

Addis Ababa University College of Health Sciences School of Medicine

Department of Anesthesia



A Comparative study between Transverse abdominus planes block and wound site local anesthesia infiltration for effective post operative pain control for lower abdominal surgery at Empress Zewditu memorial Hospital, Addis Ababa, Ethiopia 2017/18.

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JUNE, 2018

ADDIS ABABA, 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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Date of Submission: _____

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Name Signature

1. _____

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3. _____

Abstract

Introduction: Wound site infiltration with local anesthesia is a technique commonly used alone or in combination to improve postoperative analgesia, reduce opioid consumption and speed patient recovery. TAP block also reduces morphine requirements by more than 70% and consequently reduces opioid-mediated side effects provides highly effective postoperative analgesia in the first 24–48 hours.

Objective: To compare the analgesia effectiveness of Transverse abdominus plane blocks and wound site local anesthesia infiltration for post operative pain for lower abdominal procedure under general anesthesia at Zewditu memorial Hospital from Jan 1, 2018-March 30, 2018 Addis Ababa Ethiopia.

Methods: This prospective cohort study recruits 60 American Society of Anesthesiologist (ASA) class I and II, age ≥ 18 and patient who underwent lower abdominal procedures randomly. Data were analysed by using SPSS version 20. Demographic data were analysed using student t test (for normal distribution variable) and Chi square and Fisher's exact test (for categorical variable). The data were tested for normality using the Shapiro-Wilk normality test .There was homogeneity of variance assessed by Levene's Test for equality of Variances. Therefore, Mann Whitney U test was run on the non- normally distributed data for the time of first analgesic request & total analgesic consumption. Since the VNRS ordinal variable Mann-Whitney U test were used. Normal distributed data were presented as mean $\pm$ SD, not normally distributed data were presented as median (IQR) and categorical data were presented frequency percentages .A P value <0.05 considered as statistically significant.

Results: The comparison of data showed that statistically significant result during recovery room (PACU) time the Median and IQR of postoperative pain score(NRS) were 2(2-3) in Infiltration group and 4(4-5) in TAP group ($p<0.001$) and at 1st hour with the Median and IQR of postoperative pain score(NRS) were 2(2-2) in Infiltration group and 2(2-3) in TAP group ($p=0.014$). There was no statistically significant difference results at 2nd hr and 24th hour between two group and there were statistically significant difference at 4th , 6th and 12th hour showing lower Median pain score in TAP group compared to infiltration group. The Median and IQR for time to first analgesia request in minutes were longer 673(620-765) minutes in TAP group compared to 227(195-235) minutes in Infiltration group ($p<0.001$). The Median and IQR for Tramadol consumption within 24 hour was 100 mg(100-100) in TAP group compared to 175 mg(150-200) in infiltration group ($p<0.001$).

Conclusion and Recommendation: TAP group shows extended pain relief up to 12 hour; prolong time to first analgesia request and less total analgesia consumption for lower abdominal procedures done under general anesthesia. Based on this finding we recommend that use of TAP block is for effective Postoperative analgesia.

Key words: Local anesthesia infiltration, Transverse abdominal plane block

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List of Abbreviations

AAU Addis Ababa University

ASA American society of Anesthesiology

ASA American Society of Anesthesiology

BSC Bachelor of Science

C/S Caesarian Section

CI Confidence Interval

DC Data Collector

DRC Department Research Committee

IRB Institutional review board

JUSH Jima University Specialized Hospital

LAI Local Anesthesia Wound Site Infiltration

NPS Numeral Pain Score

NPSO Numeral Pain Score after Operation

PACU Post anesthesia care unit

PI principal investigator

POP Postoperative Pain

RCT Randomized Clinical Trial

SA Spinal Anesthesia

SD Standard Deviations

SPSS statistical Package for Social Science

TAP Transverse abdominus plane

TVP Trans vesical prostectomy

UK United Kingdom

USG Ultrasound Guided

VAS Visual Analogue Score

VNRS Verbal numeric rating scale

WHO World Health Organization

Chapter One

Introduction

1.1 Back ground

Pain is an unpleasant sensory or emotional experience associated with actual or potential tissue damage(1). Post-operative acute pain management is a major health issue since acute post-operative pain management is critical to patient satisfaction and a timely discharge, for improved outcomes and to reduce health care costs (2):

Although pain is a predictable part of the postoperative experience, inadequate management of pain is common and can have profound implications. Inadequately managed pain can lead to adverse physical and psychological patient outcomes for individual patients and their families (1).

Currently, the main stay of treatment for acute post-operative pain is the use of systemic opioids(3). Unfortunately, opioids are not without complications. Drowsiness, nausea, vomiting, ileus, urinary retention and pruritus, are all side effects of opioids. These side effects can lead to longer lengths of stays and poor patient outcomes (4).

Knowledge of pain pathways and mechanisms has supported the development of a variety of drugs that alleviate pain through different pharmacological action. From this, the modern concept of balanced or multi-modal analgesia has evolved. This approach advocates the use of more than one class of drug, with or without a regional anesthesia technique, to provide superior analgesia whilst reducing individual drug doses and drug-related side effects (5).

Transverse abdominus plane block is relatively newer and novel approach to regional anesthesia technique that provides analgesia to skin and muscle of the anterior abdominal wall. The TAP block allows sensory blockade of the lower abdominal wall via local anesthetic deposition between the internal oblique and the transverses abdominis. It was first described by Kuppavelumani et al. in 1993 and was formally documented in 2001 by Rafi (6,7). A single injection can achieve sensory block over a wide area of the abdominal wall (8).

Use of a 'two pop' technique is generally advocated and is supported by the cadaveric and imaging studies published to date (9). The triangle of Petit can be difficult to palpate, especially in obese patients. Rafi suggests a needle insertion point 2.5cm from iliac crest at mid axillaries line (7) .

TAP- block technique has been shown to be safe and effective postoperative adjunct analgesia methods in variety of general(10,11), gynecological(12,13,14) urological(15), plastic(16,17) and pediatric surgery(18,19) and its suggested as part of the multimodal anesthetic approach to enhance recovery after lower abdominal surgery.

Another approach to control post-operative pain and limit post-operative opioid usage is local anesthetic wound site infiltration prior to wound closure. These approaches lessen peripheral and central hyperalgesia and minimize wound inflammation producing less post-operative pain without impairing wound healing (20).

Local anesthesia wound infiltration is technique of obtaining postoperative pain relief by single injection of local anesthesia into skin and subcutaneous tissue layer at surgical incision sites, which decrease post operative pain .Wound infiltration technique commonly used alone or in combination to improve postoperative analgesia, reduce opioid and speed patient recovery (21).

Surgical wound infiltration with local anesthetics has continued to increase in popularity since the mid 1990's (22).

1.2 Statement of a problem

Effective pain management is associated with patient satisfaction, earlier mobilization, shortened hospital stay, and reduced costs. Despite these benefits, there are substantial numbers of patients who suffer from postoperative pain (23).

Globally 80% of patient experience acute postoperative pain with 11-20% experiencing moderate to extreme pain (24). In United Kingdom (UK), a recent study has reported that 30% of postoperative patient experienced pain post surgery (25).

In Nigeria; one study reported that 95% of postoperative patients experienced various degrees of POP (26). In Kenya, a study conducted in 2000 at Kenyatta national hospital on postoperative pain management following major abdominal and thoracic operations found that 60% of patients experienced pain postoperative (27).

When we come to Ethiopia incidence of POP was 91.4% according to study done 2012 in JUSH, only 50 % of patient were satisfied with their pain management and solo analgesics was used 89.29% as approach to manage POP(28). Another study done at University hospital of Gondar states that postoperative pain is still under managed(29).

These results emphasize the need of further effort to manage POP with an approach which is technically easy with low risk, cheap and without any major side effects.

TAP block reduces morphine requirements by more than 70% and consequently reduces opioid-mediated side effects provides highly effective postoperative analgesia in the first 24–48 hours (30).

The administration of a local anesthetic via infiltration of the surgical wound is one component of a multimodal approach that results in immediate pain relief, which has been proven to increase patient satisfaction (31). Today, infiltration of the surgical wound with a long-acting local anesthetic has the potential to become a foundation of multimodal pain management (32).

As far as my search and knowledge is concerned, there is no published data from Ethiopia which compare LAI with TAP block this emphasize the need of further research in Ethiopia.

1.3 Justification of the Study

Pain is a major public health issue throughout the world. The goals of postoperative pain management are to reduce or eliminate pain and discomfort with a minimum of side effect and as cheaply as possible since, adequate postoperative pain control is one of the most important factors in determining when a patient can be safely discharged from a surgical facility and has a major influence on the patient's ability to resume their normal activities of daily living.

Current management of postoperative pain is limited to either use of systemic opioids. Unfortunately; they are not without complications or regional anesthesia technique with limited duration of action.

There are many studies that have been done in different countries which comparing the efficacy of LAI with TAP block as part of multimodal analgesia but there are conflicting results.

Therefore the result of this study will have a contribution for improvement of postoperative pain management and patient satisfaction. Moreover, this study will provide evidence based data that are necessary for further development of new protocol, providing in-service education, training for hospital staff and provides stepping stone for further research activities in related topic.

CHAPTER TWO

2.1 LITERATURE REVIEW

2.1.1.POST-OPERATIVE VAS SCORE

A systematic review and meta-analysis of Nine randomized control study in China (2015) showed that TAP block was associated with significant lower rest and dynamic pain scores at 8 hour (MD = -1.08, 95% CI (-1.89-0.26), P = 0.009) and 24 hour (MD = -0.83, 95% CI (-1.60, -0.06), P = 0.03) postoperatively than wound infiltration, but no significant difference was found at 1 hour (MD = -0.94, 95% CI (-1.97, 0.09), P = 0.08) postoperatively(33).

Meta analysis of Four RCTs done in China(2014) showed that TAP block and local anesthesia infiltration provides comparable short term postoperative analgesia , the TAP-block group had lower VAS pain scores 24 hours postoperatively compared with the LAI group, both at rest (WMD [95% CI] = -0.67 [p < 0.01] and with movement (WMD = -0.89, p < 0.01(34).

According to RCT study in Pakistan (2016) peak pain scores in TAP group patients were lower as compared to the patients in group of local anesthesia infiltration except immediate at post operative time which is comparable (0.06 ± 0.23 0.12 ± 0.38 ,P-0.838) at 2hr (0.14 ± 0.35 1.28 ± 1.08 ,P-0.008) 4th hr(1.06 ± 1.01 5.38 ± 1.01 ,P- 0.015) at 6th hr (4.50 ± 0.50 7.24 ± 1.13 ,P- 0.009) (35).

According to RCT study in Turkey (2014) the NPS values of Group Infiltration at 2, 6, 12 and 24th hours were found to be statistically and clinically significantly higher than those of Group TAP (p=0.005, p=0.003, p=0.0001, p=0.0001)(36).

RCT done in the Eretria(2017) shows that VAS pain scores were significantly lower in the TAP block group at rest, deep breathing, intentional coughing, and mobilization in all cases (p<0.05)(37).

According to prospective cohort study in Gondar University (Ethiopia) in 2015 shows that there was a reduction in VAS scores over 24 hr postoperative at rest with p value of 2hr (p=0.001),at 4hr (P=0.000),at 6hr (P=0.000),at 12hr (P=0.003),at 24(P=0.013)(38).

2.1.2.TIME TO FIRIST ANALGESIA REQUEST

A systematic review and meta-analysis of Nine randomized control study in China ((2015) shows that Time to first rescue analgesic (hour) no significant difference between TAP block and wound infiltration [MD = 2.55, 95% CI (-0.36, 5.46), P = 0.09]. There was also no significant difference in number of rescue analgesic use between two groups [RR = 0.95, 95% CI (0.56, 1.60), P = 0.85](33).

RCT study conducted in Pakistan (2016)shows that The time to first analgesia needed was longer in TAP group when compared with LAI (8.92 ± 1.509 and 5.1 ± 1.971 , $P=0.05$)(35).

A prospective randomized trial in turkey (2014) shows that the first analgesic administration of Group T ($p=0.003$) was found to be significantly later than that in Group LAI (6.11 ± 6.2 v/s 2.63 ± 1.83)(36).

A prospective randomized controlled trials in Egypt(2015) shows that there is statistical highly significant difference in 1st time request analgesia per minute as comparing Control group to Bupivacaine group (95.33 ± 64.633 - 277.67 ± 41.413 , $P < 0.001$)(39).

Another a prospective randomized controlled trials in Egypt (2015) shows that Time to 1st analgesic request was highly significantly longer in group TAP than group LAI (263.1 ± 43.32 and 489.4 ± 93.2) ($P < 0.001$)(40).

According to prospective cohort study in Gondar University (Ethiopia) in 2015 shows that time from the end of surgery to the first analgesic request was significantly different between TAP group and control group($p = 0.000$). The TAP block group showed as longer duration time for the first analgesic request than the controls with (mean $\pm$ SD) (286.00 ± 166.31) vs (76.25 ± 22.05) minutes, correspondingly(38).

According to RCT study in India 2016 shows that no statistically significant difference of pain scores in the two groups at 1 hour between TAP and LAI group mean and standard deviation of (2.32 ± 1.180 , 2.36 ± 1.186) $P=0.905$, 3 hours(3.04 ± 1.719 , 3.68 ± 1.651) $P=0.186$ and 6 hours (4.28 ± 1.882 , 5.84 ± 1.724) $P=0.004$ (42).

2.1.3.TOTAL ANALGESIA CONSUMPTION

A systematic review and meta-analysis of Nine randomized control study in China ((2015) shows that TAP block reported significant reduction in 24-hour overall morphine consumption compared with wound infiltration [MD = -3.85, 95% CI (-7.47, -0.22), P = 0.04]. However, there was significant heterogeneity ($I^2 = 80\%$)(33).

Meta analysis of Four RCTs done in China (2014) showed that there were no significant difference in mean morphine requirements at 24 h between patients received TAP block and those with LAI (34).

RCT study conducted in Pakistan (2016) shows that the patients in TAP group have higher percentages for the requirement of analgesia as those in group LAI(35).

Prospective randomized double blinded study in Turkey(2017) shows that Patients in TAP block group used significantly less diclofenac than those in the wound infiltration group ($p=0.007$), patients in the TAP block group required significantly less pethidine than those in the TAP placebo group ($p<0.001$), wound infiltration placebo group ($p<0.001$), and control group ($p<0.001$). Also, patients in the wound infiltration group used significantly less pethidine than those in the TAP block placebo group ($p=0.002$), wound infiltration placebo group ($p=0.009$), and control group ($p=0.004$) in which the difference between TAP block and TAP placebo groups was again the most pronounced(41).

A prospective randomized controlled trials in Egypt(2015) shows that there is statistical highly significant difference in total pethidine consumption in 24 hours as comparing Control group to Bupivacaine group(69.33 ± 19.815 - 128.80 ± 13.34 , $P < 0.001$)(39).

Prospective randomized controlled trials in Egypt (2015) shows that Total morphine requirement in the first twenty-four hours was significantly less in TAP group when compared with LAI group. 21 patients in group LAI required supplemental morphine; while only 13 patients in group TAP required supplemental morphine (6.2 ± 1.04 and 8.4 ± 1.2 , $P < 0.001$)(40).

RCT done in the Eretria(2017) shows that Patient undergoing TAP block had reduced over all morphine and diclofenac requirement .TAP block reduced 24hr cumulative postoperative

morphine consumption (95%CI 3.74-7.08;p<0.001)and 24hr cumulative diclofenac consumption (95% CI38.84-76.36;p<0.001)(37).

According to prospective cohort study in Gondar University (Ethiopia) in 2015 shows that Patients with TAP block showed reduced total Tramadol consumption as compared with controls i.e. TAP vs control was 975 mg and 2025 mg respectively within the first 24 postoperative hours, $p = 0.001$. However, total diclofenac consumption (TAP vs control) mg was p value of 0.968(38).

2.2. Hypothesis Testing

Ho1: -There is no different in severity of post-operative pain between local anesthesia infiltration group and Transverses abdominal plane block group

HA1:-There is different in severity of post-operative pain between local anesthesia infiltration group and Transverses abdominal plane block groups

HO2: -There is no different in time to first analgesic request between local anesthesia infiltration and Transverses abdominal plane block groups

HA2: - There is different in time to first analgesic request between local anesthesia infiltration and Transverses abdominal plane block group.

HO3: -There is no different for the total analgesic consumption in the first 24 hours between the study groups.

HA3: -There is different for the total analgesic consumption in the first 24 hours between the study groups.

2.3. Conceptual frame work

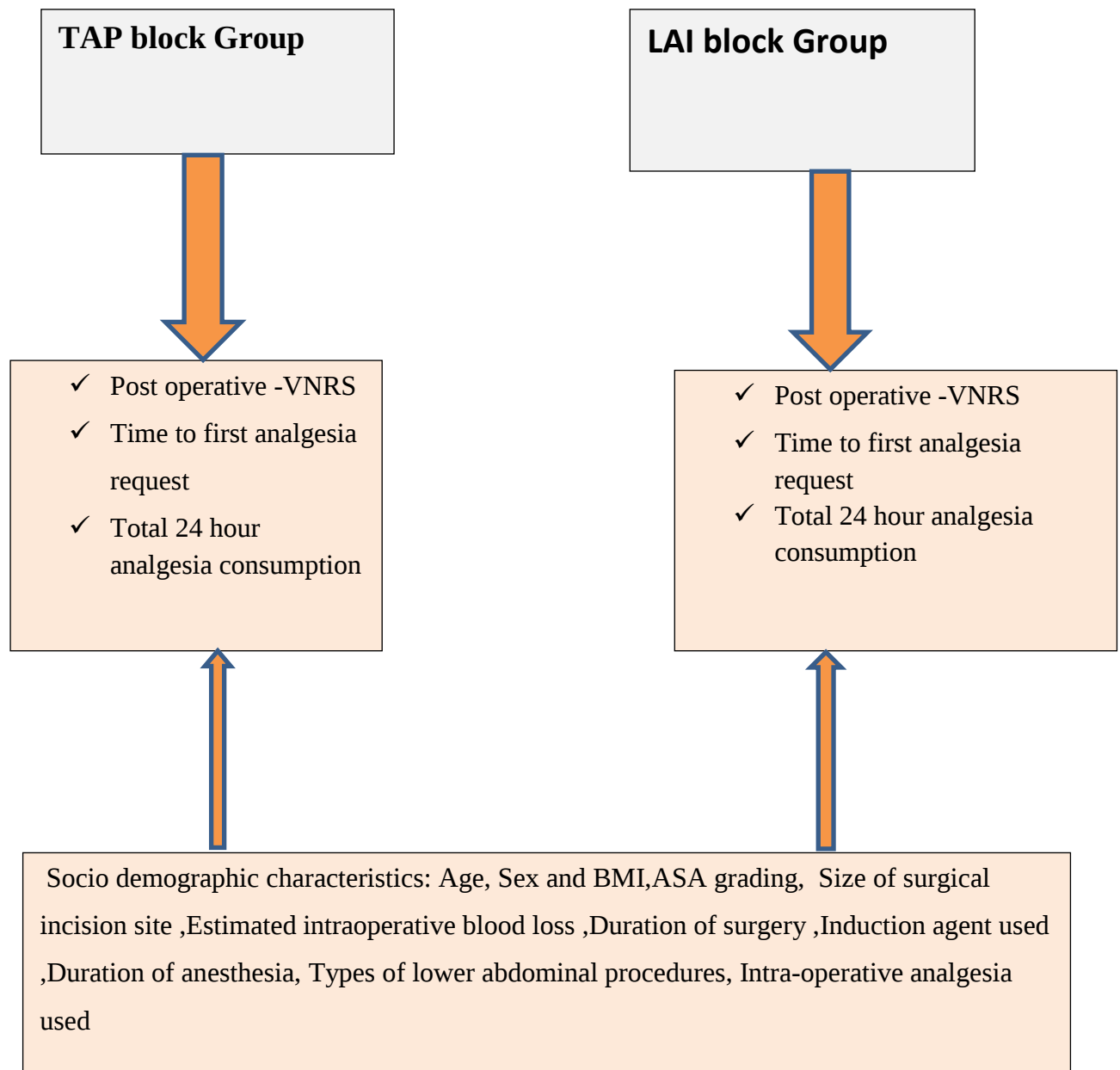


Fig1: Conceptual frame work

CHAPTER THREE

Objectives

3.1 General objective:

To compare the analgesia effectiveness of bilateral Transverse abdominus plane blocks and wound site local anesthesia infiltration for post operative pain for lower abdominal procedure at Zewditu memorial Hospital from Jan 1, 2018-March 30, 2018 Addis Ababa Ethiopia.

3.2 Specific objective:

To compare the severity of pain at 30', 1hour, 2hour, 4hour, 6hour, 12hour and 24hour between local anesthesia infiltration group and Transverse abdominus plane block.

To compare the time to first analgesia request between local anesthesia infiltration group and Transverse abdominus plane block.

To compare total 24 hour analgesia consumption between local anesthesia infiltration group and Transverse abdominus plane block.

CHAPTER FOUR

4. Methodology and materials

4.1 Study area and period

This study was conducted in Empress Zewditu Memorial Hospitals, one of the public hospitals in Addis Ababa, capital of Ethiopia. Located in Kirkos sub city woreda 08. This hospital was built owned and operated by the Seventh - day Adventist Church, but was nationalized during the Derg regime in 1976. The hospital is named after Empress Zewditu, the cousin and predecessor on the throne of Emperor Haile Selassie. Today the hospital is operated by the Ethiopian Ministry of Health. It has four major operation rooms and two PACU.

4.2 Study design: - Hospital based comparative observational cohort study Population

4.3.1 Source population:-All surgical patients who admitted for lower abdominal procedures at Empress Zewditu Hospital during study period.

4.3.2 Study population: - Patient who performs lowers abdominal surgery under general anesthesia Empress Zewditu Hospital during study period that fulfills the inclusion criteria.

4.4 Study variables

4.4.1 Dependent variables

Post operative -VNRS score

Time to first analgesia request

Total analgesia consumption

4.4.2 Independent variable

Socio demographic characteristics: Age, Sex and BMI

ASA grading

Size of surgical incision site

Estimated intraoperative blood loss

Duration of surgery

Induction agent used

Duration of anesthesia

Types of lower abdominal procedures

Intra-operative analgesia used

Analgesia before induction used

4.5. Inclusion and Exclusive Criteria

4.5.1 Inclusion criteria

- ✓ Elective lower abdominal surgery
- ✓ ASA I & II patient.
- ✓ Age (18 -65) years.

4.5.2 Exclusion criteria

- ✓ Allergy to local anesthetic infiltration agent
- ✓ Patients receiving cardio vascular drugs
- ✓ Psychiatric problem
- ✓ BMI > 30 Kg/M²
- ✓ Medical disorders or obstetrical complications as antepartum hemorrhage and pre-eclampsia.

4.6 Sample size and sampling technique

4.6.1 Sample size determination and Sampling procedure

Time to first analgesia request was one of outcome indicators. And from previous observational study which was done at Turkey(36)Time to first analgesia request TAP 6.11 ± 6.2 and LAI 2.63 ± 1.83 By assuming equal sample size for two groups, the sample size was determined by the formula as,

$$n_1 = n_2 = \frac{(z_{\alpha/2} + z_{\beta})^2 (\sigma_1^2 + \sigma_2^2)}{\Delta^2}$$

Where, $n_1 = n_2 = \frac{(1.96 + 0.84)^2 (6.2^2 + 1.83^2)}{(6.11 - 2.63)^2}$

$$\frac{327.62}{12.11} = 27.053$$

12.11

N_1 = number of patient under general anesthesia TAP group

N_2 = number of under general anesthesia LAI group

Z = 95% confidence interval = 1.96

$1 - \beta$ = the power function at 80% = 0.84

σ_1 – Standard deviation for time to first analgesia request

σ_2 - Standard deviation for time to first analgesia request

μ_1 . Mean for first analgesia request

μ_2 . Mean for first analgesia request

Ten percent of additional sample was included by assuming loss to follow up from the study and the total sample was become 30 for each group.

Patients aged (18-65) who underwent lower abdominal procedure were recruited into the study during postoperative period at Recovery room.

With 198 patients estimated to undergo lower abdominal procedure during study period 60 participants were recruited with the probability of about 33%. Considering the consecutive patients scheduled for lower abdominal procedure data collection where the sample interval will be every 3 patient underwent surgery in both groups. The first study participant will be selected by lottery method.

All patients who were scheduled for elective lower abdominal procedure who fulfill inclusion criteria and Volunteer to take part in the study were instructed on how to self-report pain using the eleven Point NRS score 0 to 10 in the morning of operation day at ward with trained nurse.

Anesthesia management for lower abdominal surgery in study hospitals are carried out by B.Sc. and M.Sc. Anesthesia professionals. After the end of surgery, M.Sc. anesthesia professionals including M.Sc. anesthesia student provide bilateral TAP block with 20 ml of 0.25% bupivacaine. While the surgical resident provides wound site local anesthesia infiltration after the end of procedure 20 ml of 0.25% bupivacaine for those patient not provided with TAP block.

In the postoperative time patients transferred to recovery room and transferred to ward when they recover from anesthesia. In ward patient were usually observed by two ward nurses and pain is usually managed by tramadol based on patient complain and sometimes on physician order.

At PACU patients were asked to report their pain based on 11 point NRS score as soon as patient fully respond to verbal command. VNRS score and other variables were documented at 30 Minutes, 1st hour, 2nd hour 4th hour, 6th hour, 12th hour and 24th hour at wards after end of surgery. A time in minutes from end of surgery to first analgesia request were documented together with total analgesia (opoid) consumed in the first 24 hours.

4.7 Data Quality Control Issue

Collected data were checked for completeness, accuracy and clarity. Incomplete data were not Entered a data base prepared on Epi-info. Data clean up and cross-checking was done before Analysis on SPSS. Supervision was done during data collection by principal investigator and M.Sc anesthesia students.

4.8 Data Analysis and Interpretation

Data was entered into Epi-info 7 and transported to SPSS V 20 for analysis. Shapiro Wilk test were used to test for distributions of data while homogeneity of variance were assessed using Levene's test for equality of variance. Numeric data were described in terms of mean $\pm$ SD for symmetric and median (Interquartile range) for asymmetric numeric data. Comparison of numerical variables between study groups were done using unpaired student t- test and Manny Whitney test based for symmetric and asymmetric data respectively.

Frequency and percentage were used to describe categorical variable and statistical difference between groups were tested using Chi square and Fisher's exact test. A p value <0.05 with power of 80% considered statistically significant.

4.9 Ethical consideration

Ethical clearance was obtained from the university ethical clearance committee before the start of the study. The importance of the study was explained & verbal informed consent was obtained from each participant by the data collector. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. Participant's involvement in the study was on voluntary bases, participants who were not willing to participate in the study & those who wish to quit their participation at any stage was informed to do so without any restriction.

4.10. Dissemination plan

The results of the study will be presented to the department of anesthesia as part of M.Sc.in advanced clinical anesthesia thesis, communicated through annual students and staff research conference, annual National conference of Ethiopian Anesthetists Association (EAA) and will be sent to journals for publishing.

4.11. Operational Definition

Duration of Analgesia: A time in minutes given analgesia poses its action.

Duration of surgery: time in minutes from skin incision to end of surgery.

Duration of anesthesia: a time in minutes it takes from pre oxygenation to a time a patient gives response to verbal command.

Local Anesthesia Wound Site Infiltration: Using local anesthetic wound infiltration prior to wound closure for the purpose of post operative pain management.

Lower Abdominal procedures: Surgical procedures done on abdomen which is below umbilicus.

Numeric Rating Scale: Is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0-10(11point scale) with the understanding that 0 equal to no pain and 10 equal to the worst possible pain (40).

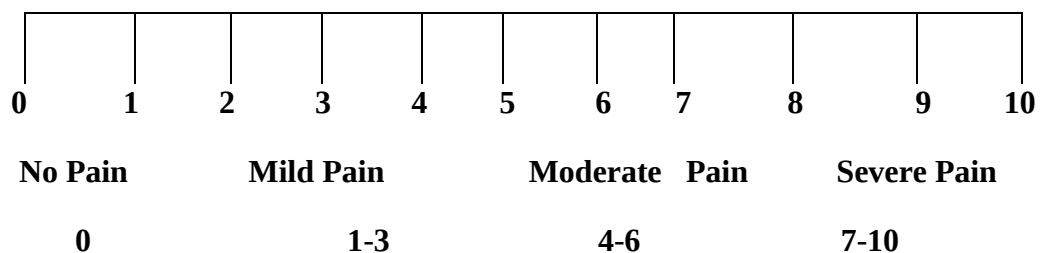


Figure 2: Verbal Numeric Rating Scale Adopted from South African acute pain guideline.

Pop Sound: Sound feels during the needle pierce external and internal oblique muscle

Time to First Analgesia Request: A time in minutes from the end of surgery to first time analgesia were given.

Total Analgesia Consumption: Total dose of medication given in mg within the first 24hr after the end of surgery.

Transverse Abdominus Planes Block: Regional anesthesia technique that provides analgesia to skin and muscle of the anterior abdominal wall.

Peri-operative : Time period from ward admission to recovery room.

Postoperative : Time immediately after surgery.

ASA status: is a surgical risk stratifications validated by American Society of Anesthesiologist; described as follows:

ASA I: a healthy patient with no organic/physiological/psychiatric problems.

ASA II: controlled medical conditions with mild systemic effect and no limitation of functional ability.

ASA III: medical condition with severe systemic effect, limitation in functional capacity.

ASA IV: poorly controlled medical conditions associated with significant impairment in functional ability that is potential threat to life.

ASA V: critical condition, little chance of survival without surgical procedure

ASA VI: brain dead patient undergoing organ donation

CHAPTER FIVE

Result

5.1 Results

5.1.1 Demographic and Peri-operative Characteristics

Sixty patients (30 patients in each group) were analyzed based on whether they received Transverse abdominal plane block or local anesthesia wound site infiltration that underwent surgery for lower abdominal procedures after the end of surgery.

There was no statistical significant difference between two groups in Demographic and Peri - operative characteristics such as age, sex, ASA classification ($P > 0.05$) as shown in Table 1.

Table 1: Demographic and Peri -operative characteristics of elective patient who undergo lower abdominal procedures at Empress Zewditu memorial Hospital Addis Ababa Ethiopia from Jan 1, 2018-March 30, 2018.

Variables	TAP GROUP (n=30)	LAI GROUP (n=30)	P-Value
AGE (years) #	41(28-59)	50(26-61)	.673
SEX: Male (n, %)	15(50%)	19(63%)	.297
Female (n, %)	15(50%)	11(37%)	
ASA Status: ASA I (n, %)	10(33%)	11(37%)	
ASA II (n, %)	20(67%)	19(63%)	
BMI #	26(26-28)	26(24-28)	.269
Types of lower abdominal Procedures:- C/S (n, %)	15(50%)	11 (37%)	.571
HERNIORAPHY (n, %)	9(30%)	12(40%)	
TVP (n, %)	6(20%)	7 (23%)	
Induction agent used: Thiopental (n, %)	8 (28%)	8 (20%)	.851
Propofol (n, %)	11(37%)	13(43%)	
Ketamine (n, %)	11(37%)	11(37%)	
Analgesia before induction: - Yes (n, %)	14(47%)	19(63%)	.194
No (n, %)	16(53%)	11(37%)	.297
Intraoperative analgesia received: - Yes (n, %)	15(50%)	11(37%)	
No(n, %)	15(50%)	19(63%)	
Size of surgical incision site in (cm)	13(8-15)	10(8-15)	.232
Duration of surgery (minutes)#	50(45-80)	58(45-80)	.829
Duration of anesthesia (minutes)#	58(50-90)	65(50-90)	.947
Estimated intraoperative blood loss (ml)#	540(150-640)	480(100-570)	.196

Hint: # = Median (Interquartile range); n (%) = number (proportion)

5.1.2 Immediate Recovery Room Vital Sign

The immediate recovery Room , at 30 minutes and 1st hour vital sign (PR, SBP, DBP, MAP) shows that statistical significant different between Two group (P<0.001) (Table 2).

Table 2: Immediate recovery room and 1st hour postoperative periods vital sign between (TAP & LAI) group at Empress Zewditu memorial Hospital Addis Ababa Ethiopia from Jan 1, 2018-March 30, 2018.

Vital sign	TAP GROUP (n=30)	LAI Group (n=30)	P - value
Immediate recovery room (PACU) vital sign			
PR (Median and IQR)	114(109-119)	75(67-89)	< 001*
SBP(Mean and SD)	138±9	11±7	< 001*
DBP(Median and IQR)	84(89-72)	71(67-74)	< 001*
MAP(Mean and SD)	99±7	85±5	< 001*
Vital sign at 30 minutes			
PR(Median and IQR)	115(110-117)	72(68-84)	<001*
SBP(Mean and SD)	137±9	114±7	<001*
DBP(Median and IQR)	85(76-89)	70(69-76)	<001*
MAP(Mean and SD)	102±6	100±6	<001*
Vital sign at 1 st Hour			
PR(Median and IQR)	103 (92-105)	72(68-82)	<001*
SBP(Mean and SD)	124 ±10	113±7	<001*
DBP(Mean and SD)	76±7	72±6	.031*
MAP(Mean and SD)	91±6	85±8	<001*

SD-Standard Deviation ,IQR – Inter-quartile range , PR – Pulse rate, SBP- Systolic blood pressure, DBP- Diastolic blood pressure, MAP- Mean arterial , blood pressure, * = statistically significant.

5.1.3 Postoperative hemodynamic status between groups

There was no statistical significant difference regarding the postoperative PR, SBP, DBP and MAP at 2nd, 12th and 24th hours of postoperative time between the groups. But TAP group shows statistical significant difference 4th and 6th hour ($P < .05$) as shown in the Table 3.

Table 3: Postoperative hemodynamic status from 2nd to 24th hour of postoperative periods between (TAP& LAI) group at Empress Zewditu memorial Hospital from Jan 1, 2018- March 30, 2018 Addis Ababa Ethiopia.

Vital sign	TAP GROUP (n=30)	LAI Group (n=30)	P - value
Vital sign at 2 nd HR			
PR(Mean and SD)	85±6	81±11	.081
SBP(Mean and SD)	118±7	124±9	.079
DBP(Median and IQR)	74(70-79)	73(70-82)	.923
MAP(Median and IQR)	89(85-91)	88(85-96)	.722
Vital sign at 4 th HR			
PR(Mean and SD)	87±10	93±14	.056
SBP(Mean and SD)	116±8	131±7	<001*
DBP(Mean and SD)	79±9	94±6	.003*
MAP(Mean and SD)	87± 5	96 ± 8	<001*
Vital sign at 6 th HR			
PR(Mean and SD)	85±8	92±11	.006*
SBP(Median and IQR)	113(110-119)	129(125-133)	<001*
DBP(Mean and SD)	74±6	79±6	<001*
MAP(Mean and SD)	87±5	95±5	<001*
Vital sign at 12 th HR			
PR(Mean and SD)	84±7	88±12	.113
SBP(Median and IQR)	118(110-121)	122(115-124)	.145
DBP(Mean and SD)	76±6	78±6	.070
MAP(Mean and SD)	87±5	89±6	.142
Vital sign at 24 th HR			
PR(Mean and SD)	84±7	82±11	.371
SBP(Median and IQR)	118(112-122)	123(117-127)	.078
DBP(Mean and SD)	75±5	75±5	.827
MAP(Mean and SD)	87±5	89±5	.226

IQR – Intequare range , PR – Pulse rate, SBP- Systolic blood pressure, DBP- Diastolic blood pressure, MAP- Mean arterial blood pressure, * = statistically significant.

5.1.4 Comparison of Postoperative Pain Severity by Verbal Numeric Pain rating scale

The Mann Whitney U test showed that the median VNRS score were lower in the (LAI) group at 30minutes and 1st hour with (P <0.05). There was no statistically significant difference results at 2nd hr and 24th hour between two group with (P >0.05). But there were statistical significant difference at 4th, 6th and 12th hour showing lower median pain score in (TAP) group when compared to(LAI) group (p<0.001) as shown in Table 4.

Table 4: Comparison of postoperative pain severity using 11 point NRS score (0-10) between (TAP and LAI) group at Empress Zewditu memorial Hospital from Jan 1, 2018-March 30, 2018 Addis Ababa Ethiopia.

Variables expressed as Median (IQR)	TAP GROUP (n=30)	LAI GROUP (n=30)	P -VALUE
VNRS 30 Minutes	4(4-5)	2(2-3)	< .001*
VNRS 1 ST HR	2(2-3)	2(2-2)	.014*
VNRS 2 ND HR	2(2-3)	2(2-3)	.157
VNRS 4 TH HR	2(2-2)	5(2-6)	< .001*
VNRS 6 TH HR	2(2-3)	4(4-6)	< .001*
VNRS 12 TH HR	4(3-6)	6(5-6)	< .001*
VNRS 24 TH HR	4(4-6)	5(4-6)	.859

IQR – Intequartile range * = statistically significant, TAP –Transverse abdominus,LAI-Local anesthesia infiltration.

5.1.5 Comparison of Time to First Analgesia Request and Total Analgesia Consumption between Groups

The Mann Whitney U test showed that the median time to first analgesia request in minutes were longer 672 minutes in (TAP) group compared to median time to 225 minutes in Infiltration group $p < 0.001$. There were also statistical significant difference with regard to median Tramadol consumption within 24 hours between the two group with $p < 0.001$ as shown in Table 5.

Table 5: Comparison of time to first analgesia request in minutes and total analgesia Consumption in milligram between (TAP & LAI) groups at Empress Zewditu memorial Hospital from Jan 1, 2018-March 30, 2018 Addis Ababa Ethiopia.

Variables expressed as Median (IQR)	TAP GROUP (n=30)	LAI GROUP (n=30)	P-VALUE
Time to 1 st analgesia request (Minute)	673(620-765)	226(195-235)	<.001*
Total analgesia consumption (Tramadol)	100(100-100)milligram	175(150-200)milligram	<.001*

IQR – Intequartile range , * = statistically significant, TAP –Transverse abdominus plane ,LAI-Local anesthesia infiltration.

CHAPTER SIX

Discussion

6.1 Discussion

Wound infiltration with local anesthetic agent is a commonly used method for reducing post operative pain (44). A single injection of local anesthesia into skin and subcutaneous tissue layer at surgical incision sites could lower the pain scores postoperatively (45). It is a convenient post operative analgesia procedure which is widely performed and employed as a multimodal approach (46).

The role of TAP block to provide effective postoperative analgesia for different types of lower abdominal surgeries has also been studied (47). It is also suggested as a part of multimodal anesthetic approach (48). It is not only effective in reducing pain but also decreases opioid consumption after lower abdominal surgery (49).

Verbal numeric rating scale which is regularly favored in clinical setting due to their simple administration relatively consistent result and its correlation with that of VAS (50). VNRS and VAS equally effective and interchangeably used for assessment of postoperative pain (51). Another study assess the compatibility of the VNRS to the VAS and they found strong correlation ($r=0.94$.95%CI+.93+.95CI) (52).

This study showed that during recovery room (PACU) time the median postoperative pain score (VNRS) were 2(3-2) in (LAI) group and 4(5-4) in TAP group ($p < 0.001$). The comparison also shows lower median pain score 2(2-2) in (LAI) group compared to 2(3-2) in (TAP) group at 1ST post-operative time ($p=0.014$). There was no statistically significant difference results at 2nd hr and 24th hour between two group and there were statistically significant difference at 4th ,6th 12th and showing lower median pain score in TAP group compared to (LAI) group.

This finding shows comparable result with study done by Manjaree M. et. al. in India (2016) shows is no statistically significant difference of VAS scores in the two groups at 1 hour (2.32 ± 1.180) and (2.36 ± 1.186) ($P=0.905$), 3 hours (3.04 ± 1.719) (3.68 ± 1.651) ($P=0.186$) (42).

This finding is in line with Prospective RCT study done by Aydogmus MT et. al. in Istanbul (Turkey) 2014. According to this study VNRS after operation values of Group TAP were found to be significantly higher than those of (LAI) Group ($p=0.012$)(36).

According to the above study by Aydogmus MT et. al VNRS values of (LAI) group at 2, 6, 12 and 24th hours were found to be significantly higher than those of Group TAP ($p=0.005$, $p=0.003$, $p<0.001$, $p<0.001$). The likely explanation for this contradiction between two studies is due to the technique they used to perform the TAP block and drug they used which is levobupivacaine (36).

This study contradicts with RCT study done by Qurat Ul Ain Amjad et.al. in Pakistan (2016) shows statically significant difference in pain score in the two group at 2hr and The peak VAS scores in group TAP patients were lower as compared to the patients in (LAI) group (0.14 ± 0.35 , 1.28 ± 1.08) ($P=0.008$) the likely explanation for this contradiction between two study is due to the technique they used to perform the TAP block and difference in study design (35).

This finding contradicts with Prospective RCT study done by Umit Gorkem et. al. in Turkey(2017) At the zero time point, patients in TAP group reported significantly lower VAS scores than those in(LAI) with mean and standard deviation of (64.3 ± 34 and 77.8 ± 18.1 , $p=0.021$) the likely explanation for this contradiction is the technical difference the used to perform TAP block and difference in study design(41).

According to our study the median time to first analgesia request in minutes were longer 672(765-620) minutes in TAP group compared to 226 (235-195) minutes in LAI group ($p<0.001$).

This finding is in line with RCT study done Sivapurapu V. et .al.in India (2013)in lower abdominal surgeries done under general anesthesia ,the time to first analgesia was longer (min) 148 ± 46.7 in group TAP as compared to 85.38 ± 38.07 in LAI group ($P< 0.001$)(13).

Also another RCT study done by Qurat Ul Ain Amjad et.al. in the Pakistan(2016) shows that the time to first analgesia was longer 8.92 ± 1.509 in group TAP as compared to 5.1 ± 1.971 in group Infiltration ($p\text{-value}=0.05$)(35).

This finding is in line with study done Aydogmus MT et. al in Turkey (2014) .The first analgesic administration of TAP group was found to be significantly later than that in LAI Group (Mean and SD) (6.11 ± 6.22 63 ± 1.83 , $p=0.003$) (36)

Another a prospective randomized controlled trials done by Abdel El-Hamid AM et .al. in Egypt (2016) shows that Time to 1st analgesic request was significantly longer in group TAP than group LAI (263.1 ± 43.32 and 489.4 ± 93.2) ($P < 0.001$)(40).

According to our study the median Tramadol consumption within 24 hour is 100 (100-100)milligram in TAP group compared to 175 (200-150)milligram in LAI group($p < 0.001$) .

This finding is in line with study done by Sivapurapu V. et .al. in turkey (RCT) in lower abdominal surgeries done under general anesthesia. Total morphine requirement in the first twenty-four hours was significantly less in group TAP when compared with LAI group (22.15 ± 4.14 29.15 ± 3.93) ($P < 0.001$) (13).

Another RCT study by Abdel El-Hamid AM et .al in Egypt(2015) shows that Total morphine requirement in the first twenty-four hours was significantly less in group TAP when compared with LAI group (6.2 ± 1.04 8.4 ± 1.2) ($P < 0.001$)(40).

This study shows that the immediate recovery Room , at 30 minutes and 1st hour vital sign (PR, SBP, DBP, MAP) in LAI group shows statistical significant different ($P < 0.001$). There was no statistical significant difference regarding the postoperative PR, SBP, DBP and MAP at 2nd , 12th and 24th hours of postoperative time between the groups. But TAP group shows statistical significant difference 4th and 6th hour ($P < 0.05$). The likely explanation for this difference is due to onset of the block.

6.2 Limitation of the Study

The main limitation of this study was:

Variability in the performance of the block since different anesthetist was involved.

This study doesn't include complication

Most studies we used for comparison were randomized control trial.

6.3 Strength

Study participant were homogenous between the TAP and Local anesthesia infiltration group.

7. Conclusion and Recommendation

7.1 Conclusion

TAP group shows extended pain relief up to 12 hour,prolong time to first analgesia request and less total analgesia consumption for lower abdominal procedures done under general anesthesia.

7.2 Recommendation

We recommend that use of TAP block for effective Postoperative analgesia.

We also recommend additional randomized controlled study.

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Annex I

Consent form



This questionnaire format designed collect information about the analgesia efficacy of land mark (blind) technique of Transverse abdominuss plane blocks and wound site local anesthesia infiltration for post operative pain control for lower abdominal procedures as part of multimodal pain management.

Your response to the study items will highly contribute to the success of the study. Therefore, you are kindly requested to give candid response to each of the items. We would like to thank you for giving your consent to participate in the study. I have been briefed that your identity would be kept confidential and the information will be used for the intended purpose only.

Thank you for your participation!

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1/4~ገለጻ ሰራህእገኛለሁ፡ 1/4~ቱደሚ፣ቶክረውከሜረግለዎትቀዶጥገናበኋላስለሚመዘግብሆይህመም

መንየተወሰኑጥያቄዎችንልጠይቅዎትእፈልጋለሁ፡ የዚህመጠይቅዋናዓላማከአፕራሲዮንበሃላ በሚሰጥህመምሚታገሻ

ምን |ርል ህመም እንደሰታገሰሎት ለመደገ ላይን እርስዎ ከጥናቱ የሚደርስበት ጉዳትየለም፡ ሕንደወም

ከዚህበኋላበአፕራሲዮንለሚሆኑትከክለኛወንየህመምሚታገሻ በመሚገጥሙ ሁኔታዎችን እርካታለመቆጣጠር፡፡ ጠቅሜል፡፡

ለመስተፍፈቃደኛነት?

ሀ/ አዎ ፊርማ _____

ለ/ አይደለሁም

ለማንኛውምጥያቄዎች ስትጥያቁካለዎትተመራሜሪወንበሚከፍለዎትወደራሻማከጋገርይቻላል፡፡

ለመሳተፍፈቃደኛነትስለሆኑእናመሰግናለን!!

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ኢሜል - birukwayu@gmail.com

Client card No. _____ operation date _____

Annex II

Pre-operative and intra-operative check list

Section 1.Socio-demographic Characteristics

Questions	Possible Responses	Code
01.Card no		
02.Age	_____years	
03.Sex		
04.weight	_____KGs	
05.Height	_____Meters	
06.BMI	_____KG/M ²	
07.ASA	I II	
08.Occupation		
09.Religion	_____	
10.Ethnicity	_____	
11.Educational status	1. Illiterate 2. Read and write 3. Diploma 4. Degree and above	
12.size of surgical incision site	_____cm	

Section 2.Data from Intraoperative period

S.no	Variables	Response	Code
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01	Does the patient receive any analgesic drug before Induction of Anesthesia?	1. YES 2. NO	If no skip....
02	If YES specify type and dose	_____ (____ mg)	
03	Type of Induction agent such as ketamine, propofol, thiopentone etc....		
05	Intraoperative analgesia given	1. YES 2. NO	If no skip...
06	If yes specify type intraoperative analgesia given		
07	Specify time to which intraoperative analgesia given		
08	Specify dose of intraoperative analgesia given	_____ mg	
09	Maintenance of Anesthesia	Halothane Isoflurane Pancronium _____ mg Suxamethonium _____ mg Vecoronium _____ mg	
10	Any complication in the intraoperative time	1. YES 2. NO	
11	If yes specfy..		
12	Does the patient responsive in the OR?	YES NO	
13	Estimated intraoperative blood loss		
14	Types of Procedures		
15	If the procedure is C/S (Gravida)	1.I 2.II	
16	Duration of surgery		
117	Duration of anesthesia		

Section 3. Postoperative Hemodynamic status of the patient

S.no	V/S	Immediately	30min	1 st hr.	2 nd hr.	4 th hr.			24 th
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		at Arrival of Recovery Room	post op	post op	post op	post op	6 th hour post op	12 th hour post op	hour post op
01	Time (local) PM/AM								
02	BP (mmHg) SBP/DBP(MAP)								
03	PR (bpm)								
04	Respiratory rate								
05	SPO2 (%)								
06	NRS								

Section 4. Time to request first analgesia

Question	Possible response	Code
01.Time to request first analgesia	mins	

Section 5.Total analgesia consumption for 24hr.

Questions	Possible answers(mg)	Code
01.Fentanyl		
02 .Morphine		
03.Diclofenac		
04.Tramadol		
05. others		

Data collector

Name

signature

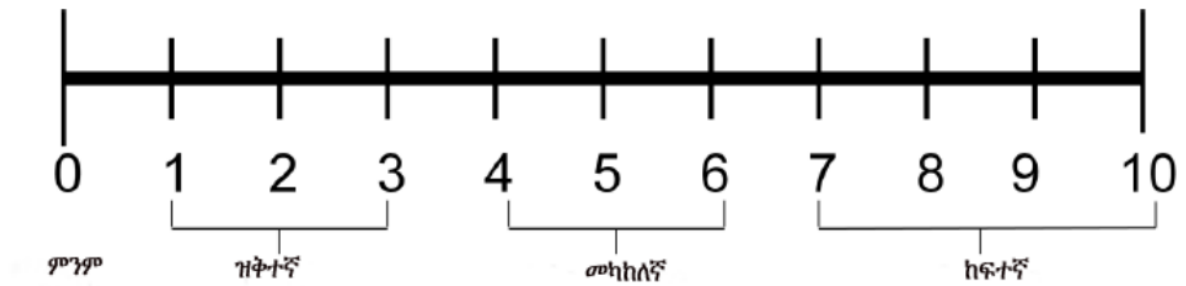
Supervisor

Name

signature

አማርኛ ትርጉም

በቁጥር አምሳያ መለኪያ (VNRS)



1. ይህ መለኪያ በመጀመሪያዉ 24 ሰአት 7 ጊዜ የሚወሰድ ሲሆን.

a. በሽተኛዉ የሚጠየቃቸዉ ጥያቄዎች

i. አሁን የሚሰማዎትን ህመም በየትኛዉ ቁጥር ይወክሉታል ;

ii. ከዜሮ እስከ አስር ካሉት ቁጥሮች አሁን የሚሰማዎትን ህመም የትኛዉ ቁጥር ይገልፀዋል ;

2. ከላይ የተሰጠዉ ማብራሪያ በቂ ሳይሆን ሲቀር፣ ለበሽተኛዉ የበለጠ መረጃ መስጠት አስፈላጊ ሆኖ ይገኛል

VNRS	Possible answers	CODE
VNRS (ምድባዊ የ ህመም መለኪያ)	1. No pain (ምንም ህመም የሚመስል ለም (0) 2. Mild pain (ጥቂት የ ህመም መስከረም (1-3) 3. Moderate pain (መካከለኛ የ ህመም መስከረም (4-6) 4. Severe pain (ከፍተኛ የ ህመም መስከረም (7-10)	

Thank you for your participation!