Study Protocol

Official Title

Ultrasound-Guided Modified Pectoral Plane (PECS II) Block versus Midpoint Transverse Process to Pleura (MTP) Block for Postoperative Analgesia after Modified Radical Mastectomy: A Randomized Controlled Trial

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What is already known on this subject? What does this study add?

Modified Radical Mastectomy (MRM) is a surgical procedure that removes the entire breast, including the skin, breast tissue, areola, and nipple, along with most of the axillary lymph nodes. However, most of the chest muscles are left intact. It is a less invasive surgery than a radical mastectomy, which also removes the chest muscles. It is a standard option for treating breast cancer that has spread to the axillary lymph nodes.

Postoperative pain in MRM is a common problem that can affect the quality of life and recovery of patients. Some factors that can influence the pain intensity are:

- The extent of the surgery and the involvement of the axillary lymph nodes.
- The type and dose of anesthesia used during the surgery.
- The use of regional blocks or multimodal analgesia to reduce opioid consumption and side effects

Postoperative pain management is becoming an integral part of anesthesia care. Optimal pain control in patients undergoing MRM is imperative for good rehabilitation and functional outcomes. Current modalities in use aim to reduce postoperative opioid consumption to control postoperative pain thus minimizing its side effects in what is recently known as multimodal analgesia techniques.

Regional blocks have been introduced for postoperative pain relief such as thoracic paravertebral block (TPVB), thoracic epidural block (TEB), and intercostal blocks. The use of ultrasound guidance has much improved the success rate of the nerve blocks and the development of new techniques. Newer pain control modalities have been used providing adequate pain relief, not affecting muscle strength and utilized as excellent solutions for multimodal analgesia peri-operatively. Examples of these modalities are serratus anterior plane (SAP) block, pectoral nerve (PECS) block, and midpoint transverse process to pleura (MTP) block.

In this study we will compare the analgesic efficacies of modified pectoral plane (PECS II) block versus midpoint transverse process to pleura (MTP) block after MRM surgery.

1. INTRODUCTION / REVIEW:

Breast cancer (BC) is the most commonly diagnosed cancer worldwide, with estimated new cases exceeding 2 million in 2020. Furthermore, it represents the leading cause of cancer death in women, with more than 680,000 deaths.

It is the most common type of female cancer in Egypt with an age-specific incidence rate of 48.8/100,000. Although incidence rate in Egypt is lower than the global figures, mortality is higher at an age-standardized rate of 20.4/100,000 compared with the US rate of 12.3/100,000 and the developed countries' rate of 12.8/100,000.

During Modified radical mastectomy (MRM), some of the nerves in the chest are severed. Most women have some level of pain in the days after the procedure. Severe acute postoperative pain following breast surgery not only increases the risk of persistent pain and affects recovery, it also leads to longer hospitalization and increased healthcare costs. Acute postoperative pain is an independent risk factor in the development of chronic post-mastectomy pain.

Multimodal techniques for pain management have been recommended by The American Society of Anesthesiologists (ASA) for the management of acute postoperative pain. These techniques include regional analgesia, intravenous (IV) and oral analgesics as opioids, paracetamol and nonsteroidal anti-inflammatory drugs (NSAIDs). Inappropriate postoperative analgesia may increase morbidity and mortality.

PECS-II is an interfascial plane block in which local anesthetic is injected between the pectoralis and serratus anterior muscles that blocks the long thoracic nerve as well as the pectoral, intercostobrachial, and inter-costal III, IV, V, and VI nerves. PECS-II is a less invasive and easier to perform alternative to thoracic paravertebral block (TPVB). This block, defined by Blanco et al., provides adequate and safe post-operative analgesia in the anterior chest wall after breast surgery. The most common complications are pneumothorax, infection, local anesthetic systemic toxicity (LAST) / allergy, vascular puncture, and failed block.

The MTP block was first described as a modified paravertebral block in 2017. The local anesthetic (LA) is administered between the transverse process and the pleura. This results in a LA spread to the dorsal and ventral rami in the paravertebral space through the fenestrations in the superior costotransverse ligament (SCTL) at the level of injection, and frequently to adjacent levels. The advantage of this novel technique is that it does not require identification

of the SCTL and the injection point, which is midway between the pleura and transverse process, which makes this approach much safer than the conventional TPVB approach since the needle is farther from the vital structures like pleura, nerves, and vasculature. This technique is used for pain relief after mastectomy, thoracic, abdominal, and spinal surgery and was found effective due to its simplicity and lower risks compared to epidural analgesia.

However, no study exists in the literature that compares these blocks in modified radical mastectomy.

2. AIM / OBJECTIVES:

This study aims to compare the analgesic efficacies of the modified pectoral plane block (PECS II) and the midpoint transverse process to pleura block (MTP), after modified radical mastectomy (MRM) surgery.

3. METHODOLOGY: Patients and Methods

- **Study Design and Ethics**

  This will be a single-center, prospective, randomized, comparative study. Approval will be obtained from the Medical Research Ethical Committee of the Faculty of Medicine, Ain Shams University (FMASU MD311/2023). The trial will be registered at ClinicalTrials.gov (NCT06187909). Written informed consent will be obtained from all participants.

- **Sample Size Calculation**

  The sample size was calculated using G*Power version 3.1.9.7 (Heinrich Heine University, Düsseldorf, Germany). The PECS II and MTP groups' mean postoperative pain scores were compared using a two-tailed independent-samples t-test. A minimum of 44 patients per group were needed based on an assumed effect size (Cohen's d) of 0.7, which was obtained from expected clinically relevant differences in VAS pain scores after 4 hours postoperatively, a power of 90% ($1–\beta = 0.90$), and a two-sided alpha level of 0.05. Pilot observations and existing clinical evidence suggesting that intergroup variations in analgesic efficacy are most noticeable in the early postoperative period served as the basis for the effect size estimate.

- **Participants**

  Eighty-eight adult female patients, aged 40 to 65 years, ASA physical status I–II, scheduled for elective modified radical mastectomy will be enrolled.

  Exclusion criteria will include: allergy to local anesthetics, coagulopathy, infection at the injection site, refusal to participate, or inability to understand the pain scale.

- **Randomization and Blinding**

Patients will be randomly assigned to one of two groups using computer-generated random numbers sealed in opaque envelopes:

1- Group PECS (n = 44): Ultrasound-guided PECS II block.

2- Group MTP (n = 44): Ultrasound-guided MTP block.

Patients will be sedated during block placement. Due to the distinct anatomical sites, full patient blinding will not be possible. Outcome assessors collecting postoperative data will be blinded to group allocation. The anesthesiologists performing the blocks will not participate in data collection.

- **Interventions**

All blocks will be performed preoperatively under standard monitoring and mild sedation with intravenous midazolam (0.025 mg/kg). A high-frequency linear ultrasound probe and a 22-gauge, 80-mm echogenic needle will be used under aseptic precautions.

PECS II block: In the supine position, 10 mL of 0.25% bupivacaine will be injected between the pectoralis major and minor muscles. The probe will then be repositioned laterally and 10 mL will be injected between the pectoralis minor and serratus anterior muscles at the level of the third to fourth ribs.

MTP block: With the patient seated, the probe will be placed parasagittally about 3 cm lateral to the midline at the T2 and T6 vertebral levels. A 22-gauge needle will be advanced in-plane to the midpoint between the transverse process and pleura, and 10 mL of 0.25% bupivacaine will be injected at each level.

- **General Anesthesia**

All patients will receive standardized general anesthesia. Induction will be with intravenous propofol 2 mg/kg, fentanyl 2 μg/kg, and atracurium 0.5 mg/kg. Anesthesia will be maintained with isoflurane (1.2–1.5 MAC) in 50% oxygen–air. Additional atracurium will be administered as required. Ventilation will be adjusted to maintain normocapnia. Neuromuscular blockade will be reversed with neostigmine 0.05 mg/kg and atropine 0.02 mg/kg. Extubation will be performed once standard criteria are met.

- **Outcome Measures**

Primary Outcome: Pain intensity at rest was assessed by a 10-cm Visual Analogue Scale (VAS; 0 = no pain, 10 = worst pain imaginable) at 4 hours post-operatively.

Secondary Outcomes:

1- VAS scores on admission to the PACU and at 2, 8, 12, 18, and 24 hours post-operatively.

2- Time to first request for rescue analgesia.

3- Total 24-hour consumption of rescue analgesia (intravenous nalbuphine 5 mg bolus for VAS ≥4).

4- Incidence of block-related complications (hematoma, pneumothorax, local anesthetic systemic toxicity).

- **Statistical Analysis**

Data will be coded, sorted, and analyzed using IBM SPSS Statistics version 28.0 (IBM Corp., Chicago, USA). Normality will be assessed with the Shapiro–Wilk test. Quantitative data will be expressed as mean ± SD and compared using an independent t-test. Qualitative data will be expressed as numbers and percentages, analyzed with Chi-square or Fisher's exact test. The log-rank test will be used to compare the time to first rescue analgesia. A p-value < 0.05 will be considered statistically significant.