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Ultrasound–Guided Erector Spinae Block Versus Serratus anterior Block for Perioperative Analgesia In Patients Undergoing Modified Radical Mastectomy Surgery

A Protocol of Thesis Submitted in Partial Fulfillment for MD Degree
In Anesthesia and Surgical Intensive care

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Introduction

Breast cancer is the most common malignancy of women all over the world. Unfortunately, two-thirds of women who undergo breast cancer surgery are reported to develop chronic pain in the postoperative period. Surgery type, radiation therapy, and clinically acute pain are the most important risk factors for the development of more intense chronic pain (**Altıparmak et al., 2019).**

With improved diagnostic techniques and treatment regimens, prognosis in breast cancer is improving, with the 5-year survival of patients diagnosed with primary breast cancer having increased to approximately 85%. Persistent post-surgical pain states in this group is reported in 30-50% of patients, up to half of whom may have pain well beyond 5 years. Over one-third of patients who underwent breast cancer surgery have inadequately controlled acute post-operative pain **(FitzGerald et al., 2019).**

There are several ways to manage pain after mastectomy. Common systemic medications, particularly opioids, have different side effects, such as itching, nausea, vomiting and respiratory depression. Non-steroidal anti-inflammatory drugs are associated with impaired renal function and hemorrhagic disorders **(Rahimzadeh et al., 2018).**

Regional anesthesia has been believed as one of the formats for effective perioperative pain control. Regional blocks using ultrasound-guide has become a perfect supplement to general anesthesia for extending analgesia after modified radical mastectomy. The advantage includes post-operative pain relief prolongation, a decrease in analgesic requirement post-operatively, a reduction in

nausea and vomiting scores and probability for ambulatory discharge and hospital stay **(Mohamady et al,. 2019).**

The complex innervation of breast tissues poses a great challenge for the anesthesiologists to provide adequate perioperative analgesia by ultrasound guided regional blocks. Thoracic epidural, interscalene brachial plexus block, paravertebral block, pectoral nerve I and pectoral nerve II blocks have been used in different studies with good results. There are also technically simple regional blocks as ultrasound-guided Serratus anterior Plane (US-guided SAP) block and erector spinae plane (US-guided ESP) block which can be used effectively for this purpose **(Singh et al., 2019).**

Forero et al. described ultrasound-guided Erector Spinae Plane (US-ESP) block as a novel analgesic technique in which local anesthetic injection is done beneath the erector spinae muscle **(Forero et al., 2016)**. Previous studies reported effective postoperative pain reduction with ESP block after radical mastectomy surgery. Nevertheless, few studies have compared the efficacy of ESP block with another block technique. **(Gad et al., 2019).**

The Serratus Anterior Plane block (SAP) provides anterolateral and partial posterior thoracic wall analgesia, affecting dermatomes from T2 to T9. SAP is affecting predominantly the lateral cutaneous branches of the thoracic intercostal nerves, along with intercostobrachial, thoracodorsal and long thoracic nerves. The block is performed further posteriorly and caudally than Pectoral Nerve Block-2, where the target nerves are located between the serratus anterior and the latissimus dorsi muscles. **(Blanco et al., 2013)**

Rationale

Modified radical mastectomy is one of the commonly performed breast surgery. Postoperative pain following mastectomy should be minimised, as in a number of women it may chronically persist for months in the form of postmastectomy pain syndrome.

Morphine administration for acute pain after mastectomy surgery has many side effects. Regional block techniques as paravertebral block and thoracic epidural anathesia has possible complications and technical difficulties.

The new alternative regional techniques such as erector spinae plane block and serratus anterior plane block are clinical trials for providing a safe, easy and painless anesthetic procedure with good hemodynamic and recovery profile with adequate perioperative analgesia for a large section of patients undergoing mastectomy operation in order to reduce opiods consumption and subsequently avoid opiod-related adverse effects.

Research question

Is there difference between the Ultrasound-Guided Erector Spinae Plane Block and the Serratus anterior plane Block in providing peri operative analgesia for patients undergoing Modified Radical Mastectomy?

Hypothesis

Null hypothesis (Ho):

There is no difference between Ultrasound-Guided Erector Spinae Plane Block and Serratus anterior plane Block in providing peri operative analgesia for patients undergoing Modified Radical Mastectomy under general anesthesia.

Alternative hypothesis (H1):

There is difference between Ultrasound-Guided Erector Spinae Plane Block and Serratus anterior plane Block in providing peri operative analgesia for patients undergoing Modified Radical Mastectomy under genera anesthesia.

Aim of the work

To compare between Ultrasound-Guided Erector Spinae Plane Block and Serratus anterior plane Block for peri operative analgesia in patients undergoing Modified Radical Mastectomy operations under general anesthesia.

Objectives

To:

- Assess sensory block (onset, quality and duration) of both erector spinae plane block and serratus anterior plane block and detect which of them gives better analgesia.
- Assess post operative static and dynamic pain.
- Assess the time of first analgesic requirement post Modified Radical Mastectomy surgery.
- Detect the presence of side effects with general anesthesia.
- Assess patient satisfactions.

Patients And Methods

1- Technical design:

- **Site of the study:**

The study will be conducted in operating room in Zagazig University Hospitals.

- **Duration of the study:**

The study will be conducted over two years.

- **Sample size:**

Assuming that the mean ± standard deviation of time of first analgesia requirement in erector spinae block group is 416+_108.2 minute and that in serratus anterior block is 343+_99.7 minute **(Eldemrdash et al., 2019)**, so sample size is calculated by open EPI programme to be 75 cases (25 cases in each group) with confidence level of 95% and power of test 80%.

Inclusion criteria:

- Written informed consent from the patient.
- Age: 21 – 60 years old.
- Gender: female patients.

- Body mass index: < 35 kg/m2.
- Physical status: ASA grade I-II (American society of anesthiologists).
- Type of operation: unilateral modified radical mastectomy operation.

Exclusion criteria:

- Patient with known history of allergy to study drugs.
- Chronic use of analgesics or drug dependence.
- Patients not able to understand pain assessment test.
- Anatomical abnormalities.
- Neuropathic disease.
- Pregnancy or breast feeding.
- Other contraindication of regional anesthesia e.g. septic focus at site of injection.
- patient with coagulopathy or on anticoagulant therapy.

- **Tools of data collection :**
  - Anesthetic sheet to all patients.
  - Intra operative assessment of vital signs by the anesthesiologist.
  - Post-operative assessment of pain, use of systemic analgesics and patient satisfaction in ward.

2- Operational design:

- **Type of the study:** prospective comparative randomized controlled clinical study.
- **Randomization:**

A computer-generated table will be used to divide patients equally into 3 study groups.

- **Group C (Control group) (n=25)** patients will receive only general anesthesia for Modified Radical Mastectomy.
- **Group E (n=25)** patients will receive Ultrasound‑Guided Erector Spinae Plane Block before induction of general anesthesia for Modified Radical Mastectomy.
- **Group S (n=25)** patients will receive Ultrasound‑Guided Serratus anterior Block before induction of general anesthesia for Modified Radical Mastectomy.

- **Equipment needed for technique:**
    - High frequency linear transducer ultrasound.
    - 22 gauge spinal needle 10 cm length.
    - Local anesthetic: bupivacaine 0.25% (for the erector spinae plane block and serratus plane block) and lidocaine 1% (for local infiltration at the site of injection).
    - Sterile preparation for the site of needle insertion, equipments and anesthesiologist.

All Cases Will Undergo:

The process

- **Patient Examination:**
    - All participating patients will be interviewed preoperatively during their preoperative preparation. The goal and endpoints of the study

will be discussed. Understanding of the block will be reviewed and emphasized, informed cosent will be taken.

- On physical examination, special attention will be given to document vital signs, cardiac, chest condition and exclude contraindications.
- All patients will be investigated by complete blood count, Liver functions test, kidney functions test and coagulation profile.

Steps of Performance:

- *Preparation:*

  - All patients will be kept fasting for minimum 6 hours before the operation.
  - All patients will be clinically examined in the preoperative period and routine investigations will be checked and at the same time, whole procedure will be explained. Ten centimeters visual analog scale (**VAS**) **(Metwally et al., 2016)**, (0 – no pain and 10 – worst pain imaginable) will be also explained during preoperative visit**.**
  - The monitors attached included non-invasive blood pressure (NIBP), electrocardiography (ECG), and pulse oximetry.
  - An 18 G I.V cannula will be secured in the opposite hand and fluid will be started. supplemental oxygen will be administered at 6 to 8 L/min via face mask. Procedural sedation will be provided intravenously by midazolam 0.03 to 0.04 mg/kg, as needed

• Technique:

• Erector Spinae Plane Block:

Position

sitting position

Type of needle

Using 22 gauge spinal needle 10 cm length.

Scanning

Linear ultrasound probe is placed in a longitudinal parasagittal orientation 3 cm lateral to the T5 spinous process.

The erector spinae muscle is identified superficial to the tip of The T5 transverse process.

Needle insertion

The needle is inserted in- plane superior to inferior approach. The tip of the needle is placed into the fascial plane on the deep aspect of erector spinae muscle.

The location of the needle tip is confirmed by visible normal saline fluid spread separating erector spinae muscle off the bony shadow of the transverse process on ultrasonographic imaging **.**

Local anesthetic and volume

Injection of 20 ml of bupivacaine 0.25 %. **(Singh et al., 2019)**

II.Serratus Anterior Plane Block:

Position

The patient lies supine with placing the ipsi-lateral upper limb in abduction at 90° position.

Type of needle

Using 22 gauge spinal needle 10 cm length.

Scanning

After skin sterilization, Ultrasound device with high frequency [9-12] and superficial linear probe that is first placed inferior to the middle of the clavicle and moved laterally and downward to locate the 1st rib where pectoralis major and pectoralis minor muscles are identified at this US window.

The US probe is moved toward axilla till serratus anterior muscle is identified above 2nd, 3rd and 4th ribs. The transducer is held at a slightly oblique angle at the level of the 4th and 5th rib, with the upper edge supero-anterior and the lower edge infero-anterior.

Needle insertion

After infiltration of the skin at puncture site with 3 ml of lidocaine 1%, the needle is inserted inplane between the anterior serratus and the latissimus dorsi muscle on the mid-axillary line.

Local anesthetic and volume

Injection of 20 mL of 0.25% bupivacaine. **(Khemka et al., 2019)**

Assessment of block:

Onset time of sensory block

Time between injection of the drugs and loss of pin prick sensation in operating field, pin prick test done with sterile 25G needle.

Quality of sensory block will be graded as :

- Grade 0 : normal sensation
- Grade 1: loss of sensation to pinprick.
- Grade 2: loss of sensation to light touch **(Swami et al., 2012).**

Duration of sensory block

Time between onset of sensory block to the first report of postoperative pain at the surgical site that is **VAS score** >**3**, with first analgesic requirement by the patient.

The patients will be delivered to the operating room to receive general anesthsia with good monitoring.

General anesthesia:

- It will be standardized for all patients.

- Fentanyl 2 mcg/kg, propofol 2 mg/kg will be intravenously administered, followed by cisatracurium 0.15 mg/kg to facilitate endotracheal intubation with a suitable size of endotracheal tube.
- Lungs will be ventilated by pressure controlled mode to maintain normocapnia (PaCo2 = 35-45 mmHg) and isoflurane/O2 mixture will be administered.
- Concentration of the inhalational agent will be 1.2 MAC of isoflurane, Heart rate and mean arterial blood pressure will be recorded every 10 minutes.
- Incremental doses of fentanyl can be given in inadequate analgesia {presented by tachycardia and hypertension (mean arterial blood pressure) >20% from baseline} after exclusion of other causes}, total amount of fentanyl consumption intraoperative will be calculated.
- Paracetamol 15ml/kg will be administered by iv infusion to all patients.
- After completion of the surgery, inhalational anesthesia will be stopped and the patient will receive neostigmine (0.05 mg/kg) and atropine sulphate (0.01 mg/kg).

Postoperative:

- After recovery from anesthesia, the patient will be transferred to the post-anesthesia care unit.
- All patients will receive paracetamol as standard intravenous infusion analgesia at dose of 15mg/Kg every 8 hours (maximum dose: 4 g / day).
- Pain will be observed and recorded using the pain assessment on a 0-10 cm line [visual analogue scale (VAS) **(Metwally et al., 2016)**; 0=no pain, 1 to 3 = mild pain, 4 to 6 = moderate pain, 7 to 10 = severe pain].

- The pain is measured both at rest and movement (arm movement of 90° and sitting from lying down position) after explanation of the procedure to the patient at 2,4,8,12,18& 24 hours after surgery by an observer blinded to treatment groups.
- All patients will be assessed for the time to first rescue analgesic and when the patient suffer from pain at score equal or above 3 on VAS, the patient will receive morphine (dose: 0.1 mg/kg intravenous as initial dose then 0.025 to 0.05 mg/kg every 5 minutes till the pain is relieved not exceeding 4 mg/h). Total morphine consumption will be calculated.
- Post-operative nausea and vomiting will be noticed, recorded using a categorical scoring system (0 = none, 1 = mild, 2 = moderate, 3 = severe) and treated, Ondansetron 4 mg IV will be administered in case of reported nausea and/or vomiting.
- Patient satisfaction will be assessed post operatively using satisfaction score (4= excellent, 3 = good, 2 = fair and 1 = poor**) (Ross et al., 2009).**

Complications and side effects:

It may include failure of the block, intra-muscular hematoma, pleural perforation, Post-operative nausea and vomiting (PONV), sedation and respiratory depression. These complications will be observed and recorded.

Data collection:

From each patient the following data will be collected upon admission:

1-Demografic data:

- Name
- Age
- Body Mass Index
- Hospital diagnosis
- Date of admission in hospital
- Medical and past history

- ASA grade I-II
- Type of operation : unilateral mastectomy surgery
- Duration of operation

2-Sensory block assessment: onset, quality of sensory block, duration of the block**.**

3-Hemodynamics (HR, Mean Arterial Bl.Pr), total intra-operative fentanyl consumption.

4-Static and dynamic pain scores (VAS) at 2, 4, 8, 12, 18 and 24 hours post-operatively.

5- The time to first rescue analgesic request.

6- Total morphine consumption during 24 hours post-operative.

7- Complications.

8-Satisfaction score of patient.

Administrative design:

- **Approval of anaesthesia department committee.**
- **Approval of ethical committee in faculty of medicine.**
- **Ethical approval:**Approval will be obtained from Institutional Review Board (IRB) at Zagazig University Hospitals.
- **A written informed consent** will be signed from all patients after discussing the study design including procedure , drugs and possible adverse effects .

Results

Collected data will be presented in tables and suitable graphs and analyzed according to standard statistical methods.

Discussion

Discussion will be done on results compared to related relevant literature and scientific researches.

Conclusion and Recommendations

It will be derived from the findings of the study.

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