

**COMPARISON OF RECOVERY PROFILE OF GENERAL ANAESTHESIA VERSUS  
SPINAL ANAESTHESIA FOR GYNAECOLOGICAL DAY CASE SURGERIES IN  
KENYATTA NATIONAL HOSPITAL**

**SUSAN KERUBO OMUNDI**

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REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE  
IN ANAESTHESIA OF THE UNIVERSITY OF NAIROBI.**

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## **DECLARATION**

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

Dr. Susan Kerubo Omundi, MBChB(UON)

Post graduate student in Anaesthesia

University of Nairobi

Registration number: H58/69689/2013

Signature: ..... Date: .....

## **SUPERVISOR'S APPROVAL**

This dissertation has been submitted with our approval as university supervisors:

Dr Nabalindo M. Susane,

MBChB, MMed Anaesthesia (UoN), Paediatric Fellowship (UoN)

Consultant Paediatric Anaesthesiologist ,

Lecturer Department of Anaesthesia,

University of Nairobi, Kenya

Tel: +254721418587

Email: nabalindosusane@gmail.com

Signature..... Date.....

Dr. Jane Gwaro

MBChB, Mmed Anaesthesia (UON)

Cert Neuroanaesthesia (Wits university SA).

Consultant Anaesthesiologist

Department of Anaesthesia, Kenyatta National hospital

Tel: +254722749667

Email: gwaroj@yahoo.com

*Signature:* ..... *Date*.....

Dr. Lee Ngugi Kigera

MBChB, MMed Anaesthesia (UoN)

Diploma (WFSA), GCSRT-(Clinical trials) Harvard Medical School

Lecturer Department of Medical Physiology-Kenyatta University

Consultant Anaesthesiologist, Pain specialist

P.O Box 43844-00100

Nairobi

Tel: +254722757875

Email: [kigera.lee@ku.ac.ke](mailto:kigera.lee@ku.ac.ke)

*Signature*..... *Date*.....

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## LIST OF ABBREVIATIONS

AAGBI	Association of Anaesthetists of Great Britain and Ireland
ASA	American society of anesthesiologists
IUCD	Intrauterine contraceptive device
KNH	Kenyatta National hospital
LMA	Laryngeal mask airway
MOH	Ministry of Health
PACU	Post anaesthetic care unit
PADS	Post anaesthetic discharge score
PDPH	Postdural puncture headache
SSA	Selective spinal anaesthesia
TIVA	Total intravenous anaesthesia
TNS	Transient neurological symptoms
UON	University of Nairobi



## **DEDICATION**

To my parents, my dear husband Alfred, my children William and Henry

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## **ABSTRACT**

### **Background**

Day care surgery is gaining popularity with more and more procedures being performed on day care basis. Recovery is a key factor in the success of day care surgery with delayed recovery resulting in increased cost, reduced efficiency and unplanned admissions.

### **Methods**

A total of ninety four patients were prospectively randomised to two groups; spinal anaesthesia and general anaesthesia. The spinal anaesthesia and general anaesthesia groups received anaesthesia as per protocol. They were monitored both intraoperatively and postoperatively at PACU. Vital signs, post operative complications, pain scores and time to achieve standardized discharge criteria were recorded in PACU. The incidence of unplanned admission was also recorded.

### **Results**

The participants in the two groups were comparable with respect to age, ASA status, diagnosis and type of surgery. Participants in the spinal anaesthesia group took twice as long to achieve discharge criteria compared to those in general anaesthesia group. This was mainly due to longer time taken to achieve ambulation for the patients in the spinal anaesthesia group. The nausea and pain scores were similar.

Only one patient in the spinal anaesthesia group was admitted for monitoring due to severe surgical bleeding.

### **Conclusion**

Patients undergoing gynaecological surgery on day care basis under spinal anaesthesia with bupivacaine 7.5mg take longer to achieve standardized discharge criteria compared to those under general anaesthesia.

## **1.0 INTRODUCTION**

Day or ambulatory surgery is the admission to hospital of selected, planned, non-emergency patients for a surgical procedure, returning home the same day (1). It was started by James Nicoll, a Glasgow surgeon who performed about 9000 surgeries on day care basis in children in 1903. In 1912 “the downtown anaesthesia clinic” was described by Ralph Waters from Iowa. He gave anaesthesia for outpatient surgery at this clinic (2)

Over the last three decades, ambulatory surgery has grown exponentially with development of ambulatory anaesthesia as a subspecialty and establishment of the society for ambulatory anaesthesia in 1984. More and more procedures are now being performed as day cases especially with the advances in minimally invasive techniques. Up to 90% of elective surgeries are performed as day cases in USA and Canada with a lesser proportion of procedures performed as day cases in many other countries (3)

In Kenya, day care surgery is still in its infancy. In most public hospitals, day care patients share wards and theatres with admitted patients while in private hospitals the day cases are separated from inpatients. Day care units with independent theatres and wards dedicated to day surgery only also do exist.

At the Kenyatta National Hospital (KNH), a gynaecological day care surgery unit was established in March 2013. It is part of the gynaecological outpatient clinic and comprises of two operation rooms and a post anaesthetic care unit. The surgeries done in this unit include;

- Examination under anaesthesia
- Biopsies
- Dilation and curettage
- Termination of non viable pregnancy,
- Mc Donald stitch insertion
- Marsupialisation of Bartholin cyst
- Repair of episiotomy
- Removal of intrauterine contraceptive device(IUCD)
- Diagnostic laparoscopy.

Both general and spinal anaesthetic techniques are used for these procedures .There are no clear guidelines on use of either of these techniques in the day care unit and their impact on patient recovery and satisfaction.

The purpose of this study was to compare the recovery profile of general and spinal anaesthesia. This is important because recovery may affect cost, patient satisfaction and incidence of unplanned admissions.

## **2.0 LITERATURE REVIEW**

### **Anaesthetic techniques for ambulatory surgery**

General anaesthesia, regional and local anaesthesia have all been used for ambulatory surgery.

Factors influencing choice of anaesthetic techniques include;

- Type of surgery
- Preference of surgeon, anaesthesiologist or patient
- Cost of anaesthesia
- Age of the patient

According to guidelines published by Association of Anaesthetists of Great Britain and Ireland (AAGBI) and British Association of Day Surgery, anaesthetic technique employed for day care surgery should ensure minimum stress and maximum comfort for patient.(4)

### **Regional anaesthesia**

Local infiltration and nerve blocks have been used safely in day care surgery. They are associated with good post operative analgesia. According to guidelines by the AAGBI, residual motor and sensory blockage should not prevent discharge of the patient as long as the limb is protected and the patient has enough social support.(4)

### **Central neuroaxial blockade for day care surgery**

Spinal and epidural anaesthesia have been safely used in day care surgery. The advantages of spinal anaesthesia include less analgesic requirements and less post operative nausea and vomiting. (5, 6)

Complications of spinal anaesthesia include; residual blockade, postural hypotension, urinary retention and post dural puncture headache (PDPH). These complications may increase time to readiness for discharge and reduce patient satisfaction but can be minimized by choosing appropriate local anaesthetic agent, use of local anesthetics and opioid mixtures and use of smaller gauge needles (for spinal anaesthesia).Incidence of PDPH can be reduced by use of smaller gauge

needles(>25 G),use of atraumatic (non cutting) needles and alignment of the bevel the needle parallel to the long axis of the spine especially when using traumatic needles(7,8,9,10)

### **Selective spinal anaesthesia**

Selective spinal anaesthesia (SSA) is the use of minimal doses of intrathecal local anaesthetic agents so as to selectively block nerve roots supplying a particular area while preserving motor function. Selective spinal anaesthesia has opened up the possibility of providing “walk in - walk out” spinal anaesthesia with a real possibility of bypassing the recovery room making spinal anaesthesia more suitable for day care surgery. This can be achieved by use of lower doses of local anaesthetic agents which can be combined with intrathecal opioids to reduce the likelihood of inadequate block (11)

Drugs that have been used to provide selective spinal anaesthesia for ambulatory surgery include lignocaine and low dose bupivacaine. Lignocaine has been more commonly used due to its short duration of action. Concerns of transient radicular irritation (TRI) following use of 5% lignocaine in spinal anaesthesia have limited its use. Recently, even the 2% solution has been associated with an increased incidence of TRI .More dilute solutions of lignocaine are currently being experimented with some studies showing that use of low doses may reduce time to discharge without compromising intraoperative conditions (12, 13)

With the neurotoxicity associated with lignocaine, low dose bupivacaine has been used in combination with suboptimal dosages of opioids for day care surgery. This has been shown to provide adequate anaesthesia with reduction in recovery time (14).Ben-David et al demonstrated that small doses of dilute bupivacaine (7.5 mg/ 0.25%) provide reliable anaesthesia for knee arthroscopies (15). A systematic review of 17 randomized clinical trials on use of spinal anaesthesia for ambulatory knee arthroscopy suggested that large doses of 10 to 15mg delayed recovery compared to lower doses of 4 to 5 mg but use of the low doses were associated with higher incidence of failure. Intermediate doses of 6mg to 7.5mg increased time to discharge by 40minutes.All the RCTS except one used hyperbaric bupivacaine (16).

Most of the studies on spinal anaesthesia for day care surgery have been done on laparoscopic gynaecological procedures, laparoscopic cholecystectomy and knee arthroscopy.

### **General anaesthesia for ambulatory surgery**

General anaesthesia has been the preferred mode of ambulatory anaesthesia. The technique used should be safe, cost effective with rapid recovery and minimal side effects.

### **Airway management**

Tracheal intubation, facemask, oral airway and laryngeal mask airway are some of the equipment that have been used in ambulatory surgery.

Tracheal intubation is associated with more complications than face mask and Laryngeal mask airway (LMA) including sore throats, croup and hoarseness of voice. In one study, the incidence of post operative sore throat after ambulatory surgery was 45% with endotracheal tube (ETT), 18% with LMA and 3% with face mask (17).

LMA also frees the anaesthetist's hands for record keeping, drug preparation and administration and avoids hand fatigue. It can be positioned blindly with no neuromuscular blocking drugs and is well tolerated with all volatile agents.

LMA has been associated with minimal cardiovascular response and is better tolerated with light levels of anaesthesia as compared to endotracheal tube. It is not suitable for patients at high risk of aspiration.

### **Anaesthetic drugs**

Propofol has superior recovery profile and has replaced barbiturates for induction of anaesthesia in the ambulatory setting. The most popular technique for maintenance of anaesthesia has been use of volatile agents with or without nitrous oxide.

TIVA with Propofol and remifentanyl has also been used for ambulatory surgery and it has been associated with earlier home readiness compared to spinal anaesthesia. However, the use of volatile agents like desflurane and sevoflurane has been associated with shorter emergence time and lower costs compared to TIVA with Propofol (18,19)



## **Discharge Criteria**

There are three stages of recovery after anaesthesia; first phase which ends when the patient is awake and has return of protective reflexes. Second stage ends when the patient is ready for discharge from post anaesthetic care unit (PACU) while the third stage which takes days to months ends with the recovery of full physiological and psychological functions.

In most patients, the first stage of recovery may occur in the operating room while the second phase takes place in PACU. The PACU should be well equipped to handle emergencies and complications of surgery such as post operative nausea and vomiting, pain and hemorrhage

Various criteria have been used to discharge patients from PACU. Traditionally, voiding and tolerating oral clear fluids was one of the requirements for discharge. Studies have shown that this only delays discharge and only high risk patients e.g. patients with prolonged instrumentation and bladder manipulation should be required to void prior to discharge (20,21)

Patients should be given written information on possible complications and when they should seek help (7)

## **Discharge after general anaesthesia**

The most commonly used criteria include the Aldrete score and modified post anaesthetic discharge scoring system (PADS).

The Aldrete scoring system may be used in deciding whether the patient has recovered enough to be transferred to phase 2 recovery. In its original form, the Aldrete score assigned a score of 0, 1 and 2 to activity, respiration, circulation, consciousness and color. The maximum score is 10 and the patient may be discharged safely to phase 2 recovery when they attain a score of 9. With the widespread use of pulse oximetry, a modified Aldrete scoring system was introduced, it uses 5 parameters: activity, respiration, circulation, consciousness and oxygen saturation. A score of 9 indicates readiness for discharge.

The Post anaesthetic discharge scoring system was developed by Chung et al at Toronto hospital where it has been used extensively to determine when patients can be safely discharged home.

The earlier version of the PADS system required the patient to have taken oral fluids and passed urine before being allowed home. These two requirements were removed after studies showed that the two factors may delay discharge and can be eliminated without evidence of adverse effects (20). This resulted in the modified PADS system with 5 parameters; Vital signs, ambulation and mental status, pain, post operative nausea and vomiting and surgical bleeding. Each parameter is given a score of 0 to 2 and the patient is ready for discharge if he scores 9 or more.

<p>1.Vital signs</p> <p>2=within 20% of preoperative value</p> <p>1=20-40% of preoperative value</p> <p>0=40% of preoperative value</p>
<p>2.Ambulation</p> <p>2=steady gait/No dizziness</p> <p>1=with assistance</p> <p>0=None/dizziness</p>
<p>3.Nausea</p> <p>2=minimal</p> <p>1=moderate</p> <p>0=severe</p>
<p>4.Pain</p> <p>2=minimal</p> <p>1=moderate</p> <p>0=severe</p>
<p>5.Surgical bleeding</p> <p>2=Minimal</p> <p>1=moderate</p> <p>0=severe</p>

Modified post anaesthetic discharge scoring system

### **Discharge criteria after spinal anaesthesia**

The same criteria is used for both spinal and general anaesthesia but due to the physiological effects of spinal anaesthesia, additional criteria has been used; voiding ,normal perianal sensation, ability to plantar flex the foot and proprioception of big toe. However some studies have shown that with use of short acting local anaesthetic agents for spinal anaesthesia, voiding may not be necessary before discharge especially in low risk patients (21)

### **3.0 JUSTIFICATION**

Day care surgery is gaining popularity worldwide with more and more surgeries being performed as day cases. In KNH a day care centre has been operational for the last 3 years. Most procedures done here are gynaecological procedures. These have been carried out using both spinal and general anaesthesia. Anaesthetic technique may impact on recovery profile which may consequently affect the cost and efficiency of day care surgery.

Most studies comparing recovery of general anaesthesia and spinal anaesthesia for day care surgery have focused on laparoscopic gynaecological procedures, laparoscopic cholecystectomy and knee arthroscopy. There are limited studies on spinal anaesthesia for non laparoscopic short gynaecological procedures. A study done at a private day care unit showed that anaesthetists preferred to use regional blocks and general anaesthesia for orthopedic day care surgery and were reluctant to use spinal anaesthesia (22). This study aims to generate knowledge on use of spinal anaesthesia for day care surgery in tertiary care hospitals in low and middle income countries.

Even with the neurological complications associated with use of intrathecal lignocaine, most studies have focused on use of lignocaine for spinal anaesthesia for day care surgery. This study aims to collect data that will help in assessing the feasibility of low dose bupivacaine as a local anaesthetic agent for gynaecological day care surgery.

#### **4.0 RESEARCH QUESTION**

Is general anaesthesia associated with improved recovery profile compared to spinal anaesthesia for patients undergoing gynaecological surgery on day care basis at Kenyatta National hospital?

#### **4.1 Broad objective**

To compare the recovery characteristics of general anaesthesia with those of spinal anaesthesia in gynaecological procedures performed as day cases.

#### **4.2 Specific objectives**

1. To determine the difference in time to achieve standardized discharge criteria
2. To compare the incidence of unplanned admissions.
3. To compare the incidence of post operative nausea and vomiting among the two groups

## 5.0 MATERIAL AND METHODS

### 5.1 Study design

A prospective open label randomized clinical trial carried out at KNH gynaecological day care unit. The study was not blinded due to the obvious difference in technique for spinal and general anaesthesia

### 5.2 Study setting

The study was carried out at the KNH which is a 2000 bed capacity National referral and teaching hospital for the University of Nairobi. It has 21 theatres, two of which are stand alone and set apart for gynaecological day care surgery. The gynaecological day care unit is composed of two theatres and a PACU. Unplanned admissions from this unit are admitted to the three gynaecological wards within KNH.

### 5.3 Study population

Patients undergoing elective gynaecological procedures on day care basis.

### 5.4 Sample size determination

Sample size calculation was based on the formula for comparison of means between two groups

$$n = \frac{2(Z_{\beta} + Z_{\alpha/2})^2 \sigma^2}{(\mu_1 - \mu_2)^2}$$

$Z_{\beta}$ =0.84 representing 80% power

$Z_{\alpha}$ =1.96 representing 95 % level of confidence

$\mu_1$  = The average duration to readiness for discharge post-surgery for patients in whom laparoscopic gynaecological procedures were performed under GA, estimated at 16.9 minutes in a similar randomized controlled trial (13)

$\mu_2$  = The average duration of to readiness for discharge in the spinal anaesthesia group estimated at 15.4 minutes representing a 9-10% relative reduction in the time to discharge in the spinal and GA group (or a 1.5 minute absolute difference in duration between treatment groups)

$\sigma$  = Standard deviation around mean time to readiness for discharge estimated at 2.5 based on SD reported in a previous and comparable RCT (13)

$$n = \frac{2(1.28 + 1.96)^2 \times 2.5^2}{(16.9 - 15.4)^2}$$

n = 45 women per treatment group

Total sample size (N) = 90

Assumption; Equal variance among the two groups

## **5.5 Sampling method**

Random block sampling; Consenting patients were randomly assigned to two groups; group GA and group spinal using computer generated tables with blocks of 4 and allocation of 1:1.

### **5.5.1 Inclusion criteria;**

1. Women who gave informed consent to take part in the study
2. ASA 1 and 2 patients

### **5.5.2 Exclusion criteria**

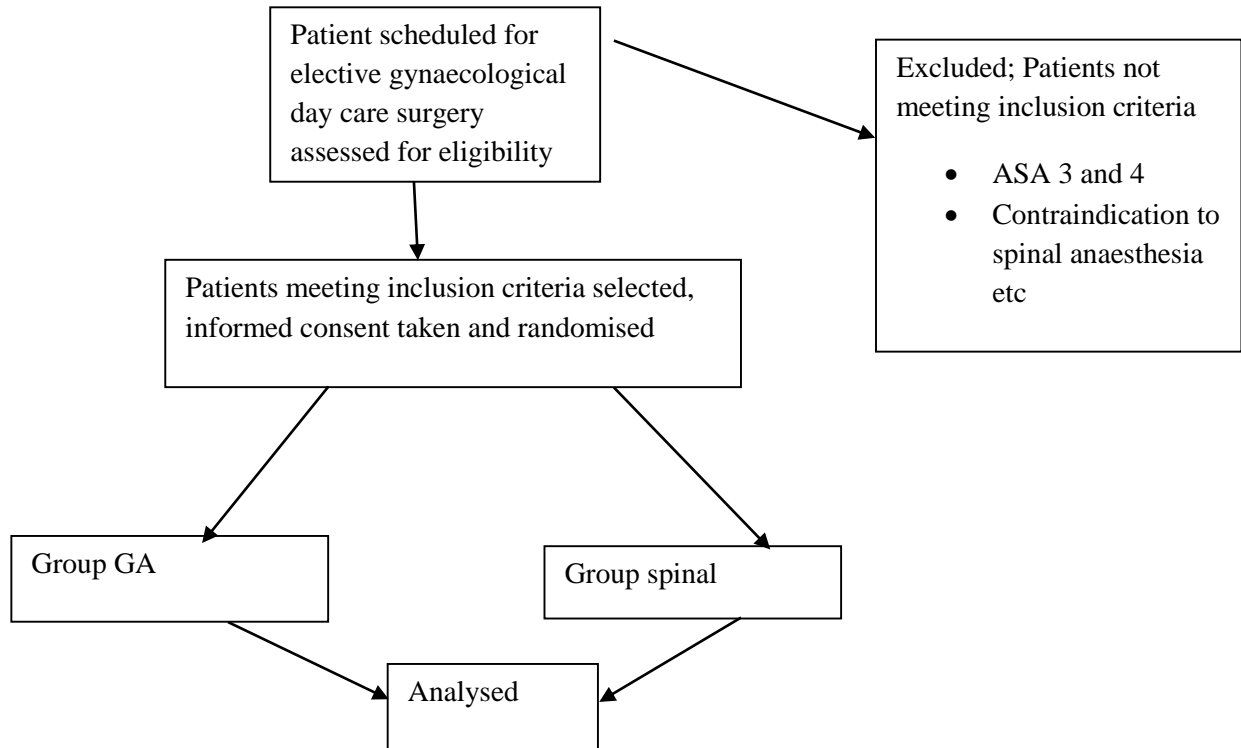
1. Patients who refused to give consent
2. ASA 3 and 4
3. Contraindications to spinal anaesthesia
4. Hypersensitivity to any of the study drugs
5. Neurological and neuromuscular disorders
6. Patient with conditions that made spinal anaesthesia more desirable e.g. possibility of difficult airway.
7. Inability to use visual analogue scales
8. Emergency surgery.

## **5.6 Recruitment**

Patients who were scheduled for elective gynaecological procedures on day care basis were recruited into the study after giving informed consent. Those who met the inclusion criteria were randomly allocated to either general or spinal anaesthesia group using computer generated tables.

They were familiarized with the visual analogue scale for pain and visual analogue scale for post operative nausea and vomiting.

### CONSORT FLOW DIAGRAM



#### 5.6.1 General interventions for all patients

Once in the operating room, standardized monitors were applied to all patients. This included electrocardiogram, non invasive blood pressure and pulse oximetry. An intravenous cannula was inserted on all patients.

#### 5.6.2 General anaesthesia group

Patients in the GA group were induced with Propofol 2-3 mg/kg. An appropriate size of LMA was then inserted once the patient was unconscious. Anaesthesia was maintained with isoflurane 1-2% and 50% nitrous oxide in oxygen to maintain acceptable depth of anaesthesia. At five minutes before end of surgery, isoflurane and nitrous oxide was turned off and the patient received 100% oxygen. LMA was removed when the upper airway reflexes were fully recovered and when the patient opened eyes on request and could follow other requests.



### **Spinal anaesthesia group**

Spinal anaesthesia was given according to a set protocol (see appendix 5). 7.5 mg of heavy bupivacaine plus fentanyl 12.5 micrograms was diluted with sterile water to make a volume of 3 mls. This was given intrathecally.

In both groups, patients received metoclopramide 10mg and analgesics as determined by the anaesthetist. They were admitted to PACU post operatively.

### **Recovery**

Recovery times were determined at 1 minute intervals from the time nitrous oxide and isoflurane were switched off to the time the patient was able to open eyes on request and was oriented in time, place and person. Subsequent observations were made at 15 minute intervals until the patient has achieved discharge criteria.

Observations in PACU were done by the research assistants who were trained by the principal investigator. The time to achieve discharge criteria was recorded. Any post operative side effects were also recorded. Unplanned admissions were monitored for the duration of admission to PACU. Their PADS score, post operative nausea and vomiting and any other side effects experienced while in PACU were recorded. Reason for admission was also recorded. They were followed up in the ward by the principal investigator on the first postoperative day and thereafter as necessary.

## **6.0 DATA COLLECTION INSTRUMENTS**

Data was collected using standard questionnaires. Two research assistants were trained on data collection.

Details recorded included age, diagnosis, technique of anaesthesia used i.e. spinal or general anaesthesia, drugs used, duration of surgery, time of completion of surgery, time to fully awaken and removal of LMA, time to leave operating room, time to attain PADS score of 9(PAD score will be assessed every 15 minutes from when the patient is fully awake), any post operative nausea and vomiting and analgesic requirements in PACU.

Nausea was defined as awareness of the tendency to vomit. Vomiting was defined as forceful expulsion of gastric contents through the mouth. The visual analogue scale for postoperative nausea and vomiting and the visual analogue scale for pain were used to assess nausea and vomiting and pain respectively.

### **Bias minimization**

Selection bias was reduced by randomly allocating the patients to the two groups using computer generated tables. Events were recorded as they took place to minimise recall bias.

## **7.0 ETHICAL CONSIDERATIONS**

Approval to carry out the study was obtained from Kenyatta National Hospital/University of Nairobi (KNH/UON) ethics and research committee.

Informed consent was obtained from each participant.

No penalty was given for the patients who declined to give consent.

No incentives were given to those who gave consent to take part in the study.

Patients were closely and actively monitored for any complications.

Any adverse effects were managed as per protocols

All information obtained from the patient was treated with confidentiality.

## **8.0 DATA MANAGEMENT**

Prior to commencing data entry the principal investigator inspected all questionnaires for completeness. Data contained in the questionnaires was then entered into a customized database designed in Microsoft excel. The databases were customized based on study questionnaire with data stored in numeric coded format, and text responses entered for open ended questions. Range and consistency checks were built into the database as a quality assurance measure aimed at reducing data entry errors. Data was transferred from Excel database to SPSS for data cleaning and analysis. Data cleaning involved inspecting each variable in the database to check for outliers, invalid entries, and inconsistencies. In cases where data entry errors were noted cleaning involved validating entries by referring back to the study questionnaire using the unique study identifier contained in each questionnaire.

### **Data Analysis**

Data was analyzed using SPSS (version 21). Analysis was conducted in two stages, namely: univariable analysis and bivariabile analysis. For the univariable analysis, each single variable was analyzed using descriptive statistics namely mean and SD for continuous variables e.g. patient age and duration of recovery from anaesthesia. Frequencies and relative frequencies were calculated for categorical data e.g. clinical signs or type of examination procedure for which anaesthesia was administered. The primary outcome was determined by calculating the median duration (SD) to achieve standardized discharge criteria for patients in the general anaesthesia and spinal anaesthesia groups. The median duration to recovery in the two groups were compared using Wilcoxon rank sum test with the accompanying p value. Incidence of unplanned admissions was then calculated as the percentage of patients in each group scheduled for day care but who end up in inpatient care.

## 9.0 RESULTS

### Characteristics of participants

A total of 94 participants were recruited for this study. Forty nine were randomised to the general anaesthesia group while forty five were randomised to the spinal anaesthesia group.

There were no significant differences between the two groups as regards to age, ASA status, type of surgery and diagnosis (Table 9.1)

**Table 9.1: Characteristics of patients undergoing gynaecological procedures as day cases**

	Anaesthetic		P-value
	General	Spinal	
<b>Age</b>			
24-29 years	5(10.2)	2(4.4)	0.456
30-34 years	5(10.2)	5(11.1)	
35-39 years	3(6.1)	7(15.6)	
40-44 years	10(20.4)	4(8.9)	
45-49 years	7(14.3)	5(11.1)	
50-54 years	7(14.3)	12(26.7)	
55-59 years	2(4.1)	3(6.7)	
60-64 years	2(4.1)	1(2.2)	
65 years and above	8(16.3)	6(13.3)	
<b>ASA classification</b>			
ASA I	17(34.7)	11(24.4)	0.278
ASA II	32(65.3)	34(75.6)	
<b>Procedure</b>			
Examination under anaesthesia	27(55.1)	27(60.0)	0.473
Dilatation and currattage	13(26.5)	9(20.0)	
Polypectomy	1(2.0)	4(8.9)	
Excision	3(6.1)	1(2.2)	
Bilateral tubal ligation	2(4.1)	0(0.0)	
Marsupialisation	1(2.0)	1(2.2)	
Other	2(4.1)	3(6.7)	
<b>Diagnosis</b>			
Cervical cancer	21(42.9)	26(57.8)	0.299
AUB	13(26.5)	8(17.8)	
Vulval mass	4(8.2)	1(2.2)	
Cervical polyps	1(2.0)	3(6.7)	
Other	10(20.4)	7(15.6)	

The baseline vital signs were compared between the two groups. The mean systolic blood pressure was significantly higher in the participants receiving spinal anaesthesia 137 ( $\pm$ 19) mmHg compared to those who had general anaesthesia 129 ( $\pm$ 19) mmHg. There was no statistically significant difference in the mean diastolic pressures ( $p = 0.095$ ).

**Table 9.2: Comparison of baseline vital signs in patients undergoing gynaecologic procedures**

	Type of anaesthesia		P value
	General	Spinal	
Mean systolic BP (SD), mmHg	129( $\pm$ 19)	137( $\pm$ 19)	0.037
Mean diastolic BP (SD), mmHg	76( $\pm$ 12)	80( $\pm$ 10)	0.095
Median heart rate (range), beats/min	83(65-125)	85(61-125)	0.907
Median SPO2 (range), %	100(95-100)	99(94-100)	0.003
Median respiratory rate (range), breaths/ min	16(12- 20)	16(12-20)	0.955

There was a significant association between anaesthetic technique and the use of systemic opioids intraoperatively. 14.3% of participants in the general anaesthetic group received systemic opioids while none of the participants in the spinal anaesthesia group received systemic opioids. (p = 0.008).

**Table 9.3: Intraoperative use of systemic opioids among women undergoing gynaecologic procedures**

<b>Mode of anaesthesia</b>	<b>Systemic opioid use</b>	<b>Percentage</b>
General	7	14.3%
Spinal	0	0

The median duration of surgery in the general anaesthetic group was 19 minutes compared to 17 minutes in the spinal anaesthetic group (P=0.241)

**Table 9.4: Duration of surgery according to anaesthetic technique used in day case gynaecologic procedures**

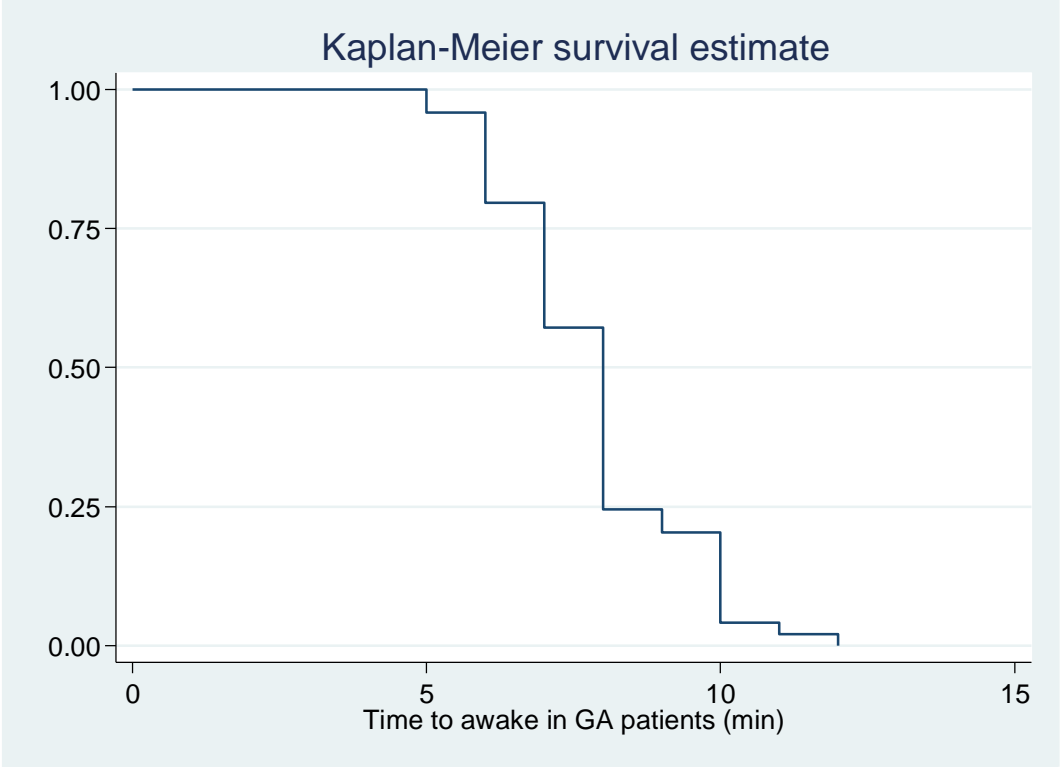
	<b>Type of anaesthesia</b>		<b>P</b>
	<b>General</b>	<b>Spinal</b>	
Median duration of surgery (min)	19(6-130)	17(10-57)	0.241



**Time to awaken in general anaesthesia**

At least half of all general anaesthesia patients were awake within 8 minutes of completing the surgical procedure (Figure 6.1). The range for the time to wake was between 5 and 12 minutes with interquartile range of 7 and 8 minutes.

**Figure 9.1: Kaplan Meier curve of time to awaken among general anaesthesia patients**



### **Difference in time to achieve standardized discharge criteria**

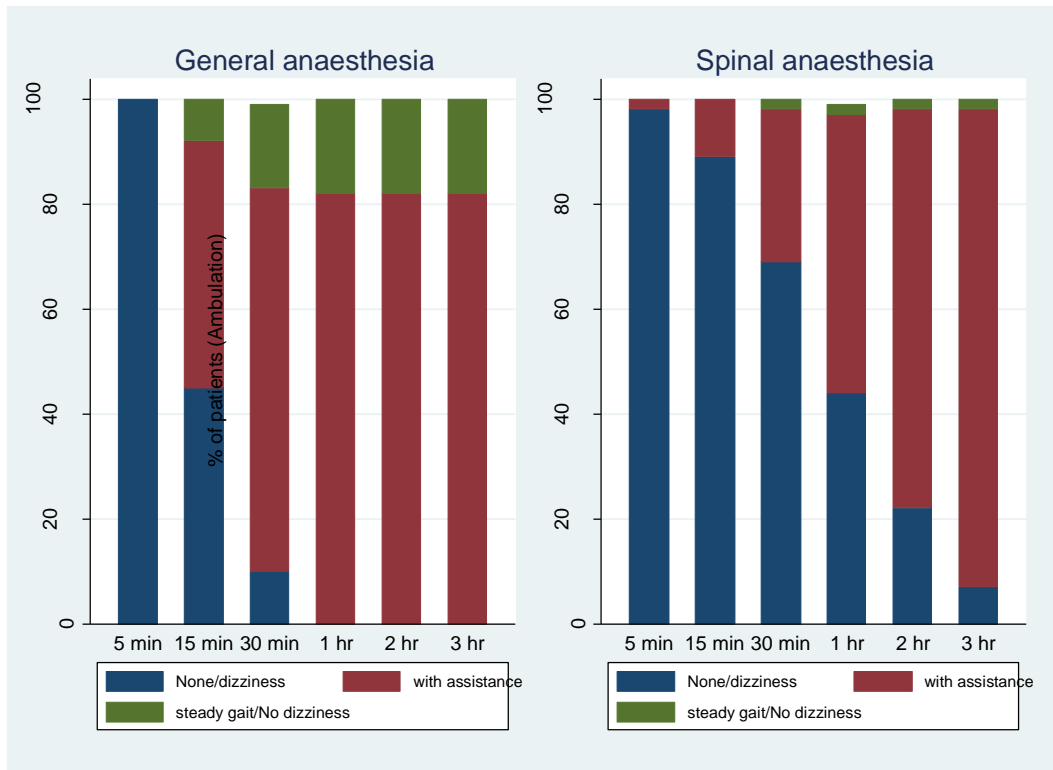
There was a significant difference in the time to achieve standardized discharge criteria between patients receiving spinal and general anaesthesia. The median time duration to attain PADS score 9 in general anaesthesia patients was 30 minutes compared to a median duration of 60 minutes ( $p < 0.001$ ) in the general anaesthesia group.

The five parameters used to derive the PAD score are vitals, ambulation, nausea, pain and surgical bleeding. Of these parameters only ambulation took a significantly longer time to achieve in the spinal anaesthesia compared to general anaesthesia group.

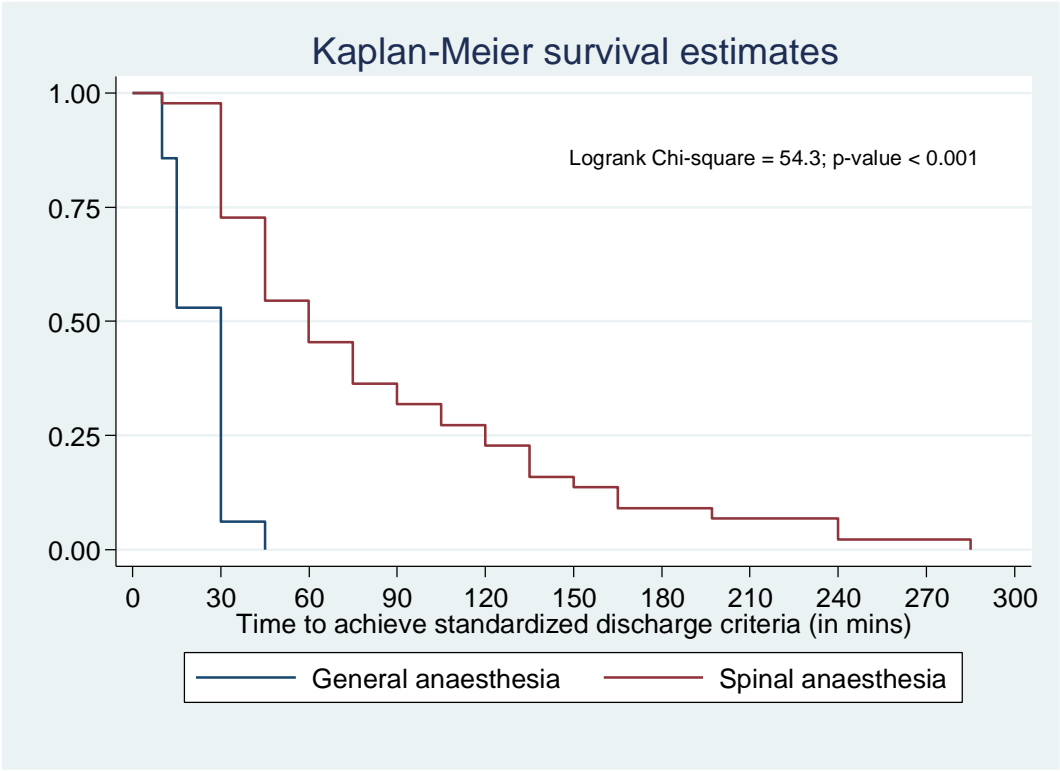
## Ambulation

All patients in the general anaesthesia group were ambulating either with assistance or had a steady gait at 1 hour while 44%, 22% and 7% of those in the spinal group had no ambulation at 1 hrs, 2 hr and 3 hr, respectively (Figure 9.2).

**Figure 9.2: Duration to achieving ambulation scores in general and spinal anaesthesia**



**Figure 9.3: Time to achieve standardized discharge criteria according to anaesthetic technique**



**Incidence of unplanned admissions**

There were no cases of unplanned admission in the general anaesthetic group while there was one unplanned admission in the spinal anaesthesia group giving an incidence of 1.1 admissions per 100 day cases undergoing gynaecologic procedures. This participant was admitted for monitoring due to severe surgical bleeding post vaginal hematoma drainage.

**Incidence of post-operative nausea and vomiting**

No cases of nausea and vomiting occurred in the general anaesthetic group. There was a single case of nausea and vomiting in the spinal anaesthesia group yielding an incidence of 1.1 cases per 100 day cases undergoing gynaecologic procedures.

## 10.0 DISCUSSION

The purpose of this study was to compare the recovery profile of general anaesthesia with spinal anaesthesia for day care gynaecological procedures.

The characteristics of the participants as regards to age, ASA score, diagnosis, type and duration of surgery were comparable. The mean age of the patients undergoing gynaecological procedures was 47.1 years (SD  $\pm$  13.2). There was no significant difference in the mean ages of patients undergoing general (46.8 SD  $\pm$  14.1) compared to spinal (47.5 SD  $\pm$  12.2) anaesthesia ( $p = 0.782$ ). The most common age group in the general anaesthesia group was 50-54 (26.7%) years and in the spinal anaesthesia group the modal age group was 40-44 years (20.4%).

There were 28 (29.8%) participant overall with ASA I score and 66 (70.2%) had ASA II score (table 4.1). ASA score was not significantly associated with anaesthetic technique used during day case gynaecological procedures ( $p = 0.278$ ). Among the patients undergoing spinal anaesthesia 75.6% had ASA II score compared to 65.3% of patients receiving general anaesthesia who also had ASA II score.

Participants in the spinal group remained fully awake and oriented throughout surgery and were transferred to PACU at the end of surgery. In the general anaesthesia group, participants took between 5 to 12 minutes to awaken after isoflurane and nitrous oxide was switched off. This is comparable to the time taken to awaken in a similar study by Steward et al (12) where the mean time to awaken was 11 minutes (SD 8.3). This may affect the patient turnover time.

The time to achieve standardized discharge criteria was significantly longer in the spinal anaesthesia group (median time 60 minutes) compared to general anaesthesia group (Median 30 minutes). This was mainly due to longer time to achieve ambulation in the spinal anaesthesia group. In Erhar et al (5) home readiness was delayed in the spinal anaesthesia group (158 minutes plus or minus 40.2) compared to GA group (94.9 plus or minus 18.8). In this study patients were required to void before discharge after spinal anaesthesia while voiding was not a requirement for discharge in our study.

In our study, the factors considered in the discharge criteria included Vital signs, Nausea and vomiting, pain, ambulation and surgical bleeding. Of these only ambulation took significantly

longer to achieve in both groups and even longer to achieve in spinal group compared to general anaesthesia. This is in contrast to a similar study (5) in which time to ambulate was comparable in the spinal and general anaesthesia (TIVA) groups. In this study (5), the mean ambulation time was 78.4 in spinal group compared to 75.9 minutes in TIVA group. The time to ambulation in this study (5) was longer than in our study despite use of lower dose of bupivacaine(5mg). The TIVA group in Erhar et al also took much longer to ambulate compared to the general anaesthesia group in our study.

The pain scores were found to be similar in the spinal and general anaesthesia groups. While none of the patients in the spinal group required intraoperative use of opioids, 14.4% of patients in the GA group had opioids administered intraoperatively. All the participants in the spinal group had good pain control postoperatively while 2% of participants in the GA group reported moderate to severe postoperative pain which resolved on administration of rescue analgesics. This findings were similar to a study by Bessa et al(6) in which all patients in the spinal anaesthesia group had good pain control while 3.3% had inadequate pain control requiring admission. Enhar et al also found that patients in the TIVA group had greater need for post operative analgesia compared to those in the spinal anaesthesia group. This findings suggest that spinal anaesthesia may be associated with better pain control and less use of opioids both in the intraoperative and post operative periods.

There was no marked difference in nausea scores among patients receiving general and spinal anaesthesia. Severe or moderate nausea was not reported in the general anaesthesia group and moderate nausea which occurred in 2% of patients in the spinal group resolved within 1 hour (after giving rescue antiemetics).All the patients received 10mg of metoclopramide intraoperatively. This could explain the low rates of occurrence of nausea. This was in contrast to a similar study by Bessa et al in which no patients in the spinal anaesthesia group experienced nausea and vomiting while 4.4% of patients in the GA group were admitted due to nausea and vomiting. The higher rates of nausea and vomiting in Bessa et al may be explained by the difference in procedures. Bessa et al looked at patients undergoing laparoscopic cholecystectomy while our study looked at non laparoscopic gynaecological procedures. In Enhar et al, it was found that 10% of the patients in

the TIVA group had nausea post operatively while none of the patients in the spinal anaesthesia had nausea.

There were no cases of unplanned admission in the general anaesthetic group while there was one unplanned admission in the spinal anaesthesia group giving an incidence of 1.1 admissions per 100 day cases undergoing gynaecologic procedures. This participant was admitted for monitoring due to severe surgical bleeding post vaginal hematoma drainage. In Bessa et al (6), all the patients in the spinal anaesthesia group were discharged on the same day while 8.9% of the patients in the general anaesthesia group were admitted. Of these patients, 4.4% were admitted due to nausea and vomiting, 3.3% due to inadequate pain control and 1.1% due to unexplained hypotension. These patients underwent laparoscopic cholecystectomy.



## **10.1 CONCLUSION**

This study demonstrated that patients undergoing daycare gynaecological surgery under spinal anaesthesia took much longer to achieve discharge criteria than those under general anaesthesia. This was due to time to ambulate which was much longer in the spinal group. The pain scores, nausea scores and unplanned admissions were comparable.

## **10.2 RECOMMENDATION**

Both spinal and general anaesthesia may be safely used for daycare gynaecological surgery with patients under spinal anaesthesia being scheduled earlier in the day due to the longer time taken to ambulate.

More studies may be required with smaller doses of bupivacaine to determine whether this may provide adequate anaesthesia while allowing faster ambulation post operatively.

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## **APPENDIX 1: CONSENT EXPLANATION**

My name is Dr Susan Kerubo Omundi. I am a postgraduate student specializing in anaesthesia. I am conducting a study to compare the recovery characteristics of spinal and general anaesthesia in day care surgery.

### *Background*

Day care surgery has gained popularity over the last two decades due to its advantages which include lower cost, reduced dependency on hospital bed availability and reduction of hospital acquired infections. Both general and spinal anaesthesia have been safely used in day care surgery. The anaesthetic technique used may have an effect on duration of recovery with longer recovery time leading to increased cost, reduced efficiency and even unplanned admissions.

### *Study purpose*

The purpose of this study is to compare the recovery profile of general anaesthesia with that of spinal anaesthesia for gynaecological day care surgery. This will help generate more knowledge on the effect of anaesthetic technique on recovery.

### *Voluntariness of participation*

Your participation in this 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 victimization. Your participation will not interfere with the regular management of your condition before, during or after surgery. You 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 probably improved efficiency in our day care unit in future.

### *Confidentiality*

All the information provided will be kept confidential and will only be used for research purpose. 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 for this study you will be randomly assigned to either spinal anaesthesia or general anaesthesia group. Both techniques are usually used but it is not known which one offers better recovery profile.

The complications of spinal anaesthesia include hypotension, headache and total spinal anaesthesia. The complications of general anaesthesia include nausea and vomiting and airway related complications.

On completion of the planned procedure the following data will be recorded; occurrence of nausea and vomiting, time to ambulation and time to readiness for discharge.

#### *Risks of participation*

Both spinal and general anaesthesia may be associated with complications as mentioned above. Participation in this study does not increase the incidence of these complications. You will be monitored for any of the complications and they will be managed appropriately should they occur

#### *Benefits of Participation*

There will be no direct benefit to you for participating in the study but your participation will help in knowledge generation and probably improved efficiency in our day care unit in future.

#### *Right to withdraw*

You are free to withdraw from this study at any point without victimization

#### *Study approval*

This study is being conducted with the approval of The Kenyatta National Hospital/University of Nairobi's Ethical and Research Committee.

For any clarifications or queries kindly contact: Dr. Susan Omundi-0721287258

You may also reach one of my supervisors as follows:

Dr. Susan Nabalindo-0721418587

Dr. Jane Gwaro-0722749667

Dr Lee Ngugi-0722757875

In addition, for any queries on ethical issues, contact:

Professor Chindia,

Secretary KNH/UON Nairobi Ethical and Research Committee – 020726300-9

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

**CONSENT FORM**

I,..... after being fully explained to by Dr. Susan Omundi 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 receive.  
Signature (Participant)..... Date.....

Name and Signature (Investigator).....

Designation..... Date.....

Name of principle investigator; Dr Susan Kerubo Omundi

Phone Number; 0721287258

Email address; [Skerubo85@gmail.com](mailto:Skerubo85@gmail.com)

Supervisor; Dr Susane Nabulindo

Phone number; 0721418587

Email address;nabulindosusane@gmail.com

Professor Chindia,

Secretary KNH/UON Nairobi Ethical and Research Committee – 020726300-9

Email; [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)

## **UFAFANUZI WA MAKUBALIANO**

Jina langu ni Daktari Susan Omundi, mwanafunzi katika chuo kikuu cha Nairobi. Ninafanya utafiti kuelewa tofauti ya anaesthesia ya kulala kabisa na ile ya kufa ganzi kutoka kwa kiuno mpaka kwa miguu katika upasuaji unaofanywa mchana na mgonjwa kupewa ruhusa ya kuenda nyumbani siku hiyohiyo. Aina zote mbili za anaesthesia zingali zinatumiwa katika upasuaji. Aina inayotumiwa yaweza kurefusha ama kufupisha muda wa kukaa hospitalini

### *Nia ya utafiti*

Utafiti huu una nia ya kulinganisha muda ambao mgonjwa anachukua ili kuwa tayari kupewa nafasi ya kuenda nyumbani anapopewa anaesthesia ya kulala kabisa na anaesthesia ya kudungwa sindano kwenye uti wa mgongo. Hii ina maana kwa sababu itasaidia katika kuimarisha matibabu.

### *Kujumuishwa kwako*

Kushiriki kwenye utafiti huu ni kwa hiari yako na una uhuru wa kujiondoa wakati wowote bila hofu ya kudhulumiwa .

### *Siri*

Majina yako na mambo yote tutakayoyajua kukuhusu yatabaki siri na yatatumika tu kwa sababu ya utafiti.

### *Jinsi utafiti utakavyofanyika*

Baada ya kupeana idhini, washiriki watajumuishwa kwa makundi mawili ambayo yataorodheshwa kama vile bahati nasibu. Wagonjwa katika kundi moja watapewa anaesthesia ya kulala na kundi la pili watapewa anaesthesia ya kuganda kutoka kwa kiuno hadi kwa miguu.

Aina zote za anaesthesia kawaida huwa na madhara. Anaesthesia ya kulala inaweza sababisa madhara kama kutapika, kuhisi kutapika na shida za kupumua. Anaesthesia ya kudungwa kwenye uti wa mgongo inaweza sababisha kuumwa na kichwa na pia pressure ya mwili kushuka..

Madhara yoyote yatakayotokea yatatibiwa.

Katika utafiti huu tutaangalia nambari ya wagonjwa watakaohisi kutapika na wale watakaotapika, muda wagonjwa watachukua kuweza kutembea na muda wagonjwa watakaochukua kuwa tayari kupewa ruhusa ya kuenda nyumbani



Madhara ya kushiriki katika utafiti

Aina zote mbili za anaesthesia kawaida zaweza sababisha madhara kama nilivyolueleza lakini Utafiti huu hauna madhara ya ziada kwako. Madhara yoyote ambayo yatatokea wakati wa oparesheni yatatatuliwa mara moja.

Manufaa ya kushiriki katika utafiti

Kushiriki katika utafiti huu hakutakuwa na manufaa yotote kwako kibinafsi lakini utafiti huu utatusaidia katika kuhimarisha matibabu ya wagonjwa hapo baadaye.

Uhuru wa kujiondoa

Kushiriki kwenye utafiti huu ni kwa hiari yako na una uhuru wa kujiondoa wakati wowote bila hofu ya kudhulumiwa.

Idhini ya utafiti

Utafiti huu umeidhinishwa na KNH/UON Ethics and Research Committee

Ikiwa utakubali kushiriki, tafadhali tia sahihi au kidole gumba kwenye fomu ya makubaliano ya kushiriki ambayo utapewa hivi punde.

Nambari yangu ya simu ni:

Dr. Susan Omundi

0721287258

## **FOMU YA IDHINI YA KUSHIRIKI**

Mimi....., baada ya kuelezewa kwa kina sababu, manufaa, madhara na kupewa hakikisho ya kuweka siri jina angu, nakubali kwa hiari kushiriki katika utafiti huu. Sitalipishwa chochote kwa kushiriki katika utafiti huu, na sitalipwa kwa njia yoyote. Nimehakikishiwa kwamba nikikataa kushiriki katika utafiti huu, sitadhulumiwa kwa njia yoyote ile.

Sahihi (mshiriki)..... Tarehe.....

Jina na sahihi (Daktari)..... Tarehe.....

Jina la mtafiti ; Dr Susan Kerubo Omundi

Nambari ya simu; 0721287258

Email; [Skerubo85@gmail.com](mailto:Skerubo85@gmail.com)

Msimamizi ; Dr Susane Nabulindo

Nambari ya simu ;0721418587

Email;nabulindosusane@gmail.com

Professor Chindia,

Katibu Mkuu KNH/UON Nairobi Ethical and Research Committee

Nambari ya simu; 020726300-9

Email; [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)

## APPENDIX 2: BUDGET

<b>ITEM</b>	<b>UNIT COST</b>
Stationery	5000
Printing and binding	7000
Internet	5000
Research assistant	20000
Statistician	20000
Ethics and research committee	2000
<b>TOTAL</b>	<b>59,000</b>

## APPENDIX 3: DATA COLLECTION TOOL

Serial number;

1. Biodata

- Research number; .....
- Age.....

2. ASA Score.....

3. Diagnosis.....

- Procedure.....

4. Anaesthetic technique (tick as appropriate)

- Spinal anaesthesia (Bupivacaine).....
- General anaesthesia.....

5. Baseline vital signs;

- Blood pressure.....
- Heart rate.....
- SPO2.....
- Respiratory rate.....

5. Systemic Opioids used intraoperatively?

- Yes.....
- No.....

6. Duration of surgery.....

7. PADS Score

Modified post anaesthetic discharge scoring system

	5Minutes	10minutes	15minutes	30minutes	45min	
1.Vital signs 2=within 20% of preoperative value 1=20-40% of preoperative value 0=40% of preoperative value						
2.Ambulation 2=steady gait/No dizziness 1=with assistance 0=None/dizziness						
3.Nausea 2=minimal 1=moderate 0=severe						
4.Pain 2=minimal 1=moderate 0=severe						
5.Surgical bleeding 2=Minimal 1=moderate 0=severe						
Total						

8. Post operative nausea and vomiting

- Yes.....
- No

9. Time ready for discharge (PADS Score 9).....

10. Reason for admission (if admitted to the wards).....

**APPENDIX 4: PROTOCOL FOR SPINAL ANESTHESIA (adapted and modified from the KNH spinal anaesthesia protocol for caesarian section)**

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

Spinal Tray should contain:-

- a) Sterile towels for draping the patient
- b) 2 gully pots for holding cleaning solutions
- c) Appropriate spinal needle (with introducer where required)
- d) 2 syringes & Needles
  - i. 5ml syringe for infiltration of L.A to the site
  - ii. 2ml syringe for administering the spinal medication
  - iii. Sterile gauze pads for cleaning & dressing
9. Reconfirm the position of the patient (knee chest)
10. Identify the site: mid-line L3-4/ 4-5 & administer 3ml of 1% lignocaine using a gauze 21 needle to maximum depth. Withdraw the needle as you continue to administer L.A and raise a skin wheal.
11. Give 1-2 minutes for the L.A to take effect as you re-assure & position patient (if administered well, this usually covers one vertebra above & below, should you need to alter position of lumbar puncture)
12. While waiting for L.A to take effect, prepare heavy bupivacaine 7.5mg(1.5mls) add 12.5mg of fentanyl and dilute with distilled water to a volume of 3mls.
13. Confirm the L.A has taken effect and note level/site for the block.

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

14. Administer the drug, dress the puncture site and position the patient appropriately to allow planned distribution of drugs. Rapid positioning after administration is critical.
15. Start your post-spinal monitoring & make adjustments accordingly. It is recommended to repeat BP readings at 1 minute intervals. You will need to respond rapidly to the initial changes in pulse & BP. Ask the patient to inform you immediately if nausea occurs. Nausea in spinal anaesthesia is most likely due to hypotension. It is an early warning sign that you must not ignore.
16. Test the level of the block. The tilt of the bed may have to be adjusted if using hyperbaric Local Anaesthetic to change drug distribution. This manipulation may only work within the first 10-20 minutes after administration of the L.A into the CSF.
17. Critical observation
  - a) Pulse –symptomatic bradycardia–Atropine 0.1 -0.6mg
  - b) SPO2 saturation  $\leq 90\%$  - Increase the O2 flow.
  - c) BP –symptomatic Hypotension
    - Ephedrine -5mg-10mg PRN (you may occasionally need an infusion)
    - Phenylephrine
    - Adrenaline
  - d) Respiration –falling respiratory rate (usually temporary)
    - Give oxygen
    - Assist with respiration briefly if required
    - Reassure
  - e) Total Spinal Anaesthesia
    - i. Convulsions /loss of consciousness
    - ii. Respiratory failure
    - iii. Cardiovascular collapseIntubate, ventilate, cardiac massage, vasopressors, anticonvulsants till vital signs stabilize.



f) Post spinal headaches

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

Management

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

18. Post-Operatively –monitor BP ¼hourly for 2hrs.

Positioning –make patient comfortable with pillow under the head.