

**ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH  
SCIENCES SCHOOL OF MEDICINE DEPARTMENT  
OF ANESTHESIA**



**THE EFFECTIVENESS OF PARAVERTEBRAL BLOCK AMONG WOMEN  
PATIENTS UNDERGOING MASTECTOMY SURGERY IN TIKUR ANBESSA  
REFERRAL SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA.**

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**JUNE, 2018**

**ADDISABABA, ETHIOPIA**

### **Declaration**

I, the undersigned, declare that this thesis is my original work in partial fulfillment of the requirements for the degree of MSc in Advanced Clinical Anesthesia. I understand that plagiarism will not be tolerated and all directly quoted material has been appropriately referenced

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Finally, I also want to express my great thanks to Tikur Anbesa Hospital staff, data collectors, my friend and family.

## **ABSTRACT**

**BACKGROUND:** -. Thoracic paravertebral block is analgesic in patient having breast surgery for post-operative pain management. mastectomy patient post operatively suffer pain not only due to surgical site and nerve manipulation but also stress is the main aggravating factor Most studies showed significant reduction in pain intensity and severity for patient whom thoracic paravertebral done when compared placebo group. Paravertebral block has been advocated as useful technique for breast surgery. Most studies show it decrease 95% total consumption of opioid, tramadol and Diclofenac in 24 hour.

**Objective:** To assess the effectiveness of Para vertebral block for post-operative pain management among women underwent mastectomy surgery at Tikur Anbesa specialized Hospital, Addis Ababa, Ethiopia.

**METHOD:** Hospital based prospective cohort study conducted on 96 patients underwent mastectomy surgery divide in to exposed group and non-exposed group. Each group contained 48 patients. One group exposed TPVB with 15 ml of 0.25% bupivacaine and the other are not exposed. Manny Whitney test were used to compare median pain score, time to first analgesia request in minutes and total analgesia consumption between groups. Homogeneity of categorical independent variable between two exposure groups was analyzed using Chi Square. Box and whisker plot were used to show a median pain score differences between groups and statistical significance were sated at p value < 0.05 with a power of 80%.

**Results:** The comparisons of the study at recovery room median (IQR) post-operative VAS score 0(0-3) for exposed group and 4(0-8) for non-exposed group (p=0.002). The median pain score at 3<sup>rd</sup>, 6th, 12th and 24<sup>th</sup> hours were also lower in exposed group when compared to non-exposed group with p value of <0.001. The time to first analgesia request in minute were longer (720 minute) in exposed compared to 180 min in non-exposed group (p<0.0001). Total consumption of tramadol, Diclofenac and morphine is significant (p<0.0001) but the incidence of nausea and vomiting is not significant between the group (p=0.836). Manny Whitney test were used for non-distributed and independent t test is for normally distributed data.

**Conclusion and recommendation:** Thoracic Para- vertebral block done post-operatively lowers pain score, total analgesia consumption and prolong time to first analgesia request. Based on these we recommend use of TPVB with 0.25 bupivacaine is effective post-operative analgesia.

**Key word:** thoracic paravertebral, bupivacaine, mastectomy, post-operative pain.

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## Abbreviation

ASA	-American society of anesthesiologist
CA	-Cancer
ICU	- Intensive care unit
IM	-Intra muscular
IV	-Intra venous
MAP	-Mean arterial pressure
MG	-Morphine group
Mg	-Milligram
PR	-Pulse rate
RR	-Recovery room
SD	-Standard Deviation
SPO2	-Spontaneous oxygen saturation
SPSS	- Statistical package for social science
TAH	-Tikur Anbesa Hospital
TPVB	- Thoracic Para vertebral block
VAS	- Visual analog score

## **Chapter one: -Introduction**

### **1.1 Background**

Postoperative acute pain is a common issue following mastectomy surgery. Although minimally invasive, postoperative pain arising from intercostal muscles, fascia, and nerve injury after mastectomy surgery is not only associated with lower patients' satisfaction, but also leads to impairment of postoperative wound healing. (1)

Recent years, the number of new cases of breast cancer has increased, with an estimated risk of 52 cases per 100,000 women. Similar to that seen in the world population, breast cancer became the leading cause of mortality among women. About 40% of the patients experience clinically significant acute postoperative pain (greater than 5 on the Visual Analog Scale) (2).

Recently for patients undergoing unilateral breast and thoracic surgeries, the thoracic paravertebral blockade (TPVB) has received much popularity as an alternative to epidural analgesia, due to similar analgesia efficacy and lower risk of developing complications.(3)

Currently regional technique like thoracic paravertebral block for breast surgery is gaining a lot of popularity. As it produces unilateral action thereby minimal hemodynamic changes with autonomic blockade, allows early ambulation, facilitates postoperative analgesia, eliminate the risks/complications of general anesthesia and thus reduces the hospital stay and cost.(4)

## 1.2 Statement of the problem

Thoracic Para-vertebral block (PVB) is used for pain relief after breast surgery for malignancy is usually performed under general anesthesia and is associated with considerable post-operative pain, nausea and vomiting. Thoracic Para-vertebral appears promising due to reduction in post-operative pain, decreased opioid consumption with reduction in PONV, risk respiratory depression and cost saving (5).

Cancer is a group of diseases characterized by the uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Breast cancer is the most common cancer in women worldwide, with nearly 1.7 million new cases diagnosed in 2012 (second most common cancer overall). This represents about 12% of all new cancer cases and 25% of all cancers in women. In low and middle income countries (LMCs), the infrastructure and resources for routine screening mammography are often unavailable. In such lower resource settings, breast cancers are commonly diagnosed at late stages, and women may receive inadequate treatment, pain relief, or palliative care. Because breast cancer is often diagnosed in late stages in women in LMCs, mortality rates are often much higher compared with rates in developed countries. However, the most significant risk factors for breast cancer are gender (being a woman) and age (with most cases developing in women after menopause. (6)

Even the diagnosis and treatment of cancer in Ethiopia late mostly the management is leads to surgery due to some women's thinks surgery have less extensive and better option. Surgery is one of the management of breast CA but the most difficult thing during surgery is pain. About 40% of breast cancer surgery patient complain from significant acute post-operative pain and 50% of them develop chronic post-operative pain, commonly due to inadequate analgesic.

Post-operative pain suffering after the surgery is common. Inadequate management of pain have long and short consequence so, it causes post-operative morbidity and mortality and increases hospital stay and cost. (7) Proper management of post-operative pain crucial to increase patient satisfaction and patient health outcome. But there difference to control post-operative pain management some of the anesthetist use IV drug like NSAID, opioid and the other prefer nerve block like PVNB and intercostal even if nerve block is not wildly practice.

### **1.3. Significant of the study**

Most of the time post operatively patient will suffer pain not only due to surgical site and nerve manipulation but also stress is the main aggravating factor. Post-operative pain management during mastectomy surgery is mandatory b/c pain disturb both physiological and mental satisfaction of the patient. Pain limits everyday activities and makes it hard to work .it can also affect how involved you are with friends and family member. (8)

Post-operative pain management is controlled by administration of either opioid or NSAID like Diclofenac injection but some are done Para vertebral neuraxial nerve block for post-operative pain.(3, 9) Even Para-vertebral block is not widely practice Tinkur Anbesa Hospitals.

Most research done in India and Europe shows significant difference. As far as my knowledge there was no study conducted in my study area thus this study was aimed to evaluate postoperative pain .This study was also helpful for program planners, policy makers, health care mangers and hospitals managers to understand the extent of the problem in the hospital and to plan different strategies which help them to improve post-operative mastectomy pain and thereby to advance quality of health care delivery.

## CHAPTER TWO:-LITRATUR REVIEW

### 2.1Literature Review

Thoracic Para vertebral nerve block is use for intra-operative or post-operative pain management during surgery like thoracic ,cholistecthectomy, sometimes use as soul anesthetics for surgery like mastectomy, inguinal hernia. However TPVB have its own complication like risk of pneumothorax, infection transmission .(10)

A study Durham done in Twenty-five patients" agreeing to have surgery per- formed under Para vertebral blocks were studied. Procedures performed varied from simple lumpectomy with axillaries dissection to modified radical mastectomy with axillary dissection. Post-operatively, patients with successful blocks had minimal nausea, vomiting and pain. No patients the procedure unsatisfactory and Patients with successful block were all very satisfied (11).

Another study Indian demonstrate post-operative analgesic efficacy TPVB for mastectomy one group receive either PVB (group A) or intramuscular Diclofenac sodium (group B); there were 25 patients in each group.. The patients given PVB experienced lower visual analog score (VAS) at rest ( $P < 0.001$ ) and longer duration of analgesia ( $P < 0.001$ ) on movement ( $P < 0.0001$ ) for 1 to 12 h in postoperative period as compared to group B. and Duration of analgesia in group A was  $14 \pm 1.5$  hours, whereas it was  $6 \pm 0.3$  in group B which was significantly ( $P < 0.0001$ ) higher in group A(4).

A Study done in china study conducted in 2016 in a In total, 72 patients undergoing breast cancer surgery were randomly divided into an intervention group and a control group; each group contained 36 subjects. Both groups received TPVBRA with 20mL 0.25% bupivacaine. In addition, subjects in the intervention group also received an additional 1mg/kg dexmedetomidine. The time first analgesic request in intervention 9.8(6.6) and 6.4(5.1)in control group ( $p=0.043$  )and total tramadol consumption in 24hour 148.9(74.8) in intervention group and 195.7(66.2) in control group (12).

A 2015 study in Karnataka conducted on comparing thoracic PVB with epidural block in a double-blinded, prospective, randomized study of 60 women scheduled for unilateral breast surgery. There was no significant difference between the groups in pain scores, consumption of additional morphine or nausea scores. Patients receiving epidural showed a fall in mean arterial pressure leading to significant ( $p > 0.05$ ) (10, 11)

Another study done 2016 Indian study in a total of forty five Patients grouped into group PB (paravertebral–bupivacaine) received PVB with 0.5 % bupivacaine 0.3 ml/kg with 1 ml normal saline;` group PBD (paravertebral–bupivacaine–dexmedetomidine) received PVB with 0.5 % bupivacaine 0.3 ml/kg and dexmedetomidine 1 µg/kg in a volume of 1 ml; and group C (control) patients were given a sham block (a subcutaneous injection with 2 ml normal saline) before receiving general anesthesia (GA). All patients received analgesia by fentanyl intraoperatively and morphine patient-controlled analgesia postoperatively. Results The control group patients required more intraoperative fentanyl than the other two groups. Patients receiving dexmedetomidine had lower morphine consumption ( $p < 0.001$ ), pain scores and incidence of postoperative nausea/vomiting ( $p = 0.011$ ); longer time to first analgesic request; earlier time to mobilize; and better satisfaction scores. Heart rate and blood pressure values during the intraoperative period were also lower at many time points in this group. However, the incidence of hypotension and bradycardia were statistically similar in all groups (13).

A 2015 literature review done in Brazil from 1966 to 2012, using specific terms in computerized databases of articles investigating the clinical characteristics, adverse effects, and beneficial effects of thoracic paravertebral block. On the selected date, 16 randomized studies that met the selection criteria established for this literature review were identified. Thoracic paravertebral block showed a significant reduction of postoperative pain, as well as decreased pain during arm movement after surgery (14).

A 2014 Egyptian study in a total of Sixty patients undergoing elective mastectomy were randomly allocated into either PVB with 15–20 ml of levobupivacaine 0.25% at the level of fourth thoracic vertebra or Pecs block with 10 ml of levobupivacaine 0.25% injected in between pectorals major and pectorals minor muscle and another 20 ml levobupivacaine 0.25% in between pectoralis minor and serratus anterior muscle.(10)

Postoperative morphine consumed at 24 h was significantly lower in Pecs group [21 (20–25) mg] than in PVB group [28 (22–31) mg], ( $p=0.002$ ). Time for first request of morphine was longer in Pecs group [175 (155–220) min] than in PVB group [137.5 (115–165) min], ( $p<0.001$ ). Numerical rating score (NRS) at rest was lower in Pecs group compared with PVB group at 1 h, 6 h and 12 h ( $p<0.001$ ) but at 18 h and 24 h it was lower in PVB group compared with Pecs group ( $p=0.008$  and  $<0.001$  respectively). During movement, NRS was significantly lower at 1st hour in Pecs group ( $p<0.001$ ) while at 18 h and 24 h it was significantly lower in PVB group ( $p<0.001$ ). PONV was comparable between both groups (10).

Another 2015 Egyptian study conducted in a total of Sixty American Society of Anesthesiologists physical status –I – III patients were randomly assigned to receive thoracic PVB with either 20 mL of bupivacaine 0.25% (Group B,  $n = 30$ ), or 20 mL of bupivacaine 0.25% + 1  $\mu\text{g}/\text{kg}$  dexmedetomidine (Group BD,  $n= 30$  . There was a significant increase in pulse rate starting 2 hours postoperative until 48 hours postoperatively in group B but only after 12 hours until 48 hours in group BD ( $P < 0.001$ ). The time of the first rescue analgesic requirement was significantly prolonged in the group BD ( $8.16 \pm 42$  hours) in comparison to group B ( $6.48 \pm 5.24$  hours) ( $p = 0.04$ ). The mean total consumption of intravenous tramadol rescue analgesia in the post anesthesia care unit in the first 48 hours postoperatively was significantly decreased in group BD ( $150.19 \pm 76.98$  mg) compared to group B ( $194.44 \pm 63.91$  mg) ( $P = 0.03$ ). No significant serious adverse effects were recorded during the study (15).

Another Egyptian study done in a total of Ninety female patients scheduled for modified radical mastectomy were allocated into 2 groups (45 patients each). Group (B) received bupivacaine 0.25% 0.3 ml/kg in the paravertebral space while group (BM) received 100 mg magnesium sulphate+bupivacaine 0.25% 0.3 ml/kg in the paravertebral space. Both blocks were done guided by ultrasound before induction of standard general anaesthetic technique which was the same in both groups. Patients in group (BM) were found to have reduced VAS scores at 30 min, 2, 4, 6, 12, 24 h intervals post-operative. The time to first analgesic request was longer in patients of group (BM) with less amount of post-operative opioid consumption and consequently less number of attacks of PONV in first post-operative 24 h. These results were significant with a P value $<0.001$ (2).

## **CHAPETR THREE:-OBJECTIVE**

### **3.1 General objective**

To assess the effectiveness of Para vertebral block for post-operative pain management among women undergoing mastectomy surgery at Tikur Anbesa specialized Hospital, Addis Ababa, Ethiopia, from December 30, 2017 G.C to May30, 2018 G.C.

### **3.2. Specific objective**

- To compare the pain severity of at Exposed group and Non-exposed group at Tikur Anbessa specialized Hospital, Addis Ababa, Ethiopia.

- To compare 24 hour drug consumption between exposed and none exposed group at Tikur Anbessa specialized Hospital, Addis Ababa, Ethiopia.

-To compare first time analgesic request between exposed and non-exposed group at Tikur Anbessa specialized Hospital, Addis Ababa, Ethiopia.

## **CHAPTER FOUR: - METHODOLOGY**

### **4.1 Study Area**

The study was conducted at Tikur Anbesa specialized Hospital is very large referral hospital and approximately 370,000-400,000 patients are served a year.(16) The hospital establish in1972as teaching hospital to provide training for medical student. The hospital has 800 beds, It got eight major operating theater rooms(17) and 2 of them are for general surgery.

### **4.2 study Design and Period**

Hospital based Prospective cohort study was employed from December 30,2017 to May 30,2018.

### **Population**

#### **4.3.1. Source of population**

All women patients scheduled for elective mastectomy surgery under general anesthesia at TASH.

#### **4.3.2. Study population**

All women patients who underwent elective mastectomy surgery during the study period under general anesthesia at TASH.

### **4.4. Eligibility criteria**

#### **4.4.1. Inclusion criteria**

- All women scheduled elective mastectomy surgery
- Patient Age gather than 18
- ASA status I and II

#### **4.4.2 Exclusion criteria**

- ✓ Allergic for local anesthesia drug
- ✓ Local site infection and Anatomical Deformity
- ✓ psychosis patient
- ✓ Intra-operative Strong opioid

## 4.5. Sampling Technique and Sample Size Determination

### 4.5.1 Sample size determination

Sample size determination Comparison of two mean with equal sample size formula for independent cohort

Two independent sample size formula based on the mean difference of time to first analgesia request was used to calculate sample size for each group. Having no previous study done in the study area, result adopted from literature has been used to calculate sample size based on the outcome variable and the largest sample size were used for recruiting study subjects.

The required sample size to show with 95% likelihood that the mean time to first analgesia within 24 hour is not equal between two groups was calculated as:

$$n = \frac{(S1^2 + S2^2)(a+b)^2}{(x_1 - x_2)^2}$$

Where n = the sample size in each of the groups

$x_1$  = Sample mean in control group

$x_2$  = Sample mean in treatment group

$x_1 - x_2$  = the difference the investigator wishes to detect

$S1^2$  = sample variance in control group

$S2^2$  = sample variance in treatment group

a = conventional multiplier for alpha = 0.05, which is 1.96

b = conventional multiplier for power = 0.80, which is 0.842

from the literature the mean time of first analgesic requirement,  $\mu_1 = 6.4$  in control group,  $\mu_2 = 9.8$  in the treatment group and  $\sigma_1 = 6.6$   $\sigma_2 = 5.1$  (12)

Substituting for this variable yields

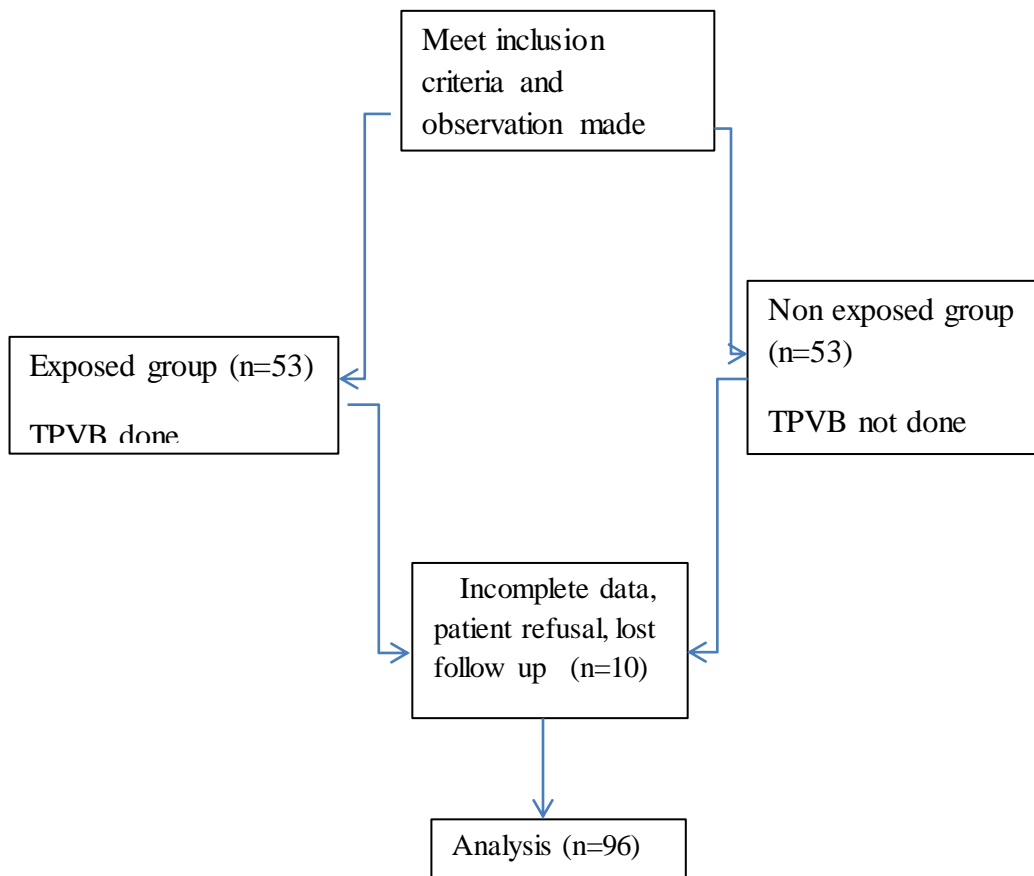
$$n = \frac{(6.6^2 + 5.1^2) \times (1.96 + 0.84)^2}{(9.8 - 6.4)^2}$$

n = 48 using 1:1 ration between groups, adding 10% contingency a total of 106 patient were required.

#### 4.5.2 Sampling technique

Systematic random sampling technique was used to get the required sample size during the study period.

Patients aged 18 and above who underwent mastectomy surgery into the study during postoperative period at Recovery room. With 127 patients estimated to undergo mastectomy during study period 96 participants were recruited with the probability of about 75%. Considering the consecutive patients scheduled for mastectomy data collection were made on 3 patients for every 4 patients underwent surgery in both groups. Patients were sorted based on time sequence of PACU admission after which data collector recruit 3 patient for every 4 consecutive patients underwent mastectomy after grouping based on whether they received TPVB or not. One number selected by lottery method used for exclusion and selection made on the rest of numbers in both groups till the required sample size is reached. We spent two extra weeks to reach the number of exposed group equal to unexposed group.



**Figure 1 Enrollment chart for elective mastectomy surgery patient at Tikur Anbesa Hospital 2018.**

All patient who were Scheduled patient for elective mastectomy who fulfills inclusion criteria and voluntary to take part in the study were instructed on how to self-report pain using the eleven point VAS score 0-10 in the morning at operation day and at ward with trained nurse.

Anesthesia management for mastectomy in study is carried out by B.Sc. and M.Sc. anesthesia professional. After surgery is completed M.Sc. anesthesia profession including M.Sc. anesthesia student provide TPVB with 15ml of 0.25 % bupivacaine. Post-operatively time at recovery and ward severity of pain is assessed by trained nurse .pain is usually managed by tramadol, Diclofenac and morphine based on patient complains. Pain score assessed using NRS score and document at recovery ,3<sup>rd</sup> hour ,6<sup>th</sup> hour, 12<sup>th</sup> hour and 24<sup>th</sup> hour and in addition that nausea and vomiting document at 24 hours.

#### **4.6. Variable of the study**

##### **4.6.1 Dependent variable**

- Average Postoperative pain severity - using VAS score
- Time first analgesia request
- Total analgesic consumption in the first 24 hours

##### **4.6.2 Independent variable**

- Age
- BMI
- ASA status
- Duration of surgery
- Duration of anesthesia
- Type induction & maintenance
- Type of Drug that use for intra-operative pain management

#### **4.7. Data Collection**

Questioner was prepared in English and translated to Amharic which includes socio demographic data, physical characteristics of the patient, postoperative vital signs, Post-operative drug consumption, duration of surgery, ASA classification, medical co-morbidities, type anesthesia drug and other variables .The data collection was under taken by one Anesthetists and two nurse after getting training and the principal investigator supervise the completeness of the data daily.

#### **4.8. Data Processing and Analysis**

Data were checked manually for completeness and then it was coded and entered in to SPSS version 20 computer program for cleaning and analysis. Descriptive statistics were used to summarize data, tables and figures. Unpaired T-test used for normally distributed data while Mann whitheney test was used for non-distributed data. Categorical variables were analyzed by chi-square.

#### **4.9 Data Quality Control and Assurance**

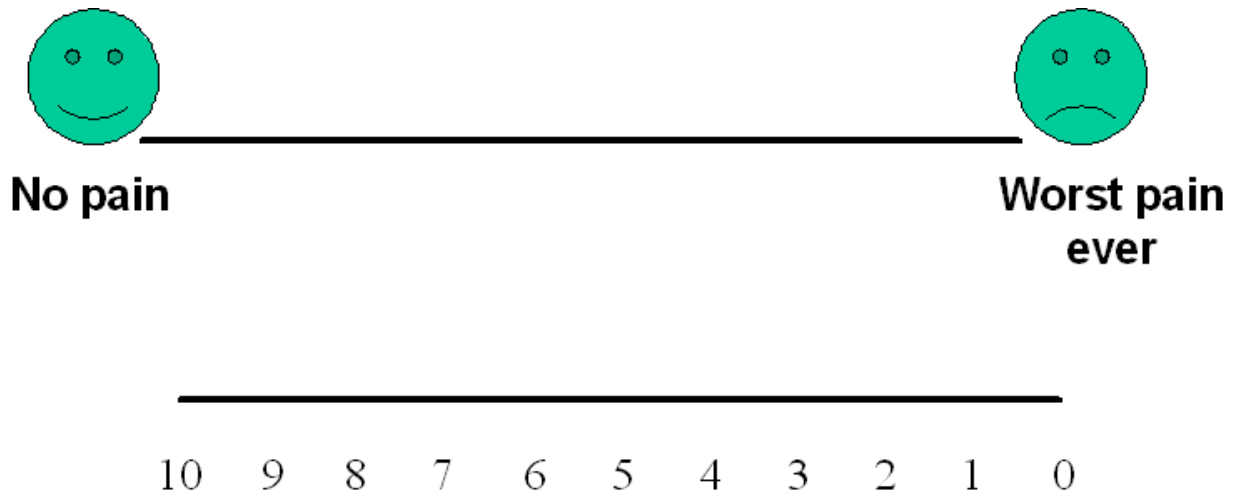
Data collectors trained by principal Investigators. Pretest was done for one week. During data collection, regular supervision and follow up made. Principal Investigator was cross check for completeness and consistency of data every day. All materials used for data collection was arranged sequentially and data stored in safe and secure place.

#### **4.10 Dissemination plan**

The final result will be Disseminated Black lion hospital, Addis Ababa University student research program offices, Anesthesia department, Addis Ababa Health bureau, Ethiopian association of anesthetist, Federal ministry of health and will also presented on different seminar. Great effort will be made to publish the finding in national and international trustworthy journal.

#### 4.11 Operational definitions

**VISUAL ANALG SCORE-** Instruct the patient to point to the position on the line between the faces to indicate how much pain they are currently feeling. The far left end indicates "no pain" and the far right end indicates "worst pain ever".



**MULTIMODAL** –it is the type of analgesia that combined two more anti pain drug pre-operatively. Intra-operatively or post operatively

**Mastectomy** -Is removal of the infected breast by surgery either total or some part of the breast.

**Thoracic Para vertebral nerve block** – is type regional anesthesia in which local anesthesia administer at end thoracic fascia.

**Post-operative pain-** the presence of pain in the postoperative period was defined as a patient complaining pain and any pain score other than zero within 24 hours.

**Time to first analgesia request:** a time in minutes from the end of surgery to a first time analgesia were given.

**Total analgesia consumption:** total dose of medication given in mg within the first 24 hour after end of surgery.

#### **4.12 Ethical Consideration**

Ethical clearance and support letter for the study was obtained from Addis Ababa University College of Health Science Ethical Review Committee. Support letter were found from Department of anesthesia. Permission was obtained from TASH chief executive offices and written informed consent was obtained from each study participants after explaining the benefits and risks of the study. Any information concerned the participants were confidential.

## CHAPTER FIVE: - RESULT AND DISCUSSION

### 5. RESULT AND DISCUSSION

#### 5.1. RESULTS

Primarily 106 patients were enrolled in the study period. From those ten patient exclude from group due to incomplete data, patient refusal and lost follow-up. 90.5% patients were responding for the questioner. There for ninety six patients included and were randomly divided in to 48 exposed group and other 48 non-exposed. The block was done after the procedure of the surgery and before extubation patient for post-operative pain management as exposed group and those who are not give TPVB is non-exposed.

##### 5.1.1 Demographic and operative characteristics

There is no statistically significant difference in demographic and operative characteristics like age, BMI, experience of surgeon with p-value 0.359, 0.269, 0.445 respectively (Table1).

**Table 1: Demographic and operative characteristics of elective mastectomy patient in Tikur Anbessa Hospital using Manny Whitney test and independent t test, Addis ABABA, Ethiopia ,2018.**

Variable	Exposed group (TPVB) (n=48)	Non-exposed group (n=48)	P- Value
Age(years)≠	45(41 -49)	46(41-50)	0.359
BMI #	20.0(19.2-21.0)	20.0(20-21)	0.269
Baseline HR (Mean ±SD)	94.71±7.52	96.48±8.48	0.282
Baseline MAP(Mean ±SD)	79.5±6.92	78.06±9.91	0.412
Baseline SPO2 #	95(94-96)	95(94-96)	0.584
Duration of surgery in minute #	80(75-80)	88(78-93)	0.095
Duration of anesthesia min. #	95(90-110)	98(90-110)	0.220
Estimated blood loss(ml )#(Mean ±SD)	416.65±76.54	430±75.37	0.391

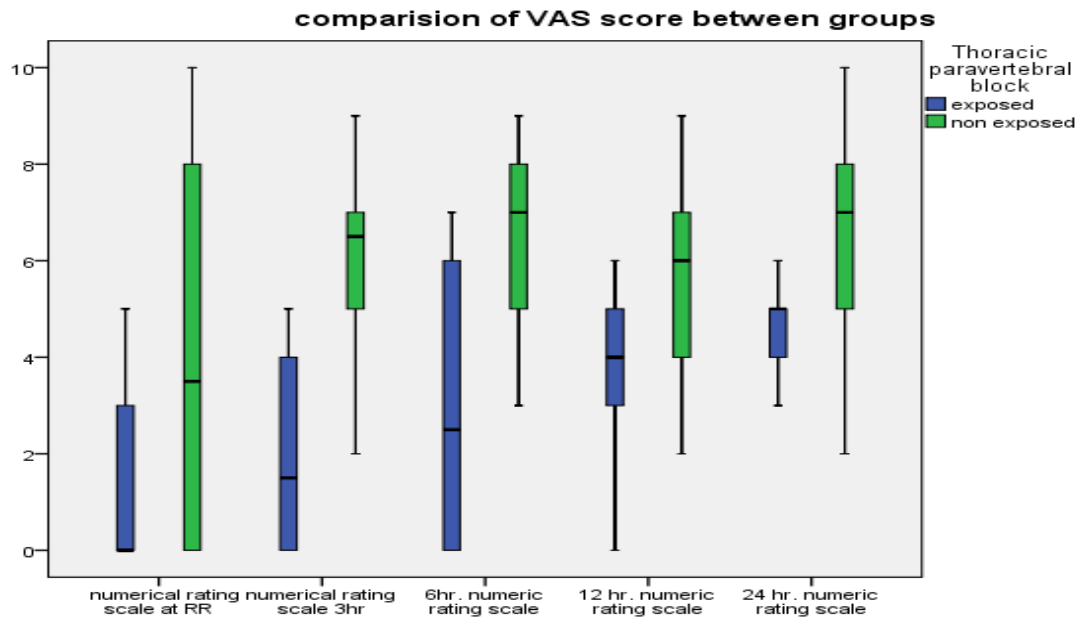
Hint: # = Median (Interquartile range), SD=Standard deviation

### 5.1.2. Postoperative Pain Severity by VAS score in exposed and non-exposed groups

The median VAS score were lower in the exposed group at recovery room, 3rd, 6th, 12th, and 24th hour. Using Many Whitney test a significant statistical difference was observed at all time between exposed and non-exposed groups.

**Table 2 post-operative pain severity comparison in vas score in exposed and non-exposed Using Many Whitney t test ,Addis Ababa, Ethiopia, 2018.**

Variables compared by medaine VAS score	Exposed group TPVB (n=48)	Non-exposed (n=48 )	P-Value
Recovery Room VAS score	0(0-3)	4(0-8)	0.002
3 <sup>rd</sup> hr. post-operative VAS Score	2(0-8)	7(5-7)	<0.0001
6 <sup>th</sup> hr. post-operative VAS score	3(0-6)	7(5-8)	<0.0001
12 <sup>th</sup> hr. post-operative VAS score	4(3-5)	6(4-7)	<0.0001
24 <sup>th</sup> hr. post-operative VAS score	5(4-6)	7(5-8)	<0.0001



**Figure 2 comparison of VAS score between groups ,Addis Ababa, Ethiopia ,2018.**

### 5.1.3 Comparison of Time to First Analgesia Request and Total Analgesia Consumption between Groups in twenty four hour.

Regarding with time to first analgesia request, there is statistically significant difference which is 720 (540-720 min) and 60(0-180 min) in median (IQR) for exposed and non-exposed groups with a p-value of less than 0.0001. There is statistically significant difference in total tramadol, Diclofenac and morphine consumption within 24 hour between two groups (p<0.0001).

**Table 3 Table 3:-comparison of total analgesia consumption between groups within 24hrs, Manny Whitney test used ,Addis Ababa, Ethiopia , 2018.**

Total analgesic consumption with 24 hour in milligram	Exposed group (TPVB) (n=48)	Non-exposed group (n=48)	P-value
Tramadol (IV)	100(50-100)	250(200-300)	<0.0001
Diclophenac (IM)	75(0-75)	75(75-75)	<0.0001
Morphine (IV)	0(0-0)	5(4-6)	<0.0001

### 5.1.4 Immediate at recovery room and ward vital sign

There was a significant difference in mean pulse rate (mean  $\pm$  SD), 92.29 $\pm$ 7.95 in exposed group and 99.31  $\pm$  5.72 in non exposed group with (p-value < 0.0001). there was a significant difference in MAP( mean  $\pm$  SD) in exposed group (79.21  $\pm$  9.03) and 85.29  $\pm$  6.91 in non-exposed group (p- value < 0.0001). There was also statistically significant difference in MAP and PR at 3<sup>rd</sup>, 6<sup>th</sup> and 12<sup>th</sup> hours post-operatively ( p-value < 0.05).

**Table 4 Vital sign in the first 24 hour post-operatively of PR,MAP,SO<sub>2</sub> , using independent t test, Addis Ababa, Ethiopia, 2018.**

Vital sign	Exposed group TPVB(n=48)	Non-exposed group TPVB (n=48)	P-Value
<b>Immediate recovery room vital sign</b>			
MAP (Mean±SD)	79.21±9.03	85.29±6.91	<0.0001*
PR (Mean±SD)	92.29±7.95	99.31±5.72	<0.0001*
SPO <sub>2</sub>	95(94-96)	95(95-96)	0.113
<b>Vital sign at 3 hour</b>			
MAP (Mean±SD)	82.23±8.11	87.90±4.45	<0.0001*
PR (Mean±SD)	93.13±7.59	99.02±5.51	<0.0001*
SOP <sub>2</sub> (median and IQR)	95(94-96)	95(94-96)	0.243
<b>Vital sign at 6 hour</b>			
MAP (Mean±SD)	81.54±4.75	89.33±4.61	<0.0001*
PR (Mean±SD)	86.73±7.62	96.19±7.54	<0.0001*
SPO <sub>2</sub>	96(95-96)	95(95-96)	0.090
<b>Vital sign at 12 hour</b>			
MAP(Mean±SD)	82.88±6.44	89.40±4.83	<0.0001*
PR (Mean±SD)	87.42±7.59	92.98±8.50	0.001*
SOP <sub>2</sub> (media and IQR)	95(94-96)	95(94-96)	0.817
<b>Vital sign at 24 hour</b>			
MAP (Mean±SD)	87.85±3.53	88.19±4.30	0.679
PR (Mean±SD)	92.35±5.35	93.73±4.53	0.177
SPO <sub>2</sub> (media and IQR)	95(94-96)	95(94-95)	0.091

IQR – Interquartile range, SD-standard deviation, PR - Pulse Rate, MAP- Mean arterial blood pressure, \*= statistically insignificant.

### 5.1.5 Incidence of Nausea and Vomiting between exposed and non-exposed group

The incidence of nausea and vomiting over 24 hours is 41.7%. The proportions of patients with nausea and vomiting is lower 19(39.6%) in exposed group compared to 21(43.8%) in non-exposed group with p value of 0.836.

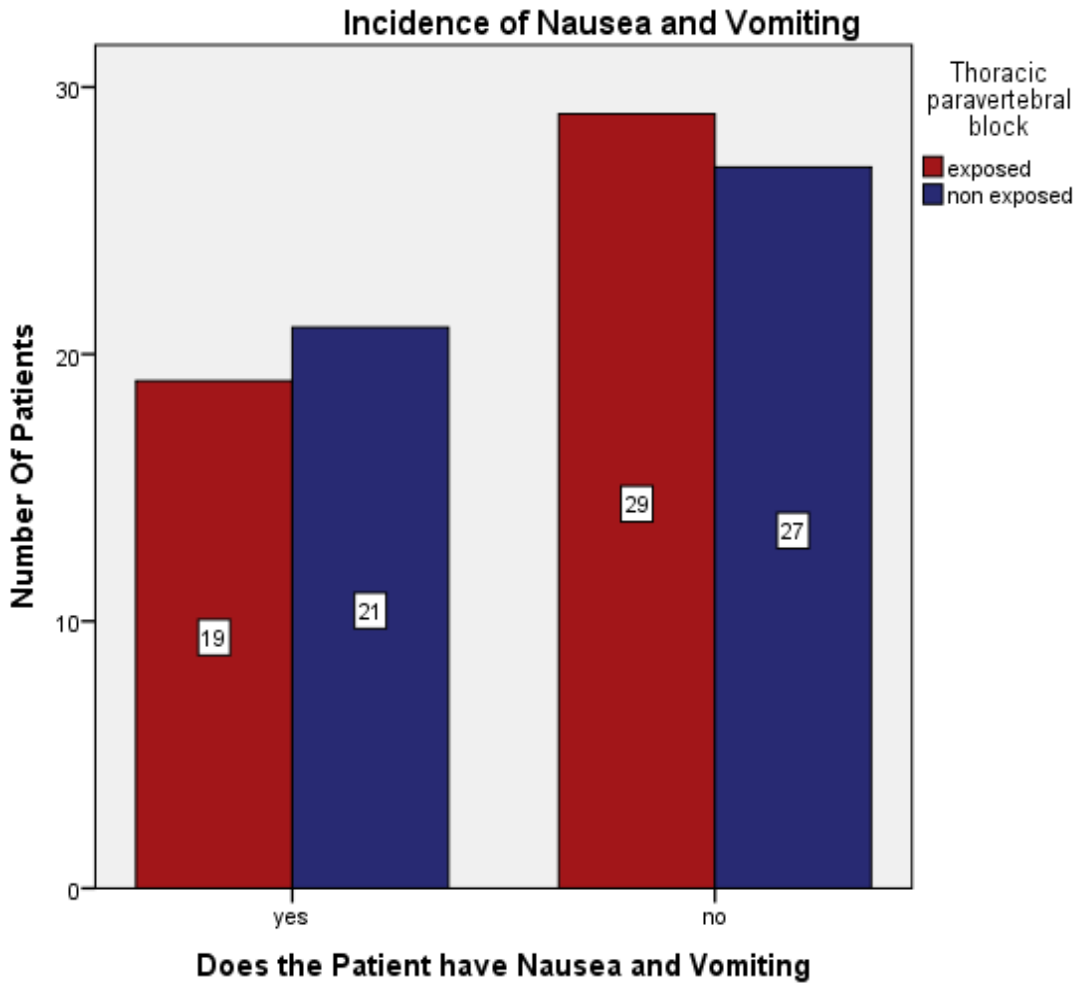


Figure 3 Incidence of Nausea and Vomiting between exposed and non-exposed group Addiss Ababa, Ethiopia ,2018.

## 5.2 Discussion

Our study demonstrate the median (IQR) pain score were lower 0(0-3) in exposed group compared to 4(0-8) in non-exposed group with p-value of 0.002 at immediate recovery room. The median VAS score at 3<sup>rd</sup> hour post-operative time is 2(0-8) in exposed group is lower compared to 7(5-7) in non-exposed group (p<0.0001). The median postoperative pain score were also lower at 6th, 12th and 24th post-operative time with statistically significant difference of <0.0001.

The result of this study in line with the study done in India, Forty-eight patients scheduled for breast cancer surgery were enrolled in this prospective, randomized, double-blinded demonstrate the median (IQR) VSA score 4.9(0.9) in exposed group and 7.0(1.4) in placebo group(p-value<0.001).The similarity of this study block done for post-operative pain management when patients in lateral position(18).

Our study also shows comparable result study done in Indian post-operative thoracic paravertebral exposed group with placebo group the first time to analgesic request 1080(450-1080 minute) in exposed group and 30(6.2-120 minute) in placebo group (p-value=0.001).our study also shows time to first analgesia request 720(540-720 minute ) in exposed and 60(0-180minute ) in non-exposed with p-value <0.0001.

In Contrary a study conducted by Bhuvanewari et al. did not show the effectiveness of paravertebral block alone. The requirement of additional fentanyl was significantly less in the 0.25% bupivacaine with epinephrine fentanyl and the 0.5% bupivacaine with epinephrine groups (P=0.001) when compared with placebo(19).The possible explanation for this contradictory result is difference in study design and pain management practice in study set up.

*In line* with our study a study conducted by Leena et al. compared PVB (group A) or intramuscular Diclofenac sodium (group B); there were 25 patients in each group. Group A patients received PVB with 0.25% bupivacaine, whereas group B patients received intramuscular Diclofenac sodium. VAS at rest was significantly lower in exposed group at 6hr.and at 12hr with p-value <0.0009 and < 0.010 respectively(4, 20).

Our study demonstrates the total post-operative consumption in exposed group. The median (IQR) tramadol in mg where 100(50-100mg) exposed group and 250(200-300mg) in non-exposed (p-value<0.0001).Our finding compared with study done in china which shows 148.9 (74.8) in exposed group and 195.7(66.2) in non-exposed group a p-value 0.035(12).

In contrary to our study a study conducted by Jin et al.had comparable result to our study. The study compared TPVB with 20mL 0.25% bupivacaine as a control group and subjects in the intervention group received an additional 1mg/kg dexmedetomidine and found that The VAS at any time point after surgery between the 2 groups were comparable (P>.05)(12) . The possible explanation for this contradictory result is difference in study design and pain management practice in study set up and follow-up of the nurse.

With regarding the time of the first rescue analgesic requirement, study done in Egypt, was significantly prolonged in the group BD ( $8.16 \pm 42$  hours) in comparison to group B ( $6.48 \pm 5.24$  hours) (p = 0.04). The mean total consumption of intravenous tramadol rescue analgesia in the post anesthesia care unit in the first 48 hours postoperatively was significantly decreased in group BD ( $150.19 \pm 76.98$  mg) compared to group B ( $194.44 \pm 63.91$  mg) (P = 0.03). No significant serious adverse effects were recorded during the study.(10)

*In Contrary* An Egyptian study conducted on thoracic paravertebral block versus pectoral nerve block for analgesia after breast surgery time for first request of morphine was longer in Pecs group [175 (155–220) min] than in PVB group [137.5 (115–165) min], (p<0.001)(10).

Our finding shows the overall incidence of nausea and vomiting after mastectomy surgery in the first 24 hours to be 41.7%. This proportion is higher in the control group with incidence of 39.6% compared to 43.8% in the treatment group. Though there is a proportion difference, there is no statistical difference between two groups with regard to decreasing the incidence of nausea and vomiting in the first 24 hours (p= 0.836). This shows higher figures compared to study by Patel, et al where the incidence of PONV is 26%(10) .The difference is may be Patel, et al used premedication with injection of midazolam hydrochloride 2mg intra venous for all patient .

## **6. Strength and limitation**

### **6.1. Limitation of this study**

-Variability in the performance of the TPVB - since different anesthetists were involved. The success rate of the block was not assessed since it given after general anesthesia.

-Pain severity was not assessed at movement.

-Lack of standard pain management protocol in the study hospital.

-Use of secondary data for preoperative and intraoperative variables was among limitation of this project.

### **6.2. Strength**

Study participant were homogenous between the exposed and non-exposed group.

## **7. Conclusion and Recommendation**

### **7.1. Conclusion**

The result of our study demonstrates thoracic Para-vertebral block performed post-operatively before extubation with 0.25% bupivacaine is an effective and useful postoperative analgesia.

### **7.2 Recommendation**

We recommend that TPVB done post-operatively for mastectomy surgery is an effective post-operative analgesia.

We also recommend additional randomized controlled study.

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**Annex 1. Consent form**

The researcher explained the aim of the study and to decide any time if I do not want to participate. So I assure that my interest to participate in this study is truly from my knowledge.

Do you agree to participate?

Yes

No

Thank you

## Questionnaires

A data collection formats for patients that underwent elective mastectomy surgery at Tikur anbesa hospital, Addis Ababa.

### Pre-operative and intra-operative check list

#### I. Section : Socio Demographic Data (chart review)

Card number		Bed no.	Code
s.no.	Question	Response	
101	Age		
102	ASA	A. ASA I B. ASA II	
103	Sex	A. Male B. Female	
104	BMI		

#### II. Section :Data during preoperative period

s.no	Question	Response	
201	Base line HR	_____bpm	
202	Base line BP(MAP)	____/____)____) MMHG	
203	Base line RR&Spo2	____br/m____%	
204	Diagnosis		
205	Procedure		
206	Does the pt. taking anticancer drug	1.YES 2.NO	
207	If yes for Q no. 206	_____	
208	Is the pt. pregnant?	1. YES 2. NO	
209	Does the pt. have bleeding disorder or abnormal lab. Result	1. Yes 2. No	
210	Does pt. take premedication?	1. YES 2. NO	

211	IF yes for the above Q what was the drug?	A. Diclofenac B. Tramadol C. Paracetamol D. Pethidine E. Morphine F. Other_____	
212	Does the pt. have any co-morbidity?	1. Yes 2. No If yes specify	A. Respiratory B. CVS C. Renal D. Liver E. other _____

III. Section : Question related to anesthetic and surgical interventions

S.no	Question	Response	Code
301	Does the patient received any analgesic drug before Induction of Anesthesia?	1. Yes 2. No	
302	If YES specify type and dose	_____ (_____ mg)	
303	Type of Induction agent	1. IV 2. Inhalational 3. Awake	
304	Induction agent type and dose	Thiopental -----mg Propofol -----mg Diazepam -----mg Suxamethonium-----mg Vecuronium -----mg Pancuronium-----mg	Halothane -----MAC Isoflurane -----MAC Sevoflurane -----MAC
305	Does Ketamine used as Induction agent?	1. Yes 2. No	

306	Time from TPVB to skin incision in minutes		
307	Vital sign before skin incision	BP:_____mmhg PR:_____bpm Sao2_____%	
308	Vital sign after skin incision	BP:_____mmhg PR:_____bpm Sao2_____%	
309	Additional Intraoperative analgesia given ?	1. Yes 2. No	
310	If yes specify type, time and dose of the drug given ?	_____mg	
311	Maintenance of Anesthesia	Halothane Isoflurane Pancronium_____mg Suxamethonium_____mg Vecoronium_____mg	
312	Does the patient extubated in the OR?	1. Yes 2. No	
313	If yes is a patient responsive?	1. Yes 2. No	
314	Experience of the surgeon	1. R3 2. R4 3. Senior	
315	Estimated intraoperative blood loss		
316	Duration of surgery		
317	Duration of anesthesia		

IV. Section : Hemodynamic parameters in post-operative period Immediately at Arrival of Recovery Room, 3rd hr, 6th hr, 12th and 24thhr.

s.no	V/S	Immediately At RR	3rd hr. post op	6th hr. post op	12th hr. post op	24th hour post op
401	TIME(local)					
	BP(mmHg ) <b>SBP/DBP(MAP)</b>					
	PR (bpm )					
	Respiratory rate					
	SPO2 (%)					
	NRS					
	Analgesia given Type and mg					
	Other medication given in mg					

402. Does the patient have nausea within the first 24 hours of surgery? A. YES B. NO

403. Does the patient develop vomiting within first 24 hours of surgery? A. YES B. NO

404. Does the patient have an episode of shivering within first 24 hours? A. YES B. NO

405. Duration in minutes till Initial analgesic requirement after the patient arrived in the recovery

A. Arrived at \_\_\_\_\_pm/am {time per 24hr/date/month/ETH .year}

B. Analgesic required time \_\_\_\_\_PM/AM {time per24hr/date/month/Eth. year}

C. Duration till first analgesic request \_\_\_\_\_

406. Total and type of analgesic consumption within 24 hours after the patient arrived in recovery/ward\_\_\_\_\_

407. Is patient re-operated within 24 hours? A. YES B. NO

## Appendix

### Visual Analogue Scale (VAS)

*Instructions for producing a VAS Bedside card:*

- ❖ Double-sided print
- ❖ The lines are exactly 10 cm in length



**No pain**



**Worst pain  
ever**

