FACULTY OF HEALTH SCIENCES, UNIVERSITY OF NAIROBI

DEPARTMENT OF ANAESTHESIA

EFFECTIVENESS OF ISOBARIC BUPIVACAINE SADDLE BLOCKS IN PELVIC SURGERY

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A DISSERTATION SUBMITTED IN PART FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN DEPARTMENT OF ANAESTHESIA, FACULTY OF HEALT SCIENCIES, UNIVERSITY OF NAIROBI.

DECLARATION

I hereby certify that this is my original work. All resources and materials used or quoted have been indicated and acknowledged by means of reference. This work has not been presented for the award of a degree in any other Institution.

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SUPERVISORS' APPROVAL

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DEDICATION

I wish to dedicate this dissertation to my parents, Zennah and Ngeny, and my sisters, Jelimo, Jeptoo and Jepkoech**.**

LIST OF ABBREVIATIONS

ASA	American Society of Anaesthesiologists
CSF	Cerebral spinal fluid
ECG	Electrocardiogram
HB	Hyperbaric bupivacaine
IB	Isobaric bupivacaine
KNH	Kenyatta national hospital
MAP	Mean arterial pressure.
Mg	Milligram
PACU	Post anaesthesia care unit
PDPH	Post dural puncture headache
S2 – S5	2^{nd} to 5^{th} sacral spaces
SSA	Selective spinal anaesthesia
SSBA	Spinal saddle block anaesthesia
TURP	Trans urethral resection of the prostate

DEFINITION OF KEY TERMS

Selective spinal anaesthesia: The use of minimal doses of intrathecal agents that result in the blockade of nerve roots supplying a specific region of the body and ensuring that only the required sensory or motor modalities are anaesthetized(1).

Saddle block anaesthesia: Saddle anaesthesia entails a selective spinal anaesthetic technique that directs a small dose of local anaesthetic towards areas of S4-S5 and coccygeal nerve roots, that provide innervation to the perineum, tip of the coccyx, medial and bottom of the buttocks and posteromedial part of the thighs covering an area that for a rider would correspond to that in contact with a saddle (2).

Isobaric bupivacaine: 'Plain bupivacaine' is a formulation with a specific gravity or density equal to cerebrospinal fluid(3).

Hyperbaric bupivacaine: a formulation with density heavier than cerebrospinal fluid. The difference in densities of the two available preparations is believed to affect the diffusion pattern that determines the effectiveness, spread and side-effect profile of bupivacaine. This is made dense by the addition of glucose (80 mg/mL) to isobaric or plain bupivacaine(3).

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ABSTRACT

Background: Saddle anaesthesia entails a selective spinal anaesthetic technique that directs a small dose of local anaesthetic towards sacral and coccygeal nerve roots, ideal for short gynaecological and urological surgery. It uses a long-acting local anaesthetic. The use of 1ml 0.5% bupivacaine (5mg) has been shown to be effective for spinal anaesthesia in other settings but local data on the effectiveness of this dose for surgical procedures is lacking.

Study objectives: The study aimed to determine the effectiveness of 1ml 0.5% isobaric bupivacaine (5mg) used in saddle blocks for short urological and gynaecological procedures using the following parameters: level and duration of sensory and motor blockade, and the adverse effect profile. Haemodynamic stability, time to ambulate and time to void were also assessed.

Patients and methods: 44 patients ASA I and II patients were recruited into the study. In theatre, they were positioned seated and 1ml of 0.5% isobaric bupivacaine was administered intrathecally. They all sat for 10 minutes and then put in lithotomy position. Level of sensory and motor blockade were noted at induction and at the end of surgery. Duration of block was also recorded. Adverse effects, time to first ambulation and voiding were noted during the perioperative period.

Results: Female patients were 97.7%, males were 2.3%. The mean BMI was 24.6 (15.9-33). Mean surgery time was 54.5 minutes (15-90). ASA I were 52%, and ASA II 48%. At induction, level of sensory blockade was S2-S5, and level of motor blockade was between 1 and 4. Duration of sensory blockade was 127.2 minutes (88-143), and motor blockade 137.2 minutes (98-200). There were no cases of post-dural puncture headache, but 2.3% had nausea and vomiting, and 11.4% had hypotension.

Conclusion: 5mg of isobaric bupivacaine is adequate for perineal surgery giving a dense sensory block lasting over 2 hours, motor blockade up to level 4 on induction lasting 137 minutes, and minimal incidence of nausea-vomiting, hypotension, and post-dural puncture headache.

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CHAPTER 1: INTRODUCTION AND PROBLEM STATEMENT

Urological and gynaecological procedures are commonly performed on day care basis under saddle block anaesthesia. This is a selective technique that provides anaesthesia over the saddle area, i.e. inner thighs, pudendal area, rectum, and genitalia.(4). Bupivacaine is an amide local anaesthetic and is commonly used for saddle anaesthesia.

Two formulations exist in the market: hyperbaric and isobaric bupivacaine. The difference in baricity of the two preparations alters how they diffuse, and this changes the utility, level of block, and adverse effect profile of the drug(5). Studies comparing the use of two formulations have shown that isobaric bupivacaine produces a slower onset but longer activity when compared to hyperbaric bupivacaine(6).

To reduce the length of hospital stay and procedure related complications, the anaesthetic agent applied for regional techniques should be used at the lowest effective dose which allows early immobilization without residual pain. A study done among 25 total knee arthroplasty patients in Canada, found a median dose of 3.5 to 5mg isobaric bupivacaine was optimal(7). A study by Liaquat and colleagues compared 3 different doses of hyperbaric bupivacaine (8) for saddle block and he found the lowest dose of 4.5mg reduced the time for home readiness after surgery.

Additional benefits of low dose isobaric bupivacaine are: significantly less cephalad spread, less motor block, reduced need for vasopressors and shorter PACU stay(9).

1.1 PROBLEM STATEMENT

Studies been done in different surgical populations comparing different dosages of isobaric bupivacaine with varying results on the effective dose.

A study by Omundi in 2018 in KNH that compared recovery profiles of patients undergoing day case surgery under general anaesthesia and spinal anaesthesia, recommended follow up studies to with smaller doses of bupivacaine to find out whether it would allow adequate anaesthesia while facilitating faster ambulation postoperatively.(10)

The effective dose of isobaric bupivacaine for saddle anaesthesia in urological and gynaecological procedures done in KNH Main theatres is however not known.

CHAPTER 2: LITERATURE REVIEW

2.1 SADDLE BLOCK ANAESTHESIA

Saddle anaesthesia entails a specific spinal anaesthetic technique that directs a small dose of local anaesthetic towards areas of S2-S5 and coccygeal nerve roots, that innervate inner thighs, the genitalia, and the rectal area (11)(2). It was first described by Adriani and Roman-Vega in 1949 (12)

The saddle block is like spinal anaesthesia. The duration of block is short, thus ideal for surgeries less than 60 minutes, and often done for ambulatory cases. It wears off quickly(2) hence the saddle block is used for various perineal surgeries, and intraoperative analgesia(13).

2.2 INDICATIONS OF SADDLE BLOCK ANAESTHESIA

Saddle block is indicated for the following procedures via perineal approach (14)(2):

a) Urological procedures: Prostate biopsies, urethral surgery.

b) Anorectal procedures: haemorrhoidectomy, pilonidal sinus repair, fistulas, sphincterotomies.

c) Gynaecological procedures: Insertion and removal of intrauterine devices, examination under anaesthesia, marsupialisation, fistula repair, McDonald stitch insertion, and dilatation and curettage.(10)

2.3 PERFORMING THE SADDLE BLOCK PROCEDURE

2.3.1 Preparation

Prior to administration of the saddle block, the following must be done(4):

1) Wide bore intravenous access and pre-anaesthetic hydration with ringers' lactate.

2) Prepare emergency drugs (atropine, vasopressors)

3) Baseline vital signs should be taken. Continuous monitoring every 5 minutes intra operatively. Administer vasopressors if the MAP is below 65mmHg or systolic blood pressure falls by 20% from the baseline.(15)

4) Keep the patient in sitting position with the feet on a footrest.

5) Establish and maintain sterility with antibacterial cleaning solutions and surgical drapes.

2.3.2 Technique

The block is done at the lumbar spine. A horizontal line is traced joining both iliac crests (inter-cristal or Tuffier's line). The line bisects L3-L4 vertebral space which is the usual insertion point for this block(4).

5 millilitres of lignocaine 2% in a syringe with a hypodermic needle is directed towards the vertebral space identified. The lignocaine is infiltrated as the needle is drawn out until a skin wheal is raised.

A gauge 25 spinal needle with an introducer needle is inserted into the same vertebral space as before. It should be aimed in a slightly cephalad direction

The needle will course through the skin, subcutaneous tissue, supraspinous ligament, and the interspinous ligament. A sudden give or 'pop' will be felt as it passes through the ligamentum flavum. A second pop is perceived as the needle goes through the subarachnoid membrane. Clear CSF should be noted flowing back in the needle as the stylet is removed (4).

Bupivacaine 0.5% 1ml diluted to 2ml solution is fixed to the spinal needle and pushed slowly at 0.5ml/second. Once the bupivacaine has been administered, the patient remains seated for 10 minutes to allow the anaesthetic to settle on the sacral segments.(2). The patient is then made to lie supine.

Sensory blockade is tested with a blunt surgical forceps around the perineum. Temperature is assessed with a cold alcohol swab(4). The 6-score modified Bromage scale is used to assess the level of motor blockade.

2.4 COMPLICATIONS OF SADDLE ANAESTHESIA

Minor complications noted include nausea, vomiting, pruritus, hypotension, and urinary retention. Park et al (16) noted prolonged sitting after saddle block led to urinary retention, and did the study positioning the patients to lie down after 1 minute.

Moderate complications like failed spinal and post dural puncture headache are common. Rafique et al (17) in 2014 noted larger spinal needles were associated with PDPH and backache. Major complications include high/total spinal, cauda equina syndrome, haematoma, infection, needle trauma, and cardiovascular collapse (18).

2.5 LOCAL ANESTHETICS USED FOR SADDLE BLOCKS

Short, intermediate and long-acting local anaesthetics have been used for saddle blocks e.g. lignocaine, prilocaine, bupivacaine, levobupivacaine, ropivacaine. (2).

Lidocaine would be an ideal agent for saddle block. It is short-acting and gives good sensory block and motor blockade. It is however associated with transient neurological symptoms as noted by Rattenberry et al (19) in 2019. Zaric et al (20) in a 2009 Cochrane review showed higher incidence of transient neurological symptoms compared to other local anaesthetics. Lithotomy position was also associated with increased risk.

The choice for saddle blocks in this study is bupivacaine based on the evidence and availability of local anaesthetics in our local set up(2).

2.6 OPTIMAL DOSES OF ISOBARIC BUPIVACAINE FOR SADDLE ANAESTHESIA

Studies comparing the optimal doses of isobaric bupivacaine for saddle anaesthesia have revealed variable results. Okwudili et al in 2014 (21) showed 1.5mg of bupivacaine was adequate in 120 patients undergoing transrectal biopsies under saddle block. Wassef et al (22) in 2007 compared 2 groups of patients, one receiving 1.5mg and the other 6mg, for perianal surgery under saddle block. The 1.5mg group had had adequate anaesthesia, limited block, faster recovery, earlier time to ambulate and discharge compared to the 6 mg group.

Al-Metwalli et al in 2015 (23) scheduled 24 adult patients for saddle block with bupivacaine for short perianal procedures. They found an effective dose of 1.9mg in 50% of patients in the study.

Gudaityte et al in 2008 (24) did a double blinded randomised control trial with 152 patients in 3 groups for adult anorectal surgery under spinal saddle block. 1st group received 7.5mg, 2nd group 5mg, 3rd group 4mg under similar conditions. The 4mg group produced adequate sensory and motor block as the 5mg group but with shorter duration and faster recovery.

2.7 MONITORING EFFICACY OF SADDLE BLOCK ANESTHESIA

Testing of the block is by 2 methods; motor (efferent) or sensory (afferent) (25).

2.7.1 Afferent function (sensory loss)

Hocking et al (25) in 2004 noted while assessing sensory loss after spinal anaesthesia, that touch was the last sensation to be blocked, preceded by temperature and pinprick.

2.7.1.1 Assessment of sensory loss

Pin prick method is used to test sensation. Fassoulaki et al(26) in 1999 described using other methods like a metal roller, skin vasomotor reflex, and electrical current.

Temperature sensation is usually assessed by the application of 'cold' using a cold cloth or alcohol swab (25).

2.7.2 Efferent function (loss of motor power)

Motor blockade increases as the local anaesthetic diffuses cranially to block the lower segments of the spinal cord.

2.7.2.1 Assessment of motor power

The modified Bromage scale is used to assess motor power after saddle anaesthesia. It was developed by Breen et al (27) in 1993 who added 2 categories; detectable hip flexion weakness, and ability to perform knee bend while standing. They wished to assess readiness of patients to ambulate while undergoing labour epidural analgesia.

Table 1: MODIFIED BROMAGE SCALE

SCORE	CRITERIA
1	Complete block (unable to move feet or knees)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

2.8 FACTORS AFFECTING EFFECTIVENESS OF SADDLE BLOCKS

Hocking et al (25) classified these factors into 3 categories; specifics of the injected solution, technique used, and patient factors.

Table 2: FACTORS AFFECTING SPREAD OF ANAESTHETIC AGENTS

Characteristics of the injected solution
- Baricity
- Volume/dose/concentration
- Temperature of injectate
- Viscosity
- Additives

Clinical technique
- Patient position
- Level of injection
- Needle type/alignment
- Intrathecal catheters
- Fluid currents
- Epidural injection

Patient characteristics
- Age
- Height
- Weight
- Sex
- Intra-abdominal pressure
- Spinal anatomy
- Lumbosacral cerebrospinal fluid volume
- Pregnancy

2.9 STUDY JUSTIFICATION

Saddle anaesthesia has been reported to have many benefits over other modes of anaesthesia like general anaesthesia. These include avoidance of airway manipulation, fewer cardiopulmonary depression incidents, less post-operative nausea and vomiting, superior post-operative pain control in addition to reduced narcotic drug requirements.

Additionally, it is the anaesthetic modality of choice for short urological and gynaecological procedures done on day care basis.

Although many studies have been done incorporating different low doses of isobaric bupivacaine for saddle blocks, the effective dose is yet to be determined for our local population.

2.10 STUDY SIGNIFICANCE

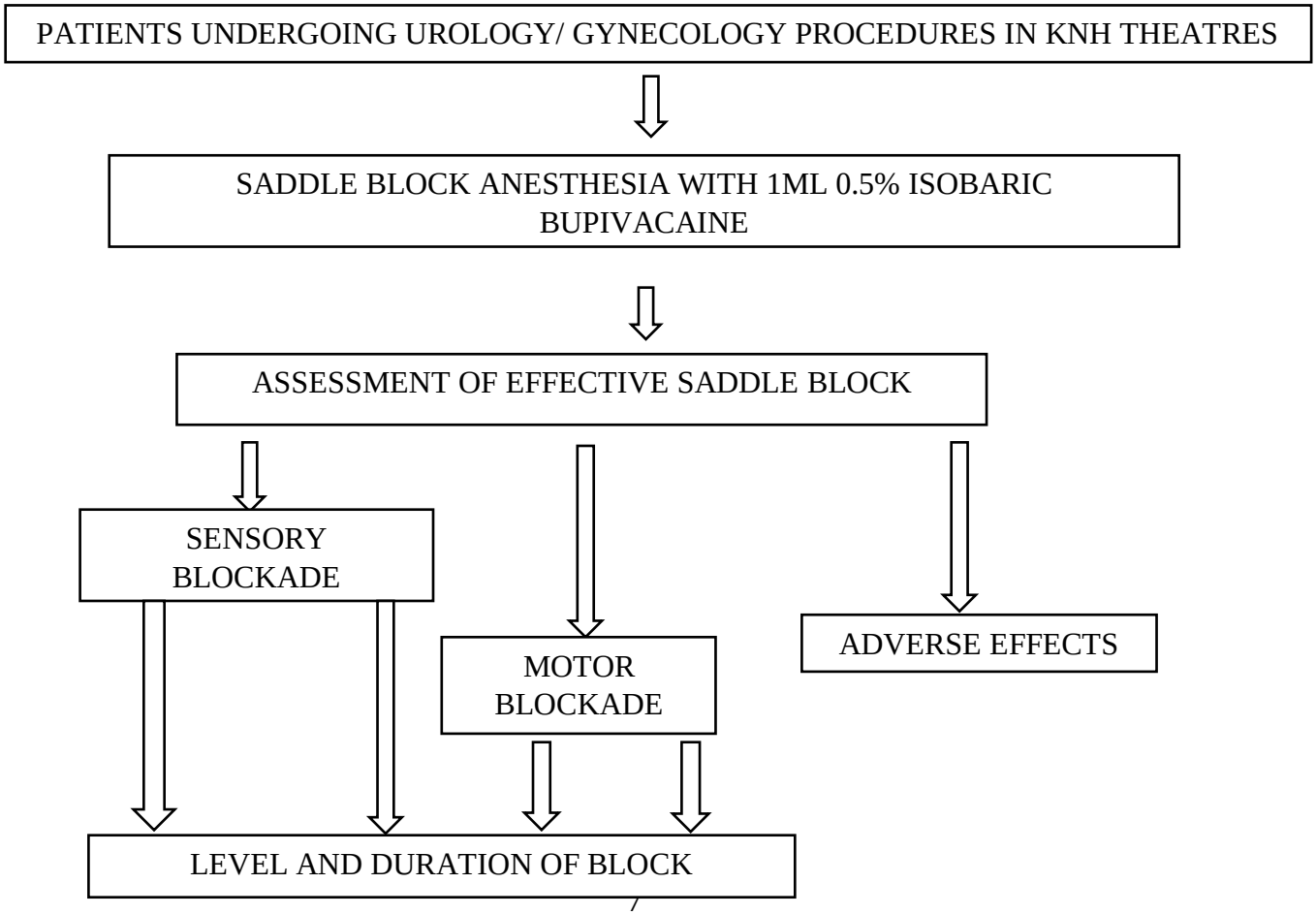
The study will help to determine whether the dose of 1ml of 0.5% bupivacaine (5mg), identified in other studies is effective in our local setting for urological and gynaecological procedures.

2.11 SCOPE OF THE STUDY

The study was conducted in the KNH Main Urological and Gynaecological theatres where most of the urological and gynaecological procedures are carried out. It will entail administration of bupivacaine 1ml 0.5% solution diluted to 2ml to achieve saddle block anaesthesia to determine efficacy of this dose and formulation for our local population.

2.12 CONCEPTUAL FRAMEWORK

Figure 1: Flowchart of the Saddle block procedure



2.13 RESEARCH QUESTION

How effective is 1ml of 0.5% isobaric bupivacaine (5mg) in saddle block anaesthesia for patients undergoing urological and gynaecological surgery at The Kenyatta National Hospital?

2.14 BROAD OBJECTIVE

To determine the effectiveness of 1 ml of 0.5% isobaric bupivacaine saddle anaesthesia for urological and gynaecological procedures at The Kenyatta National Hospital.

2.15 SPECIFIC OBJECTIVES

2.15.1 PRIMARY OBJECTIVES

1. To assess the level and duration of sensory blockade achieved with 1ml 0.5% isobaric bupivacaine (5mg) saddle anaesthesia for urological and gynaecological procedures at The Kenyatta National Hospital.

2. To assess the degree and duration of motor blockade achieved with 1ml 0.5% isobaric bupivacaine (5mg) saddle anaesthesia for urological and gynaecological procedures at The Kenyatta National Hospital using the modified Bromage scale.

2.15.2 SECONDARY OBJECTIVES

To determine adverse effects following the administration of 1ml 0.5% isobaric bupivacaine (5mg) saddle anaesthesia for urological and gynaecological procedures at The Kenyatta National Hospital

CHAPTER 3: METHODOLOGY

3.1 STUDY DESIGN

A prospective longitudinal cohort study.

3.2 STUDY SITE

This study was conducted at The KNH Main Urological and Gynaecological theatres. There are 12 theatres in the Main Theatre, with 2 theatres dedicated to urology and gynaecology procedures. Both theatres operate between Monday and Friday from 8am – 5pm. Each theatre handles between 3 to 5 cases each day of operation.

3.3 STUDY POPULATION

Patients were booked for elective day gynaecology procedures from the gynaecology clinic 18, and the urology patients are prepped from the urology ward in 5B KNH.

3.4 ELIGIBILITY CRITERIA

3.4.1 INCLUSION CRITERIA

Adult patients aged between 18 and 80 years, ASA I and II, scheduled for short elective day urology and gynaecological procedures at the KNH Main Urological and Gynaecological theatres who gave written informed consent to take part in the study.

3.4.2 EXCLUSION CRITERIA

ASA III and IV, patients known to have declined consent, coagulopathies or those on anticoagulant therapy, documented allergies to local anaesthetics, local spinal infection, severe vertebral deformities or previous lumbar surgery, mental illness or the use of psychoactive medication, patients who are morbidly obese or BMI > 40, those converted to general anaesthetic, and procedures longer than 90 minutes.

3.5 SAMPLE SIZE CALCULATION

An estimated number of 50 elective urology and gynaecology cases were seen over the 2-month period as per the KNH health records statistics. A representative sample was drawn from this finite population and sample size was determined as follows using the Krejcie formula:

$n = \frac{NZ^2P(1-P)}{d^2(N-1)+Z^2P(1-P)}$ (*Referenced from "Small Sample Techniques". Vol 38 (Dec 1960) p. 99*)

Where,

n' = sample size with finite population correction,

N = size of the target population = 50

Z = Z statistic for 95% level of confidence = 1.96

P = Estimated proportion of patients with successful sensory blockade after receiving 1ml 0.5% isobaric bupivacaine (5mg) saddle anaesthesia = 50% (no available data)

d = margin of error = 5%

$$n = \frac{50 \times 1.96^2 \times 0.5 \times 0.5}{0.05^2 (50-1) + 1.96^2 \times 0.5 \times 0.5}$$

n = 44

A minimum of 44 elective cases were sampled to determine outcomes within 5% level of precision.

3.6 SAMPLING PROCEDURE

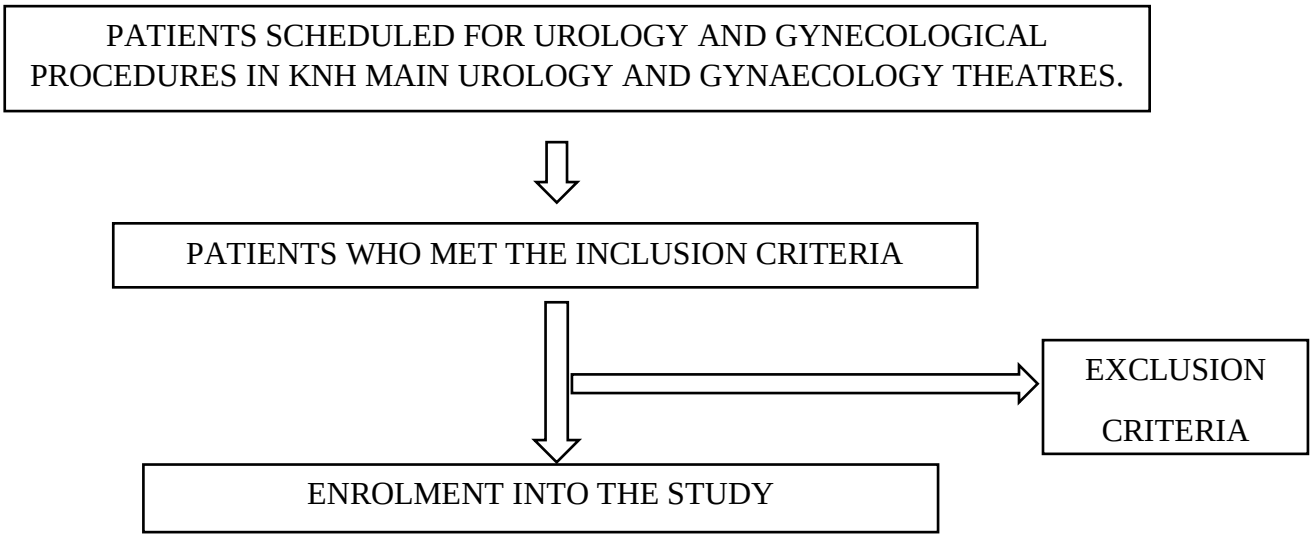
Consecutive sampling was done for every patient meeting the eligibility criteria until the sample size was achieved.

3.6.1 RECRUITMENT PROCEDURE

Urological and gynaecological patients scheduled for elective surgery were taken through the consenting process into the study. Once informed consent was taken, patients were assessed to see if they meet the inclusion criteria listed above, and those who did not were excluded.

All patients recruited were then added into the study one after the other until the study population sample size was fulfilled.

Figure 2: RECRUITMENT PROCEDURE



3.7 DATA COLLECTION PROCEDURE

3.7.1 PRE- OPERATIVE ASSESSMENT

This was done by the principal investigator. This included history taking and examination of the patient to rule out comorbidities, assess for suitability for saddle block anaesthesia, ASA classification, hemodynamic stability, drug allergies, coagulation profile, and obtaining written informed consent for the procedure.

3.7.2 SADDLE BLOCK PROCEDURE

Once the patient was in the operating room the following procedures were followed. This was indicated in a check list to filled intra- operatively.

1) Secured a wide bore intravenous access, preferably 18 Gauge cannula.

2) Connected the patient to the cardiac monitor. Took the initial vital signs (Baseline blood pressure, heart rate, oxygen saturation), and repeated at 5-minute intervals thereafter.

3) Pre-anaesthetic hydration with 10mls/kg of ringers' lactate over 15 – 30 minutes.

4) Explained the procedure again to the patient and ensured the patient is comfortable

5) Placement of the patient in sitting position and aseptic access and preparation of anaesthesia field.

6) Dural puncture using midline approach in sitting position at L3- L4 interspace using a gauge 25 Quincke spinal needle, with the tip heading cephalad.

7) Injected 1ml (0.5mg) 0.5% isobaric bupivacaine diluted to 2ml, slowly at a speed of 0.5ml/second (28).

8) Immediately post procedure, we let the patient sit for 10 minutes, then put in supine position.

9) If the patient was anxious after the block, 1mg of midazolam was administered. Rescue analgesia of ketamine 0.25mg/kg was given when there was patchy blockade. (8)

3.7.3 ASSESSMENT OF SENSORY BLOCKADE

Temperature sensation was assessed with an alcohol swab. Once the patient was in lithotomy position, a non-toothed forceps was used to assess pin prick sensation and level of blockade recorded. At the end of surgery, sensation was assessed again, and findings recorded. At PACU, it was checked again for 2 segment regressions from maximal block.

3.7.4 ASSESSMENT OF MOTOR BLOCKADE

Motor blockade was assessed using the modified Bromage scale. The score attained at induction and at the end of surgery was recorded. At PACU, the block was expected to wear off and ambulation was assessed at bedside.

3.7.4.1 MODIFIED BROMAGE SCALE

Table 3: MODIFIED BROMAGE SCALE FOR MOTOR BLOCKADE

SCORE	CRITERIA
1	Complete block (unable to move feet or knees)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

3.8 STUDY VARIABLES

Table 4: Study variables

Independent	**Dependent**
- Age - Sex - Weight - Height - Surgical procedure - ASA status - Pre-operative vital signs – BP, MAP, HR, O_2S, RR	- Level of sensory blockade - Duration of sensory blockade - Level of motor block - Duration of motor block

3.9 DATA COLLECTION AND RATIONALE

Data were collected by the primary investigator and the research assistant every morning from Monday to Friday in the operating theatres. The role of the principal investigator was pre-operative evaluation, filling the checklist intra- operatively and study pro-forma with bio data abstracted from the files, entering cleaned data into Excel sheets and subsequently into the SPSS software, recruiting and training the research assistant by providing information regarding the study protocol.

The patients recruited to the study were assigned different theatres and had different schedules which necessitated the use of a research assistant.

The research assistant in this study was a key participant in collection of data required. He was in charge in ensuring adequately and correctly filled consent forms and checking the right serial numbers have been assigned.

The assistant collected data on haemodynamic changes from induction, level and duration of sensory and motor block, assessment of time to ambulation, and any noted adverse events e.g. nausea and vomiting.

The research assistant selected was an individual with medical training; this ensured the person recruited was conversant with the nuances when getting consent and establishing rapport with potential clients to the study.

The research assistant spoke both English and Kiswahili and had utmost confidentiality observed when interacting with the patients recruited into the study.

The research assistant was trained on the consent process, the inclusion and exclusion criteria, the intraoperative checklist, and the data collection tool

3.10 DATA ANALYSIS

Data were entered and managed in Microsoft Excel 2016 data entry sheet. Data cleaning was done and then exported into the SPSS version 23.0 statistical software for analysis. Description of the population was done by summarizing the demographic and the pre-operative vital signs

into percentages and means for categorical and continuous data respectively. Level of sensory blockade at induction and end of surgery was scored and presented as percentage of patients. Similarly, percentage of patients with different levels of motor blockade was presented as assessed at induction, end of surgery and on leaving PACU. The repeated measures of motor blockade across the three points were tested for significant changes using Friedman's 2-way ANOVA test. Also, duration of sensory and motor blockade was summarized into mean number of minutes with standard deviations. Regression analysis was used to analyse level and duration of sensory and motor blockade. Adverse events were presented as percentage number of patients with the incidences. Statistical significance was interpreted at 5% level (p-value less or equal to 0.05 will be significant).

3.11 DATA STORAGE

The primary data in hard copy in the data collection tool was stored in a locked cabinet in KNH with restricted access and kept confidential. The key remained in the sole custody of the principal investigator.

Data collected was cleaned and keyed in into Excel spreadsheets. The information obtained was used to fulfil the objectives of this study only, and quality improvement in the administration of saddle blocks for urology and gynaecological procedures in the KNH operating theatres.

The secondary data in soft copy was password-protected and only the primary investigator was privy to it. Both primary and secondary data is to be stored for 5 years in the principal investigator's custody, and thereafter destroyed. Hard copies of the primary data were shredded and disposed of while soft copies of the derived secondary data are to be permanently erased from portable storage devices

3.12 QUALITY ASSURANCE & CONTROL OF ERRORS AND BIAS

The quality assurance was run concurrently with the data entry. The research assistant was appraised on the process of data abstraction before the start of the project work. Every week the principal investigator randomly inspected the data entry sheets for outliers or missing data.

Recruitment of patients at admission. Coding of data with numbers to ensure anonymity with no victimization. Use of validated data collection tools was done. The data was assessed for completeness by the principal investigator. The principal investigator oversaw the data collection, entry, and analysis.

3.13 ETHICAL CONSIDERATIONS

Enrolment of patients was voluntary after obtaining informed consent. Each study participant was assigned a number at enrolment for identification and to help in data analysis. Confidentiality was upheld, and anonymity ensured. The patients did not incur any additional costs by participating in the study. Secure storage of the written and digital data was ensured to protect that information from all unauthorized access, inappropriate use, modification of any kind, or loss.

The study was conducted after full approval by the University of Nairobi Department of Anaesthesiology, and the Kenyatta National Hospital – University of Nairobi Ethics and Research Committee.

3.14 STUDY LIMITATIONS

This study was used for short procedures less than 90 minutes done via perineal approach due to the low dose being used which will limit the scope of surgeries covered.

CHAPTER 4: RESULTS
4.1 PATIENT CHARACTERISTICS

44 patients were recruited into this prospective cohort study. We had 1 male patient and 43 female patients in total. Age ranged between 18 years to 75 years with a mean of 38.8 years (SD +/-16). There was a mean weight of 68.7 kilograms (SD +/- 11.1) amongst the participants, and a mean BMI of 24.6 (SD +/-3.9).

Table 1: Socio-demographic characteristics

Variable	**Frequency (%)**
Age	
Mean (SD)	38.8 (16.0)
Min –max	18.0-75.0
<24 years	20%
25-34 years	30%
35-44 years	16%
45-54 years	18%
>55 years	16%
Sex	
Male	1 (2.3)
Female	43 (97.7)
Weight	
Mean (SD)	68.7 (11.1)
Min –max	45.0-96.0
Height	
Mean (SD)	1.7 (0.05)
Min –max	1.6-1.8

BMI	
Mean (SD)	24.6 (3.9)
Min –max	15.9-33.0

4.2 CLINICAL CHARACTERISTICS

There were a variety of pelvic procedures done via saddle anaesthesia. Rectovaginal fistula was the most common diagnosis making up 22.7% of cases with rectovaginal repair the commonest surgery (22.7%)

ASA status was even with ASA I patients making up 52.3% of cases, and ASA II 47.7%.

13 ASA II patients had comorbidities. Hypertension was the most common in the cohort (69%). 77% of ASA II patients on medications were on antihypertensives.

Table 2: Clinical characteristics

Variable	**Frequency (%)**
Diagnosis	
Rectovaginal fistula	10 (22.7)
VVF-related procedures	7 (15.8)
Bartholin abscess	7 (15.8)
Cervical incompetence	6 (13.6)
Ca cervix-related procedures	5 (11.4)
Ca Vulva	2 (4.5)
3rd and 4th degree perineal tear	2 (4.6)
Post-menopausal bleeding	1 (2.3)
Haemorrhoids	1 (2.3)
Cervical mass	1 (2.3)
Ca endometrium	1 (2.3)
Failed EAS post RVF repair	1 (2.3)
Surgical procedure	
RVF repair	10 (22.7)
EUA + Biopsy	9 (20.5)
Marsupialisation	6 (13.6)
MacDonald Stitch Insertion	6 (13.6)
Perineoplasty + sphincteroplasty	4 (9.2)

VVF repair	4 (9.1)
Vulvectomy	2 (4.5)
Urethral dilatation	2 (4.5)
Haemorrhoidectomy	1 (2.3)
Excisional biopsy	1 (2.3)
ASA status	
I	23 (52.3)
II	21 (47.7)
Comorbidities	
Hypertension	9 (69)
Retroviral disease	3 (23)
Diabetes + Hypertension	1 (1)
Medication	
HAART	3 (23.0)
Antihypertensives	10 (77.0)

Figure 1: ASA status

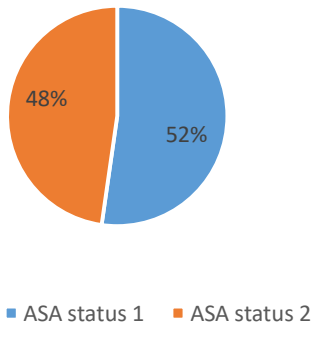
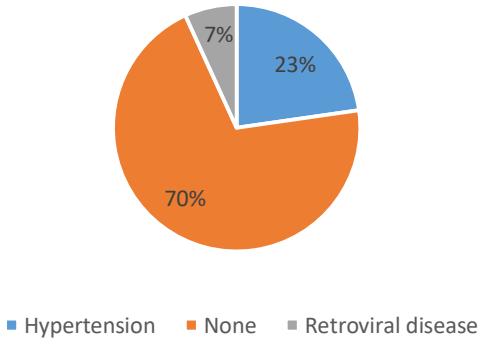


Figure 2: Comorbidities



4.3 PREOPERATIVE VITAL SIGNS

The patients in the cohort had a mean systolic blood pressure of 139.8 mmHg (+/-18.4), and a mean arterial pressure of 100.6 mmHg (+/-14.1).

Mean heart rate was 95.7 beats per minute (+/-20.9), mean oxygen saturation 97.6% (+/-2.2), and mean respiratory rate of 18.9 breaths per minute (+/-3.2).

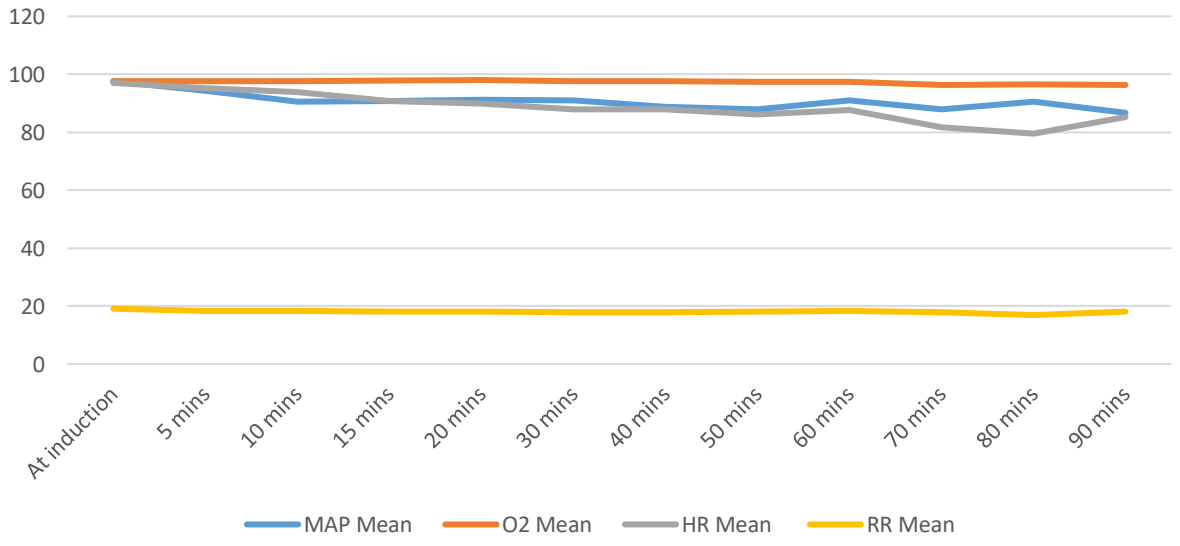
Table 3: Preoperative vital signs

Variable	Mean (SD)	Min-Max
Systolic blood pressure	139.8 (18.4)	105.0-184.0
Diastolic blood pressure	84.5 (11.7)	64.0-107.0
Mean arterial pressure	100.6 (14.1)	72.0-128.0
Heart rate	95.7 (20.9)	62.0-145.0
Oxygen saturation	97.6 (2.2)	89.0-100.0
Respiratory rate	18.9 (3.2)	11.0-26.0

4.4 INTRAOPERATIVE HAEMODYNAMICS

These vital signs were recorded from induction of saddle anaesthesia to the end of surgery. Means, standard deviations, and ranges of the mean arterial pressure, oxygen saturation, heart rate, and respiratory rate were calculated and shown below as a trend analysis graph. They were plotted to display the trend of the vital signs data from start to the end of surgery.

Figure 3: Vital signs trend from induction to end of surgery



The mean arterial pressure remained within a normal range from induction (Mean 97.6) to the end of surgery (mean 86.7). Oxygen saturation was also within normal ranges for the population**.** Heart rate also stayed within normal ranges from induction to end of surgery and trended downwards from an average of 97 beats per minute to 85.3 beats per minute at the end of surgery.

Respiratory rate amongst the population was largely within 1-2 breaths per minute of the normal ranges with minimum variation.

4.5 DURATION OF SURGERY

The average duration of surgery was 54.5 minutes (+/-19.6) with the shortest surgery being 15 minutes, and the longest lasting 90 minutes.

Table 4: duration of surgery

Variable	**Statistic**
Duration of surgery in minutes	
Mean (SD)	54.5 (19.6)
Min –max	15.0-90.0

4.6 LEVEL AND DURATION OF SENSORY BLOCKADE

All 44 patients recruited had blockade of S2 to S5 segments after induction of surgery. At the end of surgery, 34.1% still had S2-S5 blockade, 38.6% had 1-segement regression of S3-S5, and 27.3% had 2-segement regression of S4-S5.

The mean duration of sensory blockade was 127.2 minutes (+/-10.8) showing adequate pain cover for over 2 hours. Only 6 patients (13.6%) received 1 mg of midazolam to allay anxiety during the saddle block procedure. 2 patients (4.5%) received 0.25 mg/kg of ketamine after induction of the saddle block. Both patients reported a sensation of being touched and

discomfort. However the rest of the patients perceived no pain on surgical stimulus after the block.

Figure 4: Level of sensory blockade after surgery

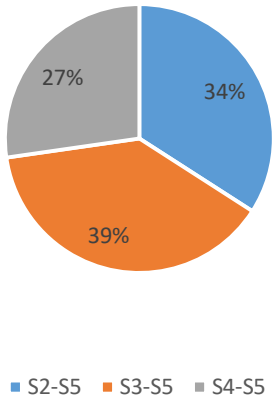


Table 5: Level of sensory blockade

Variable	**Frequency (%)**
Level of sensory block at induction	
S2-S5	44 (100)
Level of sensory block at end of surgery	
S2-S5	15 (34.1)
S3-S5	17 (38.6)
S4-S5	12 (27.3)
Duration of sensory block in minutes	
Mean (SD)	127.2 (10.8)
Min –max	88.0-143.0
Midazolam 1mg	
Yes	6 (13.6)
No	38 (86.4)
Ketamine 0.25 mg/kg	

Yes	2 (4.5)
No	42 (95.5)

4.6.1 REGRESSION ANALYSIS OF THE DURATION OF SENSORY BLOCKADE

Ordinary least squares regression technique was used to analyse the effect of explanatory (independent) variables (i.e. age in years, weight in kgs, height in meters.) on the dependent variables (duration of sensory blockade, & duration of motor blockade).

Coefficient values generated indicate the magnitude in which the duration of sensory blockade increases or decreases because of a unit change in one of the explanatory variables. For example, a negative value of coefficient shows that a unit change in the explanatory variable leads to a reduction in the duration of a dependent variable by the value of that coefficient, and vice versa for a positive value coefficient.

t-statistics measure the ratio of departure of the estimated value of a parameter (coefficient value) from its hypothesised value to its standard error. The greater the magnitude of the t-statistic, the greater the evidence that there is significant difference, and therefore a small probability value (p-value). The lower the p-value, the greater the statistical significance.

Clinically from this study, the explanatory variable "height in metres" incidentally showed that for every unit increase in height, it led to an increase the duration of sensory blockade by 82 minutes with a p-value of 0.016, which attained statistical significance.

Table 6: Regression analysis of level of sensory blockade

	Coefficient	t statistics	Standard error	Prob. Value
Height in meters	82.18**	2.53	32.42539	0.016
Observations	44			
R^2	0.226			
Adjusted R^2	0.049			

Note: Dependent variable is the duration of sensory blockade.

4.6.2 MARGINAL EFFECTS ON THE LEVEL OF SENSORY BLOCKADE

The dependent/outcome variable here is the level of sensory blockade. It is categorical in nature, and the order of the level of blockade matters. From the results in table 5, at the end of surgery, 34% of patients were in S2-S5 level, 39% were at S3-S5 level, and 27% were at S4-S5 level.

Ordinal regression approach was applied here.

In table 7, the results showed that ASA 2 patients were 32% more likely to have S4-S5 level of sensory blockade as compared to those of ASA 1. Equally, ASA 2 patients were 35.4% less likely to have S2-S5 level of sensory blockade as compared to those of ASA 1. The implication of this result is that patients of ASA status 2 were more likely to be in the reduced level of sensory blockade i.e., S4-S5 as compared to those of ASA status 1. (p-value 0.05%).

Table 7: Marginal effects on the level of sensory blockade

Variables	S2-S5	S3-S5	S4-S5
ASA status	-0.354**	0.0339	0.320*
	(0.180)	(0.0624)	(0.169)
Observations	44	44	44

*Notes: (i) Standard errors in parentheses; (ii) *** p<0.01, ** p<0.05, * p<0.1*

4.7 LEVEL AND DURATION OF MOTOR BLOCKADE

The mean duration of motor block was 137.2 minutes (+/-25.6) with a minimum duration of 98 minutes and a maximum of 200 minutes.

Patients had a mean time to ambulate of 168 minutes (+/-28.9) with a range of 120 to 230 minutes.

23 patients after surgery had a urethral catheter in-situ, leaving 21 patients who had an average time to first micturition of 266.4 minutes (+/- 21.7) with a range of 230 to 310 minutes.

Table 8: Duration of motor blockade, time to ambulation, and time to micturition

Variable	**Statistic**
Duration of motor block in minutes	
Mean (SD)	137.2 (25.6)
Min –max	98.0-200.0
Time to ambulation while in PACU/ward in minutes	
Mean (SD)	168.0 (28.9)
Min –max	120.0-230.0
Time to first micturition while in PACU/ward in minutes (n=21)	
Mean (SD)	266.4 (21.7)
Min –max	230.0-310.0
Category, n (%)	
Catheter in-situ	23 (52.3)

Level of motor blockade was analysed using the 6-score Modified Bromage scale. At induction of saddle anaesthesia, 15.9% of patients scored 1 (complete block), 29.5% scored 2 (able to move feet only), 29.5% scored 3 (able to move knees), and 11% scored 4 (detectable weakness of hip flexion while supine).

At the end of surgery, 2.3% of patients scored 2 (almost complete block), 22.7% scored 3 (partial block), 27.3% scored 4 (detectable weakness of hip flexion), and 47.7% scored 5 (No detectable weakness of hip flexion).

On exiting PACU, 34.1% of patients scored 5 (no detectable weakness of hip flexion), and 65.9% scored 6 (able to perform partial knee bend).

These results generated a p-value of <0.001 which was significant in the level of motor blockade.

Table 9: Level of motor blockade

Variable	**At induction n (%)**	**At end of surgery n (%)**	**On leaving PACU n (%)**	**P value**
Level of motor blockade				
1-Complete block (unable to move feet or knees)	7 (15.9)	0	0	<0.001
2-Almost complete block (able to move feet only)	13 (29.5)	1 (2.3)	0	
3-Partial block (just able to move knees)	13 (29.5)	10 (22.7)	0	
4-Detectable weakness of hip flexion while supine	11 (25.0)	12 (27.3)	0	
5-No detectable weakness of hip flexion while supine	0	21 (47.7)	15 (34.1)	
6-Able to perform partial knee bend	0	0	29 (65.9)	

4.7.1 REGRESSION ANALYSIS OF THE DURATION OF MOTOR BLOCKADE

Like the regression analysis of the duration of sensory blockade, ordinary least squares regression technique was employed in this analysis.

Results obtained showed for every unit increase in age, there was an increased duration of block of 0.76 minutes with a p-value of 0.042 (<5% significance). This is an incidental finding as the duration of time is not clinically significant.

ASA 2 patients were noted to have increased duration of block of 28 minutes compared to ASA 1 patients resulting in a p-value of 0.014 (<5% significance).

Table 10: Regression analysis of the duration of motor blockade

	Coefficient	t statistics	Standard error	Prob. Value
Age in years	0.764**	2.11	0.3621449	0.042
ASA Status	28.03**	2.59	10.84267	0.014
Observations	44			
R^2	0.363			
Adjusted R^2	0.218			

Note: Dependent variable is the duration of motor blockade.

4.7.2 MARGINAL EFFECTS ON THE LEVEL OF MOTOR BLOCKADE

A similar ordinal regression approach was applied to the level of motor blockade with the following results.

Concerning the weight of the patient, the results shows that a unit increase in weight reduces the probability of a patient being in level 5 of motor blockade by 1.4% and increases the likelihood of a patient being in level 3 and level 4 by 0.7% and 0.5% respectively. The implication of this finding is that increase in weight increases the chances of a patient being in the denser levels of motor blockade. (p-value <0.05)

For the preoperative MAP, a unit increase in preoperative MAP increases the probability of a patient being in level 5 of level motor blockade by 1.83%, while it reduces the chance of a patient being at level 3 and 4 by 0.9% and 0.7% respectively. (p-value <0.05%)

A similar trend is observed for the preoperative RR where a unit increase in preoperative RR increases the likelihood of a patient being in level 5 by 3.6% and reduces the probability of being in level 3 and 4 by 1.8% and 1.4% respectively. (p-value <0.05%)

Table 11: Marginal effects on the level of motor blockade

Variables	Level 2	Level 3	Level 4	Level 5
Weight in Kgs	0.00139	0.00718**	0.00545*	-0.0140**
	(0.00124)	(0.00303)	(0.00303)	(0.00571)
Preoperative MAP	-0.00181	-0.00936***	-0.00710**	0.0183***
	(0.00156)	(0.00299)	(0.00286)	(0.00460)
Preoperative RR	-0.00357	-0.0184**	-0.0140*	0.0360**
	(0.00341)	(0.00922)	(0.00768)	(0.0165)
Observations	44	44	44	44

*Notes: (i) Standard errors in parentheses; (ii) *** p<0.01, ** p<0.05, * p<0.1*

4.8 ADVERSE EVENTS

1 patient (2.3%) developed nausea and vomiting after induction of saddle anaesthesia, while 5 patients (11.4%) developed hypotension and received vasopressors. None of the 44 patients developed postdural puncture headache.

Table 13: Adverse effects

Variable	Frequency (%)
Nausea, vomiting	
Yes	1 (2.3)
No	43 (97.7)
Hypotension	
Yes	5 (11.4)
No	39 (88.6)
Post-dural puncture headache	
Yes	0
No	44 (100)

CHAPTER 5: DISCUSSION

This was a study assessing the effectiveness of isobaric bupivacaine saddle blocks for pelvic surgery. The choice of isobaric bupivacaine was informed by its availability in our local set up (2). It gave a slower onset of block but longer duration of action as described by Van Gessel and colleagues (6). It was a drug of choice for common peri-anal procedures of short duration (14)**.** Concerning patient characteristics, we had 43 females and 1 male patient recruited. The dearth in male patients was due to our inclusion criteria. Some surgeries went past 90 minutes and others converted to general anaesthesia. However the single male underwent haemorrhoidectomy uneventfully. He had adequate pain control without the need of anxiolytics or ketamine.

The mean age was 38.8 years (+/- 16), mean weight 68.7 kilograms (+/- 11.1), mean height 1.70 metres, and mean BMI of 24.6 (+/- 3.9). These are in keeping with studies by Park (16), M Schmittner (29), Gudaityte (24), and Al-Metwalli (23) who all had similar patient profiles.

During the period of data collection, there were 2 gynaecological fistula repair camps. This made rectovaginal fistula the most common diagnosis (22.7%) with rectovaginal fistula repair the commonest procedure (22.7%) amongst patients recruited to the study. Rectovaginal and vulvovaginal fistulas are a major cause of morbidity amongst women in our local setting, and saddle block is a simple anaesthetic technique that can be used in remote areas and surgical camps especially in mind of the repeat surgeries required.

ASA I and ASA II patients were almost even in numbers similar to a study by Shim et al (30) in the bupivacaine-only group. The ASA II patients had their comorbid conditions well controlled with medications prior to surgery.

From the vital signs trend analysis graph in the results section, there was insignificant deviation from the preoperative vital signs. The vital signs trended downwards but stayed within normal parameters. The mean MAP and heart rate preoperatively were 100.6 (+/-14.1) and 95.7 (+/-20.9) respectively. At the end of surgery, MAP was 86.7 (+/-7.2) and heart rate 85.3 (+/-19.9). This is similar to the 5 mg group in Gudaityte et al (24)

1 patient (2.3%) had nausea and vomiting similar to Shim et al (30) in the bupivacaine-only group. 5 patients (11.4%) developed hypotension and were treated with ephedrine and fluid boluses. In Park et al (16), 1 patient sustained hypotension requiring ephedrine bolus. However the patients in that study were subjected to the jack-knife position for surgery.

None of the patients developed postdural puncture headache (PDPH) despite using gauge 25 cutting spinal needles. 4 patients in a study by Gudaityte (24) who were in the 5 mg group developed PDPH after use of the same spinal needles, however their sample population was much larger at 152 patients.

The incidence of adverse effects noted above are like in the populations of other studies mentioned. This infers that this saddle block technique is safe in our population.

The mean duration of surgery of 54.5 minutes (+/-19.6) was in keeping with studies by Park et al (16) with 49 minutes (+/-12.8), and Wassef et al (22) with 51 minutes (+/-8).

On the level of sensory blockade, there was adequate blockade at induction with all sacral segments covered (S2-S5). At the end of surgery, 27.3% had 2-segment regression to S4-S5. The mean duration of sensory block was 127.2 minutes (+/-10.8) which was decreased compared to Gudaityte (24) et al at 150.5 (± 38.0) and Wassef (22) et al at 153 minutes (114–163). In both studies, they were using hyperbaric bupivacaine as opposed to isobaric.

Use of midazolam and ketamine was indicated when the patient experienced discomfort or pain after induction. 6 patients (13.6%) received midazolam and 2 patients (4.5%) received ketamine, and all had uneventful surgery afterwards. In Liaquat et al (8), all 3 groups of patients were pre-medicated with 1mg of midazolam and 4 patients received ketamine 0.25mg/kg.

Regression analysis on the duration of sensory blockade showed that with every unit increase in height, there was increased duration of block by 82 minutes. This inferred those taller patients tended to have longer duration of sensory blockade. However this is a purely incidental finding.

On the level of sensory blockade, patients who were ASA II were 32% more likely to be at S4-S5 level and 35.4% less likely to be at S2-S5 level at the end of surgery. This means that ASA II patients had a reduced level of blockade at the end of surgery compared to ASA I, implying the need for larger doses of bupivacaine and shorter time to rescue analgesia.

The mean time of motor blockade was 137.2 minutes (+/- 21.7) compared to Wassef et al (22) with 113 minutes (84–129). The average time to ambulation was 168 minutes (+/- 28.9) similar to Wassef (22) who had 147 minutes (118-168). The mean time to first micturition was 266.4 minutes (+/-21.7) comparable to Liaquat (8) with 192 minutes (142-300), Gudaityte (24) with 300 minutes (120-1080), and Wassef (22) with 236 minutes (184–324).

The above statistics showed the dose of isobaric bupivacaine worked similarly in the populations highlighted in the different studies.

Regression analysis of the independent variables on the duration of motor blockade showed ASA II patients had an increased duration of motor block of 28 minutes compared to ASA I. Clinically, this inferred the need to reduce doses in patients who are ASA II to facilitate early ambulation. On the level of motor blockade, the weight of the patient played a factor. Increase in weight increases the chances of a patient being at denser levels of motor blockade. This means there will be longer time to ambulate and there is need to reduce doses amongst such patients.

5.1 CONCLUSION

5mg of isobaric bupivacaine is adequate for perineal surgery providing a dense sensory block lasting over 2 hours, motor blockade up to level 4 of the Modified Bromage scale on induction lasting 137 minutes, and minimal incidence of nausea-vomiting, hypotension, and post-dural puncture headache.

5.2 RECOMMENDATIONS

Saddle anaesthesia should be used in short pelvic surgeries especially in a day-case setting and in surgical camps in marginal areas.

A dose titration may be required when working with high BMI patients and ASA II clients since they may have increased duration of blockade.

CHAPTER 6: REFERENCES

1. Valanne J V, Korhonen A, Jokela RM, Ravaska P, Korttila KK. Selective Spinal Anesthesia: A Comparison of Hyperbaric Bupivacaine 4 mg Versus 6 mg for Outpatient Knee Arthroscopy. 2001;1377–9.
2. Gentilli M. Saddle block. Updat Anaesth. 2020;35:24–6.
3. Uppal V, Shanthanna H, Prabhakar C, Mckeen DM. Intrathecal hyperbaric versus isobaric bupivacaine for adult non-caesarean- section surgery : systematic review protocol. 2016;1–5.
4. Maryam A SHSAB 2020 J 31. IS [Internet]. TI (FL): SP 2020 JP 31869179. No Title.
5. Uppal V, Retter S, Shanthanna H, Prabhakar C, Mckeen DM. Hyperbaric Versus Isobaric Bupivacaine for Spinal Anesthesia: Systematic Review and Meta-analysis for Adult Patients Undergoing Noncesarean Delivery Surgery. 2017;125(5).
6. Van Gessel EF, Forster A, Schweizer A, Gamulin Z. Comparison of hypobaric, hyperbaric, and isobaric solutions of bupivacaine during continuous spinal anesthesia. Anesth Analg. 1991;72(6):779–84.
7. van Egmond JC, Verburg H, Derks EA, Langendijk PNJ, Içli C, van Dasselaar NT, et al. Optimal dose of intrathecal isobaric bupivacaine in total knee arthroplasty. Can J Anesth. 2018;65(9):1004–11.
8. Ali L, Alam W, Abbass MA, Sharaf A, Ali U. P E R I - A N A L S U R G E R Y U N D E R S A D D L E B L O C K A N A E S T H E S I A C O M P A R I N G T H R E E D I F F E R E N T D O S E S O F H Y P E R B A R I C 0 . 7 5 % B U P I V A C A I N E.

2017;67(3).

9. Imbelloni LE, Sba TSA, Braga RL, Borges G, Filho DM, Silva A. Low dose of isobaric bupivacaine provides lower incidence of spinal hypotension for hip surgery in elderly patients. :7–10.

10. Omundi S. Comparison of recovery profile of general anaesthesia versus spinal anaesthesia for gynaecological day case surgeries in Kenyatta National Hospital. Vol. 1. University of Nairobi; 2018.

11. Bussen DG, Beck C. Influence of Sedation on Patients ' Perceptions and Recovery in Patients Undergoing Minor Perianal Procedures under Spinal Saddle Block. 2010;51–6.

12. Schmitz HE, Towne JE, Baba G. Saddle block anesthesia. Am J Obstet Gynecol. 1949;58(1):30–40.

13. Shon Y, Huh J, Kang S, Bae S, Kang R, Kim D. Comparison of saddle , lumbar epidural and caudal blocks on anal sphincter tone : A prospective , randomized study. 2016;

14. Ayesha Mariam. Saddle Anesthetic Block Https://www.statpearls.com/articlelibrary/viewarticle/28689/#ref_20243934.

15. Bhattacharyya S, Bisai S, Biswas H, Tiwary M, Mallik S, Saha S. Regional anesthesia in transurethral resection of prostate (TURP) surgery: A comparative study between saddle block and subarachnoid block. Saudi J Anaesth. 2015;9(3):268.

16. Park SY, Park JC, Park SH. Is It Useful and Safe to Maintain the Sitting Position During Only One Minute before Position Change to the Jack-knife Position? Korean J Pain. 2010;23(3):190.

17. Rafique K, Saeed M, Chaudhry IA, Mahmood S, Tamur M, Sadiq T, et al. Post spinal headache (PDPH), spinal headache, spinal needle. Pakistan J Med Heal Sci [Internet]. 2014;8(3):774–7. Available from: http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L600071137%0Ahttp://xv9lx6cm3j.search.serialssolutions.com/?sid=EMBASE&issn=19967195&id=doi:&atitle=Post+spinal+headache+%28PDPH%29%2C+spinal+headache%2C+spinal+needle&stitle=Pak.+J.

18. Adrian Chin and André van Zundert. Complications of spinal anaesthesia. In: Hadzic A, editor. HADZIC'S TEXTBOOK OF REGIONAL ANESTHESIA AND ACUTE PAIN MANAGEMENT. 2nd ed. New York: McGraw-Hill Education.; 2007. p. 330.

19. Rattenberry W, Hertling A, Erskine R. Spinal anaesthesia for ambulatory surgery. BJA Educ [Internet]. 2019;19(10):321–8. Available from: https://doi.org/10.1016/j.bjae.2019.06.001

20. Zaric D, Pace NL. Transient neurologic symptoms (TNS) following spinal anaesthesia with lidocaine versus other local anaesthetics. Cochrane Database Syst Rev. 2009;(2).

21. Okwudili Obi A. Low Dose Spinal Saddle Block Anesthesia (With 1.5 Mg Bupivacaine) For Transrectal Prostate Biopsy-Experience with 120 Cases. J Anesth Clin Res. 2014;05(11):1–4.

22. Wassef MR, Michaels EI, Rangel JM, Tsyrlin AT. Spinal perianal block: A prospective, randomized, double-blind comparison with spinal saddle block. Anesth Analg. 2007;104(6):1594–6.

23. Al-Metwalli R. The minimal effective dose of spinal hyperbaric bupivacaine for successful reliable saddle block for minor perianal surgeries. Ain-Shams J Anaesthesiol. 2015;8(2):265.

24. Gudaityte J, Marchertiene I, Karbonskiene A, Saladzinskas Z, Tamelis A, Toker I, et al. Low-dose spinal hyperbaric bupivacaine for adult anorectal surgery: a double-blinded, randomized, controlled study. J Clin Anesth [Internet]. 2009;21(7):474–81. Available from: http://dx.doi.org/10.1016/j.jclinane.2008.11.014

25. Hocking G, Wildsmith JAW. Intrathecal drug spread. 2004;93(4):568–78.

26. Fassoulaki A, Sarantopoulos C, Zotou M, Karabinis G. Assessment of the Level of Sensory Block After Subarachnoid Anesthesia Using a Pressure Palpator. 1999;(Group 1):398–401.

27. Breen TW, Shapiro T, Glass B, Foster-Payne D, Oriol NE. Epidural anesthesia for labor in an ambulatory patient. Anesth Analg. 1993;77(5):919–24.

28. Vaghadia H, Neilson G, Lennox PH. Selective spinal anesthesia for outpatient transurethral prostatectomy (TURP): randomized controlled. 2012;217–23.

29. Schmittner MD, Urban N, Janke A, Weiss C, Bussen DG, Burmeister MA, et al. Influence of the pre-operative time in upright sitting position and the needle type on the incidence of post-dural puncture headache (PDPH) in patients receiving a spinal saddle block for anorectal surgery. 2011;97–102.

30. Shim SM, Park JH, Hyun DM, Jeong EK, Kim SS, Lee HM. The effects of adjuvant intrathecal fentanyl on postoperative pain and rebound pain for anorectal surgery under saddle anesthesia. Korean J Anesthesiol. 2018;71(3):213–9.

CHAPTER 7: APPENDICES

7.1 PARTICIPANT INFORMATION SHEET (PATIENT)

My name is Dr Kiprop Kipchobit Biwott. I am a postgraduate student undertaking a Masters degree in Anaesthesia and Critical Care. I am conducting a study to assess whether a particular dose of bupivacaine provides good conditions for surgery on the groin area.

Background

Saddle anaesthesia is a spinal anaesthesia technique that uses smaller doses of local anaesthetic to achieve anaesthesia. It is a useful technique for surgery around the groin. Advantages include good pain control, faster time to walking, and earlier discharge time.

Study purpose

This study will be done to find out if a low dose of bupivacaine given into the lower back is adequate for groin surgery in both male and female patients.

Voluntariness in participation

Your participation in the research is entirely voluntary. There will be no penalties for refusing to participate in the study. You are free to withdraw from this study at any point without victimisation.

Your participation will not incur any additional cost by participating in the study. There will be no monetary benefit to you for participating in the study, but your participation will help in knowledge generation and improved efficiency in our theatres in future.

Confidentiality

All the information provided will be kept confidential and will only be used for research purposes. You will not be identified by your name, but by a number, and your information will not be shared to anyone.

Study procedure

Once you are enrolled into the study, you will proceed to the theatre area for preoperative evaluation. Vital signs like your heart rate and blood pressure will be taken. A cannula will be inserted into your hand or arm to start some fluids.

You will then sit on the theatre table with your back exposed. It will be cleaned with soap solutions to make it sterile. A needle will be connected to a syringe with numbing medication and directed to your lower back. This will be slightly painful at first but later stay numb.

A second needle with the drug bupivacaine will be inserted into the same spot on the lower back. The drug will be delivered, and you will sit upright for 10 minutes to allow the drug to work. You will then lie on the theatre bed and be positioned for surgery as we test to see if the drug has worked.

Data collected during the procedure includes level of motor and sensory block, the first time to walk after the procedure, the first time to urinate after the procedure, and any headache after injection.

Risks to participation

Complications of saddle spinal anaesthesia may include low blood pressure, injury to nerves, blood clot, back ache, headache after injection, infection, and at times complete paralysis. These sounds alarming but steps have been taken to avoid these risks. It is also a routine procedure and the staff in theatre are well trained to handle any eventuality.

Benefits of participation.

There will be no direct benefit to you as a participant, but data collected will be used to generate knowledge on the technique and help improve efficiency in our theatres. Since it involves small doses of drug, patients can recover quickly allowing for more patients to be done in a day. This also allows reduced time of stay in hospital which leads to better patient satisfaction.

Alternative treatments

The surgical procedure can also be done under general anaesthesia which means putting one to sleep. Once the procedure is done, you will be awoken gradually and given strong pain medication. Another method is through standard spinal anaesthesia which numbs a person from the waist to your feet. However you will be free of pain, but it takes time to wear out.

Right to withdraw

You are free to withdraw from the study at any point without fear of victimisation.

Study approval

The study will be conducted with the approval of the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee. P. O. Box 19676, Code 00202, Nairobi. Tel. (254-020) 2726300-9 Ext 44355. E-mail: uonknh_erc@uonbi.ac.ke, Website: www.erc.uonbi.ac.ke

For any clarifications or queries, please contact me, Dr Kiprop Kipchobit Biwott, on 0721273357.

You may also reach my supervisors as follows:

Dr Thomas Chokwe 0722528237

Dr Hypheginia Mbithe 0720325441

If you agree to participate in this study, please sign the consent form provided.

7.2 PARTICIPANT ELIGIBILITY SCREENING FORM

Serial number …….

Ward/clinic ……

Theatre ……

Date ……

Biodata:

a) Age …….
b) Sex …….
c) Weight ……
d) Height …….
e) Calculated BMI ……

Diagnosis …….

Surgery ……

ASA status …….

Comorbidities …….

Current medications and anticoagulant therapy…….

Consent status …….

Allergies to local anaesthetic agents ……

Any spinal deformities or previous lumbar spinal surgery……

If patient is of sound mind and able to give legal informed consent …….

7.3 CONSENT TO PARTICIPATE IN THE STUDY

I, ……. after being fully explained to by Dr Kiprop Kipchobit Biwott, and/or the research team, the purpose, technique, advantages, possible complications, and guarantees of confidentiality, do voluntarily agree to participate in this study.

I have also been told that declining to participate in, or withdrawing from the study, will not in any way compromise the care I will receive.

Signature (participant) ……. Date …….

Name and signature (Investigator) …….

Designation ……. Date …….

Name of Principal Investigator – Dr Kiprop Kipchobit Biwott

Telephone number – 0721273357

Email – kipchobit@gmail.com

Name of supervisor – Dr Thomas Chokwe

Telephone number – 0722528237

Email – tmchokwe@gmail.com

Name of supervisor – Dr Hypheginia Mbithe

Telephone number – 0720325441

Email – drhyphie@gmail.com

KIAMBATISHO CHA TANO

7.1 (A) FOMU YA HABARI KWA WANAO SHIRIKI

Naitwa Dr Kiprop Kipchobit Biwott. Mimi ni mwanafunzi wa uzamili anayefanya digrii ya Masters katika Anesthesia na Utunzaji Muhimu. Ninafanya utafiti kutathmini ikiwa kipimo fulani cha bupivacaine hutoa hali nzuri za upasuaji kwenye sehemu za siri.

Usuli

Anesthesia ya saruji ni mbinu ya anesthesia ya uti wa mgongo ambayo hutumia kipimo kidogo cha anesthetic ya ndani kufikia anesthesia. Ni mbinu muhimu ya upasuaji karibu na sehemu za siri. Faida ni pamoja na udhibiti mzuri wa maumivu, wakati wa haraka wa kutembea, na wakati wa kutokwa mapema**.**

Kusudi ya utafiti

Utafiti huu utafanywa ili kujua ikiwa kipimo kidogo cha bupivacaine kilichopewa mgongo wa chini kinatosha kwa upasuaji wa sehemu za siri kwa wagonjwa wa kiume na wa kike..

Kujitolea katika kushiriki

Ushiriki wako katika utafiti ni wa hiari kabisa. Hakutakuwa na adhabu kwa kukataa kushiriki katika utafiti. Uko huru kujiondoa kwenye utafiti huu wakati wowote bila kuathiriwa.

Ushiriki wako hautapata gharama yoyote ya ziada kwa kushiriki katika utafiti. Hakutakuwa na faida ya kifedha kwako kushiriki katika utafiti, lakini ushiriki wako utasaidia katika kukuza maarifa na kuboresha ufanisi katika vyumba vyetu vya upasuaji katika siku zijazo.

Usiri

Habari yote iliyotolewa itahifadhiwa kwa siri na itatumika tu kwa madhumuni ya utafiti. Hutatambuliwa kwa jina lako, lakini kwa nambari, na habari yako haitashirikiwa kwa mtu yeyote.

Utaratibu wa utafiti

Mara tu umejiandikisha kwenye utafiti, utaendelea kwenye eneo la ukumbi wa upasuaji kwa tathmini ya preoperative. Ishara muhimu kama kiwango cha moyo wako na shinikizo la damu zitachukuliwa. Kanula itaingizwa mkononi mwako au mkono kuanza maji.

Kisha utakaa kwenye meza ya ukumbi wa upasuaji na mgongo wako wazi. Itasafishwa na suluhisho za sabuni kuifanya iwe safi. Sindano itaunganishwa na sindano na dawa ya kufa ganzi na kuelekezwa kwa mgongo wako wa chini. Hii itakuwa chungu kidogo mwanzoni lakini baadaye kaa ganzi.

Sindano ya pili iliyo na dawa ya bupivacaine itaingizwa kwenye sehemu ile ile nyuma ya chini. Dawa hiyo itakabidhiwa, na utakaa wima kwa dakika 10 kuruhusu dawa hiyo kufanya kazi. Halafu utalala kwenye kitanda cha ukumbi wa upasuaji na uwekewe nafasi ya upasuaji tunapojaribu kuona ikiwa dawa hiyo imefanya kazi.

Takwimu zilizokusanywa wakati wa utaratibu ni pamoja na kiwango cha kuzuia magari na hisia, mara ya kwanza kutembea baada ya utaratibu, mara ya kwanza kukojoa baada ya utaratibu, na maumivu ya kichwa yoyote baada ya sindano.

Hatari za kushiriki

Shida za anesthesia ya uti wa mgongo inaweza kujumuisha shinikizo la chini la damu, kuumia kwa neva, kuganda kwa damu, maumivu ya mgongo, maumivu ya kichwa baada ya sindano, maambukizo, na wakati mwingine kupooza kamili. Shida hizi zinatisha lakini hatua zimechukuliwa ili kuepusha hatari hizi. Pia ni utaratibu wa kawaida na wafanyikazi katika ukumbi wa upasuji wamefundishwa vizuri kushughulikia hali yoyote.

Faida za kushiriki

Hakutakuwa na faida kwako kama mshiriki, lakini data itakayokusanywa itatumika kutoa maarifa juu ya mbinu na kusaidia kuboresha ufanisi katika vyumba vyetu vya upasuaji**.** Kwa

kuwa inajumuisha kipimo kidogo cha dawa, wagonjwa wanaweza kupona haraka kuruhusu wagonjwa zaidi kufanywa kwa siku. Hii pia inaruhusu kupunguzwa kwa muda wa kukaa hospitalini ambayo inasababisha kuridhika kwa mgonjwa.

Matibabu mbadala

Utaratibu wa upasuaji pia unaweza kufanywa chini ya anesthesia ya jumla ambayo inamaanisha kumlaza mtu. Mara baada ya utaratibu kufanywa, utaamshwa pole pole na kupewa dawa kali za maumivu. Njia nyingine ni kupitia anesthesia ya kawaida ya uti wa mgongo ambayo humfanya mtu kufa ganzi kutoka kiunoni hadi miguu yako. Walakini hautakuwa na maumivu, lakini inachukua muda kuisha

Haki ya kujiondoa

Uko huru kujiondoa kwenye utafiti wakati wowote bila hofu ya kudhulumiwa.

Idhini ya utafiti

Utafiti huo utafanywa kwa idhini ya Hospitali ya Kitaifa ya Kenyatta/Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi. P. O. Box 19676, Code 00202, Nairobi. Tel. (254-020) 2726300-9 Ext 44355. E-mail: uonknh_erc@uonbi.ac.ke , Website: www.erc.uonbi.ac.ke

Kwa ufafanuzi wowote au maswali, tafadhali wasiliana nami, Daktari Kiprop Kipchobit Biwott, kwa 0721273357.

Unaweza pia kuwafikia wasimamizi wangu kama ifuatavyo.

Daktari Thomas Chokwe 0722528237

Daktari Hypheginia Mbithe 0720325441

7.2 (A) FOMU YA IDHINI YA KUSHIRIKI

Mimi, ……. baada ya kuelezewa kikamilifu na Dk Kiprop Kipchobit Biwott, na timu ya utafiti, kusudi, mbinu, faida, shida zinazowezekana, na dhamana ya usiri, wanakubali kwa hiari kushiriki katika utafiti huu.

Nimeambiwa pia kwamba kukataa kushiriki, au kujiondoa kutoka kwa utafiti huo, hautatatiza utunzaji nitakaopewa.

Saini (mshiriki) ……. Tarehe …….

Jina na saini (Mpelelezi) ……

Uteuzi ……. Tarehe …….

Jina la Mchunguzi Mkuu - Daktari Kiprop Kipchobit Biwott

Nambari ya simu - 0721273357

Barua pepe - kipchobit@gmail.com

Jina la msimamizi - Daktari Thomas Chokwe

Nambari ya simu - 0722528237

Barua pepe - tmchokwe@gmail.com

Jina la msimamizi - Daktari Hypheginia Mbithe

Nambari ya simu - 0720325441

Barua pepe - drhyphie@gmail.com

7.3 STUDY PRO-FORMA (BIODATA/ COMORBIDITIES/ SURGICAL PROCEDURE)

Serial number…….

Theatre …….

Date……

1. Biodata
   a. Age ……
   b. Sex …….
   c. Weight ……
   d. Height …….
   e. BMI …….

2. a. Diagnosis ……
   b. Surgical procedure ……

3. a. ASA status ……
   b. comorbidities …….

4. Preoperative vital signs
   a. Blood pressure …….
   b. Mean arterial pressure …….

c. Heart rate ……

d. Oxygen saturation ……

e. Respiratory rate ……

	At induction	5	10	15	20	30	40	50	60	70	80	90	100	110	120
Blood pressure															
Mean arterial pressure															
O_2 Saturation															
Heart rate															
Respiratory rate															

Table 5: recording of vital signs at induction and during procedure.

5. Level of sensory blockade

Assessed with wet cotton dipped in spirit (temperature), and pin prick/non-toothed forceps.

a. Level of sensory block at induction …….

b. level of sensory block at end of surgery …….

c. duration of block …….

d. Did the patient receive 1mg of IV midazolam? …….. 0.25mg/kg of IV ketamine? ……

6. Level of motor block as per Modified Bromage scale

SCORE	CRITERIA
1	Complete block (unable to move feet or knees)

2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

a. Patient score at induction with saddle block ……
b. Patient score at end of surgery …….
c. Patient score on leaving PACU…….
d. Duration of block …….

7. Time to ambulation while in PACU ……

8. Time to first micturition while in PACU ……

9. Adverse events

a. Nausea, vomiting …….
b. Hypotension …….
c. Post dural puncture headache (on telephone interview 24 hours post-surgery/visiting patient in the ward) …….

7.4 SADDLE BLOCK PROCEDURE CHECKLIST (adapted and modified from the KNH spinal anaesthesia protocol for Caesarean section)

- After confirming duly signed consent, explain the saddle procedure to the patient.
- The entire theatre staff is briefed on the saddle procedure for assistance if necessary.
- Proceed to direct the patient to the theatre table and insert a large bore peripheral access, preferably gauge 20 or larger.
- Start a crystalloid solution (ringers' lactate) at 10ml/kg to run over 15-30 minutes.
- Connect the patient to the cardiac monitor and get baseline vital signs; blood pressure, mean arterial pressure, heart rate, respiratory rate, and oxygen saturation.
- Patient should be preferably in a seated position on the theatre table, sitting facing lateral to the bed with the feet supported with a stool. The back of the patient should be exposed.
- Scrub your hands and gown following aseptic technique. Open the spinal tray and proceed to clean the patient's back from the tip of the scapulae to the gluteal area.
- Confirm that the spinal tray has the following:
  - ✓ Sterile towels to drape the site.
  - ✓ Sterile gauze to clean and dress the site.
  - ✓ Gulley pots to hold the cleaning solutions.
  - ✓ One 5ml syringe and needle for infiltrating local anaesthetic, and one 2ml syringe for injecting the spinal medication.
  - ✓ Spinal needle gauge 25 with introducer

- Ensure the patient is seated upright, neck slightly flexed anteriorly. Proceed to palpate the spine as you trace a line connecting the iliac crests (inter-cristal line). This line will help locate L3-L4 vertebral space.
- Using the 5ml syringe and a gauge 23 (blue) needle, withdraw 5mls of lignocaine 2%, and proceed to infiltrate the vertebral space. Withdraw the needle as you push in the local anaesthetic and create a skin wheal.
- Wait for 30-45 seconds for the LA to take effect. This should cover 1 vertebra above and below the space. Reassure the patient on the 2nd injection.
- Draw 1ml of 0.5% bupivacaine into the 2ml syringe and add 1ml of normal saline into the same syringe.
- Proceed to insert the spinal needle via the introducer. Feel for a sudden "give" as the needle passes through the ligaments. Withdraw the stylet and observe for clear CSF flow. Once seen, connect the syringe with bupivacaine and proceed to push it in slowly over 5 seconds.
- Withdraw the spinal needle and use the sterile gauze and tape to dress the site.
- Note the time of injection and allow the patient to remain seated upright for 10 minutes.
- Continuously monitor the vital signs. Check if the patient is feeling numb or weak around the hip area. Assess if patient can extend the knee.
- Once the 10 minutes elapse, position the patient supine and check the sensory blockade caudal to cephalad, starting from the feet. Use a gauze or cotton wool soaked in spirit and check for temperature perception. Use pinprick (blunted gauge 23 needle) or non-toothed forceps to check for pain bilaterally. Note the findings.
- Perineal sensation to be assessed by the surgeons prior to surgery.
- Motor blockade to be assessed via modified Bromage scale. Note the findings and score.
- Critical observations and interventions:
- Heart rate – symptomatic bradycardia (<60bpm), give atropine at 0.02mg/kg.
- Blood pressure – symptomatic hypotension (systolic <90, MAP <55), give ephedrine 3-6mg boluses PRN. Adrenaline should be ready and diluted to 1:10000 (10mcg/kg bolus)
- Oxygen saturation <90%, increase flow.
- Respiratory rate <10 – give oxygen, assist respiration, reassure the patient.

- High spinal or total spinal anaesthesia – convulsions, arrhythmias, cardiorespiratory collapse

  Management - Intubate, ventilate, cardiac massage, vasopressors, anticonvulsants. Administer intralipid.
- Post spinal headaches – usually begin 12-48 hours after saddle anaesthesia. Worse on being in upright position.

  Management – Bed rest, oral fluids, analgesics, epidural blood patch
- Post operatively – Monitor vital signs ¼ hourly until they leave PACU. Check if ready to sit up and ambulate.

7.5 STUDY TIMELINE

	Mar 2020-Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	June 2021	July 2021	August 2021	Sept 2021	Oct 2021	Nov 2021	Dec 2021
Proposal development													
Proposal presentation													
ERC review													
Data collection													
Data analysis and presentation													
Results dissemination													

Table 6: Study timeline

7.6 BUDGET

Table 7: Budget

ITEM	COST PER UNIT (Kshs)	UNIT	TOTAL (Kshs)
Biostatistician	35000		35000
Research assistant	15000	2 months	30000
Stationery and printing	6000		6000
Airtime and internet	2000	5 months	10000
ERC approval	2000		2000
Sub-total			**83000**
Add 25% contingency			20750
TOTAL			**103750**

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Ref: KNH-ERC/A/226

28th June, 2021

Dr. Kiprop Kipchobit Biwott
Reg. No.H58/74775/2014
Dept.of Anaesthesia
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Biwott

RESEARCH PROPOSAL: ASSESSMENT OF THE EFFECTIVENESS OF 0.5% ISOBARIC BUPIVACAINE USED IN SADDLE BLOCKS FOR ELECTIVE UROLOGY AND GYNAECOLOGY PROCEDURES AT KENYATTA NATIONAL HOSPITAL (P66/02/2021

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 28th June, 2021 – 27th June, 2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. 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.
iv. 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.
v. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
vii. Submission of an executive summary report within 90 days upon completion of the study.

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 Chair, KNH- UoN ERC
The Dean, School of Medicine, UoN
The Chair, Dept.of Anaesthesia, UoN
Supervisors: Dr. Thomas Chokwe,Dept.of Anaethesia. UoN
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