Title: Does the Transversus Abdominis Plane(TAP) block effectively manage pain after laparoscopic cholecystectomy?: A Randomised Controlled Trial

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A. Introduction:

Laparoscopic cholecystectomy is the surgical treatment of choice for symptomatic and difficult gallstones [1]. It is a frequently performed upper abdominal surgery, but postoperative pain remains a cause of delayed discharge. Acute pain following the surgery is multifactorial and considered to be a combination of three components that are visceral pain (deep intra-abdominal), incisional (somatic) pain and referred (referred to visceral) pain. Multiple modalities have been utilized in dealing with it, but postoperative pain still presents as a hindrance towards early discharge[2,3].

Despite various nerve block techniques present, the Transverse Abdominis Plane (TAP) block is the modern trend favored by anesthesiologists in lower abdominal surgeries [2].
Multiple studies warrant a favorable outcome in terms of postoperative pain by using the TAP) block technique as compared to others[4,5,6].

This study aims to evaluate the efficacy of (TAP) block in terms of reducing postoperative pain in laparoscopic cholecystectomy procedures in the local region and present it as a modality that can be uniformly applied.

B. Rationale for this study

Numerous studies have demonstrated the efficacy of the Transverse Abdominis Plane (TAP) block in improving postoperative pain control when compared to procedures performed without it, however, the body of high-quality evidence originating specifically from Pakistan and similar regional settings is limited. Given the potential variability in surgical procedures, patient demographics, and analgesic regimes across healthcare systems, local research is required to evaluate the TAP block's efficacy and safety in our setting. The current study addresses this specific gap by providing critical, regionally relevant data that may support the routine incorporation of the TAPP block into the standard perioperative care pathway, with the ultimate goal of optimizing pain management and improving patient outcomes across our hospital network.

C. Objectives:

- To compare the efficacy of TAP block in the laparoscopic cholecystectomy procedure in terms of pain score and analgesic requirements by comparing it to procedures done without TAPP block.
- To evaluate and compare overall patient outcomes following laparoscopic cholecystectomy procedures done with and without TAP block.

D. Research question:

- Is it more efficient in terms of pain score and analgesic requirements to conduct a laparoscopic cholecystectomy procedure with a TAP block?

E. Methodology:

- **Type of Study:** A Randomised Controlled Trial
- **Study Setting:** Surgical Department, JPMC and Lyari General Hospital
- **Study Period:** 3 months after the approval of the proposal from IRB of JPMC and the Clinical Trials Registry.
- **Ethical Approval:** To be obtained from the Institutional Review Board of JPMC
- **Sampling Technique:** Convenience sampling.
- **Sample Size:** Using OpenEpi sample size would be 100 patients in each group with a total of 200 patients

Inclusion Criteria:

1. Patients diagnosed with symptomatic cholelithiasis and advised to undergo laparoscopic cholecystectomy.
2. Both Genders
3. Age more than 10 years and not above 60 years.

Exclusion Criteria:

1. Patients with contraindications for surgery.
2. Patients below the age of 10 years or above 60 years.

Group Allocation:

- **Group A (Laparoscopic Cholecystectomy with TAP block):** 100 patients
- **Group B (Laparoscopic Cholecystectomy without TAP block):** 100 patients

Outcome Measures:

- Primary Outcomes:
    - Pain score in terms of a visual analogue scale.
    - Analgesic requirements.
- Secondary Outcomes:
    - Length of hospital stay.

Data Collection:

Demographic Data:

- Age
- Gender
- Comorbidities.

Intraoperative Data:

- Duration of surgery
- Ease of procedure
- Technique used for laparoscopic cholecystectomy

Postoperative Data:

- **Pain Assessment:** Postoperative pain levels using a Visual Analogue Scale(VAS).
- **Analgesic requirements:** Type and Dosage used.
- **Hospital Stay:** Duration of postoperative hospital stay**.**

Follow-Up

- **Duration:** Patients will be followed for a minimum of two days post-surgery.
- **Follow-Up Visits:** Scheduled at 1 week and 1 month.
- **Assessment:** Clinical examination and ultrasonography or culture.

Data Analysis

- **Statistical Software:** SPSS version 20.
- **Statistical Tests:** Chi-square test for categorical variables(analgesia used), t-test for numerical variables(pain score and length of hospital stay)
- **Significance Level:** A p-value < 0.05 will be considered statistically significant
- **Visualisation**: Bar chart for length of stay for each group

Limitations

- **Short Follow-Up:** Limited to one month, which may not capture long-term complications

Research instrument

- Research instruments consist of consent forms for each participant, written in both English, Urdu and Sindhi for the convenience of participants; the patient data files will maintain the anonymity of participants.
- No additional investigation, intervention, or medication will be done apart from the regular procedure required for the treatment of the participants.

Ethical issues:

- Primarily, the approval will be pursued by the IRB of JPMC.
- Research will be registered with an internationally recognised Clinical Trial Registry.
- The principal investigator will acquire informed consent from the potential participants. The participant reserves the right to withdraw from the study at any time. The identities of participants and institutions will be safeguarded through encoding and password protection.

Funding:

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Conflict of interest:

The authors have no conflict of interest

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