COMPARISON OF ULTRASOUND GUIDED BILATERAL ILIOINGUINAL AND ILIOHYPOGASTRIC NERVE BLOCKS VERSUS LOCAL INFILTRATION FOR POST CESAREAN SECTION ANALGESIA.

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A DISSERTATION SUBMITTED IN PART-FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN ANAESTHESIOLOGY, UNIVERSITY OF NAIROBI

DECLARATION

I declare that this dissertation is my original work and has not been submitted for a degree award in this or any other university as to my knowledge. All resources contained herein have been duly acknowledged.

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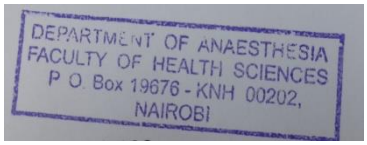

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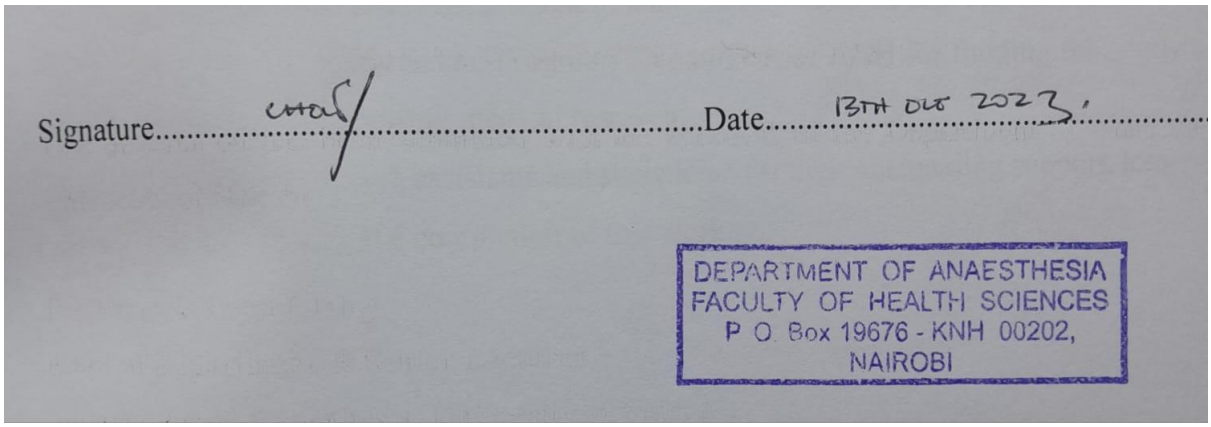

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DEDICATION

To my parents, for their endless love and inspiration that has encouraged me to pursue my dreams.

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LIST OF ABBREVIATIONS AND ACRONYMS

AAGBI-	Association of Anaesthetists of Great Britain and Ireland
ASA-	American Society of Anesthesiologists
ASIS-	Anterior superior iliac spine
CDI-	Color Doppler Image
CITI-	Collaborative institutional training initiative
CNS-	Central Nervous System
COX-	Cyclooxygenase
CPCSP-	Chronic Post Caesarean Section Pain
CS-	Caesarean Section
CVS-	Cardiovascular system
EOM-	External Oblique Muscle
ERC-	Ethics Research Committee
FDA-	Federal Drug Association
GA-	General Anesthesia
GIT-	Gastrointestinal
IASP-	International Association for the Study of Pain
IIIH-	Ilioinguinal Iliohypogastric
IINB-	Ilioinguinal Iliohypogastric Nerve Block
IM-	Intramuscular
IOM-	Internal Oblique Muscle
IV-	Intravenous
IVPCA-	Intravenous Patient Controlled Analgesia
KNH-	Kenyatta National Hospital
L1-	Lumber nerve 1 dermatome
LA-	Local Anesthetic
LAST-	Local Anesthetic Systemic Toxicity
LIIS-	Local infiltration of the incision site
NMDA-	N-methyl-D-aspartate
NRS-	Numeric Rating Scale
NSAIDs-	Nonsteroidal anti-inflammatory Drugs
OIVI-	Opioid-Induced Ventilatory Impairment
PACU-	Post-anesthesia care unit

RCT-	Randomized Control Trials
SA-	Spinal Anesthesia
SPSS-	Statistical Package for the Social Sciences
T7-	Thoracic N 7 dermatome
TAM-	Transversus Abdominis Muscle
TAP-	Transversus Abdominis Plane
TFA-	Time to first analgesia
TGC-	Time Gain Compensation
UON-	University of Nairobi
VAS-	Visual Analogue Scale
WHO-	World Health Organization

OPERATIONAL DEFINITIONS

Pain: An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.

Perioperative: Time frame surrounding surgery divided into preoperative, intraoperative and postoperative period.

Postoperative: Period after surgery.

Pfannenstiel Incision: A low transverse abdominal incision.

Postpartum: Period after delivery.

General Anesthesia: Is a reversible, drug induced, physiologically stable state of unconsciousness, analgesia, amnesia with akinesia.

Regional Anesthesia- Temporary removal of pain sensation in a region of the body with local anaesthetic drugs without loss of consciousness.

Somatic Pain: Sharp well localized pain arising from musculoskeletal system at site of injury or disease e.g., from skin, muscle and bone.

Visceral Pain- Pain arising from internal organs and is described as constant aching dull pain, poorly localized. It may be associated with symptoms like nausea or sweating and may be referred over a wide area.

Modulation: Is the process of suppressing pain at levels of the spinal cord, midbrain and brainstem.

ABSTRACT

Background: The World Health Organization (WHO) reports > 20% of childbirth is via cesarean section (CS). Most CS deliveries are performed under spinal anesthesia (SA) combined with other multimodal analgesia like epidural analgesia, local anesthetic (LA) wound infiltration, abdominal nerve blocks, and systemic analgesics. These combinations are safer and offer better maternal analgesia as compared to general anesthesia (GA).

Study Objective: To compare ultrasound guided ilioinguinal iliohypogastric nerve block (IINB) versus local infiltration of the incision site (LIIS); for postoperative analgesia in CS patients under SA.

Methodology: This is a comparative Quasi-experimental study. Participants were divided into two arms. Bupivacaine, dexamethasone and adrenalin were used in both the ultrasound guided IINB arm and the LIIS arm. Participants were patients in Kenyatta National Hospital (KNH) maternity theatres undergoing CS under SA meeting eligibility criteria. Convenience sampling was used; participants in an alternating manner fell into either arm until the desired sample size was achieved. Participants were followed up to determine time to ambulation, time to first analgesia (TFA) request and numerical rating scale (NRS) scores for pain assessment at postnatal wards. A questionnaire was used for data collection. Data was analyzed using statistical package for the social sciences (SPSS) 23.0.

Comparison of pain was done between the two groups using Chi square test of association. TFA was measured with comparison done using Student's t test and association done using Chi square test. Time to ambulation was summarized into median minutes and compared using the Mann Whitney U test. Statistical significance was tested at 5% (p-value <= 0.05). Findings were presented using tables and graphs.

Results: Lower pain scores on activity, longer duration of analgesia and early ambulation time were noted in the IINB group as compared to the LIIS group; this was not statistically but was clinically significant.

1.0 CHAPTER ON: INTRODUCTION

1.1 Background Information

Pain is defined as an unpleasant sensory and emotional experience associated with, or resembling that associated with actual or potential tissue damage (1).

Postoperative pain is mainly nociceptive in character but can be neuropathic in cases where there is a direct nerve lesion (2), (3).

Cesarean deliveries have been on the rise; in our country Kenya's rates are as high as 13% (4).

Worldwide, CS deliveries account for 21% of all childbirths as per WHO every 1 in 5 of all childbirths is via CS (5), some regions record rates higher than that (6).

Post CS pain is both somatic and visceral in nature (7). The somatic component of the Pfannenstiel incision is at the lumbar nerve 1 (L1) dermatome, it is innervated by the ilioinguinal and iliohypogastric (IIIH) nerves (8) while the visceral pain is diffuse having no peripheral nerve association (9).

The Pfannenstiel or suprapubic transverse incision is made a few centimeters above the pubis (10). It is recommended for lower abdominal surgery because of its good cosmetic look and less rates of incisional hernias (11) but has been associated with significant pain in the postoperative period that can be present for months postoperatively becoming persistent chronic pain (3), (11).

Most CS deliveries are currently performed under SA as per recommendations of the American Society of Anesthesiologists (ASA) and American Pain Society (12),(13). Spinal anesthesia offers less risk to the mother and better analgesia as compared to general anesthesia (GA).

Multimodal approaches are currently utilized to offer adequate analgesia and offer good pain control in the postoperative period without significant side effects to the mother or newborn. These approaches should be cost-effective and require minimal monitoring, especially in resource-poor setups.

Measures like epidural analgesia, local wound infiltration with LA drugs, abdominal wall nerve blocks, and systemic analgesics have often been employed (14),(15). The method performed depends on the healthcare provider's expertise, the maternal health condition, and the patient's preference (16).

Abdominal nerve blocks include the IINB, the Transversus abdominis plane (TAP) block, and the rectus sheath block. Ultrasound use has increased the safety profile and success rates of these abdominal regional nerve blocks (17).

The efficacy of the IINB is of great value in reducing post-CS pain scores both at rest and on movement and reducing total opioid consumption (18).

Similarly, local wound infiltration with LA drugs is a simple one-time procedure that requires minimal skill that has been used as an adjuvant to systemic analgesics to offer postoperative CS analgesia, it has been shown to reduce pain scores, and increase the time to request rescue analgesia and reduce opioid requirements (19).

The emotional changes in the immediate postpartum period can be negatively impacted by inadequately managed pain. Poorly managed pain is associated with negative consequences such as inadequate bonding and breastfeeding of the newborn, prolonged duration of ambulation, increased length of hospital stays, and poor maternal satisfaction (20).

Inadequate postoperative pain control is a predictor of chronic pain (21) with CS being one of the major causes in women of childbearing age (22). Severe pain in the acute postoperative period is one of the main risk factors for the development of chronic pain with one in every four patients at risk of getting chronic post-CS pain (CPCSP) (23). Postoperative pain is the main cause of dissatisfaction in patients after CS deliveries (24), (25).

Post-surgical chronic pain is seen after a surgical intervention, lasting beyond the expected healing time, it lasts more than two months and other pain causative factors have been excluded (26), (27).

Comparing the efficacy of ultrasound-guided IINB over LIIS is of great value to establish optimum analgesia care post-CS.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

The rising numbers of CS globally (6) makes postoperative pain assessment crucial. It has been shown that post-CS pain is of high intensity hence the need for assessment of pain scores to manage postoperative pain accordingly (28).

Pregnancy is a hypercoagulable state that is worsened if mobility is impaired post-CS delivery therefore good pain control ensures that mothers ambulate early hence reducing the risks of thromboembolic disease; it also makes mothers more capable of caring, breastfeeding, and bonding with their newborns (15), (25). To facilitate maternal recuperation adequate postoperative analgesia is necessary to prevent postoperative morbidity hence ensuring good quality of life, better maternal-infant bonding and reducing chances of chronic pain syndrome development (14), (21).

2.2 Abdominal Wall Anatomy

The anterior abdominal wall is superiorly bordered by the xiphoid process of the sternum with the costal margins on each side, inferiorly by the pelvic bone with the inguinal ligaments on each side, and laterally by the mid axillary line (8).

The main layers superficial to deep include the skin, superficial fascia (Camper's and Scarpa's), muscles, deep fascia, and parietal peritoneum (10).

The muscle layers have associated fascial sheaths. Five muscles make up the abdominal wall three flat muscles and two vertical ones. The three flat muscles are the external oblique being the most superficial followed by the internal oblique and the transversus abdominis being the deepest. The two vertical muscles are at the midline, the paired rectus abdominis muscle on each side, and inferiorly the triangular-shaped pyramidalis at the base of the pubic bone superficial to the rectus abdominis muscle (10), (17).

The plane of interest for anterior abdominal nerve blocks lies between the internal oblique and transversus abdominis muscles as it contains the anterior rami of the thoracic nerve 7 to the Lumbar nerve 1 (T7- L1), these nerves supply the somatic sensation to the skin, muscles and peritoneum (29).

T7-T11 enter the neurovascular plane at the level of the costal margins piercing the posterior wall of the rectus sheath this is the target for the rectus sheath block in midline incision abdominal surgeries. T7-T9 supplies the skin supraumbilical, T10 is the umbilical dermatome, and T11- L1 supplies the infraumbilical region of the skin (17).

The iliohypogastric and ilioinguinal nerves originate from the nerve root of L1, the iliohypogastric nerve supplies sensation to the skin over the inguinal area it is found between the internal oblique and transversus abdominis muscle plane, it then runs anteriorly to lie between the internal oblique and external oblique muscles and finally gives cutaneous branches (30). The ilioinguinal is inferior to the iliohypogastric at the iliac crest level it goes through the transversus abdominis muscle to supply the inguinal hernia sac, anterior labia, or scrotum and medial thigh (30).

The Pfannenstiel incision lies at the L1 dermatome. It is preferred during CS deliveries as it has been shown to have fewer incidences of incisional hernias, better cosmetic appearance, and fewer rates of wound infection and hematoma formation (11), (31),(32). It has been associated with chronic pain due to nerve entrapment of the ilioinguinal and iliohypogastric nerves (3), (11).

2.3 Physiology of Pain

Pain can be divided into two main types- nociceptive pain which is either somatic or visceral and neuropathic pain (33).

CS pain is both somatic from the Pfannenstiel surgical incision of the L1 dermatome supplied by the IIIH nerves and visceral from the uterine incision that is diffuse in nature without any peripheral nerve correlation (9).

Nociceptive pain is perceived by sensory receptors known as nociceptors, this is the commonest type of pain seen acutely during noxious stimuli brought about by tissue damage due to disease, surgical procedures, and trauma or self-harm that leads to inflammation (34). Surgical pain is mainly due to tissue injury and the inflammation that follows.

The generation of pain that is, transduction leads to an action potential that is carried by nociceptors either A-delta or C afferent fibers to the higher centers through the spinothalamic or spinoreticular tracts of the spinal cord to the thalamus and midbrain by a process known as transmission. These signals are then relayed to the somatosensory cortex in the brain where the perception of pain occurs. Along these pathways, several neurotransmitters and inflammatory mediators for example substance P and prostaglandins are produced leading to enhanced nociceptor sensitivity and excitability (34),(35).

Neuropathic pain is a consequence of a direct lesion to the somatosensory nervous system that can be central or peripheral (33). It commonly leads to chronic pain.

The modulation occurs at the level of the dorsal horn, the brainstem, and cortex by the inhibitory descending pathways, endogenous opioid systems, or segmental inhibition. Along

these pathways, the neurons release different types of inhibitory and excitatory neurotransmitters like serotonin, norepinephrine, acetylcholine, endorphin, and encephalin that will inhibit or facilitate nociception (35).

It is these neurotransmitters and pathways that are targeted by different types of analgesics. It is important therefore to differentiate whether the pain is nociceptive or neuropathic in origin to aid in the choice of therapeutic drugs to be used and their durations.

2.3.1 Pain Scores

Assessment of acute postoperative pain is an important guide on the effectiveness of the pain management plan. Unidimensional pain assessment scales like the numeric rating scale (NRS) and visual analog scale (VAS) are simple tools that are more reliable in detecting changes in the pain intensity during treatment of patients as compared to verbal categorical rating scales (VRS) (36).

These scales are used to assess pain intensity at the time of assessment. Evaluating pain at rest correlates well with the comfort of a patient while evaluation of pain intensity on movement is a good indicator of the risk of development of postoperative complications and a patient's functionality (36).

One of the common formats of the NRS used is the horizontal 11-point scale (NRS-11), from 0 being no pain to 10 being the worst imaginable pain, the higher the score the greater the pain intensity. It is a segmented numeric scale where a patient is required to pick one whole number from 0 to 10 that correlates with their pain intensity at the time. This can be administered verbally or graphically for self-completion with the patient verbally stating or marking the number that best describes their current pain intensity (37).

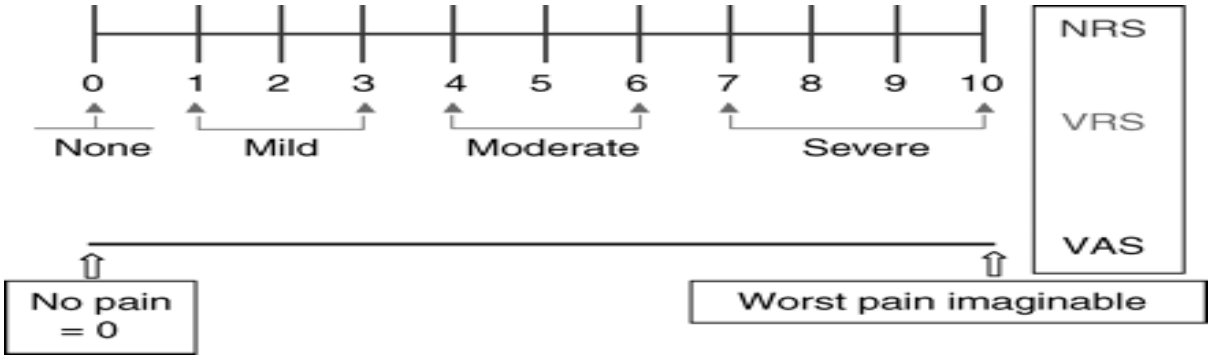

Figure 1:Numeric Rating Scale (NRS) (36)

The four categories of VRS (VRS-4) describing pain intensity as none, mild, moderate, or severe has been proved to be less sensitive than the VAS, while the sensitivity of the VAS and NRS-11 was approximately similar therefore the choice of use between the two is based on the preference of the assessor (38).

2.4 Multimodal Analgesic Approaches for Caesarian Section

Multimodal analgesic approaches have been utilized to offer perioperative pain control. One of the main measures is the use of neuraxial block over GA for CS deliveries as it offers better analgesia postoperatively compared to GA (12), (39). Spinal anesthesia has been on the rising (40),(41) with almost all CS deliveries performed under neuraxial blocks unless contraindicated. Spinal anesthesia with bupivacaine wears off in 1-4 hours, hence the need to supplement with other forms of analgesia postoperatively (42). Peripheral nerve block with bupivacaine can last for 4-16 hours therefore a good supplement to the multimodal analgesic management for CS patients. As all drugs have side effects the aim of combining different classes of analgesics is to use the minimum effective dose of each drug to achieve optimum analgesia with minimal adverse effects.

Multimodal analgesia has proved to be effective for postoperative pain. It is the use of more than one type of analgesia to control pain by offering additive and synergistic effects hence leading to better pain management with fewer side effects from individual drugs (43). The combination of different modes targets different levels of the pain pathway from the site of tissue injury, the peripheral afferent transduction to the spinal cord to the perception of pain at the somatosensory cortex.

Currently in KNH all CS deliveries are done under spinal anesthesia using bupivacaine and fentanyl unless contraindicated as per KNH protocol. All patients receive intraoperative and postoperative systemic analgesics. Depending on the surgeons' preference or upon anesthetists request some patients also receive LIIS with LA. Anesthetists trained on abdominal nerve block prefer performing either an IINB or TAP block. All these additional multimodal analgesia approaches are user dependent on their preferences, competency, and for the abdominal blocks on the availability of an ultrasound machine.

2.4.1 Opioids

Opioids are commonly used analgesics for acute perioperative pain (15),(42). Morphine being the prototype is derived naturally from opium *Papaver somniferum,* other commonly used opioids are synthetic like tramadol and fentanyl.

They bind to opioid receptors leading to agonistic effects mimicking the endogenous opioids. This leads to pain modulation mainly at the level of the spinal cord and brainstem hence analgesia (42). The opioid receptors include μ, δ, and κ receptors that contribute to the analgesic properties and unwanted side effects of opioids (33).

Intrathecal, epidural, intravenous (IV), subcutaneous and intramuscular (IM) routes have been used during the perioperative period as single shots or continuous infusions that can be patient-controlled IV analgesia (IVPCA) (15).

The side effects of opioids have led to many multimodal approaches that are opioid sparing (7),(44),(45), therefore minimizing opioid side effects (46).

Placental and breastmilk transfer can cause opioid dependency and sedative effects on the fetus and neonate respectively (42). Systemic opioids to the mother during labor have been associated with neonatal reduced alertness, respiratory compromise, and delay in effective breast feeding (47). In general, opioids short-term use of 2 to 3 days for labor and delivery pain is deemed safe for breastfeeding (48), short acting drugs taken after nursing or before neonate sleeps minimize exposure of these drugs to the baby; only 1-2% of most maternal drug dosing appears in breastmilk (47).

From minor side effects like nausea, vomiting, constipation, urinary retention, and pruritus to major ones like causing sedation, hypotension, syncope, bradycardia, and opioid-induced ventilatory impairment (OIVI) (42) opioids have led to the search for other analgesic drugs. These alternative analgesics are to reduce the total opioid consumption and simultaneously offer superior analgesia.

2.4.2 Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

NSAIDs are among the most commonly used analgesics possessing analgesic, anti-inflammatory, and antipyretic effects. They form an integral part of the multimodal pain management approach. They can be selective or non-selective cyclooxygenase (COX) inhibitors. Their mechanism of action is by inhibiting arachidonic acid from binding to the active site of the COX enzyme hence preventing prostaglandin synthesis (42).

Examples of NSAIDs used in our setup for caesarian delivery pain include diclofenac, aceclofenac, and dexketoprofen. Post CS pain has mainly somatic and visceral pain components from the wound and uterus respectively. As they have been used to treat menstruation cramping, NSAIDS should be given on a routine basis for visceral caesarian delivery pain in all women (14),(15) if not contraindicated in cases of allergies, hypotension, or kidney diseases. The visceral pain from the uterine incision and involution has been shown

to respond effectively to NSAID treatment (49). When concurrently used with opioids they improve the quality of analgesia (46),(50) and have opioid-sparing effects of 30%-50% (44),(51) therefore, reducing opioid-related side effects. Non-selective COX inhibitors are the ones mainly used as the efficacy of COX2 inhibitors for post-CS pain is limited (52).

The side effects of the main concern of nonselective NSAIDs use include platelet dysfunction and in the gastrointestinal (GIT) system potential bleeding or ulcer formation. In the cardiovascular (CVS) system there is a risk of increased cardiovascular adverse events, in the respiratory system patients with allergies or asthma have increased risks of anaphylactic reactions and in the renal system, they alter the filtration rate and plasma flow and may cause kidney injury in susceptible patients (42). The implication that NSAIDs have a role in the delay of healing led to many studies investigating the same. A Diclofenac short course for postoperative analgesia has been recommended, as it did not show disruption in wound clinical healing (53). In animal studies some studies showed wound healing being negatively affected by NSAIDs use, others having no effect while other studies showed clinical improvement, with the available data; short term use of NSAIDs for less than two weeks should not be excluded in the multimodal analgesic plan of patients (54). The scarcity of literature on NSAIDs' effect on wound healing should not preclude its use as available literature suggests no prolongation of soft tissue wound healing (55). Short-term postoperative NSAID use in patients with normal kidney function has no significant risk of acute kidney injury development (56). The benefits of short-term use of NSAIDs as part of the analgesic plan postoperatively have led to their incorporation into the multimodal analgesic approach by many health care providers worldwide.

2.4.3 Acetaminophen

Acetaminophen commonly known as paracetamol is a common over-the-counter analgesic. With excellent oral bioavailability, minimal adverse effects, and breastmilk transfer (57) making its use convenient. It has analgesic and antipyretic effects with limited anti-inflammatory action (33),(42).

Its mechanism of action despite its long widespread use is not clear. It is thought to have both central and peripheral analgesic effects. Its hypothesized effects include activating the serotonergic descending pathways, and inhibition of COX 1, 2 & 3 enzymes; it has been shown to also have antagonistic effects on N-methyl-d-aspartate (NMDA), nitric oxide pathways, and substance P at the level of the spinal cord. Other postulated effects are that it plays a role in the opioid and endocannabinoid systems (33).

Acetaminophen has an opioid-sparing effect of around 20% in the perioperative period (43). Patients who received scheduled acetaminophen had less total opioid consumption in the post-CS delivery period (58).

When combined with NSAIDS it offers an additive anti-nociceptive effect (59) and combinations with opioids are used for breakthrough pain hence making it a crucial drug in the multimodal analgesic plan for post caesarian delivery pain (14).

2.4.4 Dexamethasone

Dexamethasone a glucocorticoid during the perioperative period has been used for its antiemetic effects, as an adjuvant to analgesia in a systematic review and metanalysis, doses between 1.25-20 mg were described to lead to lower pain scores postoperatively, reduce opioid consumption, increase TFA request and have a shorter time at post-anesthesia care unit (PACU) (60). It wasn't observed to cause a delay in wound healing nor an increase in infection but was associated with high levels of blood glucose at 24 hours.

Preoperatively when given as a single dose it improved post-CS analgesia and reduced postoperative nausea and vomiting (PONV) incidences (46). Its antiemetic, analgesic and anti-inflammatory properties make it a suitable drug for use during the perioperative period for patients undergoing CS.

2.4.5 Local Anaesthetic (LA) Drugs

Local anesthetic drugs are cell membrane sodium channel blockers; these membrane stabilizers produce analgesic effects by inhibiting neuronal excitation and conduction (33),(61). The reversible blockade of sodium channels in the nerve fibers prevents depolarization hence preventing transmission of pain. They are beneficial in chronic pain that is neuropathic in nature (62). The lipid solubility determines the potency while the duration of action is dependent on the protein binding of the LA; other factors that determine the duration of action include the site of injection, the dose administered, and the presence or absence of vasoconstrictors (61). The link between the water-soluble and lipid-soluble parts of the LA determines whether it's an amide or an ester. Commonly used LA can be short-acting a major example being lidocaine or can be long-acting for example bupivacaine, levobupivacaine, and ropivacaine.

IV Lidocaine has been used as a perioperative infusion with an opioid-sparing effect (63) and has been shown to have analgesic effects for procedural pain in burns patients (64)**.** In obstetric anesthesia neuraxial techniques either an epidural or intrathecal injection of LA has

become widely practiced. Peripherally LA can be infiltrated into the incision site either as a single shot procedure or through catheters as continuous wound infiltration (65).

Peripheral nerve block use for surgical and postoperative analgesia has gained popularity due to the many advantages this mode offers. This regional technique provides better analgesia and patient satisfaction with fewer analgesic requirements and has reduced the anesthetic-related side effects, therefore, shortening recovery time postoperatively (66). Local anesthetics with or without adjuvants are injected around nerve fibers supplying the surgical field to provide surgical analgesia during the perioperative period depending on when the block is performed.

2.5 Pharmacology of Bupivacaine

Bupivacaine is a long-acting amide local anesthetic, more potent than lidocaine, mepivacaine, or procaine due to the prolonged sodium channel binding (67).

It has a higher risk (if absorbed systemically) of causing major toxicity like seizures and cardiac arrhythmias. The maximum dose with epinephrine is 3mg/kg while without epinephrine the dose is 2mg/kg. Used in ml/kg with epinephrine the dose is 1.2ml/kg of bupivacaine 0.25%, a maximum total dose of 225mg while without epinephrine it is 0.8ml/kg of bupivacaine 0.25%, a maximum dose of 175mg (68).

It comes as a preparation of 0.25% (ideal in conscious patients as 0.5% concentrations are painful on injection) and 0.5% i.e. 2.5mg/ml and 5mg/ml respectively (68).

Its onset of action is between 5-10 minutes and duration of 2-4 hours for local infiltration, 4-16 hours for peripheral nerve blocks, and 1-4 hours for SA (42).

2.6 Adjuvants to Local Anesthetics

Adjunct agents to LA have been used, these adjuvants are added to the LA drugs to increase the duration and improve analgesic effects via synergistic effects (69). Adjuvants in use can be classified as opioids, vasoactive agents/alpha-2-agonists, steroids, and NSAIDs (70).

2.6.1 Steroids- Dexamethasone

To prolong single injection techniques, perineural dexamethasone as an adjunct has been used; it has been shown to increase the analgesic duration by 4 to 8 hours (71). Doses of 4-8 mg are used. The probable mechanisms of action are via its anti-inflammatory effect and by increasing the expression of inhibitory potassium channels on the unmyelinated C nerve fibers through the glucocorticoid receptors thereby reducing the excitability and neuronal transmission of these nociceptive nerve fibers (70),(71). In meta-analysis dexamethasone as

an adjuvant to LA were proven to prolong the effects of brachial plexus blocks with no adverse events observed (72). Another randomized control trial (RCT) observed lower VAS at 2, 4, 12 hours, prolonged analgesic effects and reduced nausea and vomiting occurrences in the group that received dexamethasone as an adjuvant to their TAP block post abdominal hysterectomy (69).

2.6.2 Vasoactive Agents- Adrenaline

Adrenaline has been used as an additive to LA for a long time. It exhibits alpha-2 adrenoceptor-mediated anti-nociceptive effects. It causes vasoconstriction thereby delaying systemic uptake, this allows for higher doses of LA to be used safely with a reduction in the risk of systemic toxicity and also prolongs the duration of block. A dose of 5–10 μg/ml concentration is effective and has been associated with an increase of mean analgesic duration by 1 hour (70),(71). It is a good indicator of inadvertent vascular injection and perineural administration rarely causes tachycardia and hypertension. In a study by (73) they compared three groups that received axillary brachial plexus blockade with lidocaine 1.5%, 1 group received lidocaine with 25mcg adrenaline, another group received lidocaine with 200mcg adrenaline, and a group that only received lidocaine with saline, the groups that received adrenaline had a comparable longer duration of analgesia as opposed to the group that did not. The group of low dose adrenaline 25mcg had similar blockade with more stable hemodynamics as compared to the 200mcg adrenaline group hence low dose adrenaline was recommended as an additive for surgery of the forearm and hand.

2.7 Ilioinguinal Iliohypogastric Nerve Block (IINB)

The ilioinguinal iliohypogastric nerve block is used as an adjunctive technique in the multimodal approach for analgesia. It is indicated in the surgeries of the lower abdominal wall and inguinal region. This nerve block has been used to provide analgesia for hernia repairs, hydrocele repairs, orchidopexy, hysterectomy, and CS using the Pfannenstiel incision. It has proven useful in the diagnosis and treatment of chronic herniorrhaphy pain (74), (75).

It works by blocking the ilioinguinal and iliohypogastric nerves at the plane between the internal oblique and transversus abdominis muscle. The iliohypogastric nerve provides cutaneous sensation in the gluteal region and above the inguinal region superior to the pubis and iliac crest. The ilioinguinal nerve covers cutaneous sensation at the level of the inguinal region, proximal medial thigh, anterolateral scrotum, and base of the penis in males and mons

pubis and labial region for females. Both nerves provide motor sensation to the internal oblique and transversus abdominis muscles (74).

2.7.1 Techniques

The IINB can be performed by the use of either anatomical landmarks or ultrasound guidance.

In the anatomical landmark technique, it is the perception of two pop sensations (fascial clicks) that is sought and might prove hard at times. The patient is placed supine and the lower quadrant region is cleaned. Perpendicular to the skin using a short bevel needle 2 cm superiorly and 2 cm medially to the ASIS is the injection point. Upon the first pop sensation 5mls of long-acting LA is injected in the fascial plane between the external oblique and internal oblique muscles. The needle is then advanced deeper till a second pop sensation is felt where another 5mls of the LA is injected between the internal oblique and transversus abdominis fascial planes. The injection of LA when both pop sensations are felt is to increase the chances of depositing the LA in the correct fascial plane which is between the internal oblique muscle (IOM) and transversus abdominis muscle (TAM) where the two nerves run. Further 5mls of LA is injected subcutaneously at the injection point to cover for the cutaneous nerve supply from the intercostal and subcostal nerves. This method has been shown to have a 70% success rate (76).

Ultrasound-guided nerve blocks are on the rise because of the improved success rates, decreased time to performance, and onset of the block due to direct vision enabling lower doses of LA to be used with fewer complications (77). The ultrasound-guided IINB technique is gaining more popularity since direct vision increases the success rates by depositing the LA at the correct plane in the vicinity of the nerves, unlike the landmark technique which might fail because of anatomical variation (78).

While the patient is supine, the ultrasound probe is placed obliquely superior to the ASIS on an imaginary line connecting the ASIS to the umbilicus. The IIIH nerves are visualized in the plane between the IOM and TAM. In the same plane, the deep circumflex iliac artery is identified when the color Doppler is applied. Below the TAM the peritoneum and peristaltic motions of the bowel can be identified. 10-15mls of long-acting local anesthetic is injected in the vicinity near the nerves but upon difficult visualization, it suffices to inject the LA at the plane between IOM and TAM (74)(74).

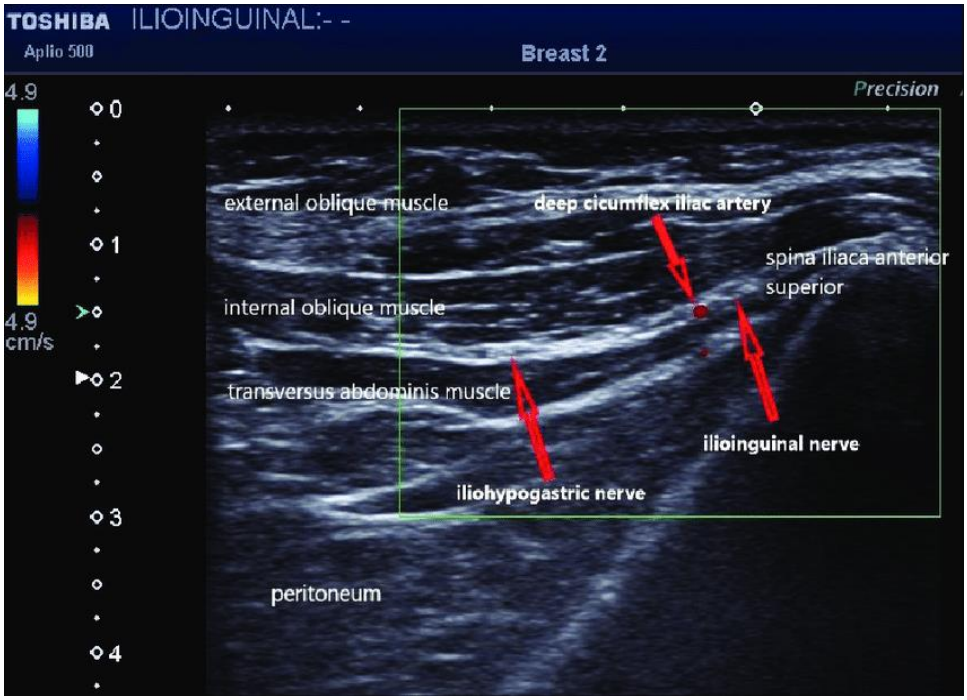

Figure 2:Ultrasound guided IINB sono-anatomy image (79)
Kale A, Aytuluk HG, Cam I, Basol G, Sunnetci B. Selective Spinal Nerve Block in Ilioinguinal, Iliohypogastric and Genitofemoral Neuralgia. Turk Neurosurg. 2019; *29*(4):237–530. https:// doi: 10.5137/1019-5149.JTN.23990-18.1

2.7.2 Previous Studies

The IINB is being used for postoperative CS pain management. Several studies have been done to assess the efficacy of this block for CS analgesia. In 2015-2017 an RCT was conducted (80), where 150 parturients undergoing elective CS under spinal anesthesia using the Pfannenstiel incision were divided into three groups. One group received ultrasound-guided IINB with ropivacaine; another group received LIIS with ropivacaine and a third group did not receive the IINB or the LIIS with ropivacaine post operatively. They found out that the IINB group had significantly lower visual analog scale (VAS) pain scores compared to the other two groups, also the IINB had a longer duration of analgesia and fewer analgesic requirements compared to the other two groups. They concluded using their study that compared to conventional analgesic techniques and LIIS; the IINB significantly increased analgesic duration post-CS, reduced pain scores, and reduced total analgesic requirements.

Nigatu YA et al in 2016 did a double-blind randomized study on 80 parturients undergoing elective CS via Pfannenstiel incision under spinal anaesthesia (81). They aimed to determine the analgesic efficacy of bilateral IINB using the landmark technique as described by (7).

They divided the participants into two groups one that would receive the block using bupivacaine and another that would not. They assessed the 24-hour numerical rating scale (NRS) pain scores both at rest and on movement, time to the first request for analgesia, and total analgesic consumption. Their results recommended the use of IINB as part of a multimodal analgesic regimen in CS as it revealed reduced NRS both at rest and on movement in all the time intervals over the 24 hours except at the 0-hour, prolonged duration to the first time to request for analgesia and decreased tramadol consumption by more than 50% in the first 24 hours post-CS.

In a prospective observational cohort study conducted by Seid AA et al in 2017 where 102 parturients were recruited, they compared the efficacy of bilateral TAP block versus bilateral IINB via landmark technique for postoperative analgesia in CS. Their results showed a lower NRS scores both at rest and on movement 24 hours after surgery for the group that received the IINB although this was not statistically significant. There was a significant reduction in the total tramadol consumption and also a prolongation in the time to first request for analgesia in the IINB compared to the TAP block hence they recommended the IINB (16).

Sakalli M, et al did an RCT to investigate the efficacy of bilateral IINB when performed after CS (18). 60 patients scheduled for elective CS under G.A were randomly divided into two groups the IINB was performed using the landmark technique described by Bell et al with one group receiving ropivacaine and another receiving normal saline NS (sham block). Both groups then proceeded to receive IVPCA tramadol and their vitals (Blood pressure and heart rate), tramadol consumption, VAS scores at rest and on movement, and adverse effects like sedation, nausea, and vomiting were all noted. Patients who had VAS scores higher than 3 despite the IVPCA with tramadol received 0.5mg/kg meperidine for rescue analgesia. Results obtained were as follows: there was no significant difference in the vitals nor when it comes to adverse events in both groups, and the mean VAS score at rest and with movement at some intervals was significantly lower in the IINB group than in the sham group, with regards to the total tramadol IVPCA consumption it was twice as high in the sham group as compared to the IINB group and only one from the IINB group needed meperidine for rescue analgesia as opposed to seven from the sham group.

A comparative study by (82) aimed to compare opioid consumption and pain relief in patients receiving the IINB compared to a group that doesn't. Sixty patients planned for non-emergent CS delivery under spinal anesthesia were divided into two groups. One group will receive the IINB using the landmark technique described by Bell et al with 10mls of 0.5% bupivacaine bilaterally while the other will receive NS instead of bupivacaine. The NS group had a higher

NRS score at all times in the first 24 hours, a shorter duration of time to the first request for tramadol postoperatively, and consumed more tramadol than the group that received the IINB with bupivacaine. This study proved that the IINB truly reduces total opioid consumption and offers good pain relief post-CS delivery.

In a relatively older study, H J Huffnagle designed a prospective randomized study to compare the analgesic efficacy of the IINB when done before or after CS delivery (83). 46 patients were randomly divided into three groups. Twenty-two patients received the block before the CS eleven of which failed; another group of twelve patients received the IINB after CS while one group of twelve patients did not receive the block at all. They used IVPCA morphine for additionally needed analgesia. The use of morphine over 24 hours did not differ and neither did patient satisfaction in all the three groups. For pain severity, the after group surprisingly at some intervals reported more pain severity as compared to the group that did not receive the block and the group that received the block before the CS. They concluded that there was no benefit in the use of the IINB in patients who received spinal anesthesia for CS deliveries.

A double-blinded RCT done by A Wolfson et al, compared two groups of patients, one group received bilateral multi-injection IINB with neuraxial morphine and the second group only received neuraxial morphine for post-CS delivery analgesia (84). 34 parturients scheduled for elective CS via Pfannenstiel incision under spinal anesthesia with morphine as one of the neuraxial drugs were randomly allocated into two groups. These two groups would receive the IINB in multiple injection sites as described by Bell et al, where one group the injectate will be bupivacaine, and the other group will be NS. The anesthesiologists performing the block would be unaware as to which drug whether bupivacaine or NS was being injected as it would have been prepared beforehand and the team that was assessing postoperative VAS pain scores, analgesic requirements, satisfaction, and adverse effects were also blinded as to which group the patient is. Ketorolac 30mg was used as the rescue drug once a patient would request analgesia, if not relieved 6 hourly two tablets of acetaminophen 500mg/oxycodone 5mg (Tylox) would be given as per patient request and IVPCA morphine would be initiated in those in pain despite ketorolac and Tylox. Lower VAS scores were noted at 6, 12, and 24 hours postoperatively in the bupivacaine group, the pain relief regimen of bupivacaine led to greater maternal satisfaction at 6, 12, and 18 hours, also the bupivacaine group had a longer duration of time to request for ketorolac for rescue analgesia and less Tylox consumption. There was no difference in adverse events like pruritus, nausea, or vomiting in the two

groups. Therefore, a multi-injection IINB was seen to offer an advantage in post-CS pain relief.

EA Bell et al in 1996 developed a two-step study to assess whether the IINB reduced the total consumption of morphine for post-CS delivery analgesia and thus lead to fewer opioid-related adverse effects. A multi-level technique of injection was developed for the performance of the IINB (7). From the ASIS 2 cm superior and 2 cm, medial perpendicular to the skin a needle is advanced till a loss of resistance or pop sensation felt upon piercing the external oblique muscle (EOM) fascia after negative aspiration the injectate is given then advancing till another loss of resistance is noted another injectate is given at the level of IOM and TAM. The needle is then withdrawn to the dermis and in the same horizontal plane 15° medially and 15° laterally the loss of resistance technique is repeated. One side would have three injection points with each injection point having two facial planes where the drug is injected by use of the loss of resistance technique. The procedure is then done on the contralateral side as well. At each injection point, 2 ml of injectate is given making a total volume of 24 ml. This technique offered > 95% success rates of the block by causing L1- L2 dermatomes to have diminished sensation to pinprick after wearing off of the spinal anesthesia.

The first step of the study was to gather data retrospectively on the patients who underwent CS and received the multilevel technique of the IINB. The results showed that the patients who received the block with bupivacaine and epinephrine had significantly administered less morphine using the IVPCA technique as compared to those who received the placebo with saline. The second step of the study was an RCT to further observe if they will be a reduction in IVPCA of self-administered morphine in the IINB group and whether this will lead to a reduction in opioid-related adverse effects. Despite the RCT again showing less self-administration of morphine by the group that received bupivacaine and epinephrine in their IINB as compared to the saline group there was no difference in the incidence of adverse events related to opioid use (itchiness and nausea). This study concluded that the IINB use for postoperative CS relief reduces total morphine consumption but not side effects related to the opioid itself. This multi-level injection technique by Bell et al has been used in several studies as quoted above before the upsurge in the use of ultrasound for peripheral nerve blocks.

2.7.3 Literature on Ultrasound Guided Nerve Blocks

The emergence of ultrasound guidance in nerve block performance has been on the rise. The direct continuous visualization of needle advancement has made it safer with increased accuracy and hence more effective (77),(85). The constant visualization increases the success rate even in anatomical variations and indirectly leads to fewer risks of complication with fewer needle passes.

Weintraud et al demonstrated in their study how unpredictable the landmark technique is in the performance of the IINB in 62 children (76). They used ultrasound guidance to observe where the injectate had been placed when the fascial click (landmark technique) was used. 86% of the LA was in the wrong plane with a block failure rate of 45%.

In a double-blinded randomized study, 100 children receiving the IINB either using the fascial click or ultrasound-guided technique were compared. Success was based on the need for analgesia intraoperatively and postoperatively. 4% of the ultrasound group received intraoperative analgesia as compared to 26% of the facial click group while only 6% of the ultrasound group required postoperative analgesia as opposed to 40% of the fascial click. More LA was used in the fascial click group. Therefore, the success rate was 96% intraoperatively and 94% postoperatively in the ultrasound group; while 74% intraoperatively and 60% postoperatively in the landmark technique group (86).

Ultrasound guidance has also been shown to reduce the time taken in performing nerve blocks, shorten the time to onset of action of the block, increase the duration of action of the block despite lower doses of LA used and offer more comfort to the patient by decreasing procedure-related pain instances (77).

Constant visualization of the needle, neurovascular structures, and the anatomical planes reduces the risk of complications but does not eliminate it. Ultrasound guidance offers the opportunity for real-time visualization of the injectate which leads to early detection of intravascular or intraneural penetration therefore timely withdrawal.

2.7.4 Possible Complications with the IINB

Complications from these blocks are rare but can occur. Incorrect placement of the needle can lead to a breach of nearby structures like vessels, nerves, and the peritoneum and the loss of the intended analgesic benefit. Ultrasound guidance is therefore recommended as opposed to blind techniques to aid in the correct placement of needle and injectate. Abdominal nerve blocks have been performed when patients are under GA or SA with no reported neurological injuries. Abdominal nerve blocks tend to be bilateral and of high volume and therefore have a

risk of local anesthetic systemic toxicity (LAST) that can be minimized by not exceeding the recommended maximum doses (85), ultrasound use has led to fewer doses of LA used while maintaining the efficacy of the block. Accidental transient femoral nerve block has also been reported (74).

2.8 Local Infiltration of the Incision Site (LIIS)

Local anesthetic wound infiltration has formed an integral part of the multimodal analgesic scheme using various approaches to the administration of the LA; one simple approach is the infiltration of the subcutaneous layer at the surgical wound site (87). The local infiltration of the incision site at the subcutaneous layer (layer below the dermis) aims at blocking the transmission of pain from the free nerve endings located in the two layers of the skin; the epidermis and dermis. This infiltration can be done before the surgical incision or after the closure of the surgical wound. The diluted solutions of local anesthetics offer analgesia with minimal interruption to the sense of touch or temperature and with preservation of motor activity (19).

2.8.1 Technique

Different techniques are used depending on the presence or absence of peritoneal spraying (87). The rectus sheath and the subcutaneous layer above and below the incision are usually infiltrated under direct visualization in a fan-like manner using a small gauge needle (23G) (19), this simple procedure proved to be effective.

2.8.2 Previous Studies

An RCT by (19) in 2017 in KNH recommended the routine use of bupivacaine for local wound infiltration. The study compared two groups of participants, 76 in each arm. One group received single shot local wound infiltration with bupivacaine as one of the modes for post-CS analgesia while another group did not. Their results showed that LIIS with bupivacaine proved effective in reducing pain scores (lower VAS), prolonged the time for the need for rescue analgesia, and reduced the total opioid requirements post-CS.

A Cochrane search of LA use for CS was conducted; RCTs were recruited in April 2009 by Bamigboyo et al, the three studies of 126 participants who received LA wound infiltration proved LIIS as useful for CS analgesia as evidenced by a reduction in morphine consumption at 24 hours (87). The studies did not find any difference in the VAS of pain.

An RCT in India in October 2015-August 2017 recruited 150 patients undergoing elective CS under SA. The participants were divided into three groups: group I received postoperative

bilateral IINB with ropivacaine 0.5% 10mls bilaterally, group L had postoperative LIIS with ropivacaine 0.5% 20mls, and group C was a sham block of saline postoperatively. The duration of analgesia in group I was significantly longer compared to group L and group C, group I also had significantly lower total analgesic requirement and lower VAS scores compared to the other two groups. They concluded that IINB had lower pain scores, less cumulative analgesic requirements, and longer postoperative pain relief compared to group L and the control group. The duration of analgesia was longer in group L than in group C and the analgesic cumulative requirement was lower in group L as compared to the control group hence in the absence of the IINB the LIIS is a good alternative as part of the multimodal analgesic management (80).

Brendan Carvalho et al described various post-CS analgesia modes and the studies that looked into the different modes (14). The studies they looked into found out that a single dose LIIS with LA was of limited value in the setting of SA with morphine and systemic NSAIDs and acetaminophen, also if to be done, then pre and post-incision LIIS is more advantageous and because of the limited time of analgesia with single shot wound infiltration then continuous wound infiltration with catheters would be more superior.

45 patients undergoing elective or emergency CS during the duration between January-April 1999 were randomly allotted into three equal groups of 15 patients each. Group A would receive GA and LIIS with bupivacaine, group B would be under SA and would receive LIIS with bupivacaine, and group C who underwent CS under GA without wound infiltration with bupivacaine. Patients then were hourly assessed postoperatively on their VAS score for pain and analgesic requirements. Neither group A nor B required any rescue analgesia with pethidine in the first 6 hours postoperatively while all group C patients required at least one dose. Group B had a longer duration of 8-12 hours postoperatively to their first analgesic request, followed by group A 6-8 hours while group C requested analgesia at time 0 this proved that group B (the SA and LIIS with bupivacaine group) offered the best pain management when compared to the two other groups. The use of 0.25% bupivacaine by wound infiltration was recommended for CS analgesia as it prolonged the time to request analgesia and reduced total opioid (pethidine) requirement (88).

A case report by Bablesh Mahawar described how they performed a CS under local anesthesia and Entonox (89). A-26-year old ASA III patient with 1 previous CS scar presented to their casualty with scar tenderness and fetal distress hence requiring an emergency CS. She was cachectic and pale with a 2-year history of weakness of all limbs as they felt SA could not be performed without completely investigating her and GA was not

possible due to lack of a ventilator and ICU; they proceeded with a high-risk consent and performed the lifesaving procedure under Entonox via a face mask and local infiltration of 0.5% bupivacaine 8mls no packs or retractors were used and the surgeon had to be as gentle as possible during the surgery. A live male infant was delivered and 20 micrograms of intravenous fentanyl were given. On closure, 10 micrograms of fentanyl were added along with 6mls of 0.5% bupivacaine infiltration of the rectus sheath, subcutaneous tissue, and skin. Stable hemodynamic parameters were recorded throughout the 45-minute surgery. Maternal comfort or request is sufficient reason to provide pain relief and if both general and regional anesthesia is either contraindicated or unavailable then the infiltration of local anesthesia is to be used in life-threatening emergency CS situations as above.

2.8.3 Complication of LIIS

LAST is a rare possible complication arising from the use of local anesthetic drugs therefore, LIIS using LA drugs can lead to this complication especially if the recommended maximum dose is exceeded or inadvertent vascular injection of the LA occurs leading to rapid systemic absorption hence high systemic concentrations of the drug (19),(66).

2.9 Local Anesthetic Systemic Toxicity (LAST)

Systemic toxicity occurs when the maximum LA dose is exceeded or inadvertent injection to a blood vessel. The main systems affected are the CNS and CVS. CNS toxicity occurs at lower doses compared to CVS toxicity. CNS symptoms include tingling and numbness around the mouth and tongue, metallic taste, slurred speech, tinnitus, lightheadedness and drowsiness, convulsions, and respiratory arrest. Not all symptoms must present in a patient and maintaining verbal contact is paramount in the early detection of CNS toxicity. Convulsions can occur without any other prior signs and symptoms, especially with bupivacaine. The seizure threshold is lowered in hypoxic, acidotic, and hypercapnic patients therefore should be avoided. In the event of a convulsion the first management institutes oxygenation, ventilatory support, and benzodiazepine administration. CVS manifestation includes alterations to the contractility of the heart, its conductivity, and rhythmicity. These may present as vasodilation, bradycardia, tachycardia, reduced myocardial contractility, ventricular arrhythmias, conduction delay, or heart blocks and asystole (19),(33).

2.10 Contraindications to the Performance of the IINB and LIIS

The use of LA drugs is contraindicated in a few instances where patients are hypersensitive to them, or the adjuvants combined with them (in this case LA can be used without the adjuvant that the patient is allergic to) or in the presence of infection at the injection site.

2.11 Study Justification

There is a significant projected increase in CS deliveries worldwide including KNH (4) therefore; there is a need for paralleled adequate post-operative pain management for the parturient mother. The post-partum is a very delicate period for recovery from surgery as well as socially to establish the bond between mother and newborn and allow effective breastfeeding; the success of which is partly dependent on optimal maternal pain control. Regional anesthesia is relatively new and may be used to maximize pain control post-CS. However, there is a paucity of local data that compares the effectiveness of different regional anesthesia modes with systemic analgesic combinations that warrant such a study. Pain control results in improved surgical and patient outcomes; early ambulation, early infant nursing, early wound healing, early patient discharges, and shorter hospital stays that will henceforth decongest the postnatal wards resulting in reduced hospital costs per CS delivery (17).

The use of multimodal approaches for postoperative analgesia in CS has been the focus of many healthcare givers in the quest to ensure a pain-free postoperative period (14),(15).

One of the methods used is local wound infiltration with a local anesthetic. It is a technique, due to its simplicity that has become widely adapted for postoperative analgesia in CS (19). The anterior abdominal wall blocks, provide excellent analgesia for the abdominal wall incision and not the abdominal viscera. Significant pain arises from the abdominal wall incision, in the case of CS the Pfannenstiel incision at the L1, these blocks are justified. The ilioinguinal iliohypogastric ultrasound-guided nerve block is simple to perform and offers great value to patient outcomes. It has been shown to provide excellent pain control for postoperative caesarian section pain but is not routinely used in our setup. The emergence of ultrasound has markedly improved the safety profile and success rate of these regional nerve blocks (17),(77).

This study aims to create awareness of the types of abdominal nerve blocks available for CS and their benefits hence encouraging anesthetists to put them into practice. Comparing analgesia effectiveness post-CS with the use of ultrasound-guided single shot bilateral IINB versus LIIS with LA with concurrent systemic analgesic administration will give a baseline for pain control strategies and post-CS pain guidelines that are evidence-based and patient-centered.

2.12 Research Question

Is ultrasound-guided bilateral ilioinguinal and iliohypogastric nerve block superior to local infiltration of the incision site for postoperative pain management after caesarian sections under spinal anesthesia?

2.13 Null Hypothesis

There is no difference in postoperative analgesic pain scores, time of need of rescue analgesia, and time to ambulation between ultrasound-guided single-shot bilateral ilioinguinal and iliohypogastric nerve block versus local infiltration of the incision site.

2.14 Objectives of the Study

2.14.1 Broad Objective

To compare the use of ultrasound-guided single-shot bilateral ilioinguinal and iliohypogastric nerve blocks versus local infiltration of the incision site for postoperative pain management after cesarean sections under spinal anesthesia at Kenyatta National Hospital.

2.14.2 Specific Objectives

- To compare postoperative pain scores at rest when ultrasound-guided single-shot bilateral IINB is used versus LIIS at 0, 6, 12, 18, and 24 hours.
- To compare postoperative pain scores during activity when ultrasound-guided single-shot bilateral IINB is used versus LIIS at 0, 6, 12, 18, and 24 hours.
- To determine the time of need of rescue analgesia after CS when ultrasound-guided single-shot bilateral IINB is used vs LIIS.
- To determine the time to ambulation after CS when ultrasound-guided single-shot bilateral IINB is used vs LIIS.

3.0 CHAPTER THREE: MATERIALS AND METHODS

3.1 Study Design

This was a quasi-experimental study with two study arms.

3.2 Study Site

The study was carried out in K.N.H, a national level 6 referral and teaching hospital for the University of Nairobi. Patients were from the maternity theatre and were followed up in the post-anesthesia care unit (PACU) and postnatal wards. Currently, KNH has two operational maternity theatres operating 24 hours a day with an average of 450 CS a month.

3.3 Study Population

The study population was all patients seeking delivery services at KNH.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

- All patients above 18 years of age.
- Patients undergoing CS done via the Pfannenstiel incision under SA who consent to the study.

3.4.2 Exclusion Criteria

- Non-consenting parturient or parturient below the age of 18 years.
- CS deliveries done under GA or SA that is converted to GA.
- CS deliveries that have other regional modalities used like epidural or other nerve blocks.
- CS deliveries of more than 2 hours.
- CS deliveries via midline incisions or any incision other than the Pfannenstiel incision.
- Parturient with contraindications or are allergic to local anesthetic or dexamethasone or both.
- Parturient with contraindications to SA.
- Parturient with neuropsychiatric disorders.

3.5 Sample Size Determination

This study compared the analgesic effectiveness of bilateral ultrasound-guided IINB and LIIS with bupivacaine postoperatively in patients undergoing cesarean sections. A previous study showed the differences between the two interventions using the duration of analgesia post-operatively (80). They used a formula for comparative studies that compares means.
The sample size required for this study was determined as follows:

$$n_1 = n_2 = \frac{(z_{1-\alpha} + z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2)}{d^2}$$

n_1 – the number of patients required in the intervention group

n_2 – the number of patients required in the comparison group

$Z_{1-\alpha/2}$ – the standard normal deviate for 95% confidence interval = 1.96

$Z_{1-\beta}$ – the standard normal deviate for 80% power = 0.845

σ_1 – standard deviation for IINB group = 82.874 minutes (80)

σ_2 – standard deviation for LIIS group = 39.473 minutes (80)

d – The minimum difference in duration of analgesia that will be considered significant between the two groups = 45 minutes

n = 33 parturients will be sampled for each group, making a minimum total sample size of 66 parturients.

2 patients will be added in each arm to cater for any loss of follow up of the study participants.

3.6 Sampling Technique

A convenience non-probability sampling technique was used to recruit the participants until the desired sample size was achieved. The participants of this study were recruited from the maternity theatre barrier. Patients listed for surgery were identified and approached for consent. Those eligible and consented to the study on an alternating basis fell into either the LIIS group or the IINB group to achieve equal numbers in each group.

3.7 Study Procedure and Recruitment

The research assistants were clinical officers with collaborative institutional training initiative (CITI) certification for clinical research. They were trained on the approved data collection tool, the NRS for pain assessment, the acquisition of informed consent from the study participants, and the data protection protocol by the principal investigator. All eligible

patients were recruited to the study as per the eligibility criteria. Patients were educated on postoperative pain and its management. The procedures, both the LIIS and the IINB were explained to them as they could fall into one of the two arms, the benefits, and risks, how to interpret the NRS tool, and how to answer the questionnaire was elaborated. Both methods provide acceptable pain relief within the standard of care and any patient requiring more pain relief was advised to ask for rescue analgesia therefore, there was no patient who was expected to be in pain.

Patients were wheeled into the theatre; they had standard monitors placed, and baseline vital signs taken.

The dose of anesthesia for the spinal anesthesia used was administered as per KNH protocol. Spinal anesthesia was provided at L3-L4 or L4-L5 with intrathecal injection of fentanyl and bupivacaine. A block height of T6 was aimed for. Once sensory block height was confirmed the patient was prepared for the start of the surgery.

Intraoperative standard analgesia was given depending on the anesthesia provider's discretion (The anesthesia provider assigned to that maternity theatre).

Upon skin closure, the LIIS group received 20 ml of 0.25% bupivacaine, 4mg dexamethasone, and 5mcg/cc concentration of adrenalin (100mcg) divided on the rectus sheath, the upper and lower edges of the incision under direct visualization in a fan-like manner infiltrating all the surgical layers of the incision, this was done by the surgeon using a 23-gauge needle as described by (19).

The IINB group received ultrasound-guided IINB bilaterally using 20ml of 0.25% bupivacaine, 4mg dexamethasone and 5mcg/cc concentration of adrenalin (100mcg) divided into two 10ml syringes on each side with 21G, 100mm stimuplex needle performed by the principal investigator in the presence of the anesthesia provider running the list.

Both the LIIS and IINB groups were expected to have a reduction in the level of pain as the spinal anesthesia wears off in 1-4 hours, hence the need to supplement with other forms of analgesia postoperatively. As both these two interventions were expected to prolong the duration of action of analgesia and lead to a reduction in the somatic pain (pain from the skin and skeletal muscles) around the incision site. This was expected to affect the outcome of the study by improving maternal satisfaction because of the lowered pain scores, longer durations before needing systemic analgesics, and the ability to ambulate.

The presence of the anesthetist assigned for that theatre (one anesthetist is usually assigned in one operating room) was to continue with the standard care for spinal anesthesia as per KNH protocol required for the CS so as to ensure no delay or disruption in the flow of patients

needing CS deliveries. The principal investigator supervised all the LIIS performed by the surgeons to make sure they followed the guidelines. The principal investigator was a senior anesthesia resident who had received training on nerve blocks during the pain rotation in the course curriculum. For uniformity only the principal investigator who was trained in performance of this block performed the ultrasound guided IINB.

In a supine position, the ultrasound probe was obliquely placed medial to the lateral one third of a line joining the umbilicus to the anterior superior iliac spine (ASIS) and part of the probe was placed proximally on the ASIS. An in-plane technique was used to advance the needle under direct visualization of the sonoanatomy.

On identification of the external oblique, internal oblique, and transversus abdominis muscles both nerves can be seen between the fascial layers of the internal oblique and transversus abdominis muscles close to the ASIS with the ascending branch of the deep circumflex iliac artery usually identified between them. The success of the block was confirmed, even in the cases that the nerves were not easily visualized, by the correct placement of the LA in between the facial plane of the internal oblique and transversus abdominis muscles.

Postoperative systemic analgesics were prescribed as the usual practice for both two groups as per the primary clinician.

Evaluation of postoperative pain in the maternity theatre at 0 hours post-surgery and in the post-natal wards was done at 6 hours, 12 hours, 18 hours, and 24 hours both at rest and on movement (side to side turning) using the NRS and the pain scores were noted down. The time of need of rescue analgesia (upon request or NRS of 5 and above) and the total analgesic consumption was noted from the time of the end of the surgery for the next 24 hours. Duration of ambulation was observed from the time of termination of surgery to the time the patient started to ambulate. The pain scores, time of need of rescue analgesia, total analgesic consumption, and time taken to ambulation were compared between the LIIS group and the IINB group.

3.8 Equipment

- The wideband linear probe connected to the high-performance Venue 50 GE tablet ultrasound system.
- Ultrasound probe cover.
- Sterile ultrasound gel.
- Antiseptic for skin disinfection- povidone-iodine.

- 23-gauge needles.
- 10 ml syringes.
- B Braun Stimuplex 21G X 4” 0.80 X 100mm insulated needles.
- 20mls of 0.25% bupivacaine (0.5% plain Bupivacaine 10cc diluted with 10cc saline to create 0.25% concentration).
- 1 ml of 4mg dexamethasone.
- 5mcg/cc concentration of adrenalin, therefore, 1 ml of the (1:10000) concentration.

3.9 Quality Assurance Procedures

The ultrasound machine used is the wideband linear probe 8-13MHz that is connected to the high-performance Venue 50 GE tablet ultrasound system with enhanced needle visibility that is currently in clinical use in KNH main theatre.

The bupivacaine used was 0.5% plain bupivacaine that was FDA approved and is currently in clinical use, and has been on manufacturer label listed as safe for use in peripheral and regional nerve blocks. The adjuvants were 4mg/ml dexamethasone and the 1mg/ml adrenaline that are currently in clinical use at KNH.

The safety and well-being of the study participants was under the care of all participating medical health professional teams as per the Kenyatta National Hospital protocol and guidelines. Covid-19 precautions were adhered to at all times. Access to the data was only available for the principal investigator and research assistants. Meetings by the Principal investigator and research assistants were held weekly to discuss study progress.

3.10 Ethical Considerations

Permission to proceed with the study was sought from the KNH/UON ethics and research committee (ERC) and K.N.H administration before the study onset. The National Commission for Science, Technology & Innovation (NACOSTI) license was obtained. Written informed consent for the additional invasive procedure was obtained from the study participant, both in Swahili and English, with verbal clarifications offered and delivered as required in the preferred official language.

Participants were assigned to either the IINB group or the LIIS group in an alternating manner. Serial study numbers were assigned to maintain confidentiality. No participant names or other identifiers were used in the study materials. Enrolment in the study was voluntary; there were neither incentives nor remunerations offered. There were no added costs to the participants for engaging in the study. The study participants were permitted to

opt-out of the study at any point during the study period without penalty for declining to participate in the study.

The safety and well-being of the study participants was under the care of all participating medical health professional teams involved in the patient's care. If a severe adverse effect develops it was to be managed as per guidelines. In the rare event of LAST developing, it was to be managed with current guidelines from the association of Anaesthetists of Great Britain and Ireland (AAGBI), the guidelines were availed as laminated cards in maternity theatre, recovery area and post-operative wards, and the Intra venous Lipid emulsion was availed in the crash carts for the emergency drugs. Permission had been sort to use these guidelines and a copyright form attached in the appendices.

Patients developing any adverse reactions and side effects were to have the incident documented and followed up and reported to the ethics committee as required by the ethical board. Primary clinicians were to carry on with other medical and surgical care as required for the patients at their discretion without interference. Standard patient care and precautionary measures for Covid-19 was to be maintained for all.

3.11 Data Management and Analysis

Data from the questionnaires were coded and entered in Microsoft Excel 2016 data entry sheet. The data set was secured using a password that was only known to the investigator. Cleaning was done and the data set exported into SPSS version 23.0 for analysis.

The study population was described by summarizing demographic and clinical characteristics into percentages for categorical variables and means or medians for continuous data.

Pain scores were categorized in an ordinal scale of no pain (0 score), mild pain (score 1-3), moderate pain (score 4-6) and severe pain (score 7-10). The severity of pain was presented as a percentage of patients assessed at 0, 6, 12, 18 and 24 hours post operation. Comparison of pain was done between the two groups using Chi square test of association or Fisher's exact test where numbers were small.

Time to first rescue analgesia was measured in hours and mean calculated for each group with comparison done using Student's t test. The duration to rescue analgesia was further categorized, presented as percentages of patients and association between groups done using Chi square test. In addition, time to ambulation after CS was summarized into median minutes and compared between the groups using Mann Whitney U test.

Statistical significance was tested at 5% (p value less or equal to 0.05). Tables and graphs were used to present the findings.

3.12 Minimization of Bias

The study followed a convenience non-probability sampling technique, where participants on an alternating basis fell into either the LIIS group or the IINB group to achieve equal numbers in each group. The participants were not informed about the type of intervention used on them until after 24 hours so as not to influence their responses during the data collection. They were given an informed consent for both the IINB and LIIS as they could have fallen into either group and both methods offered acceptable pain relief and in the event of pain, they were to request for rescue analgesia. The principal investigator was present to supervise the LIIS and performed the ultrasound guided IINB but had no access to the part of the questionnaire that fills the pain scores, time of need of rescue analgesia and ambulation therefore could not affect data entered for analysis. The research assistants collected the data for the pain scores, time of need of rescue analgesia and ambulation but were not aware of the type of intervention used in the participants hence had no bias during data collection.

3.13 Study Results Dissemination Plan

Results from this study were shared with the UON and KNH departments of anesthesia, theatre and obstetrics, and gynecology. It is believed that this will enable them to determine better pain control management for the patients.

The result was shared with the KNH-UON Ethics and Research Committee, the University of Nairobi Library, and the University of Nairobi Online Repository. There is intent to share the results in a publication in a peer-reviewed scientific journal.

3.14 Study Limitation

There were some limitations to the study:

This was a single-center study. However, a study conducted at the KNH, being the national referral hospital could trigger future bigger RCT to be conducted in KNH or another hospital in the country. The LIIS was performed by different providers (surgeon performing the CS); the principal investigator prepared the drugs to be injected and was present to ensure that the procedure was conducted as per the guidelines. The patients had different indications for the CS and since different surgeons were conducting the CS deliveries there was variability in the surgical technique.

4.0 CHAPTER FOUR: RESULTS

4.1 Socio-Demographic Characteristics

This study compared 66 participants divided into two groups the IINB group and the LIIS group, 33 participants were recruited in each group. The mean age for those in IINB group was 29.4 years (SD 5.7 years) while those on LIIS had a mean of 28.2 years (SD 4.7 years). The mean weight for the patients in LIIS group was slightly higher (81.9 kg). Similarly, the highest level of education was mainly secondary in both groups and majority understood English language.

Table 1:Socio-demographic characteristics

Variable	IINB	LIIS	P value
Age in years			
Mean (SD)	29.4 (5.7)	28.2 (4.7)	0.351
Weight in kg			
Mean (SD)	75.8 (12.9)	81.9 (16.9)	0.106
Level of education			
Primary	3 (9.1)	2 (6.1)	0.660
Secondary	19 (57.6)	15 (45.5)	
College	9 (27.3)	13 (39.4)	
University	2 (6.1)	3 (9.1)	
English language			
Yes	31 (93.9)	32 (97.0)	1.000
No	2 (6.1)	1 (3.0)	

4.2 Clinical Characteristics

As shown in Table 2, parity was not significantly different between the two groups though para 0 seemed to be slightly higher (39.4%) in IINB group compared to the LIIS group (21.2%), p=0.257. Similarly, gravidity distribution was not different between the groups (p=0.769). Also, the number of previous scars were similar between the IINB and LIIS patients (p=0.728). Though the indications for CS was mostly similar between the groups, there was a significantly higher number (9 patients) with severe preeclampsia in the LIIS group compared to none in the IINB group (p=0.002). The type of CS and the duration of surgery were similar between the two groups.

Table 2:Clinical characteristics

Variable	IINB	LIIS	P value
Parity			
Zero	13 (39.4)	7 (21.2)	0.257
Once	7 (21.2)	12 (36.4)	
2 times	7 (21.2)	10 (30.3)	
3 and more	6 (18.2)	4 (12.1)	
Gravidity			
Once	8 (25.8)	6 (18.8)	0.769
2 times	8 (25.8)	10 (31.3)	
3 and more	15 (48.4)	16 (50.0)	
Number of previous scars			
0	16 (48.5)	17 (53.1)	0.728
1	11 (33.3)	9 (28.1)	
2	5 (15.2)	6 (18.8)	
3	1 (3.0)	0	
Indication for the C/S			
Non Reassuring Fetal Status	13 (39.4)	6 (18.2)	0.057
Severe Pre-eclampsia	0	9 (27.3)	0.002
Ante-partum hemorrhage	1 (3.0)	2 (6.1)	1.000
Prolonged/ poor progress of labor	2 (6.1)	4 (12.1)	0.672
Previous scar	15 (45.5)	13 (39.4)	0.618
Type of CS			
Elective	1 (3.0)	1 (3.0)	1.000
Emergency	32 (97.0)	32 (97.0)	
Duration of surgery			
Less than 1 hour	15 (46.9)	8 (25.0)	0.068
≥1 hour	17 (53.1)	24 (75.0)	

4.3 Intraoperative Analgesia

As shown in Table 3, the use of tramadol, dexketoprofen and acetaminophen was not significantly different between the two groups ($p>0.05$). The route of administration of tramadol was 100% IV for LIIS group while 26.3% of the IINB group received through IM ($p=0.018$). The intraoperative complications or events did not differ significantly between the two groups with hypotension being the most common event.

Table 3:Intraoperative analgesia

Variable	IINB	LIIS	P value
Tramadol			
Yes	19 (57.6)	21 (63.6)	0.614
No	14 (42.4)	12 (36.4)	
Tramadol route			
IV	14 (73.7)	21 (100)	0.018
IM	5 (26.3)	0	
Dexketoprofen			
Yes	31 (93.9)	27 (81.8)	0.258
No	2 (6.1)	6 (18.2)	
Acetaminophen			
Yes	33 (100)	32 (97.0)	1.000
No	0	1 (3.0)	
Intra-operative complications			
Hypotension	9 (100)	11 (84.6)	0.494
Nausea /vomiting	0	3 (23.1)	0.240

4.4QPost-OperativeQPainQIncidence

As shown in Table 4, the incidence of pain was similar between the two groups from 0 hours to 24 hours post operation with majority of the patients reporting no pain. The highest proportion of patients experiencing pain was recorded after 6 hours (39.4% vs 36.4%, p=1.000) and 12 hours (42.4% vs 48.5%, p=0.621) with no significant difference between IINB and LIIS.

Table 4:Post-operative pain incidence

Time of assessment	IINB	LIIS	P value
At PACU 0 hours			
Yes	4 (12.1)	5 (15.2)	1.000
No	29 (87.9)	28 (84.8)	
At 6 hours			
Yes	13 (39.4)	12 (36.4)	1.000
No	20 (60.6)	21 (63.6)	
At 12 hours			
Yes	14 (42.4)	16 (48.5)	0.621
No	19 (57.6)	17 (51.5)	
At 18 hours			
Yes	6 (18.2)	4 (12.1)	0.733
No	27 (81.8)	29 (87.9)	
At 24 hours			
Yes	6 (18.2)	7 (21.2)	0.757
No	27 (81.8)	26 (78.8)	

4.5 Post-operative Pain Scores at Rest

As shown in Table 5, there was no significant difference in pain scores between the IINB and LIIS groups when the patient was at rest from 0 hours to 24 hours post operation ($p>0.05$). The patients who experienced pain reported mild pain (NRS score 1-3) in most of the time intervals after operation with only 1 patient in LIIS group reporting moderate pain at 12 hours.

Table 5:Postoperative pain scores at rest

Variable	IINB	LIIS	P value
NRS score at PACU 0 hours			
No pain	29 (87.9)	30 (90.9)	1.000
Mild pain	4 (12.1)	3 (9.1)	
Moderate pain	0	0	
Severe pain	0	0	
NRS score at 6 hours			
No pain	20 (60.6)	21 (63.6)	0.800
Mild pain	13 (39.4)	12 (36.4)	
Moderate pain	0	0	
Severe pain	0	0	
NRS score at 12 hours			
No pain	22 (66.7)	18 (54.5)	0.450
Mild pain	11 (33.3)	14 (42.4)	
Moderate pain	0	1 (3.0)	
Severe pain	0	0	
NRS score at 18 hours			
No pain	29 (87.9)	30 (90.9)	1.000
Mild pain	4 (12.1)	3 (9.1)	
Moderate pain	0	0	
Severe pain	0	0	
NRS score at 24 hours			
No pain	27 (81.8)	28 (84.8)	0.741
Mild pain	6 (18.2)	5 (15.2)	
Moderate pain	0	0	
Severe pain	0	0	

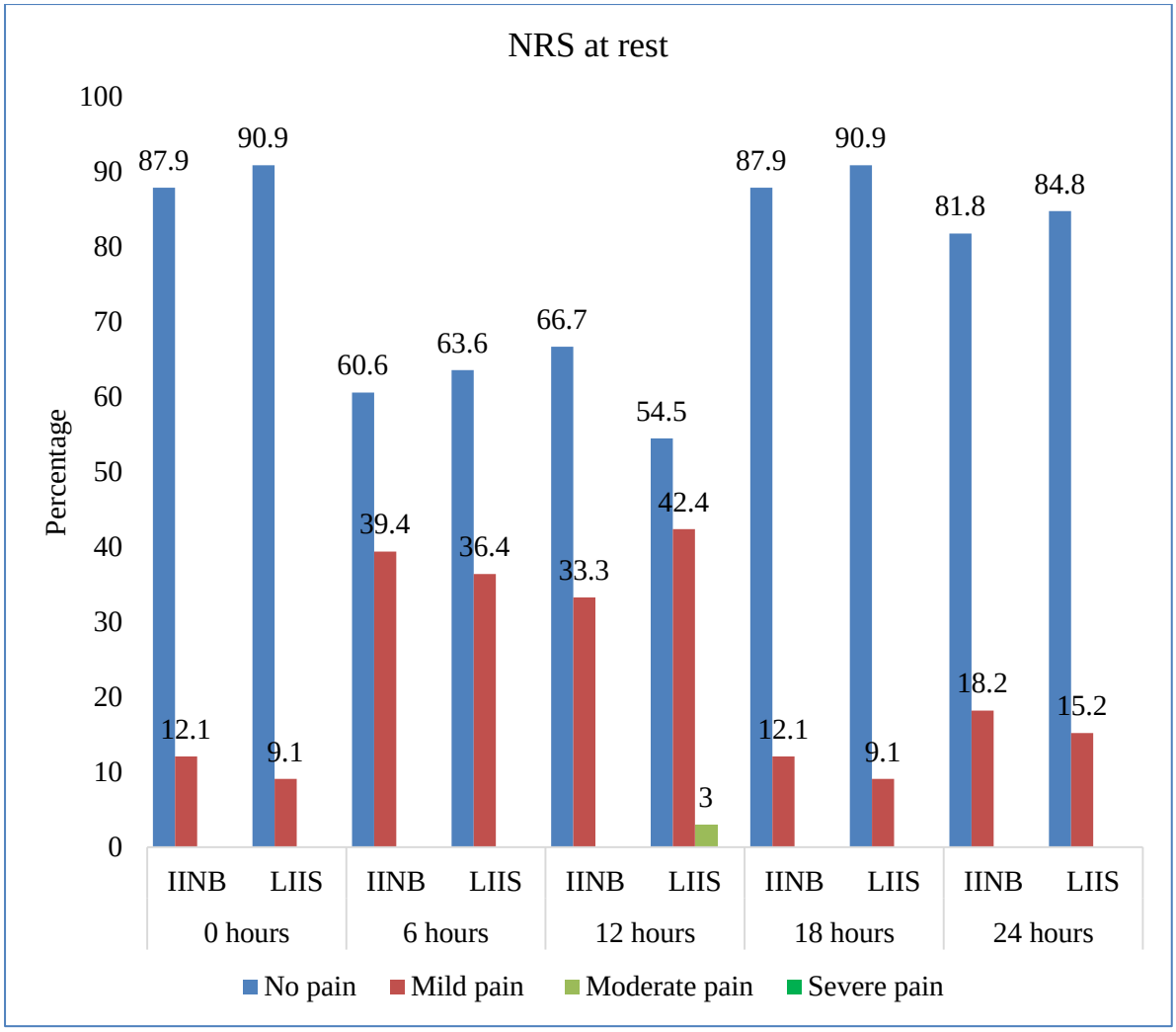

Figure 3:Postoperative pain at rest

4.6 Postoperative Pain Scores on Movement

As shown in Table 6, the pain scores on movement assessed at various intervals were mostly similar between the IINB and LIIS groups ($p>0.05$). However, though insignificant difference, a higher proportion (15.2%) of the LIIS group reported moderate pain on movement at 6 hours post operation compared to 6.1% of the IINB group ($p=0.328$). Notably, higher pain scores of up to moderate pain levels were reported on movement at 6 hours and 12 hours post operation.

Table 6: Postoperative pain scores on activity (movement)

Variable	IINB	LIIS	P value
NRS score at PACU 0 hours			
No pain	29 (87.9)	28 (84.8)	1.000
Mild pain	4 (12.1)	5 (15.2)	
Moderate pain	0	0	
Severe pain	0	0	
NRS Score at 6 hours			
No pain	20 (60.6)	21 (63.6)	0.328
Mild pain	11 (33.3)	7 (21.2)	
Moderate pain	2 (6.1)	5 (15.2)	
Severe pain	0	0	
NRS Score at 12 hours			
No pain	19 (57.6)	17 (51.5)	0.745
Mild pain	11 (33.3)	14 (42.4)	
Moderate pain	3 (9.1)	2 (6.1)	
Severe pain	0	0	
NRS Score at 18 hours			
No pain	27 (81.8)	29 (87.9)	0.492
Mild pain	6 (18.2)	4 (12.1)	
Moderate pain	0	0	
Severe pain	0	0	
NRS Score at 24 hours			
No pain	27 (81.8)	26 (78.8)	0.757
Mild pain	6 (18.2)	7 (21.2)	
Moderate pain	0	0	
Severe pain	0	0	

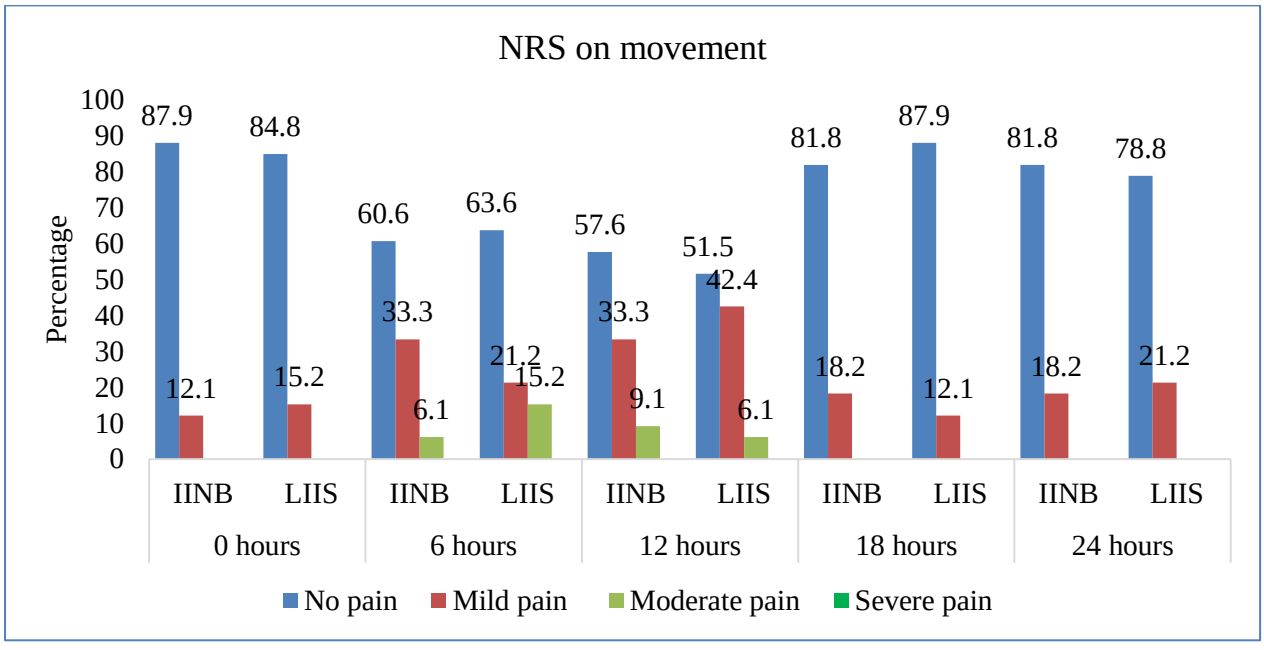

Figure 4:Postoperative pain on movement

4.7 Postoperative Pain Management

As shown in Table 7, there was a significant difference in the interventions given at 12 hours post operation with the IINB group received per oral (35.7%) with less injection (50%) while the LIIS received injection at 81.3% with no per oral (p=0.032). The interventions at all the other time intervals post operation were similar between the two groups.

Table 7:Postoperative pain management

Variable	IINB	LIIS	P value
At PACU 0 hours			
Injection	4 (100.0)	5 (100.0)	-
At 6 hours			
Injection	12 (92.3)	12 (100)	1.000
Morphine	1 (7.7)	0	
At 12 hours			
Injection	7 (50.0)	13 (81.3)	0.032
Per oral	5 (35.7)	0	
None	2 (14.3)	3 (18.8)	
At 18 hours			
Injection	4 (66.7)	2 (50.0)	0.108
Per oral	0	2 (50.0)	
None	2 (33.3)	0	
At 24 hours			
Injection	3 (50.0)	4 (57.1)	0.107
Per oral	0	3 (42.9)	
Morphine	2 (33.3)	0	
None	1 (16.7)	0	

4.8 Time to First Rescue Analgesia Need After CS

As shown in Table 8, the mean time to first rescue analgesia need was 6.4 hours in IINB patients compared to 6.1 hours in LIIS patients (p=0.659).

Table 8:Time to first rescue analgesia need

Variable	IINB	LIIS	P value
Time to first rescue analgesia			
Mean (SD)	6.4 (2.5)	6.1 (2.5)	0.659
Category, n (%)			
1-2 hours	2 (6.1)	4 (12.1)	0.832
3-4 hours	7 (21.2)	5 (15.2)	
5-6 hours	7 (21.2)	9 (27.3)	
7-8 hours	10 (30.3)	8 (24.2)	
9-12 hours	7 (21.2)	7 (21.2)	

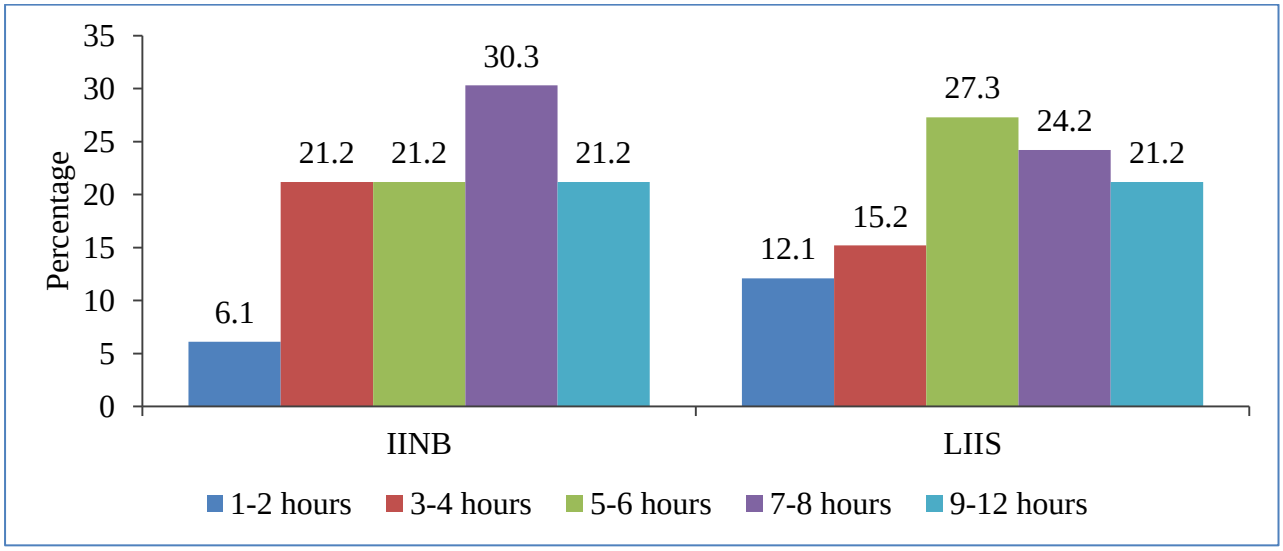

Figure 5:Time to first rescue analgesia need after CS

4.9 Time to Ambulation After CS

As shown in Table 9, the median time to ambulation after CS was not significantly different between the two groups (p=0.439). The IINB group reported a median time of 240 minutes among compared to 300 minutes in LIIS group.

Table 9:Time to ambulation after CS

Variable	IINB	LIIS	P value
Time to ambulation in mins			
Median (IQR)	240 (180.0-340.0)	300 (120.0-380.0)	0.439

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS

5.1 Discussion

Obstetric analgesia for CS is of paramount importance for better maternal and infant outcomes. Multimodal approach is the current trend that has opened up exciting possibilities for pain relief. This is achieved by combining various analgesics that act by different mechanisms resulting in additive or synergistic analgesia and fewer side effects (43).

Bupivacaine has high protein binding and lipid solubility, this result in a rapid onset of action, peak levels by 30 to 45minutes, a half-life of 2.7 hours and prolonged duration of action (6-9 hours). The addition of adjuvants to LA has been in use; these adjuncts increase the duration and improve analgesic effects of the LA via synergistic effects (69). In our study, we found that incorporating the adjuvants dexamethasone and adrenaline to bupivacaine resulted in an extension of analgesic effects, with consistently low pain scores recorded throughout the initial 24-hour period. The prolongation of pain relief in the acute post-surgical period has been shown to enhance overall recovery by mitigating the occurrence of chronic pain (23).

5.1.1QSocio-DemographicQCharacteristics

The mean age for those in IINB group was 29.4 years (SD 5.7 years) while those on LIIS had a mean of 28.2 years (SD 4.7 years). The mean weight for the patients in LIIS group was slightly higher (81.9 kg) though the difference was not significant (p=0.106). The average mean age of the 66 participants was 28.8 years while the mean weight was 78.85Kg these findings slightly varied with those of Mwenda et al (19) where they had a slightly lower mean age of 27 years & lower mean weight of 74.5Kg. The main indication for CS was a previous scar followed by non-reassuring foetal status due to meconium-stained liquor noted on examination, this is similar to the results found by Mwenda et al.

5.1.2 Pain Scores

There was no significant difference in the immediate post-operative pain scores, as most patients had no pain & this is attributed to the spinal anaesthesia effects. The incidence of pain was similar between the two groups from 0 hours to 24 hours post operatively with majority of the patients reporting no pain.

Both the US guided IINB and LIIS reduced significantly the pain scores in the immediate 24hr postoperative period. The differences in pain scores between the study groups were not statistically significant (P > 0.05). This is in keeping with a study done by Ganta et al where there were no differences in pain scores and analgesic requirements between the IINB versus wound infiltration (90).

5.1.3 Pain Scores at Rest and On Activity

Pain scores at rest were comparable between the two groups with patient reporting no pain or mild pain with no patient in the IINB reporting moderate pain at rest & only 1 patient in the LIIS complained of moderate pain, no severe pain was reported in either group.

A higher proportion 15.2% of the LIIS group reported moderate pain on activity at 6 hours post operatively compared to 6.1% of the IINB group (p=0.328) this was not statistically but clinically significant as lower pain scores in the IINB group offers more maternal comfort and satisfaction; as well as avoids the negative impacts of persistent post-surgical pain. In comparison to the study done by Krishnegowda et al (80) the IINB had a lower VAS score in the post cesarean delivery patients compared to local infiltration and placebo groups.

The low pain scores (participants mainly reported no pain or mild pain) observed all through the first 24 hours could be attributable to the addition of the adjuvants dexamethasone and adrenaline onto the bupivacaine hence prolonging its effects.

5.1.4 Rescue Analgesia & Ambulation Time

Time to first rescue analgesia need was longer in the IINB as compared to the LIIS group. The IINB group had a longer duration of postoperative pain relief of 6.4 hours versus 6.1 hours in LIIS group. The time to ambulation was shorter for the IINB group compared to the LIIS group evidenced by the IINB ambulating earlier post CS. IINB group ambulated earlier post CS with a median time of 240 minutes compared to 300 minutes in LIIS group.

These were not statistically but clinically significant as patients having a longer duration of post-operative relief will be able to ambulate earlier. This facilitates early wound healing & reduces risk of DVT. This is similar to the study done by Krishnegowda et al (80) the IINB had a longer duration of postoperative pain relief, lower VAS scores and reduced analgesic requirements post CS delivery compared to local infiltration and placebo.

The Pfannenstiel incision is the most frequently used incision for CS. Adequate pain management in the mother is crucial for the optimal care of the newborn. The lower segment CS is carried out through the Pfannenstiel incision, situated on the dermatomes L1-L2. The

sensory nerves responsible for these dermatomes are the IIIH nerves. Blocking these nerves effectively alleviates somatic pain from the Pfannenstiel incision as evidenced by lower pain scores, longer TFA need and early ambulation in the IINB group. Throughout the initial 24-hour period, the LIIS group also exhibited consistently low pain scores, as evident in the study findings. Local anesthetic infiltration is a simple and safe approach for postoperative pain management that blocks the sensory nerves surrounding the incision site. Utilizing this method is an augmentation to the multimodal approaches undertaken to ensure immediate postoperative pain is adequately managed.

5.2 Conclusions

Both US guided IINB & LIIS yielded good pain control evidenced by the low pain scores. The addition of the adjuvants dexamethasone & adrenaline led to a prolongation of analgesic effects as low pain scores were observed all through the first 24 hours. Though not statistically significant possibly attributable to a small sample size; lower pain scores, longer duration to request of rescue analgesia & early ambulation were all noticed in the IINB group compared to the LIIS group and this is clinically significant. A larger sample size projecting such results will likely achieve statistically significant differences. No complications were noted in the study therefore, both modalities are safe to use and the ultrasound guidance clearly gave a good safety margin to the use of the IINB.

5.3 Recommendations

Multimodal approaches should be practiced when safe & feasible at all times to enhance better maternal & infant outcomes. Routine use of the ultrasound guided IINB with bupivacaine is highly encouraged; lower pain scores, longer TFA need and early ambulation were noted in the IINB group in this study. Adjuvants should be added to the local anesthetic to prolong the analgesic effects. Availing an ultrasound in maternity theatre is highly recommended as it will provide accessibility at all times for the performance of peripheral nerve blocks for CS pain control and a venue for learning as KNH is a teaching hospital. If the performance of an US guided peripheral nerve block is not possible, then LIIS can be utilized as it offers comparably good analgesia as evidenced by this study. The anesthesia team should be involved in the post-operative pain management prescriptions in the treatment sheets for standardization of care as this can aid in future developments of analgesia protocols. CT studies on different multimodal approaches with larger sample sizes and longer duration of follow up are highly recommended.

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APPENDICIS

Appendix I: Data Collection Questionnaire

Study Title: COMPARISON OF ULTRASOUND GUIDED BILATERAL ILIOINGUINAL AND ILIOHYPOGASTRIC NERVE BLOCKS VERSUS LOCAL INFILTRATION FOR CESAREAN SECTION UNDER SPINAL ANESTHESIA

a) Study Serial Number ……

1. Social demographic characteristics

- Age…..
- Weight…….
- Parity…… Number of previous scar……..
- Language • English • Swahili • Other
- Level of education……...

2. Indication for the C/S

- Non Reassuring Fetal Status •
- Severe Pre-eclampsia •
- Ante-partum hemorrhage •
- Prolonged/ poor progress of labor •
- Obstructed labor •
- Previous scar •
- Others……

3. Type of C/S: Elective • Emergency •

4. Duration of surgery

- Less than 1 hour •
- 1-2 hours •

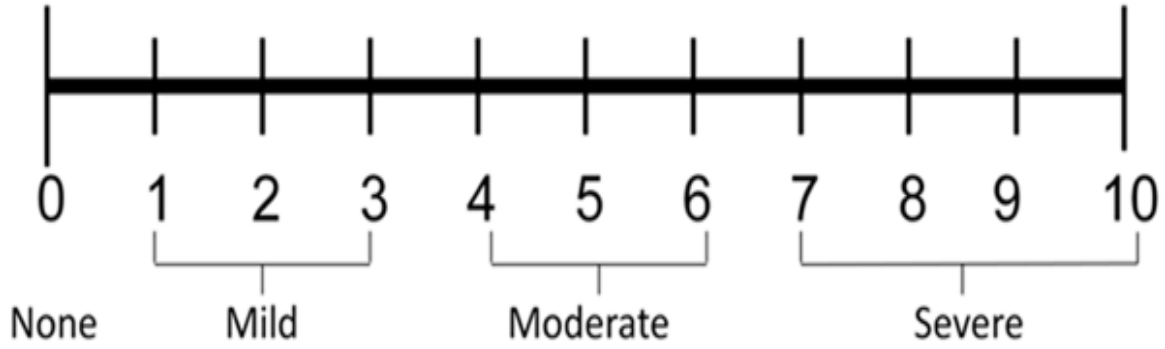
5. Intraoperative analgesia: select all that apply

Drug	Dose	Route	Time
Morphine			
Tramadol			
Dexketoprofen			
Diclofenac			
Acetaminophen			

None			

6. Intra-operative complications/Events.

- Hypotension •
- Nausea /vomiting •
- Bleeding secondary to tears •
- Bleeding secondary to uterine atony •
- Pain score •



- Drug reactions •
- Other……..

7. Numeric rating scale at 0, 6, 12, 18 and 24 hours.

Time	**NRS Score at rest**	**NRS score on movement**	**Intervention**
At PACU O hours			
At 6 hours post op			
At 12 hours post op			
At 18 hours post op			
At 24 hours post op			

8. Post operative analgesia order for the 1st 24 hours

Drug	**Dose**	**Route**	**Time**	**Number of doses in 24hrs**
Morphine				
Tramadol				
Dexketoprofen				
Diclofenac				
Acetaminophen				

9. Time to first rescue analgesia with morphine

- No rescue analgesic needed •
- 30 minutes to 1 hour after section •
- 1-2 hours after section •
- 2-3 hours after section •
- 3-4 hours after section •
- 4-6 hours after section •
- 6-8 hours after section •
- 8-12 hours after section •

10. After how long were you able to ambulate……..?

11. Complications from the nerve block or local infiltration……..

Bowel hematoma •

Bowel perforation •

LAST •

Others**……**

Appendix II: Informed Consent Form (Participant explanation in English)

I, Zulal Hassan Subea undertaking my master's program in Anaesthesia am carrying out my thesis, a requirement before attaining my Master's Degree and would like to explain to you what the research entails.

Study title

COMPARISON OF ULTRASOUND GUIDED BILATERAL ILIOINGUINAL AND ILIOHYPOGASTRIC NERVE BLOCKS VERSUS LOCAL INFILTRATION FOR CESAREAN SECTION UNDER SPINAL ANESTHESIA

Purpose of research

The purpose of this research is to find out: What is superior between two methods of pain control. One method will be to inject a drug around your incision wound so as to block the nerves of that area, it will be termed LIIS (local infiltration of incision site) arm the other method will be to inject a drug on either side of your abdomen using ultrasound guidance to block two nerves; the ilioinguinal iliohypogastric nerves, it will be termed IINB (Ilioinguinal Iliohypogastric Nerve block). This study aims to see which method will offer better pain relief to mothers after undergoing caesarean section in the first 24hours at Kenyatta National Hospital.

Research intervention

This is study entails one group receiving an injection on both sides of the abdominal wall to target two nerves by the name ilioinguinal and iliohypogastric that will be located using the ultrasound and the other group receiving an injection at the wound incision to block the nerves of that area. The drugs going to be used are bupivacaine, dexamethasone, and adrenalin. You may fall in either groups of the study and you will be informed after 24 hours which arm you fell into so as not to make you biased during your pain assessment, and as it will be after your surgery it will not affect your outcome or the outcome of the baby. Since you will still be under spinal anesthesia there will be no pain during the procedure. Both methods are expected to give you adequate pain relief and you will continue to receive pain management drugs based on your primary doctor and upon your request. Thereafter, we will follow you up for the next 24 hours to assess your pain score using the Numeric rating scale (NRS) this will be explained to you, the first time you needed additional drugs to relieve pain and the time you managed to get out of bed and move around.

Voluntary participation

Your participation in this research is solely voluntary. You are free to with draw from the study at any time with no consequences. No extra charges will be incurred upon your participation.

Duration

The study will take duration of about four months involving data collection, analysis and presentation. Your participation will be the first 24 hours after your caesarean section.

Risks

The two procedures rarely cause serious adverse effects unless the local anaesthetic (bupivacaine) is mistakenly injected in a blood vessel and to avoid this, confirmation that no blood vessel is breached will be done before injecting you. For the IINB group ultrasound guidance will be used to avoid injury to any surrounding structures. The dose going to be used will not surpass the maximum safe dose hence minimize the risk of adverse effects. Any complications arising will be managed promptly as per current guidelines to ensure your safety at all times.

Benefits

The patient will have a pain free post-operative period enabling her to carry out self-care activities and take care of the new born needs. There will be no monetary gain from participating in this study.

Confidentiality

Any information that I will collect from you in this research will be confidential. The information will have a serial number assigned to you instead of your name.

Who to contact

If you have any queries or need any clarification during or after the study contact

Principal Investigator:

Dr Zulal Hassan Subea; Cell number 0711318001, Email: zulalsaid@gmail.com

Supervisor: Dr Antony Gatheru; Cell number 0721654806

The secretary: KNH/UON Ethics and Review committee

Tel: 2726300 Ext: 44102

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

Appendix III: Informed Consent Form (Kielezo cha utafiti kwa washiriki kwa lugha ya Kiswahili)

Jina langu ni Zulal Hassan Subea, ninafanya utafiti wa shahada ya juu katika anaesthesia kwenye Chuo Kikuu cha Nairobi.

Anwani ya Utafiti

COMPARISON OF ULTRASOUND GUIDED BILATERAL ILIOINGUINAL AND ILIOHYPOGASTRIC NERVE BLOCKS VERSUS LOCAL INFILTRATION FOR CESAREAN SECTION UNDER SPINAL ANESTHESIA

Lengo la Utafiti

Utafiti huu unalenga kuchunguza mbinu bora zaidi ya kuweza kupunguza au kuondoa uchungu unaosababishwa baada ya upasuaji wa kuzaa. Utafiti huu utalinganisha mbinu mbili zinazotumika kuondosha uchungu baada ya upasuaji wa kuzaa, mbinu moja ni kulenga kugandisha mishipa ya ilioinguinal iliohypogastric na mbinu ya pili ni kugandisha mishipa iliozunguka kidonda cha upasuaji.

Mbinu ya Utafiti

Huu ni utafiti ambao utagawanya wagonjwa kwa makundi mawili, kundi moja litapata dawa ya kugandisha mishipa ya ilioinguinal iliohypogastric ambayo itadungwa kwa pande mbili za misuli ya tumbo kutumia picha ya Ultrasound ili kugandisha mishipa hio. Mishipa hii inapitisha hisia ya uchungu baada ya upasuaji kwa misuli na ngozi ya tumbo hapo karibu na kidonda cha upasuaji. Mbinu ya pili ni kudunga dawa kwa ngozi na tabaka zilio chini yake ziliozunguka kidonda cha upasuaji ili kugandisha mishipa za kubeba hisia za uchungu zilioko hapo.. Dawa zitakazotumika ni bupivacaine, dexamethasone, na adrenalin. Unaweza kuweka katika kundi moja wapo katika hizo mbili. Kundi zote mbili zinapatiana nafuu ya kupungua uchungu.

Utafiti huu utafanyiwa baada ya upasuaji wako kwa hio hutocheleweshewa huo upasuaji wala hautokudhuru mtoto wako. Bado utakuwa uko na ganzi uliodungwa wakati wa upasuaji kwa hio hutaskia uchungu utakapodungwa dawa hizo za utafiti. Utaendelea kupata matibabu yako ya kuondosha uchungu kama kawaida kulingana na daktari wako na wewe mwenyewe unapohitaji dawa. Baada ya hapo tutakufwatilia kwa masaa 24 kukuuliza kiasi chako cha uchungu kutumia kifaa cha Numeric rating scale (NRS) ambayo utaeleewa namna ya kuitumia, pia tutakuuliza muda wa kwanza uliohitaji dawa za kuondosha uchungu na muda ulioweza kuanza kutembea.

Usajili wa hiari

Kusajiliwa kwa utafiti huu ni kwa hiari na ridhaa yako na uko huru kujitoa kwa usajili huu wakati wowote ule. Hakuna malipo utakayo lipa zaidi ya malipo ya hospitali. Hakuna pesa utakayo pewa kwa kushiriki.

Muda wa Utafiti

Utafiti utaendelea kwa muda wa miezi minne mpaka kutakapotolewa matokeo wa huo utafiti. Ushirikiano wako ni kwa muda wa masaa 24 peke yake na ni muda ambao bado utakuwa kwa hospitali.

Madhara ya Utafiti

Dawa hio ya Bupivacaine inaweza kusababisha madhara ya kiafya kama itadungwa kwa mshipa wa damu, kwa hio kabla ya kudunga tutahakikisha hatuko kwa mshipa wa damu, pia hio dawa itatumika kwa kiwango kisichofikia kiwango cha ziada chenye maafa, na kwa kundi litakayodungwa kwa tumbo kwenye mishipa ya ilioinguinal iliohypogastric kifaa cha picha cha ultrasound kitahakikisha viungo vya karibu na hapo hazitodungwa wala kuathirika. Madhara yoyote yatakayotokea yatatibiwa kwa haraka ili usalama wako udumishwe.

Faida ya Utafiti

Kama mgonjwa wa upasuaji wa kuzaa utakuwa hauna uchungu baada ya upasuaji, hii itakuwezesha kujitegemea kutekeleza mahitaji yako wewe mwenyewe na ya mtoto.

Usiri katika Utafiti

Majina yako hayatatumika katika utafiti na usiri mkubwa utatumiwa katika utafiti huu kwa kutumia nambari za kujitambulisha wala majina yako hayatotumika.

Maswali yoyte:

Kama mgonjwa utahitajika kuelewa kuhusu utafiti na kutia sahihi kubalio ili wewe usajiliwe katika utafiti huu. Baada ya utafiti, uchambuzi wa takwimu utafanywa. Habari itachapishwa katika kitabu kitkachowekwa kwa maktaba ya Chuo Kikuu Cha Nairobi. Sasa nitakupa nafasi ya kuuliza masawali yoyote uliyo nayo kuhusu utafiti huu. Ikiwa umekubali kushiriki katika utafiti huu, tia sahihi yako kwenye nafasi iliyotolewa.

Maswali yoyote kuhusu utafiti huu yanaweza kuelekezwa kwa:

Mtafiti mkuu: Zulal Hassan Subea; Nambari ya 0711318001, barua pepe zulalsaid@gmail.com

Msimamizi: Dkt. A. Gatheru; Nambari ya simu 0721654806, Dkt. W. Ng'ang'a Nambari ya simu 0722350452.

KNH-ERC, Hospitali ya Rufaa ya Kenyatta, Sanduku la Posta 20723, Nairobi.

Simu: 2726300-9

Utafiti huu umeidhinishwa na Kamati ya ERC ya hospitali Kuu ya Kenyatta na Chuo Kikuu cha Nairobi, nambari _____

Appendix IV: Consent Form (English)

I …….…….……hereby give consent to participate in a study to compare what is superior between bilateral ilioinguinal iliohypogastric nerve block (IINB) versus local infiltration of the incision site (LIIS) using 0.25% bupivacaine, dexamethasone and adrenalin for post-operative pain relief after caesarean section in the first 24hours at Kenyatta National Hospital.

I confirm that I have read the cover letter that outlines the nature of the study and understand that confidentiality will be maintained. In case of any questions regarding the study, I can contact the primary researcher Zulal Hassan on 0711318001 or at zulalsaid@gmail.com for any clarifications and further information.
I have been informed that the techniques and interventions used in the study are safe and will not compromise the patient in any way.

I have the freedom to decline or withdraw to participate in the study at any time.
Name……
Signed…….. Date……

I confirm that I have explained and given the participant an opportunity to ask questions about the study and the consent was obtained freely.
Name……..
Signed…… Date……..

Appendix V: Consent Form (Kiswahili)

Fomu ya Idhini

Mimi…….……...…….……..nimekubali kushiriki katika utafiti wa: What is superior between bilateral ilioinguinal iliohypogastric nerve block (IINB) versus local infiltration of the incision site (LIIS) using 0.25% bupivacaine, dexamethasone and adrenalin for post-operative pain relief after caesarean section in the first 24hours at Kenyatta National Hospital.

Nimesoma umuhimu wa utafiti huu, na ninaelewa ya kwamba utafiti utafanyika bila madhara yoyote kwa mgonjwa.

Nina uhuru wa kujiuzulu kutoka kwa utafiti huu wakati wowote ule.

Jina…….

Sahihi……. Tarehe…….

Ninathibitisha ya kwamba nimemweleza mgonjwa Kwa ukamilifu kuhusu utafiti huu.

Jina……..

Sahihi…….. Tarehe……..

Appendix VI: Spinal Anesthesia Protocol KNH Maternity Theatre

1. Know the indications & contra-indications
2. Inform the patient what you wish to do and have their cooperation
3. Inform the rest of the team in theatre so you can be assisted appropriately
4. Insert a good gauge I/V cannula (20 or larger)
5. Pre-load with ½ -1L N/saline / Hartman's over 30- 60mins
6. Install your monitors (pulse, respiration, SPO2, BP, and ECG) and take baseline readings
7. Position the patient either sitting or lateral knee-chest. Make the patient comfortable
8. Open your Spinal Tray & clean the site & drape.

Spinal Tray should contain:-

a. Sterile towels for draping the patient
b. 2 gulley pots for holding cleaning solutions
c. Appropriate spinal needle (with introducer where required)
d. 2 syringes & Needles
e. 5ml syringe for infiltration of L.A to the site
f. 2ml syringe for administering the spinal medication
g. Sterile gauze pads for cleaning & dressing

9. Reconfirm the position of the patient (knee chest)
10. Identify the site: mid-line L3-4/ 4-5 & administer 3ml of 1% lignocaine using a gauge 21 needle to maximum depth. Withdraw the needle as you continue to administer L.A and raise a skin wheal.
11. Give 1-2 minutes for the L.A to take effect as you re-assure & position patient (if administered well, this usually covers one vertebra above & below, should you need to alter position of lumbar puncture)
12. While waiting for L.A to take effect, prepare your appropriate drug. You must have decided whether using plain or heavy L.A

a) Remember Heavy L.A is position dependent. The patient must be appropriately positioned after injection to allow desired distribution.

b) Bupivacaine is usually 0.5% concentration. The highest volume in tall patients will be 4 ml (20mg). Most patients will require between 7.5mg (1.5mls) to 15 mg (3ml).

c) Obstetric patients are more sensitive and will require between 10mg (2ml) to 12.5mg (2.5ml). Aim for a block up to T6. Test and record level of block.

d) Additive: 25mcg Fentanyl (0.5ml) is a useful additive to prevent the discomfort of gut handling during CS etc. This must still make up the total volume of 2-2.5 ml of drug injected into the spinal canal. Other drugs have been used as additives but its best to avoid them unless you have been trained to use them. The haphazard use of additives into the CSF may have disastrous results.

e) Remember for CS the volume & position is critical to achieve a good or disastrous spinal block. Aim for a block up to T6.

13. Confirm the L.A has taken effect and note level/site for the block.

Insert the spinal needle. Usually there is a sudden give when the needle goes through the dura. Withdraw the stylet and check for CSF flow. Do not allow unnecessary drainage of CSF. Use the stylet to stop the flow temporarily, if you cannot administer the spinal drug immediately.

14. Administer the drug, dress the puncture site, and position the patient appropriately to allow planned distribution of drugs. Rapid positioning after administration is critical if the drug used is hyperbaric (heavy).

15. Start your post-spinal monitoring & make adjustments accordingly. It is recommended to repeat BP readings at 1 minute intervals. You will need to respond rapidly to the initial changes in pulse & BP. Ask the patient to inform you immediately if nausea occurs. Nausea in spinal anaesthesia is most likely due to hypotension. It is an early warning sign that you must not ignore.

16. Test the level of the block. The tilt of the bed may have to be adjusted if using hyperbaric Local Anaesthetic to change drug distribution. This manipulation may only work within the first 10-20 minutes after administration of the L.A into the CSF.

17. Post-operative pain management

- € I/M Pethidine 1mg/kg 4-6 hourly for 24 hours
- € Diclofenac suppository (or equivalent) stat & 12 hourly for 48 hours then orals.
- € Follow up visit, within 24 hours.

18. Critical observation

a. Pulse – symptomatic bradycardia – Atropine 0.1 -0.6mg
b. SPO2 saturation ≤90% - Increase the O2 flow.
c. BP –symptomatic Hypotension

- € Ephedrine -5mg-10mg PRN (you may occasionally need an infusion)

- € Phenylephrine
- € Adrenaline

d. Respiration –falling respiratory rate (usually temporary)

- € Give oxygen
- € Assist with respiration briefly if required
- € Reassure

e. Total Spinal Anaesthesia

i. Convulsions /loss of consciousness
ii. Respiratory failure
iii. Cardiovascular collapse

Intubate, ventilate, cardiac massage, vasopressors, anticonvulsants till vital signs stabilize.

f. Post spinal headaches

May occur post operatively and worse on standing & relieved by lying down.

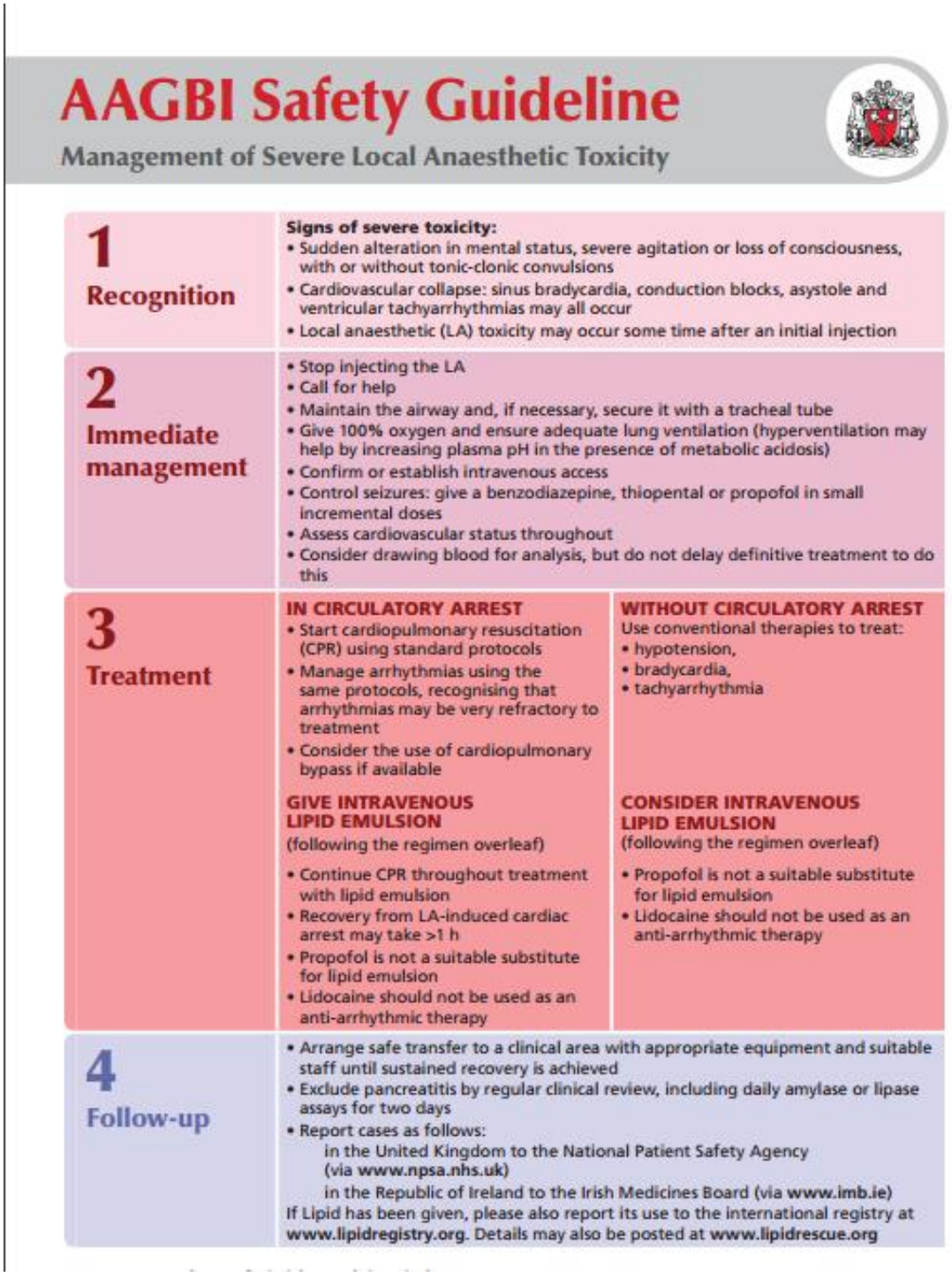
Management

i. Bed rest
ii. Plenty of fluids
iii. Non-Steroidal Anti-inflammatory Drugs (NSAIDS)
iv. Epidural blood patch as a last resort

19. post-Operatively –monitor BP ¼ hourly for 2hrs.

Positioning –make patient comfortable with pillow under the head.

Appendix VII: AAGBI Safety Guideline



AAGBI Safety Guideline

Management of Severe Local Anaesthetic Toxicity

1 Recognition

Signs of severe toxicity:

- Sudden alteration in mental status, severe agitation or loss of consciousness, with or without tonic-clonic convulsions
- Cardiovascular collapse: sinus bradycardia, conduction blocks, asystole and ventricular tachyarrhythmias may all occur
- Local anaesthetic (LA) toxicity may occur some time after an initial injection

2 Immediate management

- Stop injecting the LA
- Call for help
- Maintain the airway and, if necessary, secure it with a tracheal tube
- Give 100% oxygen and ensure adequate lung ventilation (hyperventilation may help by increasing plasma pH in the presence of metabolic acidosis)
- Confirm or establish intravenous access
- Control seizures: give a benzodiazepine, thiopental or propofol in small incremental doses
- Assess cardiovascular status throughout
- Consider drawing blood for analysis, but do not delay definitive treatment to do this

3 Treatment

IN CIRCULATORY ARREST

- Start cardiopulmonary resuscitation (CPR) using standard protocols
- Manage arrhythmias using the same protocols, recognising that arrhythmias may be very refractory to treatment
- Consider the use of cardiopulmonary bypass if available

GIVE INTRAVENOUS LIPID EMULSION
(following the regimen overleaf)

- Continue CPR throughout treatment with lipid emulsion
- Recovery from LA-induced cardiac arrest may take >1 h
- Propofol is not a suitable substitute for lipid emulsion
- Lidocaine should not be used as an anti-arrhythmic therapy

WITHOUT CIRCULATORY ARREST
Use conventional therapies to treat:

- hypotension,
- bradycardia,
- tachyarrhythmia

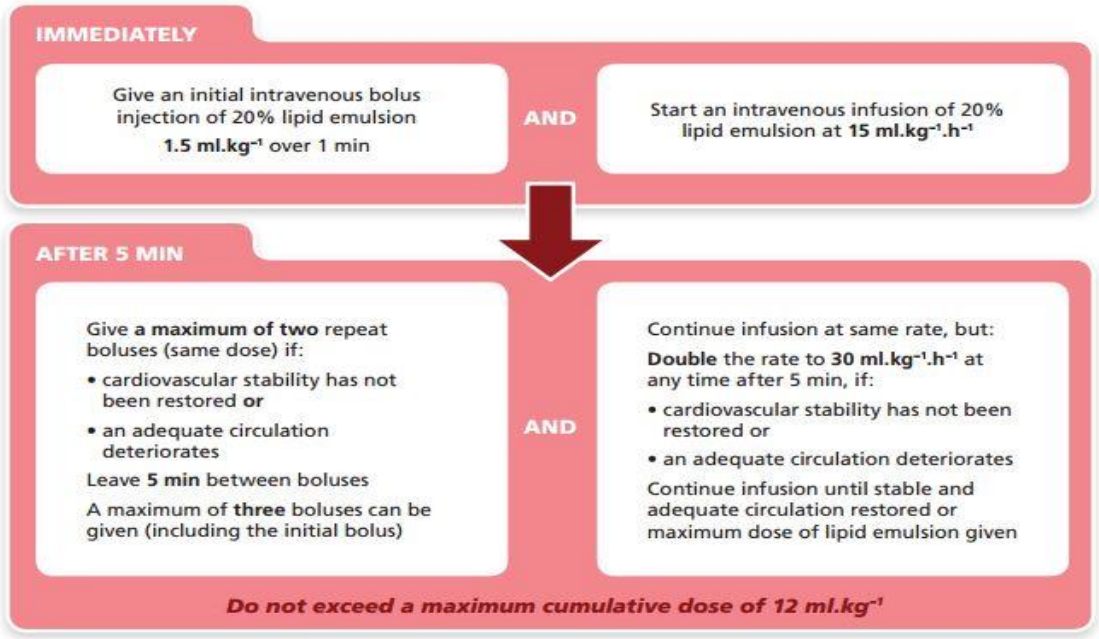
CONSIDER INTRAVENOUS LIPID EMULSION
(following the regimen overleaf)

- Propofol is not a suitable substitute for lipid emulsion
- Lidocaine should not be used as an anti-arrhythmic therapy

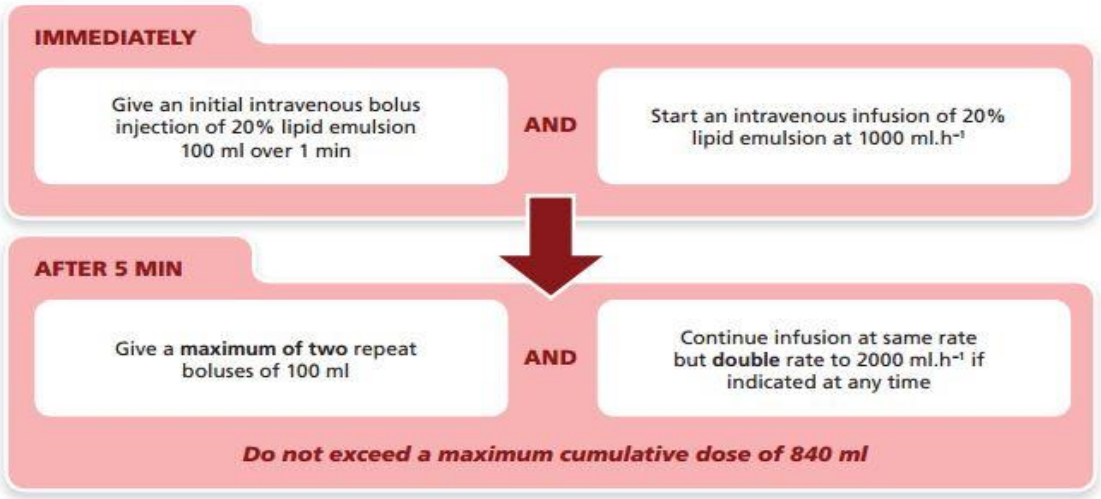
4 Follow-up

- Arrange safe transfer to a clinical area with appropriate equipment and suitable staff until sustained recovery is achieved
- Exclude pancreatitis by regular clinical review, including daily amylase or lipase assays for two days
- Report cases as follows:
  in the United Kingdom to the National Patient Safety Agency (via **www.npsa.nhs.uk**)
  in the Republic of Ireland to the Irish Medicines Board (via **www.imb.ie**)

If Lipid has been given, please also report its use to the international registry at **www.lipidregistry.org**. Details may also be posted at **www.lipidrescue.org**



An approximate dose regimen for a 70-kg patient would be as follows:



This AAGBI Safety Guideline was produced by a Working Party that comprised:
Grant Cave, Will Harrop-Griffiths (Chair), Martyn Harvey, Tim Meek, John Picard, Tim Short and Guy Weinberg.

This Safety Guideline is endorsed by the Australian and New Zealand College of Anaesthetists (ANZCA).

Appendix VIII: AAGBI Copyright Form

APPLICATION FOR PERMISSION TO COPY MATERIAL PUBLISHED BY THE ASSOCIATION OF ANAESTHETISTS

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Is there commercial gain being made from publication?	**NO**	**Approx publication date:**	**3rd April 2023**

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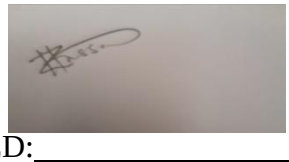

SIGNED:_____(APPLICANT)

SIGNED:_____On behalf of Association of Anaesthetists Date: 08/06/2022

Appendix IX: Certificate of Good Clinical Practice

NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Zulal Hassan Subea

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:	STATUS:
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 19 February 2022

CTN Expiration Date: 19 February 2025

Andel Frazier, Clinical Training Specialist
NIDA Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.

Appendix X: KNH/UoN-ERC Letter of Approval

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/506

14th December, 2022

Dr. Zulal Hassan Subea
Reg. No H58/34897/2019
Dept. of Anaesthesia
Faculty of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 14 DEC 2022 KNH/UON ERC P.O. Box 20723 - 00202 NAIROBI

Dear Dr. Subea,

RESEARCH PROPOSAL: COMPARISON OF ULTRASOUND GUIDED BILATERAL ILIOINGUINAL AND ILIOHYPOGASTRIC NERVE BLOCKS VERSUS LOCAL INFILTRATION FOR CAESAREAN SECTION UNDER SPINAL ANAESTHESIA (P712/09/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P712/09/2022.** The approval period is 14th December 2022 – 13th December 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept. of Anaesthesia, UoN
Supervisors: Dr. Antony Peter Gatheru, Dept. of Anaesthesia, UoN
Dr. Wilson Ng'ang'a, Dept. of Anaesthesia, KNH

Appendix XI: Certificate of Plagiarism

Comparison Of Ultrasound Guided Bilateral Ilioinguinal And Iliohypogastric Nerve Blocks Versus Local Infiltration For Post Cesarean Section Analgesia.

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