Doi: 10.5152/TJAR.2021.878

Original Article
Regional Anaesthesia

Turkish Journal of Anaesthesiology & Reanimation

Evaluation of Postoperative Analgesia of Erector Spinae Plane Block in Elective Laparoscopic Cholecystectomy: A Randomized Control Trial

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Cite this article as: Sethi D, Garg G. Evaluation of Postoperative Analgesia of Erector Spinae Plane Block in Elective Laparoscopic Cholecystectomy: A Randomized Control Trial. *Turk J Anaesthesiol Reanim.* 2021;49(6):432-438.

Abstract

Background: Only a few studies have evaluated the analgesic effect of erector spinae plane block (ESPB) for laparoscopic cholecystectomy surgery. We aimed to evaluate the analgesic effect of ESPB in patients undergoing laparoscopic cholecystectomy.

Methods: Seventy-five patients of American Society of Anaesthesiologists (ASA) grade I/II aged 18-60 years undergoing elective laparoscopic cholecystectomy were enrolled and were randomly assigned to group C or T. Patients in group C were given general anaesthesia alone, and patients in group T were given bilateral ultrasound-guided ESPB followed by general anaesthesia. The primary objective was to compare total 24 hours postoperative analgesic consumption of tramadol, and the secondary objective was to indicate the need for rescue analgesia and numeric pain rating scores (NRSs) at rest and on movement between the groups.

Results: Sixty-six patients were included for final analysis. The total tramadol consumption in 24 hours postoperative period for group T was 105.21±60.18 mg and for group C was 178.12±54.3 mg, and the difference was statistically highly significant ($P = .0001$). The need for rescue analgesia (fentanyl) was also statistically significantly lower in group T compared to group C (0.91±5.22 mcg vs 13.64±23.82 mcg, $P = .002$). The postoperative NRS at ½, 2, 4, 6, and 8 hours at rest and on movement was statistically lower in group T than group C, although this difference was not of clinical significance.

Conclusion: In patients undergoing laparoscopic cholecystectomy, bilateral ultrasound-guided ESPB provided effective analgesia as it reduced the total tramadol consumption and the need for rescue analgesia in 24 hours postoperative period.

Keywords: Erector spinae plane block, laparoscopic cholecystectomy, postoperative analgesia, ultrasound

Introduction

Laparoscopic cholecystectomy is a minimally invasive and commonly performed surgical procedure. The laparoscopic technique has the advantage of shorter hospital stay, faster recovery, and lesser pain than open surgical technique.[1,2] Nevertheless, the postoperative pain can be significant, and its intensity may vary from moderate to severe. The pain of laparoscopic cholecystectomy has different components, including somatic pain due to trochar insertion sites, visceral pain from gall bladder resection, parietal pain from peritoneal distention, and shoulder tip pain (referred visceral pain) due to diaphragm irritation from carbon dioxide insufflation.[3]

Appropriate management of pain is important to prevent patient discomfort, postoperative nausea-vomiting, and consequent delay inpatient recovery. Commonly nonsteroidal inflammatory agents, intravenous opioids, dexamethasone, gabapentin, local anaesthetics infiltration at liver bed or port site, and regional anaesthesia techniques such as epidural, transversus abdominis plane block, and paravertebral block have been used for postoperative pain management for laparoscopic cholecystectomy.[4-8]

Ultrasound-guided erector spinae plane block (ESPB) is a regional anaesthetic technique first described by Forero et al.[9] in 2016 for the treatment of thoracic neuropathic pain. In ESPB, the local anaesthetic is administered in the

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Received: 27.06.2020 Accepted: 11.02.2021
Available Online Date: December 17, 2021

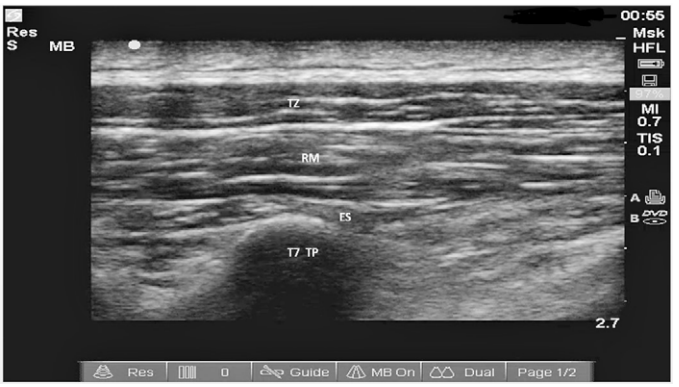

Figure 1. Parasagittal view at T7 transverse process.
TZ: trapezius; RM: rhomboid major; ES: erector spinae; TP: the tip of t7 transverse process.

interfacial plane between erector spinae muscle and transverse process of the vertebrae. The drug spreads in a craniocaudal direction over multiple paravertebral spaces blocking both ventral and dorsal rami of spinal nerve roots.[9] Since the initial description of ESPB, there have been several case reports and a few clinical trials demonstrating its analgesic efficacy in surgeries, including thoracic, abdominal, breast, hernia repair, and spinal surgeries.[10-16]

We planned the present study to evaluate the analgesic benefits of ESPB in laparoscopic cholecystectomy. The primary outcome was total 24 hours postoperative tramadol consumption, and the secondary outcomes were intraoperative fentanyl requirement, numeric pain rating score (NRS) at rest and on movement (coughing), and the need for rescue analgesia (fentanyl) postoperatively.

Methods

This prospective randomized controlled study was conducted at a tertiary care teaching institute after approval from the Institutional Ethics Committee-ESI PGIMSR (Registration number: ESIPGIMSR-IEC/2019003). Seventy patients of ASA grade I/II, aged 18-60 years of either sex undergoing elective laparoscopic cholecystectomy were enrolled for the study from January 2020 to March 2020. Patients with obesity (BMI > 30 kg m^{-2}), bleeding diathesis, and known allergy to local anaesthetics, on anticoagulants or chronic analgesic medications were excluded from the study. The principal investigator enrolled the patients for the study after a thorough preanaesthetic checkup and obtaining their written informed consent.

Main Points

- The study aimed to elucidate the postoperative analgesic effects of erector spinae plane block (ESPB) in laparoscopic cholecystectomy.
- Bilateral ESPB was performed at T7 level with 15 mL of 0.25% Levo-bupivacaine with patient in sitting position before the induction of general anaesthesia.
- The ESPB resulted in significant reduction in tramadol consumption and postoperative pain scores in 24 hour-postoperative period.
- Thus, ESPB block is a useful addition to the multimodal analgesic regime for laparoscopic cholecystectomy.

The patients were randomly assigned to either group C or T using a computer-generated random numbers list; the group allotment was concealed using sealed envelopes. On the day of surgery, the sealed envelope containing the group allotment was handed over to the anaesthesia consultant in the operation theatre. Patients in group C were given general anaesthesia alone; patients in group T were given ultrasound-guided bilateral ESPB followed by general anaesthesia.

All patients received oral alprazolam 0.25 mg on the night before and the morning of surgery. After admission to the operation theatre, standard monitors including electrocardiogram, pulse oximetry, and noninvasive blood pressure (BP) were attached to the patient, a Ringers' lactate drip was started, and midazolam 1 mg iv and dexamethasone 8 mg iv were given.

In group T, the ESPB was performed with the patient in the sitting position. A linear high-frequency (6-13 MHz) ultrasound probe (SonoSite, Bothell, WA, USA) was placed 3 cm lateral to the T7 spinous process in longitudinal parasagittal orientation. The transverse process of the T7 vertebral and the three muscle layers above it including trapezius (uppermost), rhomboid major (middle), and erector spinae (lowermost) were identified in the sonograph image (Figure 1). Using all aseptic precautions, the skin was infiltrated with 2% lidocaine, and a 22-gauge 8-cm SonoTap needle (Pajunk, Germany) was inserted in-plane in craniocaudal direction to place needle tip above the T7 transverse

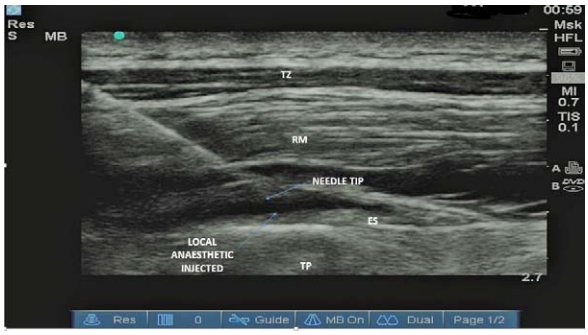

Figure 2. Lifting of erector spinae muscle on injection of local anaesthetic at T7 transverse process in ESPB. TZ: trapezius; RM: rhomboid major; ES: erector spinae; TP-T7: transverse process.

process and deep to the erector spinae muscle. Confirmation of correct needle tip placement was done by injecting 5 mL saline and visualizing the lifting of the erector spinae muscle away from the transverse process. Thereafter, 20 mL of 0.25% levobupivacaine was injected visualizing the craniocaudal spread of drug in the ESPB (Figure 2). The same procedure was repeated on the other side, thereafter the patients were made supine.

General anaesthesia was induced with fentanyl 2 mcg kg^{-1} iv and propofol 2 mg kg^{-1} iv, and vecuronium 0.1 mg kg^{-1} iv was used to facilitate endotracheal intubation and then confirmed by capnography. Anaesthesia was maintained with sevoflurane 1-2% in 50% O_2/N_2O positive pressure ventilation to maintain end-tidal carbon dioxide between 35 and 40 mmHg. Then, the surgeons proceeded surgery. During surgery, patients' hemodynamic parameters including heart rate, systolic/diastolic, and mean BP were recorded at 5-minute interval. Additional fentanyl 0.5 mcg kg^{-1} iv was given if there was a 15% increase in hemodynamic parameters (heart rate and mean BP) from baseline; the total requirement of fentanyl during surgery was recorded. After completion of the surgery, the inhalational anaesthetics were discontinued, residual neuromuscular blockade was antagonized with neostigmine and glycopyrrolate, and the patient was extubated.

The patients were transferred to the recovery room where they were assessed for pain at rest and movement (coughing) by another anaesthesiologist blinded to group allocation. The pain was assessed on 11 points NRS (0-no pain and 10—worst imaginable) at ½, 2, 4, 6, 8, and 24 hours. All patients received paracetamol 1 g iv 8 hourly and patient controlled analgesia (PCA) tramadol for postoperative analgesia. The PCA device was set to administer a bolus 20 mg tramadol iv with 20 minutes lock-time and no basal infusion. The patients were advised to use the PCA device if NRS $\geq$ 3. In the case of acute pain (NRS $\geq$ 5), fentanyl 30 mcg iv was given as rescue analgesia to the patient. Total tramadol consumption and need for rescue analgesia (fentanyl) in the first 24 hours postoperatively were recorded. The patients were assessed for any complications such as hematoma, swelling, and subcutaneous emphysema at the back before discharge from recovery.

In the study of Tulgar et al.,[17] the mean tramadol consumption in 24 hours postoperative period in the ESPB group and control group was 130±88 mg and 201±78 mg, respectively. Taking these as reference values, the minimum required sample size required to detect a 15% difference in tramadol consumption was 29 per group with a power of 90% and a significance of 5%. To compensate for any exclusions, the sample size for the study was taken as 70 patients.

Statistical analysis was done using Statistical Package for the Social Sciences (SPSS) version 21.0 (IBM SPSS Corp.; Armonk, NY, USA). Categorical variables were presented in number and percentage (%), and continuous variables were presented as mean±standard deviation (SD) and median (interquartile range). The normality of data was tested by the Kolmogorov–Smirnov test. If the normality was rejected, then the nonparametric test was used. Normally distributed continuous variables (age, weight, times, the dose of tramadol, and fentanyl) were compared using the independent t-test, whereas non-normally distributed variables (NRS) were compared using the Mann–Whitney U test. Categorical variables were compared using the Chi-square test. A P value of $<.05$ was considered as statistically significant.

Results

Details of the recruitment of patients for the study are shown in the CONSORT diagram (Figure 3). Out of 70 patients enrolled for the study, four (two in each group) were excluded from the final analysis due to the conversion of the laparoscopic procedure to open surgery. Consequently, 66 patients completed the study. The demographic variables and surgical characteristics for patients in the two groups are shown in Table 1.

Table 2 shows the analgesic requirement for the two groups during surgery and the postoperative period. The mean fentanyl requirement during surgery was statistically comparable for the two groups. The 24 hours postoperative tramadol consumption was higher in group C than in group T (178±12 mg vs 105±21 mg; $P < .001$), and the difference was statistically highly significant. Twelve patients in group C and one patient in group T needed rescue analgesia (fentanyl) in the postoperative period (36.3% vs 3%). The consumption of rescue analgesia fentanyl in 24 hours postoperative period was statistically higher in group C than in group T ($P = .002$).

The NRS at rest and movement at ½, 2, 4, 6, 8, and 24 hours postoperative period was statistically significantly

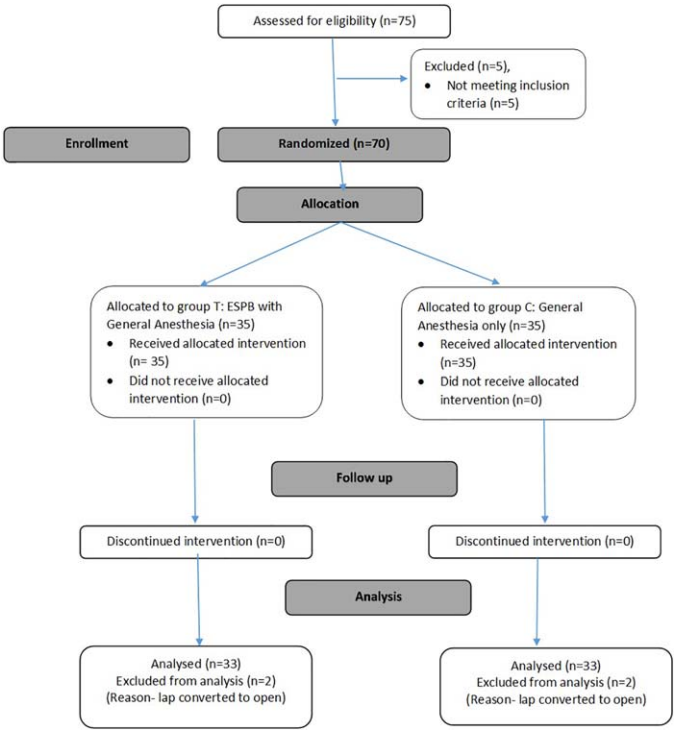

Figure 3. Consort diagram showing patient recruitment. T: test group; C: control group.

Table 1. Demographic Variables and Surgical Characteristics of the Groups

	Group T (n = 33)	Group C (n = 33)	*P*
Age (years)	34.97±10.5	39.15±11.91	.135
Gender (F/M)	24/9	21/12	.428
Weight (kg)	59.45±10.2	60.15±9.41	.773
Duration of surgery (minutes)	64.85±10.72	64.85±13.43	.938
ASA I/II	26/7	29/4	.511

F, female; M, male; ASA, American Society of Anaesthesiologists.
Data presented as N or mean (standard deviation).

Table 2. Intraoperative and Postoperative Analgesic Requirement

	Group T (n = 33)	Group C (n = 33)	*P*
Intraoperative fentanyl requirement (mcg)	120.91±21.12	116.36±16.36	.252
Postoperative 24 hours tramadol requirement (mg)	105.21±60.18	178.12±54.3	<.0001
Postoperative 24 hours rescue fentanyl requirement (mcg)	0.91±5.22	13.64±23.82	.002

Data are presented as mean (standard deviation).

Table 3. NRS at Rest

Postoperative Time	Group T (n = 33)	Group C (n = 33)	*P*
½ hour	3 (3-3)	3 (3-4)	.003
2 hours	2 (2-3)	3 (2-4)	.003
4 hours	2 (2-2)	3 (2-3)	.0008
6 hours	2 (1-2)	2 (2-2)	.027
8 hours	1 (1-2)	2 (2-2)	.002
24 hours	1 (1-1)	1 (1-2)	.371

Data are presented as median (range).

Table 4. NRS on Movement (Coughing)

Postoperative Time	Group T (n = 33)	Group C (n = 33)	*P*
½ hour	3 (3-3)	3 (3-4)	.003
2 hours	2 (2-3)	3 (3-4)	.001
4 hours	2 (2-2)	3 (2-3)	.0004
6 hours	2 (1-2)	2 (2-3)	.019
8 hours	1 (1-2)	2 (2-2)	.002
24 hours	1 (1-1)	1 (1-2)	.248

Data are presented as median (range).

lower in group T compared to group C. However, no statistically significant difference was observed between the groups at the 24 hours postoperative period (Tables 3 and 4). No side-effects or complications were observed in patients of either group.

Discussion

The results of our study show that ultrasound-guided ESPB significantly reduced the 24 hours postoperative analgesic requirement in patients undergoing laparoscopic cholecystectomy. The NRS at rest and movement was also statistically lower in the first 8 hours postoperative period, although the difference was not clinically significant.

ESPB was first described by administering local anaesthetic in the interfacial plane between Erector Spinae muscle and transverse process of the vertebrae at the T5 level.[9] Then, it was used successfully for the treatment of severe thoracic neuropathic pain in a patient who had failed response to several analgesic modalities. In a cadaveric study, Forero et al.[9] showed a craniocaudal spread of injected dye from C7 to T8 in ESPB and also deep into the intervertebral foramina and the intercostal muscles. Regarding the underlying mechanism of action of ESPB, Ivanusic et al.[19] suggested that local anaesthetics did not penetrate the paravertebral space, and the dorsal rami was blocked posterior to the costotransverse foramen. However, in the MRI gadolinium dye study, Schwartzmann et al.[19] showed the spread of contrast into the paravertebral space, through the neuroforamina, and also a circumferential epidural spread spanning over at least seven thoracic spaces. These findings were further confirmed by Altinpulluk et al.[20] in another cadaveric study, in which the dye injected in ESPB showed spread into the paravertebral spaces staining the ventral and dorsal rami.

As erector spinae muscle extends throughout the thoracic and lumbar region, ESPB performed at an appropriate vertebral level can provide analgesia for different surgeries by blocking both somatic and visceral components of pain. It has been postulated that the spread of local anaesthetic through the intertransverse connective tissue into paravertebral space that transmits sympathetic fibres provides analgesia for visceral pain.[9] A recent review of the clinical characteristics of ESPB from data pooled from previous case reports and studies found that single shot ESPB at thoracic level was the most common technique used, and that it resulted in a 35% reduction in opioid requirement. With only one adverse event of pneumothorax being reported, the authors opinioned that ESPB was a safe and effective alternative to other regional anaesthesia techniques such as epidural and paravertebral block, which may have complications including dural puncture, pneumothorax, and hematoma formation.[21] Thus, evidence from emerging literature suggests that ESPB is a feasible and effective alternative regional anaesthesia technique when the paravertebral or epidural block is contraindicated as in patients on dual antiplatelet therapy or the patient is at high risk for general anaesthesia.[22-27]

The findings of our study are similar to the previous study by Tulgar et al.[17] and Altiparmak et al.,[28] showing a significant analgesic benefit of ESPB block in laparoscopic cholecystectomy. In Tulgar et al.'s study, ESPB was performed at T9 level with 20 mL of 0.375% bupivacaine before the induction of general anaesthesia. Their study found statistically lower NRS in initial postoperative 0-3 hours, lower 24 hours tramadol consumption, and reduced need for rescue analgesia in the ESPB group compared to the control group.[17] However, there are some important differences in our methodology from Tuglar et al.'s. In the present study, the ESPB was performed at T7 for more appropriate dermatomal sensory analgesia for surgical pain with a lower concentration of levobupivacaine for safe dosing of the local anaesthetic. We thought that the total analgesic consumption was a superior objective measure for the assessment of the analgesic effect of ESPB in comparison to the pain score. Therefore, the primary outcome was PCA tramadol consumption in our study,

whereas it was postoperative pain score in Tulgar et al.'s study.[17] Tuglar et al. study had a small sample size of 15 patients in each group; in comparison to it, our sample size was 33 patients in each group.

Altiparmak et al.[28] compared ESPB with oblique subcostal transversus abdominis plane (OSTAP) block in patients undergoing laparoscopic cholecystectomy. In their study, ESPB was given at the T7 level with 20 mL of 0.375% bupivacaine. The results showed a statistically significant reduction in the tramadol consumption (139.1±21.9 mg vs 199.4±27.7 mg; $P = <.001$; ESPB vs OSTAP) and NRS in 24 hours postoperative period in the ESPB group compared to the OSTAP group. They attributed the greater analgesic benefit of ESPB over OSTAP block to the more extensive spread of local anaesthetic in the erector spinae plane anaesthetizing larger dermatomal area together with blockade of the visceral pain. The PCA tramadol with 10 mg bolus and lockout interval of 20 minutes was used for postoperative analgesia in both Tuglar et al.'s and Altiparmak et al.'s study,[28] whereas in our study, the bolus dose of PCA tramadol was set at 20 mg bolus dose. However, our observation of a 30% decline in postoperative tramadol consumption in the block group was comparable to results both the earlier studies.

The median NRS at and movement was significantly lower in the first 8 hours after surgery in group T compared to group C. However, the maximum difference of NRS between the groups was 1 point; therefore, this would not be considered to be clinically significant. The median NRS was under 4 at all points of time in both groups, which can be attributed to an effective multimodal analgesic regime comprising of dexamethasone, paracetamol, PCA tramadol, and ESPB. Local anaesthetic (levobupivacaine, bupivacaine, and ropivacaine) in concentration varying from 0.25% to 0.5% and volume ranging from 20 to 30 mL has been used in ESPB. The volume needed to anaesthetize a single dermatome has been reported to the range of 2.5-6.6 mL with a median volume of 3.4 mL.[29] In this study, we used 20 mL of 0.25% levobupivacaine in ESPB on each side, and we found it to provide effective postoperative analgesia.

The limitation of our study was not assessing the sensory block by pinprick in the postoperative period. Also, the assessment for the analgesia was limited to the 24 hours postoperative period. Therefore, further ESPB trials are needed to completely elucidate the duration of sensory block and analgesic effect, which would help in integrating it as a component of surgical multimodal analgesia.

Conclusion

In patients undergoing laparoscopic cholecystectomy, bilateral ultrasound-guided ESPB provided effective postoperative analgesia as it reduced the total tramadol consumption and the need for rescue analgesia (fentanyl) in the 24 hour-postoperative period.

Ethics Committee Approval: Ethical committee approval was received from the ESI-PGIMSR Institutional Ethics Committee (September 14, 2019; DM(A)H-19/14/17/IEC/2012-PGIMSR).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - D.S.; Design - D.S.; Supervision - D.S.; Resources - D.S.; Materials - G.G.; Data Collection and/or Processing - G.G.; Analysis and/or Interpretation - G.G.; Literature Search - D.S., G.G.; Writing Manuscript - D.S., G.G.; Critical Review - D.S.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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