ClinicalTrials.gov Identifier: Not assigned yet

Title:
Comparison of efficacy of unilateral Transversus abdominis plane (TAP) block versus bilateral Transversus abdominis plane (TAP) block in patients undergoing laparoscopic cholecystectomy.

Protocol Number: No.803/RC/KEMU

Version: 1.0
Date: 03 November, 2025
Phase: Not Applicable
Primary Purpose: Supportive Care

Principal Investigator:
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Ethical Approval:
Approved by Institutional Review Board, KEMU (Approval No.No.803/RC/KEMU, Dated: 03 Nov 2025)

Sponsor:
King Edward Medical University/ Mayo Hospital Lahore

Confidentiality Notice:

STUDY PROTOCOL:

Study design:

Randomized controlled trial

Setting:

West surgical ward, Mayo hospital, Lahore.

Duration:

03 months

Sample size:

A sample of size 82 (41 for each group) is calculated with confidence level of 95 and 80% power of test.

Sampling technique:

Blocked randomization sampling technique as per CONSORT guidelines 2010.

Group allocation:

Sampling will be done using the RANDOM ALLOCATION SOFTWARE 2.0. Patients will be allocated to either group using computer generated sets of random allocation to groups A or B (right unilateral TAP block being group A and bilateral TAP blocks being group B). The group allocation will be done in advance of the start of study.

INCLUSION CRITERIA:

1. Both genders between 18-80 years with symptomatic gallstone disease.

2. Diagnosed patients that are fit for laparoscopic cholecystectomy, having ASA status of I, II or III).

3. No documented allergies or adverse reactions to local anesthetics used.

4. Patients consenting to participate in the study.

EXCLUSION CRITERIA:

1. Non consenting individuals.

2. Active skin infection at TAP block site i.e. triangle of petit.

3. Patients with coagulopathies.

4. Patients with chronic pain disorders and chronic use of analgesics.

5. Patients with chronic liver and kidney diseases.

6. Patients with alcohol, opioid or other substance addiction.

7. History of previous major elective or emergency abdominal surgery.

8. Pregnant and breast feeding women.

DATA COLLECTION PROCEDURE:

After approval of synopsis by the research board and ethical committee, all patients presenting in Outpatient department of west surgical ward, Mayo hospital, Lahore, fulfilling the above criteria will be included in the study after informed consent and evaluation. Patients will be selected using blocked randomization sampling and allocated to groups using computer generated sets of random allocation. Clinical data will be collected in the attached proforma.

METHODOLOGY:

Patients will be included in the study after completion of diagnostic work-up (Ultrasound, Baseline investigations and anesthesia fitness). All this information will be recorded in a purpose built proforma. Surgery will be performed by same surgical team consisting of supervisor (consultant surgeon), the principle researcher, and assistants. The researcher will also be performing the procedure under supervision. Surgery will be performed under general anesthesia. IV antibiotic (Injection ceftriaxone 1g) will be administered at the time of induction of anesthesia. TAP blocks will be applied under sedation with midazolam prior to induction of general anesthesia. Decreased sensation in the appropriate dermatomal levels in TAP block groups was confirmed by pinprick before general anesthesia. For group A patients, TAP block will be applied in the right triangle of petit, using 20 ml of 0.25% bupivacaine on the right side of the abdomen as given in Sahin et al.15 whereas the patients in the group B will receive a total of 40 ml (20 + 20) of 0.25% bupivacaine at both sides of the abdomen. Laparoscopic cholecystectomy will be performed using the standard four port technique. A10mm incision will made in the midline periumbilical region for camera port, another 10mm port epigastric port in the midline approximately 2cm below the xiphoid process; and two 5mm subcostal incisions will be made for trocar insertion during laparoscopic cholecystectomy on the right side. The CO_2 insulation pressure will be limited to 12 mmHg.After surgery, The VNRS will be used to evaluate pain level, for which all patients will be informed of the pain scale in detail in the preoperative period (0 = no pain at all, 10 = the worst pain that one can ever imagine). The postoperative nausea and vomiting (PONV) scale will be used to evaluate nausea and vomiting after surgery (1: no nausea, no vomiting; 2: nausea present, no vomiting; 3: nausea present, vomiting once; 4: nausea present, vomiting twice or more or continuous retching), and a 5-point Likert-type scale will be used to evaluate patient satisfaction. Shoulder pain will be rated as present ese parameters will be evaluated at 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, and 24 hours after

surgery. Patient satisfaction will be recorded 24 hours after surgery. Paracetamol 1g will be administered as an intravenous infusion at 6 hours, 12 hours, 18 hours, and 24 hours after surgery. A tramadol infusion at a dose of 0.5 mg/kg will be administered once per hour if the patient reports a VNRS-R score of 4 or higher at rest. The maximum tramadol dose can be upto 500 mg/day. Patients with a PONV score of 3 points and higher will be administered 4 mg of ondansetron at 4-hour intervals. The total amounts of tramadol and ondansetron consumed after surgery will be recorded in the attached performa by on duty doctors, who will be blind to the type of block applied.

STATISTICAL ANALYSIS PLAN:

The statistical analysis will be performed using the latest SPSS (Version 31.0, SPSS Inc., Chicago, IL,USA, licensed to Hitit University) software package. Descriptive statistics include mean ± standard deviation for normally distributed continuous variables, median (min, max) for abnormal distributions and ordinal variables, and number and percentage for categorical variables. A Kolmogorov Smirnov test and a Shapiro Wilk test will be used to evaluate the normality of distribution. Levene used to examine the homogeneity of variances. An independent samples t-test will be used to compare the mean values of the independent samples for continuous variables, and a Mann Whitney U test will be used to analyze variables without a normal distribution. Nominal variables will be analyzed using a Chi-square test. A Kruskal Wallis test will be used to analyze ordinal variables (pain scores). A p-value of less than 0.05 will be considered statistically significant.

DATA COLLECTION INSTRUMENT:

PROFORMA

Comparison of efficacy of unilateral Transversus abdominis plane (TAP) block versus bilateral Transversus abdominis plane (TAP) block in patients undergoing laparoscopic cholecystectomy

Case No. _____ Hospital registration #_____ Contact number: _____

Name:_____ Age:____ Date of operation:_____

Address: _____

Co-Morbids: HTN____, DM____, IHD____

Antiplatelets/Antithrombotic Medications: _____

O (Group A) O (Group B)

POST-OPERATIVE PAIN ASSESSMENT:

Time (hours)	VNRS at Rest (0-10)	VNRS after Cough (0-10)
1		
2		
4		
8		
12		
24		

PONV SCORE: _____

1: no nausea, no vomiting **2:** nausea present, no vomiting **3:** nausea present, vomiting once **4:** nausea present, vomiting twice or more or continuous retching

POST-OPERATIVE IV ANALGESIC AND ONDENSETRON:

Time (in hours)	Dose of IV Tramadol (ml)	Dose of IV Ondensetron (ml)
1		
2		
4		
8		
12		
24		

PATIENT SATISFACTION: _____

CONSENT FORM

TOPIC:

Comparison of efficacy of unilateral Transversus abdominis plane (TAP) block versus bilateral Transversus abdominis plane (TAP) block in patients undergoing laparoscopic cholecystectomy

INSTITUTE: Mayo hospital Lahore.

AIM OF STUDY: Laparoscopic cholecystectomy is the gold standard surgical option for treatment of symptomatic gallstone disease. Post-operative pain remains a concern despite the minimal invasive technique. Aim of this study is to compare unilateral and bilateral TAP blocks in LC so as to establish which of the two is more efficient in providing adequate analgesia and eliminating the need for post-operative intravenous opioids. This will help us to better understand the role of in TAP block in LC. It is expected that this will help in reducing the need and dosage for postoperative IV opioids thus reducing postoperative nausea and vomiting (PONV), improve patient satisfaction and allow early mobilization of the patient.

METHOD: A single page Performa with few questions regarding patient information and post-operative pain and patient satisfaction will be filled after the informed consent from those patients only who are willing to participate in this study. Patients will be blind to the treatment modality allotted to them; however, they will have a right to withdraw from the research before the operation if they do not feel comfortable. In case of withdrawal from the research, patients will be free to choose whatever technique they feel comfortable with.

HARM OF STUDY: There is no harm to patient participating in this study.

CONFIDENTIALITY: Confidentiality of the patient and all data will be ensured.

IN CASE OF ANY QUERY: Contact Dr Aneeqah Din Muhammad, senior registrar, west surgical ward, Mayo hospital, Lahore. 0342-4067183

CONSENT:

I solemnly declare that I want to participate in this study with my own will without any pressure.

Patient name: **Investigator:**

Signature: **Signature:**

Date: