Addis Ababa University

College of Health Sciences

School of Medicine

Department of Anesthesia

EFECTIVENESS OF BILATERAL ILLIOINGUINAL ILLIO HYPOGASTRIC NERVE BLOCK AND WOUND SITE LOCAL ANESTHETIC INFILTRATION AS A PART OF POST OPERATIVE ANALGESIA IN PATIENTS UNDERGOING ELECTIVE CEASERIAN SECTION UNDER SPINAL ANESTHESIA AT DEBERE BIRHAN REFERAL HOSPITAL, DEBERE BIRHAN ETHIOPIA, 2019: A PROSPECTIVE COHORT.

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A THESIS SUBMITTED TO DEPARTMENT OF ANESTHESIA, COLLEGE OF MEDICINE & HEALTH SCIENCES, ADDIS ABABA UNIVERSITY, IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR M.S.C. IN CLINICAL ANESTHESIA.

ADDIS ABBEBA UNIVERSITY

COLLAGE OF HEALTH SCIENCE

SCHOOL OF MEDICINE

MASTER OF SCIENCE IN ANESTHESIA

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DURATION OF PROJECT	**SEPTEMBER, 2018-JUNE, 20019**
STUDY AREA	**DEBERE BIRHAN,ETHIOPIA**
TOTAL COST OF THE PROJECT	**24,910**
ADDRESS OF INVESTIGATOR	**Tel:** **Mail: bebbe.zemed2007@gmail.com**

A THESIS SUBMITED TO ADDIS ABBEBA UNIVERSITY, DEPARTEMENT IF ANESTHESIA AS PARTIAL FULFILMENT OF REQUIREMENTS FOR MSC IN ANESTHESIA.

May 2019

Addis Ababa, Ethiopi

Declaration

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

Name: _____

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Submission to MSc Tutor, Dept. of Anesthesia, Addis Ababa University.

Date of Submission: _____

This thesis work has been submitted for examination with my/our approval as Advisors and Tutors on the Master of Science degree in Anesthesia

Name Signature

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Acknowledgement

I would like thank Department of Anesthesia, School of Medicine, College of Health Science, and Addis Ababa University for giving this opportunity.

I would like to express my heartfelt gratitude to my advisors Wosenyeleh Admassu (B.Sc. M.Sc.) and Senait (B.Sc. M.Sc.) for their generous assistance, constructive criticism, guidance, and valuable comments in each & every steps of this thesis work.

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List of Abbreviations

AAU Addis Ababa University

ASA American society of Anesthesiology

BSC Bachelor of Science

BLHR Base Line Heart Rate

BLIIIHB - Bilateral illio inguinal illio hypogastric block

BLMAP Base Line Mean Arterial Pressure

C/S Caesarian Section

CD Caesarian Delivery

CI Confidence Interval

DC Data Collector

DRC Department Research Committee

IQR Inter Quartile Range

IRB Institutional review board

II IH Illio inguinal illio hypogastric

IV Intra Vascular

IM Intra muscular

LWI Local Wound Infiltration

NSAID None Steroidal Anti Inflammatory Drug

NRS-Numeric Rating Scale

NE Non Exposed

PACU Post anesthesia care unit

PI principal investigator

RCT Randomized Clinical Trial

SA Spinal Anesthesia

SD Standard Deviations

SPSS statistical Package for Social Science

TAP Transvurse abdominus plane

USG Ultrasound Guided

VAS Visual Analogue Score

VNRS Verbal numeric rating scale

WHO World Health Organization

Abstract

Introduction - Cesarean section is one of the most commonly performed surgical procedures. Even though the postoperative pain after cesarean section is moderate to severe it has been neglected due to several reasons. Untreated pain has its own negative outcomes. Lately post cesarean section pain has been treated with opoids, local wound infiltration, and abdominal nerve blocks.

Objective-This study aims to assess the analgesic effectiveness of II-IH nerve block and local wound infiltration for post cesarean section pain management along with a non- exposed groups.

Method- An institutional based prospective cohort study was conducted in DBRH, in 2019 on patients who underwent elective cesarean section under spinal anesthesia and fulfill inclusion criteria of the study. Study participants were selected by systematic random sampling technique. Data collection methods include preoperative chart review, intraoperative observation and postoperative patient interview starting from recovery room for 24 hours. Time to first analgesic request, NRS score and total analgesic consumption was used as outcome variables. Socio demographic variables and others like parity, history of previous caesarian delivery was analyzed by ANOVA and chi square test. In addition, Kruskal wallis H test with post hoc analysis was used to compare pain score, total analgesic consumption and first analgesic request time. Categorical variables were analyzed by chi square.

Result- First analgesic request is significantly different between II IH and LWI, II IH and Non-exposed, and LWI and Non-exposed groups with $p< 0.001$. Similarly, NRS score within 24 hours is significantly different between all the three groups at all times measured with $p\leq 0.05$ except at 2^{nd} and 24^{th} hour. In addition, the post hoc comparison of total tramadol consumption is significantly different between all the possible three comparisons with $p< 0.001$ but total diclofenac consumption is significantly different only between II IH and Non-exposed group with $p= 0.003$.

Conclusion and Recommendation- Though II IH nerve block provide better and prolonged pain relief, LWI is also effective analgesic technique for post CD pain. Based on this we recommend use of II IH and LWI as a part of post c/s pain management.

Key words: caesarian section, Illioinguinal illiohypogastric nerve block, Local wound infiltration

Chapter One: Introduction

1.1 Background

Caesarean section is life-saving surgical procedure to both the mother and the fetus by preventing poor maternal and fetal outcomes. However cesarean section above 15% is not reasonably indicated, there is growing percentage of the procedure globally. Moreover, rates are higher in developed countries, 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%), and lowest rates in the world in Chad (0.4%), Madagascar, Niger and Ethiopia (0.6%). (1)

Therefore, as caesarean section is one of the most commonly performed surgical procedure and postoperative pain is a great concern for those women, optimal outcome requires an effective teamwork. (2)

Anesthesia for caesarean section is usually done under general or spinal anesthesia to blunt intra operative surgical manipulations. But not infrequently, post-delivery pain relief is restricted because of wrong believes that it would be the best way to avoid sedation, to maintain the mother as mobile as possible so that she could care for her baby while preventing thromboembolism and optimizing breast feeding. On the other hand, and probably more importantly, persistent pain will negatively affect mother-child bounding and the success of breast feeding. In addition, unrelieved acute pain has consequences beyond the immediate perception of pain (3)(4)

Pain relieving techniques after caesarean section varies from a single suppository to high technique invasive analgesia for up to 48 hours and above. Knowledge of pathways and mechanisms of pain has supported the development of variety of drugs and techniques that alleviate pain through different actions. Recently the concept of multi-modal analgesia evolved and this 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 so drug related side effects (5).

There are many studies to find safe and effective ways for post caesarean delivery pain management, and they suggest methods like intravenous or intrathecal opioids, opioid or local

anesthetic skin infiltration, epidural analgesia, and abdominal field blocks like TAP, rectus sheath and II-IH blocks. (3)(5)(6)

Both the iliohypogastric and ilioinguinal nerves emanate from the lumbar spinal root. Superomedial to the anterior superior iliac spine, the iliohypogastric and ilioinguinal nerves pierce the transverses abdomens to lie between it and the internal oblique muscle. 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 anteroinferiorly to the superficial inguinal ring, where it emerges to supply the skin on the superomedial aspect of the ring. (7)(8)

Surgical wound infiltration with local anesthetics has continued to increase its popularity since the mid 1990's, and it has been used as a common modality for postoperative pain relief till today. It has evolved technically into the nerve blocks with more defined anatomical localization and relatively precise infiltration. It is technique of obtaining postoperative pain relief by single injection of local anesthesia into skin and subcutaneous tissue at surgical incision sites, which decrease post-operative pain. Wound infiltration technique commonly used alone or in combination to improve postoperative analgesia, reduce opoid consumption and speed patient's recovery up.(9)(10)

Therefore, the aim of this study is to compare the analgesic effectiveness of bilateral illio inguinal illio hypogastric nerve block and local anesthetic wound infiltration for post caesarian section pain.

1.2. Statement of the problem

According to International Association for Study of Pain (IASP), pain is defined as unpleasant emotional and sensory experience due to actual or potential tissue damage or described in terms of such damage. It has both sensory and emotional components that interact to produce an overall pain experience. (11)

Pain is ranked highest among undesirable clinical outcomes associated with caesarean section, therefore 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. 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.(12)

According to the 2011 Ethiopia Demographic and Health Survey (DHS) the rate of CS which is 22% in Addis Ababa was far more than the 10% – 15% rate recommended by W.H.O. The recommended limit has recently been backed up by the results from 137 countries.(13)

A national review of cesarean delivery in Ethiopia in 2011 showed that overall institutional CS rate has been 18%, which varied between 46% in the private sector and 15% in the public sector. In the public and not-for-profit sectors, approximately 85% of cesareans were emergencies (and 15% electives), compared with 47% in the private sector.(14)

Caesarean delivery and subsequent manipulations performed are associated commonly with a significant degree of pain in the postoperative period. Prevalence rates of chronic pain after cesarean delivery are between 6 and 18%. About 79% of women experience pain at the incision site that can last for up to 2 months. Furthermore because of different factors related to the operation, as well as maternal and neonatal wellbeing, patients who undergo cesarean delivery should have more postoperative pain relief than other surgical patients.(15)

Moreover, inadequate acute pain management has substantial consequences like impaired sleep (46%), impaired physical function, high economic costs, increased risk of developing chronic pain and psychological injuries. (3)(16)

Therefore, good pain control is important to prevent other additional negative outcomes such as hypertension, myocardial ischemia, arrhythmias, respiratory impairments, ileus, poor or delayed wound healings and psychological impairments too. 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 (17)

Traditionally opioid analgesics and NSAIDs are being used practically to alleviate postoperative pain after caesarean section. But due to multiple side effects of these drugs, especially opioids, such as nausea, vomiting, and constipation, they tend to have a major impact on pain therapy and represent one of the most significant causes behind the widespread under treatment of acute pain in recent days. It was reported that about 31%of patients had an adverse gastrointestinal event,

most commonly nausea, vomiting, ileus, or constipation. Sedation and somnolence were also the most commonly reported central nervous system effects (30.3%). Other common adverse events include purities (18.3%), urinary retention (17.5%), and respiratory complications (2.8%). (16)

Abdominal field blocks like TAP and II-IH and wound site local infiltration are suggested to be treatments, as a multi modal analgesia regimen, for post caesarean delivery pain relief for both midline and Pfannenstiel incision because of their opioid sparing effect, prolonged pain relief, and technical simplicity, and the less need for repeated injection for optimal pain relief.(18)(19)

Long acting local anesthetics administered to both sides of the wound after surgery has been demonstrated to be effective for postoperative analgesia. It has been reported that, in addition to regional analgesic techniques, local anesthetic infiltration is also useful for postoperative analgesia in cases of caesarean delivery.(20)

But most studies done to assess analgesic efficacy of BIIIHB are restricted to inguinal surgeries, thus there are limited studies done to evaluate its effect in post caesarean section analgesia, but in some studies it was observed that II-IH nerve block, performed after CS operations under general anesthesia, increased the quality of pain control in the postoperative period and apparently decreased the consumption of opioids.(21)(22)

Hence, undertaking such studies especially in resource limited area can improve pain treatment, patient comfort, satisfaction and decrease the possible complications.

1.3 Significance of the study

Single drug or single technique cannot achieve optimal pain relief and allow normal physiologic function, therefore, a variety of analgesic medications; with small doses and minimal side effects, and advanced techniques that would target different pain pathways would have additive or synergetic effect in managing post-operative pain.

Post cesarean delivery pain is graded as moderate to severe, and in most heath institutions in Ethiopia this moderate to severe pain is left untreated or else treated with weak opioids like tramadol or NSAID. Opoids, in addition to their numerous side effects, cannot adequately alleviate post-surgical pain.

Besides its side effects, most, if not all, heath institutions in our country including the study area have PACUs and wards which are not well equipped and suitable to manage post-operative patients with opioid medications.

Furthermore, even though epidural analgesia is one and probably best alternative to manage post CD pain there is again a scarcity on the supply of the epidural kit, and trained personnel here in the study area and in Ethiopia as a whole. Even if both are available, most of the parturients would not be able to afford it.

But, since effective management of post-operative pain is a fundamental human right and a back bone of ethical and patient centered medical practice, other analgesic choices which can bring good analgesic outcome and relatively better patient satisfaction with low costs should be taken in to consideration.

Therefore, the choice between II-IH nerve block and local wound site infiltration for post caesarian section pain control in terms of analgesic effectiveness and duration, needs an investigation for better, safe and patient satisfactory practice.

In this particular study II-IH nerve block and local wound infiltration, which are well known and easy to perform, was compared with each other and with non-exposed groups. Currently, both are being practiced in the study area, DBRH, for post-CD pain management.

As far as our search and knowledge is concerned, there is no published data from Ethiopia which compare LWI and bilateral II IH nerve block for post cesarean section analgesia. Therefore, the result of this study have a contribution for improvement of post cesarean section pain management, which has been neglected due to several reasons, and increase maternal satisfaction.

Moreover, this study would provide evidence based data that is necessary for further development of new protocol, providing in-service education, training for hospital staffs especially in resource limited areas, and will be used as a stepping stone for further research activities in related topics.

Chapter Two: Literature Review

Effective management of post-operative pain is a fundamental human right and must be a back bone of ethical and patient centered medical practice. Though modern and effective analgesic methods are emerging post caesarian pain which is ranked as moderate or severe is not yet well managed, VAS score analysis done on 400 parturients showed 89.7% of them have post-operative pain.(23)

It is very helpful to consider that there are many different factors that could affect the post-operative pain intensity. A study done on factors affecting patient's experience of pain in University of Leeds in 2010 states that post-operative pain is a highly individualized, complex and multidimensional which is influenced by many factors like biological, psychological, environmental and social aspects and age, culture, gender, preoperative anxiety, emergence of the procedure, previous pain experience and fear of post-operative pain would be major factors determining post-operative pain intensity.(24)

Another similar study done in Northern Peninsular of Malaysia in 2017 which reviewed chart of 400 cesarean deliveries and found that some preoperative factors like age (>31) 0.23± 0.881 p=0.001, BMI (≥30) 1.46± 1.65, p=0.001, being single 1.43±1.272 with p=0.05, general anesthesia 1.04±1.875 with p=0.014, increased operation period (>60 minute) 1.64±1.732 with p=0.02 and parity are some factors that determine intensity of post-operative pain.(25)

Adequate post cesarean analgesia is vital as it insure better surgical recovery of the parturient. Although newer analgesic modalities and drugs for post-caesarean analgesia have been introduced over the recent years, review of the literature suggests that it is still far from achieving the goals of optimum post-operative analgesia. Despite the fact that there is moderate to severe post cesarean pain and enormous side effects of opioids, until recently oral, IM and IV opioids are the only and most commonly used method for post caesarian analgesia, especially in developing countries.(15) (26)

A number of studies addressed analgesia for post caesarian pain including opioid based management, abdominal nerve blocks and epidural analgesia (5–7,9,15)

2.1 llioinguinal lliohypogastric nerve block

RCT done in Pennsylvanya state university, England, in 2016 on II-IH nerve blocks for patients undergone CS under GA involving 26 patients from which 13 of them receives the block after skin closure, before reversal is given, found that there is a statically significant($p<0.01$) lower pain score at 0, 4th, 8th, and 24th hour among the block group than the control one with mean scores of 4.08, 3.31, 3.312 , and 2.69 in the block group and 7.15, 5.30, 5.12, and 4.0 at 0,4^{th} , 8^{th} and 24^{th} hour respectively.(27)

Another RCT done in Erciycs university, Turkey, in 2012 on total of 60 patients undergoing caesarian section under general anesthesia using 3ml of 0.5% levobupivacain in which the block was performed before skin closure, morphine consumption was found to be significantly lower in levobupivacain group ($p<0.05$) than the control group. And the VAS score at 2nd, 6th, 12th post operatively was found to be significantly lower in the levobupivacain group than the control one ($p<0.05$), but no significant difference at 24th hour ($p>0.05$). It also states that there was a significantly ($p<0.01$) lower mean paraveretum consumption in the block group (16.75mg) compared with that of the control group (51.5mg)(28)

In similar study done in Ankara Training and Research Hospital, Turkey, in 2010, on 64 ASAI and II term parturient who undergone CD under general anesthesia and received II-IH nerve block with 10 ml of 0.5% ropivacain bilaterally, it was found that the mean VAS scores in II-IH block group were significantly lower than the block group at 6th, 8th, 12th, 24th hours at rest ($p < 0.05$). Tramadol usage in II-IH block group was also significantly lessened in block group at all estimated time intervals ($p < 0.05$). Total tramadol consumption was 331 ± 82 mg in II-IH block group and 622 ± 107 mg in block group ($p < 0.05$). (21)

In other double blinded randomized clinical trial conducted in Shahid Akbarabadi Hospital of Tehran, Iran in 2014, on 150 patients who undergo cesarean delivery under spinal anesthesia and received II-IH block 2 hours after operation with 20 ml of 0.25% of bupivacaine, there was no significant VAS score difference on 2nd hour($p=0.11$) and 8th hour($p=0.202$) post operatively, but there was significant difference between the groups on 4th and 6th hour post operatively with

p values of 0.0002 and 0.001respectively.In addition, in terms of opioid consumption 90.66% of the block group and 30.6% of the control group did not receive pentazoscine which is statically significant(p=0.001)(8)

Again other study done in Gonder, Ethiopia in 2016 on total of 80 patients who undergo caesarian section under spinal anesthesia which randomizes 80 parturants in two groups, a group to receive 16 ml of 0.25 % bupivacaine for II-IH nerve block and a no block (control) group, found that there was a decreased pain score in both at rest and movement at all times except 0 hour. The NRS score at rest which was stated as median(IQR) showed 0(0), 1(1), 2(1), 2(1), 2(2) and 2(1) at 0, 2, 4, 6, 8, 12, and 24 hours in the block group and 0(0), 3(2), 4(2), 3(1), 4(0), 4(0) in the control group. And total tramadol consumption over 24 hour of 71.157±37.4 and 219.51±39.73 in treatment and control group respectively(29)

2.2 local wound infiltration

In a study done in U.S.A comparing local infiltration analgesia with peripheral nerve blocks for total hip arthroplasty (THA) through common comparators showed no differences between postoperative pain scores and opioid consumption, they found local infiltration analgesia to be ranked first in more simulations than peripheral nerve blocks, suggesting that it may even be more effective.(30)

A randomized control trial done in Delma Hospital WMR, UAE in 2009 on total of 30 patients using 20 ml of 0.5% bupivacaine for subcutaneous tissue and fascia injection before skin closure found the total pethidine consumption was statically significant ($p<0.05$) with 73.3± 49.5mg and 113± 55.0mg for the infiltration and control group respectively. In addition, the control group showed higher pain intensity on visual analogue score, both clinically and statistically, in comparison with patients who were infiltrated at the end of 30 minutes, 2 hours, 4 hours, 6 hours and 24 hours.(31)

Another study done in Johannesburg, South Africa states that women who had wound infiltration after CS performed under regional analgesia had a decrease in morphine consumption at 24 hours compared with women with regional analgesia who had local anesthetic and non-steroidal anti-inflammatory cocktail wound infiltration consumed even less morphine (1 study, 60 participants; MD -7.40 mg; 95% CI -9.58 to -5.22) compared with those who had only local anesthetic infiltration. (32)

In addition, one comparative study done in Oklahoma, USA in 1994 studied the effect of bilateral II-IH nerve block and wound infiltration with 0.5% bupivacaine on total of 62 parturants who undergo CD under GA (20 patients in wound infiltration group, 21 patients in II-IH group and 21 patients in control group). This study states that both can provide a significant duration of analgesia. It also shows that infiltration could provide an equally good analgesia with II IH block though for shorter time. VAS score between II IH and control groups were significantly different at 4,8,12, and 24th hour but scores were significant different only at 4th and 12th hour between LWI and Control group. (33)

Research Hypothesis

Ho – There is no significant difference between time to first analgesic request, NRS score and total analgesic consumption between groups within 24 hours post operatively.

Hi - There is significant difference between time to first analgesic request, NRS score and total analgesic consumption between groups within 24 hours post operatively.

Chapter Three: Objective of the study

3.1 General objective:

To assess analgesic effectiveness of bilateral illioinguinal illiohypogastric nerve block and wound site local infiltration for cesarean section under spinal anesthesia at Debere Birhan Referral Hospital, Debere Birhan, Ethiopia, from January, 2019 to April, 2019

3.2 Specific objective:

- To compare time to first analgesic request between II IH, LWI and None exposed groups
- To compare pain score by NRS among groups
- To compare total analgesic consumption between groups over 24 hours.

Chapter Four: Methodology

4.1STUDY AREA:

This study was conducted in Debre Birhan Referral hospital (DBRH), Debre Birhan, Ethiopia. DBRH was established in 1929. From zonal level, it developed into referral hospital in 2002. The hospital is found in north east direction, 130 km away from the capital of Ethiopia, Addis Ababa. It has been serving for more than 2.4 million catchment populations in its catchment areas like North shoa, Amhara, Oromia, North Oromia and Afar regions**.**

DBRH also have broad category of specialties in general surgery, gynecology, obstetrics, orthopedics ophthalmology and others. It has a total of 150 beds with 36 in surgical and 21 in gynecology and obstetrics units specifically. As the data of the hospital, average surgeries and caesarean sections done annually is 1342 and 728 respectively.

4.2 STUDY DESIGN AND PERIOD

An institutional-based prospective cohort study was employed from January, 2019 to April 2019.

4.3 POPULATION

4.3.1 SOURCE POPULATION

All parturiants who underwent elective caesarian section under spinal anesthesia at DebreBirhan referral hospital.

4.3.2 STUDY POPULATION

All parturients who underwent elective caesarean delivery under spinal anesthesia at DebreBirhan referral hospital during the study period constitute the study population.

4.4 STUDY VARIABLES

4.4.1 DEPENDENT VARIABLE

The outcome variables for the study are

- Time to first analgesic request.
- Verbal numerical pain rating scale and
- Total postoperative analgesic consumption

4.4.2 INDEPENDENT VARIABLES

- Socio demographic variables (Age and BMI)
- parity
- number of previous caesarean delivery
- Base line hemodynamic variables and
- Time of surgery
- Type of nerve block done (II-IH or local wound site infiltration) will be our independent variables.

4.5 OPERATIONAL DEFINITION

Postoperative pain: the presence of pain in the postoperative period was defined as a patient as having pain and any pain score other than zero starting from recovery within 24 hours.

Verbal numeric rating scale (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.(34)

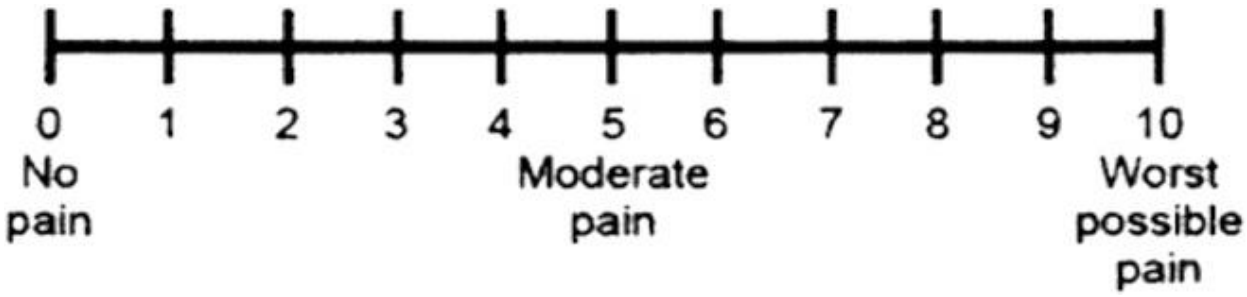


Figure 1 Adopted from the National Initiative on Pain Control™ (NIPC™)

Though most studies reviewed above used Visual Analog Score(VAS), evidence supports that there is a strong correlation between the verbally administered numerical rating scale (VNRS) and the Visual analogue scale .(35)

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

Time to first analgesic request: is a time in hours measured from the end of operation to the first time analgesia were given.

Post-operative nausea and vomiting: At least one episode of either nausea or vomiting within 24 hours.

Shivering- An involuntary repetitive skeletal muscle activity even once in 24 hour

Failed block- when patients exposed to either II IH or LWI complain pain with NRS score of >4 at the 2nd hour post operatively.

Missed follow up – patient who is not followed for total 24 hours post caesarian section.

ASA status: is a surgical risk stratifications validated by American Society of Anesthesiologist; (described on annex 6).

Non exposed- participants who did not take both II IH nerve block or infiltration after spinal anesthesia.

4.6 INCLUSION AND EXCLUSIVE CRITERIA:

4.6.1INCLUSION CRITERIA:

All American Society of Anesthesiologist (ASA) II parturients who underwent elective caesarean delivery under spinal anesthesia were included in the study.

4.6.2 EXCLUSION CRITERIA:

Parturients with history of substance(opioid) abuse, those mothers who take intrathecal adjuvants with bupivacaine, partial block of the SA, parturants who took intraoperative IV opioids, sedatives, IV/IM ketamin, obese patients (BMI; >30 kg/m^2), missed follow up and failed block were excluded from the study.(24)

4.7 Sample size and sampling technique

4.7.1 Sample size

The primary outcome of our study is to compare analgesic effectiveness of the blocks by time to first analgesic request, pain score by verbal numeric rating scale (VNRS), and total analgesic consumption between study groups for 24 hours, post operatively, after caesarian section is completed.

Sample size was calculated from the primary outcomes with a pilot study conducted prior to the actual study. From the outcome variables time to first analgesic request was taken because it gave us the largest sample size. The obtained mean for the time to first analgesic request was μ1=8.1, μ2=5.46 and μ3=3.12 and SD pooled=0.7. A prior power analysis for a one-way ANOVA with 3 groups were conducted on G power, version 3.1.9.2 with alpha 0.05 and a power of 80, and sample size was calculated to be 66 and by taking 10% attrition rate (6) the total sample size of the study was determined to be 72.

None of the patients and the corresponding results were included in the actual study and result.

4.7.2 Sampling technique

Based on situational analysis done in the study hospital, we assumed there would be a total of 160 CS in the study period. This (160/72) yield a “K” value of two (K~ 2). Selection of the first participant was carried out by using simple random sampling technique, lottery method. Starting at the random selection using lottery method every selected k^{th} participant after then was placed

to either group based on the responsible anesthetist's management plan (whether they receive illioinguinal illiohypogastric nerve block, local anesthetic wound infiltration or none). This continued until the desired sample in each groups were achieved.

4.8 Data collection technique and patients

After providing training for data collectors, data was collected using pretested questionnaires with multiple close-ended questions. Patients scheduled for elective cesarean section were assessed before surgery by history taking, physical examinations and chart review following informed consent. On the morning of the surgery data collector instructed the patient on how to self-report pain using the eleven point NRS score (0 to 10). Sociodemographic and intraoperative variables were filled by anesthetist in charge and the remaining postoperative data were collected by other trained data collectors in recovery room and obstetric wards.

On arrival of the patients to the operation theater, and after application of the routine hospital monitoring modalities, HR, noninvasive blood pressure, and SPO_2 was recorded, and metoclopramide 10 mg Iv were given for all before induction of spinal anesthesia, and excluding all others, only those who take 2.5ml of 0.5% isobaric bupivacaine for spinal anesthesia were included in this study.

In the study institution postoperative pain management for caesarian section is done either with bilateral IIIH nerve block, local anesthetic wound infiltration or none depending on the decision, skill and preference of anesthetist in charge. Therefore, those who take bilateral II IH nerve block, wound infiltration and non-exposed were included in this study.

The II IH block was done based on the land mark (Loss of Resistance) technique. Initially, the anterior superior iliac spine is palpated and a mark made 2 cm medial and 2 cm superior from it. After skin preparation 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 this

muscle 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, 2 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 12 ml of 0.25% bupivacaine was injected in a fan-like distribution between the external and internal oblique and the internal oblique and transverses abdominis muscles for each sides.

Local wound infiltration was attempted by the surgeon with 12 ml of 0.25% bupivacaine on both sides of the incision.

After wards pain was assessed with all patients in the 3 groups by recording time to first analgesic request, VNRS score, by asking the patients to report their pain at 2^{nd}, 4^{th}, 6^{th},8^{th}.12^{th}. and 24^{th} hour post operatively, and the total consumption of analgesia for each study subjects. In addition, post-operative adverse effects like nausea, vomiting and shivering were also recorded.

4.9 Data quality control

To assure the reliability and validity of the data questioner was pretested along the pilot study, before the actual data collection. Training and orientation about the objectives and relevance of the study, each items included in the study tools and the whole process of data collection had been provided for data collectors and supervisors. Informed consent was obtained from the participants. During data collection, regular supervision and follow up was undertaken. A supervisor checked each questionnaire daily with further cross check by principal investigator for completeness and consistency of data.

4.10 Data analysis and interpretation

Data was entered into Epi-info 7 and transported to SPSS V 20 for analysis. The data was tested for normality using histogram and Shapiro–Wilk normality test and homogeneity of variance between groups was assessed by Levene's test for equality of variance. Continuous data were analyzed using one-way analysis of variance (ANOVA) for normally distributed and non-normally distributed data were analyzed using kuruska-walih H rank test and a subsequent post hoc Tukey test.

The comparisons of categorical variable were analyzed using Pearson chi-square test. Data were presented as mean ±SD for normally distributed, median ± IQR (25th–75th percentile) and mean rank for non-normally distributed (decision made by visual inspection of box plot) for non-normally distributed and categorical data were presented as numbers and frequencies (percentages). P-values <0.05 was considered statistically significant.

4.11 Ethical consideration

Ethical clearance was obtained from the department of Anesthesia, Collage of health science, school of medicine, Addis Ababa university ethical clearance committee before beginning of the study. Official support letter was written to Debre Birhan Hospital and permission for data collection were sought from the responsible authorities. The purposes and the importance of the study was explained and verbal as well as written informed consent were taken from each participant. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify participants.

4.12 Dissemination plan

The research will be presented for the entire department of anesthesia staff. It will also be presented at the annual research conferences and will be submitted to reputable journals for publication.

Chapter Five Result

5.1 Demographic and perioperative characteristics

During the study period 72 patients were included for analysis and based on whether they take II IH block, local wound infiltration or none for post cesarean section analgesia they were classified into three groups.

The sociodemographic and patient characteristic data collected like age, BMI, previous caesarian delivery, parity, indications for the c/s, duration of surgery and base line HR and MAP were normally distributed and homogeneous across groups. And the overlook shows most of the parturients were multiparous and the commonest indications for c/s were mal presentations.

Table 1socio demographic and peri operative characteristics of patients who underwent c/s under spinal anesthesia in Debre Birhan Referal Hospital, Debre Birhan 2018/19

	II-IH(n=24)	**LAI(n=24)**	**NON EXPOSED(n=24)**	**P value**
AGE	25.63±4.0	25.50±3.29	25.21±3.45	0.48
BMI	21.83±2.47	21.82±2.66	21.81±2.42	0.84
PARITY				0.55
Nulliparous	10(41.6%)	9(37.5%)	11(45.83%)	
Multiparous	14(58.3%)	15(62.5%)	13(54.16%)	
PREVIOUS CD				0.29
Yes	7(29.16%)	7(29.16%)	5(20.83%)	
No	17(70.83%)	17(70.83%)	19(79.16%)	
Indication for c/s				0.48
PREVIOU C/S	6(25%)	7(29.16%)	5(20.83%)	
Mal presentation	11(45.83%)	9(37.5%)	10(41.66%)	
Big baby	4(16.6%)	4(16.6%)	3(12.5%)	
Others	3(12.5%)	4(16.6%)	6(25.5%)	
Duration of surgery	41.92±7.52	41.08±6.60	40.04±6.41	0.662
BL HR	93±10	93±9	94±9	0.79
BL MAP	82± 7	79±7	83±9	0.72

Value are presented as: Mean±SD, Number (%), One-way ANOVA test, chi-square test and $p<0.05$ is statistically significant (BL HR- baseline heart rate, BL MAP- Base line mean arterial pressure)

5.2. Comparison of time to first analgesia request between groups

Time to first analgesia request, as assessed by Shapiro-Wilk Test, was not normally distributed. and the Kruskal Wallis test reviled that there is a significant difference in time to first analgesic request between groups with ($\chi 2$ (2) =61.95, p< 0.001). Subsequent post hoc Tukey test done reviled significant difference between II-IH and LWI groups, II-IH and Non-exposed groups and between LWI and Non-exposed group in their first analgesic request time with p< 0.001 for all the three comparisons. The overlook shows that the patient in II-IH group had a much longer time before first analgesic request and the patients who were non-exposed on contrary, requested analgesia in recovery room.

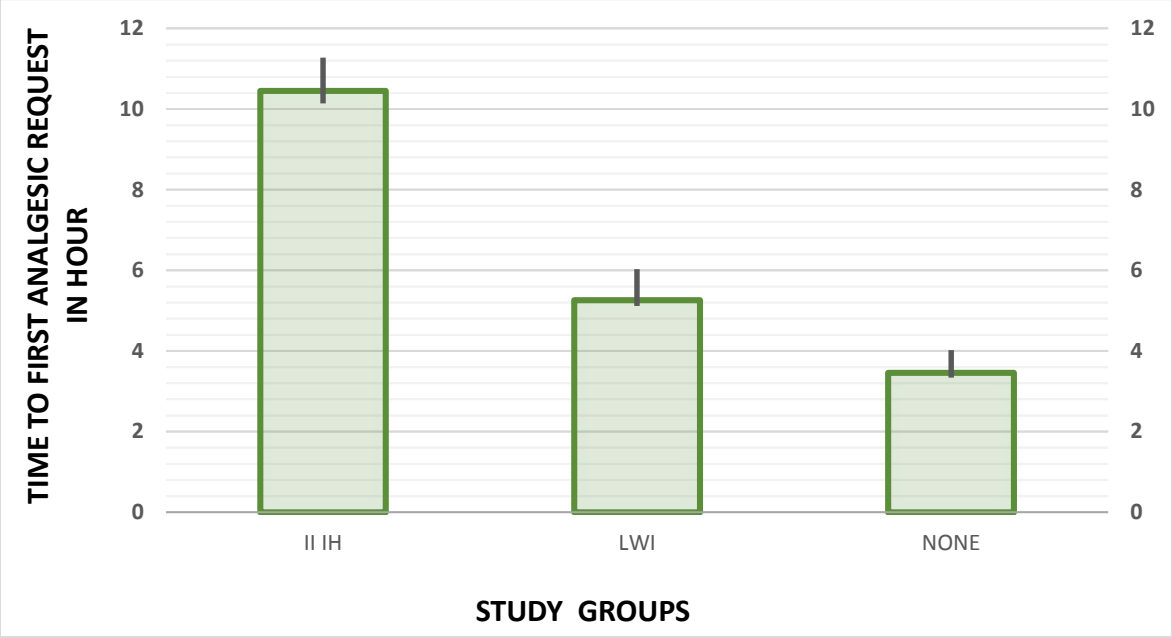


Figure 2 Time to first analgesic request of the study groups in hours

5.3. Comparison of Postoperative Numeric Pain Rating scale

Kruskal Wallis test of NRS score revealed a significant difference in mean rank of NRS score in the II IH, LWI groups and non-exposed group at 4th hour with $\chi 2(2)$ =35.64, p<0.001, 6th hour with $\chi 2(2)$ =46.05, p<0.001, 8th hour with $\chi 2(2)$ =22.34, p<0.001 and 12th hour with $\chi 2(2)$ =30.10, p<0.001. In opposite the score on 2nd and 24th hour was not significantly different with $\chi 2(2)$ =2.28, p=0.318 and $\chi 2(2)$ =2.13, p=0.344 respectively.

In addition, the post hoc analysis, with Tukey test, shows significant reduction in NRS score between II-IH and LWI, II-IH and non-exposed groups with adjacent p value <0.001 at all hours

measured, except on 2nd and 24th (p value>0.05). However, the significant difference between LWI and non-exposed group with adjacent p value<0.05 is only at the 4th and 6th hour, with p value of 0.04 and 0.02 respectively.

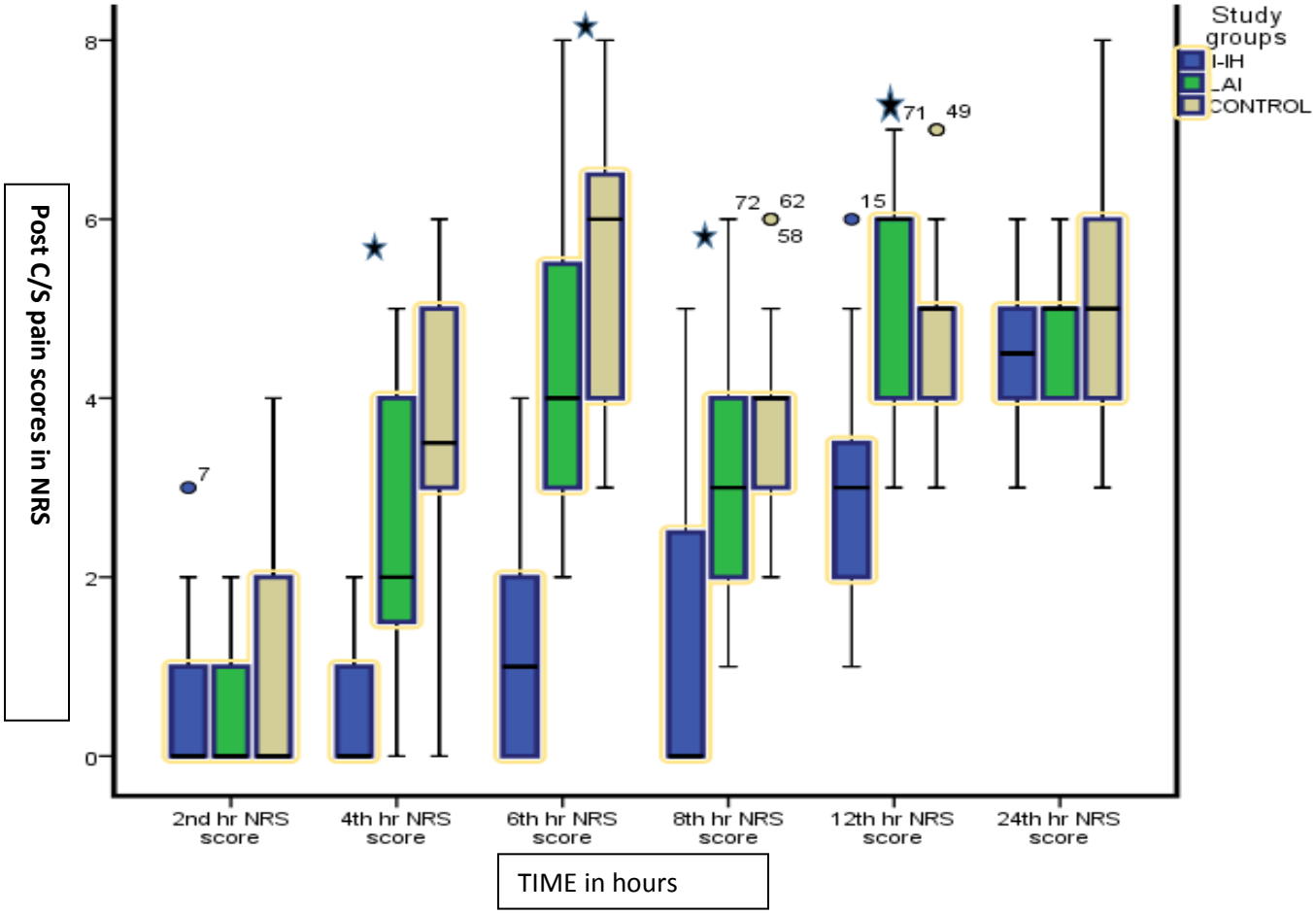


Figure 3.Comparison of median NRS score of study groups

5.4 Comparison of total analgesia consumption between groups

As total analgesic consumption analyzed by kruskal Wallis test showed that the total tramadol and diclofenac consumption had statically significant difference between the study groups with ($\chi^2(2) = 7.519$, p=0.006 and $\chi^2(2) = 6.660$, p=0.010 respectively.

Post hoc comparison for total tramadol consumption is significantly different between all the possible three comparisons with p<0.001 for both II IH and non-exposed groups and LWI and non-exposed groups and with p=0.022 for II IH and LWI groups. On the other hand, post hoc for

total diclofenac consumption shows that there is a significant difference between IIIH and Non exposed groups with p value of 0.003 and II IH and LWI groups with p value of 0.010, but not between LWI and non-exposed groups (p=0.293).

Table 2 Time to first analgesic request and total consumption of tramadol and diclofenac

	II IH	**LAI**	**NON EXPOSED**	**P value**
1st analgesic request in hour	10.45(10.14-11.28)	5.26(5.12-6.03)	3.46(3.34-4.02)	0.000
Total diclofenac in mg	75(75-75)	75(75-150)	75(75-150)	0.010
Total tramadol in mg	50(25-50)	50(50-100)	50(150-200)	0.006

Values are presented by median (IQR), kruskal Wallis test P value ≤ 0.05 statically significant difference between the study groups.

5.5. Incidence of postoperative complications

Of all patients in all the three groups 11(15.3%) had nausea,6(8.3%) had vomiting and 11(15.3%) had shivering. But the incidence of the complications has no significant difference between groups (p>0.05)

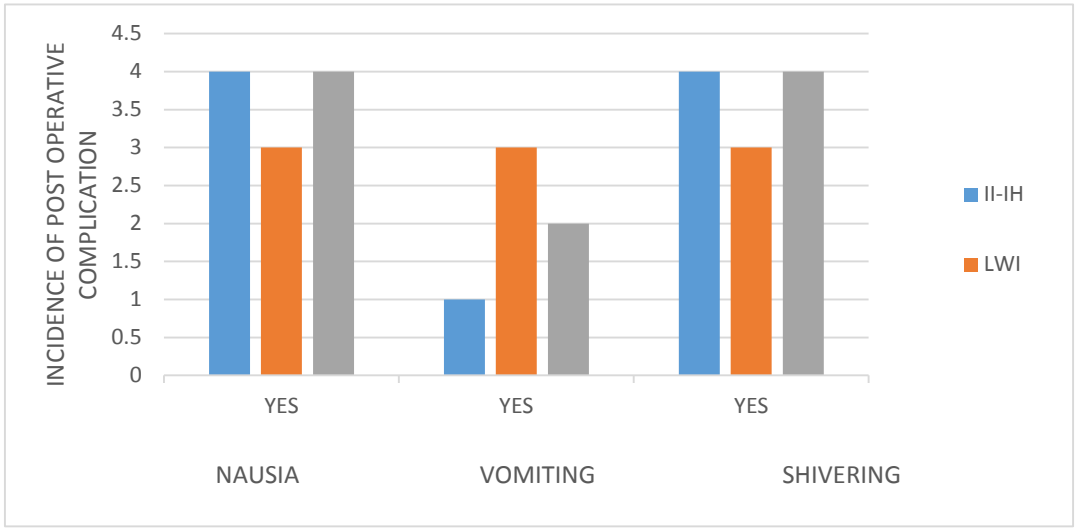


Figure 4 incidence of post-operative complications in percentile

CHAPTER Six. Discussion

Effective perioperative block of nociceptive inputs from the wound as well as use of analgesic drugs in combination is studied to be the best way to control post-operative pain and specifically to prevent central sensitization. Hence use of multimodal analgesia is rapidly becoming the standard of care for preventing post-operative pain and its complication.(4)(5)

Our study depicted that II IH nerve block and local wound infiltration with local anesthetics remarkably decreases post cesarean delivery pain, total analgesic consumption and prolong time to first analgesic request compared to the non-exposed group.

Previous studies also reviled good analgesic inputs of II IH nerve block for parturants undergoing CD under spinal anesthesia (18) (29) or general anesthesia. (21)(28)(33) Similarly, there are studies showing LWI has good analgesic effects for post CD pain. (20)(31)(33)

This study demonstrates that the first analgesic request time is different between II IH, LWI and non-exposed groups significantly with $p<0.001$. In line with our study a study done by *Nigatu et al*, in Gonder in 2016 reviled a similar result regarding time to first analgesic request, with median(IQR) of 12(6-24) hour and 4(4-6) hour for II IH and control group respectively with p value ≤ 0.0001.(29). Similarly study done in 2017 by *Sreekumar.M et al* also disputed that median of first analgesic request time is 10.5±4.49 for II IH and 2.4±0.56 for control group (7) which is in agreement with our study too.

But another study done in Turkey by *AydogmusMT et al* in 2014 comparing TAP block and LWI (20)has reviled that the LWI group had mean ±SD of 2.63±1.83 hours before first analgesic request, which is not in agreement with our findings. This may be due to the possible difference in populations, study designs and different techniques of wound infiltration used.

We found that there is significant ($p<0.05$) difference in pain score among the II IH, LWI and non-exposed groups at all time it was measured except on 2^{nd} and 24^{th} hour. The "no significant difference" on the 2^{nd} and 24^{th} hour can possibly be due to the prolonged sensory effect of spinal anesthesia providing analgesia at 2^{nd} hour post operatively and by the fact that effects of blocks done with bupivacaine could last for 4-12 hours.

This would go in consistence with a study done in Turkey in 2012 by *Abdulah et al*, which compare II IH nerve block group with non-exposed and found that the VAS score at 6^{th} and 12^{th} hour post- operatively is significantly different between the groups but not at 24^{th} hour with $p> 0.05$. (28)

Similarly, study done Ethiopia by *Nigatu.et al* shows that the median NRS score difference is not significant at 0hr between II IH and Non block group, but significant at all times measured afterwards. The study shows NRS score of II IH and Non exposed group is significantly different at 24^{th} hour with $p<0.001$, which is not in line with our post hoc results showing that there is no significant difference between II IH and non-exposed groups at 24^{th} hour with $p\geq 0.05$.(29)

As mentioned, there is significant NRS score difference in post hoc comparison between II IH and LWI as well between II IH and non-exposed group at all times measured except 2^{nd} and 24^{th} hour, but the statically significance is only at 4^{th} and 6^{th} hour between LWI and non-exposed group in this study. This as well could go in accordance with a study done in Oklahoma by *Raghuvender G. et al* which shows the significant difference between the LWI and control groups is only at 4^{th} and 12^{th} hour with $p<0.05$, and here a longer analgesic effects by the LWI up to 12 hour can be explained as they used more concentrated (0.5%) bupivacaine.(33)

Our study revealed that the total analgesic consumption of tramadol and diclofenac over the postoperative 24 hours was significantly different between the II IH, LWI and non-exposed groups with p value <0.05. A study done in Turkey by *Abdulah et al*, in 2012, though it shows that there is a significant difference with $p< 0.05$ regarding total analgesic consumption between II IH and control group, it is not in line with the results of our study as it reviled the mean (SD) of morphine being 34.36(8.1) and 52.23(11.5) for II IH and control group respectively, when using opoid conversion factor of morphine to tramadol which is 1:10.(28). This difference may be due to the difference in pain management protocol, study design, and population.

Besides, our post hoc comparison for total analgesic consumption shows significant difference between II IH and LWI group, II IH and non-exposed group, and LWI and non-exposed groups in case of total tramadol consumption. This is not in agreement with a study done in 1994 in Britain by *R.Ganta et al* to compare analgesic efficacy of II IH and LWI with control group. The study showed that total analgesic consumption was not statically significant between II IH and LWI.(33). In contrary the same study shows there is a significant difference in total analgesic

consumption between LWI and control group, which is not statically significant in ours, this difference may possibly be due to different analgesic drugs (papaveretum Vs tramadol, and diclofenac) used and different doses of bupivacaine for infiltration, as they used more concentrated, 0.5% bupivacaine which could produce a denser block and a significantly lower pain compared with the non-block group.

On the other hand results of our study regarding total analgesic consumption is in accordance with the study done by *Nigatu et al* which found that there is a significant difference in total tramadol consumption comparing the II IH and control group (71.15±37.4 Vs 219.51±39.73) with $p \leq 0.05$.(29)

As regard to postoperative nausea, vomiting and shivering, the present study depicted that there is no significant difference between the study groups. This may be due to the metoclopramide(10mg) given for all parturients pre-operatively as an institutional protocol which is effective in reducing nausea and vomiting episodes, and the tramadol provided for pain could reduce shivering significantly. This goes in line with a study done in Ankara, Turkey by *Sakalli et al* in 2009 which found that there is no statically significant difference regarding nausea and vomiting between the II IH and Non- block group(21). Study by *Abudulah et al* in turkey in 2012 also have similar result(28)

CHAPTER Seven. Strength and Limitation of the study

7.1. Limitation

This study has certain limitations, including the inability to use ultrasound-guided blockade, lack of control over some factors like incision size, and participation of different anesthetists and obstetricians and limited studies found for comparison and discussion are some of the limitations.

7.2. Strength

The study groups are comparable in terms of socio demographic distribution and perioperative factors, hence the difference observed may probably be due to the exposure factors.

CHAPTER Eight Conclusion and Recommendation

8.1. conclusion

We concluded though II IH nerve block provides a longer analgesic effect, both II IH and LWI are effective analgesic techniques for treatment of post cesarean delivery pain by reducing post-operative pain score, total analgesic consumption and prolong time to first analgesic request. Therefore, both techniques can be safely used for post cesarean section pain accordingly.

8.2. Recommendation

- We recommend that senior anesthetists who are capable and well exposed should do the II IH nerve block routinely as a part of post cesarean analgesia, and in resource and skilled man power limited area LWI should be considered.
- Researchers

  Further study with randomized control trial and adequate follow up period and postoperative complication study is recommended.

Reference

1. Betrán AP, Merialdi M, Lauer JA, Bing-shun W, Thomas J, Look P Van, et al. Rates of caesarean section : analysis of global , regional and national estimates. Paediatr Perinat Epidemiol. 2007;21:98–113.
2. Natcher WH. NIH State-of-the-Science Conference : Natl Inst Heal. 2006;1:119.
3. Pdbiad C. Persistent post-partum pain after vaginal birth and cesarean section. Lada Kalagac Fabris Oper. 2011;113(2):239–41.
4. Vercauteren M. Analgesia after Caesarean section : are neuraxial techniques outdated ? 2009;16(2):129–33.
5. Elvir-lazo OL, Paul F. The role of multimodal analgesia in pain management after ambulatory surgery. 2010;
6. To H, List J. Efficacy of the Bilateral Ilioinguinal- Iliohypogastric Block with Intrathecal Morphine for Postoperative Cesarean Delivery Analgesia. ScientificWorldJournal. 2012;2012(107316).
7. Yakkara E, Yakkara E. Ilioinguinal and Iliohypogastric Nerve Blockade for Post Caesarean Analgesia. J Med Sci Clin Res. 2017;05(05):22100–4.
8. Raoofi Z, Karimi MB, Parvar SP, Parvar SP. Ilioinguinal and Iliohypogastric Nerve Block with Anatomical Landmark and Direct Visualization Technique. Bangladesh J Obs Gynaecol. 2014;29(2):83–6.
9. Kvolik S, Kristek J, Aki K, Taka I, Gulam D. A wound infiltration as a method of postoperative analgesia. Period Biol. 2009;111(2):241–6.
10. Scott NB. Wound infiltration for surgery. J Assoc Anesth Anesth Gt Britain Irel. 2010;65:67–75.
11. Amanda C de. Keywords Experience; Sensation; Emotion; Cognition; Social; Assessment Word count: 1996 1 Canada. Int Assoc Study Pain. 2016;2–5.
12. To H, List J, Anaesth IJ, Kerai S, Saxena KN, Taneja B. Post-caesarean analgesia : What is new ? indian J Anesth. 2017;61(3):200–14.
13. Ababa A, Thupayagale- G. Patterns of caesarean-section delivery in. African J Prim Heal care Fam Med. 8:1–6.
14. Univer- K, Anesthesia O, Anesthesia EM. Spinal anesthesia in the obstetric patient : prevention and treatment of hypotension. Acta Anaesth Belg. 2006;57:383–6.
15. Shahraki AD, Jabalameli M, Ghaedi S. Pain relief after cesarean section : Oral methadone vs . intramuscular pethidine Background : Results : Conclusion : J Res Med Sci. 2012;17:2.
16. Sinatra R, Pain C. Causes and Consequences of Inadequate Management of Acute Pain. pain Med.

2018;11(August):1859–71.

17. Boekel R Van. Improving postoperative pain Improving postoperative pain care. 1st ed. geboren op 2;

18. D BPP, Greengrass RA, Penning DH, Reynolds JD. O b s t e t r i c a l a n d P e d i a t r i c A n e s t h e s i a Iliohypogastric-ilioinguinal peripheral nerve block for post-Cesarean delivery analgesia decreases morphine use but not opioid-related side effects. Can J Anesth. 2002;49:694–700.

19. Mei W, Jin C, Feng L, Luo A, Zhang C, Tian Y. Bilateral Ultrasound-Guided Transversus Abdominis Plane Block Combined with Ilioinguinal-Iliohypogastric Nerve Block for Cesarean Delivery Anesthesia. Int Anest Res sociiety. 2011;113(1):134–7.

20. Mt A, Sn S, Mm N, Nb O, Sanlı N, Alagol A. Comparison of analgesic efficiency between wound site infiltration and ultra - sound-guided transversus abdominis plane block after cesarean delivery under spinal anaesthesia. Hippokratia. 2014;18:28–31.

21. Uysal HY. Original Article The efficacy of ilioinguinal and iliohypogastric nerve block for postoperative pain after caesarean section. JRMS. 2010;15(1):6–13.

22. Aldehayat G, Royal J, Services M. ILIOINGUINAL-ILIOHYPOGASTRIC PERIPHERAL NERVE BLOCK FOR ILIOINGUINAL-ILIOHYPOGASTRIC PERIPHERAL NERVE BLOCK FOR ANALGESIA AFTER CAESAREAN. JRMS August. 2014;15(2):70–2.

23. Pharmacol JAC. Observational study to assess the effectiveness of postoperative pain management of patients undergoing elective cesarean section Background : J Anaesthesiol Clin Pharmacol. 2012;28(1):36–40.

24. Ford S. Roundtables , analysis , interviews and. Nurs times J. 2010;106(42).

25. Jasim HH, Azhar S, Syed B, Khan AH. Factors Affecting Post Caesarean Pain Intensity among Women in the Northern Peninsular of Malaysia. J Clin Diagn Res. 2017;11(9):07–11.

26. Size M, Soyannwo OA, Justins DM. Pain management in developing countries. J Compil Assoc Anaesth Gt Britain Irel. 2007;62(1):38–43.

27. Bunting P, Mcconachie I. ILIOINGUINAL NERVE BLOCKADE FOR ANALGESIA AFTER CAESAREAN SECTION. Br J Anesth. 1988;61:773–5.

28. Boztosun A. Abdominal blockage of iliohypogastric and ilio-inguinal nerves for management of post-caesarean pain : A novel method. SAJOG. 2012;18(1):23–7.

29. Nigatu YA, Gebremedhn EG, Tawuye HY, Gebreegzi AH. Analgesic Efficacy of Bilateral Ilioinguinal and Iliohypogastric Nerve Block for Post Caesarean Delivery Under Spinal Anaesthesia , 2016 . Double blind randomized Study. J Anesth Clin Res. 2017;8(8).

30. Filters R. Is Local Infiltration Analgesia Superior to Peripheral Nerve Blockade for Pain Management After THA : A Network Meta-. Clin Orthop Relat Res. 2016;495(2):495–516.

31. Article O. THE EFFECT OF LOCAL ANAESTHETIC WOUND INFILTRATION ON POST-OPERATIVE PAIN AFTER CAESAREAN SECTION. J Surg Pakistan 15. 2010;15(3):2–5.

32. Bamigboye AA, Hofmeyr GJ. O RIGINAL A RTICLES Caesarean section wound infiltration with local anaesthetic for postoperative pain relief – any benefit ? south Africa Med J. 2010;100(5):313–9.

33. Ganta R, Samra SK, Maddineni VR, Furness G. Comparison of the effectiveness of bilateral ilioinguinal nerve block and wound infiltration for postoperative analgesia after Caesarean section.

Br J Anesth. 1994;72:229–30.

34. Breivik H, Borchgrevink PC, Allen SM, Rosseland LA, Romundstad L, Hals EKB, et al. Assessment of pain. Br J Anesth. 2008;101(1):17–24.

35. JA1 P, Cohen FL. Validity of a verbally administered numeric rating scale to measure cancer pain intensity. CANCER Nurs. 1997;20(2):88–93.

Annex 1: 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 research investigator.

The research team includes Msc students, two senior advisors from AAU and two anesthetists for data collection from Debere Birhan Referal Hospital.

Name of Principal investigator: Bezaye Zemedkun

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

Ms.: - Seniet Aweke

Name of sponsor: - AAU

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

This information sheet is prepared by the above mentioned investigator.

Risk

There is no 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. Participants' name will not be written but by a code. Every piece of information will be confidential.

Benefits

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

1. Bezaye Zemedkun - principal investigator
   Department of anaesthesia, Addis Ababa University
   Tel:
2. Wosenyeleh Admasu – advisor
   Department of anaesthesia, Addis Ababa University
   Tel:
3. Seniet Aweke – advisor
   Department of anaesthesia, Addis Ababa University

ANNEX 2: Informed consents

Data collectors will read the Following Paragraph for the Selected Person:

"To conduct our study, I would like to ask you some question which may take about 10 minutes in three different times. As your participation is very important to the outcome of the study we kindly request you to give us your sincere and truthful answer. All the information that you and other patients going to provide us will remain confidential and you don't need to mention your name."

Are you willing to participate in the interview? Yes - continue), No - (thank & stop here)

Signature -_____ Date _____

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

Questionnaire

It is prepared to collect data on "comparison of the analgesic effectiveness of Illio inguinal illiohypoastric nerve block, local wound infiltration and spinal alone after caesarean delivery for the mothers operated under SA in Debere Birhan Referral Hospital from September 21, 2018 to February 30, 2019

I. English version questionnaire

Department of Anaesthesia College of Medicine and Health Sciences, AAU

Questionnaire identification number_____

Greeting

Hello, I am_____. I am working in the research team of Addis Ababa university Department of Anaesthesia. I would like to ask you a few questions about experiences of your post caesarean pain.

The purpose of this questionnaire is to gather information about "post-operative analgesic effectiveness of Illioinguinal illiohypoastric nerve block, local wound infiltration and spinal alone after caesarean delivery under spinal anesthesia. The research will be beneficial to those who need caesarean section to control their postoperative suffering from pain with less need of other analgesic drugs and reduced risk of postoperative nausea and vomiting side effects of those drugs, especially opioids.

We will ask you some questions which will take few minutes in three different times. The answer to those questions is confidential. We will not write your name in the questionnaire.

You can refuse to respond to any of the questions and you can interrupt at any point in the interview. Do I have your permission to continue?

1. If yes, continue to the next page 2. If no, skip to the next participant

Informed consent Certified by

Interviewer: Code _____Name_____ signature_____

Date of interview _____Time started _____ Time completed_____

Result of interview: 1. Completed 2. Respondent not available 3. Refused 4. Partially completed

Supervisor (Checked by): Name _____ Signature _____Date_____

Guide line for the interviewer

For selected patients introduce yourself as coming from AAU after greeting the person you meet first. Then explain the purpose of the study for the respondent by saying that:

The reason why I came here is to ask you few questions about experiences of your post caesarean section pain. The purpose of this study is to gather information about post -operative analgesic efficacy Illio inguinal illiohypoastric nerve block, local wound infiltration and spinal alone after caesarean delivery in Debere Birhan Referal Hospital and forward some recommendation to concerned bodies that will help to improve postoperative pain management after caesarean delivery.

ጤና ይስጥልን እኔ_____እባላለሁ፡፡ከቀዶ ጥገና ወሊድ በኁላ ለሚመጣው ህመም ማስታገሻ ዘዴዎች ላይ የሚሰራ ጥናት መረጃ ሰብሳቢ ነኝ:: ጥናቱ ለእርሶ ምንም አይነት የገንዘብ ጥቅም አያስገኝም ነገርግን የጥናቱ ውጤት በህክምና ዘርፍ ላይ ያሉትን ችግሮች ለመቅረፍ እና የታካሚዎችን ደህንነት የሚያረጋግጡ ህጎች እንዲስተካከሉ እና ሥራ ላይ እንዲውሉ የበኩሎን አስተዋፅዖ ያበረክታሉ፡፡ ስምዎ በዚህ ጥናት ላይ አይፃፍም፡፡ ስለዚህም የእርሶ ምላሽ ሚስጥራዊነቱ የተጠበቀ ነው::በዚህ መጠይቅ ላይ ለመሳተፍ መስማማትም ሆነ አለመስማማት ይችላሉ፡፡ ባለመስማማቶ ምንም የሚጎዱት ነገር የለም፡፡

ምንም አይነት ጥያቄ ካለዎት ቀጥሎ በተፃፈው አድራሻ ተመራማሪውን ማግኘት ይችላሉ፡፡

1. ቤዛየ ዘመድኩን (ዋና ተመራማሪ): ስልክ

2. ወሰንየለህ አድማሱ (አዲስ አበባ ዩኒቨርሲቲ መምህር እና የጥናቱ አማካሪ)
   ሠናይት (አዲስ አበባ ዩኒቨርሲቲ መምህር እና የጥናቱ አማካሪ)

የመረጃ ሰብሳቢ ስምና ፊርማ

ስም_____ፊርማ_____ቀን_____

ANNEX 3 Data collection tool

Section 1: Socio Demographic Data

Card no		**Bed no**	**Code**
Sno	**Question**	**Response**	
101	Age		
102	BMI		
103	ASA(I/II)	ASA I ASAII	1 2
104	gravida	Primigravida Multigravida(….)	1 2
105	No of previous C/S		
106	Time of surgery	In min	
107	Indication for caesarian section		

Section 2: Data during preoperative period

Ser no	**Questions**	**Response**
201	Base line heart rate	
202	Base line Blood Pressure (MAP)	
203	Base line Spo2	
204	Does the patient take premedication?	
205	If yes, what was the drug? And its dose?	a/ diclofinac--------mg b/ paracitamol------mg c/ tramadol -------mg

		d/ petidine---------mg e/ morphine--------mg f/ others (specify)

Section 3: Question related to anesthetic and surgical interventions

Ser no	Question	Response	Code
301	Time of spinal anesthesia given	----------LT	
302	Type of local anesthetist used for spinal anesthesia	A/ Bupivacain B/ Lidocain	
303	Type of post-operative analgesia given	1/II-IH 2/ LAI 3/ None	**B** **I** **C**
304	Time the block is done	……..LT	
305	Dose of local anesthesia given For the block	-----mg	

Section 4: Hemodynamic parameters in post-operative period Immediately at Arrival of Recovery Room, 2ndhr,4thhr, 8thhr and 12thhr16thhr,20thhr,24thhr

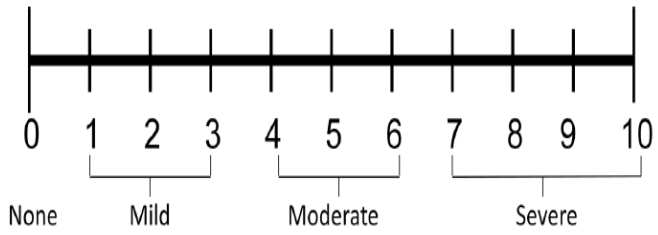
Mother arrived at recovery room at _____ {time in local time, day or night time, date/month/ year in EC}

S.NO	***Time (in hour)***	***Parameter***	***Value***
401	***At 2 hour of post-operative period***	***HR*** ***SBP***	***……bpm*** ***…….mmh***

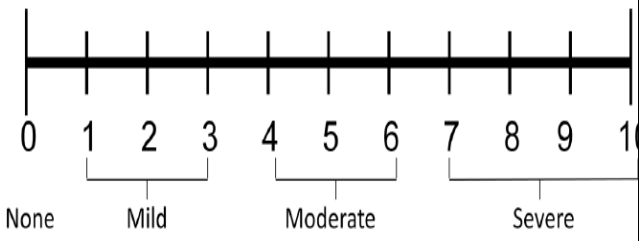
		DBP	***……..mmhg***
402	***At 4 hour of post-operative period***	***HR***	***……. Bpm***
		SBP	***……. mmhg***
		DBP	***……. mmhg***
403	***After 6 hour of post-operative period***	***HR***	***……. Bpm***
		SBP	***……...mmhg***
		DBP	***……mmhg***
404	***After 8 hour of post-operative period***	***HR***	***……bpm***
		SBP	***……mmhg***
		DBP	***……mmhg***
405	***After 12 hours of post-operative period***	***HR***	***……...bpm***
		SBP	***……mmhg***
		DBP	***……mmhg***
406	***After 16 hours of post-operative period***	***HR***	***……...bpm***
		SBP	***……mmhg***
		DBP	***……mmhg***
407	***At 24 hour of post-operative period***	***HR***	***……. Bpm***
		SBP	***……. Mmhg***
		DBP	***……. Mmhg***

Section 5: Questions on Severity of pain after 2hours at rest

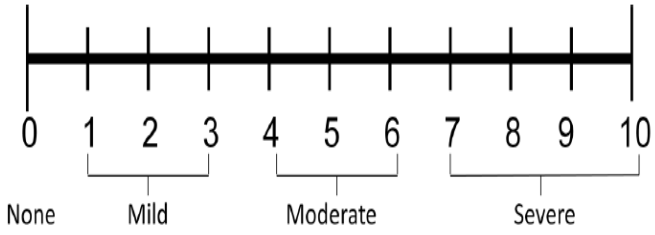
S.NO	***Question***	***Possible answers***	***score***

501	***Numerical pain score***		

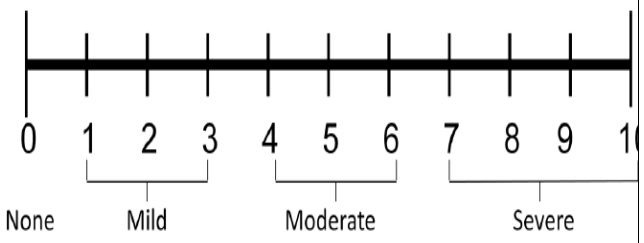
<u>Section 6</u>: Questions on Severity of pain after 4 hours at rest

S.NO	***Question***	***Possible response***	***Score***
601	***Numerical rating pain scale***		

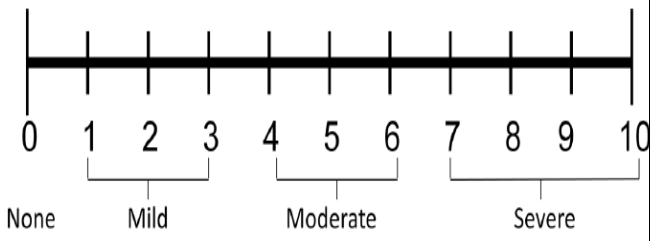
Section 7: Questions on Severity of pain after 6 hours at rest

S.NO	***Question***	***Possible response***	***Score***
701	***Numerical rating pain scale***		

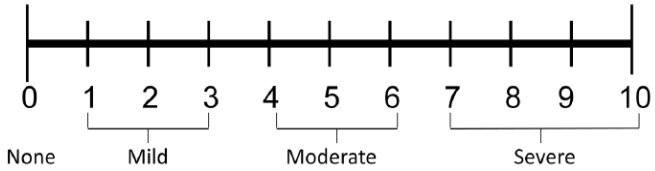
Section 8: Questions on Severity of pain after 8 hours at rest

S.NO	Question	Possible response	Score
801	Numerical rating pain scale		

Section 9: questions on severity of pain after 12 hours, at rest

S.NO	Question	Possible response	Score
901	Numerical rating pain scale		

Section10: question on severity of pain after 24 hours, at rest

S.NO	Question	Possible response	score
1101	Numerical rating pain scale		

Section 11: question about over all experience of post-operative pain in the past 24 post-operative hours

S.NO	***Question***	***Possible response***	***S core***
1201	***Time before the first request of further analgesia (from time of blocl to first request)***	***……..……min/hour***	
1202	*Total amount and type of analgesia given in the last 24 hours*	*……..…, ……mg*	

1301. Does the patient have nausea within the first 24 hours of surgery? A. YES B. NO

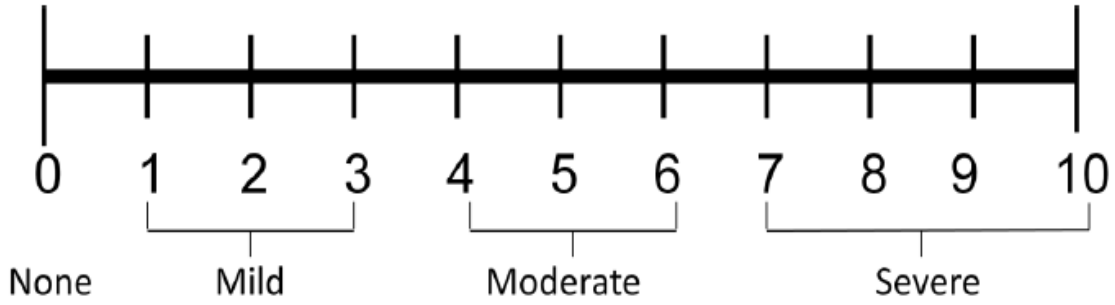
1302. Does the patient develop vomiting within first 24 hours of surgery? A. YES B. NO

1303. Does the patient have an episode of shivering within first 24 hours? A. YES B. NO

Annex 4: Data accuracy check sheet

S.No.	Tools	Yes	No
1	Are the Inclusion criteria /exclusion criteria done appropriately		
1	Are all questions on Sociodemographic data filed appropriately?		
2	Are all questions on preoperative period data filled appropriately?		
3	Are all questions on intraoperative period data filled appropriately?		
4	Are all questions on postoperative period data filled appropriately?		
5	Did the postoperative analgesic drugs filled with appropriate type of drug, time and dose		

ANNEX 5 The verbal numeric analogue scale (VNRS)



a) The scale will be taken 12 (6 at rest and 6 on coughing/movement) times within the first 24 hours. The patient will be asked one of the following questions:

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

- 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)

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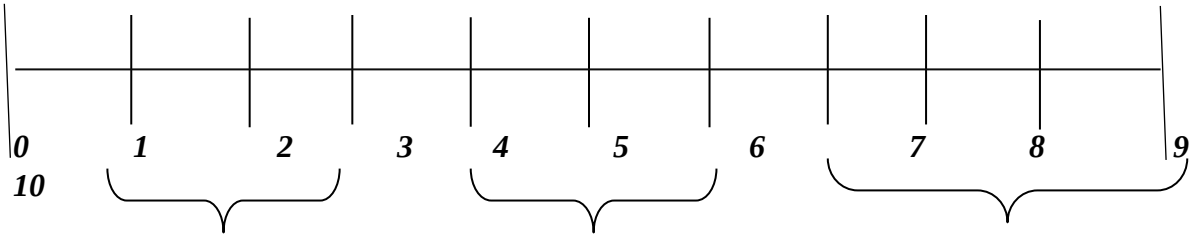

የለም መካከለኛ ከፍተኛ በጣም ከፍተኛ

መለኪያዉ በ 24 ሰአት ዉስጥ 12 ጊዜ የ ሚለካ ሲሆን ታካሚዎች የሚሰማቸዉ የህመም መጠን በየ 6 ሰአት ልዩነት እንዲያሳዩን እንጠይቃለን

ታካሚዎች የሚከተሉትን ጥያቄዎች ይጠየቃሉ፤-
ሀ . አሁን ከተገለጹት ቁጥሮች ማለትም (0-10) ባሉት ዉስጥ የእርስዎ የህመም መጠን ስንት ላይ ነው
ለ. ከላይ የተገለጸዉ በቂ ካልሆነ ተጨማሪ ማብራሪያ ይሰጥታል ፡
0 ህመም የለም
1-3 መካከለኛ ህመም (መነጫነጭ፣መረበሽ፣ወ.ዘ.ተ)
4-6 ከፍተኛ ህመም (ከ ህመሙ በተያያዘ ስራን በ አግባቡ አለመስራት)
7-10 በጣም ከፍተኛ ህመም (እለታዊ ትግባራትን ማከናወን አለመቻል)

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Annex 6: ASA PHYSICAL STATUS CLASSIFICATION SYSTEM

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (<3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

*****The addition of "E" denotes Emergency surgery:
(An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

Adopted from the ASA House of Delegates on October 15, 2014

ANNEX 7 Classification of Obesity based on BMI.

BMI(kg/m2)	*Description*
<18.5	Underweight
18.5–24.9	Normal
25–29.9	Overweight
30–34.9	Obesity (class I)
35–39.9	Obesity (class II)
≥40	Morbid obesity (class III)
≥50	Super obesity
≥60	Super -super obesity

Adopted from Paul G. Barash clinical anesthesia 7th edition.