POSTOPERATIVE PAIN MANAGEMENT AFTER INVASIVE LOWER LIMB ORTHOPAEDIC SURGERY AT KENYATTA NATIONAL HOSPITAL: A PROSPECTIVE STUDY

By

Dr. Nyambegera Zacharia Bosire

H58/6960/2017

Email Address: nyambegera3@gmail.com

Mobile Number: +254 728247911

A Research Proposal Submitted to the Department of Orthopedic Surgery, School of Medicine, University of Nairobi in partial fulfillment for the Award of the Degree of Master of Medicine (Orthopedics)

April 2022

DECLARATION

Signed..... Date..... 2/8/2022

I, Dr. Zacharia Bosire Nyambegera hereby declare that this dissertation is my original work and has not been presented as at any other university.

This dissertation has been submitted for examination with our approval as university supervisors.

Signature..... Date..... 4/8/2022

DR J.C MWANGI

Lecturer, department of surgery University of Nairobi, Orthopedic Surgeon, Division of Orthopedic Surgery, Kenyatta National Hospital

P. O. Box 19076 – 00202

NAIROBI

Signature..... Date..... 2/8/2022

DR EZEKIEL OBURU

Lecturer, Department of Surgery University of Nairobi, Orthopedic Surgeon, Division of Orthopedic Surgery, Kenyatta National Hospital

P. O. Box 19076 – 00202

NAIROBI

Departmental Approval

This is to certify that this proposal is the original work of Dr. Nyambegera Zacharia Bosire, a student of Master of Medicine in Orthopedic Surgery at the University of Nairobi. This research will be carried out at Kenyatta National Hospital.

Signature..... Date...22nd Aug 2022.

DR. VINCENT MUOKI MUTISO,
Senior lecturer, Department of Orthopedic Surgery, University of Nairobi,
Orthopedic Surgeon, Division of Orthopedic Surgery, Kenyatta National Hospital.
Email address: mutiso@uonbi.ac.ke

iii

Dedication

This book has been dedicated to my family for the unending support and love in my career and life.

Acknowledgements

Gratitude to:

My Supervisors: DR. J.C Mwangi, Dr. Ezekiel Oburu and Dr. Timothy Mwiti for the guidance, inspiration and support while conducting this study.

Dr. Timothy Mwiti of the department of anaesthesia for accepting to render a helping hand in conducting this study

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee for approving this study and accepting to conduct this study of their patients

Fred Nyaaga for conducting the data collection

Wycliffe Oyieko for analyzing data for this study

To many others who contributed in whatever way, I am greatly grateful

ABBREVIATIONS

Aβ	Alpha Beta
Aδ	Alpha Delta
APSPOQ	American Pain Society Patient Outcome Questionnaire
BMI	Body Mass Index
cAMP	Cyclic Adenosine Monophosphate
CNS	Central Nervous System
GABA	Gamma Aminobutyric Acid
IPOQ	International Pain Outcome Questionnaire
KNH	Kenyatta National Hospital
KNH-UON-ERC	Kenyatta-National Hospital University of Nairobi Ethics and Research Committee
MER	Mixed Effect Regression
MUAC	Mid Upper Arm Circumference
NA	Noradrenaline
NRM	Nucleus Raphe Magnus
NRS	Numerical Rating Scale
NSAID	Non Steroidal Anti-inflammatory drugs
OR	Operating Room
PACU	Post Anaesthetic Care Unit
PAG	Periaqueductal Grey Matter

PRN	Pro re Nata (As needed)
REDCAP	Research Electronic Data Capture
SPSS	Statistical Package for the Social Sciences
TENS	Transcutaneous Electrical Nerve Stimulation
5-HT	Serotonin

LIST OF FIGURES

LIST OF TABLES

TABLE OF CONTENTS

ABSTRACT

Background Postoperative pain management forms an integral part of healing and rehabilitation following orthopedic surgery procedures. Adequate pain control prevents the occurrence of postoperative complications and chronic pain. These pose a big challenge to clinicians. It has been shown that postoperative pain is largely undertreated due to several factors, including not having well organized pain management protocols. This study assessed postoperative pain management following orthopedic surgical procedures in Kenyatta National Hospital, that was shown to remain undermanaged.

Study Objective: To assess the adequacy of postoperative pain management following orthopedic surgery procedures.

Study Design: This was a prospective study,

Study procedure: This study was conducted on patients scheduled for an invasive lower limb orthopedic surgery and entailed collection of data preoperatively and at 0, 6, 12 and 24 hours postoperatively. The International Pain Outcome Questionnaire (IPOQ) was used for data collection with evaluation of additional covariates influencing pain control following orthopedic surgery procedures. Patients aged between 18 and 65 years who are scheduled for an invasive lower limb orthopedic surgery were recruited into the study. Convenient sampling was used as all patients stood an equal chance for recruitment.

Data Processing: Descriptive data was analyzed using SPSS® version 24 and presented as central tendencies (means, medians and percentages). The inferential results was then presented in details using simple charts, tables, and diagrams.

Utility of the study: The study will help identify gaps in postoperative pain control following orthopedic surgeries and possibly influence development of a postoperative pain management protocol.

Study Time: The study was conducted between March 2022 and May 2022.

CHAPTER ONE: INTRODUCTION

The international association of study of pain defines pain as “An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.” Pain is broadly classified as being either acute or chronic. It can also be classified based on the predominant mechanism as either nociceptive or neuropathic. Pain can be either somatic or visceral.

Since the Declaration of Montreal, access to pain management is now considered a human right (1) (2) (3). Poorly managed post-operative pain has been linked to increased risk of several postoperative complications including; (see figure 1 below). Immunological and neural changes associated with sub-optimally treated acute pain maylead to occurrence of chronic pain (4).

Development of chronic pain is a feared complication of acute pain. It can display symptoms such as anorexia, impaired sleep, impaired immunity and reduced concentration and adversely affect an individual’s daily work. Patients with chronic pain also go through psychosocial torment as they depend on caregivers and often experience social isolation. They are also four times likely to have depression compared to patients without pain. Chronic pain limits ambulation and rehabilitation following surgery leading to stiffness and slowed recovery that then increases the cost of healthcare. It is also major reason for repeated clinical visits that can be daunting to both the clinician and the patient (5) (6,7).

Poorly managed postoperative pain has been linked to increased disease morbidity, increased need and duration of opioid use, impaired functional capacity and quality of life, delay in recovery and resultant increase in cost of healthcare (8). More effective pain management modalities need to be used to prevent progression to chronic pain (7).

Most patients experience moderate and severe pain scores following orthopedic operations. It was reported to be 41%-45% in China, 80-86% in United States of America and up to 73% in Ethiopia. This is due to poor and inconsistent assessment of pain (9).

A study conducted in Ethiopia in 2019 on assessment of quality of postoperative pain management found a high prevalence of moderate to severe pain following surgery with a resultant significant interference with function like mobility. The longitudinal prospective study quantified moderate and severe postoperative pain using the IPOQ tool and adequacy of treatment using the pain management index (10).

This study aims at assessing the effectiveness of post-operative pain control following orthopedic surgical procedures. The IPOQ tool will be used for data collection with assessment of covariates that have been shown to influence postoperative pain. The IPOQ tool is an ideal tool for assessment of postoperative pain and improvement of care that has demonstrated a good psychometric quality (11). It will bring out any gaps in pain control and areas to improve on in postoperative pain management in the orthopedic unit at KNH.

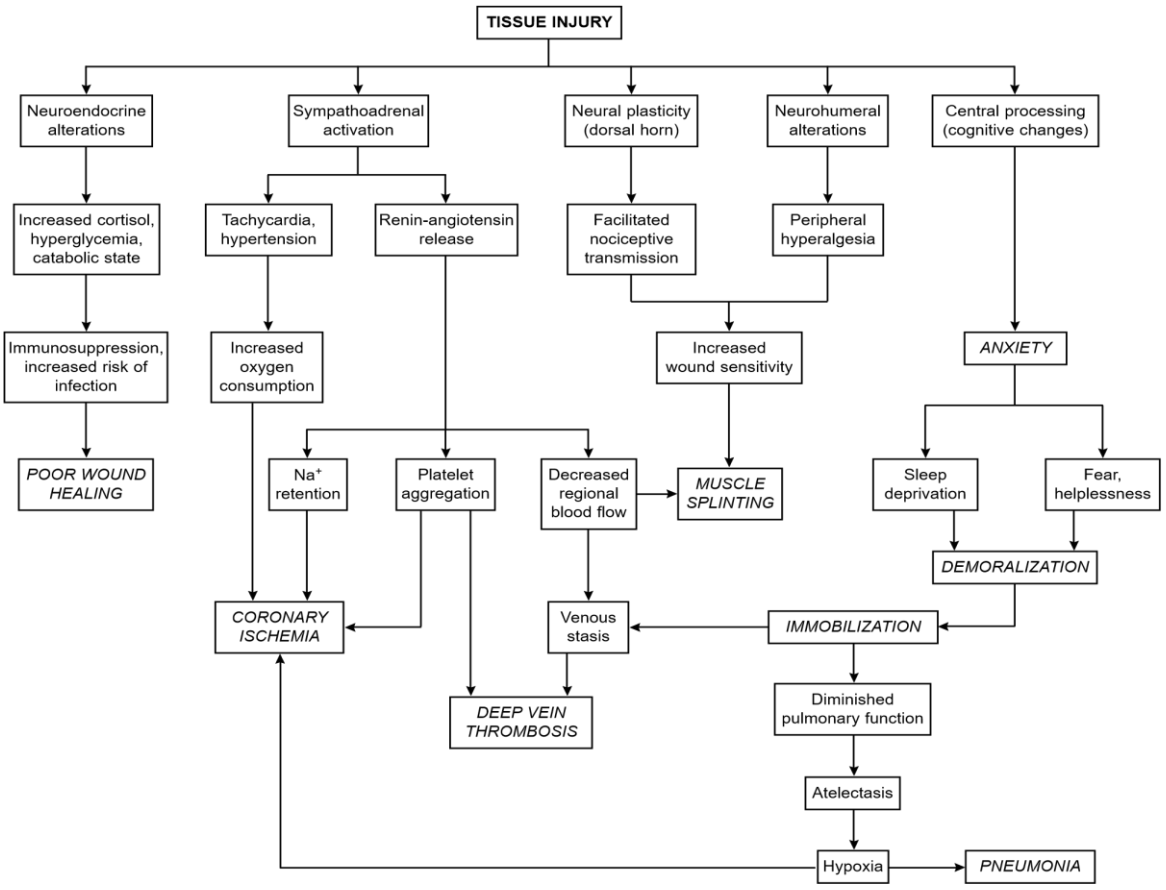


Figure 1: Cognitive and pathophysiologic responses associated with surgical trauma and their effect on key target organs

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Pain is a subjective experience with two complementary aspects- physical perception of pain at a particular body part and a psychological and behavioral response towards relieving the pain (12). Pain can be classified as acute or chronic. Acute pain is caused by disease or tissue injury, is associated with muscle spasms, sympathetic activity and is usually self-limiting. Acute pain serves a useful purpose in tissue healing and elimination of the causal injury. Chronic pain on the contrary is usually considered a disease state. It is brought about by protraction of the healing time, has no recognizable end point and serves no important biological importance (7,13). Clinicians should employ the use of the pain relief modalities that have improved over time (as will be illustrated in this chapter) bearing in mind the physiology.

2.2 Pain Pathways

Pain perception (nociception) entails four aspects- transduction, transmission, modulation and perception. Transduction is the process by which tissue damaging stimuli is converted into an action potential. Transmission refers to the relaying of the stimuli to the brain region responsible for the perception. Modulation is the regulation of the signal to either reduce or enhance the transmission of stimuli and perception entails the awareness of the stimuli (14).

2.2.1 Transduction

Three commonly known noxious stimuli that activate pain receptors (nociceptors) are: mechanical (pressure and pinch), heat and chemical. Nociceptors are unmyelinated free nerve endings that are small and scattered in the body. There are two types of nociceptors:High-threshold mechanoreceptors that respond to mechanical deformation

and polymodal nociceptors that respond to chemical substances released when there is tissue damage as listed below(14,15)

Table 1: Sources of pain neurotransmitters

SUBSTANCE	SOURCE
Potassium	Damaged cells
Hydrogen ions (Protons)	Damaged cells
Histamine	Mast cells
Serotonin	Platelets
Bradykinins	Enzymatic reaction form damaged cells
Prostaglandins	Enzymatic reaction form damaged cells
Leukotrienes	Enzymatic reaction form damaged cells
Substance P	Primary nerve endings

These substances bathe the free nerve endings and excite an action potential relayed as a pain signal by the afferent nerve fibers (free nerve endings with the nucleus at the dorsal root ganglion) to the second order neurons found in the spinal cord. Nociceptors can also be classified as:

- Slow conducting, narrow diameter unmyelinated neurons. These are C Fibers that conduct pain slowly at speeds of 2m/sec (7.2 km/hr) and respond to thermal, chemical and mechanical stimuli.
- Fast conducting wide diameter partially myelinated neurons, These are the Aδ fibers that respond to mechanical and mechano-thermal stimuli.

This explains the two phases of pain sensation- a fast sharp well localized (epicritic) pain followed by a slow dull long lasting (protopathic) pain. Repeated stimulation of these neurons lower the pain threshold, and act as a means to causing chronic pain. (7) (14) (15)

2.2.2 Pain Transmission

The Primary afferent neuron (first order neuron) has its cell body in the dorsal root ganglion. They synapse with the second order neuron at the dorsal horn of the spinal cord and use polypeptides including substance P, somatostatins and amines such as aspartic acid and glutamic acid as the neurotransmitters at the synapse. Although pain fibers terminate at the dorsal horn, their route thereafter varies. Most pain fibers enter the dorsal horn at the ventrolateral segments and travel juxta-lateral to the large fibers myelinated Aβ fibers that respond to the non-painful vibration and light touch. 30% of C fibers however enter the spinal cord through the ventral route and may divide into the ascending and descending channels that enter the dorsal root one or two segments above or below the segment of origin. (14) (7)

The dorsal root is divided into laminae (Rexed laminae) that have connections with each other. Lamina I is referred to as the marginal zone and lamina II as the substancia gelatinosa. C fibers terminate in lamina II and Aδ fibers terminate in lamina I and V. Aβ fibers (that carry light touch and vibration) enter the cord medial to the dorsal horn and pass without synapsing at the dorsal columns. They give off several collaterals which terminate in several laminae (III-V) and also synapse directly with terminal of the C unmyelinated fibers in lamina II. Laminae II and V serve a role in modulation. (16)

The second order neurons decussate and ascend to the higher center via the contralateral spinothalamic and spinoreticular tracts. At the Thalamic level, pain neurons terminate at two sites- the ventro-caudal and medial thalamus. The ventro-caudal portion receives direct input from the spinal tracts and sends signals to the somatosensory cortex. The medial portion receives inputs indirectly from the spinal cord and also a major input from the reticular formation in which the ascending nociceptive spinoreticular fibers terminate. The medial thalamus projects widely into areas of the forebrain such as the somatosensory cortex. Thus, the two major ascending pain pathways are the spinothalamic and spinoreticulothalamic tracts. Lesions of the ventrocaudal and somatosensory regions of the brain produce deficits in similar

fashion to lesions of the anterolateral region of the cord (spinothalamic tracts). Lesions of the medial thalamus however do not produce sensory deficits per se but the emotional and reactive aspect to pain is abolished.(14) (15) (16)

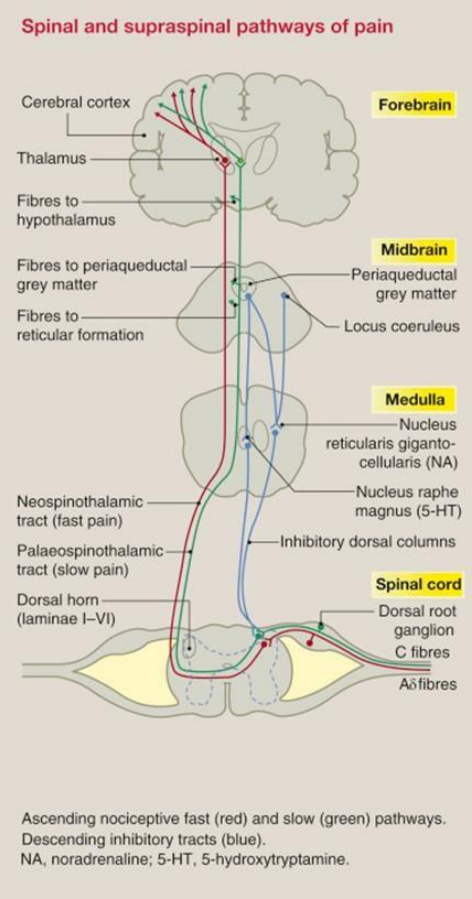


Figure 2: Spinal and Brain pathways for pain

Steeds CE, The anatomy and physiology of pain, Surgery (2016), http://dx.doi.org/10.1016/j.mpsur.2015.11.005

2.2.3 Modulation

Beecher, an anesthesiologist in World war II noticed a reduction in pain intensity in severely wounded soldiers. This implied an existence of a modulation process to pain. Three important processes have been suggested: The segmental inhibition, endogenous

opioid system and descending inhibitory tracts. Other behavioral coping mechanisms and cognitive strategies may also help in reducing pain perception. (15) (17)

Melzack and Wall in 1965 described the “Gate theory of pain control” where stimulation of the Aβ fibers, large diameter myelinated fibers through touch and vibration inhibited transmission of the impulses conducted by the C type noxious fibers at lamina II of the dorsal horn. This formed the principle of transcutaneous electrical nerve stimulation (TENS) in pain control and the reason why rubbing a body part after blunt trauma would cause relief of pain emanating from that site. (14) (15)

Opium and its derivatives such as morphine are known powerful analgesics and remains the mainstay of pain control even today. In the 1960s and 1970s, opioid receptors were found in the central nervous system especially in the periaqueductal grey matter, ventral medulla and spinal cord. (9) Endogenous analogues that bind to these receptors were discovered (encephalins, dynophins and endorphins) and are therefore referred to as the endogenous opioid system. Other compounds including inhibitory amino acids such as GABA, cholecystokinin, galanin, nitric oxide and endogenous cannabinoids are implicated in reduction of pain endogenously and others like substance P increase the pain transmission. (16) (17)

There also exist descending tracts that use serotonin and noradrenaline as neurotransmitters involved in reduction of pain transmission. Two areas in the brainstem are involved- periaqueductal grey (PAG) and nucleus raphe magnus (NRM) in the medulla. The PAG surrounds the cerebral aqueduct in the brainstem and receive inputs from the thalamus, hypothalamus, brain cortex and collateral from the spinothalamic tracts. Antinociceptor neurons from this region excites the NRM that in turn sends inhibitory pain signals to the spinal cord’s dorsal horn cells. It has been

shown that injection of morphine in the PAG produced far greater effects compared to injection in other regions of the CNS. (16)

The second inhibitory descending channels contain neurons with nucleus in the NRM and just like noradrenaline containing neurons, have axons that synapse at the Lamina II of the dorsal horn. Serotonin produced by stimulation of the NRM activates inhibitory interneurons even greater than noradrenaline, producing a great analgesic effect. Descending tracts therefore inhibit pain by directly acting on the dorsal horn cells, exciting inhibitory channels to pain and inhibition of excitatory dorsal horn cells. (15–17)

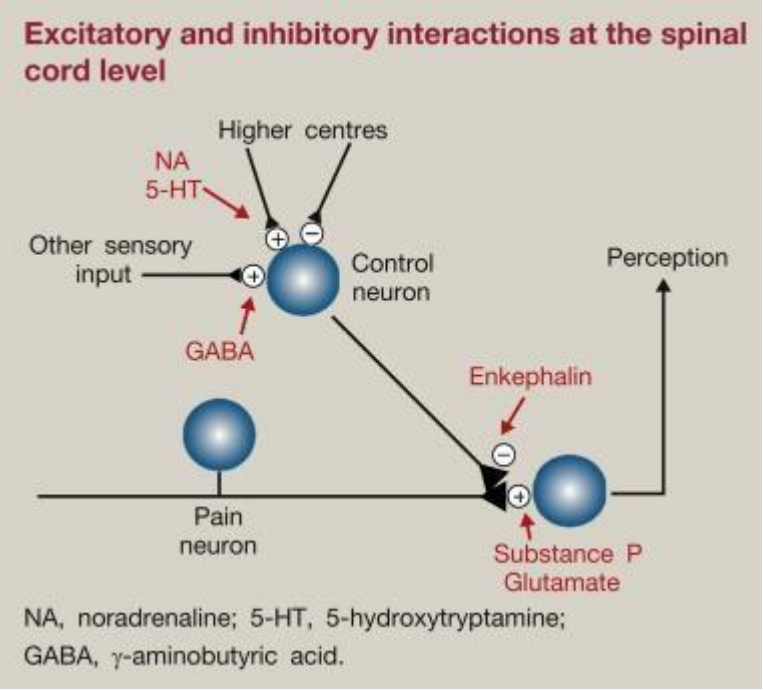


Figure 3: Central Excitatory and inhibitory pain pathways

Steeds CE, The anatomy and physiology of pain, Surgery (2016), http://dx.doi.org/10.1016/j.mpsur.2015.11.005

2.3 Referred Pain

Patients may sometimes perceive pain at different region away from the pathology. Four theories explain the occurrence of referred pain.(15) (15)

The sympathetic nervous outflow following injury or inflammation might sensitize afferent sensory neurons at the region of referred pain or lead to vasoconstriction of the vessels supplying the nerves in the region therefore causing pain sensation.

Branching of peripheral neurons might cause the body to perceive pain as emanating from the nerve branch that supply the other part of the body not involved in the disease process.

The convergence projection theory states that nociceptive inputs from visceral organs terminate at the same site with nociceptive neurons from the somatic sites (Lamina II) leading to perception of visceral pain as arising from muscles.

Convergence facilitation hypotheses states that pain neurons in the spinal cord receiving inputs from one part of the body might be amplified by signals from nociceptors of a different region. (15,18)

2.4 Physiological processes that may enhance pain and lead to chronicity

2.4.1 Sensitization

Repeated tissue damage and activation of afferent pain neurons lead to lowering of the threshold needed for pain stimulation. An innocuous stimulus that would not be enough to cause pain then becomes painful. This is illustrated by sunburn where pouring warm water on it becomes excruciatingly painful (15).

2.4.2 Complex regional pain syndrome

Complex regional pain syndrome is characterized by disproportionate pain compared to the stimulating injury that also persists past the expected time of healing. Sensory

symptoms include: allodynia (non-painful stimuli is perceived as painful), hyperalgesia (painful stimuli is disproportionately exaggerated), sudomotor (swelling and sweating) as well as vasomotor changes characterized by skin colour and temperature changes. CRPS has been further categorized into two: Type I CRPS (reflex sympathetic dystrophy and type II CRPS (causalgia). (10)

Type I (Reflex Sympathetic dystrophy) is mediated by increases sympathetic outflow beyond the time of tissue injury caused by central dysregulation of nociceptive impulses. This leads to vasoconstriction, further tissue ischemia and pain that cause further increase in sympathetic outflow to the affected region. Patients eventually develop osteopenia due to disuse atrophy, muscle atrophy and stiffness. Associated psychological effects such as depression also ensue. Type II (Causalgia) is caused by injury or trauma to the peripheral nerve leading to pain and sympathetic system activation. (15,19)

2.5 Psychosocial variables to pain

Pain is a largely a subjective experience. Perception of pain is influenced by genetic, gender, developmental, behavioral and cultural factors varying from geographical locations and ethnic groups (20). Understanding of pain therefore also requires understanding and control of other psychosocial and environmental attributes that alter pain perception. No matter how clear the source of pain is, pain must be addressed from a wider angle as environmental and emotional factors can also lead to pain.

Anxiety sensitivity (AS) is a psychopathological process characterized by exaggerated sensitivity or fear of anxiety symptoms (such as palpitations) that emanates from the belief that these symptoms will lead to psychological, somatic or physical consequences. It has been shown to influence acute and chronic pain related conditions involving musculoskeletal and other systems. AS is related to pain catastrophizing, which is defined as a heightened negative cognitive and emotional experience from an

anticipated or an actual pain stimulus. Patients with these pathopsychological conditions have been shown to have low pain threshold and increased use of analgesics. (21,22)

2.6 Predictors of poor postoperative pain control

It is prudent to preoperatively stratify patients at risk of severe postoperative pain and poor pain control. This is important in calculating and adjusting dosage of analgesics as required intraoperatively and postoperatively and deciding on the appropriate analgesic modality to use.(23)

Yang et al in a meta-analysis found nine predictors associated with negative postoperative pain control: female gender, younger age, smoking, sleeping disorders, higher BMI, preoperative anxiety, depressive disorders, use of preoperative analgesia and presence of preoperative pain. The important negative prognosticator was the sleeping difficulties and depressive disorders which has a twofold risk of poor postoperative pain control. (24)

Ip et al described additional factors that influence pain control and result to an increase in analgesic consumption namely: type of surgery-orthopedic surgeries being associated with most pain, duration of surgery, level of education, cancer surgery, intraoperative opioid use and patients' information about the surgery. (25)

Type of anaesthesia used intraoperatively has been shown influence the intensity of postoperative pain. Patients who were operated under general anaesthesia were shown to be 4.08 times more at risk of developing severe postoperative pain than those operated under regional anaesthesia (9). This was also consistent with a study done in brazil on 98 patients where patients operated under general anaesthesia were 9.5 times more likely to develop severe postoperative pain compared to those operated under

regional anaesthesia (26). Spinal anaesthesia patients experience more pain scores than patients operated under general anaesthesia- 85% versus 75% respectively 12 hours postoperatively according to study done in Ethiopia where 150 patients were followed prospectively following orthopedic operations (27). Another study done in the UK showed that postoperative pain significantly reduced within 4-6 hours after regional anaesthesia postoperatively and there was however similarities in pain scores between patient operated under regional and spinal anaesthesia 6 hours postoperatively in peripheral vascular disease operations (28).

2.7 Pain Management Techniques

2.7.1 Opioid crisis and multimodal analgesia

Opioids have been the mainstay drugs for pain control especially in musculoskeletal medicine. They act by mimicking the action of endogenous opioids by interacting with mu, kappa or delta receptors as well as reduce the release of Substance P by decreasing intracellular cAMP (29). Prolonged and improper use of opioid has however been implicated in worsening the opioid crisis leading to predisposition to opioid addiction and opioid overdose that can even cause death. This is aggravated by the easy availability and low cost of some opioid drugs, lack of policies to proper pharmaceutical administration and no adherence to set guidelines to opioid use. In addition to causing respiratory depression, opioids may also cause constipation, ileus, urinary retentions and moderate to severe pruritus which may prolong the hospital stay (30). There are also no local guidelines or evidence based protocols pertaining to the duration of opioid use. Clinicians therefore battle with the balance of optimal pain relief and potential to causing adverse effects of opioid use.

To minimize the dose-dependent adverse effects to a drug and the potential toxicity associated with a single monotherapy, it has been advocated to employ multiple

analgesia use in a stepwise approach- a concept referred to as “Multimodal analgesia”. Multimodal analgesia has been defined as the concurrent and/ or progressive use of different analgesics, adjuvants or different forms of analgesia delivery in control of pain. Administration of analgesics with different mechanism of action at low but effective doses has an additive and synergistic effect in pain control with minimization or even elimination of dose related adverse effects (6,9,30)

There are several formulations of opioids with varying potency, half-life and modes of usage. This has a connotation to varying potential of adverse effects of the medication. Fentanyl for example is 50-100 times more potent than morphine. Although oxymorphone and oxycodone have similar effectiveness in pain control, oxymorphone is 3-7 times and oxycodone 1.5 times more effective than morphine. Opioids also exist in immediate and extended release formulations. Extended release opioids have a 4-fold risk of leading to opioids abuse. Opioid abuse had been shown to directly correlate with the duration of opioid use.

Combination of opioids with other medication such as NSAIDs has been shown to be more effective in pain control as compared to monotherapy (31). Combination with benzodiazepines however has no synergistic benefit and has been shown to increase the risk of respiratory depression due to overdose by 3.9 times (32).

The main cause of death in opioid related complication is respiratory depression. This is dose dependent, with other variables such as BMI, obstructive sleep apnea, opioid tolerance and concomitant respiratory pathology increasing the chances of respiratory depression. Non-life threatening complications including: somnolence, nausea, dizziness, head ache and pruritus have been reported in approximately 10% of patients (33).

2.7.2 NSAIDS

NSAIDs are effective analgesic and anti-inflammatory medication that act by reducing the production of prostaglandins- a potent nociceptive agent. They irreversibly or reversibly inhibit Cyclo-oxygenase (the enzyme responsible for production of prostaglandins). There are concerns of NSAID use especially in the setting of fractures with the worry that its use delay or inhibit fracture healing. Studies quoted on the detrimental effects of NSAIDs in bone healing however failed to show high quality evidence in support of this (30).

Francesca et al in their propensity matched analysis study of patient who presented at the emergency department in moderate to severe pain following motor vehicle accidents found equivalent pain control between patients treated with NSAIDs (Ibuprofen 400-800mg) and opioids (Hydrocodone and oxycodone 5-10mg) with lower risk profile in patients managed with NSAIDs (34).

The role of NSAIDs in relieving musculoskeletal pain is undeniably strong for it to be scrapped off the armamentarium of postoperative pain control in musculoskeletal operations (30,35).

2.7.3 Gabapentins and pregabalin

Central and peripheral sensitization with hyperalgesia has been shown to be caused by surgical trauma. Antihyperalgesia medication have been shown to reduce incidence of central sensitization. Although gabapentinoids were introduces initially as antiepileptics, they have been shown to have analgesic, anxiolytics and anticonvulsant effects (36). Gabapentin binds to the alpha-2 subunit of the presynaptic voltage gated calcium channel and inhibit calcium release from the presynaptic terminal thereby inhibiting propagation of the pain signal. Perioperative gabapentin has demonstrated an opioid sparing effects therefore reducing the pain scores relative to the control group. It leads to “overexcited” neurons returning to their “normal” state.

Pregabalin is a structural analogue of gamma aminobutyric acid (GABA) and acts by presynaptic binding α -2-λ subunit of the voltage gated calcium channels in the spinal cord and brain. This modulates release of nociceptive excitatory neurotransmitters (36).

A meta-analysis on spine surgeries showed a decrease in pain scores at 12 and 24 hours with a reduction in morphine consumption and a decrease in adverse effects related to morphine use (37).

2.7.4 Regional Anesthesia and Nerve Blocks

Regional blocks are often used as intra and postoperative pain control modalities. They can be administered as single blocks or continuous catheter infusions. Their use has been shown to improve pain scores and reduce opioid use in the immediate and short-term postoperative period. A variety of cocktail mixtures exist that include the use of local anaesthetic agents and opioids, NSAIDs, steroid and hyaluronidase. Rebound pain and falls have however been reported in patients who have received lower limb blocks. Attempts to address this challenge involves using continuous regional infusions, using local anesthetic agents and cocktails with longer duration of action and co- administration with systemic pain relieving medication (6,30).

2.8 Physical Pain Management Strategies

2.8.1 TENS (Transcutaneous Electrical Nerve Stimulation)

TENS involve the application of low voltage electrical signals over the skin by a small portable device. It acts by stimulating large diameter afferent fibers that in turn activate the inhibitory descending pathways to pain, thereby causing pain relief. Contraindications to its use include the presence of a skin breach at the site of applications, lymphedema and presence of a pacemaker device (14,30).

2.8.2 Cryotherapy

Cryotherapy involves the use of an external cold source leading to a drop in tissue temperature. Lowering of tissue temperature causes vasoconstriction, reduction in tissue edema and vascular permeability and reduced production of inflammatory mediators with an overall decrease on tissue metabolic demand and hypoxia. Cryotherapy also increases pain threshold and pain tolerance (30).

2.9 Psychosocial Interventions

A number of patients exhibit pain anxiety and catastrophizing symptoms. A number of interventions have been studied and been shown to decrease the rate of postoperative anxiety, depression and pain. These include: cognitive behavior therapy, access to educational information, peer support, self-management intervention and training and online social networking. Other modalities such as aromatherapy and music therapy have also shown positive effects of pain relief (30) (38).

2.10 Routes of Drug administration

Pain medication can be administered orally or parenterally through intramuscular or intravenous routes. Roger Chou et al in their guidelines on management of postoperative pain recommend the use of oral opioid over intravenous opioid in patients who can use oral route. Most studies have shown no superiority of intravenous opioids over oral opioids. Intramuscular injection of medication over intravenous injection is also discouraged as intramuscular injection causes pain and is characterized by erratic drug absorption leading to inconsistent pain control (38).

2.11 Assessment of postoperative pain

Pain assessment is important to determine whether pain is adequately managed, whether there is need to change the medication dosage or pain management strategy or whether to specialty consultation is warranted in pain that is hard to manage. Pain is a subjective experience. Self- reported assessment is the mainstay of patient postoperative pain assessment but clinicians can use behavioral assessment tools. Clinical intuition is needed in accurate evaluation of pain (38).

Some validated tools used in pain assessment include the visual analogue score (VAS), numerical rating scale (NRS) and verbal rating scale (VRS), symbols and others. Choice of assessment tool should be on the based on the patient's cognitive status, level of education, developmental status, level of consciousness and language or cultural differences. Timing of assessment is based on the time taken to achieve maximum effects which is usually 15-30 minutes after parenteral administration. Assessment after regional drug administration is done immediately after the intervention as the effects as pain relief often occurs immediately after their administration. Frequency of assessment is dependent on the type of surgery, presence of comorbidities, changes in clinical status, presence of adverse effects and adequacy of initial pain relief (30,38).

The American Pain Society (APS) recommends that to improve the quality of pain management, focus should be put on the severity of pain and the effects of pain on patient outcomes(39) . It is therefore important to correlate pain score with physical activity and functionality in assessment of postoperative pain. The psychosocial

impact of postoperative pain need not to be ignored. The IPOQ provides a key tool in pain assessment as it records patient-reported outcome measures in addition to their perception of care and possible detection of adverse effects related to pain treatment. It was originally developed from the American Pain Society Patient Outcome Questionnaire (APSPOQ) (40). It has been translated into 15 different languages and validated in 8 European countries and Israel (11).

IPOQ items are scored mainly on an 11 point NRS but also has close ended "yes" and "no" answers. Patients' worst, least, and current pain intensity are measured as an NRS score from 0 = "no pain" to 10 = "worst pain possible." The percentage of time the patient had spent in severe pain since surgery ismeasured from 0% = "never in severe pain" to 100% = "always in severe pain." Pain interference is measured as functional disability due to pain (NRS score from 0 = "did not interfere" to 10 = "completely interfered") and anxiousness and helplessnesscaused by pain (NRS score from 0 = "not at all" to 10 = "extremely") (41).

Additional segments will be added for measurements of preoperative, intraoperative and postoperative factors that influence pain in line with the specific objectives.

2.12 Statement of Research Problem

Postoperative pain control remains a major challenge and problem among surgeons and anesthesiologists especially in developing countries. This is attributed to lack of resources in terms of personnel and medication and the low attention given to pain

management (12,42). Underassessment and under treatment of pain in also not uncommon in the developed nations in spite of the tremendous improvement of understanding of pain physiology and inventions of new and advanced pain management modalities. Up to 30 % of postoperative patients report pain score of more than 3 in the visual analog score (moderate to severe pain). Orthopedic patients in particular experience more pain as compared to patients who have undergone a laparotomy surgery immediately postoperatively, necessitating the use of more analgesic medication than dictated in most PACU guidelines and protocols (43).

Despite pain being the commonest reason for seeking medical attention, it has been shown to be incorrectly assessed as per the international guidelines. A study done by Lisa et al showed that there is underestimation of pain up to 39% and overestimation of 15% despite the widespread increase of routine screening (44). This renders pain management ineffective impairing the patient's quality of life. One of the main reasons for poor pre and postoperative pain control is lack of appropriate guidelines. A study done in Holland in 2013 evaluating the use of protocols in management of postoperative pain in fractures found a wide variety of protocols used with no single protocol formulated on evidence based, specialized protocol for postoperative fracture pain. In addition, the available protocols failed to clarify dosages and include examination of side effects, contraindications of patient's age- factors that significantly influence the effect of pain medication (45).

According to a study by Okello et al, postoperative pain management among orthopedic patients in KNH is suboptimal (46). Despite the lapse in time from the study, the trend still persists, depicted by delays in mobilization after surgery and longer hospital stays of patients following orthopedic surgical procedure. Most patients experience more pain than expected and express dissatisfaction with pain control. This consequentially increases the risk of developing pain related complications such as postoperative infection. There also lacks a definite protocol to management of pain postoperatively following orthopedic surgical procedures. Clinicians therefore

prescribe and administer interventions subjectively, based on the best modality thought to aid in pain control.

Research question

How effective is the postoperative pain management following orthopedic operations at KNH and what factors influence pain outcomes?

2.13 Study Justification

This study aims at assessing adequacy of postoperative pain control among orthopedic patients in KNH by observing trends and practices of analgesic usage, demographic and surgical factors that influence pain control and their correlation with pain scores and impairment of function. Patient's satisfaction of pain control and side effects to analgesics prescribed also will be analyzed.

Conducting this study will highlight shortfalls if any in pain control among orthopedic surgery patients and recommend strategies to improve pain management. It is expected that adequate pain management will enhance early mobilization of patients, reduce incidence of pain related complications including postoperative infections and also lead to short hospital stays for orthopedic surgery patients. Confidence in prescription and utilization of pain management modalities will improve among clinicians and nursing personnel. Consideration of this study in formulating a pain management protocol following orthopedic surgical procedures will be of great help.

2.14 Study Objectives

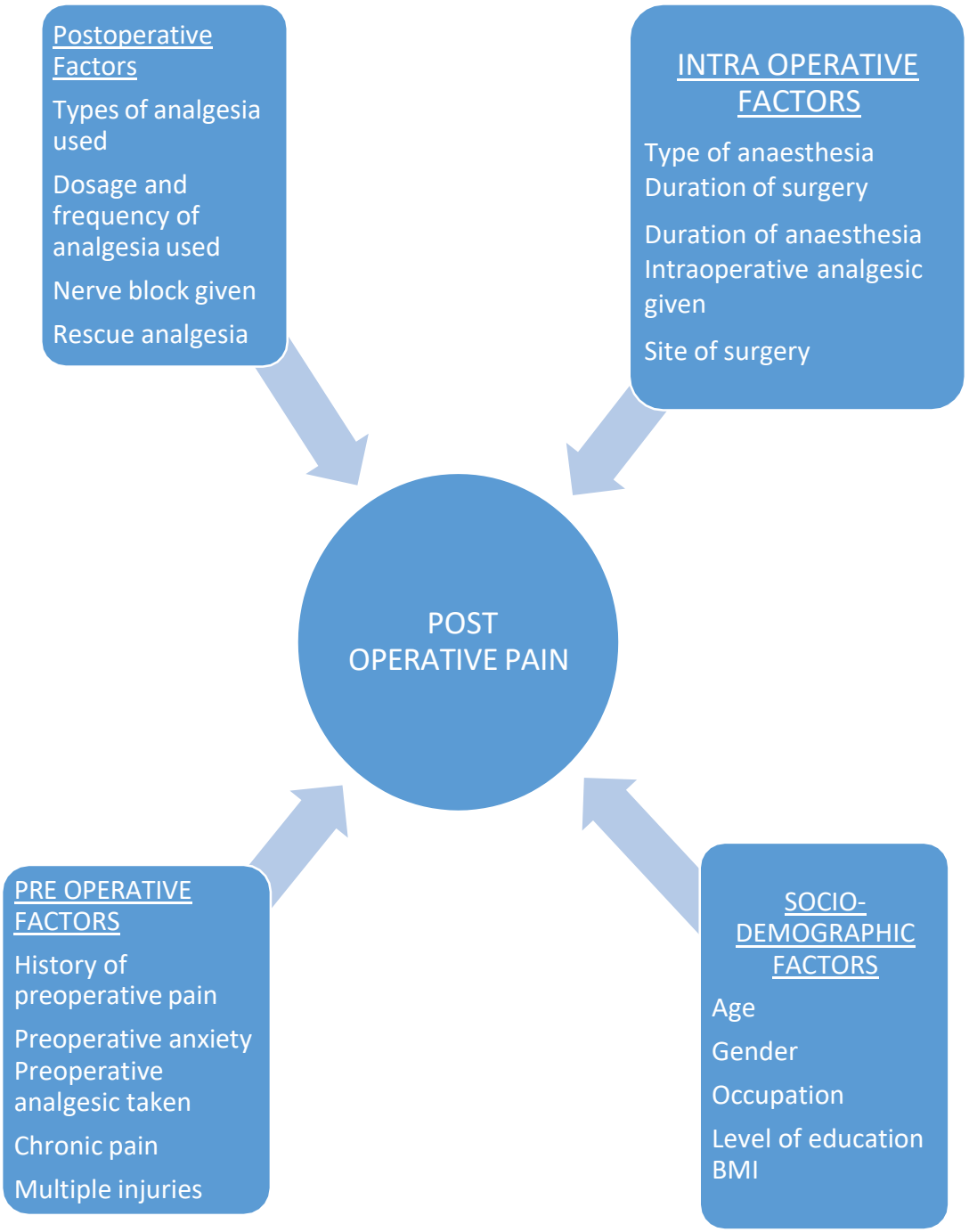
2.14.1 General Objective

i. To assess the adequacy of postoperative pain management following orthopedic surgery procedures of the lower limbs

2.14.2 Specific Objectives

i. To determine the pain intensity following lower limb orthopedic surgical procedures at KNH and determine the incidence of severe postoperative pain.
ii. To determine the intraoperative and postoperative analgesia offered following lower limb orthopedic surgical procedures at KNH
iii. To evaluate the postoperative requests for rescue analgesia following lower limb orthopedic surgical procedures at KNH.
iv. To establish preoperative and intraoperative risk factors of severe pain in patients following lower limb orthopedic surgical procedures.

Figure 4: Conceptual framework



CHAPTER THREE: METHODOLOGY

3.1 Study Design

This is a prospective study. It involved collection of data using a standard questionnaire at the receiving area preoperatively and at 0, 12, 24 and 48 hours postoperatively. The questionnaire was administered by a research assistant. Patients in PACU who were not be able to answer questions coherently following general anesthesia were assessed at the first point of regaining full consciousness.

3.2 Study Setting

The study was conducted in Kenyatta National Hospital- a tertiary referral hospital in Nairobi, Kenya. Subject recruitment was conducted preoperatively in the orthopedic wards and preoperative covariates taken upon consenting to participation into the study. Intraoperative data variables were collected in the OR. Assessment of pain scores and postoperative data variable collection was conducted in PACU and in the orthopedic wards at 12, 24 and 48 hours postoperatively.

About 45 orthopedic surgery operations are conducted in a week in KNH orthopedic operating theaters with majority being on the lower limb. Sample size attainment was within 3 months

3.3 Study Population

Patients scheduled for an invasive lower limb orthopedic surgical procedure as inpatients at KNH and who have met the inclusion criteria were recruited into the study. Participation was entirely on a voluntary basis and no remuneration was given to the participants.

3.4 Selection criteria

3.4.1 Inclusion criteria

Inclusion criteria for participants in the study included patients between the age of 18 and 75 years of age who were scheduled to undergo an invasive lower limb orthopedic surgical procedure. Patients included in the study were also be required to give an informed consent and have a good understanding of English and/or Swahili language

3.4.2 Exclusion Criteria

Exclusion criteria included patients who had mental or cognitive impairment, patients in intensive care or requiring intensive care support postoperatively, patients at 17 years of age and younger, elderly patients who were 76 years and older, patients with neuropathies, patients with hepatic and/or renal dysfunction, patients who did not understand English or Swahili and patients who declined to participate in the study.

3.5 Sample Size determination

Sample size was calculated using the formula; (47)

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 73% i.e. 0.73, from a prospective observation study conducted by Ansbert et al (2020) at a tertiary hospital in Tanzania; looking at postoperative pain after orthopedic surgery, found 73% of them had moderate to severe pain).(48)

d = desired precision (0.07)

$$n_0 = \frac{1.96^2 x\ 0.73(1 - 0.73)}{0.07^2} = 154$$

A Sample size of 154 patients will be required for the study.

3.6 Sampling

Convenient sampling method was used on all patients who were scheduled for an orthopedic surgery procedure to identify the participants of the study. Every patient who had been scheduled for an orthopedic surgical procedure and fits the inclusion criteria was a potential subject for recruitment. Patients were conveniently recruited until the realization of the set sample size. The patients were taken through an overview of the study before determining their eligibility in participating in the study. A signed consent (through online signatures) was taken from the participants by the research assistant/s before recruitment into the study. Those who met the criteria were then recruited. Subject recruitment was conducted in the KNH orthopedic wards preoperatively before proceeding to theater.

3.7 Variable definition and assessment

Data was divided into two variables: dependent and independent variables

3.7.1 Independent variables

Sociodemographic factors taken included: age of the patient, gender, BMI, occupation and level of education. In patients with challenges in calculating BMI (patients who might not be able to stand on a scale for example) the MUAC will be used to estimate the BMI as described by Benitez et al (49).

Preoperative factors assessed included: presence of multiple fractures, preoperative anxiety, history of chronic pain and history of preoperative analgesic use including longstanding opioid use and analgesia given as part of preoperative patient preparation.

Intraoperative variables assessed included: duration of surgery, type and duration of anesthesia and intraoperative analgesic used.
Postoperative variables included use of nerve or regional blocks and types, dosage and frequency of analgesics and type, dosage and frequency of rescue analgesia given.

3.7.2 Dependent variables

Dependent variable were pain outcome measured using the NRS in the data collection tool, pain interference with activity, time to mobilization, pain control interventions applied and number and type of rescue analgesics if given.

3.8 Data collection and storage

Data was collected using a standard questionnaire that was administered by a research assistant/s at the receiving area preoperatively and at 0, 12, 24 and 48 hours postoperatively. Two research assistants with a diploma qualification in clinical research were hired and remunerated for data collection. The data was collected and saved on an online platform- Research Electronic Data Capture (REDCAP) that has been shown to be secure and can be accessed from a device with an internet connection (50). This ensured collection of uniform and verifiable data. Data was afterwards extracted into a Microsoft excel sheet for analysis using SPSS.

Pain outcome was measured using a modification of the international pain outcome Questionnaire (IPOQ) that has been validated in 9 countries and translated in 10 different languages (11) (51). It includes questions on pain severity, pain interference with emotion and activity including mobilization, side effect of pain medication and patient's perception regarding pain control. It also includes non-pharmacological modalities of pain control and the presence of preoperative chronic pain. IPOQ outcomes are scored on an 11-point scale (NRS 0-10). The questionnaire also covers limitations of activities due to pain, detection of early complications related to pain and pain control modalities, as well as other non-pharmacological ways of treating pain. Modification to the questionnaire will include addition of independent variables- sociodemographic, preoperative, intraoperative and postoperative factors, as highlighted earlier.

Research assistants collected and filled the questionnaires. The research assistants collecting data were not involved in prescribing analgesics or in patients' pain management. They however raised alarm to the medical caregivers in instances where the patient had severe neglected pain.

The questionnaire was filled in soft copy and stored in a file folder only accessible by a password to the research assistants, investigator and the statistician.

3.9 Ethical Consideration

Permits- Ethical approval was sought from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UON ERC). Approval copies are attached to the appendices.

Guiding principle- The study was conducted in line with the declaration of Helsinki that guides studies on human subjects.

Consent- A written informed consent was verbally taken and duly signed by the participants before enrollment to the study. No remuneration was given to the study participants. Participation in the study was voluntary. There was no victimization of patients declined to be included in the study.

Confidentiality- No patient information was disclosed to ensure confidentiality. Participants were allocated serial numbers to conceal their true identity.

The study was purely observational and no invasive procedure was conducted. Patients who will had severe pain score (above 7 in NRS) had their primary /prescribing physician or the nursing officer on duty contacted to treat the severe pain.

3.10 Data management and analysis

The analysis method for the descriptive data will be done using SPSS® and presented as central tendencies measures (means, medians and percentages). Mixed Effect Regression (MER) was used for data analysis and data correlation (51). The inferential results will be presented in details using simple charts, tables, and diagrams.

3.11 Quality Assurance

Data collection was done by two research assistants who understand medical terminologies and pain management practices. The research assistants were trained on the data collection tool. A pilot of the data collection tool had been conducted to analyze its appropriateness and detect any need for amendments. The questionnaire was filled on an online document to reduce risks of data loss.

3.12 Data Dissemination plan

The results of this study will be disseminated to the University of Nairobi (UON) Department of Orthopedic surgery, Department of Anesthesia, KNH orthopedic and anaesthesia departments, the University of Nairobi Library and afterwards a peer reviewed journal for publishing.

3.13 Study Limitations

Foreseen limitations included: Subjective nature of pain, generalizability of the findings to the general population due to the subjective nature of pain and different sociodemographic factors among participants. Adherence to the exact time frame of data collection was also a challenge. Mixed Effect Regression was however used for data analysis to minimize any statistical errors that may arise from this limitation.

Chapter 4 Results

4.1 Introduction

This study was to access the adequacy of postoperative pain management following invasive lower limb orthopedic surgical procedures of the lower limb. A total of 150 patients were recruited into the study. Preoperative and intraoperative data including patient demographics, BMI, level of education, intraoperative analgesia, type of anaesthesia and duration of surgery was taken. Postoperative data was collected using the IPOQ questionnaire with variables of analysis being postoperative pain intensity, time of ambulation and rescue analgesics administered. Correlation of intraoperative and postoperative variables influencing pain intensity postoperatively was also assessed.

4.2 Patient Demographics

The mean age of the participants was 34.8 (SD 11.4) years, where the minimum age was 17.0 years, and the maximum age was 73.0 years. The median age was 33.0 (IQR 26.0 – 43.0) years.

Table 2 Age distribution

	Frequency (n=150)	**Percent**
Age		
≤20	13	8.7
21 – 30	45	30.0
31 – 40	47	31.3
41 – 50	33	22.0
>50	12	8.0

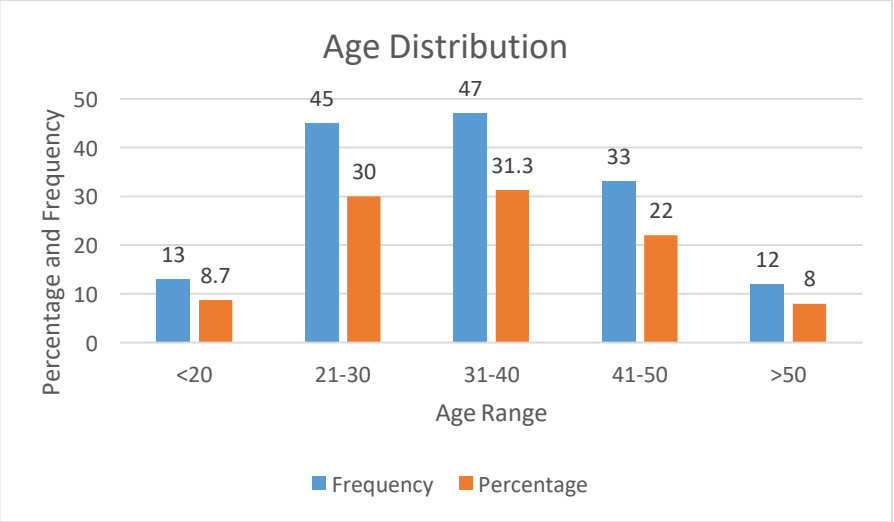


Figure 5 Figure illustrating age distribution in range of 10 years

Table 3 Gender distribution

Gender	Frequency	Percentage
Male	128	85.3
Female	22	14.7

Majority of patients recruited into the study were middle aged (between 20 and 50 years of age), with male gender accounting for 85% of patients.

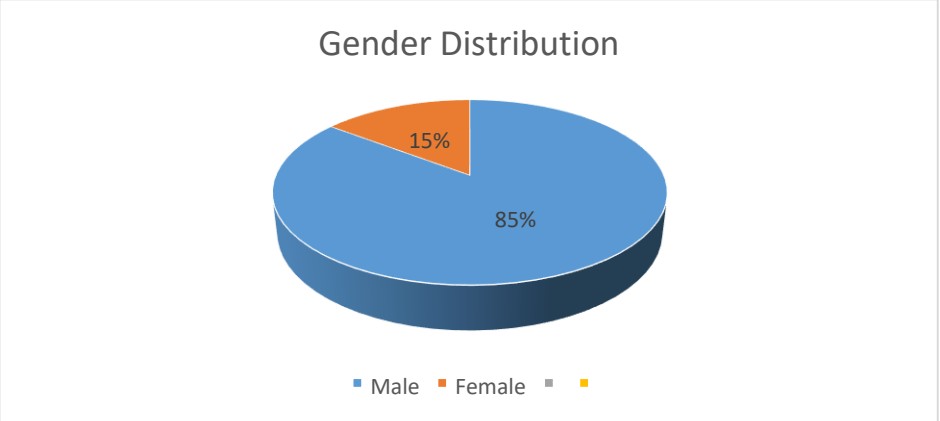


Figure 6 Pie chart illustrating gender distribution

Table 4 Patients' BMI

BMI	Frequency	Percentage
<18.5	6	4.0
18.5 – 24.9	110	73.3
25.0 – 29.9	31	20.7
≥30.0	3	2.0

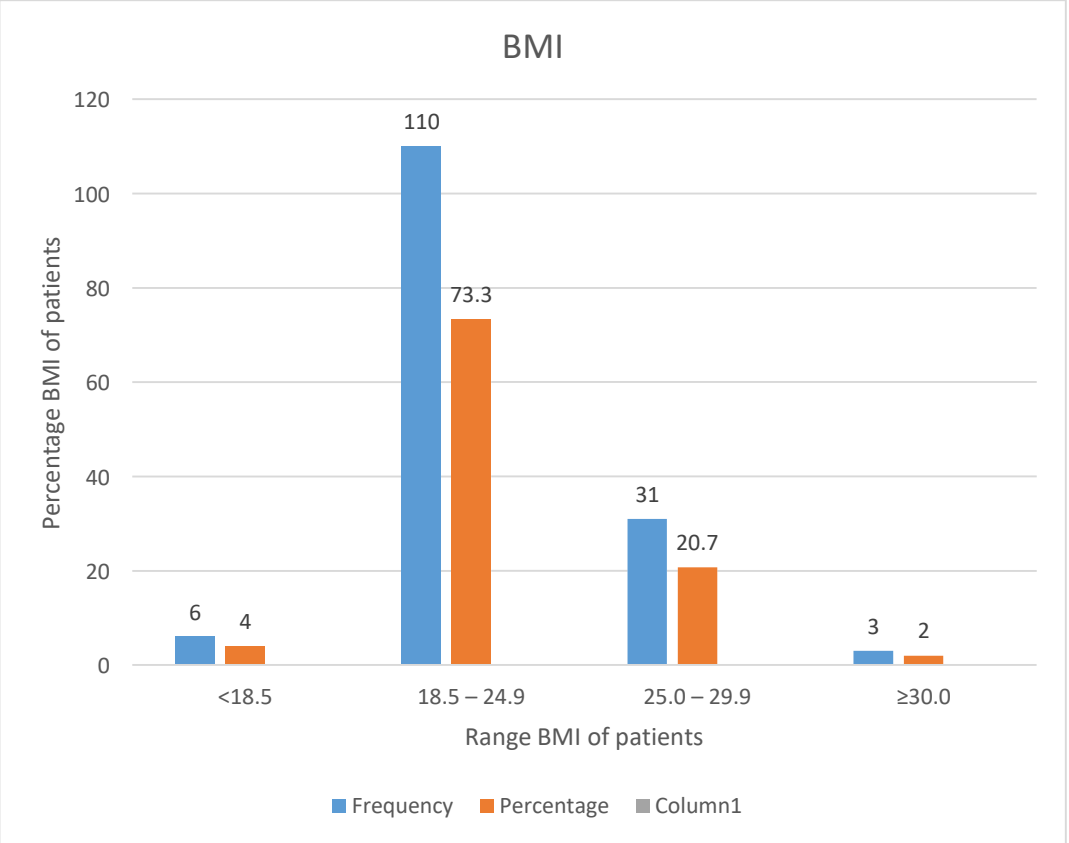


Figure 7 Bar graph illustrating patients' BMI

Table 5 Occupation of patients

Occupation	Frequency	Percentage
Employed	14	9.3
Self-employed	33	22.0
Unemployed	103	68.7

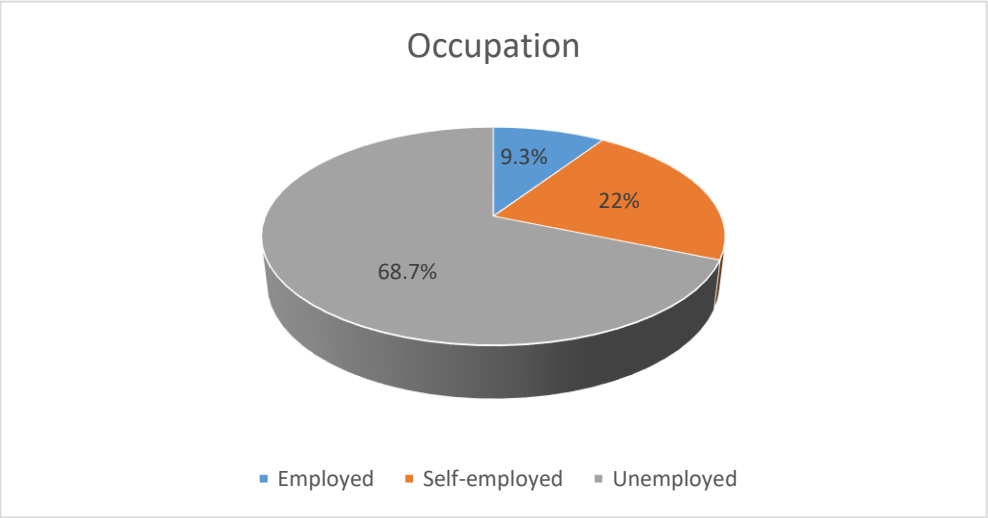


Figure 8: Figure illustrating occupation of patients

Table 6: Level of Education

Education	Frequency	Percentage
No formal education	24	16.0
Primary	56	37.3
Secondary	56	37.3
Tertiary	14	9.3

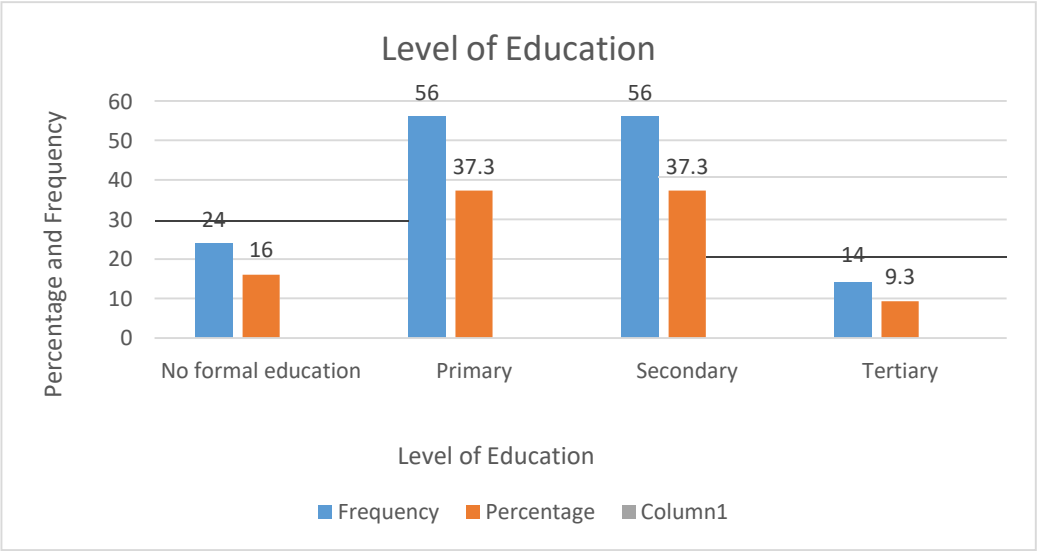


Figure 9: Pie chart illustrating level of education

4.3 Preoperative factors

Table 7: Preoperative factors

	Frequency (n=150)	Percent
Type of fracture		
Single fracture	116	77.3
Multiple fracture	34	22.7
Preoperative anxiety		
Yes	120	80.0
No	30	20.0
Chronic pain		
Yes	28	18.7
No	122	81.3
Chronic opioid use		
Yes	19	12.7
No	131	87.3

Most patients recruited into the study sustained single fractures. Majority has preoperative anxiety. Patients with chronic pain accounted for approximately 19%. This is consistent with the percentage of patients who has chronic use of opioids which accounted for approximately 13% of patients.

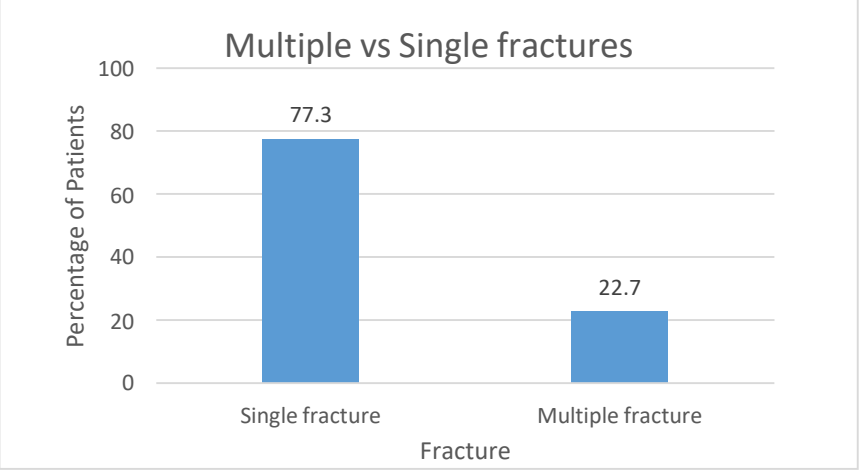


Figure 10: Bar chart illustrating percentage of patients having multiple versus single fractures

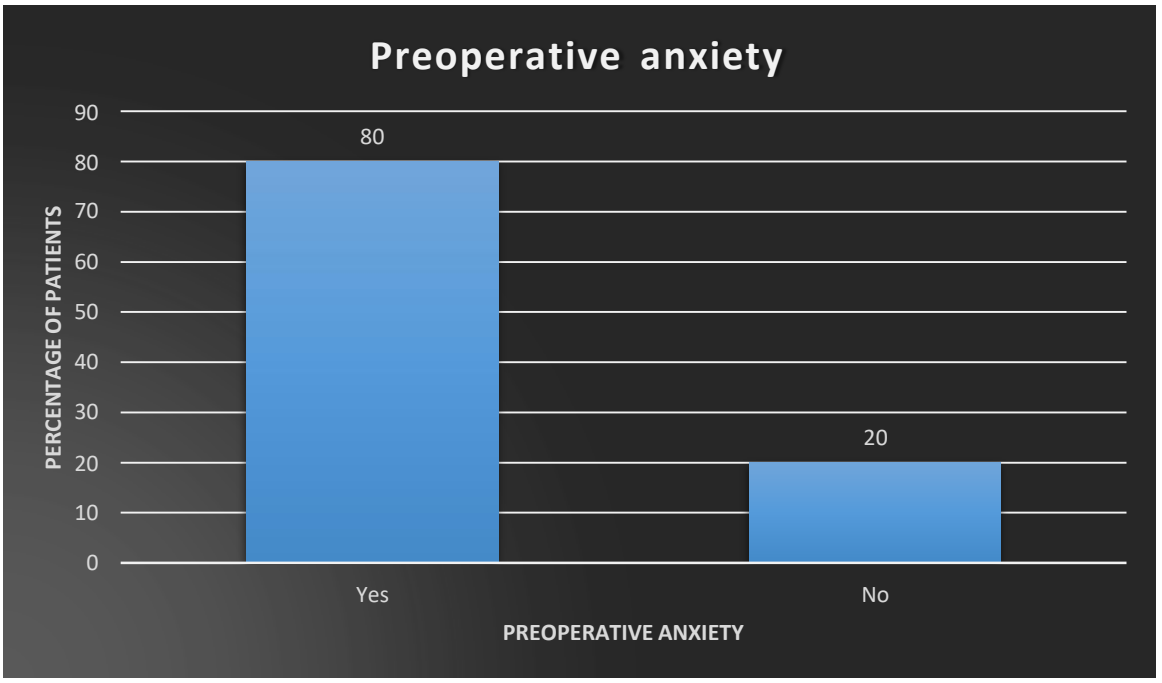


Figure 11: Figure illustrating percentage of patients with preoperative anxiety

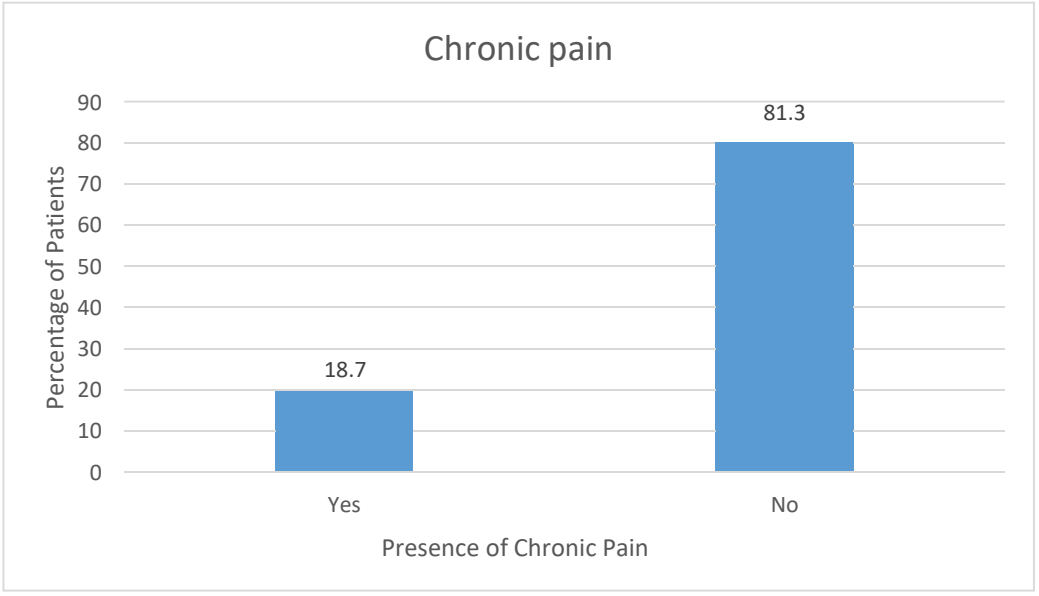


Figure 12: Figure illustrating percentage of patients who had chronic pain preoperatively

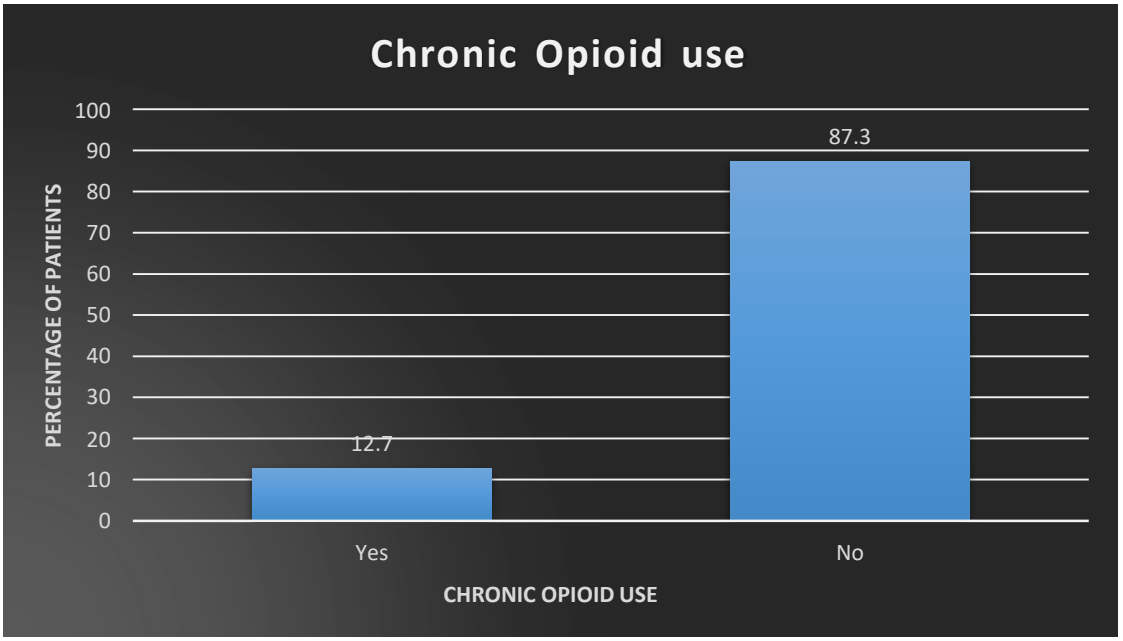


Figure 13: Figure illustrating percentage of patients who had chronic use of opioid analgesics

4.4 Intraoperative factors

Table 8: Duration of surgery in 30 minute range

Range (minutes)	**Frequency**
31-60	1
61-90	15
91-120	30
121-150	25
151-180	28
>180	51

Most surgeries performed took more than two and a half hours with a median time of surgery of 155 minutes.

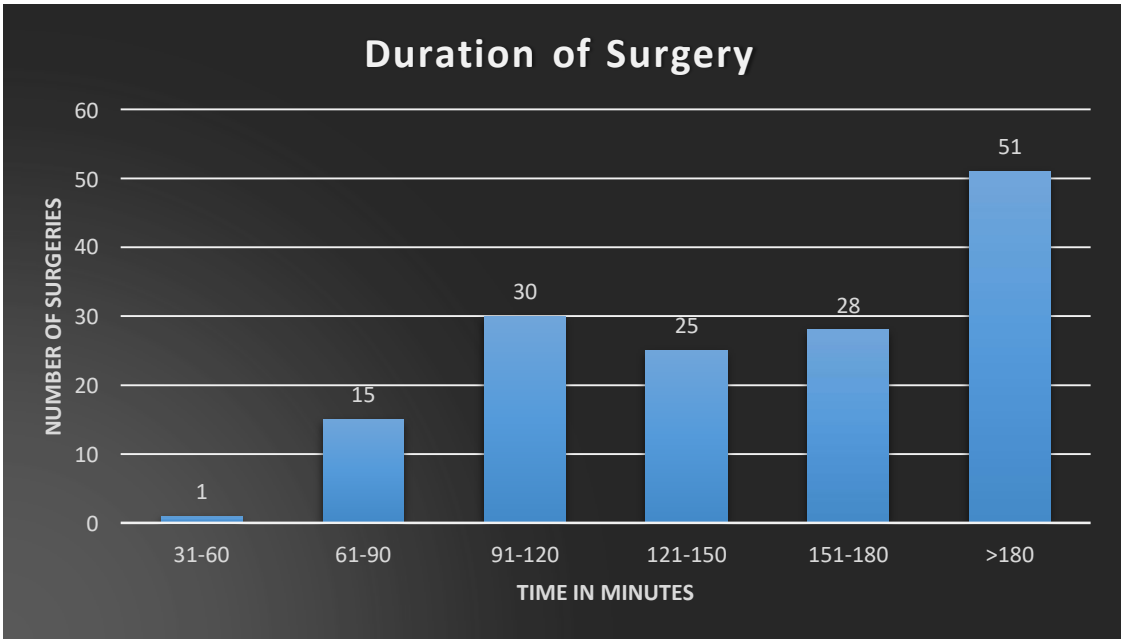


Figure 14: Figure illustrating duration of surgery (Range in minutes)

Table 9: Intraoperative and postoperative analgesia and anaesthesia administered

	Frequency	**Percent of patients** *(n=150)*
Tramadol, *(n=15)*		
80.0mg	2	1.3
100.0mg	13	8.7
Morphine, *(n=63)*		
2.5mg	2	1.3
3.0mg	3	2.0
4.0mg	2	1.3
5.0mg	36	24.0
6.0mg	3	2.0
7.0mg	2	1.3
8.0mg	5	3.3
10.0mg	10	6.7
Paracetamol, *(n=126)*		85.7
1.0g	126	84.0
Dexketoprofen, *(n=92)*		
50.0mg	92	61.3
Ketamine, *(n=16)*		
0.8mg	3	2.0
25.0mg	4	2.7
50.0mg	9	6.0

Midazolam, *(n=24)*		
1.0mg	5	3.3
2.0mg	10	6.7
3.0mg	8	5.3
5.0mg	1	0.7
Intraoperative anaesthesia	**Frequency,** *(n=150)*	**Percent**
General	23	15.3
Regional	1	0.7
Spinal	105	70.0
Spinal & Epidural	13	8.7
General & Epidural	7	4.7
General & Spinal	1	0.7

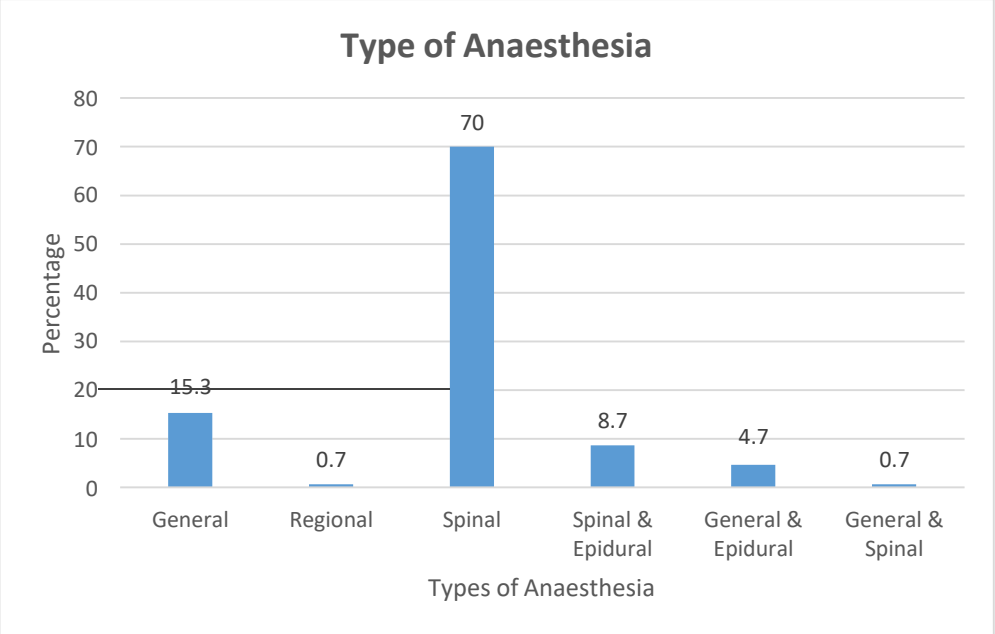


Figure 15: Bar graph illustrating percentage of different anaesthesia modalities given intraoperatively

Most patients received spinal anaesthesia alone (n=105). The use of regional anaesthesia such as nerve blocks was noted too be low at 0.7% (n=1). NSAIDs and paracetamol accounted for 86% and 61% of intraoperative analgesics prescribed respectively. Opioids accounted for 52% of intraoperative analgesics.

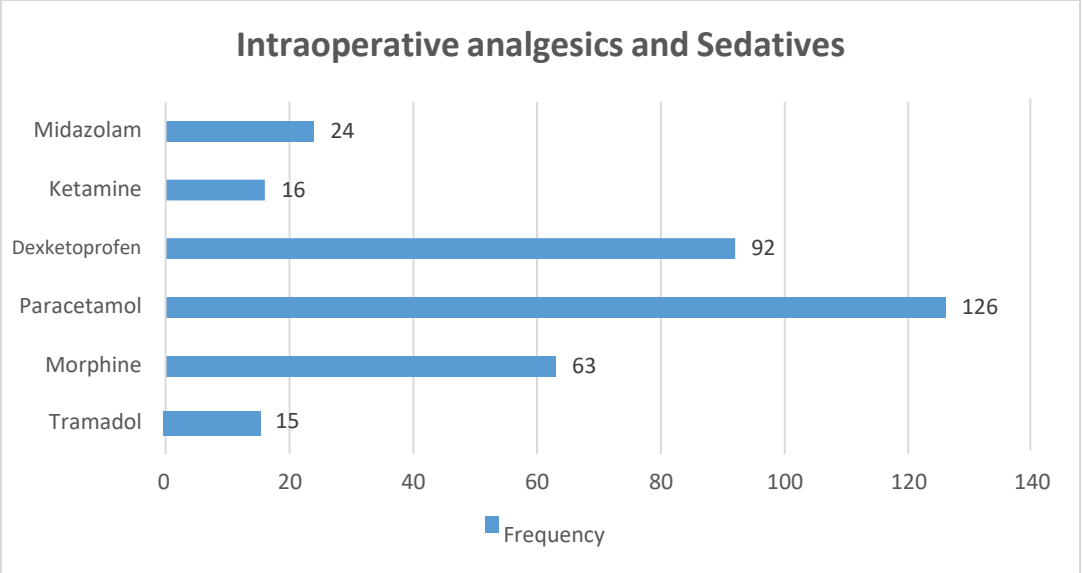


Figure 16: Figure illustrating analgesics given intraoperatively

4.5 Postoperative variables

Table 10: Pain intensity at 0,12,24 and 48 hours postoperatively

Time (0)	Frequency (n=150)	Percent
Worst pain		
Mild (0 - 3)	31	20.7
Moderate (4 - 6)	93	62.0
Severe (7 - 10)	26	17.3
Time (12)		
Worst pain		
Mild (0 - 3)	14	9.3
Moderate (4 - 6)	67	44.7
Severe (7 - 10)	69	46.0
Time (24)		
Worst pain		
Mild (0 - 3)	1	0.7
Moderate (4 - 6)	55	36.7
Severe (7 - 10)	94	62.7
Time (48)		
Worst pain		
Mild (0 - 3)	58	38.7
Moderate (4 - 6)	51	34.0
Severe (7 - 10)	41	27.3

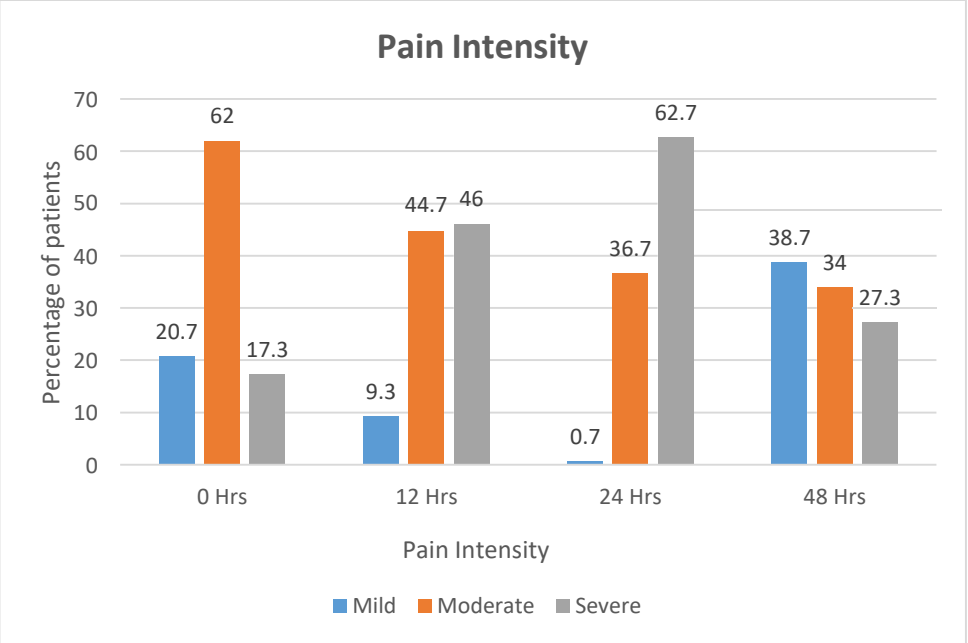


Figure 17: Bar graph illustrating pain intensity at 0, 12, 24 and 48 hours postoperatively

Pain intensity increased postoperatively peaking at 24 hours and reducing thereafter. Incidence of severe pain was 46%, 62.7% and 27% at 12, 24 and 48 hours respectively.

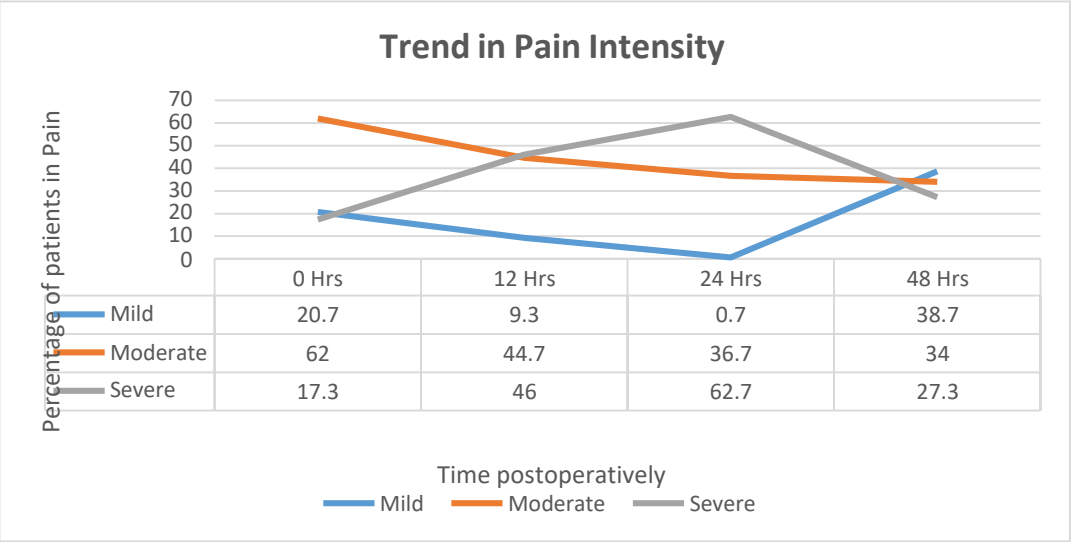


Figure 18: Line graph illustrating trend of pain intensity

Table 11: Table illustrating percentage of patients who were out of bed at 0, 12, 24 and 48 hours postoperatively

	Frequency (n=150)	Percent
Time (0)		
Yes	-	-
No	150	100.0
Time (12)		
Yes	53	35.3
No	97	64.7
Time (24)		
Yes	98	65.3
No	52	34.7
Time (48)		
Yes	132	88.0
No	18	12.0

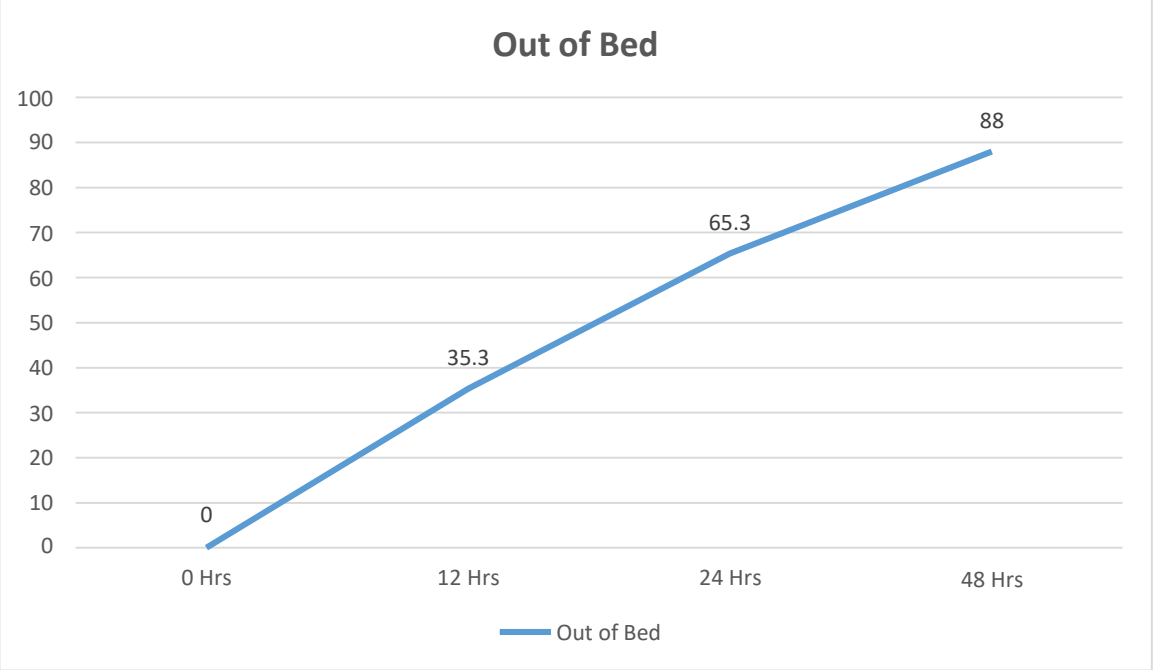


Figure 19: Line graph illustrating time of moving out of bed of patients postoperatively

Table 12: Number of rescue analgesia given and medication and dosage administered

	Frequency (n=150)	Percent
Rescue analgesia		
Yes	28	18.7
No	122	81.3
Rescue analgesia received (n=28)	**Frequency**	**Percent of patients (n=150)**
Fentanyl 100mcq	3	2.0%
Fentanyl 2mcq	1	0.7%
Ketamine 25mg, Midazolam 1g	2	1.3%
Morphine 10mg	4	2.7%
Morphine 2.5mg	1	0.7%
Morphine 2mg	2	1.3%
Morphine 3mg	1	0.7%
Morphine 5mg	9	6.0%
Morphine 6mg	5	3.3%

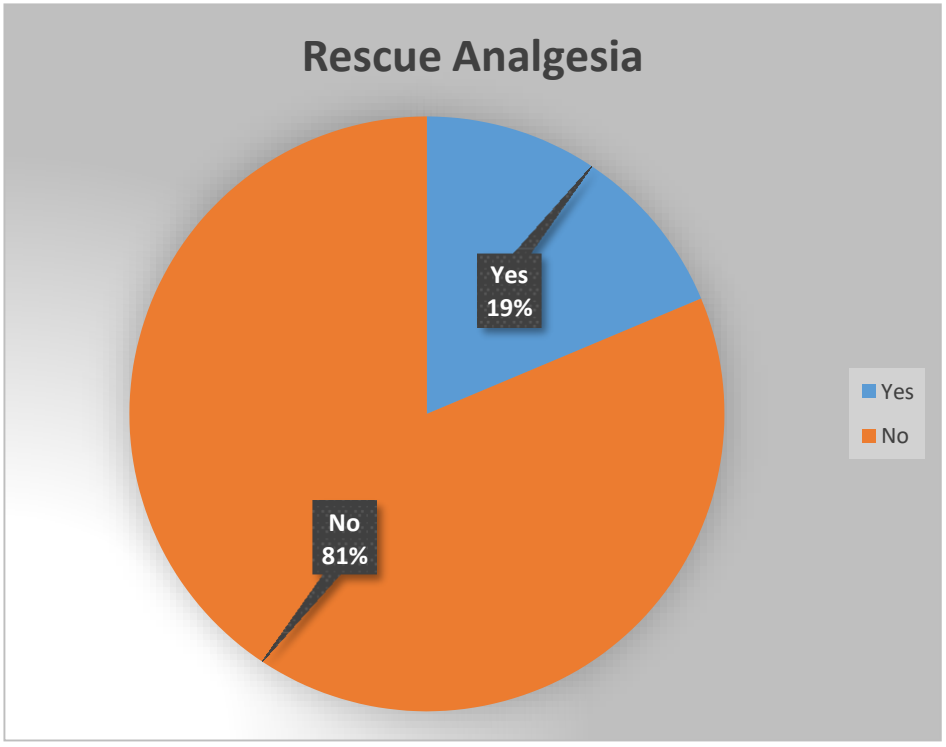


Figure 20: Pie chart illustrating proportion of patients who requested and received rescue medication

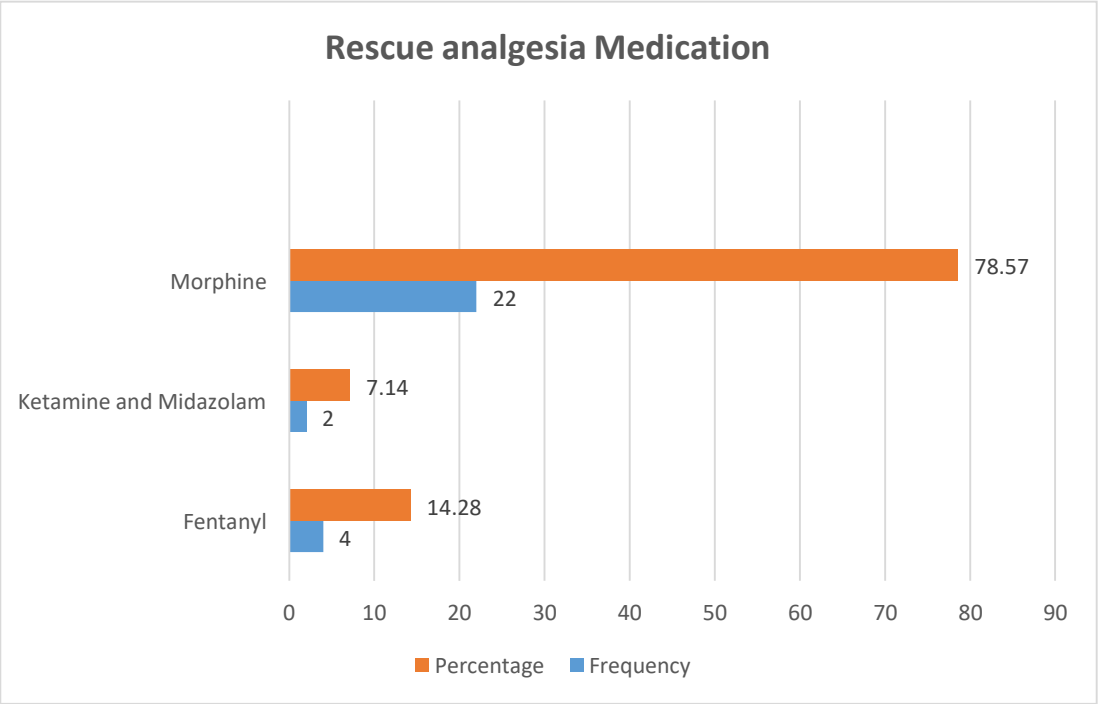


Figure 21: Graph illustrating rescue analgesics given

4.6 Association between patient characteristics and pain

Patients were grouped into two categories; those with mild pain scores (0-3 NRS) were categorized as having no pain and those with moderate and severe pain scores (NRS 4-10) as having pain. The pain scores were taken at 12 hours and 48 hours postoperatively and correlation of the pain to preoperative and postoperative variables determined.

Table 13: Table showing correlation of postoperative and preoperative variables to severity of pain postoperatively at 12 hours

	Pain	No pain	OR (95% CI)	p-value
Age				
≤20	13 (9.6)	0 (0.0)	-	
21 – 30	41 (30.1)	4 (28.6)	Reference	
31 – 40	42 (30.9)	5 (35.7)	0.8 (0.2 – 3.3)	0.778
41 – 50	29 (21.3)	4 (28.6)	0.7 (0.2 – 3.1)	0.643
>50	11 (8.1)	1 (7.1)	1.1 (0.1 – 10.6)	0.952

Gender				
Male	118 (86.8)	10 (71.4)	2.6 (0.7 – 9.3)	0.134
Female	18 (13.2)	4 (28.6)	Reference	
BMI				
<18.5	5 (3.7)	1 (7.1)	2.5 (0.1 – 62.6)	0.577
18.5 – 24.9	100 (73.5)	10 (71.4)	5.0 (0.4 – 60.1)	0.205
25.0 – 29.9	29 (21.3)	2 (14.3)	7.3 (0.4-118.7)	0.165
≥30.0	2 (1.5)	1 (7.1)	Reference	
Occupation				
Employed	13 (9.6)	1 (7.1)	1.6 (0.2 – 13.1)	0.685
Self-employed	31 (22.8)	2 (14.3)	1.9 (0.4 – 8.8)	0.438
Unemployed	92 (67.6)	11 (78.6)	Reference	
Education				
No formal education	20 (14.7)	4 (28.6)	Reference	
Primary	51 (37.5)	5 (35.7)	2.0 (0.5 – 8.4)	0.323
Secondary	52 (38.2)	4 (28.6)	2.6 (0.6 – 11.4)	0.205
Tertiary	13 (9.6)	1 (7.1)	2.6 (0.3 – 25.9)	0.415
Preoperative anxiety				
Yes	108 (79.4)	12 (85.7)	0.6 (0.1 – 3.0)	0.577
No	28 (20.6)	2 (14.3)	Reference	
Chronic pain				
Yes	25 (18.4)	3 (21.4)	0.8 (0.2 – 3.2)	0.781
No	111 (81.6)	11 (78.6)	Reference	
Chronic opioid use				
Yes	17 (12.5)	2 (14.3)	0.9 (0.2 – 4.2)	0.848
No	119 (87.5)	12 (85.7)	Reference	
Type of fracture				
Single fracture	103 (75.7)	13 (92.9)	Reference	
Multiple fracture	33 (24.3)	1 (7.1)	4.2 (0.5 – 33.1)	0.177
Prior persistent pain				
Yes	9 (6.6)	2 (14.3)	0.4 (0.1 – 2.2)	0.308
No	127 (93.4)	12 (85.7)	Reference	
Prior pain severity				
Moderate (4 - 6)	132 (97.1)	12 (85.7)	5.5 (0.9 – 33.2)	0.063
Severe (7 - 10)	4 (2.9)	2 (14.3)	Reference	

Table 14: Table showing correlation of preoperative, intraoperative and postoperative variables to severity of pain at 48 hours postoperatively

	Pain	No pain	OR (95% CI)	p-value
Age				
≤20	9 (9.8)	4 (6.9)	Reference	
21 – 30	25 (27.2)	20 (34.5)	0.6 (0.1 – 2.1)	0.381
31 – 40	34 (37.0)	13 (22.4)	1.2 (0.3 – 4.4)	0.826
41 – 50	19 (20.7)	14 (24.1)	0.6 (0.2 – 2.4)	0.468
>50	5 (5.4)	7 (12.1)	0.3 (0.1 – 1.6)	0.171
Gender				
Male	82 (89.1)	46 (79.3)	2.1 (0.9 – 5.3)	0.103
Female	10 (10.9)	12 (20.7)	Reference	
BMI				
<18.5	4 (4.3)	2 (3.4)	4.0 (0.2-75.7)	0.355
18.5 – 24.9	69 (75)	41 (70.7)	3.4 (0.3-38.3)	0.328
25.0 – 29.9	18 (19.6)	13 (22.4)	2.8 (0.2-33.9)	0.425
≥30.0	1 (1.1)	2 (3.4)	Reference	
Occupation				
Employed	9 (9.8)	5 (8.6)	1.2 (0.4 – 3.8)	0.769
Self-employed	21 (22.8)	12 (20.7)	1.2 (0.5 – 2.6)	0.724
Unemployed	62 (67.4)	41 (70.7)	Reference	
Education				
No formal education	13 (14.1)	11 (19)	Reference	
Primary	33 (35.9)	23 (39.7)	1.2 (0.5 – 3.2)	0.693
Secondary	37 (40.2)	19 (32.8)	1.6 (0.6 – 4.4)	0.315
Tertiary	9 (9.8)	5 (8.6)	1.5 (0.4 – 5.9)	0.543
Preoperative anxiety				
Yes	69 (75.0)	51 (87.9)	0.4 (0.2 – 1.0)	0.059
No	23 (25.0)	7 (12.1)	Reference	
Chronic pain				
Yes	12 (13.0)	16 (27.6)	0.4 (0.2 – 0.9)	**0.029**
No	80 (87.0)	42 (72.4)	Reference	
Chronic opioid use				
Yes	9 (9.8)	10 (17.2)	0.5 (0.2 – 1.4)	0.186
No	83 (90.2)	48 (82.8)	Reference	
Type of fracture				
Single fracture	75 (81.5)	41 (70.7)	Reference	
Multiple fracture	17 (18.5)	17 (29.3)	0.5 (0.3 – 1.2)	0.125
Prior persistent pain				
Yes	5 (5.4)	6 (10.3)	0.5 (0.1 – 1.7)	0.269
No	87 (94.6)	52 (89.7)	Reference	
Prior pain severity				
Moderate (4 - 6)	91 (98.9)	53 (91.4)	8.6 (1.0-75.5)	0.053
Severe (7 - 10)	1 (1.1)	5 (8.6)	Reference	

Chapter 5 Discussion

In this study, we found that the prevalence of severe pain postoperatively was 46%,62% and 27% at 12, 24 and 48 hours respectively. This compares with a local study done by Kimani et al in KNH which illustrated incidence of moderate and severe postoperative pain to be 40.7%. Another study conducted on orthopedic patients postoperatively found a postoperative pain prevalence of 61%, 73%, 67% and 58% at 4, 24, 36 and 48 hours after surgery respectively. Postoperative pain peaked 24 hours postoperatively. Clinicians should therefore be more vigilant in handling pain within this window. (54) (48)

The Audit Commission (Uk) in 1997 proposed that less than 20% of patients should experience severe pain following surgery after 1997 and that this should have reduced to 5% by 2002. Although the source of these values are not substantiated, it has stood as a standard for ideal postoperative pain management (55). According to this study therefore, postoperative pain is not adequately managed following orthopedic surgical patients, despite the huge armamentarium of medication and interventions available for postoperative pain management.

NSAIDs (Dexketoprofen) and paracetamol accounted for majority of intraoperative and postoperative analgesics prescribed at 86% and 61% respectively. Opioids (Morphineand tramadol) accounted for 52% of intraoperative analgesics. Kimani et al in 2013

found that Pethidine accounted for the bulk of intraoperative analgesics prescribed in KNH (84.5% of patients), diclofenac prescribed in 77.2% of patients, other opioids (morphine and tramadol) prescribed in 58% of patients and paracetamol used in 3.6% of patients intraoperatively.(54) The declined trend in pethidine use is highly due to its lower safety profile in comparison to other opioids and is in many instances reserved for patients who are intolerant or exhibit allergic reactions to other opioids.(56)

Rescue analgesia was administered in 19% of patients with morphine accounting for the bulk of the rescue analgesics given (78.5%). Fentanyl, ketamine and midazolam were the rescue medication administered in PACU while morphine was the probable rescue medication given in the orthopedic wards. This is in tandem with a study done by Rajagopalan et al that found morphine to be more effective than fentanyl in managing pain following spinal fusion. (57)

65.3% and 88% of patients had been out of bed within 24 and 48 hours respectively. Early mobilization- sitting out of bed within 2 days as defined by Zhou et al is a good practice in having good functional outcomes and reducing postoperative complications as well as being a good indicator for pain management. (58,59)

Median duration of surgery was 155 minutes with majority of surgeries taking more than three hours. Duration of surgery has been directly shown to increase chances of postoperative pain (9). Efficiency in surgical procedures is highly advised in managing postoperative pain effectively. To alleviate postoperative pain, regional and peripheral nerve blocks are recommended. This study however highlighted

underutilization of this pain management modalities. Regional anaesthesia was used in only 1 patient (0.7%) and epidural anaesthesia in 20 patients (13.4%).

Factors found to increase the risk of postoperative pain in our study were: Prior moderate and severe pain (p value 0.053), preoperative chronic pain (p value 0.029) and preoperative anxiety (p value 0.059).

Chapter 6 Conclusion and recommendation

6.1 Conclusion

Pain following lower limb orthopedic surgeries remain undermanaged, peaking at 24 hours postoperatively. The full armamentarium in addressing pain postoperatively is not fully utilized. Need for rescue analgesia following orthopedic surgical procedures with the current trend in pain control is low with a good indicator of early mobilization depicting a favourable response to pain control. Factors highlighted to increase the risk of postoperative pain were prior preoperative moderate and severe pain and preoperative anxiety.

6.2 Recommendations

Clinicians involved in pain management are encouraged to consider and use all available resources at their disposal in managing postoperative pain including regional and epidural anaesthesia. Multimodal analgesia should be used in managing pain postoperatively. Operating surgeons should be more efficient in their surgical practice and technique to reduce the duration of surgery. Interdisciplinary consultations are highly encouraged in utilizing the whole scope of available modalities in managing pain in orthopedic surgical procedures. Preoperative evaluation of patients using validated tools should be done to derive a patient specific postoperative pain management strategy.

REFERENCES

1. Brennan F, Lohman D, Gwyther L. Access to Pain Management as a Human Right. Am J Public Health. 2019 Jan;109(1):61–5.

2. Lohman D, Schleifer R, Amon JJ. Access to pain treatment as a human right. BMC Med. 2010 Jan 20;8(1):8.

3. Declaration of Montréal: declaration that access to pain management is a fundamental human right - PubMed [Internet]. [cited 2022 Jan 31]. Available from: https://pubmed.ncbi.nlm.nih.gov/21426215/

4. Gan TJ. Poorly controlled postoperative pain: prevalence, consequences, and prevention. J Pain Res. 2017 Sep 25;10:2287–98.

5. Holmes A, Williamson O, Hogg M, Arnold C, Prosser A, Clements J, et al. Predictors of pain severity 3 months after serious injury. Pain Med Malden Mass. 2010 Jul;11(7):990–1000.

6. Pasero C, McCaffery M. Orthopaedic postoperative pain management. J Perianesthesia Nurs Off J Am Soc PeriAnesthesia Nurses. 2007 Jun;22(3):160–72; quiz 172–3.

7. Grichnik KP, Ferrante FM. The difference between acute and chronic pain. Mt Sinai J Med N Y. 1991 May;58(3):217–20.

8. Untreated Pain, Narcotics Regulation, and Global Health Ideologies [Internet]. [cited 2022 Feb 2]. Available from: https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001411

9. Arefayne N, Seid S, Gebregzi A, Mustofa S. Incidence and associated factors of post-operative pain after emergency Orthopedic surgery: A multi-centered prospective observational cohort study. Int J Surg Open. 2020 Jan 1;27:103–13.

10. Eshete MT, Baeumler PI, Siebeck M, Tesfaye M, Haileamlak A, Michael GG, et al. Quality of postoperative pain management in Ethiopia: A prospective longitudinal study. PLoS ONE. 2019 May 1;14(5):e0215563.

11. Patients' perception of postoperative pain management: validation of the International Pain Outcomes (IPO) questionnaire - PubMed [Internet]. [cited 2022 Jan 31]. Available from: https://pubmed.ncbi.nlm.nih.gov/24021577/

12. Bérubé M, Choinière M, Laflamme YG, Gélinas C. Acute to chronic pain transition in extremity trauma: A narrative review for future preventive interventions (part 2). Int J Orthop Trauma Nurs. 2017 Feb;24:59–67.

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

14. Patel NB. Chapter 3 Physiology of Pain. :6.

15. Institute of Medicine (US) Committee on Pain D, Osterweis M, Kleinman A, Mechanic D. The Anatomy and Physiology of Pain [Internet]. Pain and Disability: Clinical, Behavioral, and Public Policy Perspectives. National Academies Press (US); 1987 [cited 2022 Jan 31]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK219252/

16. Steeds C. The anatomy and physiology of pain. Surg Oxf. 2013 Feb 1;31:49–53.

17. Purves D, Augustine GJ, Fitzpatrick D, Katz LC, LaMantia AS, McNamara JO, et al. The Physiological Basis of Pain Modulation. Neurosci 2nd Ed [Internet]. 2001 [cited 2022 Jan 31]; Available from: https://www.ncbi.nlm.nih.gov/books/NBK10985/

18. Woessner JW. Overview of Pain: Classification and Concepts. In: Weiner's Pain Management. 7th ed. CRC Press; 2007.

19. Dey S, Guthmiller KB, Varacallo M. Complex Regional Pain Syndrome. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 [cited 2022 Jan 31]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK430719/

20. Turk DC, Okifuji A. Psychological factors in chronic pain: evolution and revolution. J Consult Clin Psychol. 2002 Jun;70(3):678–90.

21. Vancleef LMG, Peters ML. Pain catastrophizing, but not injury/illness sensitivity or anxiety sensitivity, enhances attentional interference by pain. J Pain. 2006 Jan;7(1):23–30.

22. Quartana PJ, Campbell CM, Edwards RR. Pain catastrophizing: a critical review. Expert Rev Neurother. 2009 May;9(5):745–58.

23. Kalkman JC, Visser K, Moen J, Bonsel JG, Grobbee ED, Moons MKG. Preoperative prediction of severe postoperative pain. Pain. 2003 Oct;105(3):415–23.

24. Yang MMH, Hartley RL, Leung AA, Ronksley PE, Jetté N, Casha S, et al. Preoperative predictors of poor acute postoperative pain control: a systematic review and meta-analysis. BMJ Open. 2019 Apr 1;9(4):e025091.

25. Ip HYV, Abrishami A, Peng PWH, Wong J, Chung F. Predictors of postoperative pain and analgesic consumption: a qualitative systematic review. Anesthesiology. 2009 Sep;111(3):657–77.

26. Dias TLF, Costa APM, Anjos CM, Andrade JM de L, Funez MI. General anesthesia is predictive for occurrence of postoperative pain. Braz J Pain [Internet]. 2020 [cited 2022 Feb 1]; Available from: http://www.gnresearch.org/doi/10.5935/2595-0118.20200024

27. Admassu WS, Hailekiros AG, Abdissa ZD. Severity and Risk Factors of Post-Operative Pain in University of Gondar Hospital, Northeast Ethiopa. J Anesth Clin Res [Internet]. 2016 [cited 2022 Feb 1];7(10). Available from: https://www.omicsonline.org/open-access/severity-and-risk-factors-of-postoperative-pain-in-university-of-gondarhospital-northeast-ethiopa-2155-6148-1000675.php?aid=81493

28. Nesek-Adam V, Rasić Z, Schwarz D, Grizelj-Stojcić E, Rasić D, Krstonijević Z, et al. The effect of spinal versus general anesthesia on postoperative pain and analgesic requirements in patients undergoing peripheral vascular surgery. Coll Antropol. 2012 Dec;36(4):1301–5.

29. Bovill JG. Mechanisms of actions of opioids and non-steroidal anti-inflammatory drugs. Eur J Anaesthesiol Suppl. 1997 May;15:9–15.

30. Hsu JR, Mir H, Wally MK, Seymour RB, Orthopaedic Trauma Association Musculoskeletal Pain Task Force. Clinical Practice Guidelines for Pain Management in Acute Musculoskeletal Injury. J Orthop Trauma. 2019 May;33(5):e158–82.

31. Singla N, Pong A, Newman K, MD-10 Study Group. Combination oxycodone 5 mg/ibuprofen 400 mg for the treatment of pain after abdominal or pelvic surgery in women: a randomized, double-blind, placebo- and active-controlled parallel-group study. Clin Ther. 2005 Jan;27(1):45–57.

32. Park TW, Saitz R, Ganoczy D, Ilgen MA, Bohnert ASB. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. BMJ. 2015 Jun 10;350:h2698.

33. Benyamin R, Trescot AM, Datta S, Buenaventura R, Adlaka R, Sehgal N, et al. Opioid complications and side effects. Pain Physician. 2008 Mar;11(2 Suppl):S105-120.

34. Beaudoin FL, Gutman R, Merchant RC, Clark MA, Swor RA, Jones JS, et al. Persistent pain after motor vehicle collision: comparative effectiveness of opioids vs nonsteroidal antiinflammatory drugs prescribed from the emergency department-a propensity matched analysis. Pain. 2017 Feb;158(2):289–95.

35. Gerstenfeld LC, Einhorn TA. COX inhibitors and their effects on bone healing. Expert Opin Drug Saf. 2004 Mar;3(2):131–6.

36. Imani F, Rahimzadeh P. Gabapentinoids: Gabapentin and Pregabalin for Postoperative Pain Management. Anesthesiol Pain Med. 2012;2(2):52–3.

37. Peng C, Li C, Qu J, Wu D. Gabapentin can decrease acute pain and morphine consumption in spinal surgery patients: A meta-analysis of randomized controlled trials. Medicine (Baltimore). 2017 Apr;96(15):e6463.

38. Chou R, Gordon DB, de Leon-Casasola OA, Rosenberg JM, Bickler S, Brennan T, et al. Management of Postoperative Pain: A Clinical Practice Guideline From the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Committee, and Administrative Council. J Pain. 2016 Feb;17(2):131–57.

39. Köse Tamer L, Sucu Dağ G. The Assessment of Pain and the Quality of Postoperative Pain Management in Surgical Patients. SAGE Open. 2020 Apr 1;10(2):2158244020924377.

40. Schwenkglenks M, Gerbershagen HJ, Taylor RS, Pogatzki-Zahn E, Komann M, Rothaug J, et al. Correlates of satisfaction with pain treatment in the acute postoperative period: results from the international PAIN OUT registry. Pain. 2014 Jul;155(7):1401–11.

41. Gordon DB, Polomano RC, Pellino TA, Turk DC, McCracken LM, Sherwood G, et al. Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R) for Quality Improvement of Pain Management in Hospitalized Adults: Preliminary Psychometric Evaluation. J Pain. 2010 Nov;11(11):1172–86.

42. An examination of the prevalence of acute pain for hospitalised adult patients: a systematic review - PubMed [Internet]. [cited 2022 Jan 31]. Available from: https://pubmed.ncbi.nlm.nih.gov/26778249/

43. Haonga BT, Makupa JE, Muhina RI, Nungu KS. Pain management among adult patients with fractures of long bones at Muhimbili Orthopaedic Institute in Dar es Salaam, Tanzania. Tanzan J Health Res. 2011 Oct;13(4):107–11.

44. When race matters: disagreement in pain perception between patients and their physicians in primary care. [Internet]. [cited 2022 Jan 31]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2576060/

45. Ossendorp R, Forouzanfar T, Ashton-James CE, Bloemers F. Protocols for treating the postoperative pain of fractures in Dutch hospitals. J Pain Res. 2013;6:635–9.

46. Immediate postoperative pain management in adult patients following orthopaedic surgery at the Kenyatta national hospital [Internet]. [cited 2022 Feb 1]. Available from: http://erepository.uonbi.ac.ke/handle/11295/96429

47. Jung SH. Stratified Fisher's Exact Test and its Sample Size Calculation. Biom J Biom Z. 2014 Jan 7;56:129–40.

48. Ndebea AS, van den Heuvel SAS, Temu R, Kaino MM, van Boekel RLM, Steegers MAH. Prevalence and Risk Factors for Acute Postoperative Pain After Elective Orthopedic and General Surgery at a Tertiary Referral Hospital in Tanzania. J Pain Res. 2020 Nov 19;13:3005–11.

49. Benítez Brito N, Suárez Llanos JP, Fuentes Ferrer M, Oliva García JG, Delgado Brito I, Pereyra-García Castro F, et al. Relationship between Mid-Upper Arm Circumference and Body Mass Index in Inpatients. PloS One. 2016;11(8):e0160480.

50. Patridge EF, Bardyn TP. Research Electronic Data Capture (REDCap). J Med Libr Assoc JMLA. 2018 Jan;106(1):142–4.

51. Garcia TP, Marder K. Statistical Approaches to Longitudinal Data Analysis in Neurodegenerative Diseases: Huntington's Disease as a Model. Curr Neurol Neurosci Rep. 2017 Feb;17(2):14.

52. Janeway H, O'Reilly G, Schmachtenberg F, Kharva N, Wachira B. Characterizing injury at a tertiary referral hospital in Kenya. PloS One. 2019;14(7):e0220179.

53. Gathecha GK, Githinji WM, Maina AK. Demographic profile and pattern of fatal injuries in Nairobi, Kenya, January–June 2014. BMC Public Health. 2017 Jan 6;17(1):34.

54. Mbugua KG. Acute Post-Operative Pain Management At The Kenyatta National Hospital. :67.

55. Dolin SJ, Cashman JN, Bland JM. Effectiveness of acute postoperative pain management: I. Evidence from published data. Br J Anaesth. 2002 Sep;89(3):409–23.

56. Pan HH, Li CY, Lin TC, Wang JO, Ho ST, Wang KY. Trends and characteristics of pethidine use in Taiwan: a six-year-long survey. Clinics. 2012 Jul;67(7):749–55.

57. Venkatraman R, Pushparani A, Balaji R, Nandhini P. Comparison of low dose intravenous fentanyl and morphine infusion for postoperative analgesia in spine fusion surgeries – a randomized control trial. Braz J Anesthesiol Engl Ed. 2021 Jul;71(4):339–44.

58. Xiang Z, Chen Z, Wang P, Zhang K, Liu F, Zhang C, et al. The effect of early mobilization on functional outcomes after hip surgery in the Chinese population – A multicenter prospective cohort study. J Orthop Surg. 2021 Sep 1;29(3):23094990211058904.

59. De Luca ML, Ciccarello M, Martorana M, Infantino D, Letizia Mauro G, Bonarelli S, et al. Pain monitoring and management in a rehabilitation setting after total joint replacement. Medicine (Baltimore). 2018 Oct;97(40):e12484.

APPENDICES

CONSENT FORM: ENGLISH

Dear Sir \ Madam,

I am Dr. Nyambegera Zacharia Bosire pursuing Degree of Master of Medicine (Orthopedics) at the School of Medicine, University of Nairobi. We would be grateful if you would participate in our survey on how patients feel after surgery. The aim of the survey is to improve the management of pain after surgery in this department.

Your participation is voluntary and the information you provide will be made anonymous once you hand in this questionnaire. This means that your name or other form of identification will be deleted from the questionnaire after you hand it in and will not be included in any records we will hold.

There is no direct monetary benefit to you for participating. Your answers in this questionnaire will not be shared with your medical or nursing team.

The team will treat you in the same way whether or not you choose to participate in our survey.

We wish to request for your participation and co-operation in answering the questions in the patient outcome questionnaire.

The information you give will be used for academic purposes and for bettering the practice of medicine.

For any inquiry regarding the study you may contact:

The supervisor:

Ethical review Board; cell phone Number-

PARTICIPANT'S CONSENT

The aims of this study have been sufficiently explained to me. I have voluntarily accepted to participate in this study. I understand that I may withdraw at any given time from this study without giving any reasons and that I will not be penalized for my withdrawal at any given time.

I consent to participate in this study, provided my privacy and confidentiality is guaranteed.

Name of the Participant……..……Sign…….....Date……

Name of the data collection officer.....Sign.....Date.....

CONSENT FORM: SWAHILI

IDHINI BAADA YA MAELEZO KAMILIFU

Kwa bwana/bi,

Habari. Jina langu ni Dkt. Nyambegera Zacharia Bosire mwanafunzi wa hada ya pili katika chuo kikuu cha Nairobi shule ya udaktari (Degree of Master of Medicine Orthopedics). Tungependa kufanya utafiti huu ili kujua wagonjwa wanavyohisi baada ya upasuaji.

Habari utakayotoa itatumika kwa madhumuni ya utafiti pekee, hivyo usiri wako utahakikishwa. Jina lako halitanakiliwa kwenye dodoso.

Uko huru kujiondoa kutoka kwenye utafiti huu wakati wowote upendavyo na hakuna madhara yatakayo tendeka kwako. Uamuzi wako kujiondoa kutoka kwenye utafiti hautaadhiri huduma unayopata kutoka kwenye kliniki hii.

Hakuna manufaa ya kifedha kwako. Ninakuomba uwe mshiriki katika utafiti huu, na kuomba ushirikiano wako katika kujibu maswali yaliyo kwenye dodoso.

Iwapo una maswali yoyote, unaweza piga simu:

Msimamizi wetu; Dkt Mwiti-

Bodi ya Ukaguzi wa Kimaadili;

RUHUSA YA MSHIRIKI

Nimeelezwa malengo ya utafiti huu ya kutosha. Ninakubali kwa hisani yangu kushiriki katika utafiti huu. Ninaelewa kuwa niko huru kujiondoa kutoka kwenye utafiti wakati wowote ule bila kutoa sababu zozote na sitapata adhabu kwa sababu ya kujiondoa.

Ninakubali kushiriki katika utafiti huu iwapo usiri wangu utahakikishwa.

Jina la mshiriki …… Sahihi ……. Tarehe ……..

Jina la mtafiti ……..... Sahihi …….. Tarehe ……

Patient Demographics

Patient number:

Age:

Gender:

Weight_____ Height MUAC:

Occupation:

Level of Education: No formal education ☐

Primary ☐

Secondary ☐

Tertiary ☐

Preoperative Factors

Single fracture ☐ Multiple Fractures ☐

Preoperative Anxiety Yes ☐ No ☐

Chronic Pain Yes ☐ No ☐

Chronic Opioid use Yes ☐ No ☐

Intraoperative Factors

Intraoperative Analgesics and dosage ……

……

…….....

…….

Intraoperative anesthesia: General Anaesthesia ☐ Spinal Anaesthesia ☐

Regional Anesthesia ☐ Epidural Anaesthesia ☐

Duration of Surgery (Minutes)……..

Postoperative Factors

Analgesics prescribed and received (with dosage)

…… ……

……..

……

……...

……..

Rescue Analgesia **YES** **No**

If Yes Number of times…..... ,.

Medication administered and dosage……

……

Regional anaesthesia /nerve blocks **Yes** **No**

Patient outcomes questionnaire

The following questions are about pain you experienced since your surgery.

P1. On this scale, please indicate the **worst pain** you had since your surgery:

0	1	2	3	4	5	6	7	8	9	10

No pain

worst painpossible

P2. On this scale, please indicate the **least pain** you had since your surgery:

0	1	2	3	4	5	6	7	8	9	10

No pain

worst painpossible

P3. How often were you in **severe pain** since your surgery?
Please circle your best estimate of the percentage of time you experienced **severe pain**:

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

Neverinseverepain

alwaysinseverepain

P4. Circletheonenumberbelowthatbestdescribeshowmuch,sinceyoursurgery,**pain interfered with or prevented you from...**

a. Doing **activities in bed** such as turning, sitting up, changing position:

0	1	2	3	4	5	6	7	8	9	10

Didnotinterfere

completelyinterfered

b. **Breathing deeply** or **coughing**:

0	1	2	3	4	5	6	7	8	9	10

Didnotinterfere

completelyinterfered

c. **Sleeping**:

0	1	2	3	4	5	6	7	8	9	10

Didnotinterfere

completelyinterfered

d. Haveyoubeen**outofbed**

Yes No

If yes,howmuchdid**paininterfereorpreventyoufromdoingactivitiesout ofbed**suchas walking, sitting in a chair, standing at the sink:

0	1	2	3	4	5	6	7	8	9	10

Didnotinterfere

completelyinterfered

Patient outcomesquestionnaire

P5. Pain can affect our mood and emotions.
On this scale, please circle the one number that best shows how much, since your surgery,
pain caused you to feel...

a. **anxious**

0	1	2	3	4	5	6	7	8	9	10

Notat all

☐ **extremely** ☐

☐ ☐

b. **helpless**

0	1	2	3	4	5	6	7	8	9	10

Notat all

extremely

P6. Have you had any of the following **side effects** since your surgery?
Please circle"0"if no; if yes, circle the one number that best shows the severity of each:

a. Nausea

0	1	2	3	4	5	6	7	8	9	10

None **severe**

b. Drowsiness

0	1	2	3	4	5	6	7	8	9	10

None **severe**

c. Itching

0	1	2	3	4	5	6	7	8	9	10

None **severe**

d. Dizziness

0	1	2	3	4	5	6	7	8	9	10

None **severe**

P7. Since your surgery, how much **pain relief** have you received?
Please circle the one percentage that best shows how muchrelief you have received from all of your **paintreatments** combined(medicineand non-medicinetreatments):

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

No relief **completerelief**

P8. Would you have liked **MORE pain treatment** than you received?

Yes No

P9. Did you receive any **information** about your **pain treatment** options?

Yes No

P10. Were you **allowed to participate in decisions** about your **pain treatment** as much as you wanted to?

0	1	2	3	4	5	6	7	8	9	10

Not at all **very much so**

P11. Circle the one number that best shows how **satisfied** you are with the results of your **pain treatment** since your surgery:

0	1	2	3	4	5	6	7	8	9	10

extremely satisfied **extremely dissatisfied**

P12. Did you use or receive any **non-medicine methods** to relieve your **pain**?

Yes No

If yes, **check all** that apply:

coldpack	meditation	deep breathing
heat	acupuncture	prayer
talkingtomedicalstaff	walking	massage
talking to friends orrelatives	relaxation	imagery or visualization

TENS (Transcutaneous Electrical Nerve Stimulation)

distraction(likewatchingTV, listening to music, reading) other

(pleasedescribe):

P13. Did youhavea **persistentpainfulconditionfor 3 months** ormorebefore cominginto hospital for this surgery?

Yes No

a. Ifyes,**howsevere**wasthe**pain**mostofthetime? Please circlethenumberthatindicatesthis.

0	1	2	3	4	5	6	7	8	9	10

no pain **worstpain possible**

b. If yes, **where** was this **persistent pain** located?

siteofsurgery elsewhere both (site of surgeryand elsewhere)

Thank you for your time and feedback

Tobe filledinbytheresearchassistant Research assistantcode:

Patientwas interviewed: Yes No

If yes, please mark the reason(s):

Too ill / weak	Too much pain	Requested assistance	Did not understand

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/175

10th May, 2022

Dr. Zacharia Bosire Nyambegera
Reg. No H58/6960/2017
Dept. of Orthopaedic Surgery
Faculty of Health Sciences
University of Nairobi

Dear Dr. Nyambegera,

RESEARCH PROPOSAL: POSTOPERATIVE PAIN MANAGEMENT AFTER INVASIVE LOWER LIMB ORTHOPAEDIC SURGERY AT KENYATTA NATIONAL HOSPITAL; A PROSPECTIVE STUDY (P116/02/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P116/02/2022.** The approval period is 10th May 2022– 9th May 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 Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept. of Orthopaedic Surgery, UoN
Supervisors: Dr. J.C. Mwangi Dept. of Orthopaedic Surgery, UoN
Dr. Ezekiel Oburu, Dept. of Orthopaedic Surgery, UoN

POSTOPERATIVE PAIN MANAGEMENT AFTER INVASIVE LOWER LIMB ORTHOPAEDIC SURGERY AT KENYATTA NATIONAL HOSPITAL: A LONGITUDINAL PROSPECTIVE STUDY.

ORIGINALITY REPORT

10%	8%	7%	5%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	physiologyplus.com Internet Source	1%
2	summit.sfu.ca Internet Source	1%
3	Joseph R. Hsu, Hassan Mir, Meghan K. Wally, Rachel B. Seymour. "Clinical Practice Guidelines for Pain Management in Acute Musculoskeletal Injury", Journal of Orthopaedic Trauma, 2019 Publication	1%
4	Submitted to University of Nairobi Student Paper	1%
5	Marco Aurelio Pinho Oliveira, Thiers Soares Raymundo, Jose Duvan Lopez-Jaramillo, Jorge Dario Lopez-Isanoa et al. "Chapter 10 Neuroanatomical Insights in Adolescents with Endometriosis and Pain", Springer Science and Business Media LLC, 2020 Publication	1%

DEPT OF ORTHOPAEDIC SURGERY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 19676 - 00200 KNH
NAIROBI
TEL: 2720940 / 2726300, Ext. 43590