PREOPERATIVE PATIENT FACTORS ASSOCIATED WITH ACUTE POSTOPERATIVE PAIN FOLLOWING ABDOMINAL SURGERIES AT THE KENYATTA NATIONAL HOSPITAL

Dr. Sally Bochere Getugi (MBChB)

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PRINCIPAL INVESTIGATOR:

Dr. Sally B. Getugi

MBChB (Kenyatta University)

SUPERVISORS

1. **Dr. Mark V. Gacii**

MBChB, MMed Anaesthesia (UoN)

Lecturer,

Department of Anaesthesia

University of Nairobi

2. **Dr. Lee N. Kigera**

MBChB, MMed Anaesthesia (UoN)

Lecturer,

Department of Medical Physiology

Kenyatta University

DECLARATION OF ORIGINALITY

Principal Investigator

I hereby state that this proposal is my original work and has not been presented for any other purpose. Information used from other sources have been rightfully cited.

Dr. Sally B. Getugi,
Master of Medicine, Anaesthesia
University of Nairobi
Registration Number: H58/6954/2017

Signature..... **Date**...28/11/2022.....

SUPERVISORS' APPROVAL

We hereby declare that we have approved the submission of this proposal to the Kenyatta National hospital/University of Nairobi Ethics Review Committee for review.

Dr. Mark V. Gacii

MBChB, MMed Anaesthesia (UoN)

Signed..... **Date** 2nd December 2022

Dr. Lee N. Kigera

MBChB, MMed Anaesthesia (UoN)

Signed..... **Date** 2nd Decembe 2022

DEPARTMENTAL APPROVAL

This proposal has been reviewed by the department and approved for submission for ethical review.

Signed.....

CHAIRMAN,

Department of Anaesthesia

Faculty of Health Sciences

Date 2/12/2022.....

DEPARTMENT OF ANAESTHESIA
FACULTY OF HEALTH SCIENCES
P. O. Box 19676 - KNH 00202,
NAIROBI

DEDICATION

I dedicate this book to my loving and supportive parents; Amb. Japheth Getugi and Mrs. Gladys Getugi. Thank you for moulding me to become the person I am, encouraging me to pursue my dreams and to always strive to do the best. We did it!

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LIST OF ABBREVIATIONS

APS- Acute Pain Service

BMI- Body Mass Index

ERC- Ethics Research Committee

KNH – Kenyatta National Hospital

NRS- Numerical Rating Scale

PACU- Post Anaesthesia Care Unit

SSA- Sub Sahara Africa

UoN – University of Nairobi

VAS – Visual Analogue Scale

WHO- World Health Organization

ABSTRACT

Background:

Over the years, the number of surgical procedures performed has increased worldwide and abdominal surgeries constitute a significant percentage of these surgeries. The burden of postoperative pain has been quoted to be as high as 80%. The complications of untreated postoperative pain increase morbidity and mortality.

Broad Objective:

To investigate preoperative patient factors that are associated with acute postoperative pain following abdominal surgeries at the Kenyatta National Hospital (KNH).

Methodology:

A prospective cross-sectional study was conducted at the KNH. The target population consisted of patients scheduled for abdominal surgery, above 18 years and had the capacity to provide informed consent. Using consecutive sampling, 195 patients were enrolled over the course of 6 months. 14 variables were assessed and categorised into nine demographic variables, 2 psychological variables and 3 independent variables. The Numerical Rating Scale (NRS) was used to assess pain scores preoperatively and postoperatively. The Hospital and Depression Scale (HADS) was used to assess psychological factors preoperatively. The primary outcome measured was the acute postoperative pain following abdominal surgery.

Data Analysis:

Data was entered into the Microsoft Excel 2017 spreadsheet prior to exporting to the Statistical Package for Social Sciences version 23.0 for analysis. Demographic characteristics were analysed and presented as frequencies and percentages for categorical variables, and as means with standard deviations or median with interquartile range for continuous variables. The postoperative pain score (0-10) was dichotomized into two categories: presence of no pain to mild pain (0 – 3) and presence of moderate to severe pain (4 – 10).

Results:

The study illustrated that 24 hours postoperatively, 67.2% of patients experienced moderate to severe acute postoperative pain. There was a significant association of preoperative pain with acute postoperative pain, p=<0.001. Underweight patients were more 2.5 times more likely than obese patients to experience acute postoperative pain. Patients with primary education were 2.5 times more likely to experience acute postoperative pain. Employed individuals were more likely than unemployed individuals to experience acute postoperative pain.

Conclusion:

Acute postoperative pain remains a problem to surgical patients in our institution. Identification of patient factors that are associated with acute postoperative pain can assist in enhancing perioperative pain management strategies in at risk patients.

CHAPTER ONE: INTRODUCTION

1.1 Background

In the last three decades, the global prevalence of postoperative pain has been reported to vary between 20-80%(1). Commendable efforts have been made to try and reduce the incidences of untreated postoperative pain; however, a significant proportion of individuals still suffer from suboptimal postoperative pain control. Surgery predisposes to postoperative pain in an almost predictable manner and is the most common cause of postoperative pain(2). It has also been suggested that the surgeries associated with a high pain intensity include thoracic surgeries, orthopaedics with major joint surgery and open abdominal surgery(3).

Complications of untreated postoperative pain are numerous, devastating and can be life-threatening to the patient. These complications include delayed wound healing, increased risk of deep vein thrombus, pulmonary embolism, myocardial infarctions and development of chronic pain syndromes (4–6). Great strides have been made in research surrounding postoperative pain management and in the developed world there has been appreciable research done to elucidate preoperative predictors of acute postoperative pain. However, there is scarcity of data in Sub-Sahara Africa (SSA) in preoperative pain research, and the burden of postoperative pain is high.

In SSA, the incidence of postoperative pain highly differs from country to country. One study in Nigeria reported that 95% of postoperative patients experienced varying degrees of postoperative pain, while in Tanzania, postoperative pain accounted for 40% of all postoperative complications(7). In Ethiopia, moderate to severe pain postoperative was reported in 57% of patients in the immediate postoperative period and 78% in the first 12 hours(8). In South Africa, from a study of 1,231 patients, 62% indicated their maximum pain as moderate or severe(9). While in Kenya, a study done on patients following major abdominal and thoracic operations at the KNH, 56% of reported postoperative pain was within moderate and severe classification(6). These above figures highlight that there is still a gap in our understanding and knowledge of postoperative pain. Preoperative pain research could help bridge some of these gaps and offer more insight into reducing the burden of pain.

The study aims to investigate the following preoperative patient factors which have been categorised into demographic, psychological and other independent variables. Due to the

discrepancies and the conflicting findings in literature, it will be prudent assess a total of 14 variables to see which correlate with high postoperative pain intensities. The two psychological factors under investigation, anxiety and depression will be assessed using the HADS and this will be done prior to the surgery.

For purpose of this study, the assumption made is that the preoperative patient factors are not known in the local setting and thus are to be investigated. The information from previous studies and literature serves as a great framework and guideline to delineate which factors to pay close attention to. It is the hope that the answer to this assumption will assist in adding insight for surgical patients and adding to the pool of knowledge of preoperative pain research.

Current literature points towards predictors of postoperative pain as younger age, female gender, preoperative pain, education status, socioeconomic status, physical status, history of depressive anxiety and depressive symptoms amongst others(1,3,5,8). The systematic review done in 2009 by Ip *et al*, was able to illustrate four significant predictors of pain as age, anxiety, preoperative pain and type of surgery from 48 eligible studies with 23,037 patients. In as much as they able to demonstrate the findings, they acknowledged the need for studies to ideally be homogenous in terms of demographics, surgical procedure, medical and psychological history and large-scale(3). According to the latest systemic review and metanalysis done by Yang *et al* in 2019, out of the 33 studies included, they found that the most well-studied predictors were female sex, presence of preoperative pain and younger age. However, only 20 studies included sex as a variable, 13 considered preoperative pain and only 14 studied younger age as a variable of predictors of pain. These incongruencies in the predictors studied or lack thereof, make it difficult to draw definite conclusions that can be generalised.

Some of the studies have differing findings and conclusions on the predictors of postoperative pain. Factors such differences in studied surgical population, methodology, study end points and included variables could be explanations for the differing findings. This makes some of the findings difficult to generalise outside the population studied and the study design used. Mamie *et al* concluded in their study to answer 'Are there reliable predictors of postoperative pain?' found that neither gender nor age seemed to increase the risk of postoperative pain in the present results. These two factors are extremely controversial in the literature(10). To elaborate further, the study done at the KNH done on patients following major abdominal and thoracic operations found that sex, weight, age, and type of surgery did not significantly affect the postoperative pain scores(6).

Further shortcomings faced in preoperative pain research is that the African population has not been adequately represented in the majority of the studies done. The systematic review done by Yang *et al,* only had one South African study included in their meta-analysis. This could dampen the application of the results outside the populations studied. This gap offers an opportunity for research into preoperative risk factors of acute postoperative pain in SSA, particularly Kenya. The outcome from this research will highlight preoperative predictive factors with the aim to assist in enhancing individualised pain management plans in surgical patients.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

There has been a significant increase in the number of surgeries performed worldwide. For the year 2012 in a report published by the World Health Organisation (WHO), the estimated total global volume was 312.9 million operations(11). An increasing number of patients undergo abdominal surgery multiple times during their lifetime, due to higher life expectancies and advances in surgical technology this number is expected to increase even further. It is estimated that 10 to 37 % of patients undergoing elective abdominal surgery will require repeat abdominal surgery (12).

Surgery commonly causes postoperative pain that should be alleviated as soon and as effectively as possible to reduce suffering, to promote the healing process, rehabilitation and to prevent complications(13). An important component of the surgical patient care plan is adequate management of postoperative pain. This is necessary in order to avoid negative patient outcomes and experiences(4). The management of postoperative pain can be done using evidence-based treatment pathways from analysing the characteristics of the surgical pain and successful treatment modalities from literature specific to the procedures(13).

Pain is a multifaceted and highly personal experience, as McCaffrey described “pain is whatever the experiencing person says it is and exists whenever he/she says it does.”(3) Inadequately treated postoperative pain is still a prevalent phenomenon worldwide that adversely affects patient experience and outcome(9). Postoperative pain has been reported to be as high as 80% in certain studies and globally the prevalence varies between 20-80% in the past 3 decades(1). It is a combined constellation of several unpleasant sensory, emotional and mental experience precipitated by the surgical trauma and associated with autonomic, endocrine-metabolic, physiological and behavioural responses(14).

According to Ip *et al*, one of the most commonly reported postoperative symptoms is postoperative pain (3). By studying preoperative predictive factors, it would greatly benefit the understanding of how to mitigate the effect of untreated postoperative pain prior to surgery. The identification of these factors would facilitate better pain management strategies and early interventions can be instituted (3). This, coupled with the present knowledge on pain management, would help reduce the incidence of postoperative pain significantly. Patient

satisfaction will also be improved as it has been found that recovery after surgery and satisfaction of the service rendered is related to the adequacy of pain management (15).

The complications of untreated postoperative pain are devastating to the patient and negatively impact the society. An appreciable amount of money is spent within the healthcare system on rehabilitation of patients who due to unrelieved pain develop adverse pain conditions. These conditions can reduce a patient quality of life, requiring more rehabilitation and affect their productivity at work. More days are spent on rehabilitation instead of at places of work and this ultimately affects the economy(16). It has been estimated that the United States contributes an estimated $560 billion to disability programs, lost productivity and direct medical costs due to chronic pain cases each year (17,18).

Preoperative pain research is not as robustly studied in developing countries as with developed countries. Unfortunately, in SSA, there are many barriers to adequate pain control. Some of these barriers, include deficient pain management education for healthcare workers, prescribing errors of pain medication, opioid unavailability either due to unreliable supply or unclear national drug policies (19). Kenya has made admirable efforts to reduce some of these barriers and there has been better service delivery of pain medication through national drug policies and strategies.

Despite hospitals being better equipped, better trained healthcare staff and the availability of affordable medication, the incidence of postoperative pain remains high in Kenya. A local study done at the Kenyatta National Hospital on postoperative management of pain following major abdominal and thoracic surgery concluded that the standard of post-operative pain relief is poor. 56% of the patients experienced moderate to severe pain, with 34.4 % experiencing mild pain(6). Additionally, in a study done at another tertiary hospital in Nairobi, an overall prevalence of postoperative pain was found to be 55.3% after 24 hours and 34.7% 48 hours following day surgery (20).

One challenge that faces Kenya with postoperative pain control is the lack of acute pain services (APS) in of hospitals. The APS team, headed by an anaesthesiologist, practice in the wards and recovery rooms to ensure optimal pain control after discharge from theatre. They assist in the management of patient-controlled analgesia (PCA), epidurals, optimal drug dosing and indwelling catheters (21). Their contribution to pain management is invaluable as they also

they also educate medical staff on the use of the PCA pumps and provide education on pain management strategies (21). Pain in most hospitals is managed by the different cadres of doctors present in the wards, and this often leads to variability in pain management. This is especially the case if pain protocols are not available or adhered to. Unfortunately, not all hospitals have anaesthesiologists to consult on optimal patient pain management strategies. This underscores the importance of preoperative preventative measures to lessen the burden of pain in the surgical population.

2.2 Pain Physiology

The revised 2020 International Association of the Study of Pain (IASP) revision defines pain as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage,"(22). From this definition, the following components of pain are appreciated, its subjectivity, emotional and psychological nature which is coupled with its physiological and objective sensory aspects (23). The susceptibility and experience of pain in most individuals is from the different steps involved in the neuronal processing of nociceptive information and the intricate interaction of numerous genetic variants, as well as the involvement of other factors such as prior learning, psychosocial factors and the sociocultural environment(3).

There are various ways that pain can be classified, according to its duration; the classification of acute and chronic pain. Acute pain being of sudden onset and limited duration less than 6 months and chronic pain persisting more than 6 months(24). Based on the following three characteristics of mechanisms, symptoms and syndromes, pain can be classified into the following three types; nociceptive, neuropathic and inflammatory pain (16).

The neural response to noxious stimuli and traumatic insult is described as nociception and nociceptive pain is the mode of communicating tissue irritation and impending or actual tissue injury (14,23). Following noxious insults, affected nociceptors relay messages to the brain through the transmission of signals via peripheral nerves into the spinal cord and then finally to the brain. Complex spinal reflexes such as the withdrawal reflex can be initiated in the spinal cord. The rest of the signals that are transmitted in the brain are subjected to perception, affective and cognitive responses to result in voluntary actions (14,23).

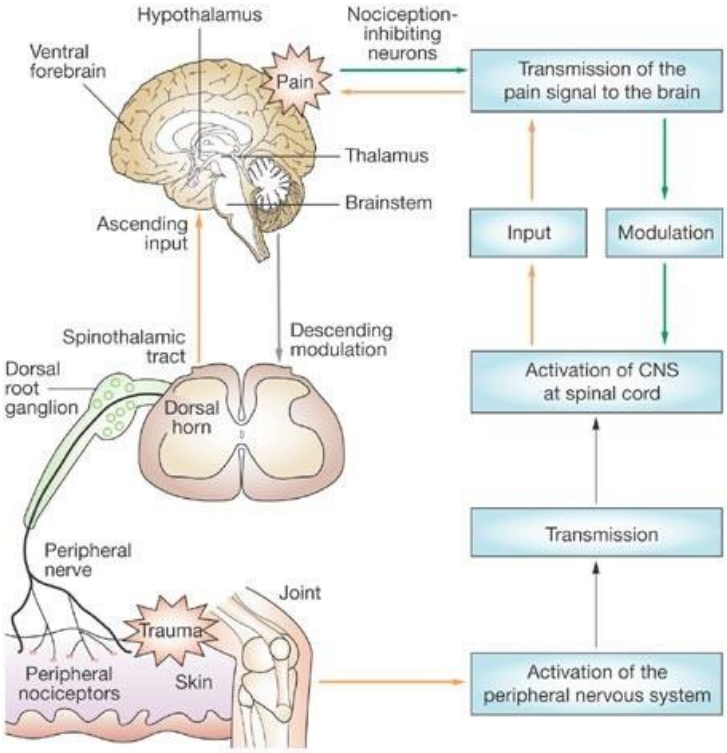

Figure 1(25)**:** *The nociceptive pain pathway.*

There are two primary afferent pain fibre systems, the myelinated Aδ fibres and unmyelinated C fibres. The myelinated Aδ fibres are responsible for the first "sharp" pain which is a well localized sensation. This is because Aδ fibres are large myelinated fibres with a diameter of 2-5µm and therefore have faster rates of conduction of 12-30m.s-1. C fibres on the other hand, are smaller unmyelinated fibres with a diameter of 0.4-1.2µm and have slower rates of conduction between 0.5- 2.0m.s-1. These C fibres are responsible for the characteristic second "dull" pain (14,16).

It is only in the presence of apparent noxious stimuli, that these receptors are activated, otherwise they remain "silent". Broadly speaking, there are three main events in the mechanism of pain once these nociceptors are activated; transduction, transmission and modulation (16).

1) The majority of nociceptors are free nerve endings that have the capability of sensing chemical, mechanical or heat damage (23). These stimuli need to be transduced into a form that can be propagated through the sensory neurons and so need to be converted to an electric event (16). As the neuronal pathway is composed of multiple neurons, a synaptic cleft serves as a bridge between these neurons. At this cleft, transduction of

the electric event occurs to a chemical event to pass through the cleft and then back again to an electric event to be carried in the next neuron. Once this process of transduction is completed, transmission of the electric event occurs along the neurons in the different neuronal pathways (16).

2) Transmission occurs through the Aδ myelinated and C unmyelinated fibre systems and these terminate in different areas of the dorsal horn of the spinal cord (23). This is part of the process of peripheral transmission, whereby there is complex interplay between neurons, receptors, neurotransmitters and dorsal horn neuronal synapses (26). The dorsal horn plays as an important role in the integration of the numerous inputs entering the spine which includes the primary sensory afferents and the local interneuron networks (16). The perception and transmission of these electric signals from the spinal cord to the brain form the basis of central transmission (23).

   The ascending and descending pathways are two routes that signal transmission is conducted through. The ascending pathway is responsible for carrying sensory information in an upward fashion from the body through the spinal cord and into the brain. The descending pathway runs in the opposite direction transmitting information from the brain to organs responsible for reflex action via the spinal cord (16).

3) Modulation occurs to either facilitate or inhibit pain and occurs both peripherally and centrally (23). At all levels of the nervous system the transmission of pain signals is modulated by inhibitory and excitatory interneurons (25).

Postoperative pain can be classified as acute pain because of the identifiable cause that surgical trauma produces (24). There is an inflammatory reaction associated with the instigation of afferent neuronal barrage(14). Significant levels of pain are caused by the retraction of tissues which produces ischaemia due to disrupted blood supply; this then contributes to low pH levels and high lactate levels around the site of incision (21). It has also been discovered that different surgical procedures produce different pain states with varying severities and in different locations. Due to this observation, the development of procedure specific postoperative pain management has been developed as a concept and should serve as a guide for postoperative pain management(13).

2.3 Complications of Postoperative Pain

Through the years, the understanding of the human brain and its processing of pain as earlier demonstrated has dramatically improved. What remains poorly understood however, is the neuroplasticity and activity in the pain matrix after an incision has been made that contributes to pain-related behaviour(13). Undeniably, the manifestations of acute postoperative pain span through autonomic, behavioural and psychological responses. These responses then result in unwanted, unpleasant sensory and emotional patient-specific experiences(20). Untreated postoperative pain may result in clinical and psychological changes that increase morbidity, mortality and also decrease quality of life(8).

Pain affects the psychology of the patients by leading to increased anxiety, feelings of helplessness(27) and particularly delirium in the elderly.(5,28). Sleep patterns are also affected which causes either an inability to sleep(27) or disturbed sleep patterns(5) and this can lead to patient irritability and worsen patient distress. Untreated acute postoperative pain can evolve into persistent postoperative pain and then chronic pain. Persistent postoperative pain is assumed to be triggered by the high-intensity post-surgical pain from damage to nerves. This, along with the neuroplastic change in the central nervous system (20).

There is evidence that certain procedures have a high incidence of persistent postoperative pain between 30-50% and these include; hernia repair, thoracotomy and mastectomy(21). According to Correll, chronic postoperative pain is a devastating sequalae of untreated acute postoperative pain and unfortunately is a poorly recognised outcome. In the United States of America, millions of patients suffer from chronic postoperative pain and it is estimated that $560 billion dollars per year in direct medical costs and disability programs (29).

Significant distress to patients is a consequence of untreated pain and this can lead to problematic manifestations of the endocrine system and immune function(3). Hormones that play a role in the stress response are increased(6) causing a rise in the circulating catabolic hormones such as adrenaline and cortisol and a decrease in anabolic hormones. The response of which contributes to the ensuing hyperglycaemia, increased protein metabolism and lipolysis and decreased insulin secretion (23). For diabetic and other prone patients, this can be devastating to the control of their sugar levels and lead to other distressing effects. There are also reports of delayed wound healing as a complication due to the immunosuppressive effects of unrelieved postoperative pain(4). Elderly and frail patients have the risk of development of

pressure sores due to prolonged immobility and muscle atrophy caused by unrelieved postoperative pain(6).

For all patients, certain periods immobility can lead to potentially life-threatening thromboembolic events(3,5,14,15) such as thrombi dislodged from deep vein thrombosis(4,6,8) leading to pulmonary emboli. The respiratory system can also be affected in a predictable manner due to untreated postoperative pain. There could be decreased vital capacity(4) splinting of the diaphragm, atelectasis and increased pulmonary infections(27). Pain also has undesirable effects on the cardiovascular system which include tachycardia, hypertension(6) and increased oxygen consumption. In certain patients, these cardiovascular complications can lead potentiate the risk of myocardial ischaemia and infarction(4). The gastrointestinal implications of untreated pain include postoperative ileus(6), nausea and vomiting(4,6).

Another aspect of untreated postoperative pain is the financial burden the placed on the patient, of which trickles down to the healthcare system. It has been shown that there is delayed patient recovery and an increase in number of days in hospital due to poorly managed postoperative pain(7). Increased hospital stay poses extra costs to both the patient and the hospital; additional resources are required to treat the patient due more hospital days. In developing countries, the increased number of patients in a hospital may lead to overburden on the hospital by the excess of patients in a ward. The result of which is patient overcrowding in surgical wards making matters worse. This is because of the relatively low hospital bed capacity especially in surgical wards in the SSA region(7).

2.4 Pain Assessment

In order to provide effective pain control postoperatively, pain assessment and reassessment are of vital importance and provide a way of communication between patients and clinicians(30). Over the years, the assessment of pain has diversified and there many ways to measure pain intensity in all age groups for a myriad of pain causing conditions. Pain assessment tools include symbols, checklists, visual scales, verbal or numeric scales and questionnaires(30). The importance of pain assessment is that it helps the clinician know whether pain control is adequate from the intervention used, whether the analgesic dose is adequate or not based on response. It can also inform if additional medication should be added

or other interventions are required such as the use of specialist consultations for pain that is difficult to manage(30).

The majority of pain assessment tools rely on self-report measures and this is a highly viable option considering pain is very subjective. When carried out properly, these measures are consistent and sensitive(27). The accuracy of these assessment tools to detect and quantify the severity of pain have been extensively validated and further tested for inter-rater and intra-patient reliability (30). For purpose of this study, the common scale measurements of acute pain in adults will be briefly discussed.

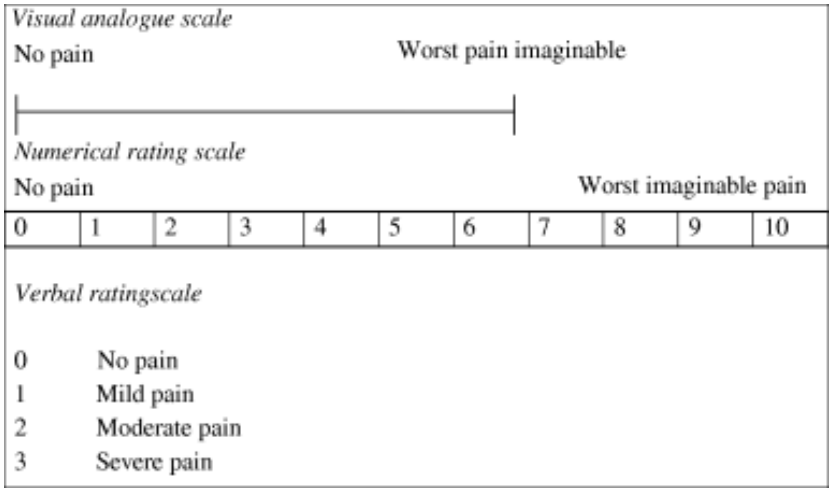

Figure 2(31): Common Pain Rating Scales

The basis of categorical scales, is that they use certain words which can be use to describe different dimensions of pain such as its magnitude or its relief. These scales have the advantage of simplicity, being quick and have diverse use in visually impaired patients, elderly patients and some older children. On the flip side, they have a narrow choice of descriptors of pain and so may not be useful for all patients if they do not understand the meaning of the descriptors(27).

The VAS is a unidimensional scale that has two points on either extreme of a line between 0mm and 100mm and it is commonly used to measure pain intensity. The patient is asked to assess and rate their pain by pointing on the scale between the two extremes labelled “without any pain” or “worst imagined pain”(15). For interpretation of the scale, 0 to 4mm is no pain, 5mm to 44mm mild pain, 45mm to 74mm moderate pain and beyond 75mm severe pain(32).

Numeric rating scales (NRS) employ the use of numbers to reference the intensity of the pain on a scale of 0 to 10. The higher the number the higher the intensity of pain, 0 representative of no pain and 10 refers to worst possible pain. Numeric scales are easy and quick to use and favoured by many clinicians for acute pain assessment. However, some patients have trouble expressing their pain in numeric values. For these patients, another tool such as a categorical scale would be better suited(27).

With the Verbal Rating Scale (VRS) patients are asked to use adjectives used to describe their increasing pain intensities. The most common words used are: “no pain; mild pain; moderate pain; and severe or intense pain”(31).

Both the VAS and NRS are easy unidimensional scales to administer, complete and score(32). They are useful in providing estimates of patient pain intensity and can be used sequentially to see if pain intensity increases or decreases following interventions. Research has shown that the VAS and NRS and (VRS) are highly correlated with each other for pain assessment(15).

2.5 Predictors of Postoperative Pain

It has been shown that, in addition to the correct management of medications to relieve pain resulting from surgery, demographic and psychological factors are closely related(15). This notion helped form the basis of research on preoperative pain with a focus on predictive factors of postoperative pain. With the evolution of research in this field, there has been better understanding of these predictors over time. The following section will elaborate more on some of the demographic and psychological factors being investigated namely; age, gender, ethnicity and socioeconomic status, anxiety, depression, use of preoperative analgesia and presence of preoperative pain.

Table 1 summarises the various studies mentioned in the review and the predictors of pain the studies investigated. Suffice to say, there has been some controversy in the literature of a few of these predictive factors; age and gender primarily being the most contentious factors. As an example, Mamie *et al* concluded in their study that neither gender nor age seemed to increase the risk of postoperative pain(10). Additionally, the study done at the KNH on patients following major abdominal and thoracic operations, sex, weight, age, and type of surgery did not significantly affect the postoperative pain scores(6).

The first systematic review was done in 2009 by Ip *et al*, and their findings revealed four significant predictors of postoperative pain as; age, pre-existing pain, anxiety (or other psychological distress), and type of surgery(3). Unfortunately, representation from the SSA region in this review was lacking. As well as possible genetic differences, there are appreciable cultural and social differences in different countries, making it hard to generalise results outside the studied population.

A decade later in 2019, Yang *et al* published a systematic review and a meta-analysis of 33 studies on preoperative predictors of poor postoperative pain control(5). Nine predictors were found to be negatively associated with postoperative poor pain control, three of which were similar to Ip *et al*. The nine predictors included female sex, younger age, history of anxiety and history of depressive symptoms, smoking, presence of preoperative pain, sleeping difficulties, use of preoperative analgesia and as a continuous variable; higher body mass index (BMI)(5). Only one study from South Africa represented the SSA and the majority of studies represented the American and European nations**.** Furthermore, of the 33 studies included, the mean age in years of the studied was mainly above 50 years, with 11 of studies having ages below 49 years. Again, this could be a limitation of generalising the results, especially in a younger surgical population.

As for generalisability, it should be noted that much of the literature available on preoperative predictive factors have been done in the developed world, with little contribution from the developing world, particularly in SSA. In addition, very little is known about the incidence and associations of postoperative pain in developing countries(9). Factors such as methodology and study design, population studied and sampling procedures could be very different in relation to developing countries. Ip *et al* acknowledged that there was need for studies to investigate a wider range of variables using clear definitions of pain and sound instruments. Also, they state the need for studies to ideally be homogenous in terms of demographics, surgical procedure and medical and psychological history and be large-scale(3). Furthermore, variety of treatment options in the perioperative period could have an impact on the results of postoperative pain intensities. The prevalence of poor pain control is higher in SSA due to more barriers to adequate pain control(19).

Table 1: *Summary of studies on predictors of postoperative pain*

Author, Year	Study Design	Sample size	Incidence of poor postoperative pain (%)	Significant Predictors of postoperative pain	Type of surgery	Time of assessment (hrs)
Admassu et al, 2016	Quantitative cross sectional	150	57- 87 classified as severe	American Society of Anaesthesiologist's (ASA) Classification I and II, age < 60year, General anaesthesia, incision length >10cm	Mixed surgical	2, 12, 24
Adwok et al, 2000	Prospective descriptive	65	56 classified as severe	Age, Sex, weight, Type of operation	Cardiac and major abdominal	24, 36 and 72
Caumo et al, 2002	Prospective cohort study	346	43.4	ASA III, age, preoperative moderate to intense pain, chronic pain, high trait-anxiety and depressive mood moderate to intense	Abdominal surgery	12 and 24
Ip et al, 2009	Systemic Review- 48 studies	23, 037	Varied	Preoperative pain, anxiety, age, type of surgery	Mixed surgical groups	Varied

Kalkman et al, 2003	Analysed from cohort randomised trial	1,416	Varied	age, gender, preoperative pain, incision size, and type of surgery	Mixed surgical group, excluded cardiac and intracranial neurosurgical surgeries.	Every 15 min until discharge from the PACU
Mamie et al, 2004	Prospective cohort study	304	25.1	General anaesthesia, high doses of analgesics, expectation of postoperative pain, fear of postoperative pain, chronic sleeping difficulties, history of pain in family	Abdominal and orthopaedic	24
Masigati et al, 2014	Prospective descriptive	106	85.5 and 77.4 classified as mild and severe	Not stated	Mixed surgical group	24, 48, 72
Murray et al, 2016	Prospective cohort	1231	62	Younger age, female gender, emergency surgery, surgery to the abdomen and lower limbs	Mixed surgical group	24
Mwashambwa et al, 2018	Prospective descriptive	136	95.6 classified as moderate to worst pain	Male sex and orthopaedic procedures	Mixed surgical group	12, 24, 48
Theodoraki et al, 2013	Prospective observational	65	Not stated	None	Abdominal surgery	2, 4, 8, 24 and 48

Woldehaimanot et al, 2014	Prospective cross sectional	252	91.4	ethnicity, education and preoperative information	Mixed surgical group	24, 72
Yang et al, 2019	Systemic Review- 33 studies	53, 362	Varied	female sex, younger age, history of anxiety and history of depressive symptoms, smoking, presence of preoperative pain, use of preoperative analgesia, higher BMI, sleeping difficulties	Mixed surgical group	Varied

2.5.1. Age

Age has been a controversial predictor of pain in literature with conflicting conclusions. It has been hypothesised that with increasing age there is a blunting of peripheral nociceptive function leading to decreased pain perception. Furthermore, there is evidence that influence of specific genes in pain modulation and therefore experience of pain decreases with age(3). There are other reasons such as biopsychosocial factors, changes in neural, inflammatory, immune responses and life-stage factors that could explain the pain differences associated with age(33).

Certain studies have suggested that older patients are less likely to suffer pain to the same extent as younger patients. In Ethiopia according to Admassu *et al*, consistent with the above, patients less than 60 years were 2 times more likely to report pain as moderate or severe compared to older patients(8).Yang *et al*'s systematic review was able to outline that younger age as a dichotomous variable is a significant predictor for poor postoperative pain(5). Moreover, their systemic review went on to highlight that the studies that examined age as a continuous variable may not have detected a statistically significant difference because most of these studies had more older patients and fewer younger patients.

In Tanzania, a study by Mwashambwa *et al* on postoperative pain prevalence, predictors, management practices and satisfaction among operated cased at a Regional Referral Hospital outlined that young patients were less likely to get severe to worst pain(4). Mamie *et al* concluded in their study that neither gender nor age seemed to increase of postoperative pain(10). The systemic review done by Ip *et al* in 2009 found age as a significant predictor of postoperative pain. However, their limitation to this, was that the age range was not large enough to highlight the statistical significance of age and that not all the studies examined age as a predictor(3).

2.5.2 Gender

Another source of controversy regarding predictors of postoperative pain is gender. There has been variability of gender responses to noxious stimuli in both the experimental and clinical setting of several studies. In experimental models to assess pain modulation at the spinal cord on different types of stimulation and the response of men and women, women were found to exhibit lower noxious inhibitory control. Men, however, were found to have more effective descending inhibitory pathways following chemical or mechanical stimulation(34). In past years, previous studies have been inconsistent with their conclusions in regards to the

association of the female sex with worse pain than male counterparts following surgery(5). Pain perception and the differences in gender still remain tentative and mechanisms to explain these differences are still elusive(4).

The reasons for the differences in sex could arise from the complex biological and psychosocial factors. These include the willingness of women to communicate discomfort and pain compared to men. There are also subjective differences in both genders with pain perception and experience(5). Indeed, Admassu *et al* found that gender was a predictive factor for postoperative pain 12 hours postoperatively and 67% females reported their pain as moderate to severe in comparison to 30% of males. Their research suggested the reason for the difference was that psychosocial factors played a bearing on the findings. Sex roles beliefs and pain related expectancies could have exposed women to exhibiting greater sensitivity to noxious stimuli compared to men(8).

Females had about 30% increased odds of poor postoperative pain control as compared to males in the meta-analysis done by Yang *et al*. Furthermore, they required averagely 11% greater doses of morphine than males to achieve adequate postoperative pain control(5). In the South African study by Murray *et al* on acute postoperative pain, in agreement with a previous study they found that younger females had a higher incidence of moderate and severe pain, although differences in procedures could have contributed for this result(9).

In a study done by Theodoraki *et al*, on Postoperative Pain after Major Abdominal Surgery: Is It Gender Related?, the results of their study did not demonstrate differences in acute postoperative pain of males and females following abdominal surgery(34). Huang *et al* demonstrated that hospitalized patients in Western Kenya experienced a significant amount of pain however, they did not find that female gender was a predictive factor of pain and was not correlated with symptom burden. They identified the correlates of pain as increasing age, suspected or diagnosed cancer and positive HIV status(19). Despite the fact that gender is a non-modifiable risk factor, the research on gender differences can be used to help individualize preoperative analgesia requirements and anticipate pain trajectories(5).

2.5.3. Ethnicity and Socioeconomic Status

Ethnicity coupled with socioeconomic status (SES) are factors that have a role in pain experience and patient satisfaction of postoperative pain management(1). In the past two

decades, a considerable and vast growing body of research on disparities in health across ethnic or racial groups has accumulated. Evidence suggests that these disparities extend all the way through prevalence, treatment, progression and outcomes of pain related conditions(35). In studies done in Singapore and Nigeria, ethnic background was found to affect pain perception and satisfaction. Woldehaimanot *et al*'s study in Ethiopia was able to extend these findings by highlighting that individuals from the Southern parts of the country had higher pain scores(1).

Campbell and Edwards illustrate that ethnic differences have been documented in a variety of clinical pain conditions. Particularly for African-Americans, there is a greater pain burden and suffering when compared to whites especially in conditions characterized by persistent pain complaints(35). Due to the role ethnicity plays on postoperative pain, Campbell and Edwards rightly advise that clinicians should consider ethnicity as a factor in patient management and treatment options. Ethnic groups may have differing outcomes of specific treatments especially where analgesia is concerned(35).

The role of SES has not been as clearly elucidated to contributing to higher postoperative pain scores and is mainly tied with ethnicity. Indeed, SES is one way of explaining how differences in pain treatment may manifest across ethnic groups but does not fully account for poor postoperative pain control. It has been suggested that SES may account for ethnic differences in health but this is not generalisable due to the large intra-ethnic variability than between-group differences(35). This may explain why Yang *et al*., were unable to find any significant association with socioeconomic status and poor postoperative pain control(5). It should be noted that age, education and information status, and attitude are likely indicators patient perception of power and this can be linked to the experience and perception of pain. Woldehaimanot *et al* surprisingly reported less pain intensity by the elderly, less educated and informed and patient's with poor attitude. This finding underpins that such group of patients require more attention and are a highly vulnerable patient group(1).

2.5.4. Psychological factors

The current definition of pain acknowledges an emotional aspect of pain. This can be viewed from the lens of psychological and behavioural perspectives. To some extent, it can be argued that there has been an element of neglect of psychological and behavioural factors in the management of postoperative pain(4). Pain is a highly personal experience that is also

influenced by a previous pain experience and a person's ability to cope. Additional, pain is motivated by various external influences such as culture, societal norms, belief and mood(27).

Unpleasantness and fear of pain have been postulated to be risk factors for the development of chronic pain even in the absence of organic pain to describe the individual's source of stress. The "fear avoidance model" can be used to explain the association between fear of pain and chronic pain(20). The anxious state has been implicated in the lowering of pain threshold, activation of the entorhinal cortex of the hippocampal formation and the overestimation of pain intensity(4).

Preoperative anxiety has consistently been shown to be a risk factor for poor postoperative pain control. It has also been shown to be an important predictor in obstetrical, gynaecological and gastrointestinal surgeries(4). Preoperative anxiety has been demonstrated to predispose to higher pain intensity scores in the first one hour following different surgical procedures such as coronary artery bypass, varicose vein surgery and gynaecological surgeries i.e. laparoscopic tubal ligation(27).

In the most recent meta-analysis on predictors of pain, the presence of depression was shown to be related with worse pain outcomes following surgical procedures. Noteworthy, the spectrum of depression was well represented; which consisted of mildly and moderately depressed individuals. This could explain the increased odds of poor postoperative pain control in depressed individuals(5).

These findings strengthen the previous postulation about the relationship between development of chronic pain and a depressed mood. Therefore, psychological factors should not be neglected or ignored because it is necessary to consider these factors in the preoperative management of patients undergoing surgical procedures. Physical, psychosocial and social function of older adults is affected by the presence of recurrent of persistent clinical pain. And so, it is imperative to disrupt processes that lead to the transition to chronicity of pain(4).

2.5.5. Use of preoperative analgesia and Pre-emptive Analgesia

Use of preoperative analgesia or pre-emptive analgesia are modalities that can be used with the idea of blocking afferent nociceptive transmission prior and during surgery. This helps prevent the neurochemical changes that can account for central sensitisation(21). Both preoperative

analgesia and pre-emptive analgesia are types of preventative analgesia. Research has led to the hypothesis that enhanced post-operative pain management is achieved when there is good pain relief prior to surgery. Additionally, certain laboratory studies have shown that following administration of an analgesic before a nociceptive stimulus predisposes to minimal change in the dorsal horn linked to central sensitisation. This is in comparison to when the same analgesic is used in a similar fashion following the nociceptive stimulus(27).

The difference between preoperative analgesia and pre-emptive analgesia lies in the timing of administration of the medication. Preoperative analgesia is given during the preoperative period and pre-emptive analgesia is specifically given in the immediate period prior to the surgical incision. However, there have been debates and conflicting conclusions in clinical studies on the outcomes of 'pre-incisional' and 'post-incisional' comparisons(27). Preoperative analgesia has lost some favour in certain studies due to the fact that opioid analgesia is linked to poor postoperative pain management. This is hypothesised to be due to opioid-induced hyperalgesia, greater severity of pain and possible sensitisation at either a peripheral or central level to pre-existing nociception(5).

The majority of these studies conducted are outside of Sub-Sahara Africa, and even within East Africa this information is scarce. It could be because these practices are not part of routine care or they are not formally practiced in many hospitals in SSA. This happens to be the case in Ethiopia where pre-emptive analgesia is not part of common practice and additionally formal documentation of pain is not common(1). Patients are still in pain depending on disease state or need for surgical intervention and analgesia forms a massive component of patient care. It would impossible to argue that any form of preoperative analgesia is not practiced in our local setting. It would be insightful to see the effect of preoperative or pre-emptive analgesia on postoperative pain control.

2.5.6. Presence of preoperative pain

Research has demonstrated that factors such as low preoperative pain threshold, pre-existing pain and chronic pain are significant predictors for pain . Preoperative pain specifically has been found to be a consistent risk factor for persistent postoperative pain in breast surgery, thoracotomy, hysterectomy, hernia repair and limb surgery(36). Following surgical tissue trauma, an intense influx of nociception leads to responsiveness and enhanced excitement of

the dorsal horn neurons in the pain transmission(3). Research suggests that reducing this response and proper pain management can reduce transition into chronic states of pain(3).

Kalkman *et al*, found that one of their most striking predictors of severe postoperative pain in the immediate postoperative period was preoperative pain. Explanations given for the association was that neuroplasticity and sensitisation of the spinal cord that occurred due to continuous chronic noxious afferent stimuli of the affected area. The product of which manifest in the postoperative period as a fairly hyperpathic state(28).

In a South African study by Murray *et al*, patients who had emergency surgery were more prone to higher postoperative pain scores than their elective counterparts. Moreover, the emergency patients were more likely to receive inadequate analgesia and due to the nature of the emergent surgery were inadequately optimised for the surgery. This included preoperative pain assessment and administration of analgesia. Even in this study, the presence of preoperative pain was a strong predictive factor for higher postoperative pain intensity(9).

However, contrary to the above, Mamie *et al*, had opposing conclusions regarding preoperative pain. They showed no causal relationship between preoperative chronic pain and the postoperative pain intensity(10). Currently, local data regarding association of preoperative pain and worse postoperative pain scores or intensity is limited. More studies need to be done to ascertain the risk that preoperative pain poses on postoperative pain scores in surgical patients.

2.6 Study Justification

The number of surgical operations is increasing nationally and globally and yet, there is still an alarmingly high incidence of postoperative pain of up to 80%(1). Abdominal surgeries constitute one of the most common surgery types thereby carrying a huge burden of postoperative pain in any surgical population, particularly in Kenya. The complications have been comprehensively elaborated, showing that unrelieved pain is immunosuppressive, life-threatening and inhumane(4). The sequalae of postoperative pain poses both individual and societal burdens, as well as having negative financial and economic implications.

The insights into predictive preoperative factors will assist in early identification of at-risk patients allowing for adequate management in the perioperative period. This will translate into superior individualised surgical treatment plans, earlier postoperative ambulation, faster recoveries and timely discharges. Hospitals benefit by better resource management, less crowded surgical wards, an increased turnover of patients promoting revenue. There are also cost savings for patients by reducing their hospital stay and early rehabilitation back to their livelihoods.

To reiterate, there is paucity of data regarding preoperative factors associated with postoperative pain in Kenya, of which is highlighted by the few studies found in this topic. The literature gap poses unique clinical and academic opportunities for new research. The research has the capability to enhance hospital pain protocols and inform national policies for better healthcare of citizenry.

2.7 Study Question

Which preoperative patient factors are associated with acute postoperative pain in patients undergoing abdominal surgeries in Kenyatta National Hospital?

2.8 Objectives

2.8.1. Broad objective

To investigate preoperative patient factors may be associated with acute postoperative pain following abdominal surgeries at the Kenyatta National Hospital.

2.8.2. Specific Objectives

1. To determine the intensity of acute postoperative pain among patients undergoing abdominal surgery.
2. To evaluate the relationship between preoperative pain and acute postoperative pain among patients undergoing abdominal surgery.
3. To investigate the association of demographic factors with acute postoperative pain among patients undergoing abdominal surgery.
4. To investigate the association of psychological factors with acute postoperative pain among patients undergoing abdominal surgery.

2.9 Aim

To enhance knowledge on preoperative patient factors that are associated with acute postoperative pain following abdominal surgeries at the Kenyatta National Hospital. This will assist in profiling surgical patients that require additional pain management interventions to reduce the burden and suffering of acute postoperative pain in Kenya.

CHAPTER THREE: METHODOLOGY

3.1 Study Design

A prospective cross-sectional observational study was conducted over the period of 24 hours following abdominal surgery at the KNH. This was because the expected main outcome was measured at different intervals in a short time frame. Secondly, the most common time-interval when postoperative pain was measured in a multitude of similar studies was between 24-48hours after surgery(5).

3.2 Study Site

KNH is the largest hospital in Kenya that serves as a public tertiary referral facility under the Ministry of Health. It is also closely related to the University of Nairobi, College of Health Sciences, as it the teaching hospital for undergraduate and post graduate students(37).
KNH has 24 consultant clinics that attends to 600,000 patients annually. There are 24 operating theatres and 50 wards in KNH, with bed capacity of 1,800 and takes care of up to 80,000 inpatients annually(38).

As a tertiary care facility, there is a wide variety of abdominal pathologies present at the KNH. KNH through its' resources is able to handle the complexity of these pathologies and provide the necessary management required.

The intended study sites were the KNH surgical wards and gynaecology wards.

3.3 Study Population

Patients scheduled for surgery, coming to the operating theatres in the KNH for either elective or emergencies surgeries were invited to participate in the study. Informed consent was sought and patients who fit the inclusion criteria were recruited to the study.

3.4 Inclusion/ Exclusion Criteria

3.4.1. Inclusion Criteria

Age above 18 years

Scheduled for abdominal surgery

Capacity to provide informed consent

3.4.2. Exclusion Criteria

Absence of the legally authorised representative to give informed consent

Unable to communicate; visually impaired

Neurological deficits, GCS less than 15

Polytrauma patients

Those with allergy or hypersensitivity or contraindication to use of Opioid, NSAIDs and paracetamol

Obstetrical surgeries

Urological surgeries

3.5 Sampling Size Determination

Fischer's formula for a single population proportion will be used as the basis to determine sample size. The reference study used is by Admassu *et al*, on Severity and Risk Factors of Postoperative Pain in University of Gondar Hospital which revealed 62% prevalence of moderate to severe postoperative pain following intraabdominal procedures(8).

$$\boldsymbol{n_0 = \frac{Z_{\frac{\propto}{2}} * p(1-p)}{e^2}}$$

Where: -

$\propto$ - Level of significance (estimated as 0.05); probability of type I error.

$Z_{\frac{\propto}{2}}$ – The critical value associated with significance level

p – Proportion estimate from the general population (62%)

e - Margin of error (acceptable random sampling error) 7%

$$\boldsymbol{N = \frac{1.96^2 * 0.62 * 0.38}{0.07^2}}$$

$$\boldsymbol{= 184.71 \cong 185}$$

After factoring in 5% refusal/spoilt questionnaires, the calculated minimum sample size of :

$$\boldsymbol{\frac{185}{(1-(\frac{5}{100}))} = 195}$$

3.6 Sampling Procedure

Consecutive sampling was used to select and enrol a total of 195 participants.

3.7 Recruitment

Recruitment of the study was done in the surgical wards and gynaecology wards over the course of 6 months to achieve the determined sample size. Both patients undergoing elective and emergency abdominal surgeries were invited to participate. Participants were recruited either on the day of surgery or the before scheduled surgery for emergency and elective cases respectively from surgical theatre lists made.

3.8 Consenting Procedures

The study was explained to the participants which involved the conduct, purpose, and role of the participant. Informed consent was obtained once participants had received the information and had had their questions or concerns answered. The pretested data collection tool was then administered with the aid from the research assistant, where necessary.

The consent process was the same for both the elective and emergency participants. However, the participant's rights, comfort and care plan came first. If the participant for emergency surgery was unable to tolerate the consent process due to discomfort from the nature of their abdominal pathology and/or lacked the capacity to give consent they were immediately withdrawn. The consent process did not interfere or delay the patient's transit to theatre.

3.9 Variables

3.9.1. Dependent Variable

The postoperative pain scores were measured using the NRS.

3.9.2. Independent Variables

Demographic factors for participants included age, gender, marital status, level of education and socioeconomic status, preoperative pain, smoking and use of preoperative analgesia, body mass index (BMI).

The psychological factors to be assessed are anxiety and depression.

Other independent variables will include, intraoperative analgesia and variability of anaesthesia plan, and type of surgery.

3.10 Training Procedures

The principal investigator completed an online certificate course on International Council on Harmonisation (ICH) Good Clinical Practice E6 R2, and trained the research team on the conduct of research.

The principal investigator and the research team also completed an online certificate course on Informed Consent. This was done prior to data collection to ensure that the research team wa well-versed on the ethical considerations of human subjects' research.

The Principal Investigator also trained the research assistants on data collection using the REDCap application prior to the commencement of the study.

3.11 Quality Assurance Procedures

The list of quality assurance procedures is elaborated below according to sections and the Quality Assurance protocol is found in the appendices.

Clinical care

The study adhered to Government of Kenya guidelines for the perioperative care of patients; however, no clinical care was provided by the study staff.

Additional data to be collected for part of the study was abstracted from the study participants' clinic medical records, particularly the anaesthesia record sheet and the surgeon's postoperative notes and treatment sheet.

Adherence to protocol

The members of the research team were assigned roles and responsibilities prior to the commencement of the study. The data manager/quality control manager was assigned within the team and the rest of the team were the research assistants who interacted with the participants.

To facilitate adherence to the protocol, weekly reporting of enrolment, follow-up, results and any encountered issues were carried out to monitor that the study was running according to approved protocol.

Frequent reporting enabled quick response to any problems that arose during the study and corrective measures were pursued by the principal investigator.

Data collection instruments

Data collection instruments for the study were submitted to ERC and the study did not commence until these instruments were reviewed and approved by the KNH-UoN ERC. The study data collection instruments included sections to record data from:

- Participant surveys: demographics, anxiety and depression scores, pain scores.
- Medical and clinical records: Theatre anaesthesia chart- intraoperative management, Surgeon's postoperative notes- diagnosis and procedure done, Treatment sheet- pain medication.

Data Collection Tool

The data collection tool was pre-tested as a pilot study. This assisted in clarity and evaluation of data collection tool and the comprehensibility of patients. It also assisted in gauging the amount of time it would take a participant to fill the data collection tool form.

The data collection tool was administered using the REDCap form on mobile devices and computer devices. Clinical and baseline data were collected at recruitment and entered into study data collection tools.

Postoperative data was collected and entered into study data collection tool. The tablets were password-protected, and the data collection tool was transmitted to a secure server daily and erased from the tablets. Data was transmitted via secure socket layer (SSL) and only accessible by authenticated users. Tablets were stored in a secure, locked office accessible to study staff only.

All participants were assigned a non-identifiable study ID number upon enrolment. All data records were identified by study ID only. The link between identifiable participant information and study IDs were locked in a secure, locked location and destroyed following study completion. The statistician received only coded data.

Paper records

Consent forms were stored in paper forms. One signed copy of the consent from was stored in a secure, locked location and destroyed following study completion. The other copy remained with the participant.

Data Ownership

The study adhered to the KNH data ownership policy. The principal investigator had full access to the data. Authorship on publications, conference presentations, abstracts and other materials generated from this study would reflect contribution to design, execution, and analysis of the study.

Data Release/Sharing Policy

The study complied with the U.O.N ERC and Kenyatta National Hospital department of Research & Programs policy on data release and sharing policy upon completion of the study.

3.12 Ethical Consideration

The principal investigator sought departmental permission to carry out the study and thereafter submission to the KNH- UoN ERC for ethical review and approval.

The study upheld and complied with the ethical considerations set by the Helsinki Declaration 1964; safeguarding the rights, safety and well-being of the participants involved in the study(39).

The study was conducted by trained research assistants under supervision of the principal investigator.

Participants had the study explained to them in a simplified manner with understandable language. Only informed and voluntary participants were recruited into the study and written consent obtained.

At any time, a participant was allowed to withdraw from the study and this did not affect their intended surgery and other ongoing treatment.

The identity of participants was withheld and confidentiality maintained at all times during the study and precautions were be taken to protect these rights.

The nature of the study posed minimal risk to the participants and precautions were taken to ensure no psychological or physical harm.

No financial expenses or burdens were imposed on the participants during the study. Additionally, there were no financial benefits by participation in the study.

The authors of the study were ethically bound to preserve the accuracy of the results of the study upon publication.

3.13 Data Management

3.13.1 Data Entry, Cleaning and Storage

Retrieved data was handled with care and data collected was saved in a password protected computer and backup in a securely preserved flash disk, only accessible to the principal investigator. The data collection tool coded on REDCap was then transferred to Statistical Package for Social Sciences (SPSS) version 23.

3.13.2 Data Analysis

Data was entered into the Microsoft Excel 2017 spreadsheet from RedCAP prior to exporting to the Statistical Package for Social Sciences version 23.0 for analysis. Demographic characteristics were analysed and presented as frequencies and percentages for categorical variables, and as means with standard deviations or median with interquartile range for continuous variables.

The primary outcome measured was the acute postoperative pain following abdominal surgery. The postoperative pain score (0-10) was dichotomized into two categories: presence of no pain to mild pain (0 – 3) and presence of moderate to severe pain (4 – 10). Thus, postoperative pain was defined as experiencing moderate to severe pain 24 hours postoperatively, after coughing.

The intensity of acute postoperative pain among patients undergoing abdominal surgery was categorized as none, mild, moderate and severe, and analysed and presented as frequencies and percentages. The evaluation of the relationship between preoperative pain and acute postoperative pain among patients undergoing abdominal surgery was analysed with the use of the Student's Paired Sample t-test. The association of demographic factors with acute postoperative pain among patients undergoing abdominal surgery were assessed with the use of Pearson Chi-square test. The association of psychological factors with acute postoperative pain among patients undergoing abdominal surgery were also analysed with the use of Pearson Chi-square test.

Factors found to be statistically significant were subjected to multivariate analysis with the use of Logistic Regression. Odds ratio as well as their 95% confidence interval were calculated and reported where appropriate. All tests were considered significant where the p-value < 0.05.

CHAPTER FOUR: RESULTS

4.1 Introduction

236 patients were assessed for eligibility, 44 patients were excluded from the study. 195 patients were recruited for the study as shown in the study flow diagram in Figure 1.

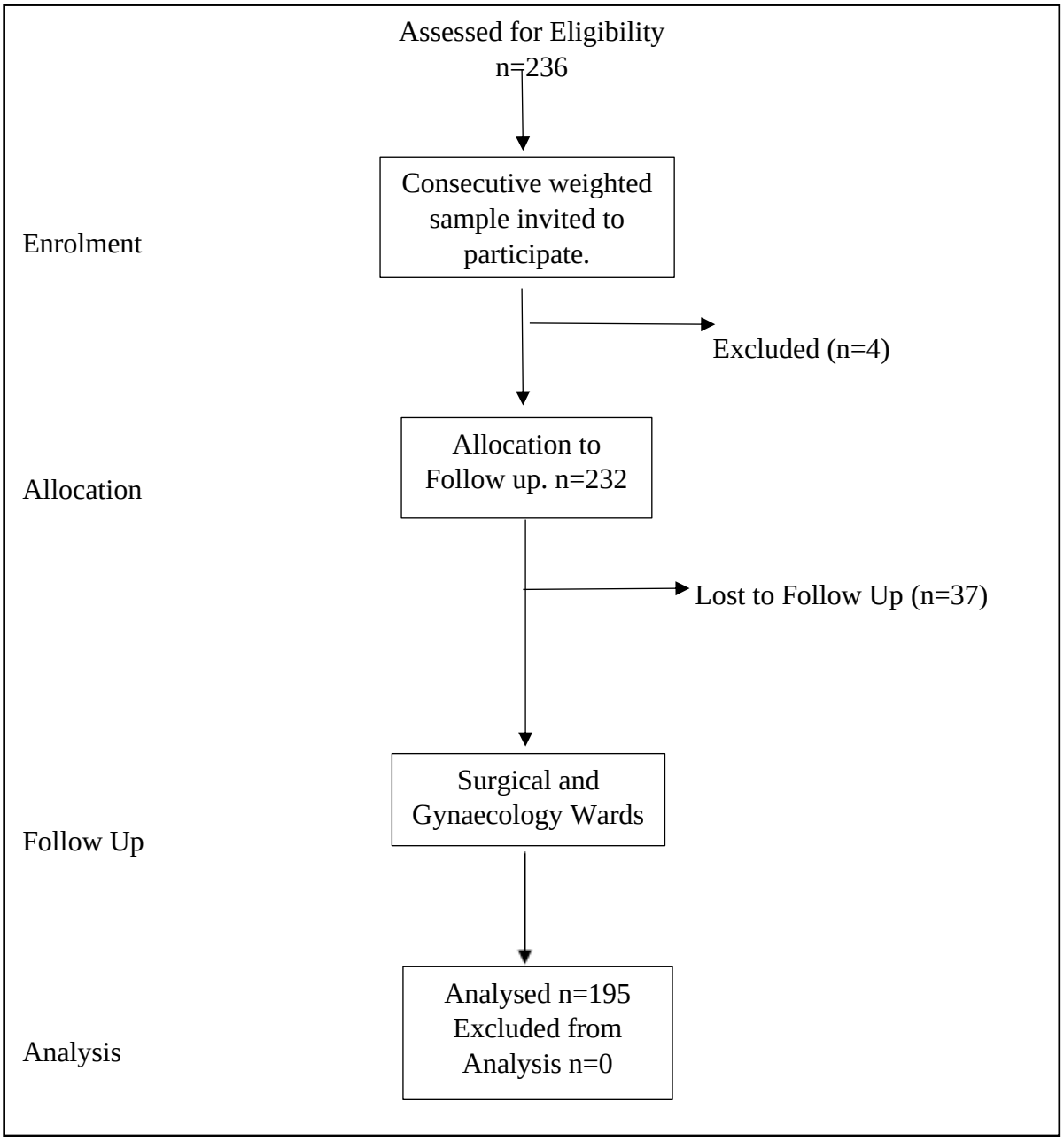

Figure 3: Study flow diagram

4.2 Patient Characteristics

The characteristics of the patients are shown below in table 2. The majority of the patients were female accounting for 162 (83.1%). The mean age of the patients was 44.1 (SD 13.9) years,

where the minimum age was 19.0 years and the maximum age was 88.0 years. The median age was 41.0 (IQR 35.0 – 51.0) years. There were 138 (70.8%) married patients and 99 (50.8%) of patients lived in the urban areas.

Table 2: Patients Characteristics

		Frequency *(n=195)*	**Percent**
Sex	Male	33	16.9
	Female	162	83.1
Age	18 – 39	83	42.6
	40 – 59	83	42.6
	≥60	29	14.9
BMI	<18.5 (Underweight)	15	7.7
	18.5 – 24.9 (Healthy)	83	42.6
	25.0 – 29.9 (Overweight)	60	30.8
	≥30.0 (Obese)	37	19.0
Education	Informal/ Cultural Education	4	2.1
	Primary	51	26.2
	Secondary	69	35.4
	Tertiary	71	36.4
Marital status	Single	41	21.0
	Married	138	70.8
	Once married	16	8.2
Residency	Urban (Within city)	99	50.8
	Sub urban (around city)	38	19.5
	Small towns (county towns)	39	20.0
	Rural (outside county towns)	19	9.7
Employment	Employer/Self-employed	70	35.9
	Employed	63	32.3
	Retired	18	9.2
	Unemployed	44	22.6
Smoker	Yes	6	3.1
	No	189	96.9

4.3 Preoperative Pain

To evaluate preoperative pain, all patients were asked if they had preoperative pain prior to surgery. A total of 45 (23.1%) patients experienced preoperative pain of which,19 patients had moderate to severe pain. The NRS pain score of the preoperative pain is shown in Figure 4.

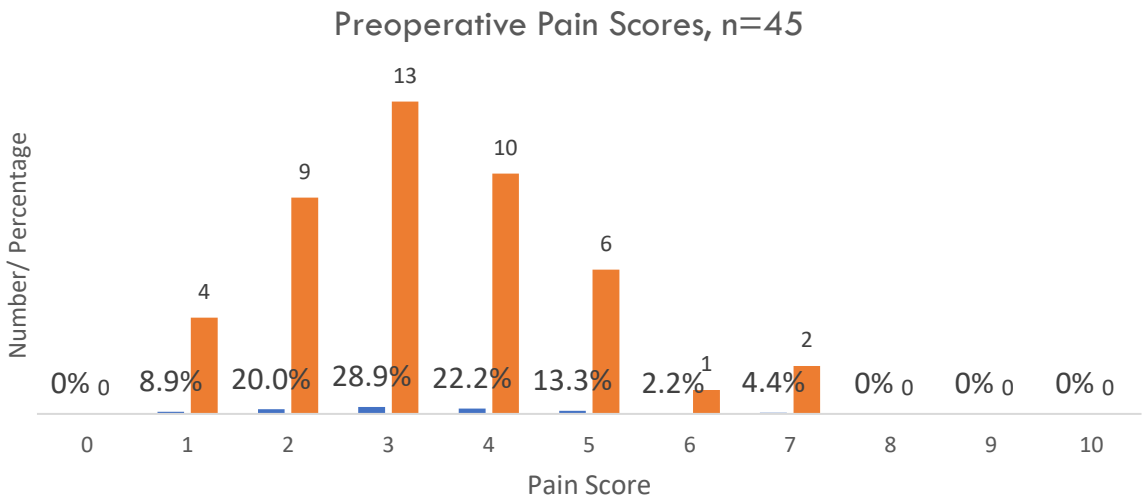

Figure 4: Pain scores of patients who experienced preoperative pain

Use of preoperative analgesia prescribed in the treatment sheet was also analysed as one of the variables. Only 3 (6.7%) patients of the 45 patients had preoperative analgesia prescribed yet 19 patients experienced moderate to severe preoperative pain. The three patients who received preoperative analgesia had moderate to severe preoperative pain as shown in figure 5.

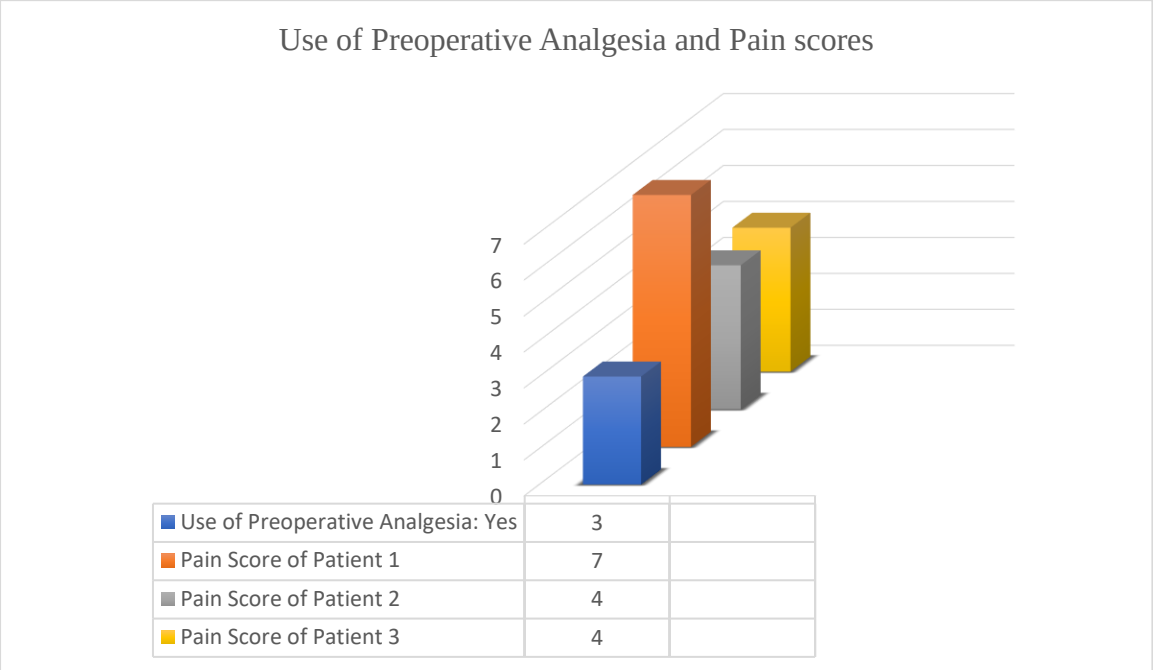

Figure 5: Use of preoperative analgesia and corresponding pain scores

4.4 Anxiety and Depression Scores

Anxiety and depression were the psychological factors assessed using the Hospital Anxiety and Depression Scale (HADS). The results are shown in table 3. The majority of patients were within normal ranges of anxiety and depression, 79% and 76.9% respectively.

Table 3: HADS Scores

		Frequency *(n=195)*	**Percent**
Anxiety	Normal (0-7)	154	79.0
	Borderline (8-10)	34	17.4
	Abnormal (11-21)	7	3.6
Depression	Normal (0-7)	150	76.9
	Borderline (8-10)	31	15.9
	Abnormal (11-21)	14	7.2

4.5 Theatre time and Technique

Theatre time, which was from the induction of anaesthesia to the reversal of anaesthesia, was recorded from the anaesthesia chart. Most surgical cases, 107 (54.9%) took between 2 to 4 hours as shown in table 4.

Table 4: Theatre time (duration of anaesthesia)

	Frequency *(n=195)*	**Percent**
Less than 1 hour	3	1.5
1 hour to 2 hours	70	35.9
2 hours to 4 hours	107	54.9
More than 4 hours	15	7.7

The main operative technique used was general anaesthesia which accounted for 184 (94.4%) cases, with very few patients undergoing spinal or epidural anaesthesia as shown in Figure 4.

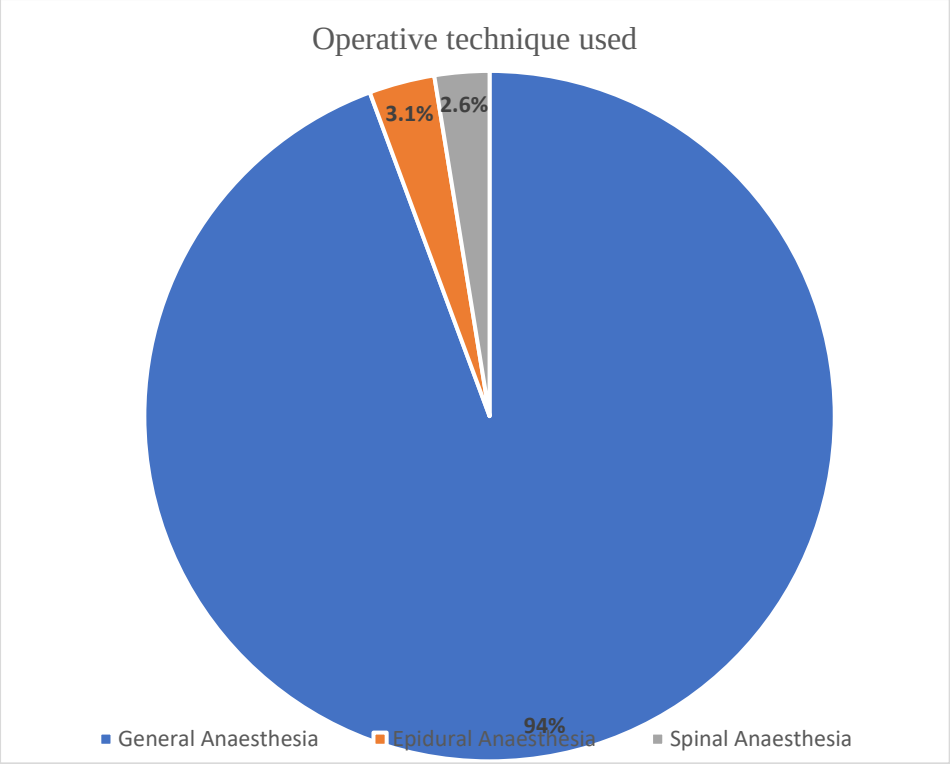

Figure 6: Operative technique used

4.6 Intensity of Postoperative Pain

To determine the intensity of acute postoperative pain following abdominal surgery, patients were asked to rate their pain on the NRS from 0 to 10, at rest and after coughing as shown in table 4.

Moderate to severe pain after coughing was experienced in 131 patients (67.1%). This is in comparison to 18 (9.2%) patients who at rest rated their pain as moderate and severe combined.

Table 5: Pain scores 24 hours postoperatively

		Frequency *(n=195)*	**Percent**
At rest	No pain (0)	76	39.0
	Mild (1 – 3)	101	51.8
	Moderate (4 - 6)	16	8.2
	Severe (7 - 10)	2	1.0
After coughing	No pain (0)	0	0
	Mild (1 – 3)	64	32.8
	Moderate (4 - 6)	99	50.8
	Severe (7 - 10)	32	16.4

4.7 Preoperative and Postoperative Pain

To evaluate the relationship between preoperative pain and acute postoperative pain a paired sample t-test was used. This was used to determine if there was a difference between the pain score preoperatively and postoperatively, and the results are as shown on Table 6. The results indicate that there was a statistically significant difference in the mean pain scores.

Table 6: Preoperative and Postoperative Pain Score

	Mean	**Std. Deviation**	**p-value**
Preoperative pain	0.77	1.58	**<0.001**
Postoperative pain	4.49	1.90	

4.8 Demographic factors and Postoperative Pain

To investigate the association of demographic factors with acute postoperative pain among patients undergoing abdominal surgery univariate analysis was performed, shown in table 7. Due to the low numbers of smokers and the patients who received preoperative analgesia, they were not included in the univariate analysis.

There were partial statistical differences observed were for BMI, education, area of residency and employment as shown in Table 7. The univariate analysis highlights that the demographic factors sex, age, marital status, and smoking status did not show any statistical associations or differences with acute postoperative pain.

Table 7: Univariate analysis for association between demographic factors and moderate to severe acute postoperative pain

	In Moderate to Severe Pain			
	Yes, *n (%)*	**No,** *n (%)*	**OR (95% CI)**	**p-value**
Sex				
Male	18 (13.7)	15 (23.4)	0.5 (0.2 – 1.1)	0.093
Female	113 (86.3)	49 (76.6)	Reference	
Age				

18 – 39	53 (40.5)	30 (46.9)	0.5 (0.2 – 1.3)	0.130
40 – 59	55 (42.0)	28 (43.8)	0.5 (0.2 – 1.4)	0.193
≥ 60	23 (17.6)	6 (9.4)	Reference	
BMI				
<18.5 (Underweight)	14 (10.7)	1 (1.6)	13.2 (1.6 – 111.5)	**0.017**
18.5 – 24.9 (Normal)	55 (42.0)	28 (43.8)	1.9 (0.8 – 1.4)	0.123
25.0 – 29.9 (Overweight)	43 (32.8)	17 (26.6)	2.4 (1.0 – 5.6)	**0.045**
≥30.0 (Obese)	19 (14.5)	18 (28.1)	Reference	
Education				
Informal/ Cul. Edu	3 (2.3)	1 (1.6)	2.3 (0.2 – 23.5)	0.474
Primary	39 (29.8)	12 (18.8)	2.5 (1.1 – 5.6)	**0.023**
Secondary	49 (37.4)	20 (31.3)	1.9 (0.9 – 3.8)	0.073
Tertiary	40 (30.5)	31 (48.4)	Reference	
Marital status				
Single	29 (22.1)	12 (18.8)	2.4 (0.7 – 7.9)	0.146
Married	94 (71.8)	44 (68.8)	2.1 (0.8 – 6.0)	0.154
Once married	8 (6.1)	8 (12.5)	Reference	
Residency				
Urban (Within city)	59 (45.0)	40 (62.5)	0.2 (0.04 – 0.8)	**0.024**
Sub urban (around city)	24 (18.3)	14 (21.9)	0.2 (0.04 – 1.0)	0.051
Small towns (county towns)	31 (23.7)	8 (12.5)	0.5 (0.1 – 2.4)	0.353
Rural (outside county towns)	17 (13)	2 (3.1)	Reference	
Employment				
Employer/Self-employed	49 (37.4)	21 (32.8)	0.8 (0.3 – 1.8)	0.563
Employed	35 (26.7)	28 (43.8)	0.4 (0.2 – 0.9)	**0.042**
Retired	14 (10.7)	4 (6.3)	1.2 (0.3 – 4.3)	0.817
Unemployed	33 (25.2)	11 (17.2)	Reference	

4.9 Psychological factors and Postoperative Pain

The association between psychological factors, namely anxiety and depression and acute postoperative pain is shown in table 8. There was no significant association between the psychological factors and acute postoperative pain.

Table 8: Association of psychological factors with acute postoperative pain

	In Moderate to Severe Pain			
	Yes, *n (%)*	**No,** *n (%)*	**OR (95% CI)**	**p-value**
HADS Depression				
None (0-7)	99 (75.6)	51 (79.7)	1.1 (0.3 – 4.0)	0.873
Mild (8-10)	22 (16.8)	9 (14.1)	1.4 (0.3 – 6.0)	0.652
Moderate (11-14)	7 (5.3)	4 (6.3)	Reference	
Severe (15-21)	3 (2.3)	0 (0.0)	-	
HADS Anxiety				
None (0-7)	108 (82.4)	46 (71.9)	7.0 (0.7 – 69.5)	0.095
Mild (8-10)	20 (15.3)	15 (23.4)	4.0 (0.4 – 42.4)	0.250
Moderate (11-14)	1 (0.8)	3 (4.7)	Reference	
Severe (15-21)	2 (1.5)	0 (0.0)	-	

CHAPTER FIVE: DISCUSSION

5.1 Discussion

Many studies have demonstrated that numerous patients still suffer moderate to severe pain despite improvements in present-day pain treatment and management(40). Postoperative pain following abdominal surgeries is detrimental to patient recovery. The associated with ill effects include delayed wound healing, splinting of the diaphragm, nausea and vomiting, and tachycardia(4,6,27). The current study illustrated that 24 hours postoperatively, 67.1% of patients experienced moderate to severe acute postoperative pain.

This finding is similar to a South African study done by Murray et al in 2016, with 62% of patients experiencing moderate to severe pain postoperatively(9). The study also highlighted that abdominal surgeries were associated with higher incidences of postoperative pain(9). A related study done by Singh et al on patients undergoing abdominal surgery found the prevalence of moderate to severe acute postoperative pain on the second postoperative pain was 56.7%(41). A finding that is slightly lower than our study.

The present study finding is within upper limits of the global prevalence of acute postoperative pain which is between 20-80% (1), but it is much higher than reported studies done at the Kenyatta National Hospital (KNH). A previous study done in 2000 by Adwok et al, at the KNH found that 56% of patients experienced moderate and severe pain following major thoracic and abdominal surgery(6). Another study done years later in 2016, on acute postoperative pain management at the KNH reported an incidence of moderate and severe acute postoperative pain in 40.7% of patients(27).

The present study findings come as an interesting revelation, as it would be expected that the incidence of moderate and severe pain would reduce even further over the years. This may because of the assumption of the authors that over the years there have been more modalities and advances in pain management practices at the KNH. Our findings possibly show that postoperative pain management still remains poor in our institution, a finding of which has been shared with previous authors and this could explain the high incidence of postoperative

pain in our study. Though, this remains an assumption as there were differences in methodology and variety of the scoring systems in each study.

Similar studies done within the region also report lower incidences of postoperative pain. One study done in Tanzania by Masigati et al, revealed that at rest, 40.3% of patients experienced moderate to severe postoperative pain and on movement, 49.2% experienced moderate to severe pain(7). Another study also done in Tanzania done by Mwashamba et al, also highlighted the prevalence of moderate and severe postoperative pain at 32.4%, much lower than the present study(4). An explanation to some of these contrary findings could be due to differences in surgical populations studied and differences in study design. The studies done in Tanzania were done on a mixed population of surgical patients as opposed to the current study which focused on abdominal surgeries. As previously mentioned, it has also been suggested that the surgeries associated with a high pain intensity include thoracic surgeries, orthopaedics with major joint surgery and open abdominal surgery(3). In addition, Mamie et al, in their study on 'Are there reliable predictors of postoperative pain?', found that intraperitoneal surgeries was found to increase the risk of severe pain(10). This could explain why our study had higher levels of pain.

Preoperative pain has been assessed in various studies and has been demonstrated to be a predictor of worse postoperative pain(9). A study showed that preoperative pain has the ability to induce various central neuroplastic changes such as facilitation and inhibition(2). In accordance with the above, our study found a significant association of preoperative pain with acute postoperative pain, p=<0.001. (2). Likewise, in their meta-analysis, Yang et al, demonstrated through various studies that preoperative pain was one preoperative predictor that was negatively associated with poor pain control after surgery, p=<0.001(5). Our finding is similar to Caumo et al, who revealed a significant association between acute postoperative pain and preoperative pain. Ip et al, in their meta-analysis also revealed the same association between preoperative pain and postoperative pain(3).

The aim of this study was to enhance knowledge on preoperative patient factors that are associated with acute postoperative pain following abdominal surgeries at the Kenyatta National Hospital. A total of 14 variables were investigated to evaluate which factors were associated with acute postoperative pain. Of the nine demographic variables evaluated, the 4 preoperative patient factors found to be statistically significant were presence of preoperative

pain, BMI, level of education, and socioeconomic status; evaluated through employment status and area of residence.

The remaining 5 patient factors, namely age, sex, smoking, marital status and use of preoperative analgesia were not associated with acute postoperative pain. The 2 psychological variables evaluated; anxiety and depression were not found to be associated with acute postoperative pain. Furthermore, the remaining 3 independent variables, type of surgery, intraoperative analgesia used and variability of anaesthesia plan were also not found to be associated with acute postoperative pain.

In terms of BMI, those who were underweight were more likely than obese patients to experience moderate to severe acute postoperative pain and this was statistically significant. This differs from other studies, as a higher BMI has been associated with poor pain control. Yang et al, reported that higher BMI as a continuous variable was a predictor of poor postoperative pain control(5).

On the aspect of education, the only partial difference were patients with primary education, who were more likely to have postoperative pain as compared to those who had tertiary education. This finding is different with Woldehaimanot *et al* as they found that less educated individuals report less pain intensity(1). Education and information status, and attitude are likely predictors of power and this can be linked to experience and perception of pain(1). However, more research will need to be conducted to ascertain the role of education and pain control.

For socioeconomic status, on employment, the only statistically significant difference found was between the employed and the unemployed, of which the employed were more likely to have postoperative pain when compared to the unemployed. This finding comes as a surprise as it does not correlate with studies done on preoperative patient factors such as Mwashamba et al, who found that employment as a predictor of postoperative pain was not a statistically significant finding(4). On socioeconomic status again, for residency, the only statistically significant difference was Urban residency (Within city) when compared to Rural residency (outside county towns), where they were less likely to have acute postoperative pain. This is unlike Yang *et al* who also studied the association of socioeconomic status and poor pain control and did not report any significant associations(5).

It comes as a surprise that some of the remaining preoperative factors were not found to be associated with acute postoperative pain. The two controversial factors being age and sex and also the two psychological factors. There have been inconsistencies in conclusions regarding age and gender in literature(5). In this study, these two controversial predictors were not correlated with acute postoperative pain.

For sex, in comparison to females, males were more likely to experience pain but this was not statistically significant. However, due to the small sample size of men in this study, gender differences cannot be fully appreciated. There are many theories regarding the gender difference and acute postoperative pain, though the mechanism remains elusive(3). Some of these theories are based on hormonal differences, and more specifically the menstrual cycle being related to pain perception(34). In experimental pain models, it has been found that women have a lower threshold pain to pressure and heat stimuli than men(34).

It has been thought that upbringing and education traditionally encourages boys not to express pain and girls to be more expressive, fragile and sensitive(10). In addition, due to different socialization, women are more readily willing to communicate their distress and their bodily experience(3). Our study found that men actually had more pain than women and this is in contrast to the above literature. Additionally, Theodoraki et al, found no differences in pain intensity between elderly male and female patients during the first 48 hours following major abdominal surgery. They go on to further to justify that based on their study, elderly patients should receive the same postoperative analgesia(34).

Following abdominal surgery, research done in Spain put age as a major factor of predictors of postoperative pain(8). The younger the patient, the more likely to report moderate and severe pain as compared to older patients. Literature has commented on the physiologic reasons of why younger patients are at more risk of experiencing pain. With advancing age, there is a reduction of peripheral nociceptor function and so less likely to experience pain(8). Evidence also suggests that there is a reduction in influence of specific genes on experience of pain with advancing age(3). Possible explanations for the contrary findings with age in the present study and above research could be due to the mean age of the patients was 44.1 (SD 13.9) years and the median age was 41.0 (IQR 35.0 – 51.0) years. The patients were within the same age bracket and thus we could not appreciate age related differences. Confounders to this, could also be the

varied types of surgeries and skewing results in favour of the 'typical' patient presentation characteristics, age being one of these characteristics.

Interestingly, our study did not reveal any association between anxiety and depression and acute postoperative pain. Our study showed that even though patients with no or mild anxiety more likely than moderately anxious patients to experience acute postoperative pain this was not statistically significant. This is unlike the well elaborated findings of numerous studies that link psychological states and acute postoperative pain. An anxious state for example, has been linked as a factor in lowering pain threshold, activation in entorhinal cortex of the hippocampal formation and facilitating the overestimation of pain(3). In Ip et al's study, they illuminated that in regards to gastrointestinal, reproductive and obstetrical surgery, anxiety was found to be an important predictor for postoperative pain(3).

A relationship has also been suggested between depressive mood and development of chronic postoperative pain(3). In our study, in comparison to moderately depressed patients, patients with no depression or mild depression were more likely to experience acute postoperative pain. Caumo et al's study on Preoperative Predictors of moderate to intense acute postoperative pain in patients undergoing abdominal surgery, revealed that the two psychological factors were associated with postoperative pain. Moderate to intense acute postoperative pain was associated with high trait anxiety and depressive mood moderate to intense.(2). There could be various theories as to why the study did not find any association, the main one being that the HADS has not yet been validated in Kiswahili. This could have bearings on the differences observed in our study and other studies investigating the above psychological predictors.

5.2 Recommendations

1. Sensitisation of healthcare workers in managing postoperative pain especially the doctors prescribing postoperative analgesia.
2. The need for an acute pain service to deliver services and to augment pain management of patients.
3. To pay particular attention to underweight patients when undergoing abdominal surgery as they are at increased risk of acute postoperative pain.
4. More studies should be conducted to investigate the effect of preoperative patient factors on acute postoperative pain following surgery.

5.3 Limitations

- One limitation of this study was the use of consecutive sampling. This made the sample population surgical procedures very varied as it included both minor and major surgeries. This could have a bearing on pain scores as some procedures may have been minor with little pain compared to major and longer surgeries.
- There was gender disparity as more females were recruited than males and this had a bearing when analysis gender differences.
- The pain assessment tool has its own limitations too. As a unidimensional tool it oversimplifies pain experience and in terms of comprehension, it may be difficult for use in certain individuals such as the elderly.
- The pain assessment tool used is not yet validated when using Kiswahili or in the Kenyan set up such as our institution.
- Another limitation of this study is that it was a single centre study and as such, the findings cannot be generalized to other institutions.

5.4 Conclusion

Our study highlighted that a majority of patients experienced moderate to severe postoperative pain following abdominal surgery within the institution. This shows that acute postoperative pain remains a problem to surgical patients and is still uncontrolled. Factors that could be responsible for this from the study included preoperative pain, patients of primary education levels, underweight and employed patients. Attention to these factors can assist in perioperative pain management strategies and reduce the burden of post operative pain following abdominal surgeries.

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APPENDICES

Appendix Ia: English Consent Explanation and Consent Forms

PREOPERATIVE PATIENT FACTORS ASSOCIATED WITH ACUTE POSTOPERATIVE PAIN FOLLOWING ABDOMINAL SURGERIES IN KENYATTA NATIONAL HOSPITAL

Investigators

Principal Investigator: Dr. Sally B. Getugi

Supervisors: Dr. Mark V. Gacii

Dr. Lee N. Kigera

Background

My name is Sally Getugi, a postgraduate student studying Anaesthesia at the University of Nairobi. I am conducting an observational study on the preoperative patient factors associated with acute postoperative pain following abdominal surgeries at the Kenyatta National Hospital.

Purpose

The purpose of this study is to evaluate if there are certain factors prior to surgery and patient factors that are associated with pain following abdominal surgeries. This information will be useful in understanding factors regarding postoperative pain and hopefully assist in enhancing patient pain management plans.

Study Procedure

This study will be done in three parts and participation will end 24 hours following surgery. Following your consent, you will be asked to fill a data collection tool prior to surgery which is the first part. The second part of the study is during your stay in the recovery room, you will be asked questions on your pain intensity on a validated pain scale. The third part will be done while in the ward 24 hours postoperatively and you will be asked questions about any pain you are experiencing.

Role of the Participant

Your role in the study is to answer the data collection tool and to rate pain on a validated pain scale. Other information pertinent to the study will be taken from your anaesthesia record chart by trained research assistant during the second part of the study in the recovery room.

Participation

You will be welcomed to participate in the study after the information regarding the study has been explained to you. After this, you will be asked to sign the consent form. Participation is

entirely voluntary and you have the right to withdraw from the study at any time without consequence in your treatment plan. You will not incur any extra cost due to participation in this study other than the usual cost of care at the Kenyatta National Hospital. There will be no financial gain or benefits from participation.

Please note:-

Your participation is voluntary

- You do not have to be in this study if you do not want to.

You have the right to withdraw from the study

- You may decide not to answer any question or stop being in the study at any point in time without losing your regular medical care and without obligation to explain why you withdraw. Inform us at the point you wish to discontinue from being in the study and this decision will be respected.

Risks of participation

Minimal risk and discomfort, outside of the nature of your treatment, will be experienced by participating in the study. Your planned treatment will not be affected.

Confidentiality

We will keep your identity as a research subject confidential. Your responses to questions will be kept private. We will not publish or discuss in public anything that could identify you, any patient identifiers will be omitted from the study. All the information obtained will be handled with respect and confidentiality.

Sharing of results

The results obtained from this study will be shared during the departmental presentation of results and other relevant platforms. Any publication of this study will not use your name or identify you personally.

Questions and Concerns

For any other questions, enquires or concerns, you may contact me on the following:-

Mobile: 0732 490555

Email: sbr.getugi@students.uonbi.ac.ke

Or :

Kenyatta National Hospital- University of Nairobi Ethics Review Committee

Telephone number: 2726300 ext 44102

Email: uonknh_erc@uonbi.ac.ke

CONSENT FORM

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with the principal researcher/ research assistant. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me.

I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.
By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

Participant printed name:_____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ Date: _____

Signature _____ Role in the study: _____

Appendix Ib: Kiswahili Consent Explanation and Consent Forms

SABABU ZA MGONJWA ZA KABLA YA UPASUAJI ZINAZOAMBATANA NA UCHUNGU MKALI WA BAADA YA UPASUAJI UNAOTOKANA NA UPASUAJI WA TUMBO KATIKA HOSPITALI KUU YA KENYATTA.

WATAFITI

Mchunguzi mkuu: Dr. Sally B. Getugi

Wasimamizi : Dr. Mark V. Gacii

Dr. Lee K. Ngugi

Msingi

Jina langu ni Sally Getugi, mwanafunzi wa uzamili katika chuo kikuu cha Nairobi. Ninasomea nusukaputi (anaesthesia). Ninafanya utafiti wa kiuchunguzi kuhusu sababu za mgonjwa za baada ya upasuaji zinazohusiana na uchungu baada ya upasuaji wa tumbo katika Hospitali Kuu ya Kenyatta.

Lengo

Lengo la huu utafiti ni kutathmini kama kuna sababu fulani kabla ya upasuaji na sababu za mgonjwa zinazohusiana na uchungu unaoambatana na upasuaji wa tumbo. Hii habari itasaidia katika kuelewa sababu zinazohusu uchungu wa baada ya upasuaji na kwa matumaini kusaidia katika kuboresha mipango ya kudhibiti uchungu wa baada ya upasuaji kwa mgonjwa.

Taratibu za utafiti

Utafiti huu utafanywa kupitia sehemu tatu na kushiriki kutakamilika saa ishirini na nne baada ya upasuaji. Kufuatia idhini yako, utaombwa kujaza hojaji kabla ya upasuaji ambayo ni sehemu ya kwanza. Sehemu ya pili ya utafiti ni, wakati wa kukaa kwako kwenye chumba cha kupata nafuu utaulizwa kuhusu kiwango cha uchungu kwa kutumia mizani inayopima uchungu iliyowekwa. Sehemu ya tatu itafanywa utakapokuwa kwenye wodi saa ishirini na nne baada ya upasuaji na utaulizwa maswali kuhusu uchungu wowote unaohisi.

Jukumu la mshiriki

Jukumu lako katika utafiti huu ni kuyajibu maswali kwenye hojaji na kutathmini uchungu kupitia kwenye mizani iliyowekwa.

Kushiriki

Kushiriki ni kamwe kwa hiari yako na una uhuru wa kujiondoa wakati wowote kwenye utafiti huu. Hutaombwa kulipa gharama yoyote kwa ajili ya kushiriki katika utafiti huu kando na gharama ya kawaida ya matibabu katika Hospitali Kuu ya Kenyatta. Hakutakuwa na faida ya kifedha au manufaa kwako kwa kushiriki katika huu utafiti. Kushiriki au kukosa kushiriki hakutaathiri au kuchelewesha matibabu yako.

Tafadhali kumbuka:-

Ushiriki wako ni wa hiari

• Sio lazima uwe katika somo hili ikiwa hautaki.

Una haki ya kujiondoa kwenye utafiti

• Unaweza kuamua kutokujibu swali lolote au kuacha kuwa kwenye utafiti wakati wowote bila kupoteza huduma yako ya kawaida ya matibabu na bila wajibu wa kuelezea kwanini unajiondoa. Tufahamishe mahali unapotaka kuacha kuwa kwenye utafiti na uamuzi huu utaheshimiwa.

Athari za kushiriki

Athari kidogo na kukosa starehe, tofauti na matibabu yako ya kawaida itahisiwa kwa kushiriki katika huu utafiti. Matibabu yako ambayo yamepangwa hayataathiriwa.

Usiri

Habari yote itakayotolewa kwenye huu utafiti itashughulikiwa kwa heshima na usiri. Vitambulisho vyovyote vya mgonjwa vitaondolewa kwenye utafiti huu.

Kusambazwa kwa matokeo

Matokeo yatakayo kusanywa kwenye huu utafiti yatasambazwa wakati wa kuwasilishwa kwa matokeo na kupitia njia nyinginezo.

Maswali na wasiwasi

Kwa maswali yoyote ya kina au wasiwasi wowote wasiliana nami kupitia

Simu: 0732 490555

Barua pepe: sbr.getugi@students.uonbi.ac.ke

Hospitali Kuu ya Kenyatta – Kamati ya utafiti ya Maadidili ya chuo Kikuu cha Nairobi

Nambari ya simu: 2726300 ext 44102

Barua pepe: uonknh_v@uonbi.ac.ke

FOMU YA IDHINI

Nimesoma fomu hii ya idhini/nimesomewa habari kwenye hii fomu ya idhini. Nimekuwa na fursa ya kujadili kuhusu utafiti huu na mtafiti mkuu/ mtafiti masidizi. Maswali yangu yamejibiwa kwa lugha ambayo ninaelewa. Nimeelezewa athari na manufaa ya kushiriki. Ninaelewa kuwa kushiriki kwangu katika utafiti huu ni kwa hiari yangu na ninaweza amua kujiondoa wakati wowote. Ninakubali bila kulazimishwa kushiriki kwenye utafiti huu. Ninaelewa kwamba juhudi zote zitafanywa ili kuweka siri habari zinazonihusu. Kwa kutia sahihi kwenye hii fomu ya idhini, sijajiondolea haki zangu za kisheria ambazo ninazo kama mshiriki katika huu utafiti.

Jina la mshiriki lililochapishwa_____

Sahihi ya mshiriki / kidole gumba _____ Tarehe_____

Researcher's statement

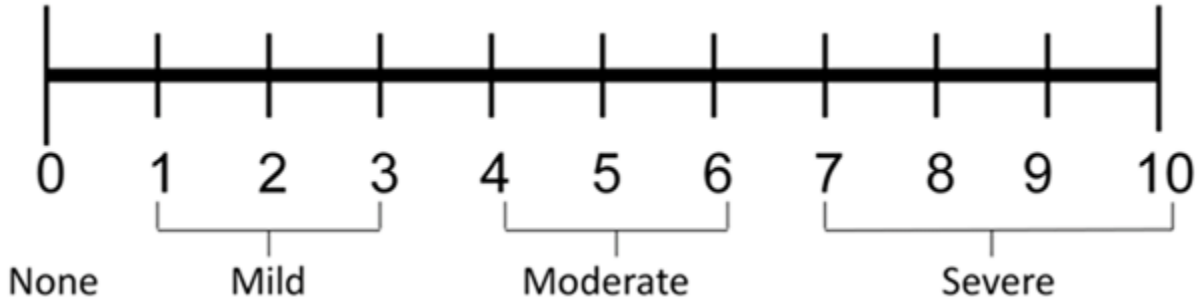
I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher‘s Name: _____ Date: _____

Signature _____ Role in the study: _____

Appendix II: Data Collection Tools

Appendix IIa: Study Instrument : Pain Rating Scale -NRS



Appendix IIb: Data Collection Tool: English

PREOPERATIVE PATIENT FACTORS ASSOCIATED WITH ACUTE POSTOPERATIVE PAIN FOLLOWING ABDOMINAL SURGERIES IN KENYATTA NATIONAL HOSPITAL AND KENYATTA UNIVERSITY TEACHING, REFERRAL AND RESEARCH HOSPITAL

SECTION 1: PREOPERATIVE

Please tick or mark where appropriate and specify where appropriate

1. Sex **2. Age (Years)** **3. Nationality**

Male ☐ **Female** ☐ _____ **Kenyan** ☐ **Other**_____

1. Height (cm) **5. Weight (kg)** **6. BMI** ***. Ulna Length (cm)/ MUAC**

_____ _____ _____ _____/_____

• **Highest level of Education Completed**		**8. Marital Status**	
Informal/ Cultural Education	☐	Single	☐
Nursery Level	☐	Married	☐
Primary	☐	Divorced	☐
Secondary	☐	Separated	☐
Tertiary	☐	Widow/Widower	☐
9. Area of Residence		**10. Employment Status**	
Urban (Within city)	☐	Employer/ Self Employed	☐
Sub urban (around city)	☐	Employed	☐
Small towns (county towns)	☐	Retired	☐
Rural (outside county towns)	☐	Unemployed	☐

11. Comorbidities (*Please tick or mark all that apply)*

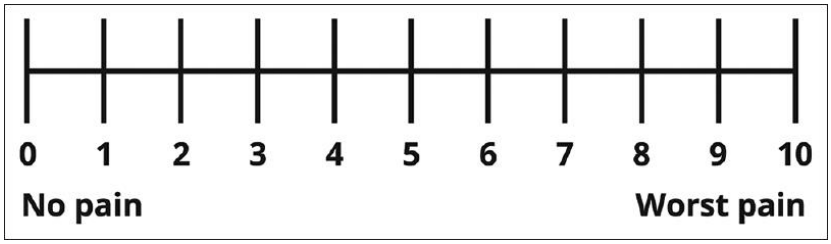
Hypertension	☐	Malignancy/ Cancer	☐
Diabetes Mellitus	☐	Immunocompromised	☐
Coronary Heart Disease	☐	Chronic Kidney Disease	☐
Epilepsy	☐	Dementia	☐
Asthma	☐	Smoking	☐
Arthritis	☐	None	☐
Cerebrovascular Accident (Stroke)	☐	Other (Please Specify) _____	

12. Current Experience of Pain

a. Are you currently in any pain?

Yes ☐ No ☐

b. Please mark the point on the following line that describes your pain at this moment.



c. What pain medication are you currently using and how often do you take them?

_____

Once a day ☐ Twice a day ☐ Thrice a day ☐ Four times a day ☐

d. Medication prescribed on treatment sheet

e. Has your pain lasted for more than 3 months?

Yes ☐ No ☐

If so, how long for?_____

f. Which pain medication have you been using?

13. Hospital and Anxiety Depression Scale

(*Please tick the following that applies per question in the past week)*

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down**
		Most of the time			Nearly all the time
		A lot of the time			Very often
		From time to time, occasionally			Sometimes
		Not at all			Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
		Definitely as much			Not at all

		Not quite so much			Occasionally
		Only a little			Quite often
		Hardly at all			Very often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
		Very definitely and quite badly			Definitely
		Yes, but not too badly			I don't take as much care as I should
		A little, but it doesn't worry me			I may not take quite as much care
		Not at all			I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
		As much as I always could			Very much indeed
		Not quite so much now			Quite a lot
		Definitely not so much now			Not very much
		Not at all			Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
		A great deal of the time			As much as I ever did
		A lot of the time			Rather less than I used to
		From time to time, but not too often			Definitely less than I used to
		Only occasionally			Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
		Not at all			Very often indeed
		Not often			Quite often
		Sometimes			Not very often
		Most of the time			Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
		Definitely			Often

		Usually			Sometimes
		Not often			Not often
		Not at all			Very seldom

Total D: **A:**

SECTION 2: POSTOPERATIVE

Diagnosis

_____

ASA Classification **Theatre Time** (*Induction to Reversal)*

_____ **(**hr:min) _____

Surgical Intervention Done

_____

NCEPOD Classification of Intervention

- Immediate ☐
- Urgent ☐
- Expediated ☐
- Elective ☐

If not Specified

Theatre list classified as : Emergency ☐

: Elective ☐

Operative Technique Used

General Anaesthesia (GA)

GA + Regional Anaesthesia (*Specify)*

_____

Spinal Anaesthesia

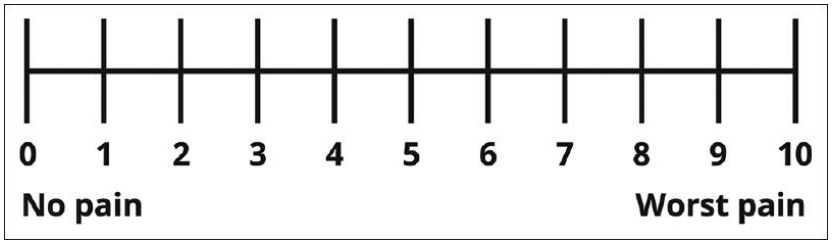
Epidural Anaesthesia

Intraoperative Analgesia Used (*indicate the type and amount***)**

1. **Postoperative Pain Experience**

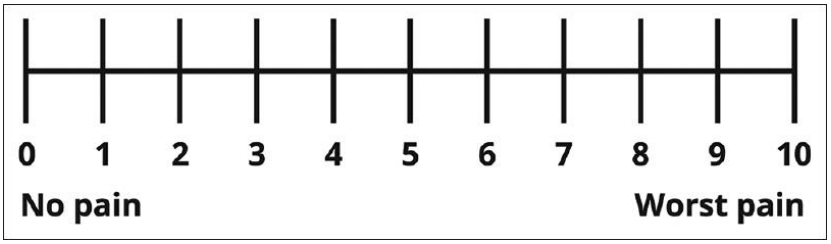
a. **IN THE WARD: 24 HOURS POSTOPERATIVELY**

Please mark the point on the following line that best describes your pain **when you woke up in PACU.**

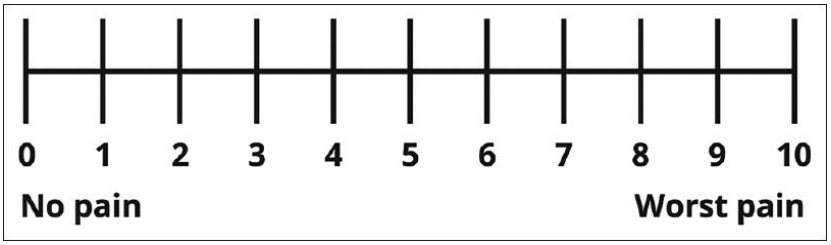


b. IN THE WARD: 24 HOURS POSTOPERATIVELY

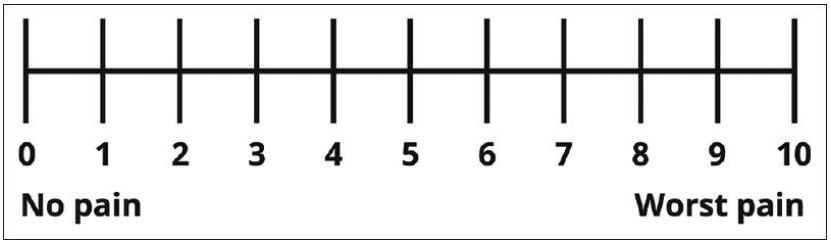
1. Please mark the point on the following line that best described **the worst pain you experienced after surgery.**



2. Please mark the point on the following line that **describes your pain at this moment. (At rest)**



3. Please mark the point on the following line that best describes your **pain at this moment. (After coughing)**



4. Did you request more pain medication when in pain?

Yes ☐ No ☐

a. Was the pain medication given when asked for?

Yes, but took time. ☐ Yes, was immediate. ☐ No ☐

Appendix IIc: Data Collection Tool: Kiswahili

SABABU ZA MGONJWA ZA KABLA YA UPASUAJI ZINAZOAMBATANA NA UCHUNGU MKALI WA BAADA YA UPASUAJI UNAOTOKANA NA UPASUAJI WA TUMBO KATIKA HOSPITALI KUU YA KENYATTA NA HOSPITALI YA KUFUNDISHA NA RUFAA NA CHUO KIKUU CHA KENYATTA.

SEHEMU YA 1: KABLA YA UPASUAJI

Tafadhali weka alama mahali panapostahili na taja mahali panapostahili

1. Jinsi **2. Umri (miaka)** **3. Utaifa**

Kiume ☐ Kike ☐ _____ Mkenya ☐ mkenya _____

4.Urefu (cm) **5. Uzani (kg)** **6. Taja utaija** ***Ulna Length (cm)/ MUAC**

_____ _____ _____ _____/_____

7. Kiwango cha juu cha elimu kilichokamilishwa		**8. Hali ya Ndoa**	
Isiyo rasmi/ elimu ya kitamaduni	☐	Sijaolewa/Sijaoa	☐
Kiwango cha chekechea	☐	Nimeolewa/ Nimeoa	☐
Shule ya msingi	☐	Nimetalikiwa	☐
Shule ya upili	☐	Tumetengana	☐
Kiwango cha juu	☐	Mjane	☐

9.Maeno ya Makaazi		**10. Hali ya Kazi**	
Mjini (ndani ya jiji)	☐	Mwajiri/ Nimejiajiri	☐
Mji mdogo (karibu na jiji)	☐	Nimeajiriwa	☐
Miji midogo (miji ya kaunti)	☐	Nimestaafu	☐
Kijiji (nje ya mji)	☐	Sijaajiriwa	☐

11.Kuwepo kwa hali nyingine au magongwa mengine (*tafadhali weka alama mahlai ambapo panafaa)*

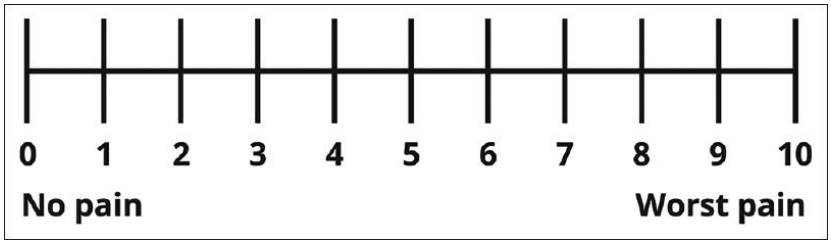
Ugonjwa wa shinikizo la damu	☐	Saratani	☐
Ugonjwa wa sukari	☐	Kinga ya mwili iliyo hatarini	☐
Ugonjwa wa moyo	☐	Ugonjwa sugu wa figo	☐
Kifafa	☐	Shida ya akili (kusahau)	☐
Ugonjwa wa pumu	☐	Kuvuta sigara	☐
Ugonjwa wa yabisi kavu (mifupa)	☐	Hakuna	☐
Kiharusi	☐	Mengineyo: (Tafadhali eleza) _____	

12. Kuhisi kwa uchungu kwa sasa

a. Unahisi uchungu wowote sasa?

Ndiyo ☐ La ☐

b. Tafadhali weka alama kwenye mstari ufuatao mahali ambapo panaelezea vizuri uchungu ambao **unahisi wakati huu.**



Ni dawa gani za kupunguza maumivu ambazo umekuwa ukitumia/au unatumia kwa sasa na mara ngapi?

_____

Once a day ☐ Twice a day ☐ Thrice a day ☐ Four times a day ☐

c. Medication prescribed on treatment sheet

d. Uchungu wako umekawia kwa zaidi ya miezi mitatu?

Ndiyo ☐ La ☐

Kama ni ndiyo, muda gani?_____

e. Ni dawa gani unatumia kwa maumivu yako sugu?

KIPIMO CHA WASIWASI NA MFADHAIKO/HUZUNI CHA HOSPITALI

(*Weka alama(✓) kwenye kijisanduku kilicho kando ya jibu linalokaribiana na jinsi ambavyo umekuwa ukihisi katika juma lililopita usichukuwe muda mrefu kwenye majibu yako:yako ya haraka ni bora***.)**

D	A		D	A	
		Ninahisi fadhaha au wasiawasi			**Ninahisi kuwa ninapunguziwa mwendo**
		Mara nyingi			Karibu kila wakati
		Wakati mwingi			Kila mara
		Mara kwa mara, mara chache			Mara nyingine
		La			La
		Bado ninafurahia vitu nilivyokuwa nikifurahia awali			**Ninapata hisia za uoga au wasiwasi**

		Kabisa			La
		Sio sana			Mara chache
		Kidogo tu			Mara kwa mara
		Nadra sana			Mara kwa mara zaidi
		Ninapata hisia za uoga kana kwamba jambo mbaya litafanyika hivi karibuni			**Nimepoteza mvuto katika mwonekano wangu**
		Kabisa na vibaya sana			Kabisa
		Ndiyo lakini si vibaya sana			Sijali jinsi ninavyofaa kujali
		Kidogo lakini hainijalishi			Ninaweza kukosa kujali kabisa
		La			Ninajali sana kama kawaida
		Ninaweza kucheka na kuona vitu vya ucheshi			**Ninajihisi mwenye kukosa utulivu kwani ni lazima niwe kwenye mwendo**
		Kadri niwezavyo kila wakati			Mara nyingi kabisa
		Si sana sasa			Wakati mwingi
		Haswa si sana sasa			Si sana
		La			La
		Mawazo ya kunipa wasiwasi hunijia akilini			**Ninatazamia vitu kwa furaha**
		Mara nyingi			Jinsi ilivyokuwa hapo awali
		Wakati mwingi			Kidogo kuliko ilivyokuwa hapo awali
		Mara kwa mara,lakini sio kila mara sana			Kidogo kabisa kuliko Ilivyokuwa hapo awali
		Mara chache tu			Nadra sana
		Ninajihisi mchangamfu			**Ninapata hisia za hofu za ghafla**
		La			Mara kwa mara kabisa
		Si kila mara			Mara kwa mara
		Mara nyingine			Sio mara kwa mara
		Mara nyingi			La

		Ninaweza kuketi kwa utulivu na nihisi kuburudika			**Ninaweza kuburudishwa na kitabu kizuri au kipindi kwenye televisheni**
		Kabisa			Kila mara
		Kawaida			Mara nyingine
		Si kila mara			Sio kila mara
		La			Nadra sana

Tafadhali angalia ikiwa umeyajibu maswali yote.

Total D: **A:**

SEHEMU YA 2: BAADA YA UPASUAJI

Diagnosis

_____

ASA Classification **Theatre Time** (*Induction to Reversal)*

_____ **(**hr:min) _____

Surgical Intervention Done

_____

NCEPOD Classification of Intervention

- Immediate ☐ If not Specified
- Urgent ☐ Theatre list classified as : Emergency ☐
- Expediated ☐ : Elective ☐
- Elective ☐

Operative Technique Used

General Anaesthesia (GA) GA + Regional Anaesthesia (*Specify)*

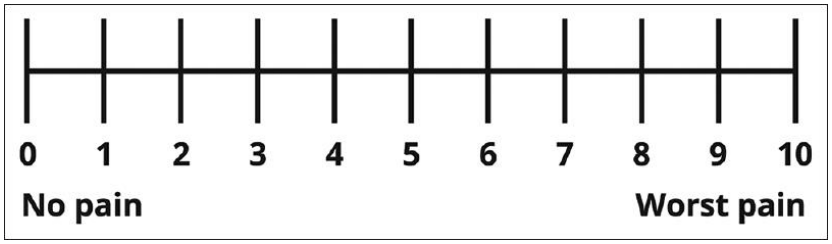
_____

Spinal Anaesthesia Epidural Anaesthesia

Intraoperative Analgesia Used (*indicate the type and amount***)**

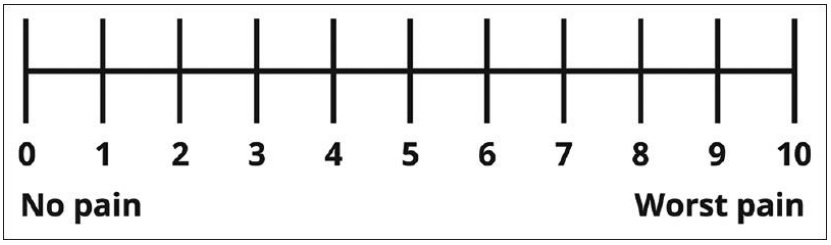
1. KATIKA WODI: SAA ISHIRINI NA NNE BAADA YA UPASUAJI

Tafadhali weka alama kwenye mstari ufuatao mahali ambapo panaelezea vizuri uchungu ambao **unahisi wakati huu.**

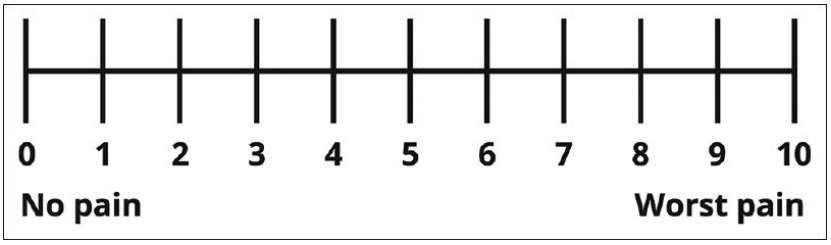


2. KATIKA WODI: SAA ISHIRINI NA NNE BAADA YA UPASUAJI

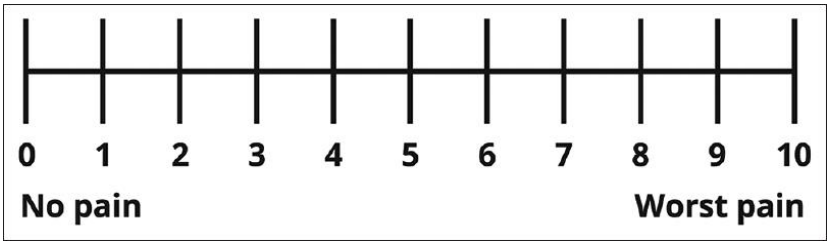
a. Tafadhali weka alama kwenye msitari ufuatao mahali ambapo panaeleza uchungu mbaya ambao **ulihisi baada ya upasuaji**.



b. Tafadhali weka alama kwenye mstari ufuatao mahali ambapo panaelezea kiwango cha uchungu ambao unahisi kwa wakati huu. (**WAKATI WA MAPUMZIKO**)



c. Tafadhali weka alama kwenye mstari ufuatao mahali ambapo panaelezea kiwango cha uchungu ambao unahisi kwa wakati huu. (**KIKOHOZI**)



d. Uliomba dawa ya kutuliza maumivu ulipokuwa unahisi maumivu?

Ndiyo ☐ La ☐

e. Dawa ya kutuliza maumivu iliepeanwa wakati ulipoomba?

Ndiyo, lakini ilichukua muda ☐ diyo, ilikuwa kwa wakati ☐ La ☐

Appendix III: Quality Assurance Protocol

Study Details ***Preoperative patient factors associated with acute postoperative pain following abdominal surgeries at the Kenyatta National Hospital*** Principal Investigator: Dr. Sally B Getugi Location: KNH: Casualty, Medical and Surgical wards, PACU of theatres Sample size: n=381		
Quality Procedure Manager		
QUALITY ASSURANCE ACTIVITIES		
Data Point/ Activity	**Location/ Source/ People**	**100% Validation/ Notes**
Training of Team	Principle Investigator Quality Assurance Manager Research Assistants	Completion and certification in ICH GCP (PI), Informed Consent (entire team) and REDCap Training **prior** to commencement of data collection.
Eligibility of Participants - Inclusion and Exclusion criteria from Protocol	Study sites from protocol	100% of all Participants
Informed Consent Provided	Signed consent forms	100% of all Participants Secure copy of signed consent form. (Data Management)
Serious adverse events Protocol violations Loss to follow up Withdrawals	Participants Research Team	100% Validation Checks.

Data Management	REDCap Paper Records Clinical records/data	Quality Assurance Manager to assess the vigour of data management. PI to secure the tablets and paper documents.

Appendix IV: Anti-Plagiarism Report

Preoperative Patient Factors Associated With Acute Postoperative Pain Following Abdominal Surgeries At The Kenyatta National Hospital

ORIGINALITY REPORT

13%	8%	9%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.ncbi.nlm.nih.gov Internet Source	1%
2	hdl.handle.net Internet Source	1%
3	www.sajaa.co.za Internet Source	1%
4	Michael M H Yang, Rebecca L Hartley, Alexander A Leung, Paul E Ronksley, Nathalie Jetté, Steven Casha, Jay Riva-Cambrin. "Preoperative predictors of poor acute postoperative pain control: a systematic review and meta-analysis", BMJ Open, 2019 Publication	1%
5	Campbell, Claudia M, and Robert R Edwards. "Ethnic differences in pain and pain management", Pain Management, 2012. Publication	1%

www.surgeryresearchjournal.com

Appendix V: Ethical Approval

UNIVERSITY OF NAIROBI
COLLEGE 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/71

25th February 2021

Dr. Sally Bochere Getugi
Reg. No.H58/6954/2017
Dept.of Anaesthesia
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Getugi

RESEARCH PROPOSAL – PREOPERATIVE PATIENT FACTORS ASSOCIATED WITH ACUTE POSTOPERATIVE PAIN FOLLOWING ABDOMINAL SURGERIES AT THE KENYATTA NATIONAL HOSPITAL (P637/11/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 25th February 2021 – 24th February 2022.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect 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.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information Dept, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Anaesthesia, UoN
Supervisors: Dr. Mark V. Gacii, Dept. of Anaesthesia, UoN
Dr. Lee N. Kigera, Dept. of Medical Physiology, Kenyatta University