13) and Tulgar et al. (14). Our prospective study was conducted on patients undergoing laparoscopic cholecystectomies with 0.375% ropivacaine, as ropivacaine is associated with less cardiovascular and neurological toxicity. Ropivacaine provides better sensory-motor dissociation, hence enhancing the recovery of the motor component, thus assisting in early patient movement (15).

MATERIAL and METHODS

Study Design

The present study was approved by the Institutional Ethical Committee of Dr. Ram ManoharLohia Institute of Medical Sciences (IEC no- 149/20) as a prospective, interventional, quasi-randomized, single-blind study, conducted in patients undergoing laparoscopic cholecystectomy with general anaesthesia.

Patients between the age groups of 18 to 65 years, with an American Society of Anesthesiologists physical status classification score of 1 or 2 and body mass index (BMI) between 20-30 kg/m^2, were included in the study.

Patients on anticoagulants, having local sepsis, pre-existing peripheral neuropathies or chronic pain conditions, having any contraindication to regional anaesthesia administration; or those who refused to give consent were excluded from the study.

After taking an informed consent, a total of 82 patients were included in this study. The patients were divided into two groups -ESPB receiving case group and a control group that received conventional analgesia- with 41 patients each.

Patient Grouping

After screening for eligibility, participants were allocated alternately to each group (quasi-randomisation), such that there were 41 participants in each group.

In the preoperative area, patients were instructed on the usage of 10-cm visual analogue scale (VAS) for assessment of pain, graded from 0 (no pain) to 10 (most severe pain). An intravenous line was inserted, and a crystalloid was started.

In group A, the block was not performed, and the patient was shifted to the operation theatre (OT). A placebo was not administered via the ESPB technique due to its invasiveness, which made it ethically incorrect to administer placebo this way. In group B, the patient underwent ultrasound-guided ESPB 30 minutes prior to surgery.

Preoperative ESPB

All patients were monitored for their oxygen saturation, heart rate, blood pressure (non-invasive) and ECG. The group B patients received 15 mL of 0.375% ropivacaine, at the level of T8 vertebrae, bilaterally in either prone or sitting position under USG (Sonosite) guidance using high frequency linear probe (l7-12 Hz). The procedure was performed by a single senior anesthesiologist with expertise in ultrasound-guided procedures.

Details of procedure: After part preparation and under all aseptic conditions, the lower border of the scapula (corresponding to the T7 vertebra) was traced, and the T8 vertebra was localized by moving caudally. The USG linear probe was placed longitudinally, 3-cm lateral to the T8 spinous process. After identification of trapezius and erector spinae muscles superficial to the hyper-echoic transverse process (TP), a 22-gauge, 100 mm insulated, facet-type needle was introduced in a cephalo-caudal orientation. The needle was advanced until it gently hit the TP of T8 vertebra (Figure 1a, 1b). The needle was then retracted slightly, and normal saline (1-2 mL) was administered to check for adequacy of the plane by hydrodissection. After confirmation of the correct location of the needle tip, local

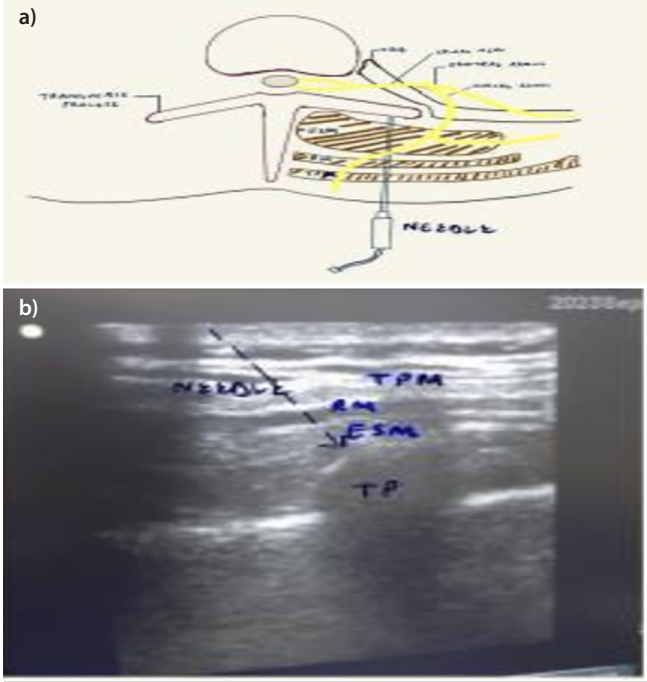

Figure 1. 1a) Line diagram depicting needle localization of needle at T8 transverse process beneath erector spinae muscle, 1b) USG guided image depicting localization of needle at T8 transverse process beneath erector spinae muscle.

TPM: Trapezius muscle, RM: Rhomboid muscle, ESM: Erector spinae muscle, TP: Transverse process

anesthetic agent, ropivacaine 15 mL in 0.375% concentration, was administered (Figure 2a, 2b). The procedure was repeated on the other side. After 15 minutes of block administration, the sensory level was assessed by pin prick 2 levels above and below the administration site, i.e., from T6-T10 vertebral level. If no sensory loss was observed, it was considered a block failure and the case was excluded from the study.

The patient's vitals were assessed every 5 minutes for 30 minutes for any hemodynamic changes and/or any other adverse effects, such as pneumothorax, bradycardia, or hypotension. In the absence of any post procedure, the patient was shifted to the OT.

General Anaesthesia

In the operation theatre, after the standard monitoring devices were connected, patients were given IV midazolam 0.02 mg/kg and fentanyl (0.02 mg/kg) as premedication. Induction was with IV propofol (1.5 mg/kg) and vecuronium (0.08-0.1 mg/kg). All patients were intubated with appropriately sized endotracheal tubes, connected to mechanical ventilators, and maintained on inhalational isoflurane, oxygen, and air. At the completion of surgery, an intravenous dose of ondansetron at 0.1 mg/kg was administered, and isoflurane was discontinued.

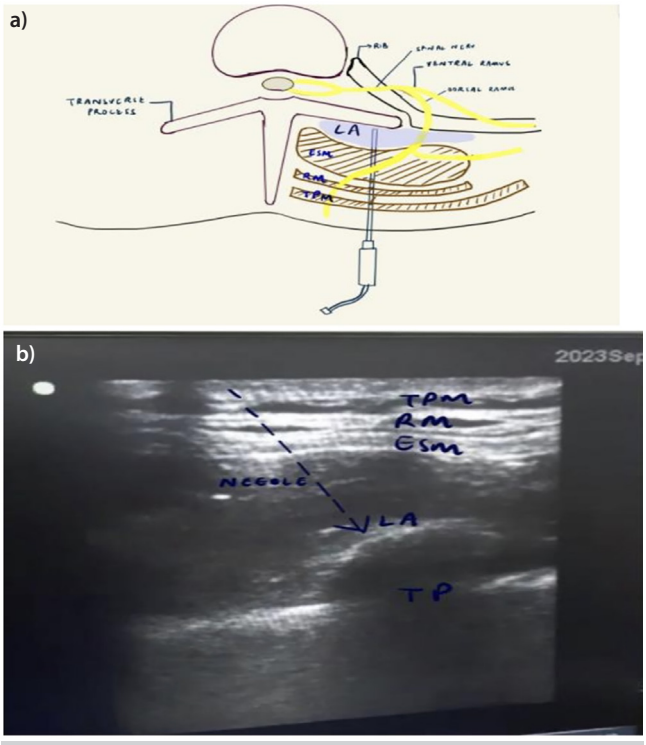

Figure 2. 2a) Line diagram depicting spread of local anaesthetic agent at T8 transverse process beneath erector spinae muscle, 2b) USG guided image depicting spread of local anaesthetic agent at at T8 transverse process beneath erector spinae muscle.

TPM: Trapezius muscle, RM: Rhomboid muscle, ESM: Erector spinae muscle, TP: Transverse process, LA: Local anesthetic

The neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg.

Intraoperatively, for patients of both groups, the standard protocol for analgesia included IV fentanyl (2 mcg/kg) at the time of induction, and repeated as required. Total intraoperative fentanyl consumption was recorded as a marker for adequacy of nerve block. Paracetamol 1 gm IV and inj. tramadol 100 mg (slow over 10 minutes in 10 mL normal saline) were given 15 minutes prior to extubation.

Post-operative Monitoring and Outcome Measures

In the post-operative recovery room, the hemodynamics of patients, of both groups, were monitored. Post-operative multimodal analgesia with IV paracetamol 15 mg/kg every 6 hours was given in all patients. The VAS was assessed by a medical health professional, who was blinded to the grouping of the patients. VAS score was measured at rest (Figure 3a), on coughing (Figure 3b) and on movement (Figure 3c) immediately after being shifted to post-operative area and then at the 2nd hour, 4th hour, 8th hour, 12th hour and in the 24th hour of the post-operative period.

Inj. tramadol 100 mg was given as first line treatment for rescue analgesia if VAS >4 and/or at the patient's request. If pain still failed to subside, injection diclofenac 75 mg, IM was given.

The primary outcome measure of the study was the frequency of tramadol and other analgesic modalities requirements in the first 24 hours of the post-operative period.

Secondary outcome measures were time to rescue analgesia, VAS score as measured at rest, on coughing and on movement in the immediate 1st hour following extubation and then at the 2nd hour, 4th hour, 8th hour, 12th hour and in the 24th hour of the post-operative period along with occurrence of any post procedural side effect.

RESULTS

Age distributions, averageweight, height, and BMI, are shown in Table 1. No statistically significant difference with regard to these parameters was noted between the two groups. Vitals

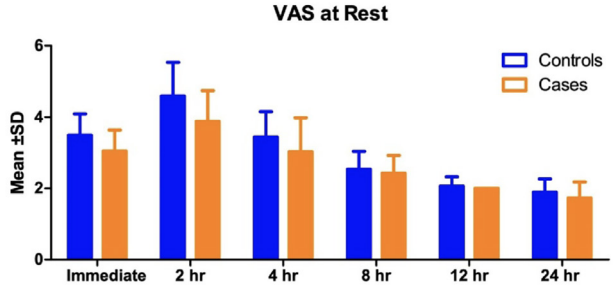

Figure 3a. Bar chart show the mean VAS at rest in control and cases at immediate, 2 hr, 4 hr, 8 hr, 12 hr and 24 hr.

VAS: Visual analogue scale, SD: Standard deviation

of patients in both groups were comparable and ESPB did not result in any post-procedure hemodynamic instability.

Nausea was significantly more prevalent in the control group than in the case group, and no complications such as pneumothorax or hematoma formation were seen with the ESPB.

Table 2 demonstrates the comparison of frequencies regarding the requirement of tramadol as 0 (not required), 1 (single dose), 1+1 (two doses), and other analgesics during the 24-hour post-operative period, along with intraoperative fentanyl consumption, between controls and cases. The requirement of tramadol (p=0.005), other analgesics (p=0.006) in the post-operative period, as well as intraoperative fentanyl consumption (p=0.015), were significantly more in the control group (group A) as compared to the cases (group B).

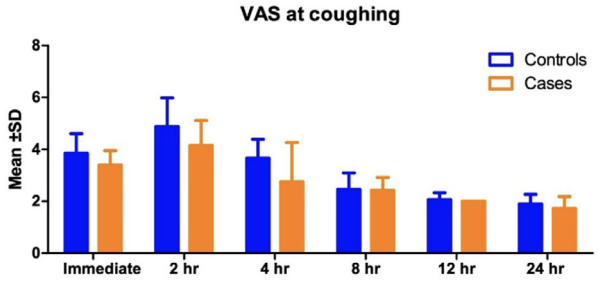

Figure 3b. Bar chart shows the mean VAS at coughing in between controls and cases at immediate, 2 hr, 4 hr, 8 hr, 12 hr and 24 hr.

VAS: Visual analogue scale, SD: Standard deviation

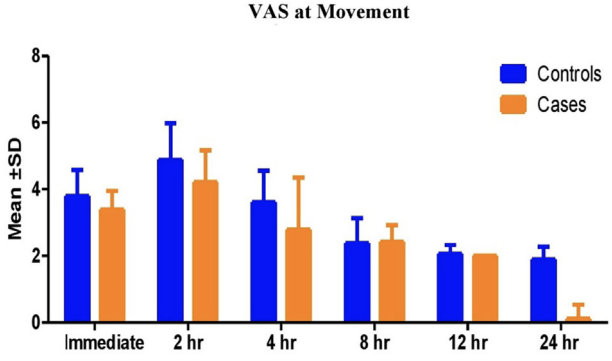

Figure 3c. Bar chart shows the mean VAS at movement in between controls and cases at immediate, 2 hr, 4 hr, 8 hr, 12 hr and 24 hr.

VAS: Visual analogue scale, SD: Standard deviation

The association of the mean time to rescue analgesia (hours) between the control group (group A) and the case group (group B) is shown in Table 3. The mean time required for administration of rescue analgesia was significantly more in group B (p=0.002).

DISCUSSION

Regional anaesthesia and pain management have experienced advances in recent years, especially with the advent of fascial plane blocks. The present study was carried out to assess the efficacy of ESPB for post-operative analgesia in patients undergoing laparoscopic cholecystectomy.

In our study, it was found that the mean duration of rescue analgesia was 1.67±0.42 hr in controls and 2.16±0.54 in cases, and this duration was statistically significantly higher in the ESPB group compared to the control group. Our findings were in agreement with other studies, which used ESPB in various other surgeries. Krishna et al. (16), who performed ESPB using 3 mg/kg 0.375% ropivacaine in patients undergoing elective cardiac surgery with cardiopulmonary bypass, reported the time to first rescue analgesia was 6 hours in the control group vs. 10 hours in the ESPB group. However, they did not conduct a statistical analysis, hence significance through the p-value could not be analyzed.

The exact mechanism of action of ESPB is still not clear. However, the rationale for the statistically significant longer duration of rescue analgesia demand in patients receiving ESPB could possibly be due to the spread of the local anesthetic agent in the paravertebral space, leading to effective analgesia for somatic and visceral pain (17). Studies, comparing the efficacy of ESPB with other blocks in breast surgeries have shown varying results. Sinha et al. (18), who conducted a study to compare efficacy of ESPB and pectoral nerve block (PECS) in patients posted for modified radical mastectomy found that mean duration of analgesia in patients of PECS block group was 7.26±0.69 hours while that in the ESPB group was 5.87±1.47 hours. However, when compared with the control group, fewer scores and lower morphine usage were found in patients receiving ESPB preoperatively in MRM surgeries. It was speculated that

Table 1. Comparison of age, weight, height and BMI between cases and control group

	Controls (n=41)		Cases (n=41)		t	p-value
	Mean	± SD	Mean	± SD		
Age (years)	37.37	11.43	40.95	12.26	-1.37	0.175
Weight (kg)	61.41	7.14	62.71	6.90	-0.83	0.407
Height (cm)	160.78	6.66	158.59	5.50	1.63	0.108
BMI (kg/m^2)	23.74	2.22	24.13	3.06	-2.14	0.035

SD: Standard deviation, BMI: Body mass index.

Table 2. Comparison of frequencies of requirement of tramadol, requirement of other analgesic (inj. diclofenac) in 24 hours and intra-operative fentanyl consumption in between controls and cases

Tramadol frequency	Controls (n=41)		Cases (n=41)		Chi-sq.		[1]p-value
	n	%	n	%			
0a	14	34.15	26	63.41	10.60		0.005*
1b	21	51.22	15	36.59			
1+1c	6	14.63	0	0.00			
Other analgesic inj. diclofenac							
Required	17	41.46	5	12.20	7.52	0.006*	
No requirement	24	58.54	36	87.80			
	Controls (n=41)		Cases (n=41)		t	[1]p-value	
	Mean	± SD	Mean	± SD			
Intra-op fentanyl consumed in miligram	162.80	24.45	151.83	14.13	2.49	0.015*	

*: Significant, [1]: Independent t-test, 0a: -(no requirement), 1b: (single dose), 1+1c: (two doses), SD: Standard deviation.

Table 3. Association of mean duration of rescue analgesia (hr) in between controls and cases

	Controls (n=41)		Cases (n=41)		t	[1]p-value
	Mean	± SD	Mean	± SD		
Time to rescue analgesia (hour)	1.67	0.42	2.16	0.54	-3.24	0.002*

*: Significant, [1]: Independent t-test, SD: Standard deviation.

the better analgesic profile with PECS block was due to the blockade of the medial and lateral pectoral, long thoracic, and thoracodorsal nerves (median and lateral pectoral nerves have been implicated in post-mastectomy surgical pain).

In our study, VAS score was significantly higher in the control group till 0-4th hour after surgery as compared to the case group receiving ESPB. There was no significant difference in VAS score between the two groups from the 8th hour till 24 hours after surgery. The findings of our study are supported by previous studies, like Tulgar et al. (14), who also observed in their study that numerical rating scale (NRS) values were higher and statistically significant in the control group for the first 3 hours after surgery. NRS scores at rest, at the 20th minute, 40th minute, 1st hour, and the 3rd hour were statistically significantly lower in the ESPB group ($p<0.0045$).

We found a statistically significant reduction in total intra-operative fentanyl consumption in the ESPB group. The mean intra-op fentanyl consumed was 162.80±24.45 in controls and 151.83±14.13 in cases. Our results are supported by the study conducted by Sethi and Garg (19), who observed that mean fentanyl requirement during surgery was statistically comparable for the two groups. Therefore, with the administration of ESPB, the intraoperative requirement of opioids is reduced, which further reduces post-operative nausea and vomiting and aids in a smoother recovery for the patient.

No complications such as pneumothorax or hematoma formation were seen with ESPB in the present study, although Ueshima (20) and Hamilton et al. (21) reported pneumothorax as a complication following ESPB.

Most authors affirm that ESPB is a technique that has great advantages over other blocks performed close to the neuronal axis. El Ghamry and Amer (22). Thoracic epidural analgesia, paravertebral block, and quadratus lumborum block are alternative approaches that are used to block somatic and visceral pain for post-operative analgesia. However, these approaches involve difficult and time-consuming techniques.

Study Limitations

Our study is limited by a small sample size; therefore, we were unable to reach enough power to analyze less common side effects. The study was a quasi-randomized study, hence there was an inherent risk of selection bias, however, it provides a possible insight for planning large-sample, well-designed RCTs to draw definitive conclusions. Since ESPB is an invasive procedure, sham placebo was not administered, and therefore, the absence of such a group is a limitation of this study. At the

end of surgery, 1 gm paracetamol and 100 mg tramadol were administered to all the patients, including the case and control groups, and could arguably have affected the initial hour pain scores and time to rescue analgesia. However, the bias due to this was controlled by standardizing the amount of drugs and administering them at the same designated time point in both the case and control groups.

CONCLUSION

ESPB for laparoscopic cholecystectomy is an easy-to-perform, relatively less time-consuming, effective, and safe technique for multimodal anaesthesia, which provides better pain relief, reduced opioid requirement, lower post-operative pain scores, and reduced total post-operative analgesic consumption, with prolonged time to rescue analgesia.

Optimal dose and drug concentration to achieve adequate analgesia are still not clear. Hence, further research and more comparative trials with other regional anaesthetic techniques are required.

Ethics

Ethics Committee Approval: The present study was approved by the Institutional Ethical Committee of Dr. Ram ManoharLohia Institute of Medical Sciences (IEC no- 149/20) as a prospective, interventional, quasi-randomized, single-blind study, conducted in patients undergoing laparoscopic cholecystectomy with general anaesthesia.

Informed Consent: Informed consent was obtained.

Footnotes

Author Contributions

Concept - M.H., S.C., A.G.; Design - M.H., S.C., A.G.; Materials - S.C.; Data Collection or Processing - M.H., S.C., M.K.G., A.G.; Analysis or Interpretation - M.H., S.C., M.K.G., A.G.; Literature Search - M.H., S.C., A.G.; Critical Review - M.H., S.C., M.K.G., A.G.; Writing - M.H., S.C., A.G.

Conflict of Interest: No conflict of interest was declared by the authors.

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