ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

ILIOINGUINAL-ILIOHYPOGASTRIC PERIPHERAL NERVE BLOCK FOR ANALGESIA AFTER LOWER SEGMENT CAESAREAN SECTION, OBSERVATIONAL COHORT STUDY DONE IN TIKUR ANBESSA SPECIALISED HOSPITAL BETWEEN AUGUST 07,2017 TO OCTOBER 06,2017

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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: _____

This thesis work has been submitted for examination with my/our approval as Advisors and Tutors on the MSc in Advanced Clinical Anesthesia course

Name Signature

1. _____ _____

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3._____ _____

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ABSTRACT

Introduction: Postoperative caesarean section pain is an unpleasant experience. Provision of effective postoperative analgesia is of key importance in this subgroup of parturient to facilitate early ambulation, infant care and prevention of postoperative morbidity.

Objective: To assess and compare the post lower segment caesarean section pain scale in parturient undergoing surgery under spinal anesthesia with or without iliohypogastric and ilioinguinal nerve block at Tikur Anbessa hospital.

Methods: The study was observational cohort study carried out at Tikur Anbessa hospital. A total of 56 ASA I and ASAII parturient for elective LSCS under spinal anesthesia were studied. The data were analyzed using two independent sample t-tests for demographic parameters. For tramadol consumption, time to first analgesia request and NRS was done using Manny Whitney test. Chi Square test was used to study the association between different parameters measured. Box and Whisker plot were used to show a median pain score between groups and statistical significant were stated at P-value <0.05 with a power of 80%.

Result: At all the time interval low pain score was observed in BIIIHNB group with a P-value of <0.05.The duration of analgesia was prolonged in BIIIHNB group as compared to non-exposed group. The median time to first dose of Tramadol in exposed group 250(250-1440) minutes was observed to be longer than non-exposed group 89(75-89) minutes. Decreased consumption of Tramadol was observed in exposed group 125(0-150) mg as compared to non-exposed group 250(0mg) and these difference were statistically significant (P-value <0.0001). The incidence of nausea associated with Tramadol was also significantly lower with exposed group (P-value<0.003).

Conclusion and Recommendation: Bilateral ilioinguinal and iliohypogastric nerve block using plain Bupivacaine, in combination with intrathecal Bupivacaine results in low pain scores following LSCS. Thus we conclude that adequate postoperative pain relief is provided with the BIIIHNB, it significantly lowers the consumption of and side effects associated with Tramadol.

Contents

LIST OF ABBREVIATIONS

ASA – American Society of Anesthesiologist

ANC-Anti Natal Care

BIIIHB – Bilateral Ilioinguinal and Iliohypogastric Block

CS-Caesarean Section

DBP –Diastolic Blood Pressure

MAP – Mean Arterial Pressure

NRS – Numeric Rating Scale

NSAIDS-Non-Steroidal Anti-Inflammatory Drugs

PACU – Post Anesthesia Care Unit

PI -Principal Investigator

PONV – Post Operative Nausea and Vomiting

PR –Pulse Rate

SBP –Systolic Blood Pressure

ILIH –Ilioinguinal and Iliohypogastric Block

SD – Standard Deviation

VAS – Visual Analogue Scale

WHO-World Health Organization

IASP-International Association for the Study of Pain

DHS- Demographic and Health Survey

SPSS-Statistical Package for the Social Sciences

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1. INTRODUCTION

1.1 BACKGROUND INFORMATION

Caesarean section can be life-saving to both the mother and the fetus by preventing poor obstetric outcomes. However, there is a growing concern on the increasing percentage of the procedure of live births globally. The risks and costs associated with caesarean deliveries are significant, especially where there was no medical indication. Evidence shows that caesarean delivery and maternal death are significantly and positively associated(1).

The global rate of CS is estimated here as 15%. Rates are higher in developed countries and in Latin America and the Caribbean, but lower in other developing countries. The average rate of CS deliveries is 3.5% in Africa, with highest rates in South Africa (15.4%), Egypt (11.4%) and Tunisia (8%), Chad (0.4%), Madagascar, Niger and Ethiopia (0.6%) show the lowest CS rates in the world. Central African Republic, Burkina Faso, Mali and Nigeria all show CS rates below 2%(2).

About 800 women die from pregnancy or childbirth-related complications around the world every day(1). Ultrasound scans during pregnancy, delivery care in high-tech-equipped medical centers or hospitals and use of caesarean section (CS) are the most prominent features. These services can be obtained based on either medical indications or client‟s preference to use them(3).

According to the 2016 Ethiopia Demographic and Health Survey (DHS) the caesarean section rate in urban areas is more than 10 times (11%) that in rural areas (1%).The caesarean rate for deliveries for women with more than secondary education is 21%, compared with women with secondary education (6%), primary education (3%), and no education (1%). Among women who had their most recent live birth in a health facility, 79% of those who gave birth by Caesarean section spent three or more days at the facility after delivery compared with 5% of those who had a vaginal birth(4).

Every pregnant woman in Ethiopia has the right to information about her health; discuss her concerns, thoughts and worries; know in advance about any planned procedure to be performed;

privacy; confidentiality; and express her views about the services she receives. To fulfill these rights, in 2010 the government of Ethiopia developed an Obstetrics Management Protocol based on WHO‟s goal-oriented model. The protocol focuses on a limited set of essential antenatal, delivery, postnatal and newborn care services and prescribed statements about indications in the use of procedures such as CS and ultrasound scanning(1)(5).

Anesthesia for caesarean section is usually done under general or spinal to blunt surgical manipulations. Pain relief after Caesarean section varies from a single suppository to, high technology, invasive analgesia techniques for 48hr.(6) Despite ethnic differences in pain perception, similar to postoperative pain relief in general, analgesia after Caesarean section may be severely undertreated for several reasons(7). Parturient are not always considered as „patients" because there is no disease involved(8). Unlike a hysterectomy they receive „something" in return which may motivate them to suffer a little(9). Not infrequently, pain relief is restricted because of the incorrect belief that this is the best way to avoid sedation, to optimize breast feeding and mobilize the patient eager to care for her baby while preventing thrombo-embolism(9)(10). Fifteen years ago the duration of hospital stay after Caesarean section patients was approximately 10 days and the choice of analgesic modality had little effect maternal outcome(11).There are several hundred studies have been undertaken on analgesia after Caesarean delivery to minimize duration of hospital stay and maternal morbidity and mortality(12). Now a days II-IH nerve block is used in pain treatment for postoperative LSCS in developed world.

Both the iliohypogastric and ilioinguinal nerves emanate from the lumbar spinal root(13). Superomedial to the anterior superior iliac spine, the iliohypogastric and ilioinguinal nerves pierce the transverses abdominis to lie between it and the internal oblique muscle(13). After traveling a short distance infero medially, their ventral rami pierce the internal oblique to lie between the internal and external oblique muscle before giving off branches, which pierce the external oblique to provide cutaneous sensation. The iliohypogastric nerve supplies the skin over the inguinal region. The ilioinguinal nerve runs antero inferiorly to the superficial inguinal ring, where it emerges to supply the skin on the superomedial aspect of the ring(14).

1.2 STATEMENT OF THE PROBLEM

Pain is integral to life; it is a critical component of the body‟s natural defense system, signaling threats to body integrity and provoking self-preservation behaviors to further survival(5).

Pain has both sensory and emotional components that interact to produce an overall pain experience. Unrelieved pain after surgery can interfere with sleep and physical functioning and can negatively affect patient wellbeing on multiple levels(15).

Good pain control is important to prevent negative outcomes such as hypertension, myocardial ischemia, arrhythmias respiratory impairments, ileus and poor wound healings(5).In addition to the significant personal suffering and social burden that result, considerable financial expense is incurred, both directly in extra healthcare costs and indirectly as a result of absenteeism, lost production and welfare payments(16).

Although it has bigger health impact, the number of studies done to asses‟ analgesic efficacy of BIIIHNB are limited to inguinal surgery, where there is insufficient work done to evaluate its effect in caesarean section in developing country. So, undertaking such studies in resource limited area can improve pain treatment and patient comfort by counteracting the effect of high patients to nurse ratio(17).

Opioid analgesics and NSAIDs are being used practically to alleviate postoperative pain after caesarean section. Poor practices and awareness of Patient Controlled Analgesia (PCA) are the other basis for such a research made. To decrease the analgesic requirements and it‟s side effect on the mother and her baby and enhance patients‟ quality of life, an alternative analgesia technique should be sought (14).

A multimodal approach could provide significant benefits including reductions in pain intensity, opioid dose requirements, and opioid-related adverse effects (15).

On the other hand, conducting such a study will open the gate to bring quality of pain management in obstetrics anesthesia practice and used as a baseline for further research activities.

1.3 JUSTIFICATION OF THE STUDY

Optimal pain relief allowing normal physiologic function cannot be achieved by a single drug or a single technique without imposing additional risks on the patients. Multimodal analgesia advocates use of different drugs and techniques which act in different sites so as to increase the analgesic effect and also decrease the unwanted effect of single drug therapy. Managing the moderate pain of caesarean section with administration of opioid amplifies the postoperative nausea and vomiting inherent with procedure. Many studies done about the efficacy of BIIIHNB for post lower segment caesarean section in different part of the world(18)(19).The controversies and inter racial difference in pain perception is one of the reasons which call for the study.

BIIIHNB which is popular regional anesthetic technique, reduce the opioid and NSAIDs requirements. The technique will also reduce the incidence of PONV by decreasing the opioid requirements and pain which were the risk for PONV. The use of BIIIHNB not only reduces the analgesic requirements it also reduce the dose of analgesic required during post-operative period(15).Moreover, its landmarks are simple and the block is technically easy to learn and master(13).Low risk of life-threatening complications associated with this block. Likewise, the superlative and longstanding analgesia effects of the block, hemodynamic stability, and rare complication with the procedure is making it an attractive option for anesthesia management of post lower segment caesarean section (16). Therefore this study was conducted to see the analgesic efficacy of bilateral iliohypogastric-ilioinguinal nerve block for post lower segment caesarean section delivery.

Undertaking such studies in resource limited area can improve pain treatment and patient comfort by counteracting the effect of high patients to nurse ratio. So, conducting such a research which intended to find alternatives for pain management in the postoperative period is expected to have of great value since it will decrease the side effects of opioids and other systemic medications.

2. LITERATURE REVIEW

Pain is defined by the International Association for the Study of Pain (IASP) as „„an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage(20). Acute pain may be regarded as a biochemical and behavioral cascade initiated by tissue injury(21).It is usually beneficial and generally subsides, but if pain responses are not adequately suppressed it may progress to chronic pain(22).

Poor management in the case of post-operative acute pain can contribute to medical complications such as pneumonia, deep vein thrombosis, infection, chronic pain and depression(23)(24). It is also one of the most common medical causes of delayed discharge after ambulatory surgery(25). In addition to the significant personal suffering and social burden that result, considerable financial expense is incurred, both directly in extra healthcare costs and indirectly as a result of absenteeism, lost production and welfare payments(25).

Pain is ranked highest among undesirable clinical outcomes associated with caesarean section (CS)(26).Adequate post-operative analgesia in the obstetric patients is crucial as they have different surgical recovery needs which include breastfeeding and care of the newborn; these can be impaired if analgesia is unsatisfactory. The ideal post-CS analgesic regime should be efficacious without impacting the ability of mother to take care of the neonate and with minimal drug transfer through breast milk. (26)(27). In the past 5 years, there has been a surge in studies describing newer post-operative analgesic modalities. Some of these modalities require less expertise and reduce consumption of opioids in post-operative period(9).

Preoperative ilioinguinal-iliohypogastric (II-IH) nerve blocks have been widely used to provide analgesia for children and adults undergoing surgery for inguinal hernia repair(28)(29). and for postoperative analgesia after cesarean delivery(30).

The Pfannenstiel incision has both a somatic and a visceral component and the somatic pain generated at the incision site is conducted by the II-IH nerve, which innervate the L1–2 dermatome distribution, bilateral II-IH block provided analgesia after lower transverse caesarean delivery(31)(32).

Randomized, controlled, double-blinded trial was conducted at the Johns Hopkins Hospital **25** patients were recruited to each arm of the study. No patients were excluded or withdrawn during

the study period.All subjects underwent cesarean delivery via Pfannensteil incision. When compared with the saline group, however, a significant decrease in VAS pain scores at 6, 12, 18, and 24 hours postoperatively was seen in the bupivacaine group.

A study done in Ankara Training and Research Hospital on the efficacy of II-IH nerve block for caesarean section showed that the VAS score in the block group was significantly lower than the placebo group at a given time interval both on movement and at rest. The study also showed that opioid consumption was apparently lower than the control group throughout the study period(30).

In a clinical trial done in the United States of America, 34 women who underwent for elective caesarean delivery having 0.5% bupivacaine versus normal saline and lower VAS score was seen among bupivacaine group as compared to the placebo group. The first analgesic request in the block group was also significantly lower than the control group(33). Another clinical trial study showed that II-IH nerve block significantly reduced postoperative VAS pain score and total opioid consumption than the control group after caesarean delivery(34).A similar study which was done by Ghazi Al-Dehayat in Jordan demonstrated that II-IH nerve block significantly reduced VAS pain score and opioid consumption for the first 24 hrs than the control group for parturients who underwent caesarean section under general anaesthesia. A comparative study done by Bessmertnyj AE showed that there was no stastically significant pain score deference between II-IH and TAP block after low segment caesarean section(35).

A randomized, prospective, double blinded study was done at Prince Ali Ben Al-Hussein Hospital,Karak-Jordan,60 patients undergoing caesarean section under general anaesthesia were included. Patients were randomized into two groups. The study group (n=30) had ilioinguinal and iliohypogastric nerve block with 0.5% bupivacaine bilaterally before skin incision, while the control group (n=30) received normal saline injection instead of bupivacaine. Both pain scores and morphine used were significantly reduced in the study group ($P<0.05$)(36).

A double blind randomized study done in Gondar university hospital over a total of 80 parturient with the objective of assessing analgesic efficacy of Bilateral Ilioinguinal and Iliohypogastric nerve block for post caesarean delivery under spinal anaesthesia. Pain severity was decreased both at rest and on movement at all-time intervals for 24 h of operation in the treatment group ($P<0.001$) except at 0 h. Tramadol consumption was decreased by more than 50% in the treatment group compared to the controls for 24 h following surgery ($P<0.001$). The first analgesia request time was also significantly prolonged in the intervention group than to the control group ($P<0.001$)(37).

3. OBJECTIVE OF THE STUDY

3.1 General Objective

To asses analgesic efficacy of bilateral ilioinguinal and iliohypogastric nerve block (BIIIHB) for post lower segment caesarean section pain control in Tikur Anbesa specialized hospital from August 08, 2017 to Oct,06 2017

3.2 Specific Objective

- To compare pain severity between exposed and non-exposed groups.
- To compare time to first analgesic request between exposed and non-exposed groups
- To compare total 24 hour analgesic consumption between exposed and non-exposed groups.

4. METHODOLOGY

4.1 STUDY AREA:

This study was conducted in Tikur Anbesa specialized hospitals. This Hospitals is among the 11 public hospitals situated in Addis Ababa.

4.2 STUDY DESIGN AND PERIOD

Institution based observational cohort study was carried out from August 08,2017 to 2017 to Oct,06 2017.

4.3 POPULATION

4.3.1 SOURCE POPULATION:

All mothers who came for elective Pfannenstiel incision caesarean delivery under spinal anesthesia at Tikur Anbessa specialized hospital.

4.3.2 STUDY POPULATION:

All mothers who came for elective Pfannenstiel incision caesarean delivery under spinal anesthesia at Tikur Anbessa specialized hospital during the study period.

4.4 STUDY VARIABLES:

4.4.1 DEPENDENT VARIABLE:

Severity of postoperative pain (NRS, total postoperative analgesics consumption, first analgesia request time)

4.4.2 INDEPENDENT VARIABLES

Socio demographic variables age, previous history of CS and parity. Anesthesia and surgery related variables; Duration of surgery, ASA status, level of sensory block, time to plantar flexion of the big toe, hemodynamic variables and nerve block done II-IH were our independent variables.

4.5 OPERATIONAL DEFINITION

NRS: Is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0-10(11 point scale) with the understanding that 0 is equal to no pain and 10 equal to the worst possible pain(38).

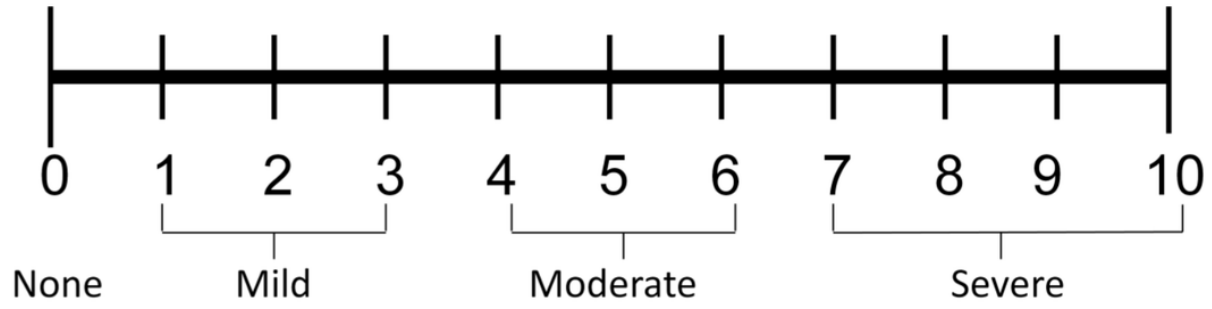

Figure 1: Adopted from the National Initiative on Pain Control™ (NIPC™)

Total analgesia consumption: is total amount of analgesic drugs in milligrams used in 24 hours counted after the BIIIHB has done.

Iliohypogastric-Ilioinguinal nerve block-is a particular nerve block designed to anesthetize the lower anterior abdomen wall (L1-L2).

Pfannenstiel incision:-a long, horizontal abdominal incision made below the line of the pubic hair and above the mons veneris down to and through the sheath of the rectus abdominis muscles but not the muscles themselves which are separated in the direction of their fibers.

Transverse abdominis plane (TAP) block-is a peripheral nerve block designed to anesthetize the nerves supplying the anterior abdominal wall (T7 – L1).

Time to first analgesic request: is a time in hours measured from the end of BIIIHB procedure to time where patient request analgesics.

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/ psychotic 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.

4.6 INCLUSION AND EXCLUSIVE CRITERIA:

4.6.1 INCLUSION CRITERIA:

All American Society of Anesthesiologist (ASA) class I and II parturient underwent elective caesarean delivery via Pfannenstiel incision under spinal anaesthesia were included in the study.

4.6.2 EXCLUSIVE CRITERIA*:*

Caesarean delivery requiring epidural analgesia, BMI greater than 30, history of substance abuse, those mothers who take TAP block, intrathecal adjuvant with bupivacaine, failed spinal, partial or failed IIIH block and mothers who were not willing to give consent to participate in this study were excluded from the study.

4.7 SAMPLE SIZE CALCULATION AND SAMPLING TECHNIQUES

Two independent sample size formula based on the mean difference of VAS score, time to first analgesia request and total analgesia request among two groups were 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 three 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 NRS score within 24 hour is not equal between two groups was calculated as:

$$n = \frac{(S^2_1 + S^2_2)(a+b)^2}{(x^1 - x^2)}$$

Where n = the sample size in each of the groups

x_1 = Sample mean in exposed group

x_2 = Sample mean in non-exposed group

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

S^2_1 = Sample variance in exposed group

S^2_2 = Sample variance in non-exposed 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 VAS score, μ1= 1.86 in control group, μ2= 1.18 in treatment group and sample variance from the literature σ1 = 0.89, σ2 = 0.92

Substituting for this variables yields

$$n = \frac{(0.92)^2 + (0.89)^2 \times (1.96+0.842)^2}{(1.18-1.86)^2} = 27.8$$

n = **28**, using 1:1 ratio between groups a total of **56** patients were required.

Parturient age 18 and above who underwent Pfannenstiel caesarean section under spinal anesthesia recruited by systematic random sampling technique into the study.Around 130 parturient estimated to undergo elective CD during the study period, 56 participants were recruited. Dividing the estimated parturient undergo for elective CD during the study period to the calculated sample size, which yields approximately K= 2.And selected the random start using

lottery method, it is 2, every k^{th} unit is selected. The data collectors differentiate those who took BIIIHNB and participant who didn‟t take BIIIHNB either of the two group was included. This continued till the required sample size was reached.

4.7.1 DATA COLLECTION PROCEDURES

All patients who were scheduled for elective caesarean delivery 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 nurses or anesthetists.

Around 56 caesarean delivery clients who fulfill inclusion criteria were followed for 24hrs. The primary outcome measure is NRS score, with 0 being no pain to 10 the worst imaginable pain. Time to first analgesic request and total postoperative analgesic consumption was used to assess efficacy of analgesia as secondary outcome measures. Additionally incidence of nausea and vomiting was also used to evaluate analgesic efficacy of BIIIHB.

Anesthesia management for caesarean delivery clients in the study hospital is usually carried out by MSc and BSc anesthesia professional. Pre anesthetic evaluation is done in the evening of days before surgery. Patients usually pre medicated with metoclopramide 10mg IV. Vital sign, Organ function test together with history and physical examinations are among the parameters used to decide for anesthesia plan, weather to cancel or proceed. Sub arachnoid block is done with 0.5% of 2.5ml isobaric bupivacaine for all parturient. Level of block was checked with needle pin prick.

After the surgery is done, MSc anesthesia professionals usually provide BIIIHB. Initially, the anterior superior iliac spine is palpated and a mark made 2 cm medial and 2 cm superior from it. After skin preparation and infiltration with local anesthetic, a small puncture is made in the skin with a sharp needle to allow subsequent insertion of a blunt needle. The needle is inserted through the skin puncture site perpendicular to the skin. Increased resistance is met as the needle encounters the external oblique muscle. A loss of resistance is appreciated as the needle passes through the muscle to lie between external oblique muscle and the internal oblique. After the initial loss of resistance and negative needle aspiration for blood, 2 mL of local anesthetic are injected. The needle is then inserted farther to encounter another resistance, which is the internal

oblique muscle. A further loss of resistance is appreciated once the needle passes through the internal oblique to lie between internal oblique muscle and the transverses abdominis muscle. After the second loss of resistance, another 2 mL of local anesthetic is administered. The needle is then withdrawn to skin and redirected at a 45-degree angle medially to again pierce the external and then the internal oblique muscles .After each loss of resistance, the remaining mL of local anesthetic is again administered. The needle is then returned to skin and inserted 45 degrees laterally, and the procedure is repeated. Thus, a total of 10 ml of 0.25% isobaric bupivacaine was injected in a fan-like distribution between the external and internal oblique and the internal oblique and transverses abdominis muscles for both sides. The sensory assessment following the BILIHNB block was done after confirming the spinal regression below the level of L2 dermatome. This was checked by using needle pinprick. The block was considered "Successful" when the patient was not able to perceive the cold sensation at L1dermatome (inguinal region) on both sides. We used these technique which was described by L. Vamsee Kiran (39)

Those patients to whom BIIIHB is done, were used as exposure group for our study, where trained data collectors were observed the procedure according to the checklist (questionnaires).

Most of anesthesia professionals, holding BSc usually didn‟t provide BIIIHNB as supplementary and our study used them as non-exposed group, where the same checklist was used to observe the case.

4.8 DATA QUALITY CONTROL

One of the trained data collectors asked and recorded preoperative necessary information, reviewed their charts and document intraoperative information.

Post-operatively each parturient was interviewed. Those who received bilateral ilioinguinal-iliohypogastric nerve block with 0.25% of 10ml isobaric bupivacaine for each side were " exposed group " and those who didn‟t received ilioinguinal-iliohypogastric nerve block were "nonexposed" group.

Starting from 0hr. postoperative time, presence and severity of pain, time for the first analgesic request as well as analgesic need were assessed systematically using strurctuered questionaire by the other trained data collector.

Pain assessments were performed at 0hr, 4hr, 8hr, 12hr and 24hr in the ward or labour ward. As well as total analgesic consumption within 24 hours was recorded.Almost all ward BSC nurse

were selected to collect data. And training was given every day on how to collect data for those who didn‟t take the training. Another MSc anesthetist was assigned to assist and supervise data collectors. Collected data were checked for completeness, accuracy and clarity by principal investigator and M.Sc. anesthesia students. Data clean up and cross-checking was done before analysis on SPSS. Supervision were done during data collection.

4.9 DATA ANALYSIS AND INTERPRETATION

Data were 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 ± 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 U test 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. A p value<0.05 with power of 80% considered statistically significant.

4.10 ETHICAL CONSIDERATION

Ethical clearance was obtained from the university ethical clearance committee before the start of the study. The importance of the study were 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.4.11 DISSEMINATION OF RESULTS

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

5. RESULT AND DISCUSSION

5.1 Results

5.1.1 SOCIO DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS

A total of fifty six participants were enrolled in this study, 28 in each Group. There was normal distribution socio demographic data could be observed among the study groups (Table 1).

Table1: Socio demographic and other data of exposed and non-exposed group of patients who underwent elective caesarean delivery under spinal anesthesia at Tikur Anbessa Hospital, from Aug.07-Oct.06, 2017.

Demographic data	**Exposed** (n=28)	**Non exposed** (n=28)	**P-value**
Age(year)	26.50±4.105	28.46±4.050	0.077
Weight(kg)	90.64±16.754	88.11±16.061	0.566
Duration of surgery	55.54±3.636	55.93±4.045	0.704
ASA I/II (n/%)	21/7(75%/25%)	22/6(78.6%/21.4%)	0.752

Table 2:The mean ±SD time(in minutes) for plantar flexion of big toe for both groups

Observation	**Exposed**	**Non-exposed**	**P-value**
Time to plantar flexion of the big toe(minutes)	144.11±12.327	144.29±11.604	0.956
Key: Data are expressed as mean±SD			

These result shows that there is no statistically significant difference in the duration of motor block in both groups.

Table3: Socio demographic and other data of each group of parturient who underwent elective caesarean delivery under spinal anesthesia at Tikur Anbessa hospital, Ethiopia, 2017.

Data	**Exposed (n=28)**	**Non-exposed(n=28)**
Parity=n (%)		
Nulliparous	5(17.9)	3(10.7)
Multiparous	23(82.1)	25(89.3)
History of previous CD=n (%)		
Yes	24(85.7)	20(71.4)
No	4(14.3)	8(28.6)
Key: Data are expressed as number and percentage (%)		

5.1.2 POST-OPERATIVE HEMODYNAMIC PARAMETERS

Table 4: Systolic blood pressure (SBP) at various time intervals.

Group	**Median SBP at various time intervals (mmHg)**				
	Time	4h	8h	12h	24h
Exposed	Median(IQR)	105(100-110)	120(115-125)	123(120-126.75)	120(120-127)
Non-exposed	Median(IQR)	125(121-130)	120(115-125)	125(120-129.5)	120(120-125)
P-value	**---**	**0.0001**	**0.863**	**0.127**	**0.456**
Key: mmHg: millimeter of mercury; Value are expressed using median and IQR					

There were no significant differences in systolic blood pressure values at 8h, 12h and 24h within the group comparisons (**p > 0.05**),except 4h.

Table 5: Diastolic blood pressure at various time interval

Group	**Median DBP at various time intervals (mmHg)**				
	Time	4h	8h	12h	24h
Exposed	Median(IQR)	70(70-73.75)	75(70-80)	77.5(75-80)	80(72.75-80)
Non exposed	Median(IQR)	90(90-95)	77(75-79.75)	77(75-80)	80(75-80)
P-value	**------**	**0.0001**	**0.067**	**0.841**	**0.533**
Key: Data are expressed using median (IQR); **= Statistically significant					

Table 6: Heart rate (HR) at various time intervals

Group	**Median HR at various time intervals (mmHg)**				
	Time	4h	8h	12h	24h
Exposed	Median(IQR)	70(0)	75(75-80)	80(0)	75(74-81.5)
Non exposed	Median(IQR)	95(90-95)	84(77.25-93)	80(80-81)	77(75-81.5)
P-value	**---**	**0.0001**	**0.0001**	**0.198**	**0.181**
Key: Data are expressed using median (IQR); **= Statistically significant					

5.1.3 POSTOPERATIVE PAIN SEVERITY SCORE USING NRS

Since the numeric rating pain score was not normally distributed, Mann Whitney U test was used to test the NRS. The median pain score is shown in (**Tables 7**).Paine score were similar on arrival in the ward in both group but were significantly decreased at 4h,8h,12h, and 24h in II-IH block group (P<0.001).Median numeric rating scale in both groups at different times were plotted against time. They are also represented graphically.

Table 7: Postoperative pain severity using 11 point **NRS** score (0-10)

	Median numeric rating scale at different time interval				
Time intervals	0h	4h	8h	12h	24h
Exposed	0(0)	2(0.5-3)	3(2-3)	2(2-4)	2(1-2.75-)
Non-exposed	0(0)	7(6-8)	5(4-6)	5(4-6)	3(2-4)
P-value	**1.00**	**<0.0001****	**<0.0001****	**<0.0001****	**0.002****

Key: Data are expressed using median (IQR); **= Statistically significant

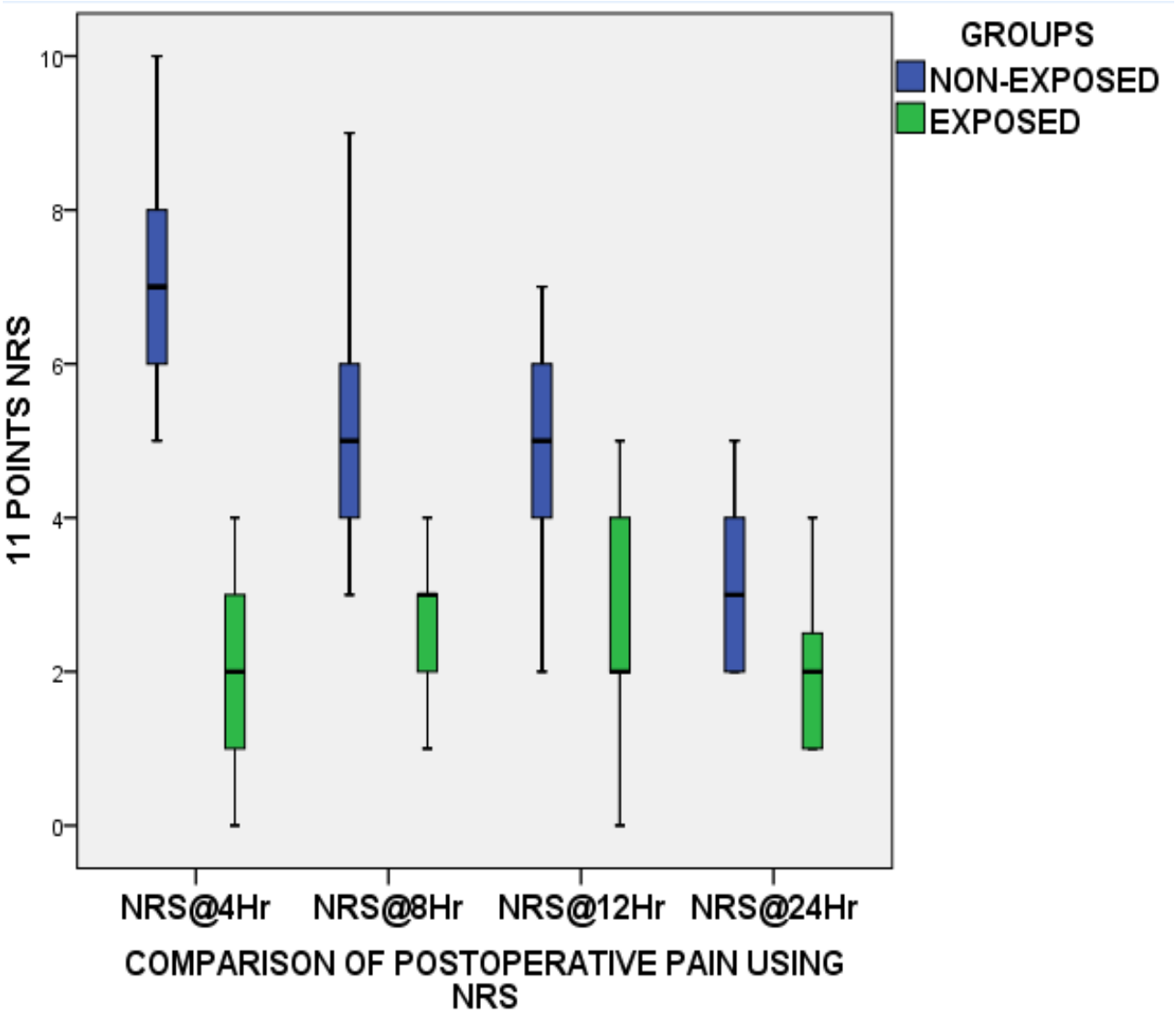

Figure 2: Comparison of postoperative pain severity using (0-10) points NRS scores

5.1.4TIME TO FIRST DOSE OF TRAMADOL AND TOTAL DOSE OF TRAMADOL IN BOTH THE GROUPS

The median time to first dose of tramadol in exposed group was observed to be 250(250-1440) minutes as compared to 89(75-89) minutes in non-exposed group this difference is statistically significant (P<0.0001).The total consumption of Tramadol in 24hrs. post operatively has been 125mg in exposed group as compared to 250mg in non-exposed group and this is statistically significant .

Table 8: Comparison of time to first analgesia request in minutes and total Tramadol consumption between two groups

Observation	**Exposed**	**Non-exposed**	P-value
Time to first analgesia request (minutes)	250(250-1440)	89(75-89)	<0.0001**
Total tramadol consumption in 24 h (mg)	125(0-150)mg	250(0)	<0.0001**
Key: Data are expressed using median (IQR); **= Statistically significant			

5.1.5 INCIDENCE OF NAUSEA AND VOMITING BETWEEN EXPOSED AND NON-EXPOSED GROUP

Non-exposed group were more likely to have nausea than exposed group (64.3% to 25.0%), $X^2(1, N=56) = 8.743$, $p<0.05$ which is 0.003

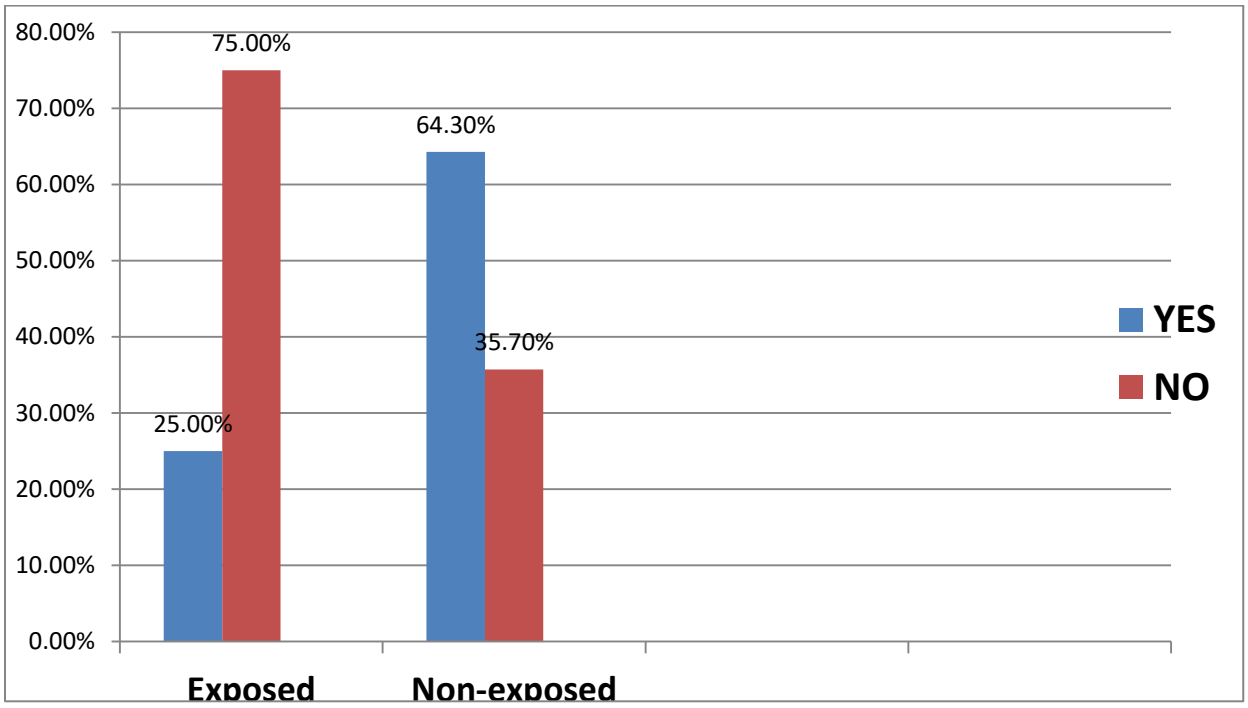

Figure 2: Incidence of nausea and vomiting between the exposed and non-exposed groups

55.2 DISCUSSION

Our results indicated that IL and IH nerve block decreased the intensity of pain following CS. Lower segmental CS is performed by Pfannenstiel incision which lies on L1-L2 dermatomes. Sensory innervation of L1-L2 dermatomes is accomplished by ilioinguinal and iliohypogastric nerves. Block of these nerves enables somatic pain relief in CS operations, but is ineffective for visceral pain, as visceral are innervated by nerve roots from T10-L1segments(31).Many previous studies have demonstrated a benefit of II-IH nerve block for parturient undergoing cesarean delivery under spinal anesthesia(34)(40).or general anaesthesia(41)(34). In our study, the pain was assessed using numeric rating scale. The median NRS was low in the II-IH block group than the non-exposed group. The median NRS was found to be statistically significant(P-value<0.05) at all times of measurement except at **zero** hour.

The NRS pain scores were similar between exposed and the non-exposed group immediately after the patient transferred to the labour ward. This could attribute to prolonged analgesic effects of spinal anesthesia. Pain severity in the II-IH block group and the non-exposed group were different at 4hr, 8hr12hr and 24hr at rest, it was clinically significant. This finding was supported a study done at the Johns Hopkins Hospital. No difference in pain scores or maternal satisfaction with the pain treatment regimen was seen immediately on arrival in the Post anesthesia Care Unit (PACU).When compared with the saline group, however, a significant decrease in VAS pain scores at 6, 12, 18, and 24 hours postoperatively was seen in the bupivacaine group(33). Similarly, a study done in Jordan showed a significantly reduced mean VAS score by II-IH nerve block using local anesthetics when compared with placebo group in parturient underwent caesarean delivery under general anaesthesia(34). Moreover, our finding was also consistent with a study conducted by Yonas et al. where the median NRS score was low in those who received II-IH block compared with the placebo group in parturient underwent caesarean delivery under spinal anesthesia(37).

However, a study conducted in USA, nerve block did not produce a significant reduction in pain after cesarean delivery under spinal anaesthesia with intrathecal morphine (ITM) compared to ITM alone(33) (P>0.05). This could be due to neuraxial morphine produces analgesia by binding to opioid receptors in the dorsal horn of the spinal cord. In addition, unlike that of peripheral

nerve blocks, subarachnoid morphine is effective in the treatment of both somatic and visceral pain.

Moreover, the median total analgesics requirement was significantly lower in exposed group 125(0-150) mg than non-exposed group 250(0) mg respectively (P<0.0001). This finding was in agreement with a study performed by Sakali et al, where the mean patient controlled analgesia tramadol consumption was decreased by 50% in the intervention group using local anesthetics compared with the placebo group.(30). In their study, the mean PCA tramadol consumption in the innervation group was (331 ± 82 mg vs. 622 ± 107mg) respectively. The difference in mean total opioid consumption compared with the current study, might be due to a difference in anaesthesia technique and analgesic administration technique. In the previous study, general anaesthesia and patient controlled analgesic administration technique were use, whereas spinal anaesthesia and nurse controlled analgesic administration techniques were used in the present study. Similarly, Bell et al. also reported PCA morphine use was remarkably lower in the intervention group than the placebo group during the first 24 h postoperative period in patients underwent caesarean delivery under spinal anaesthesia(31). Furthermore, our finding was comparable with trials conducted by Yucel E et al. and Naghshineh et al., where postoperative analgesics consumption was significantly lower in the nerve block group compared with the control group(42)(43).

This might be because of Pfannenstiel incision is principally conducted by L1 and L2 dermatomes and depositing a local anaesthetic on the target nerves gives prolonged pain relief.

In contrast to with our result, study done in Medical College of Georgia no difference in morphine use was observed between the two groups (47.3 mg in treatment group vs. 45.9 mg in control group ; p = 0.85). There was a trend toward lower pain scores after surgery in control group, but this was not statistically significant(44).In the present study the median time for first analgesia request was significantly delayed in exposed group than in non-exposed group (p-value of <0.0001).This finding was in accordance with a study conducted by Wolfson et al. that the mean time to first analgesics request were significantly prolonged in the block group than the control group (P<0.01) (34).This might be because of the prolonged effect of nerve block.

In contrast with present finding, Study done by Dominique, et al the mean time to initiate oral narcotics was 23.3 h(1398minutes) in Group I and 22.8 h(1368minutes) in Group II ($p = 0.7$).

6 STRENGTH AND LIMITATION

6.1 LIMITATION OF THE STUDY

Pain severity were not assessed at movement.

Lack of standard pain management protocol in the study hospital.

Most studies we used for comparison were randomized control trial

6.2 STRENGTH

The two groups were almost similar in socio demographic distribution.

Similar type of analgesia were used between the groups.

7 CONCLUSION AND RECOMMENDATION

7.1 CONCLUSION

Bilateral II-IH blocks in patients undergoing caesarean delivery with Pfannenstiel incision had significantly improved pain relief at rest and resulted in significantly less tramadol consumption in the first 24h they don‟t have nausea.

7.2 RECOMMENDATION

These results support the use of bilateral II-IH nerve blocks as part of a multimodal analgesic regimen after lower segment caesarean section.

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ANNEX I

Information sheet to get permission for the research

Introduction

This information sheet is prepared to explain the research project that you are asked to join by a group of research investigators.

The research team includes MSc students, one senior advisor from AAU and lots of Anesthetists and Nurses for data collection from Tikur Anbessa specialized hospital.

Name of Principal investigator: - Alazar Kefiyalew (2nd year MSc Student)

Advisor's name: - Mr.:- Wossenyelleh Admasu

Name of sponsor: - AAU

Name of organization: - AAU, Health science college, anesthesia department

This information sheet is prepared by the above mentioned investigator.

Risk

There is no any risk or harm that you will face by participating in this research. Any personal information recorded will not be copied and transferred to other bodies. No need of writing participants‟ name but by a code. Every piece of information will be kept confidentially.

Benefits

There is no incentive or payment to be gained by taking part in this project. The information collected from this research project will be kept confidential and only accessed the researcher and research assistant only. This research project will be reviewed and approved by ethical committee of the AAU. If you want to know more information, you can contact the committee through the address below.

Tel: - +251912678705

e-mail:alazar16askalemariam@gmail.com

ANNEX II

Consent form

Dear participant:

This is a research designed to assess analgesic effectiveness of BIIIHPNB

As part of analgesia postoperatively for lower segment caesarean section delivery.

As a chance you were included in the study. So, we kindly request your involvement in the study and honest response to achieve the objective of the study. Your response completely confidential and you have full right either to refuse a single question or leave the study. However, your honest response to those question will help us to asses and understand the effect. So, we are requesting you to give honest response and keep participation.

Would you willing to participate in the study please? YES/NO

Thanks for taking part in the study!!!!

For further question ask investigator

Tel: - +251912678705

E-mail:alazar16askalemariam@gmail.com

ANNEX III

የመጠይቅ ፈቃድ

የተከበራችሁ የጥናቱ ተካፋዮች

የዚህ ጥናት ዋና አላማ በ አድስ አበባ ጤና ቢሮ ስር በሚገኝዉ የTikur Anbessa ሆስፒታል ኦፕራሲዮን ክፍል ለCaesarean delivery ቀዶ ህክምና ለሚደረግላቸዉ ህሙማን ከspinal anesthesia በኋላ የሚሰጠዉን Iliohypogastric-ilioinguinal nerve block ከኦፕራሲዮን በኋላ ህመም በምን ያህል እንደሚቀንስ ለማወቅ ነዉ።

በአጋጣሚ እርስዎም በዚህ ጥናት እንዲሳተፉ ተመርጠዋል። የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ መሰረት መረጃዎችን በማጣላት በሚገኝዉ ዉጤት መሰረት መረጃዎችን በማጠናቀር ውጤቱን እየተሰራበት ካለው ጋር ለማገናዘብ እንዲቻል ነዉ። ጥናቱ በትክክል አላማውን እንዲመታ የእርሶዎን ድጋፉ እንጠይቃለን።

የማንኛውም ግለሰብ ስም አይመዘገብም እንዲሁም ሀሳቡ ብቻውን ይፋ እንዲዎጣ አይደረግም:: ሙሉ በሙሉ በሚስጥር የተጠበቀ ነው፡ በጥናቱ መሳተፍ አለመሳተፍ የራስዎ መብት ብቻ ነዉ። ግልፅ የሆነ ምላሽንና ከልብ የመነጨ ተሳትፎዎን እንዲሰጡን በአክብሮት እንጠይቃለን።

ለመሳተፍ ፈቃደኛ ነዎት

ሀ/ አዎ ፊርማ ---------

ለ/ አይደለሁም

ለመሳተፍ ፈቃደኛ ስለሆኑ እናመሰግናለን።

QUESTIONNAIRE

Section I: Socio Demographic Data

Card number#_____		Bed no#	Code
S.no	**Question**	**Response**	
1	Age		
2	Weight		
3	BMI is	A)<30Kg/m B)>30Kg/m	
4	ASA status	A. ASA I B. ASA II	
5	Previous history of caesarean section.	A) Yes B) No	
6	Type of parity	A)Nulliparous---------- B)Multiparous----------	
7	Pre medicated with	_____mg _____mg _____mg	

Section II : Data during preoperative period

Ser.no	**Question**	**Response**	
1	Base line Heart rate	____ bpm	
2	Base line Blood pressure(MAP)	____/____(____) mmhg	
3	Base line RR & Spo2	_____br/m &_____%	
4	Bleeding disorder or coagulations profile revealed abnormal?	1)YES 2)NO	
5	Does the patient take premedication?	1)YES 2)NO	
6	If yes for the above question, what was the drug?	A. Diclofenac B. tramadol C. pethedine	

Section III: Question related to anesthetic and surgical interventions

S.no	Question	Response	Code
1	Type of local anesthetics used for spinal	A)Bupivacaine(Hyperbaric) B)Bupivacaine(Isobaric) C) Bupivacaine(Hypobaric) D)Lidocane ____%___ml	
2	Does of local anesthetics given.	___ %____ml_____ mg	
3	Additives to local anesthetics	A)Morphine------mg B)Fentanyle -----ug	
4	Is Intraoperative analgesia given?	YES NO	
5	If yes specify type, time and dose of the drug given	_____,____,____mg	

Section IV: Hemodynamic parameters in post-operative period Immediately at 0hr,4thhr, 8thhr,12thhr and 24thhr

S#		Follow up time	HR	BP mmHg	Analgesic dose	Analgesic time
1	0hour post op					
	4 th hr post op					
	6 th hr post op					
	12thhrpost op					
	24thhr post op					

2. Does the patient have nausea within the first 24 hours of surgery? A. YES__ B. NO__

3. Does the patient develop vomiting within first 24 hours of surgery? A. YES__ B. NO__

4. Does the patient have an episode of shivering within first 24 hours? A. YES__ B. NO__

5. Duration in minutes till Initial analgesic requirement after the end of the surgery.

A. Time to movement of great toe @_____& _____ minute since level of block was confirmed.

B. First analgesia required time@ _____

C. Duration in minutes of first analgesic request since 0hr. postoperatively_____

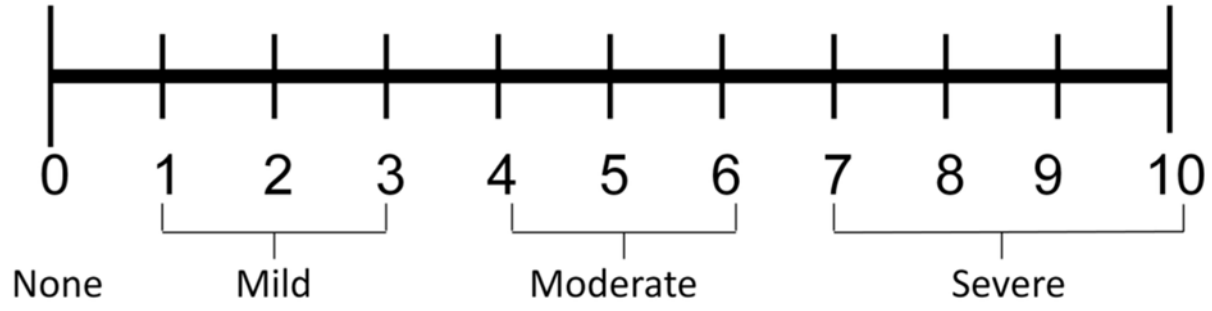
6. Total and type of analgesic consumption within 24 hours after the patient arrived in PACU/ward/Labor Ward.

Type_____ Total _____ respectively

Appendix

English version

The numeric Rating scale (NRS)



The scale will be taken 5 times within the first24 hours. Patients will be asked to rate their pain will be

assessed and recorded at 0 min (immediately on acceptance of patient at recovery room) and 0-4,4-8,8-12,12-24 hours post-operatively.

The patient will be asked one of the following questions:

A. What number on a 0 to 10 scale would you give your pain right now?

B. When the explanation suggested above is not sufficient for the patient, further explanation or conceptualization of the scale will be done:

0 = No Pain

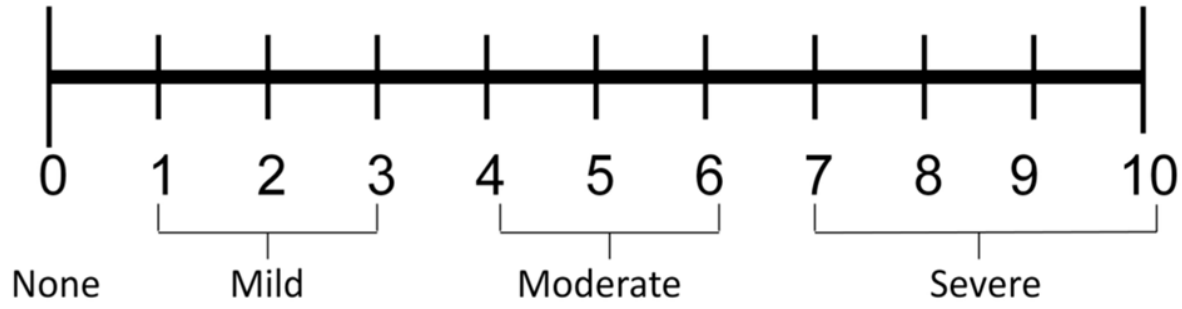
1-3 = Mild Pain (nagging, annoying, interfering little with ADLs)

4–6 = Moderate Pain (interferes significantly with ADLs)

7-10 Severe Pain (disabling; unable to perform ADLs)

አማርኛ ትርጉም

በቁጥር አምሳያ መለኪያ **(VNRS)**



1. ይህ መለኪያ በመጀመሪያዉ 24 ሰአት 5 ጊዜ የሚወሰድ ሲሆን.

a. በሽተኛዉየሚጠየቃቸዉጥያቄዎች

i. አሁንየሚሰማዎትንህመምበየትኛዉቁጥርይወክሉታል ;

ii. ከዜሮእስከአስርካሉትቁጥሮችአሁንየሚሰማዎትንህመምየትኛዉቁጥርይገልፀዋል ;

2. ከላይየተሰጠዉማብራሪያበቂሳይሆንሲቀር፣ለበሽተኛዉየበለጠመረጃመስጠትአስፈላጊሆኖይገኛል

a. 0- ምንምህመምየለም

b. 1-3 - ትንሽህመምአለ

c. 4-6 - መካከለኛህመምአለ

d. 7-10 - ከባድህመምአለ