24-Feb-26

COVER LETTER

To:
Protocol Registration and Results System (PRS) Team
ClinicalTrials.gov
U.S. National Library of Medicine

Subject: Clinical Trial Registration Submission

Dear Sir/Madam,

I am submitting our study titled **"Comparison Of Postoperative Analgesia In Landmark Guided Erector Spinae Plane Block V/S Subcostal Transversus Abdominis Plane Block In Laparoscopic Cholecystectomy: A Randomized Controlled Trial"** for registration on ClinicalTrials.gov.

This is a prospective, randomized controlled trial to be conducted at Patel Hospital, Karachi, Pakistan. The objective of this study is to compare the postoperative analgesic efficacy of landmark-guided erector spinae plane block versus subcostal transversus abdominis plane block in adult patients undergoing elective laparoscopic cholecystectomy.

The study protocol adheres to Good Clinical Practice (GCP) guidelines. Ethical approval will be obtained from the Ethical Review Committee of Patel Hospital and CPSP prior to participant enrollment. Written informed consent will be obtained from all study participants.

We kindly request registration of this clinical trial and assignment of a ClinicalTrials.gov Identifier. Please let us know if any additional information or documentation is required.

Sincerely,
Dr. Kulsoom Mehmood
Principal Investigator
Patel Hospital, Karachi, Pakistan

24-Feb-2026

TITLE

COMPARISON OF POSTOPERATIVE ANALGESIA IN LANDMARK GUIDED ERECTOR SPINAE PLANE BLOCK V/S SUBCOSTAL TRANSVERSUS ABDOMINIS PLANE BLOCK IN LAPAROSCOPIC CHOLECYSTECTOMY: A RANDOMIZED CONTROLLED TRIAL

Introduction:

Postoperative pain after laparoscopic cholecystectomy is significant despite its minimally invasive nature.(1) Fascial plane blocks have gained popularity in laparoscopic surgery for its potential to provide effective postoperative pain relief. (2)

Recent studies have shown promising results regarding the efficacy of the novel block Erector Spinae Plane Block in laparoscopic surgeries. First described by Forero et al. demonstrated that ESPB significantly reduced postoperative pain scores and opioid consumption in patients undergoing laparoscopic procedures compared to standard analgesic regimens.(3, 4) Another study by Ciftci et al. (2022) reported similar findings, highlighting the potential of ESPB as a valuable adjunct to multimodal analgesia in laparoscopic surgery.(5)

The ESPB is peri paravertebral block, involves deposition of Local anesthetic between erector spinae muscle and transverse process. (6)It's simpler to perform and rather safer as it aims on bony surface and away from pleura and said to target both dorsal and ventral rami thus good for both somatic and visceral pain relief.(6-8) This together with spread at multiple levels makes it excellent choice for a wide range of surgical interventions like thoracic, breast, spinal and abdominal surgeries.(9, 10)

A study by Tulgar et al, comparing ultrasound guided ESPB with control demonstrated mean fentanyl use to be 6.66ug+-12.44 in ESPB vs 32.33+-22.69 in control group which is statistically significant.(6) Another study showed mean pain scores were 4.2+-1 in TAP group as compared to 1.7+-1.5 in ESPB group ($p<0.0001$)(8).

The landmark-guided ESPB can be a valuable technique in low resource countries lacking ultrasound access. The landmark guided block can be performed using easily accessible instruments. (11) While ultrasound-guided procedures have become the gold standard for regional anesthesia, the landmark-guided approach offers an alternative when ultrasound equipment is unavailable or costly.(12)

RATIONALE:

- To the best of our knowledge, there is paucity of data since landmark guided Erector spinae plane block has not been evaluated to see the effectiveness of the block.
- Due to lack of significant data comparing both blocks, we want to compare the postoperative analgesic effect of ESPB v/s STAP block by landmark technique as landmark guided approach offers an alternative when ultrasound equipment is unavailable or costly.

OBJECTIVE:

To compare postoperative analgesia in Erector Spinae Plane Block (ESPB) v/s Subcostal Transversus Abdominal Plane Block (STAP) in adults undergoing Laparoscopic Cholecystectomy at a Tertiary care hospital.

OPERATIONAL DEFINITIONS:

Postoperative Analgesia:

- Analgesia is a medication that relieves pain.
- Postoperative analgesia is a medication used to relieve pain or discomfort of a patient on the operating site. A pain due to which patient cam not perform small tasks like sitting, walking or sleeping comfortably.

Erector Spinae Plane Block (ESPB):

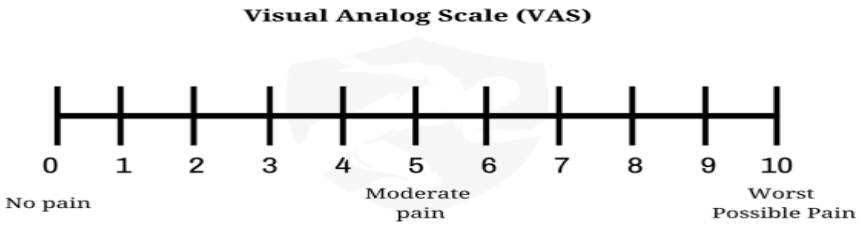
- A newer regional technique used in which local anesthetic is injected between the erector spinae muscle and the transverse process.
- The solution crossing the internal intercostal membrane blocks the dorsal and ventral rami of spinal nerves.
- The local anesthetic blocks both the somatic and sympathetic nerves.

Subcostal Transversus Abdominis Plane Block (STAP block):

- It is a regional analgesia technique which involves the injection of a local anesthetic solution into a plane between the internal oblique muscle and the transversus abdominis muscle.
- It blocks the sensory nerves of the anterolateral abdominal wall (T6-L1).

Pain score (visual analogue scale):

- The visual analogue scale is a straight line from 1 to 10 with one end meaning no pain and the other end meaning the worst pain.
- A patient will tell the score according to his/her pain intensity.



HYPOTHESIS:

Landmark guided Erector Spinae Plane Block can reliably be performed and can provide better analgesia than Subcostal Transversus Abdominis Plane Block in laparoscopic cholecystectomy.

MATERIALS AND METHODS:

Study design: Double blinded, Randomized controlled trial

Setting: The study will be conducted at the Operating room, Postoperative anesthesia care unit (PACU) and wards of the Patel Hospital, Karachi.

Study duration: After approval from the REU of College of Physicians and Surgeons, 3 to 6 months or till the sample size achieved.

Sample size:

The sample size was calculated via Open EPI software for 'Sample size for comparing Two Means' by using finding of Tulgar, et al. who reported PACU rescue analgesic requirement 9.4% in ESPB and 31.3% in STAPB group(8). α =5% 1-β =90% P_0 =0.094 P_α = 0.313 n = 25 using formula below:

$$n = \frac{\left\{z_{1-\alpha}\sqrt{P_0(1-P_0)} + z_{1-\beta}\sqrt{P_a(1-P_a)}\right\}^2}{(P_a - P_0)^2}$$

We will take 30 patients in each group, total sample size will be 60.

- Group A (ESPB group): 30 patients
- Group B (STAP group): 30 patients

Sampling technique:

Non probability consecutive sampling

SAMPLE SELECTION:

INCLUSION CRITERIA:

Following patients will be included:

- ✓ Both male and female patients.
- ✓ Patients between the age of 18 to 65years.
- ✓ Patients scheduled for Laparoscopic Cholecystectomy.
- ✓ Patients with American Society of Anestheologists (ASA) Physical status I, II and III.
- ✓ Give consent.

EXCLUSION CRITERIA:

Following patients will be excluded:

- ✓ Hypersensitivity to local anesthetics.

- ✓ Infection at the block site.
- ✓ Coagulation disorder.
- ✓ BMI >40kg/m2
- ✓ Patients having pregnancy.
- ✓ Conversion to open surgery.
- ✓ Drain placement.
- ✓ Any neurological or psychiatric disease making them unable to cooperate.
- ✓ Patients unwilling to co-operate.

DATA COLLECTION PROCEDURE:

This study will be performed after the permission of Research evaluation unit (REU) of College of Physicians and Surgeons Pakistan (CPSP) and allotment of Trail registration number, written informed consent for the study will be obtained from the patient who fulfill the inclusion criteria.

Patients admitted at Patel Hospital Karachi and who fulfills the inclusion criteria will be included in the study. Detailed demographic details of each patient including name, gender and age will be obtained. Weight and height of each patient will be measured by using digital weighing machine and stadiometer, respectively. BMI of each patient will be calculated by using BMI formula (BMI=weigh/height^2). Medical history of each patient will also be inquired. Upon enrolling a patient in study a case number will be allotted to each patient. Simple Randomization will be done by the closed envelope method to determine which group the patient will be included in. The case number will be used to collect data in the postoperative period.

Patient and the pain assessor both will be blinded to the block given. Anesthesia provider doing the perioperative care in the theatre will be handed over the sealed envelope enclosing the name of the group, A or B. This anesthesiologist will also perform the block but will not take part in collecting data postoperatively nor in the data analysis.

On arrival to the OT, both groups will be monitored with pulse oximetry, NIBP, ECG and continuous waveform Capnography prior to induction of anesthesia. All patients will be induced with Propofol 2-3mg/kg, Nalbuphine 0.1-0.2mg/kg and relaxed with Atracurium 0.5mg/kg. All patients will receive paracetamol 1g IV at induction. Anesthesia will be maintained with isoflurane in air oxygen mixture.

After induction, Group A patients will be positioned in left lateral decubitus position. Spinous processes will be identified. At T9 level 2 cm from the midline transverse process will be identified at 4cm depth and 30ml of 0.25 % ropivacaine will be given on right side just after hitting the transverse process.

Group B will receive landmark guided Transversus Abdominis plane block with 30ml of 0.25% ropivacaine on right side in the supine position.

All patients will receive 4mg of ondansetron and 4mg of dexamethasone intraoperatively. Upon completion of the surgery, all patients will be reversed with Neostigmine and glycopyrrolate and will be shifted to the recovery.

Standard Analgesia Plan: All patients will receive Paracetamol 1gram IV every 6 hours for 24 hours postoperatively.

Postoperative pain assessment and management:

After 30 minutes in the PACU, postoperative analgesia will be scored by VAS scoring. VAS is 11 points scale ranging from 0 to 10 with 0 representing absence of pain and 10 as worst imaginable pain. 1-3 will be categorized as mild pain, 4-7 as moderate and 7-10 as severe pain.

All patients reporting VAS score of >3 upon arrival in the PACU will receive 50mg of Tramadol IV by the recovery nurse as rescue analgesic. If pain score stayed >3 after 20 minutes, another rescue analgesic 30mg of ketorolac will be given IV.

Outcome measures:

Primary outcome will be VAS score upon 30 minutes to PACU, and postoperative 6, 12 and 24 hours. Secondary outcomes will be need for rescue analgesia and time for first analgesic request.

Confounder and Biases:

To address confounding factors and to reduce biases in the study, we used randomization in assigning subjects in both groups, we restricted our subjects to specific surgical population that is coming for laparoscopic cholecystectomy, and we did double blinding that's both participant and investigator and the person who did data analysis were blinded to the group.

Statistical analysis:

The data will be entered and analyzed by the SPSS version 21. Descriptive statistics will be summarized by mean +- SD, median with interquartile range will be reported for quantitative variables. Frequencies and percentages will be

reported for categorical variables. To check the normality factor on quantitative variables such as age and NRS score will be seed by Shapiro Kolmogorov test.

To check the significant association between field blocks with ASA status, pain scores will be seen by t test or Mann Whitney U test. P value less than 0.05 will be taken as significant.

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