



ADDIS ABABA UNIVERSITY

TIKUR ANBESA SPECIALIZED HOSPITAL

COLLEGE OF HEALTH SCIENCE

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

COMPARISON OF POSTOPERATIVE ANALGESIC EFFECTIVENESS OF ERECTOR SPINAE PLANE BLOCK VS THORACIC PARAVERTEBRAL BLOCK FOR ELECTIVE BREAST SURGERY UNDER GENERAL ANESTHESIA IN SELECTED GOVERNMENTAL HOSPITAL, ADDIS ABABA; PROSPECTIVE COHORT STUDY, DECEMBER 20 -APRIL 30, 2022/23

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THIS RESEARCH THESIS WILL BE SUBMITTED TO DEPARTMENT OF ANESTHESIA AT ADDIS ABABA UNIVERSITY FOR THE PARTIAL FULFILLMENT OF MSC IN ADVANCED CLINICAL ANESTHESIA

ADDIS ABABA, 2022/23

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BREAST SURGERY**

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**DECLARATION**

This thesis is my original work for the partial fulfillment of the requirements for MSC in advanced clinical anesthesia. I understood that plagiarism will not be tolerated and all quoted materials in this thesis were appropriately referenced

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Sign-----

Submitted to: MSC tutor, Department of Anesthesia, Addis Ababa University

Date of admission -----

Approval of the advisors:

Name	sign	date
1-----	-----	-----
2-----	-----	-----

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## **List of Abbreviations**

ASA- American Society of Anesthesiology

CI- confidence interval

ERAS-Enhanced recovery after surgery

ESPB- Erector spinae plane block

ETB- Ethiopian Birr

G. C- Gregorian calendar

IQR-Inter-quartile range

MMA-Multimodal analgesia

MRM-Modified radical mastectomy

NRS- Numerical rate scaling

PACU- Post-anesthesia care unite

POP- Postoperative pain

RCT-Randomized control trial

SPSS - Statistical package of social science

TPVB- Thoracic para vertebral block



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**Fig 1-**Sociodemographic and perioperative patient characteristics between TPVB &ESPB group for breast surgery at TASH, Minillik II referral hospital, and St.peter hospital from December 20-Aprile 30/2023

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## Abstract

**Background:** Breast surgery is one of the most common types of surgery done worldwide. Inadequate postoperative analgesia leads to serious medical problems. TPVB has been a commonly used nerve block technique for post-surgical analgesia for breast surgery. ESPB the recently introduced nerve block method for providing anti-pain after mastectomy is safer, easily performed, and provides an adequate level of sensory blockage

**Objective:** The objective of this research thesis was to compare postoperative analgesic effectiveness of erector spinae plane block vs thoracic paravertebral block for breast surgery, in selected governmental hospitals of Addis Ababa; a comparative prospective cohort study, 2022/2023.

**Methods:** After ethical committee approval, a prospective cohort study was conducted among 66 patients who undergo breast surgery from December 20-2022 to April 30, 2023. Data were collected by structured questionnaire and collected data were entered into Epi data version 3.1 and transported to SPSS version 25. Categorical data were analyzed by chi-square while Continuous data were analyzed by student t-test and Mann-Whitney U test for parametric & non-parametric data respectively. Data were reported by mean and standard deviation, median and inter-quartile range (IQR) based on data normality. 80% power and 95% Confidence. Results were considered as statistical significant when p value is  $<0.05$

**Result:-**A total of 33 patients were involved with 100% response rate shows that the mean duration of 1<sup>st</sup> analgesic request time was significantly longer in the ESPB group ( $7.36 \pm 1.168$ hr) compared to the thoracic paravertebral group ( $6.61 \pm 1.321$  hr) with a p-value of 0.016. Total postoperative analgesic consumption and pain severity score were comparable across the group with p-value  $>0.05$ .

**Conclusion & recommendation:-**ESPB provides prolonged postoperative analgesia for breast surgery and using it as a postoperative pain management plan improves patient satisfaction compared with TPVB. We would like to recommend setups that lack strong opioids for postoperative pain management should do ESPB for elective breast surgery as a post-operative pain management plan.

## Chapter One: Introduction

### 1.1 Backgrounds

Breast cancer is a serious medical problem because one out of eight women will develop the disease during her lifetime. (1) Breast surgery is associated with significant post-surgical pain which can significantly affect postoperative recovery and return to daily living activities. (2) Acute post-surgical pain has the probability to change into chronic post-surgical pain. Breast surgery is mostly associated with post-surgical pain, phantom breast (nipple) pain, hyperalgesia, allodynia, neuromas sensation of burning, constricting, or stabbing type of pain and loss of feeling or numbness which can adversely affect the patient's perioperative experience and thought to be due to traumatic nerve injury during surgery, inflammation, and peripheral & central sensitization, and regional anesthesia or nerve block is the mainstay of treatment to prevent the transition of acute surgical pain to such kind of breast surgery-related complications. (3). Thoracic paravertebral block has been a commonly used nerve block technique for post-surgical analgesia for many different surgeries like thoracic surgery, breast surgery, and upper abdominal surgery. (5) Local anesthetic injection into the paravertebral space which gives ipsilateral and segmental analgesia. Single injection of local anesthetics to the thoracic paravertebral space has three to four dermatomal spreads. Multiple site injections of local anesthetics with smaller volumes at the level of T1, T3, and T5 provide sole anesthetic analgesics for breast surgery. (6)

Erector spinae plane block was 1<sup>st</sup> introduced by Forero et al in 2016 as a novel analgesic technique for thoracic neuropathic pain. Then after it was studied for many different indications. (5) ESPB is a novel nerve block technique in which LA is deposited between erector spinae muscle and transverse process. A single injection of local anesthetics at the level of thoracic vertebra five has crano-caudal spread between cervical vertebrae seven and thoracic vertebrae eight in a cadaveric model based on radiographic imaging. (1)

## 1.2 Statement of problem

Breast surgery is one of the most common types of surgery done worldwide and 30-50% of the patients report moderate to severe acute pain and 8-12% of the patient experiences persistent post-operative pain. The prevalence of breast cancer surgical treatment increased in recent year, however, postoperative pain remains a troubling problem. Inadequate postoperative analgesia after breast surgery leads to serious medical problems including delayed wound healing, increased length of hospital stay, delay patient rehabilitation, and induce psychological illness, particularly anxiety and depression. Intravenous opioid analgesics were routinely administered for post-operative analgesia after breast surgery and this leads to a series of side effects including respiratory depression, postoperative sedation, and opioid abuse. (7)(8)(9) Poorly managed acute post-surgical pain is related to a decrease in functional recovery increase discharge time from PACU, delayed ambulation patient dissatisfaction, and increase length of hospital stay, and can also leads to persistent chronic pain. (10) (11) Breast surgery is associated with pain that ranges from moderate to severe level which can adversely affect post-operative recovery and return to daily living activities.

The complex nerve supply of the breast due to its anatomy of the chest and the armpit, post mastectomy pain management is difficult so identification of a safe and effective type of regional nerve block technique to relieve post-operative pain is needed. (7) Many regional anesthesia techniques were employed to manage post-operative pain after mastectomy. The paravertebral block was the most effective regional technique used to provide adequate analgesia but its structural proximity to the plural and neuraxial system makes this technique very challenging and many clinicians are not willing full to perform this block in daily practice. While the alternative technique of analgesia was searched to replace the paravertebral technique, clinicians implement interfascial block techniques like serratus anterior plane block or pectoralis nerve block. Even though both PNB and PVB have effective analgesia they have several implications, Distribution of local anesthetics interfere with surgical site( pectoralis nerve block) & PVB associated with serious complications.

Novel interfascial nerve block provides better analgesia with minimal risk. ESPB is a newly applied novel technique where local anesthetic is injected into the interfascial plane between the

thoracic vertebra transverse process and the erector spinae muscle with minimal complication rate and with no technical difficulty. (12)(13)

### **1.3 Justification of the study**

For a long period TPVB was one of the most used peripheral nerve block techniques for controlling pain after breast surgery, however a rare serious complication like pneumothorax may occur due to the deep and narrow triangular space site immediately adjacent to the parietal plural, to decrease the risk of such type of complication ultrasound-guided technique and skill full anesthetist are required. In contrast, ESPB provides anti-pain after mastectomy when performed at the level of 4<sup>th</sup> and 5<sup>th</sup> thoracic vertebrae seems to be safer, easily performed, and provides an adequate level of sensory blockage. (10)

According to the standard care for managing postoperative pain after breast surgery in our clinical practice, TPVB and ESPB were done for every patient. However the ESPB was introduced to our and some other hospitals clinical activity in a couple of years and thus procedures were done without ultrasound using anatomic land mark technique by rule of three. A patient underwent breast surgery in our clinical practice always receive one of these regional nerve block technique and also to date there is no studies done in our country to compare the analgesic effect of ESPB vs PVB for breast surgery. Even though no statistical difference is seen between the two group some studies show a controversy were seen in terms of analgesic request hour duration after breast surgery, postoperative opioid consumption and the aim of this study was to asses analgesic effectiveness of erector spinae plane block vs thoracic paravertebral block for breast surgery in terms of 1<sup>st</sup> analgesic request ,total opioid consumption within 24 hours of post breast surgery and numerical pain severity score. If the outcome is comparable between these groups, I will recommend to anesthesia professionals and clinical areas who have scarcity of opioid medication they should have to do ESPB over TPVB due to its easy to perform & less risk of complication as evidenced by many researchers.

## Chapter Two: Literature Review

For breast surgery improvement of analgesic technique has increased advantage for post-surgical patient rehabilitation. Adequate pain management is a vital component of ERAS protocol. For breast surgery, different nerve block technique is applied. TPVB was the most commonly used analgesic technique in the past decayed and since a recent period, ESPB was introduced into clinical practice for different surgeries including mastectomy. Different studies were conducted to compare the analgesic effect of ESPB & TPVB for breast surgeries. (16)

A cohort study was done in 2021 at the University of Texas Southwestern Medical Center, Dallas, Texas. Twenty-five patients undergoing bilateral mastectomies who received both PVB and ESPB for postoperative pain control were studied. Of these participants 14 patients received PVB and the rest received ESPB. Median pain scores of patients at rest and during movement were similar between PVB and ESPB at any postoperative time point (all  $P > 0.077$ ). Patients in paravertebral group have a significant decrease in sensation than erector spinae plane block group with p value of  $<0.05$ .(2)

A prospective RCT was conducted in the USA, the University of California San Diego in 2019 to test the hypothesis that the analgesic effect in recovery room & intraoperative and recovery room opioid consumption is not inferior with ESPB among patients who underwent breast surgery. One hundred subjects were enrolled in the study. The median length of PACU stay was 105 minute in TPVB group & 124 minute in ESPB with p value of 0.047. After PACU discharge the median dose of oxycodone requirement was 5mg in PVB group & 10 mg in ESPB group. This study also shows that the median score of 1<sup>st</sup> analgesic request between ESPB group and TPVB group is 17.7 hour and 16 hour respectively with p value of 0.833.(15)

A study done in Delhi India in 2021 which involves 80 patients to compare postoperative analgesic effectiveness between ESPB and TPVB for patients underwent MRM. Even though it is not a statistically significant difference, 1<sup>st</sup> analgesic request time is longer in ESPB than PVB (232.5min and 205 min p-value =0.29 respectively) which is a related result with the RCT study done in the USA which has a 1.7 hour more prolonged median blockage in ESPB than TPVB. Intraoperative fentanyl consumption and the dose of rescue analgesics required in the 24-hour postoperative period were comparable. (16)

A retrospective RCT was done in India in 2020, the study involves 102 female patients who underwent MRM. They categorize patients into two groups who receive paravertebral and erector spinae block respectively. Between the two groups the time for 1<sup>st</sup> analgesic request, post-surgical morphine requirement, and hemodynamic change were not statistically significant. (17)

A study was done at Zhejiang University School of Medicine, China, in 2020 shows that the analgesic effectiveness of thoracic paravertebral block over erector spinae plane block were shows a statistical significance reduction in postoperative pain score at 1,4-6,&24 hour during rest and 4-6,8-12 & 24 hour during movement for thoracic surgery but no significant change were seen for breast surgery. (14)

A retrospective Cohort study in 2020 in Khon Kaen University, Thailand. Involving 30 patients per group after propensity match done. There is a significant lower VAS score in TPVB than ESPB at rest 6<sup>th</sup> hour postoperatively before and after matching. VAS on movement, requirements for rescue analgesics, and incidence of postoperative nausea and vomiting were not different within 24 h. The level of sensory blockage up to 6 hours of administration of local anesthetic is higher in the TPVB group than ESPB group. After 6<sup>th</sup> hour they have comparable sensory blockage levels. For a better level of blockage during intraoperative analgesia, needle insertion site should be to the level of the surgical site for ESPB group. The level of cutaneous sensory blockage between the ESPB group and PVB group ranged from T2 to T10 and from T1 to T10 dermatomes, respectively. This has a similar finding to a cohort study conducted in 2019 which shows the level of sensory blockage is higher in TPVB than in ESPB but comparable results after surgery. (18)

In a retrospective cohort study done at Khon Kaen University, Thailand in 2019 24 patients were enrolled in the study who underwent breast surgery from these 10 patients were receive TPVB and 14 patients were receive ESPB. The mean difference of VAS within 24 hours and four-time points of measurement at rest and movement were not statistically significant between these groups. The percentage of the level of sensory blockade 10 minutes after the block was significantly higher in TPVB (100.0 vs. 28.6, P 0.001). However, the percentage of the level of sensory blockade after surgery was comparable (100.0 vs. 78.6, P 0.239). (10)

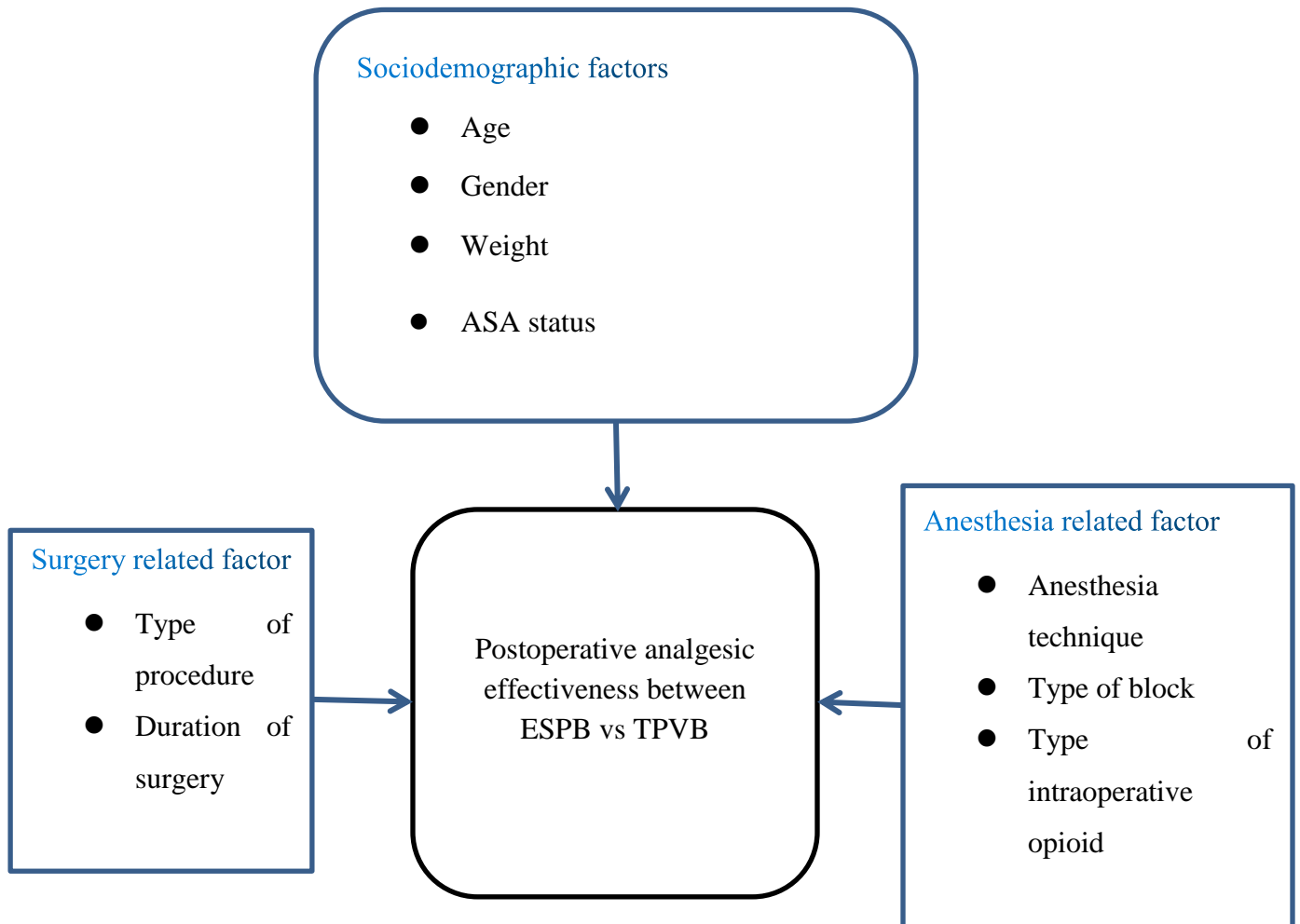
A study was conducted at Suez Canal University, Egypt in 2022 to compare the total morphine consumption within 24 hours as a primary objective and intraoperative opioid consumption & postoperative VAS score as a secondary objective. 90 patients were involved in the study. The result shows control group has statistically significant higher intraoperative fentanyl consumption than both ESPB & TPVB group with p value of <0.001. But there is no difference between ESPB & TPVB with a p value of 0.45.

Total morphine consumption were  $4.9 \pm 1.2$  mg in ESPB group,  $5.8 \pm 1.3$  mg in TPVB group &  $16.4 \pm 3.1$  mg in control group with p value of <0.00. The total morphine consumption between the two block technique has no significant change with p value of 0.076. 1<sup>st</sup> analgesic request hour between the three groups were  $7.9 \pm 1.2$ ,  $7.5 \pm 0.9$  &  $2 \pm 1.2$  in ESPB, TPVB & control group respectively with p value of <0.001. ESPB & TPVB had low VAS score within 24 hours than the control group with p value of <0.001 but no significant difference between the two groups. The ESPB had an extended analgesic effect than the PVB as indicated by the significant differences in the VAS score at 8 h (median=5 (4.75–6) versus 6 (5–6.5), respectively; p=0.001) and at 12 h (median=5 (4–5) versus 5 (4.5–6), respectively; p=0.002) after the operation. (19)

Another similar study randomized control trial was studied at Tanta University in 2019, Egypt which 70 participants were included in the study scheduled for MRM, they categorized patients into paravertebral and erector groups. After surgery within 24 hours, analgesic consumption, 1<sup>st</sup> analgesic request, postoperative pain severity score using VAS & intraoperative fentanyl consumption were recorded. No significant differences were observed regarding intra-operative fentanyl and 24-h postoperative morphine consumption between paravertebral & erector group with p value of 0.11 & 0.32 respectively. Time to first request for analgesia was also comparable ( $6.35 \pm 0.42$ ,  $6.5 \pm 0.60$  h, respectively; P = 0.075). Pain scores were not significantly different between both groups on admission to PACU and at 2, 4, 6, 8, 12, 18, and 24 h after surgery (P = 0.487, 0.927, 0.878, 0.316, 0.228, 0.628, 0.102 and 0.942, respectively). In both groups, VAS began to increase to >3 at 6 h after surgery. But, the visual analog scale (VAS) in both groups was significantly increased at 6 h (P = 0.001). (20)



## 2.1 conceptual frame work



## **Chapter Three: Objective**

### **3.1 general objectives**

The aim of this study is to compare postoperative analgesic effectiveness of erector spinae plane block vs thoracic paravertebral block for breast surgery from December 20-2022 -April 30, 2023, at governmental hospitals of Addis Ababa, Ethiopia.

### **3.2 Specific objectives**

- To compare postoperative analgesic effectiveness in terms of pain severity score by NRS among the TPVB group and ESPB group
- To compare postoperative analgesic effectiveness in terms of total opioid consumption within 24 hours of the postoperative period among the TPVB group and ESPB group .
- To compare postoperative analgesic effectiveness in terms of time to the first analgesic request between the TPVB group and ESPB group

### **3.3 Research hypothesis**

- HO-there is no difference in postoperative analgesic effectiveness of ESPB vs TPVB in postoperative 1<sup>st</sup> analgesic request
- HA- there is a difference in postoperative analgesic effectiveness of ESPB vs TPVB in postoperative 1<sup>st</sup> analgesic request
- HO-there is no difference in the postoperative analgesic effectiveness of ESPB vs TPVB in postoperative total analgesic consumption
- HA- there is a difference in the postoperative analgesic effectiveness of ESPB vs TPVB in postoperative total analgesic consumption
- HO-there is no difference in the postoperative analgesic effectiveness of ESPB vs TPVB in postoperative pain severity score
- HA- there is a difference in the postoperative analgesic effectiveness of ESPB vs TPVB in postoperative pain severity score.

## **Chapter Four: Methodology**

### **4.1 study area and Period**

Addis Ababa is the capital city of Ethiopia which has an area of around 527 square kilometers. There are around 13 public hospitals in different sub-cities from them TASH, Minillik II Referral Hospital, and St. Peter Referral Hospitals serve the society with different departments; the general surgery department is one of them. Tikur Anbesa Specialized Hospital was established in 1872 EC, at Lideta sub-city. This specialized hospital gave surgical health service with a capacity of 9 OR tables, 1 adult, and 1 neonatal ICU.

Minillik II Referral Hospital was established in 1910 EC at Yeka sub-city. This hospital gave health services with a surgical bed capacity of 135. The surgery department is one of the major departments having 3 major OR table

St. Peter Specialized Hospital was established in 1965 EC at Gulele sub-city. They gave health services including surgery with a capacity of 54 surgical beds, 5 major OR tables, and 1 ICU. They schedule general surgery five days a week. This study was conducted from, December 20-2022 to April 30 2023 G.C.

Therefore they were selected to be our study area after situational analysis was done and breast surgery was mostly undergone in thus hospital.

### **4.2 study design**

Multi-centered-based Prospective cohort study

### **4.3 populations**

#### **4.3.1 Source population**

All elective Patients admitted for breast surgery in Tikur anbesa specialized hospital, St. Peter Hospital, and Minillik II referral hospital

#### **4.3.2 Study population**

Patients who underwent breast elective breast surgery under general anesthesia with endotracheal tube and received ESPB and PVB at Tikur Anbesa Specialized Hospital, St. Peter Hospital, and Minillik II referral Hospital who fulfilled the inclusion criteria during the study period

## 4.4 Eligibility criteria

### 4.4.1 Inclusion criteria

From scheduled patients who underwent elective breast surgery under general anesthesia with endotracheal tube in the selected study period, those who were ASA I & II and age 18-80 years and were receiving ESPB or PVB were included.

### 4.4.2 Exclusion criteria

- Patients with known allergies to local anesthetics
- Patients unable to communicate or have a psychological disorder
- Patients with respiratory problems

## 4.5 sample size determination and sampling techniques

### 4.5.1 Sample size determination

There was no previous study done with the same title in the study area. After getting the sample mean and sample standard deviation of total postoperative morphine consumption from the study done in Egypt was taken to calculate the sample size. (19) The sample size was calculated manually and using a priori power analysis (G Power version 3.01) by taking 80% power, alpha 5%, and 10% attrition was added.

Sample size estimation will be done with equal independent sample size formula for the comparison of two means:-

$$n = (Z_{\alpha/2} + Z_{\beta})^2 \frac{(\delta_1)^2 + (\delta_2)^2}{(\mu_1 - \mu_2)^2}$$

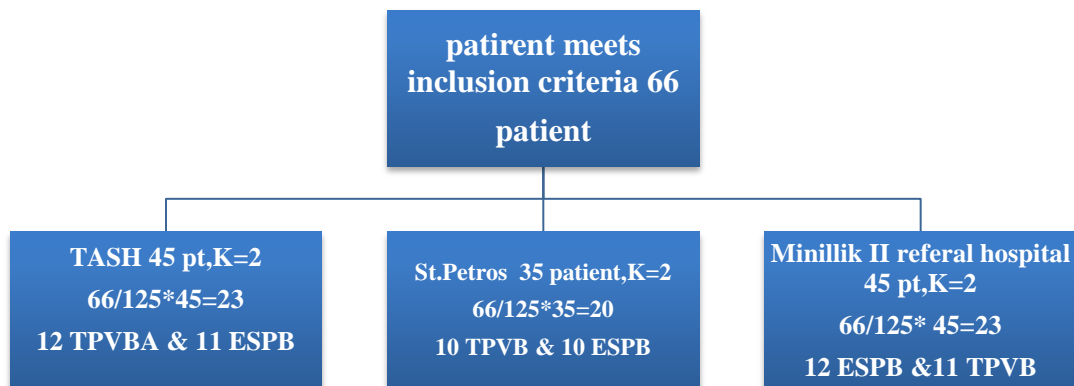
**Z1**=1.96 for  $\alpha$ -error of 5% (95% CI)       **$\mu_1$** =4.9 &  **$\delta_1$** =1.2 which is the mean & SD of postoperative total morphine consumption for patients who took TPVB

**Z2**=0.84 for 80% power       **$\mu_2$** =5.8 &  **$\delta_2$** =1.3 which is the mean &SD of postoperative total morphine consumption for patients who took ESPB

The estimated sample size was 30 per group plus 10 % contingency the final sample size was 66 patients. Systematic random sampling technique was used to select study participants.

#### 4.5.2 Sampling technique

Tikur Anbesa, Minillik, and St Petros Hospital were selected as my study area by doing situational analysis most breast surgeries were undergone in these hospitals. By taking the prevalence of cases done within one year average prevalence of three months was taken to avoid seasonal variation. From the three hospitals total of N=125 patients were undergone breast surgery with in three months by using the two nerve block technique and from sample size n=66 the sample interval was calculated as  $K^{th} = N/n = 125/66 = 1.89$  which is approximately 2. The patients who underwent operation were posted on the operation room board so the 1<sup>st</sup> study participant was selected by lottery method and the rest of the participants were based on K=2 & this technique was continued until the calculated sample size was achieved during the study period.



## 4.6 Study variable

### 4.6.1 Dependent variables

- Postoperative Analgesic effectiveness of thoracic paravertebral block versus erector spinae plane block in terms of 1<sup>st</sup> analgesic request time, total postoperative analgesic consumption, and postoperative pain severity score for elective breast surgery

### 4.6.2 Independent variables

- ❖ Demographic data
  - Age
  - Sex
  - Weight
  - ASA status
- ❖ Procedure-related variables:
  - Type of procedure
  - Duration of surgery
  - Anesthesia technique
  - Type of intraoperative opioid used for adjuvant
  - Type of block

## 4.7 data collection procedure and Tool

All patients scheduled for elective breast surgery who full fill inclusion criteria were assessed after taking informed consent. After completing the preoperative evaluation and full laboratory investigation, patient consent was token preoperative. After applying standard ASA monitoring the two nerve blocks were performed before the induction of the patient. After an aseptic technique with Povidone iodine and alcohol, the nerve block was performed by MSC anesthesia student and MSC anesthetist by landmark technique using the rule of three to avoid the potential risk of complication and the volume of local anesthetic was 25 ml of 0.25 % bupivacaine as the same volume as their routine practice and the injection site was single injection at the level of T4 for both ESPB & TPVB group. After the nerve block was done level of the block was assessed

by cold sensation using alcohol at 15 minutes of nerve block. Then after the patient is induced with intravenous analgesic and IV anesthetic agent, muscle relaxant agent used for intubation was suxamethonium or vecronium and relaxation was maintained by either vecronium or cisatracurium and amnesia was maintained by either Isoflurane or Halothane. After the end of the surgery, the patients were extubated fully awake. After the end of the procedure and the patient is fully communicating the time of 1<sup>st</sup> analgesic request, a 24-hour total dose of analgesic consumption and pain severity score by NRS at rest and during movement at 1<sup>st</sup>, 6<sup>th</sup>, 12<sup>th</sup> & 24<sup>th</sup> hour were recorded and all procedures were performed and data were collected by MSC anesthesia students and MSC clinical anesthetists.

#### **4.8 data quality control and Assurance**

Data collectors and Supervisors were trained briefly about the general significance of the study. After giving the training for those data collectors, data were collected based on the structured questionnaire. 5% of the calculated sample size pretest was conducted at Tikur Anbesa Specialized Hospital 1 month and 2 weeks before actual data collection and thus data collected for the pretest were not included in actual sample data. The completeness, clarity, and accuracy of the collected data were always evaluated by the principal investigator and supervisor.

#### **4.9 Data analysis**

Data were entered into Epi data version 3.1 and transformed into SPSS version 25. Normality of data were checked by Shapir-Wilk test & Histogram. Homogeneity of data were assessed by Levene's test. Categorical data were analyzed by chi-square while Continuous data were analyzed by independent student t-test and Mann-Whitney U test for parametric and non-parametric data respectively. Normally distributed data were reported by mean and standard deviation while non-normally distributed data by median and IQR. 80% power and 95% Confidence Interval were used to show the strength of association and a p-value of <0.05 was considered statistically significant and categorical data were expressed in percentage.

#### **4.10 Ethical considerations**

Ethical clearance was obtained from the Department of ethical clearance committee and Addis Ababa public health research and emergency management directorate before the start of the study and an official support letter was written to responsible personnel to Tikur Anbesa specialized hospital, St. Petros Hospital, and Minillik II referral hospital to gate permission for

data collection. Informed written consent was obtained from each voluntary participant to the study after giving full information about the use and importance of conducting the study i.e. involvement in the study is voluntary basis. Confidentiality was preserved at all levels of the study by avoiding personal identifiers and using codes to identify patients.

#### 4.11 dissemination plan

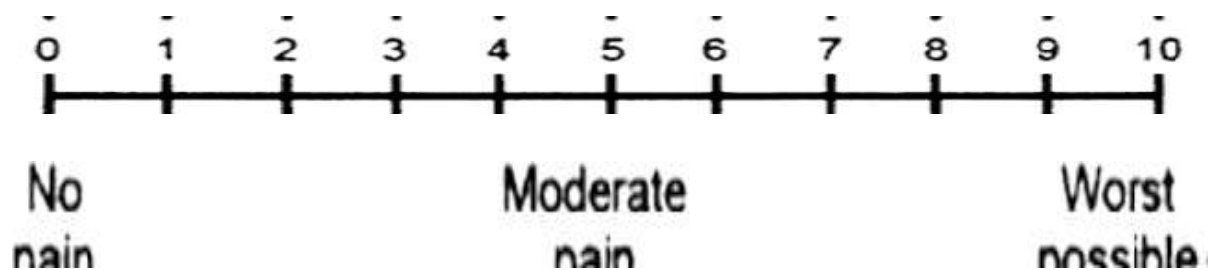
The result of the study will be presented to the entire department of anesthesia staff and submitted to Addis Ababa university department of Anesthesia and Addis Ababa public health research and emergency management directorate. It will also be submitted to journals for publication. The research will recommend to a policy maker or curriculum reviser to allocate resource utilization for the prevention and intervention of pain. It will also be present at the annual anesthesia association conference.

#### 4.12 operational definitions

**TPVB-** A regional anesthesia technique performed to deposit local anesthetic into the paravertebral space. The needle insertion site of 2.5-3 cm lateral to the spinous process. After needle insertion with a perpendicular direction to the skin when the bone contact is in-countered the needle direction is redirected either caudal or cephalad direction preferably to the caudal direction to decrease the risk of intravascular LA injection and nerve injury with up to 1cm depth which is the potential space called paravertebral space. (6)

**ESPB-** A novel regional anesthesia technique introduced in 2016 by Forero et al . Injection of local anesthetic between erector spinae muscle and transverse process. (6)

**The numerical rating scale:-**represented by 10 point scale which can be reported either graphically or verbally which represents zero no pain one up to three mild pain, four up to six moderate pain, and above seven represents severe pain





**Adopted from the National Initiative on Pain Control (NIPC)**

**First analgesic request:** - the time at which the patient report to get anti-pain medication postoperatively

**Total post-operative analgesic consumption:** - the amount of anti-pain drug that the patient takes postoperatively within 24 hours.

## CHAPTER FIVE: RESULT

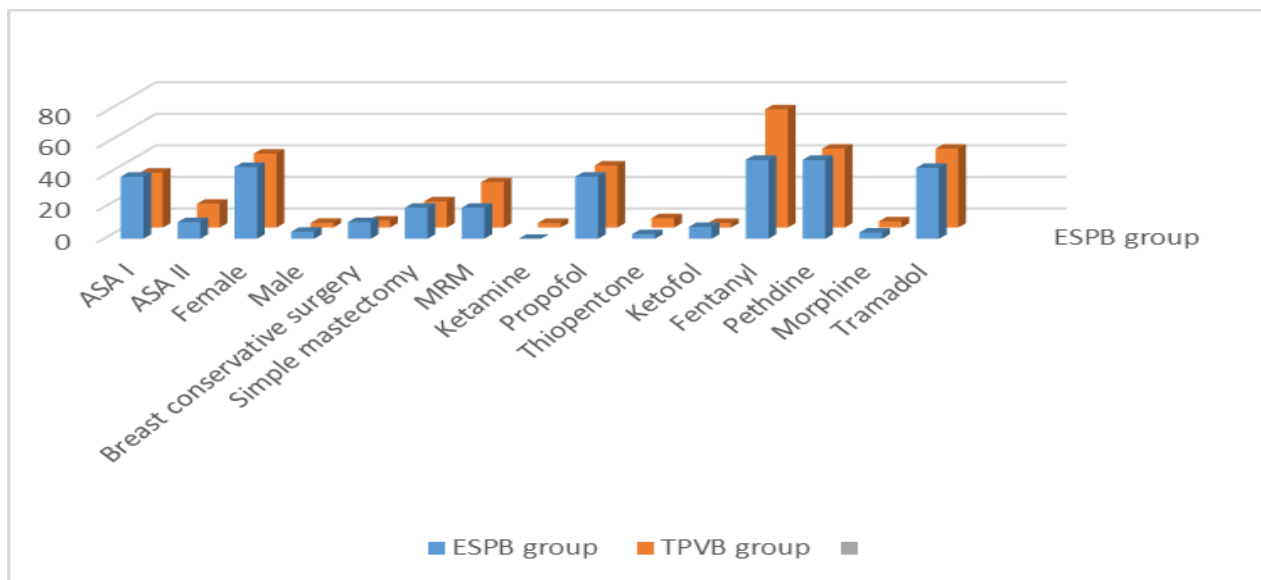
### 5.1 Sociodemographic and perioperative characteristics

A total of 66 patients (33 patients in each group) were involved in this prospective cohort study based on the type of block they took(ESPB & TPVB).. The Sociodemographic characteristics and perioperative characteristics were similar without statistically significant differences between the two groups with p value of > 0.05.

**Table 1.**Sociodemographic and perioperative patient characteristics

Variable	ESPB	TPVB	P-Value
Age *	54.09±8.2	55.3±13	0.654
Weight *	54.7±3.9	55.64±3.54	0.315
Duration of the surgery(minute) *	130.18±19.76	130.24±25.3	0.991

**Hint:** ESPB- Erector spinae plane block, TPVB- Thoracic paravertebral block.\* mean and standard deviation. Analyzed by independent t test



**Fig 1.** Sociodemographic and perioperative patient characteristics between TPVB & ESPB group for breast surgery at the study hospital from December 20-Aprile 30/2023

**Hint:** ESPB- Erector spinae plane block, TPVB- Thoracic paravertebral block. ASA status, Gender, Type of surgery, Induction agent were expressed in N(%)-number (proportion), Intraoperative analgesic agent were expressed in M(IQR)-median and inter-quartile range. Mann Whitney U test and Chi-square test were used and P-value <0.05 was considered statistically significant

### 5.2 Comparison of 1st analgesic request hour

Post-operative patient analgesic request hour also shows a statistically significant difference between groups ESPB (7.36±1.168 hr ) & TPVB (6.61±1.321hr ) with a p-value of 0.016

**Table 2** Comparison of 1<sup>st</sup> analgesic request and number of dermatomes after block between ESPB &TPVB group

	ESPB	TPVB	P-value
1 <sup>st</sup> analgesic request hour :Mean ± SD	7.36± 1.168	6.61±1.321	0.016

**Hint:** ESPB- Erector spinae plane block, TPVB--Thoracic paravertebral block, SD-Standard deviation. P-value <0.05 is statistically significant

### 5.3 Comparison of postoperative pain severity by using the Numerical rating scale at rest and movement

As assessed by NRS the median pain score was comparable between TPVB & ESPB at the 1<sup>st</sup> hour, 6<sup>th</sup> hour, 12<sup>th</sup> hour, and 24<sup>th</sup> hours postoperatively without statistical significance difference seen between groups with P-value >0.05 as shown in the figure below.

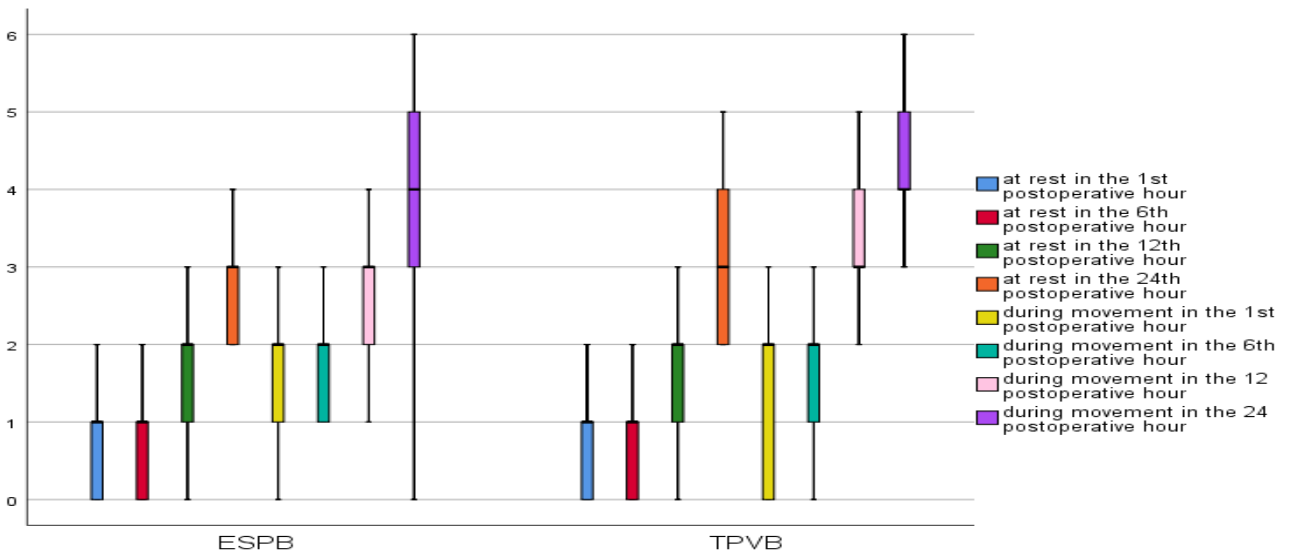
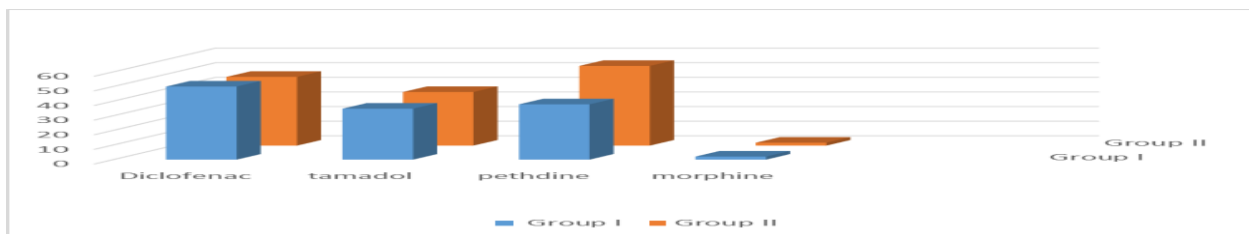


Fig 2. Comparison of pain severity score using NRS between two blocks

**Hint:** pain severity assessed by NRS (0-10). Mann Whitney u test was used. P-value <0.05 is considered statistically significant

Fig.2. Comparison of postoperative pain severity score between ESPB & TPVB groups in breast surgery at study hospital from December 20-aprile 30

### 5.4 Comparison of postoperative total analgesic consumption between groups



**Hint:** group I-- ESPB & group II- TPVB

Fig:-3 A mean value of patients postoperative analgesic consumption between groups over 24 hour undergoing breast surgery at study hospital from December 20-aprile 30.Analyzed by independent t test. Post operative total 24 hour analgesic consumption were comparable between two groups as shown from the fig above with a p-value of  $> 0.05$

### 5.5 Comparison of number of local anesthetic dermatomal coverage between ESPB & TPVB group

The dermatomal coverage of local anesthetic between two groups (ESPB &TPVB groups ) at 15 minutes after block shows a statistically significant difference with median (IQR) of 1(2) & 3(2) respectively, a p-value of 0.00, but there is no statistically significant difference in dermatomal coverage immediately,6<sup>th</sup> hour and 12<sup>th</sup> hour after surgery.

Table 3:Comparison of number of local anesthetic dermatomal coverage between ESPB & TPVB group

Variable	ESPB	TPVB	P-Value
Number of dermatomes 15 minute after block:M(IQR)	1(2)	3(2)	0.001
Immediately after surgery:M(IQR)	4(1)	4(0)	0.401
6 <sup>th</sup> hour after surgery:M(IQR)	4(0)	4(0)	0.614
12 <sup>th</sup> hour after surgery:M(IQR)	4(1)	3(1)	0.274

**Hint:** ESPB- Erector spinae plane block, TPVB--Thoracic paravertebral block, M(IQR)-Median & Inter quartile range. Mann Whitney u test was used P-value  $<0.05$  is statistically significant

## Chapter 6. Discussion

Breast surgery is associated with significant post-surgical pain which can significantly affect postoperative recovery and return to daily living activities. (2) Acute post-surgical pain has the probability to change into chronic post-surgical pain so adequate perioperative analgesia technique is vital. Breast surgery is mostly associated with post-surgical pain, phantom breast (nipple) pain, hyperalgesia, allodynia, neuromas sensation of burning, constricting, or stabbing type of pain and loss of feeling or numbness which can adversely affect the patient's perioperative experience and thought to be due to traumatic nerve injury during surgery, inflammation, and peripheral & central sensitization, and regional anesthesia or nerve block is the mainstay of treatment to prevent the transition of acute surgical pain to such kind of breast surgery-related complications. (3) Although opioids are mostly used as systemic analgesic medications to manage post-surgical pain following mastectomy they have multiple unwanted side effects such as drowsiness, nausea and vomiting, respiratory depression, and pruritus. (4)

Various confounding factors like Sociodemographic, perioperative patients, and anesthetic variability may affect our outcome variables if these factors were not taken into account. In this study, these variables were comparable between the two groups.

This study shows that the mean duration of 1<sup>st</sup> analgesic request hour is statistically significant longer duration in the erector spinae plane block group ( $7.36 \pm 1.168$  hr ) than thoracic paravertebral group ( $6.61 \pm 1.321$  hr ) with 25 ml 0.25% bupivacaine for both ESPB & TPVB ( $p= 0.016$ ). Time of 1<sup>st</sup> analgesic request assessed by Chopra S, Bansal P et al between erector spinae plane block ( 6.24 hr ) & thoracic paravertebral block (6.15 hr ) was comparable with  $p=0.75$  this result also have inline with the study conducted by El Ghamry M et al have a comparable analgesic request hour between TPV group ( $6.35 \pm 0.42$  hr) and ESPB group ( $6.5 \pm 0.6$  hr ) with a p-value of 0.075.

A study done by Elewa AM, Faisal M, Sjöberg F et al shows a similar result in terms of patient analgesic request time without statistically significant difference between groups, ESPB mean analgesic duration or request hour was  $7.9 \pm 1.2$  hr and the TPVB group was  $7.5 \pm 0.9$  hr with a p-value of 0.24. (20)(19)(12)

In contrary the study conducted by Moustafa M, Alabd A, Ahmed A et al shows the time for 1<sup>st</sup> analgesic request is 11.04±1.9 hr for erector spinae block group and 11.22±1.95 hr for thoracic paravertebral group but they are comparable across the group with p value of 0.66 and this time prolongation may be the use of US guided nerve block that is correctly targets the nerve.

Another study done by Swisher MW, Wallace AM et al shows that the median analgesic request hour for erector spinae plane block is 17.5 hour and for thoracic paravertebral block group is 16 hour with p=0.833. Inline with the study done by Agarwal S, Bharati S, Bhatnagar S et al the median(IQR) duration of analgesia(time for 1<sup>st</sup> analgesic request ) was 232.5(140-1200) minute for erector spinae plane block group as compared with paravertebral block group which has a median duration of 205(135-1190) minute with p value of 0.29. This prolonged time for 1<sup>st</sup> analgesic request time may be the concentration of local anesthetic they use 20ml of 0.5% ropivacaine whereas in this study 25ml of 0.25% bupivacaine was used. (16)(15)(17)

The severity of pain between erector spinae plane block and thoracic paravertebral block is comparable without statistical significance in different time points 1<sup>st</sup>, 6<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hour after surgery in both at rest and during movement this result shows similar outcome with the study conducted Agarwal S, Bharati S, et al, the pain severity was recorded at rest and during movement at 0,30min,1,2,6,12,24 hours and they showed that there is no difference in pain severity score between erector spinae and paravertebral group.

El Ghamry M, Amer A, et al they record the pain severity at PACU and 2,4,6,8,12,18 and 24 hours after surgery and there was no significant difference between erector spinae plane block group and thoracic paravertebral group with a p-value of 0.487,0.927,0.878,0.316,0.228,0.628,0.102 and 0.942 respectively. and VAS score begins to increase up to 3 after the 6<sup>th</sup> hour of surgery which has a similar outcome with this study but the difference between the group is insignificant. (16)(20)

Post-operative analgesic consumption between the two groups didn't show a statistically significant difference. The mean morphine consumption of the erector spinae group and the paravertebral group is 2.1 ± 3.4 mg & 2.0 ± 3.8 mg respectively with p-0.21. Even though there is no statistical significant deference in 24 hour total morphine consumption between the two group the mean morphine consumption is small in amount when it compared with the study done

by Gürkan Y et al the mean total post operative 24 hour morphine consumption was  $5.6 \pm 3.43$  mg in the ESPB group and  $5.64 \pm 4.15$  mg in TPVB group

Similarly study done by Moustafa M, Alabd A et al shows the total post operative morphine consumption were  $6.17 \pm 2.08$  mg for ESPB group and  $6.22 \pm 2.09$  mg for paravertebral group.

Elewa AM, Faisal M et al studied the total 24 hour morphine consumption between ESPB & TPVB group and the result shows that the mean total post operative morphine consumption was  $4.9 \pm 1.2$  mg for ESPB group and  $5.8 \pm 1.3$  mg for PVB group with  $p=0.076$  and the reason for this significant dose variation may be due to the use of another post operative analgesic medication (mean diclofenac, pethidine and tramadol consumption were  $50 \pm 69.3$  mg &  $47.7 \pm 95.2$  mg,  $37.8 \pm 89.2$  mg &  $54.5 \pm 81.8$  mg,  $34.8 \pm 49.5$  mg &  $36.6 \pm 60.59$  mg  $p=0.912, 0.432$  &  $0.894$  in ESPB VS TPVB group respectively) and the reason for low total 24 hour morphine consumption in this study may be due to the use of the above analgesic medication consumption. (19)(13)(17)

Fifteen minutes after the block the number of dermatomes for loss of cold sensation between two blocks erector spinae plane block and thoracic paravertebral block shows a significant difference with a p-value of 0.001 which has a similar result to the study done by Wittayapairoj A, Sakura S, et al shows that the percentage of sensory blockade 10 minutes after block were statistically significant difference between thoracic paravertebral block and erector spinae plane block (100 vs 28.6%,  $p=0.001$ ). however, the number of dermatomal blockades with loss of cold sensation is comparable after surgery and the rest of the point time with a P-value of greater than 0.05 which has also similar result to the study done by Wittayapairoj A, Sakura S, Hirade R et al shows the percentage of sensory blockage after surgery is 100 vs 78.6 with  $p=0.239$  between thoracic paravertebral and erector spinae plane group respectively and the median dermatomal blockage is 1(2) & 3(2) with a p-value of 0.000 in TPVB & ESPB group at 15 minutes of block respectively and the delay in sensory blockade at 15 minute with ESPB is may be due to its site of injection (compartment effect). (10)

## 6.1. Conclusion

Erector spinae plane block performed preoperatively before induction of anesthesia had comparative post-operative analgesia in terms of postoperative opioid consumption and pain



severity score as compared to thoracic paravertebral block and also it had a statistically significant prolonged post-operative analgesia or higher 1st analgesic request hour than thoracic paravertebral group for patients undergoing elective breast surgery.

### **6.2. Strength of the study**

Use of multi centered study area

### **6.3. Limitation of study**

The limitation of this study was no patients follow up after 24 hours to see the effects of thus nerve block on the reduction of chronic post-mastectomy

### **6.4. Recommendation**

We would like to recommend setups that lack strong opioids for postoperative pain management and practitioner who fear procedure-related complications of TPVB will do ESPB for elective breast surgery as a post-operative pain management plan.

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## **Annexes**

### **Annex I: English Version Oral Consent**

Dear participant:

My name is Getnet Gashaw, I have been attending a postgraduate program in the field of anesthesia at Addis Ababa University. I am doing research to compare the postoperative analgesic effectiveness of Erector spinae plane block and thoracic paravertebral block for unilateral breast surgery. Data collection will be done for 24hr. To conduct our study, I would like to ask you some questions which may take about 10 minutes . As your participation is very important to the outcome of the study.And for you in helping you to get treatment by recognizing your complications and pain intensity early, we kindly request you to give us your sincere and truthful answer. All the information that you and other patients going to provide us will remain confidential and you don't need to mention your name.

Are you willing to participate in the study, please? YES/NO (please encircle your response)

If your answer is no, you don't have to continue to the following questions. Thank you!

If your answer is yes, please continue your response to the following questions.

Thank you for taking part in the study!

Signature of the interviewer certifying that consent has been obtained verbally.

Signature \_\_\_\_\_ Date \_\_\_\_\_

For further question ask investigator Getnet Gashaw

Tel: - +251918702489 E-mail :- [getgashaw12@gmail.com](mailto:getgashaw12@gmail.com)

**Annex II: Amharic Version Oral Consent**

**የተከበራችሁ የጥናት ተከፋዮች**

የዚህ ጥናት ዋና አላማ ኦፕራቲቦን ክፍል ለጠት ቀዶ ህክምና ለማድረግ ላቸው ህመማን ከጠቅላላ አንስቼዥያ በፊት ጀርባ ላይ የሚሰጡ የሚከታተሉ ሙሉ ህይወት አሰጣጥ ዘዴዎች ኦፕራቲቦን በኋላ ህመማን ለመቀነስ የሚሰጡትን ለመወቅ ነው። በአጋጣሚ እርስዎ በዚህ ጥናት ላይ እንዲሳተፉ ተመርጠዋል። የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ ማረጋገጥ ማረጋገጥን በማምረት በሚካተተው ውጤት ማረጋገጥ ማረጋገጥን በማጠናቀር ውጤቱ እየተሰራበት ካለው ጋር ለማገናኘት እንዲቻል ነው። እርስዎ ምስጢር ጥናት ላይ ሲሳተፉ የህመም ማጠን በ24 ሰዓት ውስጥ እየታየ እንዲቀንስ እንዲታከሙ ይረዳዎታል። ለኛም ጥናቱ በትክክል አላላውን እንዲሁም የእርስዎን ድጋፍ እንጠይቃለን። የሚከተለው ግለሰብ ስም አይመዘገብም እንዲሁም ሃሳባቸውን በይፋ እንዲወጣ አይደረግም። ማህተም በሚሰጡበት ጊዜ የተጠበቀ ነው። በጥናቱ የሚተኩሩ ለሚተኩሩ ማህተም መብት አለዎት። ግልጽ የሆነ ምላሽ እና ከልብ የሚጮ ተሳትፎዎን እንዲሰጡን በአክብሮት ለማጠየቅ እንወዳለን።

-ለሚተኩሩ ፈቃደኛ ነዎት?            ሀ, አወ            ለ, አይደለሁም

-ሚስዎ አወ ከሆነ የሚተኩሩን ጥያቄዎች ይመልሱልን። :

-ለሚተኩሩ ፈቃደኛ ስለሆኑ እና ማሳገጥ ለን። :

weight -ለጥያቄ ሚስዎ ለሚሰጡት እርስዎ የቃል ፈቃድ ማህተምን ለመረጋገጥ ማረጋገጥ ሰብሳቢ ባለሙያ ይፈረሳል። :

-የሰብሳቢው የሚረጋገጥ ጭፍር ማረጋገጫ \_\_\_\_\_ ቀን :

### Annex III: Questionnaire

1. Type of block : 1. ESPB 2. TPVB
2. Age in year.....
3. Weight .....
4. ASA status.....
5. SEX.....
6. Type of surgery : 1. breast conservative 2. simple mastectomy 3 . MRM
7. Duration of anesthesia in hour.....
8. Medication used as induction.....
9. Intraoperative analgesia medication : 1. Fentanyl 2. Morphine 3. Pethidine 4. Tramadol 5. Fentanyl and morphine
10. Number of dermatomes with loss of cold sensation
  1. Fifteen minute after block.....
  2. Immediately after surgery.....
  3. 6<sup>th</sup> hour after surgery.....

- 4. 12<sup>th</sup> hour after surgery.....
- 11. Number of dermatomes with loss of cold sensation
  - 2. Fifteen minute after block.....
  - 5. Immediately after surgery.....
  - 6. 6<sup>th</sup> hour after surgery.....
  - 7. 12<sup>th</sup> hour after surgery.....
- 12. 24 hour total dose of diclofenac consumption in mg after surgery.....
- 13. 24 hour total dose of tramadol consumption in mg after surgery.....
- 14. 24 hour total dose of pethidine consumption in mg after surgery.....
- 15. 24 hour total dose of morphine consumption in mg after surgery.....
- 16. Time of 1<sup>st</sup> analgesic request postoperatively.....
- 17. NRS at rest in the 1<sup>st</sup> postoperative hour .....
- 18. NRS at rest in the 6<sup>th</sup> postoperative hour .....
- 19. NRS at rest in the 12<sup>th</sup> postoperative hour .....
- 20. NRS at rest in the 24<sup>th</sup> postoperative hour .....
- 21. NRS during movement in the 1<sup>st</sup> postoperative hour .....
- 22. NRS during movement in the 6<sup>th</sup> postoperative hour .....
- 23. NRS during movement in the 12<sup>th</sup> postoperative hour .....
- 24. NRS during movement in the 24<sup>th</sup> postoperative hour .....