UNIVERSITY OF NAIROBI

PREVALENCE AND RISK FACTORS ASSOCIATED WITH NEUROPRAXIC AND GENITOPERINEAL COMPLICATIONS FOLLOWING FRACTURE TABLE USE AT KENYATTA NATIONAL HOSPITAL

BY

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A dissertation submitted in partial fulfilment of the requirement for the award of the Degree of Master of Medicine in Orthopaedic Surgery, the University of Nairobi ©

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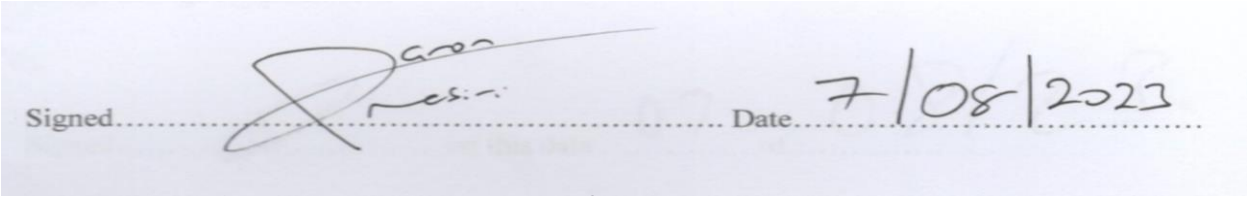
DECLARATION

I hereby declare that this dissertation is my original work and has not been presented at any other University. Where other people's work has been used, this has been acknowledged and referenced according to the University of Nairobi's requirements. I have not sought or used the services of any professional agencies to produce this work.



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LIST OF ABBREVIATIONS AND ACRONYMS

WHO: World Health Organization

KNH: Kenyatta National Hospital

SPSS: Statistical Package for the Social Sciences

THA: Total hip arthroplasty

KESSOT: Kenya Society of Orthopaedic Trauma Technologist

UoN: University of Nairobi

KNH/UON ERC: Kenyatta National Hospital/ UNIVERSITY OF Nairobi Ethics and Research Committee

RA: Research Assistant

NACOSTI: National Commission for Science, Technology and Innovation

OPERATIONAL DEFINITIONS

Fracture table: Also referred to as an orthopaedic table or traction table is a table designed to provide for the suspension and immobilization of the lower extremities and trunk, without lifting or moving the patient in any way, and to afford reliable support and traction of the lower limbs.

Genitoperineal: This is the area between the anus and genitals, extending from either the vaginal opening to the anus or the scrotum to the anus

Neuropraxia: Refers to injury of the peripheral nerves

Post-op: post-operative

Perineal post: Padded part of the fracture table that provides hip and leg counter traction for surgical procedures performed in the supine position.

Pudendal nerve injury: Pelvic condition caused by damage, injury or irritation of the pudendal nerve

Traction: The act of drawing or exerting a pulling force applied to limbs, bones, or other tissues along the longitudinal axis of the structure to pull the tissues apart, often for realignment

External fixation: A minimally invasive technique accomplished by placing a scaffold-like frame with attached wires, pins, or both outside of the extremity. The wires and pins have small diameters and transfix the bone.

Compartment syndrome: Condition where the Osseo fascial compartment pressure rises to a level that decreases perfusion to the leg

ABSTRACT

Background

Fracture tables are frequently used in lower limb surgeries, but they can result in complications like genitoperineal and neuropraxic injuries. These injuries include lower limb nerve damage, skin death, pudendal nerve injury, and urethral injuries. Recovery time varies, and patients may have partial or permanent dysfunction. Prolonged use of the perineal post is the main cause of these severe complications. However, there is limited data on the occurrence and complications of using fracture tables in developing countries like Kenya.

Study Objective: To determine the prevalence and risk factors associated with neuropraxic and genitoperineal complications following the use of fracture tables in Kenyatta National Hospital.

Study setting: The study was conducted at the orthopaedic surgery wards and theatre of Kenyatta National Hospital.

Methodology: The study used an analytic cross-sectional design to explore the relationship between the use of fracture tables and the perineal post duration, age of patient, and surgery duration. The target population were all patients admitted for hip, femur, or pelvis surgical procedures.

A purposive sampling was used to identify the appropriate sample size from a pre-set inclusion and exclusion criteria.

Data Analysis: The data was entered into an excel sheet and exported to the Statistical package (SPSS version 27) for analysis. Descriptive statistics were applied and continuous data summarization was done using mean, median, mode and standard deviation. The incidence of genitoperineal and neuropraxic complications after operative

procedures utilizing a fracture table was calculated as a percentage of the total number of procedures performed. A p-value of less than 0.05 was considered in determining the association between risk factors and complications, as well as the link between fracture table use and the occurrence of complications. Data is also presented in figures and tables where applicable. To analyse the risk of complications in relation to the duration on fracture table, inferential statistics were used. Logistic regression analysis was used to identify any risk factors associated with the complications. The results of the logistic regression analysis were presented using odds ratios and confidence intervals.

Significance of the Study: The study promoted evidence-based care in Kenyan Hospital facilities by advancing knowledge on the prevalence, types, and factors of fracture-table related complications. The findings should help health providers provide timely management of soft-tissue and neurological sequelae, eventually contributing to improved patient outcomes. The study is also significant to the state of healthcare research in developing countries, where empirical evidence is lacking substantially.

Results: The most occurring complication was pudendal nerve neuralgia (93.3%) with perineal pain that worsens while sitting down being the most occurring symptom. Of the three female patients two had vulval swelling. Perineal dysthesia occurred in two patients, while no one experienced scrotal swelling

Conclusion: The use of a fracture table with perineal post when treating femur fractures on a fracture table poses risks for pudendal neurapraxia and perineal soft tissue injury among other complications. Measures to reduce occurrence of these complications should focus on reducing

time on perineal traction as well as reducing amount of pressure on perineum. There is also need for a more extensive study with a larger number of patients, and a longer follow up to track complications

1.0 INTRODUCTION

1.1 Background

Genitoperineal and neuropraxic injuries are a sequela known to arise from the perineal post component of a fracture table. The prevalence of genitoperineal and neuropraxic complications associated with the use of the fracture table for orthopaedic procedures varies widely among different studies. The reported prevalence rates of genitoperineal complications range from 0% to 40%, while the reported prevalence rates of neuropraxic complications range from 0% to 16% (1). Similarly, the true incidence of complications related to fracture tables remains unclear and is likely unreported (2). The complications associated with the fracture table include lower limb neuropraxia (including the well lower limb), cutaneous necrosis, pudendal nerve injury (commonly presenting as perineal dysesthesias and/or transient erectile dysfunction), and urethral injuries (3). However, the reported recovery time is unpredictable, and several patients experience only partial recovery or suffer permanent dysfunction (4). Flierl et al. attributed the cause of significant complications to prolonged application of the perineal post (2).

Fracture tables are essential tools in numerous operative procedures about the hip and femur despite the complications. Currently, traction tables are routinely used in femoral fracture fixation, fractures around the hip, surgical management of acute slipped capital femoral epiphysis, primary total hip arthroplasty, hip resurfacing, and hip arthroscopy.

The orthopaedic surgeon who uses a fracture table must be cognisant with the associated potential dangers and risks and must develop a plan to avoid traction-table associated complications (2). However, there is little information about the incidence rate in Kenyatta National Hospital, the complications resulting from nerve injury, and, subsequently, the prognosis.

1.2 Problem Statement

Orthopaedic surgical procedures often require the use of specialized equipment to stabilize and position the patient during the operation. The use of fracture tables in orthopaedic surgeries provides better exposure, reduction, and fixation of fractures. However, while the fracture table has been shown to be effective in achieving good surgical outcomes, it can also pose a risk of injury to the patient, particularly in the genitoperineal region (4).

Previous studies conducted in developed countries have reported various genitoperineal complications associated with the use of the fracture table, such as urethral injuries, penile injuries, scrotal injuries, and rectal injuries (3;5). Studies report that, for instance, pudendal nerve palsy and erectile dysfunction, which are the most frequent complications that occur due to the use of perineal post-traction, have an estimated incidence rates ranging from 1.9% to 15% (6). On the other hand, there is a lack of information on the occurrence and management of such complications in developing countries, particularly in sub-Saharan Africa. In Kenya, for instance, the use of fracture table is widespread in major hospitals, yet the genitoperineal and neuropraxic complications secondary to fracture table related operative procedures in these institutions are currently unknown.

Understanding the occurrence of genitoperineal and neuropraxic complications associated with the use of the fracture table during orthopaedic procedures is crucial for developing effective procedural protocols and post-operative monitoring strategies. The current study aims to improve clinical understanding of the prevalence, risk factors, and types of these complications in Kenyan hospitals, where there is a dearth of literature on

the topic. Effective care provision and improved patient outcomes are critical goals of Evidence-Based Practice in healthcare, which involves applying data-backed solutions that incorporate clinical expertise and current research into the decision-making process. By enhancing the knowledge base on fracture-table related complications, this study should support timely management of soft-tissue and neurological sequelae, ultimately contributing to improved patient outcomes.

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1.3 Study questions

The orthopaedic table is essential for orthopaedic procedures requiring sustained skeletal traction. However, the fracture table has been linked to genitoperineal and neuropraxic complications such as erectile dysfunction, lower limb neuropraxia, and pudendal nerve palsy among others. The prevalence of these complications is yet to be studied in the Kenyan orthopaedic setting, as well as the intraoperative factors that might play a hand. To better understand, this study answered the following research questions:

- What is the prevalence of genitoperineal and neuropraxic complications after using the fracture table for orthopaedic procedures?
- What are the different types of genitoperineal and neuropraxic complications related to fracture table use?
- What are the risk factors associated with genitoperineal and neuropraxic injuries following the use of fracture table?

On the basis of the answers to the research questions, measures to prevent and reduce complications can be implemented, as well as hospital policies on intraoperative orthopaedic procedures that utilise the fracture table1.4 Study objectives

1.4.1 Broad Objective

- To investigate the prevalence and risk factors of genitoperineal and neuropraxic complications after the use of a fracture table

1.4.2 Specific Objectives.

- To determine the prevalence of genitoperineal and neuropraxic complications after using the fracture table for orthopaedic procedures. The prevalence was the number of people in the population that develop complications over the period of admission.
- To determine the types of genitoperineal and neuropraxic complications related to fracture table use. These was the specific complications that develop within the study population.
- To determine the risk factors associated with genitoperineal and neuropraxic injuries following the use of the fracture table. The age, length of procedure and length of perineal post application was considered.

2.0 LITERATURE REVIEW

Introduction

Fracture tables are routinely designed to allow the surgeon to perform numerous orthopaedic procedures on the hip, including hip arthroscopy, hip resurfacing, anterior approach total hip arthroplasty, and surgical management of acute slipped capital femoral epiphysis, thoracic and lumbar spine and femoral fracture fixation (4). They provide suspension and restriction of the lower limbs and trunk, as well as support and traction.

The primary advantage of using a traction table in orthopaedic trauma surgery is that it facilitates indirect fracture reduction and maintenance by consistent traction throughout the procedure. Hip fractures which include femoral neck and trochanteric fractures represent the classic indication for using a fracture table (2). Regardless of which approach is performed, the patient must be safely positioned on the table to minimize complications.

Several studies have indicated the use and effectiveness of the Fracture tables in hip and femur operations. Several guidelines have recommended using a traction table as the standard of care for hip arthroscopy. A study on safety and efficacy of using fracture tables for prosthetic hip dislocations described that using a fracture table in the hip and femur operative setting is a safe and effective way to handle the closed reduction of prosthetic hip dislocation (7).

2.1 Indications for the Fracture Table

Fracture tables are valuable tools in hip resurfacing and less invasive hip arthroplasty. A study done by Benoit et al. (8) reported that 100 patients who underwent hip resurfacing on a traction table had no adverse effects. Conversely, another study by Woolson et al. (9) also reported excellent results in a series of 231 patients who underwent minimally invasive

primary THA on a traction table. A survey of total hip arthroplasty for osteoarthritis in patients aged 80 years or older describing the Influence of comorbidities on outcome reported no traction table–related complications in 72 consecutive Total Hip Arthroscopy patients aged ≥80 years (10).

A fracture table may also be used for selected indications related to the surgical management of paediatric disorders about the hip. Loder et al. indicated that a fracture table greatly facilitated a reduction of an acute slipped capital femoral epiphysis (11).

The fracture table is also used in reduction of proximal and diaphyseal femur fractures as well as subsequent internal fixation. The foot is usually fitted into a tightly tied boot, which is then connected to the traction of the fracture table. This allows for accurate and stable control of traction, abduction or adduction and internal and external fixation of the lower limb (12).

Proximal and diaphyseal femur fractures are frequently internally fixed using fracture tables, as well as femoral neck fractures that are treated with total hip arthroplasty by means if a direct anterior approach. The fracture table adequately exposes the hip joint using traction, rotation and extension to implant hip arthroplasty components (13).

2.2 Types & design of fracture table

A fracture table is designed to allow for controlled positioning of each lower extremity independently, including complete freedom of rotation and movement into hyperextension (14). Orthopaedic fracture tables are used as an aid in numerous surgical procedures. Patient positioning, including supine, prone, lateral decubitus, can vary significantly according to the table model used, the surgical procedure, and surgeon preference.

They provide an elevated surface that supports the patient's body during surgical procedures, stabilizing the patient's position and providing optimal exposure to the surgical field. They are designed to allow procedure-specific patient positioning. Orthopaedic tables include

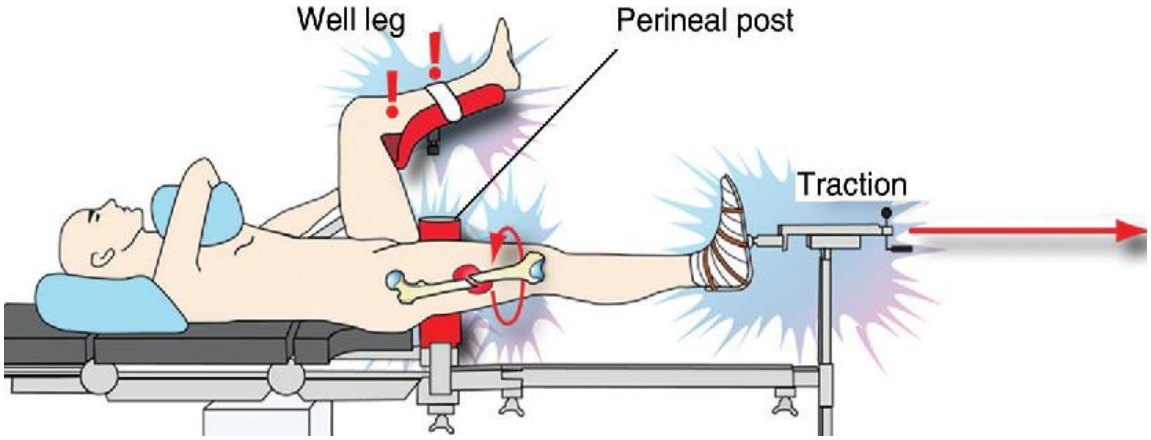
specific apparatus for supporting and providing traction for the patient's limbs during orthopaedic procedures. Applications for these tables include both upper-extremity techniques.

Fracture tables typically consist of a rectangular top made of metal, plastic, or a metal/plastic/carbon fibre composite supported by a fixed base (pedestal) or a movable, swivel-caster base. Fixed-base operating tables are available with tops that can be interchanged to accommodate specific surgical procedures; the tops can also be transferred to trolleys to transport patients to and from the operating room. Orthopaedic tables also have padding for upper-body support, a perineal post, an apparatus for lower body support, and many orthopaedic accessories. Some orthopaedic upper-body supports are interchangeable to accommodate specific orthopaedic procedures; other models are available with table tops that convert the orthopaedic table to a full-length surgical table.

Some fracture tables, like the Jackson table, do not have a perineal post. The fractured extremity is positioned superiorly, and patient positioning is maintained with a bean bag, pegs on a peg board, or other appropriate positioning aids. Care is taken to ensure that the operative extremity can be fully ranged to allow for unimpeded fracture reduction manoeuvres. All bony prominences are well padded, a safety strap is applied, and the operative leg is prepped and draped in the usual sterile fashion from the iliac crest to the distal knee. An assistant can be utilized to pull manual traction by standing at the foot of the bed, grasping the ankle with both hands, and using his or her body weight to apply longitudinal traction utilizing a “water ski manoeuvre” (15)

Principles of operation of fracture tables and their individual segments are raised and lowered by mechanical gears or hydraulic piston systems using manual controls or electrical controls.

Figure 1: Example of patient positioning on a Fracture table with perineal post



Flierl et al, 2010 (2)

Figure 2:A Fracture Table

2.3 Complications of the fracture table

Fracture tables are used in numerous procedures about the hip and femur, including fracture fixation, hip arthroscopy, and less invasive arthroplasty. However, the use of a fracture table is not without risks, and significant complications have been described, including injury to the

perineal integument and soft tissues, neurologic impairment, and iatrogenic compartment syndrome of the well leg (2). Although these complications are rare, they can have a devastating effect on the patient. These injuries are the most commonly reported complications of fracture table.

2.3.1 Genitoperineal Complications

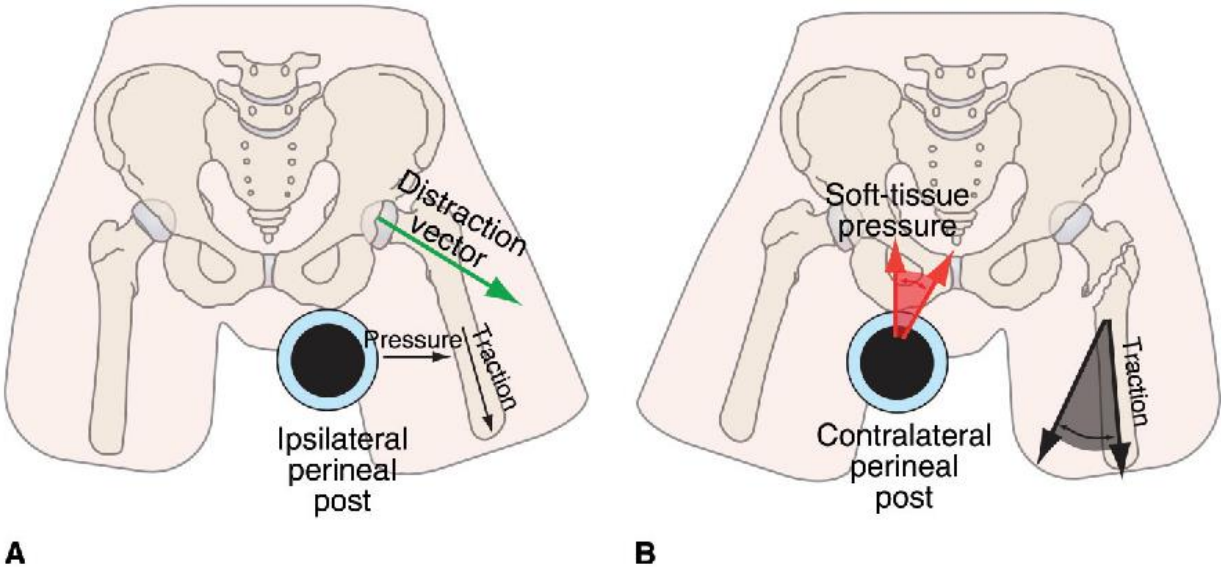
Reduction and fixation of lower extremity fractures commonly involve the use of the orthopaedic fracture table, with the incorporation of the perineal post for positioning and counter-traction. Prolonged application of perineal pressure thereby is possible, with vulnerability to genitoperineal injury.

During arthroscopy of the hip, mechanical traction with the use of fracture table is necessary to separate the femoral head from the acetabulum and thereby provide space for introducing the arthroscope and instruments. This could lead to genitoperineal injuries associated with the traction itself or with the perineal post used to provide counter traction. These injuries are the most commonly reported complications of hip arthroscopy (16).

Several studies have indicated genitoperineal injury as a complication associated with using the fracture table. A study on genitoperineal Injuries associated with the use of an orthopaedic table with a perineal post-traction found that all patients developed a partial-thickness necrotic area involving the perineum and scrotum after the surgery. The study concluded genitoperineal skin necrosis induced by perineal traction post-table was a morbid complication that demands surgical debridement and prolonged hospitalization for treatment (3). Coelho et al. in a report described a case in which prolonged traction against a perineal post during surgical fixation of a femoral fracture resulted in significant vulval hematoma and

dysesthesia (3). Hammit et al., in a study described Perineal soft tissue trauma and urogenital injuries are associated with some pelvic and acetabular fractures (17). The perineal region is most vulnerable to compromise after such injuries when using a traction table. This illustrates severe perineal integument injuries represent the classic complication associated with the use of a traction table.

Figure 3: Ipsilateral and Contralateral Positioning of Perineal post



Flierl et al, 2010

2.3.2 Neuropraxic Complications

Neurapraxia is a disorder of the peripheral nervous system in which there is a temporary loss of motor and sensory function due to blockage of nerve conduction, usually lasting an average of six to eight weeks before full recovery. Several causes contribute to common neuropraxic complications, including external compression (Plaster cast, brace or immobilization), direct trauma, traction injury, and entrapment in the fibular tunnel (18).

Positioning on a fracture table predisposes specific nerves to potential iatrogenic injury. Pudendal nerve palsy incidence has been reported to range from 1.9% to 27.6% due to excessive and/or prolonged traction against the perineal post. (19) Erectile dysfunction (E.D.) is a common complication associated with the incidence of pudendal nerve palsy.

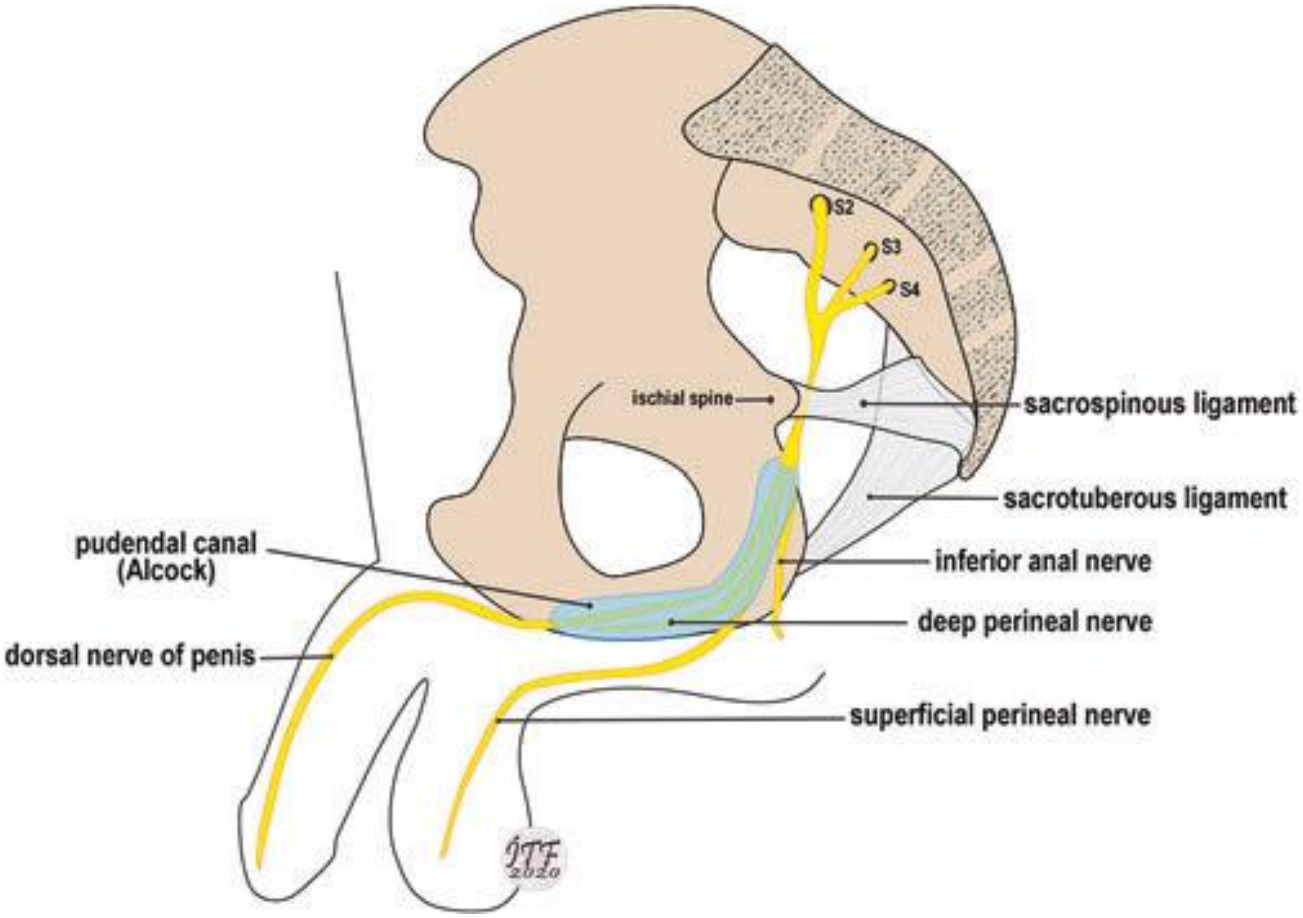
A study by Rajbabu et al. described four cases of sexual dysfunction attributed to perineal neurovascular traction injury acquired during surgery on a fracture table (20). The most commonly reported complication of hip arthroscopy is distraction-type injuries (22), with incidence rates reaching up to 7% in small series (14). Indeed, the most commonly used method in hip arthroscopy is distraction. It has been suggested that if traction does not initially create sufficient distraction, distension can be used to achieve it (23). They have been usually associated with prolonged procedures or excessive traction force and almost invariably present as transient nerve palsies in the form of neurapraxia

Fracture table neurapraxia is considered a benign complication and usually resolves fully and quickly within hours from surgery (21). The sciatic and femoral nerves are most vulnerable to undue traction, but no cases of permanent sequelae have been reported. Sciatic and common peroneal nerve injuries appear to be related to the hemilithotomy position on the fracture table.

A more recent study described the dangers of hemilithotomy positioning on traction tables. The report indicated a case of unexpected common perineal nerve palsy developed on the contralateral side, manifesting with drop foot after a femoral nailing. A possible iatrogenic neuropathy secondary to position-related compression is speculated as the cause. Position adjustment at intervals or complete avoidance of prolonged knee hyperflexion is recommended to prevent contralateral common peroneal nerve morbidity was recommended (22).

Paediatric patients who require rodding of the femoral shaft may be especially prone to neurologic traction injury. A study done in a review of 54 children treated with I.M. nailing for traumatic femoral fractures reported traction-induced neurologic injuries related to the common peroneal nerve (9.3%) and the sural and pudendal nerves (1.9% each). Great care should be taken when using a traction table in the treatment of paediatric patients (24).

Figure 4: The Anatomic Course of the Pudendal nerve and possible compression areas in men



Adopted from Ayık, Ö., Kozanoğlu, E., Önol, Y., & Durmaz, H. (2021). Post-traumatic double crush pudendal nerve entrapment syndrome after fracture of the pelvis: A case report. *Acta Orthopaedica et Traumatologica Turcica*, *55*(3), 277-280.

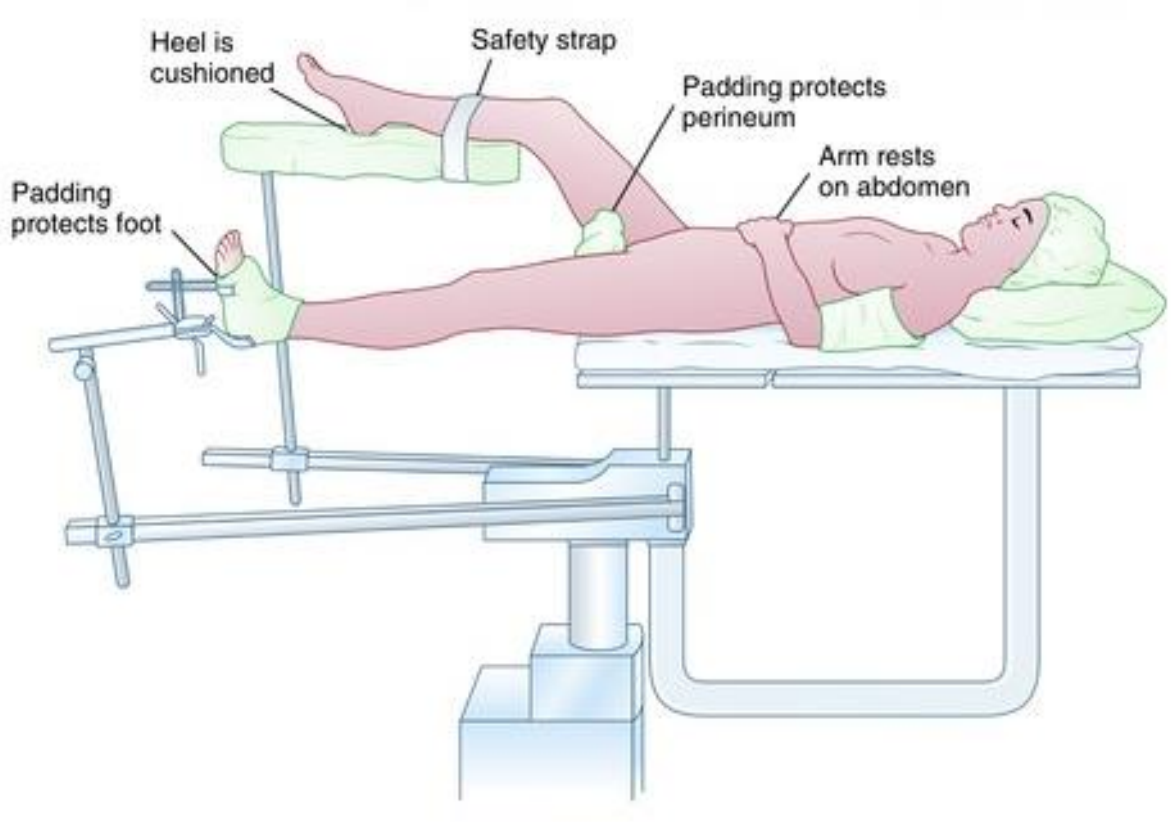
2.4 Prevention of the complications

To prevent pressure induced tissue necrosis, Flierl et al suggest periodic release in procedures that require prolonged traction (2). However, to prevent development of pundedal nerve palsy, the magnitude of intraoperative traction should be as minimal as possible. Additionally, complications such as sciatic nerve palsy in the well leg can be attributed to the hemilithotomy position, which sometimes causes overstretching of the sciatic nerve. Therefore, to avoid these complications, the hemilithotomy position should only be used as a last option.

This is in line with Vig et al (25), who state that placing the patient in hemilithotomy while using a fracture table increases the risk for perineal injury, compartment syndrome and nerve injury. In obese patients, the hemilithotomy position increases their risk of complications. This is because full knee flexion increases pressure in the soft tissues due to interposed fatty tissue posterior to the knee. This leads to an increased risk for compartment syndrome. Therefore, hip and knee flexion should be done at a minimal degree (25).

Adequate positioning of the perineal post can also reduce complications. The size of the perineal post is directly related to the development of pudendal nerve palsy. Flierl et al (2) reports that smaller posts cause deeper pelvis penetration which leads compression of the pudendal nerve. To prevent this, perineal post padding should be more than 10 cm, which causes lower pressure. To avoid well leg compartment syndrome and neurological injuries, the perineal post should be placed between the contralateral leg and the genitalia. The surgeon should also reduce surgical time and traction time as much as possible. If surgical time goes beyond two hours, traction should be released to avoid tissue damage.

Figure 5: Hemilithotomy Positioning with protective padding



2.5 Gaps in the literature

Recent attention to hip and femur operative procedures has focused on minimally invasive techniques and short-term outcomes. Despite much debate over the effects and complications of the two-incision and the mini-lateral and mini-posterior approaches, complications arising from the fracture table use are not well documented (19).

Studies have indicated the potential advantages of using a fracture table (26). Operating surgeons should be aware of the possible complications of trochanteric fractures, perforations, and wound-healing problems associated with this technique. However, we lack information on the incidence rate in patients after hip and femur operative procedures in our local setup and the complications that occur from nerve injury and, subsequently, the prognosis. Further studies can

also be carried out to determine a low-cost model that is easy to move around and reduce complications as an alternative to the fracture table in a low economic setup such as a large femoral/fracture distractor.

2.6 Justification

Empirical evidence reveals that fracture tables are widely used in lower limb orthopaedic procedures about the pelvis, hip and femur. However, their use carries potential complications that increase patient morbidity. This study should provide orthopaedic surgeons with information on the occurrence of genitoperineal and neuropraxic complications related to the use of fracture tables. It should aid in policymaking in areas such as patient positioning on the fracture table, amount of traction, and length of surgical procedure. For instance, they can impact sexual function, particularly in relation to erectile dysfunction (ED) (Schmid et al., 2021). Studies have indicated that the prolonged use of fracture tables during lower limb orthopaedic procedures can lead to an increased risk of developing ED. This complication not only affects a patient's quality of life but also poses psychological and emotional challenges.

Since the fracture table is a vital part of orthopaedic procedures in our set up, it’s important to investigate the occurrence of these complications and the associated risk factors and the main objective of this study is to investigate the occurrence of genitoperineal and neuropraxic complications after pelvis, hip and femur surgical procedures.

3.0 METHODOLOGY

3.1. Study design

This study utilized an analytical cross-sectional study design. This entails defining the study group based on the outcome (i.e., presence of genitoperineal and neuropraxic complications), not exposure to the risk factor. According to Setia, cross-sectional studies are faster, less expensive, and are useful in studying the prevalence of outcomes and exposures (1). Cross-sectional studies do not follow the participants over an extended time. They only aim to measure the connection between a condition or outcome, exposure, and disease within a specific population. This was assessed through a thorough three-day post-op assessment of the study subjects. Patients were assessed on admission to rule out pre-existing neuropraxic or genitoperineal conditions, at day one post-op after successful surgery and on day three post-op to assess for any genitoperineal and/or neuropraxic complications.

3.2 Study area

The study was conducted at the Kenyatta National Hospital (KNH). KNH is located in Nairobi County, Kibra constituency, is about 3.5 Kilometres from Nairobi CBD. And has a bed capacity of about 1800.

3.3 Study duration

The patients were followed up for three days post-operation. The reason for the three days post-operation follow-up is to monitor for any immediate complications that may arise from the use of fracture tables. This timeframe is sufficient to identify any early complications that may require urgent intervention.

3.4 Study population

All patients admitted for surgical procedures around the pelvis, hip and femur were included. Patients with autoimmune diseases and pre-existing genitoperineal and neuropraxic disorders were excluded.

3.4.1 Eligibility criteria

Consecutive patients of either sex scheduled for pelvis, hip and femoral surgical procedures using fracture tables were recruited

3.4.2 Inclusion criteria

All patients of either sex admitted for surgery that used a fracture table.

3.4.3 Exclusion criteria

Presence of Pre-existing genitoperineal and neuropraxic disorders.

Patients with autoimmune diseases

3.4.4 Sample size calculation

Due to the small population of orthopaedic patients within the inclusion criteria, the Slovin's formula was used to calculate the sample size (10).
$n = N/(1+Ne^2)$

Where n is the sample size, N is the population size and e is the margin of error (MOE). This study used an MOE of 5%

The patients admitted at KNH in the orthopaedics ward at the time of data collection were sixteen

Therefore, with a population of 16 patients,

$n = 16/(1+16*0.05^2)$

n= 15.38

n = 15 patients

3.4.5 Sampling procedure

This study used a convenience sampling method. There is no specific pattern used to obtain the subjects other than the fact that they are available and accessible. Convenience sampling is most applicable in clinical research and is quick, convenient, and inexpensive. Mathieson adds that consecutive sampling adds rigor to the structure of the study as it includes all accessible patients (27). Each consecutive and eligible patient was approached and recruited for participation in the study. Therefore, patients were approached on admission in the orthopaedics wards at KNH and recruited until the sample size was achieved.

Every patient who consented had a data capture form attached to their file. They were then assessed peri-op, on day one post-operation, and day three for any signs of genitoperineal and neuropraxic complications.

3.4.6 Informed consent and confidentiality

Informed and voluntary consent was obtained on admission to the orthopaedics ward. For patients who could not consent, relatives were allowed to consent for them. To maintain the confidentiality of the subjects, their names were omitted, and a serial number was used to identify them instead. The serial numbers were generated to indicate patient's sex, age and surgical procedure. For example, a 50-year-old male patient undergoing THA had a serial number as MTHA50. Patients were allowed to withdraw from the study at any point if they chose to do so.

3.4.7 Variables

This study's independent variable was the use of the fracture table. The perineal post duration, age of patient, and surgery duration acted as intermediate variables. The duration of

application of the perineal post and how this might influence occurrence of complications was considered. The dependent variable was the occurrence of genitoperineal and neuropraxic complications.

3.4.7.1 Indicators

- Injury to the perineal integument and soft tissues was assessed through examination of the perineum.
- To assess pudendal nerve palsy, symptomatology-based approach was applied using Nantes criteria. A positive result had the patient describe burning pain (often unilateral), tingling, or numbness in any of the buttocks, genitals, or perineum

3.4.8 Data collection procedures

After admission into the orthopaedics ward, patients whose injuries required the fracture table were approached. Data collected by the researcher included patient demographics, type of surgery, and previous medical history. Those that consented had a data capture form attached to their file to be filled in theatre. This form collected information about the type, length of orthopaedic procedure, length of perineal post application, and the patient's condition before and after the procedure. Patients were reviewed on day 1 and day 3 post procedure to check for any genitoperineal and neuropraxic complications.

3.5 Ethical considerations

The proposal was presented to the Thematic Unit of Orthopaedics, UoN, for review and approval. Permission was also sought from UoN/KNH Ethics and Research Committee for ethical review and approval. Confidentiality was guaranteed to each patient, and they were allowed to withdraw at any point of the study.

3.6 Data management, analysis, and presentation plan

The primary data set for this study was collected from patients who underwent operative procedures utilizing a fracture table at KNH. This data set included patient demographics, type of surgery, biographic information about the subjects, type and length of orthopaedic procedure and length of perineal post-application.

The variables analysed included the occurrence of genitoperineal and neuropraxic complications after operative procedures utilizing a fracture table. Other variables considered included patient demographics, type of surgery, previous medical history, and the length of perineal post application.

The data collected for this study was analyzed using SPSS version 27. Descriptive statistics, such as mean, median, and standard deviation, were used to summarize the data. The incidence of genitoperineal and neuropraxic complications after operative procedures utilizing a fracture table were calculated as a percentage of the total number of procedures performed. Logistic regression analysis was used to identify any risk factors associated with these complications. The data was then presented using tables and graphs.

3.7 Study results dissemination plan

To ensure the outputs from this study inform practice and maximizes benefits to the patients, a dissemination plan was created using evidence for translating knowledge into practice. This included written feedback to study participants, and sending detailed written reports to KNH and to the Kenya Society of Orthotrauma Technologists (KESOTT). A summary of the study results was sent to the Ministry of Health to further inform practice. The study was also published at the UON library, available for reference to future researchers. These proactive dissemination strategies offer breadth to reach multiple audiences and the depth to conduct more in-depth work with key audiences such as KESOTT.

3.8 Study Limitations

- The study was dependent on the number of patients admitted to the orthopaedics wards at KNH which limited the sample size
- Patients were monitored on only the first- and third-day post-surgery, which does not cater for long-term genitoperineal and neuropraxic complications.

3.9 Study Delimitations

- Limited Sample Size: The study's sample size was determined by the small population of orthopedic patients meeting the inclusion criteria at Kenyatta National Hospital (KNH). This limited sample size may affect the generalizability of the study findings to a larger population.
- Short-term Follow-up: The study only monitored patients on the first and third day post-surgery to assess for genitoperineal and neuropraxic complications. This short-term follow-up duration may not capture long-term complications that could potentially arise

beyond the three-day period. Hence, the study's findings may not reflect the complete spectrum of genitoperineal and neuropraxic complications associated with the use of fracture tables.

4.0 DATA ANALYSIS, PRESENTATION AND INTERPRETATION

Introduction

This chapter presents the analysis and findings with regard to the objectives of the study. On completion of data entry, the data was exported to the statistical package (SPSS 27) for analysis. Descriptive statistics were applied to the data collected and continuous data was summarized using mean, mode and median. Percentages were used for categorical or nominal data. Data was presented in tables and figures. The t-test was used to compare the duration of traction versus development of complications to determine any significant association. A p value of <0.05 was considered significant in determining the association between the risk factors and complications. Inferential statistics were used to analyse risk of complications as compared to duration of patients on traction. All patients were in supine position with the perineal post placed ipsilaterally.

RESULTS

During the study period, fifteen patients that fit the inclusion criteria were recruited into the study. The study revealed a 93% occurrence rate of genitoperineal complications after use of a fracture table, with perineal post application. Of the 15 patients, 12 we male and three were female. The average age of the patients was 40, with the ages ranging from 28 to 64 years. The female patients were on average younger than the male patients with averages of 30.6 and 42.3 years respectively. All female patients were below 40 years, and the two patients above 55 years were male (Table 1).

Table 1: Types of Surgical procedures

Surgical Procedure	Frequency	Percentage
Dynamic hip screw	5	33.3%
Proximal Femur Nail	6	40%
Reconstruction Nail	4	26.7%

Table 2: Basic Demographic Characteristics of Patients
:

	Frequency (n=15)	Percentage(%)
SEX		
Male	12	80
Female	3	20
Age Categories		
25-34 years	6	40
35-44 years	3	20
45-54 years	4	26.7
55 years and above	2	13.3

Table 3: Duration of traction in Minutes

N	Valid	15
	Missing	0
Mean		227.67
Median		180.00
Mode		150
Minimum		65
Maximum		452

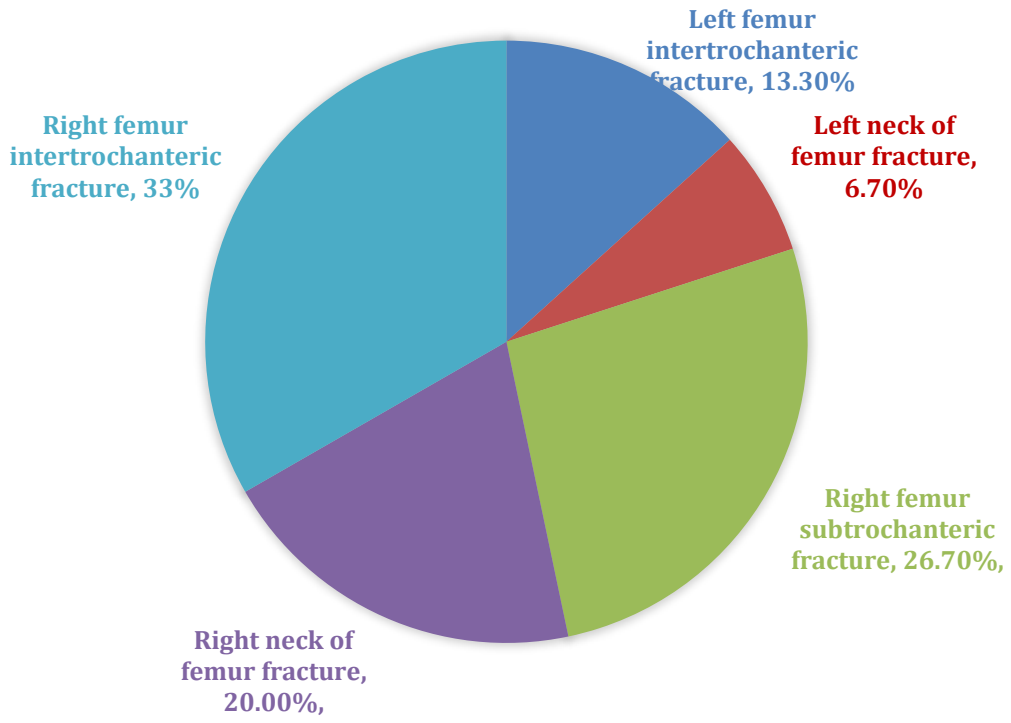
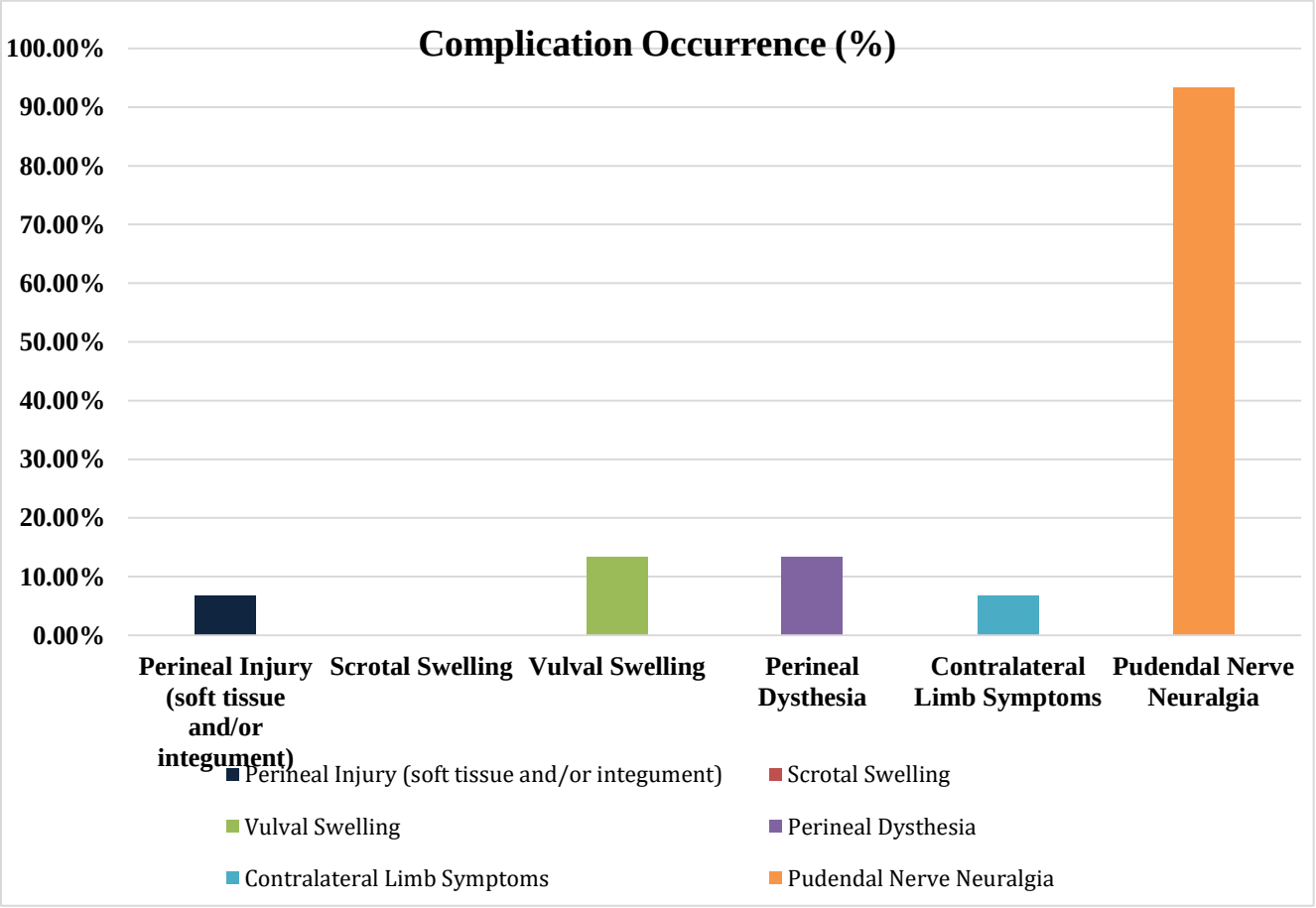


Figure 6: Patients' Diagnoses

The most common diagnosis was Right femur Intertrochanteric fracture (33.3%), and the lest common was left neck of femur fracture (6.7%) (Figure 6). There were three different procedures that the patients underwent. Dynamic hip screw (33.3%), proximal femur nail (40%) and Reconstruction nail (26.7%) (Table 2). Table 3 reveals the total duration of traction, while table 4 indicates the amount of time spent on perineal traction. The longest amount of traction in both cases is 452 minutes, with the least duration being 65 minutes. The mean duration on perineal traction was 229.67 minutes, with most patients spending about 180 minutes on perineal traction. According to Attenasio et al, just the use of perineal traction when treating orthopedic patients on a fracture table poses a risk for pudendal neuropraxia and perineal soft injury

Table 4: Incidence of Complications



93% of the patients experienced genitoperineal complications post-surgery. Only one patient had symptoms of perineal injury on day 3 post-surgery. None of the male patients experienced scrotal swelling, which makes it the only complication that did not occur within the population. Of the three female patients, two got vulval swelling, one on the first day post-surgery and the other on day three. 13% had perineal dysthesia and one patient had contralateral limb symptoms. The most common complication was pudendal nerve neuralgia, with 93.3% occurrence. Of the 14 patients that had pundedal nerve neuralgia, 86% experienced symptoms on both day 1 and 3, while the other 14% experienced symptoms on day 3 only.

Table 5: Perineal traction and occurrence of Complication

Patient	**Age**	**Sex**	**Duration on perineal Post (Minutes)**	**Complication(s) DAY 1**	**Complication (s) DAY 3**
1	64	Male	315	None	Perineal Injury Perineal Dysthesia Pudendal Nerve Neuralgia
2	49	Male	330	Buttock Pain on sitting	None
3	45	Male	121	Pudendal Nerve Neuralgia	
4	50	Male	140	None	Pudendal Nerve Neuralgia
5	28	Female	150	None	Vulval Swelling Pudendal Nerve Neuralgia
6	35	Male	180	Perineal Dysesthesia	Perineal Dysesthesia Pudendal Nerve Neuralgia
7	37	Female	140	Pudendal Nerve Neuralgia	Unilateral Pain Buttock Pain when sitting
8	40	Male	340	Pudendal Nerve Neuralgia	Pudendal Nerve Neuralgia

9	32	Male	155		Pudendal Nerve Neuralgia
10	29	Male	65	Pudendal Nerve Neuralgia	Pudendal Nerve Neuralgia
11	31	Male	452	Pudendal Nerve Neuralgia	Pudendal Nerve Neuralgia
12	57	Male	340	Pudendal Nerve Neuralgia	Pudendal Nerve Neuralgia
13	27	Female	113	Vulval Swelling Contralateral Limb Symptoms Pudendal Nerve Neuralgia	Vulval Swelling Contralateral Limb Symptoms Pudendal Nerve Neuralgia
14	26	Male	294	Pudendal Nerve Neuralgia	Pudendal Nerve Neuralgia
15	50	Male	310	Numbness	Numbness

The mean duration on perineal post was 229.67 minutes. Pain in the territory of pudendal nerve, buttock pain on sitting, predominantly unilateral pain and buttock pain on sitting were the initial clinical presentations in most patients on day one post-operation. However, some patients did not have any symptoms indicative of complication on day1, while most had complications by day 3. The most occurring complication was pudendal nerve neuralgia, and the rarest was scrotal swelling, with zero incidence. Nantes criteria (Table 7) was used to asses for pudendal nerve neuralgia.

Of the fifteen test subjects, only one, Case 2, a 49-year-old man, did not have any complications within the study period, he only complained of buttock pain on sitting on day one. The first patient, a 64-year-old male who spent 315 minutes on perineal traction, had symptoms indicative of complications on day 3. These included perineal injury, which was accompanied by symptoms such as bruising and tenderness on perineal area, as well as perineal pain. The

patient also had Pudendal Nerve Neuralgia, which presented on day 3 post-surgery. This was similar to case 4, where the patient, a 50-year-old male, experienced signs of Pudendal nerve neuralgia on day 3 post-surgery. However, on examination, case 4 had exquisite tenderness on palpation of the ischial spine. Only one patient experienced perineal dysesthesia, Case 6, which happened on both the first- and third-day post-operation. This was characterized by

- Numbness of the scrotum
- Sudden urination urge
- Difficulty starting a urinal flow
- Burning pain in the genital area

Of the three female patients, two experienced vulval swelling, Case 13 on both days and Case 5 only on day 3. Case 13 also had contralateral limb symptoms as well as pudendal nerve neuralgia. All the other patients had pudendal nerve neuralgia, except Case 15, a 50-year-old male who only had numbness on both days.

REGRESSION ANALYSIS

SPSS version 27 was used to investigate the relationship between the occurrence of pudendal nerve neuralgia and the total duration of traction.

Correlation Analysis

Correlations

			Age	Pudendal_Nerve_Neuralgia	Perineal_Dysesthesia
Spearman's rho	Age	Correlation Coefficient	1.000	-.159	-.079
		Sig. (2-tailed)	.	.571	.780
		N	15	15	15
	Pudendal_Nerve_Neuralgia	Correlation Coefficient	-.159	1.000	-.080
		Sig. (2-tailed)	.571	.	.777
		N	15	15	15
	Perineal_Dysesthesia	Correlation Coefficient	-.079	-.080	1.000
		Sig. (2-tailed)	.780	.777	.
		N	15	15	15

The research study examined the connections, between age, pudendal nerve neuralgia and perineal dysesthesia. The focus was on how age relates to these factors. After analyzing the data the following findings emerged;

There was a correlation coefficient of 0.159 between "Age" and "Pudendal_Nerve_Neuralgia " suggesting an inverse relationship. However this correlation did not meet the criteria for significance (p = 0.571).

Similarly, there was a correlation coefficient of 0.079 between "Age" and "Perineal_Dysesthesia," indicating a negative association between these variables. Again, this correlation did not reach significance (p = 0.380).

The correlation coefficient between "Pudendal_Nerve_Neuralgia" and "Perineal_Dysesthesia" was found to be 0.080 showing a link between them. However as before this relationship did not meet the requirements for significance (p = 0.777).

In conclusion the correlation analysis did not reveal any associations among age pudendal nerve neuralgia and perineal dysesthesia. Based on the presented data it can be inferred that there is no linear relationship between these variables due, to correlation coefficients.

Regression model

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.042	1	.042	.610	.449[b]
	Residual	.892	13	.069		
	Total	.933	14			

a. Dependent Variable: Pundendal nerve neuralgia (Nantes criteria)

b. Predictors: (Constant), Duration of traction

Table 6: Pudendal Nerve Neuralgia vs Duration of Traction

The goal of this analysis was to check whether there was any significant effect of total traction on pundendal nerve neralgia. However, the result revealed a significant value of 0.449. which is greater than the set p value of 0.05. Therefore, our model was not significant and traction duration has no effect on pudendal nerve neuralgia. The model used was F(1,13) = .61, P=0.449

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.212[a]	.045	-.029	.262

a. Predictors: (Constant), Duration of traction

b. Predictors: (Constant), Duration of traction

Equation

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	.958	.155		6.173	.000
	Duration of traction	.000	.001	.212	.781	.449

a. Dependent Variable: Pundendal nerve neuralgia (Nantes criteria)

Y=mx+b

Y=X+.958

To check the effect of perineal traction on occurrence of pudendal nerve neuralgia, a regression analysis of both variables was conducted as below

Table 7: Perineal Traction and Pudendal Nerve Neuralgia

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.039	1	.039	.573	.041[b]

	Residual	.894	13	.049		
	Total	.933	14			

a. Dependent Variable: Pudendal nerve neuralgia (Nantes criteria)

b. Predictors: (Constant), Duration of perineal post application

The ANOVA table revealed a significant value of 0.041, which is less than the p-value of 0.05. Therefore, our model revealed a significant correlation between increased time of perineal post application, and occurrence of pudendal nerve neuralgia with the first three days post operation

A similar analysis to determine the relationship between surgical time and pudendal nerve neuralgia was also conducted, revealing a significant value of 0.045. This indicates a directly positive relationship between time taken for surgery and occurrence of pudendal nerve neuralgia.

Discussion

Fracture tables are widely used in lower limb surgeries at the Kenyatta National Hospital and even in lower-level hospitals in Kenya. This is despite literature suggesting that their use potentially increases the risk of complications and therefore increases patient morbidity. The most occurring complication was pudendal nerve neuralgia, with 93.3% incidence. According to Kaur and Singh (15), pudendal neuropathy is a classic complication of orthopedic surgery involving traction on the fracture table. The authors note that it is often caused by pudendal nerve entrapment (PNE) and affects both males and females in equal nature. It is characterized by

severe pain in the area supplied by the pudendal nerve. One of the main symptoms, experienced by more than 50% of the patients, is perineal pain that worsens when sitting and improves when standing or lying down. Additionaly, Attenasio et al (1) found that perineal post use in ytrating femur fractures while on. A fracture table increase the risk for pudendal neurapraxia and perineal soft tissue injury. The study recommends post padding and supplemental padding if needed.

Moreover, the physio-pathologic mechanism is nerve compression of varying intensity. According to Kaur and Singh (15), the nerve originates from the ventral rami of the sacral plexus, specifically the S2, S3, and S4 roots. It contains various types of fibers responsible for sensory, motor, and autonomic functions. However, when the pudendal nerve is damaged, it primarily affects sensory functions rather than motor functions. Initially, the nerve travels between two muscles known as the piriformis and coccygeus muscles. It then exits the pelvic cavity by passing through the greater sciatic foramen, positioned in front of the sacrotuberous ligament. It should be suspected in case of the onset of stereotypic perineal symptoms following orthopaedic surgery involving perineal traction on the fracture table.

Notably, this is in line with a study by Brumback et al (6), who found that the use of a perineal post when treating femur fractures on a fracture table poses risks for pudendal neurapraxia and perineal soft tissue injury. Attenasio et al (1) argued that post padding is mandatory to provide cushioning around the perineal post, which is the support structure used to stabilize the patient's perineum during fracture treatment. The padding helps distribute the pressure and reduce the risk of injury to the underlying soft tissues. Also, supplemental padding may also be required depending on the specific patient's needs. This extra padding can provide further protection and ensure that the pressure on the perineum is adequately cushioned.

Furthermore, appropriate perineal skin examination prior to use is also important. Occurring at a higher rate than previously thought, appropriate post-operative examination for any genitoperineal soft tissue complications and sensory disturbances should not be ignored (1). Before using the perineal post, it is crucial to conduct a thorough examination of the perineal skin. The examination aims to assess the skin's condition, identify any existing injuries, or evaluate the presence of any risk factors that may make the patient more susceptible to perineal injury. By examining the perineal skin beforehand, healthcare providers can tailor the treatment approach and take necessary precautions to minimize the risk of complications.

Two of the three female study subjects had vulval swelling. Existing research indicates that the vulva receives blood from both the internal and external pudendal arteries. It is known that the vulva has multiple connections between its blood vessels, resembling a sponge. Prolonged pressure on the distal blood supply caused by traction from a perineal post can lead to various complications, including swelling of the vulva, neuralgia (nerve pain), and potentially even tissue death due to reduced blood flow (ischemic necrosis) (24). Some recommended measures to prevent such injuries include placing a properly sized perineal post against the inner thigh with sufficient padding around the vulva to evenly distribute compression forces (24). The authors further argued that it is crucial to minimize the duration of traction by reducing operative time and using minimal traction force along with muscle relaxants. In some cases, intermittent release of traction is mentioned, particularly during lengthy procedures, and agar may be used between the vulva and perineal post. Additionally, the use of a fracture distractor can be beneficial in reducing fractures, eliminating the need for a perineal post. It is important to avoid adducting the limb and instead keep it in 20 degrees of abduction, while the other limb is flexed, abducted, and externally rotated.

Perineal dysesthesia also occurred in two patients, with symptoms of numbness in the perineal area and burning pain. Several investigations have validated sustained pressure as the specific mode of nerve injury (8, 20). Lesser pressures applied during a longer interval have also been proven capable of producing significant injury (9). Smart et al. (30) pointed out the use of manual traction during femoral nailing to avoid a pudendal post altogether. In reviewing our patients' cases, we realized that prolonged traction was the most probable cause of perineal dysesthesia.

Conclusion and Recommendations

The risk factor predisposing to the development of these complications is the use of a fracture table, the long duration of perineal post-application and long surgery duration. Therefore, in order to decrease the occurrence of complications, the shortest time possible should be taken to perform a surgical procedure, which translates to a shorter duration on perineal traction. In addition, the following recommendations are suggested for positioning the perineal post during traction to prevent pressure injury

- The post should be the widest available, with at least a 10cm diameter with adequate cotton padding: The choice of an appropriately sized and padded perineal post is crucial in preventing pressure injuries. A wider post distributes the pressure over a larger surface area, reducing the risk of localized tissue damage. A minimum diameter of 10cm ensures that the post adequately supports the perineum without exerting excessive pressure on a smaller area.
- Complete anaesthetic relaxation should be attained: Achieving complete anaesthetic relaxation is important during perineal traction to minimize resistance and tension in the muscles and tissues. When the patient is adequately relaxed, it reduces the risk of

excessive force being applied to the perineal area during traction, which could lead to complications. The anesthesiologist should work closely with the surgical team to ensure optimal relaxation and muscle tone control throughout the procedure.

- Using forceful traction judiciously: Forceful traction should be applied judiciously, avoiding excessive or prolonged traction. Excessive force can increase the risk of tissue damage, including pressure injuries, and may also lead to nerve damage or vascular compromise. The amount of force applied should be carefully monitored and adjusted based on the patient's individual tolerance and response. Surgeons should exercise caution and be mindful of the potential consequences of excessive traction.
- Intermittently checking the status of the perineum: Regular assessment of the perineal area is essential to detect early signs of tissue damage or pressure ulcers. Healthcare professionals should periodically inspect the perineum during the surgical procedure to identify any areas of redness, discoloration, or skin breakdown. Prompt identification allows for early intervention and appropriate measures to prevent further complications.
- Padding the post thoroughly: Proper padding of the perineal post helps to distribute pressure evenly and minimize direct contact between the post and the perineal area. The padding material should be sufficient to provide a soft and protective layer between the post and the patient's skin. Care should be taken to ensure that the padding remains intact throughout the procedure, as any displacement or inadequate padding can increase the risk of pressure injuries.
- Intermittently releasing traction: To alleviate prolonged pressure on the perineum, it is advisable to release traction intermittently during the surgical procedure. This allows for periodic relief of pressure and reperfusion of the affected tissues. The risk of sustained

tissue ischemia and subsequent complications can be reduced by releasing traction at regular intervals.

- Avoid adduction of the affected limb: Adduction, or inward movement, of the affected limb, can exert additional pressure on the perineal area during traction. Surgeons should be cautious and avoid adducting the limb excessively to prevent undue stress on the perineum. Proper positioning and alignment of the limb should be maintained throughout the procedure to minimize the risk of complications.
- Periodic release of traction during operations that require high traction forces for a prolonged time: In certain surgical procedures that necessitate high traction forces over an extended period, it is vital to release traction to mitigate the risk of complications periodically. Prolonged and continuous traction can lead to tissue damage and pressure injuries. By allowing intermittent periods of rest and relief from traction, the perineum can recover from sustained pressure, reducing the likelihood of adverse outcomes.

By implementing these recommendations, healthcare providers can minimize complications associated with perineal traction during surgical procedures. It is crucial to prioritize patient safety, optimize the surgical technique, and continuously monitor the perineal area to ensure early detection and management of potential complications.

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APPENDICES

APPENDIX I: INFORMED CONSENT FORM

Title of Study: Prevalence And Risk Factors Associated With Neuropraxic And Genitoperineal Complications Following Fracture Table Use At Kenyatta National Hospital

Principal Investigator: Dr Aaron Masini, University of Nairobi

Introduction

The purpose of this consent form is to give you the information you should need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I should request you to sign your name on this form. You should understand the general principles which apply to all participants in medical research:

i) Your decision to participate is entirely voluntary

ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal

iii) Refusal to participate in the research should not affect the services you are entitled to in this health facility or other facilities. We should give you a copy of this form for your records.

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

Purpose of the Study

The researchers was interviewing individuals who have undergone orthopaedic procedures that require the use of a fracture table. The purpose of the interview is to find out the prevalence and risk factors associated with genitoperineal and neuropraxic injuries after use of a fracture table. Participants in this research study was asked questions about their recovery process, as well as permission to review medical records and assessments.

There was approximately 40 participants in this study. We are asking for your consent to consider participating in this study.

What Should Happen If You Decide to Be in This Research Study?

If you agree to participate in this study, the following things should happen: You was interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview should last approximately 15 minutes. The interview should cover topics such as previous medical history, age, procedure to be performed, sex, and consent to review medical records as well as consent to perform physical assessment post-surgical procedure. After the interview has finished, you was notified whether you are an eligible candidate for the study. We should ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it was used only by people working for this study and should never be shared with others. The reasons why we may need to contact you include: _ asking for

clarification regarding some information and following up on your recovery to asses for any complications.

Potential Risks, Harms and Discomforts

Participation in this research may involve personal information but your records was handled as confidentially as possible. No names was used in any report from this study. We should use a code number to identify you in a password-protected computer database and should keep all of our paper records in a locked file cabinet. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview. We should do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these interviews. You may also feel discomfort during physical assessment after surgery, and this may be stressful. We should ensure that we only perform assessments in the most comfortable manner for you. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff should treat you for minor conditions or refer you when necessary

Potential Benefits

You may benefit by receiving free post operative check-up and testing in case of suspected complications. Complications are also bound to be caught and treated early, saving your time, money and improving your recovery. The information you provide us was a huge contribution in understanding the occurrence of genitoperineal and neuropraxic complications related to the use of fracture tables. It should aid in policymaking in areas such as patient positioning on the

fracture table, amount of traction, and length of surgical procedure. This is expected to significantly reduce the risk of the development of complications.

Costs

This study should not cost you financially. It should however cost you some of your time, for the period of your hospitalization. However, in case you spend any money as a result of this study, kindly contact the principal investigator, and it was refunded.

Your participation in this study is highly appreciated and should help form future protocol in use of fracture tables. Feel Free to contact the provided numbers for further questions or any clarification

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. 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 was made to keep information regarding my personal identity confidential.

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: _____

For more information contact Dr Aaron Masini Kabora at 0720540340 from 10AM to 3PM

Primary Supervisor Dr T. Mogire: 0722854139

KNH-UoN-ERC: 0799495830

SWAHILI CONSENT FORM

MAELEZO CHA KIBALI CHA RUHUSA

Nambari ya Hospitali: **……**

Nambari ya Utafiti: **…….**

Mada : Kiwango cha kuenea na mambo yaliyo na uwezo wa kusababisha matatizo ya sehemu za siri za uzazi baada ya upasuaji unaotumia meza hususa inayotumika kurahisisha upasuaji wa mifupa

Utafiti huu unafanywa na Dr Aaaron Masini Kabora, mwanafunzi wa upasuaji katika Chuo Kikuu cha Nairobi, upande wa upasuaji wa mifupa. Kiini cha utafiti huu nikuchunguza Kiwango cha kuenea na mambo yaliyo na uwezo wa kusababisha matatizo ya sehemu za siri za uzazi baada ya upasuaji unaotumia meza hususa inayotumika kurahisisha upasuaji wa mifupa

Sababu ya utafiti

Utafiti huu unafanywa kuchunguza Kiwango cha kuenea na mambo yaliyo na uwezo wa kusababisha matatizo ya sehemu za siri za uzazi baada ya upasuaji unaotumia meza hususa inayotumika kurahisisha upasuaji wa mifupa

Utafiti huu utafanyika katika hospitali kuu ya Kenyatta. Taarifa zitakazo kusanywa zita tumika

kufahamisha wapasuaji na kuwapa ujuzi zaidi.

Hatari na manufaa

Kuhusika kwa huu utafiti kutahusisha taarifa zako za kibinafsi lakini ni uahidi wangu kuwa. Historia na majibu yako yote yatawekwa vizuri wala hayata sikikwa au kutangazwa kwa mtu mwengine yeyote.

Utafiti huu utatoa taarifa muhimu kwa madaktari kuhusu matokeo ya Uvutaji ya miguu kwa matibabu ya kuvunjika mifupa. Huenda ikawa itatengeneza msingi wa masomo ya baadaye ambayo wagonjwa watakao faidika na upasuaji wa mifupa. Hakuna madhara au hatari yanayo tarajia kwa kushiriki katika utafiti huu.Hata hivyo, kama matatizo yata tokea, matibabu zinazofaa zitapewa.

Hakuna vipimo vya ziada isipokuwa yale yakawaida kwa matibabu yatakayofanika. Hakuna gharama za ziada zitakazostahitika na wanaoshiriki katika utafiti huu.

Uhusika kwa Hiari

Kuhusika kwa utafiti huu ni kwa hiari yako mwenyewe na hauwezi kushurutishwa. Utahudumiwa ata kama ukikataa kuhusika kwa huu utafiti.Una uhuru kutamatisha kuhusika wakati wowote bila madhara yoyote ile

Usiri

Habari zozote zitawekwa kwa siri na jina lako halitachapishwa popote .

Mimi ninayeweka sahihi/kidole changu rasmi hapa chini nimeelezwa na kuelewa yaliyoandikwa hapa na nimekubali kwa hiari yangu kujiunga kwa utafiti huu.

Sahihi/ Kidole ……

Tarehe ……

Nambari ya Simu ……

Mimi Dr Aaron Masini Kabora nahakikisha kuwa nemeeleza mgonjwa sababu ya hi utafiti name kubali kujiunga kwenye hi utafiti.

Sahihi …….. **Tarehe** ……

Kwa Mswali yeyote tafadhali umpigie simu

1. Dkt Aaron Masini: 0798587400
2. Msimamizi wa msingi: Dkt T. Mogire: 0722854139
3. KNH-UoN-ERC: 0799495830

APPENDIX II

Nante's Criteria

Essential Criteria • Pain in the territory of the pudendal nerve: From anus to the penis or clitoris • Pain is predominantly experienced by sitting • Pain does not wake the patient at night • Pain with no objective sensory impairment
Complementary Diagnostic Criteria • Burning, shooting, stabbing pain, numbness • Allodynia or hyperpathia • Rectal or vaginal foreign body sensation (sympathalgia) • Worsening of pain during the day • Predominantly unilateral pain • Pain triggered by defecation • Presence of exquisite tenderness on palpation of the ischial spine
Associated signs not excluding the diagnosis • Buttock pain on sitting • Referred sciatic pain • Pain referred to the medial aspect of the thigh • Suprapubic pain

APPENDIX III: DATA COLLECTION FORM

SERIAL NO: …….....

1. **AGE** …….
2. **SEX**

    € Male

    € Female

3. **DIAGNOSIS …….**
4. **SURGICAL PROCEDURE …….**

INTRA-OP

5. **PATIENT POSITION**

    € Hemi lithotomy

    € Supine

    € Lateral

    € Prone

6. **POSITION OF PERINEAL POST (IF APPLICABLE)**

€ Ipsilateral

€ Contralateral

€ Other …….

7. **DURATION OF TRACTION (In minutes) ……...**
8. **DURATION OF PERINEAL POST APPLICATION (in minutes)**

    …….

9. **DURATION OF SURGICAL OPERATION (in minutes)……**

10. **COMPLICATION OCCURRENCE**

	DURATION AFTER SURGERY	DAY 1 POST OP	DAY 3 POST OP
COMPLICATION			
Perineal injury (soft tissue and/or integument)			
Scrotal Swelling			
Vulval Swelling			
Perineal Dysthesia			
Contralateral limb symptoms			
Pundendal Nerve neuralgia? (Nantes Criteria)			

Essential Criteria ● Pain in the territory of the pudendal nerve: From anus to the penis or clitoris ● Pain is predominantly experienced by sitting ● Pain does not wake the patient at night ● Pain with no objective sensory impairment		
Complementary Diagnostic Criteria ● Burning, shooting, stabbing pain, numbness ● Allodynia or hyperpathia ● Rectal or vaginal foreign body sensation (sympathalgia) ● Worsening of pain during the day ● Predominantly unilateral pain ● Pain triggered by defecation ● Presence of exquisite tenderness on palpation of the ischial spine		
Associated signs not excluding the diagnosis ● Buttock pain on sitting ● Referred sciatic pain ● Pain referred to the medial aspect of the thigh ● Suprapubic pain		

APPENDIX III: BUDGET

Components	Unit of Measure	Duration/ Number	Unit Cost (Kshs)	Total Cost (Kshs)
Personnel				
Research coordinator	1	1 weeks	15000	10000
Statistician (Quantitative)	1	1 weeks	15000	10000
Qualitative Data Analysts	1	1 weeks	15000	10000
Transcribing Fee	1		10000	10000
Printing				
Consent Form (English and Kiswahili)	1		10	10
Assent Form (English and Kiswahili)	1		10	10
Questionnaires (English and Kiswahili)	1		10	10
Final Report	1		600	600
Photocopying				
Consent Form	15		20	300
Assent Form	15		20	300
Questionnaires	15		40	600
Final Report	5		600	3000
Final Report Binding	5		1500	7500
Other costs				

Stationaries			2000	2000
Training of RA			8000	8000
ERC Fees			3000	3000
NACOSTI			1000	1000
Airtime			2000	2000
Miscellaneous				6800
Total				75, 130

APPENDIX IV: ERC APPROVAL

Appendix V: STUDY TIME FRAME

This time frame is for the year 2023

Activity	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**
Protocol Devt, ERB Approval								
Site Preparations								
Data collection								
Data Analysis Report Writing								
Dissemination of findings and publication								
Finalization of the report								