DISSERTATION

UNIVERSITY OF NAIROBI-COLLEGE OF HEALTH SCIENCES.

An Observational study on blood transfusion requirements in patients undergoing Total Abdominal Hysterectomy /Myomectomy for Uterine Fibroids in Kenyatta National Hospital

PRINCIPAL INVESTIGATOR:

DR. LINDA KAMATHI NGUU, (MBCh.B).

REGISTRATION NUMBER, H58/69779/2013.

POST-GRADUATE STUDENT IN ANAESTHESIOLOGY.

SUPERVISORS:

DR. MARK GACII, MBCh.B, M.Med. (Anaesthesia).

DR. EMMA MUTIO, MBCh.B, M.Med . (Anaesthesia).

A Dissertation submitted to the Department of Anaesthesia, School of medicine in partial fulfilment of the requirements for the award of the degree of Master of Medicine in Anaesthesiology of University of Nairobi.

DECLARATION

This Dissertation is my original work and has not been presented for a degree or any other purposes in any institution.

Signature……. Date…….

Dr. Linda Kamathi Nguu, MBCh.B.

Registration Number: H58/69779/2013.

Postgraduate student in Anaesthesiology.

University of Nairobi.

This proposal/thesis has been submitted for examination with our approval as the university supervisors.

Signature…….. Date……

Dr. Mark Gacii, MBCh.B, M.Med (Anaesthesia)

Lecturer, Department of Anaesthesia, University of Nairobi

Anaesthesiologist, Kenyatta National Hospital.

Signature……. Date……

Dr. Emma Mutio, MBCh.B, M.Med (Anaesthesia),

Pediatric anesthesiologist.

Mbagathi District Hospital.

Nairobi.

DEDICATION

To my parents Mr. & Mrs. Justus Nguu for their unwavering love, guidance and support throughout my life, education and career

To my beloved husband Darius Njenga Waithaka who has stood by me throughout my career and being the ever supportive friend

To my precious daughter Leilani Moraa Njenga who has given me a reason to push on.

To all my teachers who have held my hand through my education

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LIST OF ABBREVIATIONS

TAH-Total Abdominal Hysterectomy

Hb-Haemoglobin

g/dl-Grams per decilitre

GnRh - gonadotropin-releasing hormone

MRI- Magnetic Resonance Imaging.

U.O.N- University of Nairobi.

KNH-Kenyatta National Hospital

WHO- World Health Organization.

ERC- Ethics and Research Committee.

IV- Intravenous.

SPSS-Statistical Package For the Social Sciences

GA-General Anaesthesia

ASA-American Society of Anaesthesiologist's physical status classification.

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ABSTRACT

Background:
Uterine fibroids are benign monoclonal tumors of the uterine myometrium that often appear during childbearing years. In Kenyan Public hospitals, surgery for Uterine Fibroids is mainly by Total abdominal hysterectomy and Myomectomy.

Kenyan County hospitals have infrastructural challenges lacking enough storage facilities for blood and blood products. Therefore they depend on the regional transfusion centres that transport blood to the various centres. Kenyatta National Hospital, which is situated next to the National Blood transfusion centre also, has challenges when it comes to blood transfusion. This is because it is usually affected by acute shortage of blood and blood products that occur from time to time.

Also, KNH being one of the 2 main National Referral Hospitals tends to admit a large number of patients requiring emergency blood transfusion. Thus when patients in need for elective surgeries have borderline Haemoglobin levels and there is no available blood on standby in the hospital, surgeries are cancelled and postponed to a later date when blood will be made available.

There are however no studies in Kenyatta National Hospital that show the incidence of blood transfusion for TAH and Myomectomies perioperatively.

Overall objective:
To determine blood transfusion rates in patients undergoing total abdominal hysterectomy or myomectomy for uterine fibroids in Kenyatta National Hospital.

Methodology:
A prospective observational study was conducted among patients undergoing TAH and myomectomy for uterine fibroids in Kenyatta National Hospital. This was done over a 2 month period with the help of 1 research assistant. Preoperative haemoglobin levels, size of fibroids from the ultrasound reports and /or clinical examination were taken and recorded. Intraoperatively, the estimated blood loss was recorded and 24 hours post-operatively haemoglobin level was taken. The data collected was analysed using computer statistical package for the social sciences (SPSS) version 22.

Results: The mean age of patients was 41.9 (SD ± 8.8) years, range 22 to 60 years. The modal age group was between 40 and 49 years with 24 (37.5%) patients being in this age group. There were 23 (35.9%) women who had previously lost a pregnancy, and 39 (60.9%) were multiparous. The mean BMI among the patients was 27.7 (SD ± 6.7) and 26 (41.3%) patients were overweight. Of the 64 patients undergoing total abdominal hysterectomy or myomectomy for uterine fibroids 19 were transfused yielding an intraoperative blood transfusion rate of 30% (95% CI 18.9 to 42.4%). No significant association between BMI and Blood transfusion rate.

There was a significant association between transfusion rate and ASA classification (p = 0.019). The transfusion rate in patients in ASA II was 44.4%, approximately four times greater (OR 4.0, 95% CI 1.25-12.75) than that in ASA 1 (16.7%). The mean haemoglobin declined by 0.2 units in the 24-hour postoperative period but his change was not statistically significant (p = 0.329).

Conclusion: The mean change of Hb in TAH/Myomectomy is 0.5 g/dl thus patients with Hb of 10g/dl and above may proceed with surgery. Thus there have been a number of unnecessary cancellations for patients who have Hb of 10 and above because of lack of blood on standby.

The size and number of Fibroids may affect amount of blood loss.

Increase in ASA status also is associated with increase in blood loss and other perioperative complications.

Recommendations: Need for proper preoperative evaluation of patients scheduled for surgery as this may enable on to predict whether or not the patient will lose a lot of blood intraoperatively.

Proper documentation especially on the uterine size will enable a care provider to predict Intraoperative events.

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CHAPTER ONE

1.0 INTRODUCTION

Uterine fibroids are benign monoclonal tumors of the uterus that often appear during childbearing years. Also known as leiomyomas or myomas, uterine fibroids develop from the smooth muscular tissue of the uterus (myometrium). A single cell divides repeatedly, eventually creating a firm, rubbery mass distinct from nearby tissue. The growth patterns of uterine fibroids vary — they may grow slowly or rapidly, or they may remain the same size. Some fibroids go through growth spurts, and some may shrink on their own. Despite the fact that their cause is still unknown, there is considerable evidence that estrogens and progestogens proliferate tumor growth as the fibroids rarely appear before menarche and regress after menopause.

Uterine fibroids are the most common benign tumors in women and the leading indication for hysterectomies in the USA. It is estimated that approximately one in three women in the United States has undergone hysterectomy by the age of 60 years[1]. Uterine fibroids account for approximately 67% of all hysterectomies performed in middle-aged women[2]. The associated burden in health care costs and morbidity are not trivial. Most are assymptomatic, however they may present with menorrhagia, dysmenorrhoea, pelvic pain, infertility/ subfertility , recurrent pregnancy loss.

The exact aetiology of uterine fibroids is not clearly understood, but the current working hypothesis is that genetic predisposition, prenatal hormone exposure, and the effects of hormones, growth factors, and xenoestrogens cause fibroid growth. Known risk factors are African descent, nulliparity, obesity, polycystic ovary syndrome, diabetes, and hypertension.

Several studies have documented an increased incidence of uterine fibroids in African women[3]. Some evidence also indicates that African women are more likely than Caucasian women to have larger and more symptomatic fibroids at the time of treatment. After accounting for body mass index (BMI) and other known risk factors, African women experience a higher incidence and relative risk of uterine fibroids than other racial and ethnic groups including Caucasian, Hispanic, and Asian women[4,5,6].

A few studies have been conducted on this subject in Africa. The exact rate or incidence of uterine fibroids in the continent is not known. A United States Census Bureau and Population estimates report extrapolated the prevalence of uterine fibroids at 1,649,105 cases (approximately 10-20% of the women population) in Kenya[7].

Treatment of women with uterine leiomyomas must be individualized, based on symptomatology, the size and location of fibroids, age, the needs and desires of the patient for preservation of fertility or the uterus, the availability of therapy, and the experience of the therapist.

Hysterectomy is the definitive management for uterine fibroids however there includes other management option such as:

- Myomectomy
- Medical management e.g. Gn RH analogues
- Uterine fibroid embolisation

In Kenyan Public hospitals, surgery for Uterine Fibroids is mainly by Total abdominal hysterectomy and Myomectomy. This is carried out in most Level IV to VI Hospitals.

Hysterectomies have different approaches i.e. Abdominal, laparoscopic and vaginal.

An abdominal hysterectomy is performed by removing the uterus through a horizontal incision (cut) on the lower abdomen (pfannensteil incision). If the uterus is very large or if there is a scar from an earlier operation, it may be necessary to make a vertical incision on the lower abdomen. Total abdominal hysterectomy means removing the uterus and the cervix (the lowest part of the uterus). The usual hospital stay is 3 days. The typical recovery involves 6 weeks resting at home. Some women experience a complication that requires a longer recovery time.

For open myomectomy,a pffannesteil incision is made and the fibroids are removed from the wall of the uterus. The uterine muscle is sewn back together using several layers of stitches. The typical recovery involves 2 nights in the hospital and 4-6 weeks resting at home. In most hospitals in Kenya, the preferred approach of hysterectomies and myomectomies for uterine fibroids is Abdominal. This is due to lack for laparoscopic facilities.

County hospitals have infrastructural challenges where they lack enough storage facilities for blood and blood products. Thus they store limited amounts of blood and blood products that are meant to be used for emergency situations and also the elective surgeries. They have to depend on the regional transfusion centres to keep transporting blood to various centres. Thus when patients are in need for surgeries and have borderline Hb levels they are cancelled and surgery postponed to a later date when blood will be available. Kenyatta National Hospital, which is situated next to the National Blood transfusion centre also, has challenges when it comes to blood transfusion. This is because it is usually affected by acute shortage of blood and blood products that occur from time to time.

Also, KNH being one of the 2 main National Referral Hospitals tends to admit a large number of very sick patients requiring emergency blood transfusion. Thus when patients in need for elective surgeries have borderline Haemoglobin levels and there is no available blood on standby in the hospital, surgeries are cancelled and postponed to a later date when blood will be made available.

1.1 JUSTIFICATION

The most common benign gynaecological disorder in women of reproductive age in Kenya is uterine fibroids. Some of these are symptomatic and require myomectomy/ hysterectomy. There is however a high case cancellation rate / postponement due to lack of availability of blood.

In Kenya there are 6 National blood transfusion centres and 9 regional centres in the country. These centres derive blood from Kenyan population through campaigns or targeted donors. They then distribute to the hospitals all over the country. There may be certain delays in this distribution and thus many centres end up having blood shortage intended for transfusion. Therefore major surgeries like hysterectomies and myomectomies for uterine fibroids end up being cancelled due to unavailability of blood.

The National blood transfusion centre is next to the Kenyatta National hospital. However it being a National and referral hospital, it tends to have a large number of emergency cases

which are given priority in terms of blood transfusion. Thus when patients in need for elective surgeries for example in this case TAH/Myomectomies have borderline haemoglobin levels and there is no available blood on standby in the hospital, surgeries are cancelled and postponed to a later date when blood will be made available.

This leads to inconveniences especially on the part of the patient who is otherwise suffering from the burden of disease, increase in her healthcare costs and time spent going to hospital only for the surgery to be cancelled. There is also under utilization of surgeons who have undergone rigorous training to be able to perform these surgeries thus leading to demotivation.

My study therefore will help practitioners realize exactly how much blood is lost during TAH/Myomectomy surgeries for uterine fibroids and ultimately the need of blood transfusion during the perioperative period. In this way there will be objective decision making and pre operative preparation of the patient for surgery. This will avoid unnecessary cancellation of surgeries. Also there will be better utilization of the facilities in the county hospitals thus reducing the number of patients being referred to the referral hospitals .

1.2 OVERALL OBJECTIVE

To determine blood transfusion rates in patients undergoing total abdominal hysterectomy or myomectomy for uterine fibroids in Kenyatta National Hospital

1.3 SPECIFIC OBJECTIVES

i. To determine the intraoperative blood transfusion rate in patients undergoing total abdominal hysterectomy or myomectomy for uterine fibroids
ii. To determine haemoglobin changes in the 24 hour postoperative period compared to preoperative haemoglobin levels
iii. To determine estimated volume of blood loss in the intraoperative period and predictors of high volume loss

CHAPTER TWO

2.1 LITERATURE REVIEW

Myomatous uteri have an increased number of arterioles and venules and myomectomy may involve significant blood loss. Though associated with a high probability of recurrence, Myomectomies are considered safe option for hysterectomy for those who want to conserve fertility[8].Some studies have shown that myomectomies are associated with less blood loss compared to hysterectomies and also other complications e.g. visceral injury[9]. However, it has been shown that there is no difference in amount of blood loss hence no significant difference in haemoglobin changes between myomectomy and total abdominal hysterectomy for the large fibroid[10,11,12]. Another study by Unger JB showed that there was increase in blood loss with increase uterine weight in total abdominal hysterectomy[13].

The average volume of blood loss during abdominal myomectomy (performed via laparotomy, also referred to as open myomectomy) is 200 to 800 mL[10] and for laparoscopic myomectomy is 80 to 250 ml[10]. Surgical hemorrhage may result in anemia, hypovolemia, and coagulation abnormalities.

Hysterectomy is the definitive treatment for uterine fibroids. With subtotal hysterectomy, surgery is shorter and intraoperative blood loss and fever are reduced but women are more likely to experience ongoing cyclical bleeding up to a year after surgery with subtotal hysterectomy compared to total hysterectomy[14].

Newer methods have been used to perform hysterectomies and myomectomies i.e. laparascopic myomectomy and hysterectomy. Laparascopic myomectomy has been shown to be more superior to open myomectomy in terms of complications e.g. hemorrhage regardless of uterine size[15].

In two parallel randomised trials, one comparing laparoscopic with abdominal hysterectomy, the other comparing laparoscopic with vaginal hysterectomy carried out between 1996 and 2000, Laparoscopic hysterectomy was associated with a significantly higher rate of major complications than abdominal hysterectomy. It also took longer to perform but was associated with less pain, quicker recovery, and better short term quality of life. Blood transfusion rate in vaginal hysterectomy was 3% while that of abdominal hysterectomy was 2.5%.The trial comparing vaginal hysterectomy with laparoscopic hysterectomy was underpowered and was inconclusive on the rate of major complications[16]

Later in 2009 another study showed that there was less blood loss and hence lower drop in haemoglobin levels in laparoscopic hysterectomy than in abdominal hysterectomy. It also showed that vaginal hysterectomy had less blood loss than laparoscopic hysterectomy[17]. This change in complication rates compared to the previous trial is may be attributable to improvement in surgical skills with experience.

Anaemia has been shown to be the main risk factor and thus predictor for blood transfusion requirements in patients undergoing Hysterectomy for Benign Disease[18 ,19] . Low preoperative haematocrit, particularly haematocrit less than 30, is associated with increased risk of the need for a transfusion. Anaemic patients are more likely to have open procedures and higher blood loss for larger uterine fibroids. Iron deficiency anemia associated with menorrhagia or dietary deficiency is the most common cause of anemia in the gynecologic patient population. A preoperative hemoglobin of ≤10 g/dL is associated with a three-fold or higher increase in serious perioperative morbidity (cardiac events, respiratory failure, or serious bacterial infection) or mortality[20]. In women with abnormal uterine bleeding, a common symptom of uterine leiomyomas, laboratory testing for anemia should be part of the diagnostic evaluation.
There are pre operative measures that have been used to improve haemoglobin levels pre operatively i.e. Iron supplementation.

Preoperatively, GnRH agonists can help correct anemia by temporarily inducing amenorrhea. They also shrink the fibroids in size. However these agents make enucleation of fibroids more difficult by obscuring the tissue plane between the myoma and the myometrium. They also may increase the risk of persistent myomas, because small myomas would shrink in size and would not be palpable during myomectomy. Thus there is no evidence that use of GnRH agonists prior to myomectomy reduces the risk of blood transfusion and such use may increase operative difficulty and the risk of myoma persistence/recurrence.

Intraoperatively other methods have been employed to reduce intraopertive blood loss. These include Intramyometrial vasopressin injected into the planned uterine incision site for each fibroid reduces blood loss[21] . Vasopressin acts by constricting the smooth muscle in the walls of capillaries, small arterioles, and venules. Randomized trial data show that blood loss during myomectomy with vasopressin is significantly less than with placebo (299 mL less) and less than or comparable to use of a uterine artery tourniquet. Vasopressin use during myomectomy has been associated with rare cases of bradycardia, cardiovascular collapse, and death[22] ,[23], [24]and has thus not been approved by Food and Drug administration.

Uterotonics have been used during myomectomy. One small randomized trial [25] found that use of vaginal misoprostol (400 mcg, one hour before surgery) compared with placebo significantly reduced blood loss (149 mL less)

Some patients are advised to bank autologous blood, but this should be done only by patients with an appropriate hematocrit and sufficient time before surgery to avoid anemia at the time of surgery. Transfusion of banked autologous blood avoids some of the risks that are associated with allogeneic blood transfusion. One may also use intraoperative blood salvage using a cell saver in patients with significant blood loss (>300 ml). Thus patients are able to receive homologous blood transfusion.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Study design

A prospective observational Cohort study was conducted among patients undergoing TAH and myomectomy for uterine fibroids in Kenyatta National Hospital.

3.2 Study Site

The study was conducted at Kenyatta National Hospital in Nairobi. The main units where the study took place were Main theatre, Gynaecology wards and gynaecology outpatient clinics. Kenyatta National Hospital serves an estimated 30,000 daily traffic. The hospital has a 2000 bed capacity, 50 ward,24 theaters, with the following services: Accident and Emergency, Surgical Units both general and specialized units, Medical Units, Paediatric and New Born Units, Maternity and Gynaecoligical Units , Renal unit, Cancer Care Centre, Critical Care Units. Outpatient Services include: Dental Clinic, Opthalmology Clinic, ENT Clinic, Cardiology Unit, Antenatal, Family Planning, Surgical Outpatient Clinics, Medical Outpatient Clinics, Gynaecological Outpatient services, Paediatric Outpatient Clinics, Comprehensive Care Centre and many more. It also offers diagnostic service including laboratory, Radiological including CT Scan and MRI.

3.3 Target population

The study population included all ASA I and II patients with uterine fibroids undergoing TAH/Myomectomy in Kenyatta National Hospital.

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion criteria

1. All patients uterine fibroids undergoing TAH/Myomectomy who have given consent
2. Patients with haemoglobin levels of 8g/dl and above
3. ASA I and II patients

3.4.2 Exclusion criteria

1. Patients who declined to be enrolled in the study
2. Patients who have haemoglobin levels less than 8g/dl
3. ASA III and IV patients
4. Patients with bleeding disorders

3.5 Sample size estimation

Considering finite number of patients with uterine fibroids undergoing total abdominal hysterectomy or myomectomy in Kenyatta National Hospital, the Cochran's formulae for estimating sample size was used with a finite population correction as suggested by Daniels WW (1999)[26].

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

N = the population of patients with uterine fibroids undergoing total abdominal hysterectomy or myomectomy in Kenyatta National Hospital during a two month period (corresponding to the study period).

P = perioperative blood transfusion rate reported in South west Nigeria in 2011 where they were carrying out a clinical study on uterine leiomyomata, their management and outcome(12.8%)[27]

1-P = 1 minus the intraoperative blood transfusion rate (1-0.01 = 0.99)

Z = Z statistic representing 95% level of confidence (1.96)

d = desired level of precision set to 0.5% (0.005)

$$n = \frac{N \times 1.96^2 0.002(1-0.06)}{0.005^2(N-1) + 1.96^2 \times 0.01(1-0.06)}$$

sample size =64

Assumptions

1. That all the uterine fibroids have not undergone malignant transformation as histologies are done post operatively
2. That all surgeons have similar surgical technique and surgery time

3.6 Data management

3.6.1 Data collection

This was done over a 2 month period with the help of 1 research assistant. Eligible patients were recruited from Gynaecology ward. Informed consent was obtained from the patients through explaining the purpose and procedure of the study, as well as assurance of confidentiality of the information obtained. Once the patient understood the study, they were requested to consent and confirm their participation in the study by writing their identification

number and signing the informed consent form provided by the principle researcher or by the research assistant. All the patients enrolled in the study had preoperative pelvic ultrasounds done to diagnose the uterine fibroids and also to estimate the size of the fibroids.

The principle researcher / the research assistant took all the pre-operative haemoglobin and haematocrit levels, size of fibroids from the ultrasound reports and clinical examination .The preoperative haemoglobin levels were valid upto 2 weeks before date of surgery. During the surgery the estimated blood loss was recorded. Intraoperative estimated blood loss was quantified from the amount of blood from suction machines, abdominal packs and gauzes

24 hours after surgery post-operative haemoglobin and haematocrit levels were taken. Prior to the commencement of collection of data, the research assistant was trained to ensure that data will be collected in a standard manner and thus minimize person to person variability.

3.6.2 Study tool

A questionnaire was filled to capture all the variables. It was be filled by myself or research assistant.

Study variables

1. Number of patients who will undergo perioperative blood transfusion
2. Intraoperative estimated blood loss
3. Haemoglobin level changes preoperatively and 24 hrs postoperatively

3.6.3 Data handling

Quality control measures were implemented prior to data collection to reduce errors in data. This included training of research assistant on study procedures, interviewing and data recording on the study tools. Additional measures included developing standard operating procedures (SOPs) and data collection manual to guide data collection. I supervised all data collection. Upon receiving the completed questionnaire form, I examined all questionnaires for completeness. This was done at every stage of data collection including initial contact in the ward before surgery, intraoperatively and 24 hours post operatively.

All incomplete questionnaires were completed by referring back to patient record and in cases where data is missing from records a code was assigned for missing values. Data was entered

into databases designed in MS Office Access (2007). The databases were customized using the study questionnaire structure with data stored in numeric coded format, and text 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 Access databases to SPSS for data cleaning and analysis. Data cleaning involved inspecting each variable in the database to check for invalid entries, and inconsistencies using SPSS procedure for summarizing variables. 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. Any inconsistency between the questionnaire and data contained in the database will be resolved by checking patient records and re-entering the data contained in the records.

3.6.4 Data analysis

Data was analyzed using SPSS (IBM version 21 or 22. Analysis was conducted in three stages, namely: univariable analysis, bivariable analysis and multivariable analysis. For the univariable analysis, each individual variable in the dataset will be analyzed using descriptive statistics. During this stage continuous variable like age and duration of surgical procedure were analysed by calculating mean and standard deviation for normally distributed variables and median and ranges for skewed variables.

Categorical variables were analyzed using frequencies, and relative frequencies or percentages calculated using the relevant denominator values and presentation done by using frequency distributions. The main objective related to determining incidence of blood transfusion during myomectomy and total abdominal hysterectomy involved calculation of a percentage with the number of transfused patients as numerator and the total number of study patients as denominator.

The numerator included patients meeting the criteria of perioperative transfusion comprising questions contained in the questionnaire. Analysis of the factors associated with perioperative transfusion involved calculating the percentages of patients with each of the factors namely:

size of the uterine fibroids, length of surgery. Next, bivariate analysis was conducted by cross tabulating each factor with the dependent variable.

Depending on how commonly perioperative transfusion occurs then statistical tests were used to compare the prevalence of these factors in patient who underwent perioperative blood transfusion. For continuous factors for example age, mean age in patients with and without perioperative transfusion were compared using Student's t-test. Comparison of percentages across levels of categorical independent variables were done using Chi square test or Fisher's exact test. Statistical significance was based on an alpha cut-off level of 0.05. The final stage of analysis was a multivariable analysis conducted using logistic regress for binary outcomes represented by the percentage of patients with documentation for each dependent variable. The independent variables in the logistic regression included all variables showing significant association with quality of care in the bivariate analysis. Odds ratios and 95% confidence intervals were reported from the multivariable analysis.

3.7 Ethical considerations

The study protocol was reviewed by the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee and was undertaken once approval was given. Participants in the study were enrolled after the nature of the study was explained to them and informed consent obtained. Confidentiality of information obtained from the participants was strictly adhered to at all times. There were no additional costs to the patient for participating in the study and no treatment was withheld from non-consenting patients. Patients found to be anaemic at any point during the study appropriate interventions were taken in form of haematinics and /or blood transfusion.

Study findings will be availed to the Ethics Committee of Kenyatta National Hospital and the University of Nairobi.

3.8 Challenges

1. There were a number of challenges that affected data collection eg Doctors' , Nurses' strikes, leading to delay in data collection
2. Record keeping paused a challenge as some parameters were missing from the patients' records

CHAPTER 4: RESULTS

4.1 Sample characteristics

A total of 64 patients undergoing TAH or myomectomy were recruited into the study. Table 1 presents the characteristics of the TAH and myomectomy patients in KNH. The mean age of patients was 41.9 (SD ± 8.8) years, range 22 to 60 years. The modal age group was between 40 and 49 years with 24 (37.5%) patients being in this age group. There were 23 (35.9%) women who had previously lost a pregnancy, and 39 (60.9%) were multiparous. The mean BMI among the patients was 27.7 (SD ± 6.7) and 26 (41.3%) patients were overweight.

Table 1: Biodata of patients undergoing TAH or myomectomy in KNH

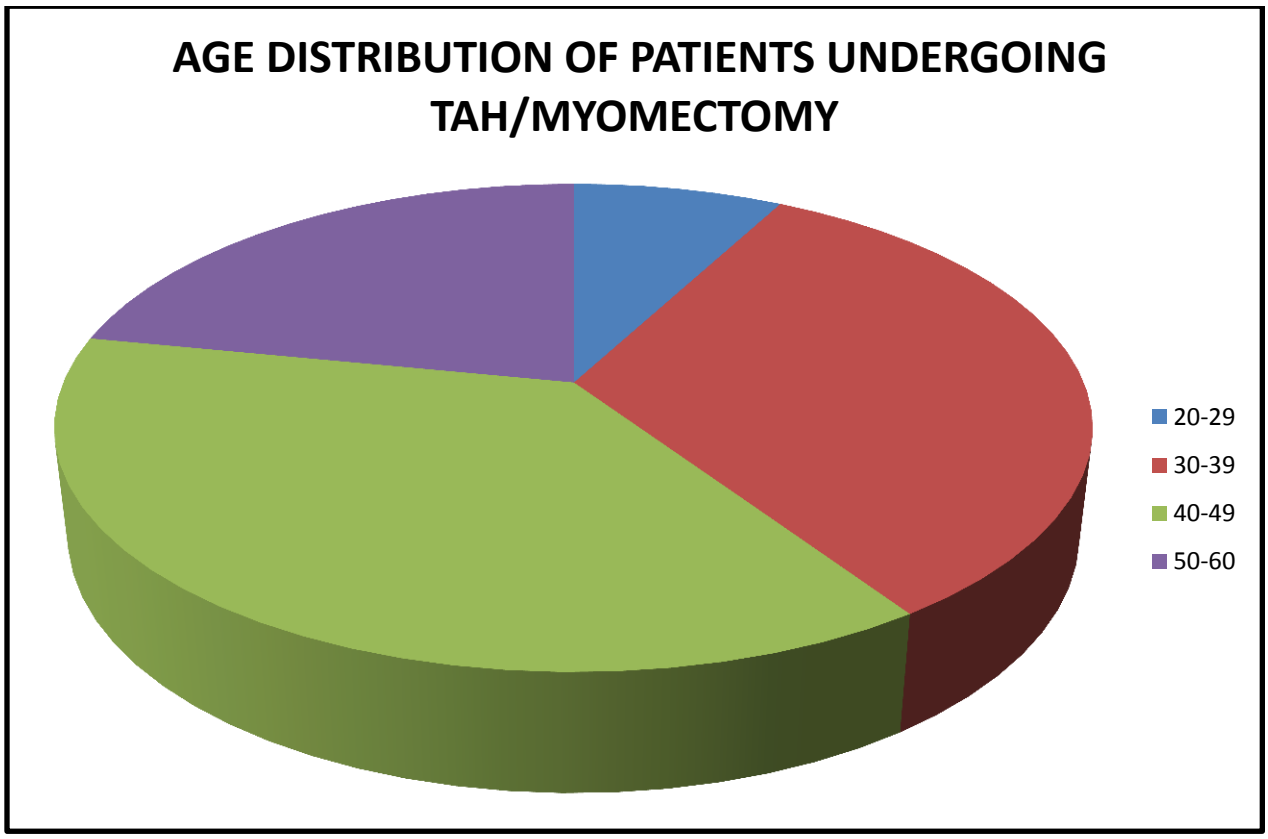
	Frequency (n)	**Percent (%)**
Mean age (SD)	41.9*	8.8**
Age group		
20-29 years	5	7.8
30-39 years	21	32.8
40-49 years	24	37.5
50-60 years	14	21.9
Previous pregnancy loss		
No	41	64.1
Yes	23	35.9
Parity		
Nulliparous	9	14.1
Primiparous	9	14.1
Multiparous	39	60.9
Grand multiparity	7	10.9
Mean BMI (SD)	27.7*	6.7**
Underweight	3	4.8
Normal weight	18	28.6

Overweight	26	41.3
Obesity	16	25.4

*figure represents mean

**figure represents SD

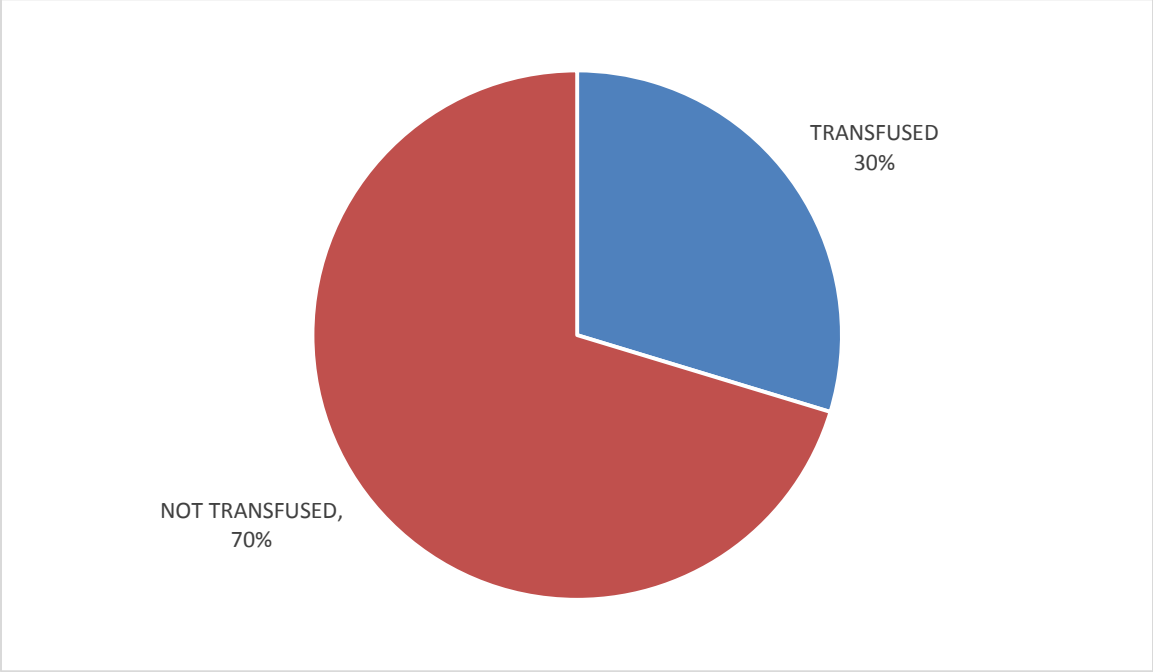
Fig. 1: Percentage age distribution of patients undergoing Myomectomy/TAH in KNH



4.2 Intraoperative Blood Transfusion Rate

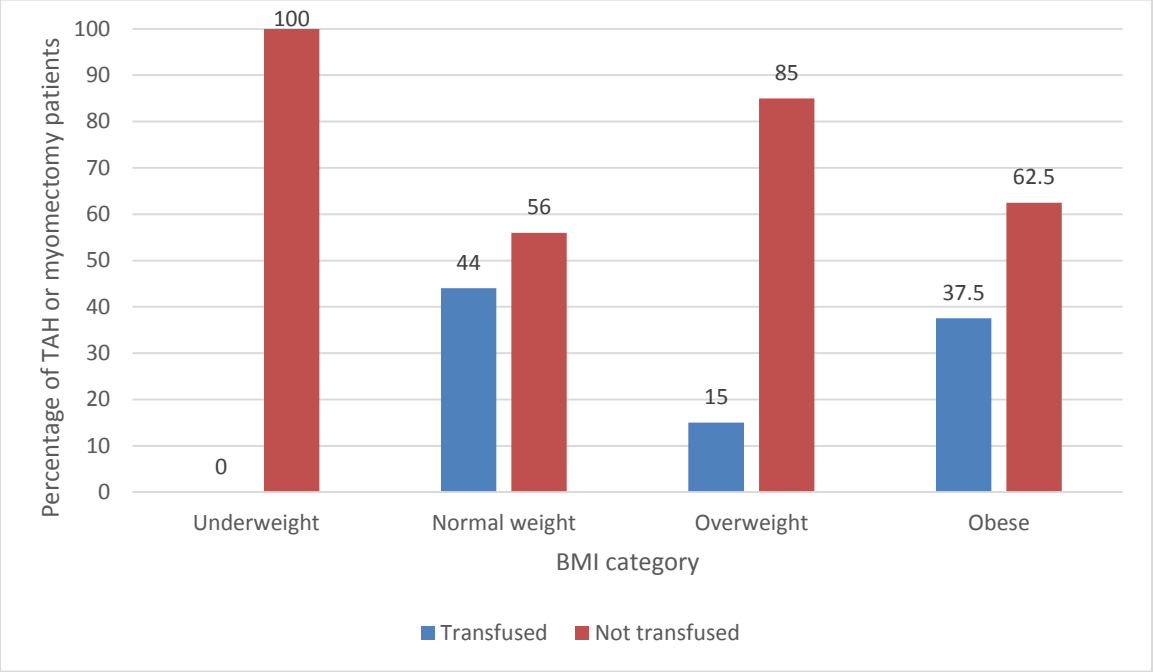
Of the 64 patients undergoing total abdominal hysterectomy or myomectomy for uterine fibroids 19 were transfused yielding an intraoperative blood transfusion rate of 30% (95% CI 18.9 to 42.4%).

Fig. 2: Rate of blood transfusion in patients undergoing Myomectomy/TAH in KNH



Transfusion rate was not significantly associated with BMI (p = 0.10) or age group (p = 0.946). The transfusion rates in the patient age groups were 20% (20-29 years), 33.3% (30-39 years), 29.2% (40-49 years) and 28.6% (50.-60 years). Figure 2 shows higher transfusion rate in obese (37.5%) and normal weight (44.4%) although the increase in transfusion did not attain statistical significance.

Figure 3: Rate of transfusion according to BMI category in KNH



There was a significant association between transfusion rate and ASA classification (p = 0.019). The transfusion rate in patients in ASA II was 44.4%, approximately four times greater (OR 4.0, 95% CI 1.25-12.75) than that in ASA 1 (16.7%), table 2.

Table 2 shows that transfusion rate was not significantly associated with history of surgery (p = 0.292), history of transfusion (p = 0.073) or comorbid illness (p = 0.317).

Table 2: Rate of transfusion according to history of past illness in KNH

	Transfused			
	Yes	No	OR (95% CI)	P
History of surgery				
No	10(25.0)	30(75.0)		
Yes	9(37.5)	15(62.5)	1.80(0.60-5.37)	0.292
History of transfusion				
No	11(23.4)	36(76.6)		
Yes	8(47.1)	9(52.9)	2.91(0.91-9.35)	0.073
Comorbidity				
No	12(26.1)	34(73.9)		
Yes	7(38.9)	11(61.1)	1.80(0.57-5.72)	0.317
ASA				
I	6(16.7)	30(83.3)		
II	12(44.4)	15(55.6)	4.00(1.25-12.75)	0.019
III	1(100.0)	0(0.0)	-	-

4.3 Uterine size estimation

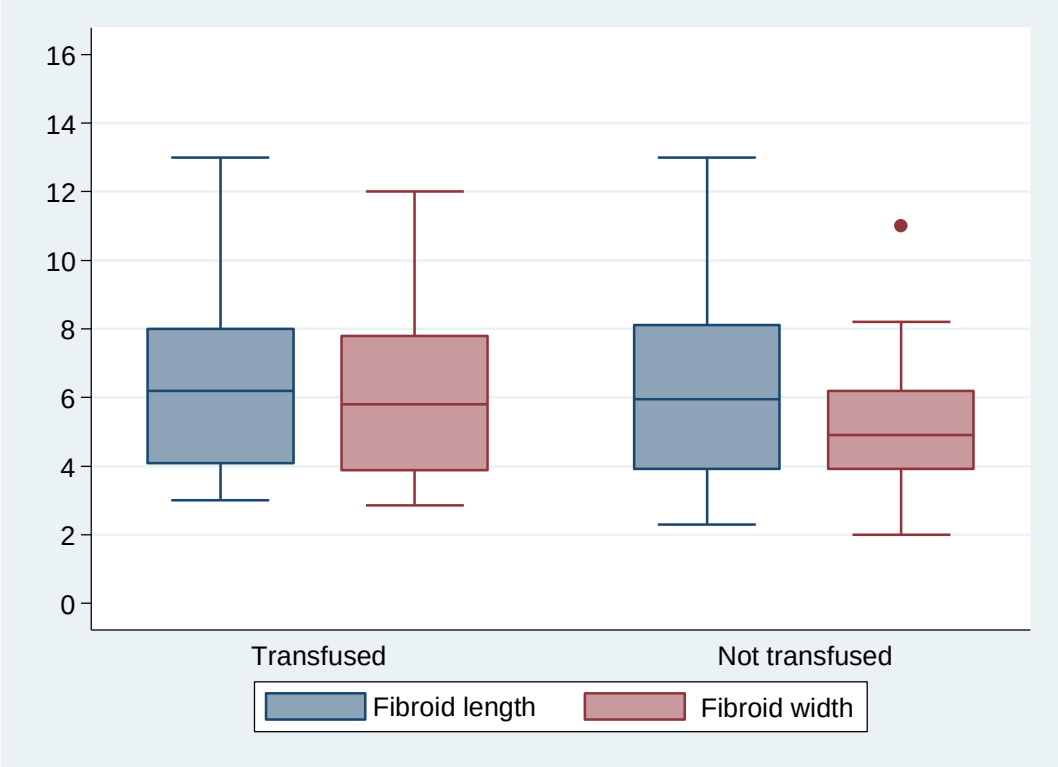
Uterine size was estimated separately using ultrasound in 36 out 64 (60.9%) patients and using clinical examination of fundal height in 56 (87.5%) patients. Of the patients who underwent clinical examination of fundal height 48 (85.7%) had fundal heights corresponding to the second trimester (13 to 27 weeks), table 3. Fundal height on clinical examination was not significantly associated with transfusion rates.

Table 3: Clinical examination of uterine fundal height and transfusion rate in KNH

	Transfused			
	Yes	No	OR (95% CI)	P
Fundal height				
< 13 weeks	1(25.0)	3(75.0)		
13-27 weeks	12(25.0)	36(75.0)	1.00(0.09-10.54)	1
28 weeks and above	2(50.0)	2(50.0)	3.00(0.15-59.89)	0.472

The mean dimension of the uterus on ultrasonography was 10.9 × 7.8 cm. Of the 39 patients with ultrasonography dimension of fibroids 11 (28.2%) were transfused. Figure 3 shows that there was no significant difference in the dimensions of fibroids (length p = 0.574; width p = 0.465) of patients who were transfused and not transfused.

Figure 4: Comparison of median length and width of fibroids in transfused patients and patients not receiving transfusion in KNH



4.4 Haemoglobin changes in the 24-hour postoperative period

The mean haemoglobin in TAH or myomectomy patients in the preoperative period was 11.7 ± 1.7 compared to postoperative haemoglobin level of 11.5 ± 1.8 (table 4). The mean haemoglobin declined by 0.2 units in the 24-hour postoperative period but his change was not statistically significant (p = 0.329).

Table 4: Haemoglobin changes in the 24-hour postoperative period in KNH

	N	Mean ± SD	Difference (95% CI)	P value
All TAH/ myomectomy patients				
Preoperative haemoglobin	64	11.7 ± 1.7	0.2 (- 0.2 to 0.5)	0.329
Postoperative haemoglobin	64	11.5 ± 1.8		
TAH/ myomectomy patients with haemoglobin > 8 g/dl				
Preoperative haemoglobin	62	11.8 ± 1.7	0.3 (- 0.1 to 0.6)	0.112
Postoperative haemoglobin	62	11.5 ± 1.8		

4.5 Estimated volume of blood loss in the intraoperative period and predictors of high volume loss

Table 5: Average blood loss in TAH and Myomectomy patients in KNH

	TAH	Myomectomy	Difference (95% CI)	P
Mean estimated loss (± SD), mls	569(±201)	682(±343)	114(-55-282)	0.201
Range of estimated loss (mls)	290-1100	300-1800		

CHAPTER 5: DISCUSSION

Uterine leiomyoma are the most common female reproductive tract tumours, however majority of cases are asymptomatic. Several studies have documented an increased incidence of uterine leiomyoma in black women and women of African descent[3]. In the study done in South west Nigeria in 2011 where they were carrying out a clinical study on uterine leiomyomata, their management and outcome, it accounted for 9.3% of all gynaecological cases over the 25 years period. A United States Census Bureau and Population estimates report extrapolated the prevalence of uterine fibroids at 1,649,105 cases (approximately 10-20% of the women population) in Kenya[28].

The average age of the patients recruited into the study 41.9 ± 8.8 years. The modal age group was between 40 and 49 years with 24 (37.5%) patients being in this age group .This was similar to the study done in South west Nigeria where they reported a mean age of 39.4+/- 7.3[27]. In the Caucasians population uterine leiomyoma tend to occur around the age of 30years and commonly causes symptoms between ages 35 and 45 years[29,30] . Thus, this study showed the age of occurrence of uterine fibroids is in keeping with results from our environment.

In this study, there were 18 (28.2%)nulliparous/primparous women, and 39 (60.9%) were multiparous. . This is comparable to findings that showed Women of black origin tend to develop fibroids at a younger age despite having had children[31]

Patients with Uterine fibroids may present with recurrent pregnancy losses. This study found that 23 (35.9%) women had previously lost a pregnancy. In a retrospective review of cases of abdominal myomectomy between January 2010 and December 2013 in Ilorin Teaching Hospital in Nigeria 23.5% of the women presented with recurrent pregnancy losses[32]. This difference may be attributed to the fact that my study was carried out over a shorter period and also a smaller sample size vis. a. vis 128.

The study found that the rate of blood transfusion in patients undergoing TAH/Myomectomy in Kenyatta National hospital is 30%. This is in contrast to the study done in South west Nigeria in 2011 where they were carrying out a clinical study on uterine leiomyomata, their management and outcome (12.8%)[27.] This may be explained by several differences in the 2 studies.

The study of south west Nigeria was a Retrospective study done over a 25 year period (from January 1st 1982 to December 31st 2006),was done in 2 centres and had a larger sample size(1259).

There was a significant association between transfusion rate and ASA classification (p = 0.019). The transfusion rate in patients in ASA II was 44.4%, approximately four times greater (OR 4.0, 95% CI 1.25-12.75) than that in ASA 1 (16.7%), table 2. This is in keeping with studies that have shown that there is a direct relationship In Increase of blood transfusion rates with Increase in ASA status of the patient.

Transfusion rate was not significantly associated with BMI (p = 0.10) or age group (p = 0.946). The transfusion rates in the patient age groups were 20% (20-29 years), 33.3% (30-39 years), 29.2% (40-49 years) and 28.6% (50.-60 years). Figure 2 shows higher transfusion rate in obese (37.5%) and normal weight (44.4%) although the increase in transfusion did not attain statistical significance.

Out of the 19 patients who were transfused 12 of them had fundal heights of 13 -27 weeks which correspond to the second trimester. However this did not achieve statistical significance in our study.Pundir et al., in an analysis of 200 abdominal myomectomies, found that uterine size of 20 weeks or more was a major predictor of perioperative bleeding requiring blood transfusion[33].

39 patients had uterine sizes being described in ultrasonography. This may show that we have inadequate reporting or poor record keeping practices in the hospital.

CHAPTER 6: CONCLUSION AND RECOMMENDATION

CONCLUSION:

1. The mean change of Hb in TAH/Myomectomy is 0.5 g/dl thus patients with Hb of 10g/dl and above may proceed with surgery. Thus there have been a number of unnecessary cancellations for patients who have Hb of 10 and above because of lack of blood on standby.
2. The size and number of Fibroids may affect amount of blood loss
3. Increase in ASA status also is associated with increase in blood loss and other perioperative complications.

RECOMMENDATIONS

1. Need for proper preoperative evaluation of patients scheduled for surgery as this may enable on to predict whether or not the patient will lose a lot of blood intraoperatively.
2. Proper documentation especially on the uterine size will enable a care provider to predict Intraoperative events.
3. Increase in ASA status also is associated with increase in blood loss and other perioperative complications.

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APPENDIX I: RESEARCH QUESTIONNAIRE

Date (DD/MM/YY) _____

Part A: Bio-Data

Age ……

Parity …….. Weight …… Height ……

Part B: x

Uterine Size, by Ultrasound ……..

by Clinical Examination (Fundal Height) ……..

Number of fibroids by Ultrasound and/or clinical examination

Ultrasound…….

Clinical examination……..

History of Blood Transfusion Yes( ) No ( )

If Yes, give reasons

……..

……..

History of previous surgeries ……..

……

If Yes, give details ……

……..

Comorbidities if any

……

……

……

Current medications if any

……

……

……

ASA Classification

……..

Pre-operative Haemoglobin (g/dl)

…….

Post-operative Haemoglobin (g/dl)

……

Part C:

Type of surgery;

a) Myomectomy
b) Total Abdominal Hysterectomy

Operative time: ……Hrs. ……..minutes

Weight of specimen …… gms

Mode of Anaesthesia;

a) General Anaesthesia
b) Spinal Anaesthesia
c) Others, please specify

……

Estimated Blood Loss (ml)

……

Was patient transfused intraoperatively or within 72 hours post operatively?

Yes ( ) No ( )

Specify the blood product(s) transfused;

a) Whole Blood
b) Packed Red cells
c) Fresh Frozen Plasma
d) Platelets

How many pints of the blood product(s) were transfused?

……

……

Hospital stay …….. days

APPENDIX II: CONSENT TO CARRY OUT THE STUDY

INFORMED CONSENT FORM

An Observational study on blood transfusion requirements in patients undergoing Total Abdominal Hysterectomy /Myomectomy for Uterine Fibroids in Kenyatta National Hospital

Back ground

I am Dr. Linda Kamathi Nguu, a post graduate student in Anaesthesia at the University of Nairobi. I am conducting a study on blood transfusion requirements in patients undergoing Total Abdominal Hysterectomy/Myomectomy for Uterine Fibroids in Kenyatta National Hospital.

Study Objective

The purpose of the study is to help health care providers in improving care given to patients by being able to predict those that will need blood transfusion during surgery. The study procedure will involve the use of a questionnaire to collect data.

Voluntariness of participation

Your participation in this study is entirely voluntary. You reserve the right to withdraw from the study at any stage. No treatment will be withheld from non consenting patients.

Confidentiality

I will not use your name for confidentiality purposes. This will guarantee that the data collected will remain confidential.

Benefits

The study will help health care providers improve the management of patients undergoing surgery for uterine fibroids.

Risks

You are not exposed to any risks by participating in this study. I will contribute to the care given to you as a healthcare provider.

For any questions and clarifications about the study you can contact me on;

Dr Linda Kamathi Nguu, Mobile: 0720718338, E-mail:lindanguu@gmail.com

Thank you

CONSENT FORM

PATIENT SECTION

I .....do hereby give consent to participate in the above study whose nature, benefits and risks have been fully explained to me by the researcher. I have not been coerced or enticed to participate and voluntarily gave permission. I have been assured of my confidentiality and that am free to withdraw from the study at any point and this will not influence the treatment I receive.

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

RESEARCHER'S SECTION

I .....have explained the nature of the study to the participant detailing the benefits and risks of the study and have not withheld any information. I have assured the participants of their confidentiality and the right to withdraw from the study at any stage and this will in no way influence the patient's treatment.

Name (initials).....

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

For further information, issues or clarification you may contact:

Dr. Nguu Linda - Mobile Number – 0720718338

Dr. Mark Gacii - Mobile Number - 0733709953

KNH/UON - Ethics & Research Committee. Telephone number – (020)2726300-9

MAELEZO YA IDHIBATI

Kitangulizi

Mimi ni Dkt.Linda Kamathi Nguu mwanafunzi wa shahada ya post graduate katika sehemu ya Anaesthesiology kwenye chuo kikuu cha Nairobi. Ninafanya utafiti kuhusu matukio ya kuongezewa damu katika upasuaji kwa uterine fibroids katika hospitali kuu ya Kenyatta.

Madhumuni ya utafiti

Madhumuni ya utafiti huu ni kujua matukio ya kuongezewa damu katika upasuaji kwa uterine fibroids katika hospitali kuu ya Kenyatta. Umuhimu wa utafiti huu ni kuwasaidia wataalamu kuboresha huduma kutolewa kwa wagonjwa na kuwa na uwezo wa kutabiri wale kwamba haja kuongezewa damu wakati wa upasuaji.Matokeo ya utafiti huu yatatumika kuboresha huduma za wagonjwa katika hospitali.

Fomu ya maswali itatumika kupata ujumbe inayohitajika kwa utafiti.

Hiari

Kushiriki katika utafiti huu ni huru na kwa hiari kwa kila mtu. Kukataa kushiriki kwa utafiti huu, haitadhuru huduma utakayoipata katika hospitali hii.

Siri

Habari yoyote utakayopeana katika utafiti itawekwa kama siri.

Fomu zote za maswali hazitakuwa na majina na ujumbe wote utawekwa siri.Wataalamu ambao wanaoshiriki katika utafiti huu pekee watakaowezakufikia habari utakayopeana

Athari na kero

Kujuimka kwako katika utafiti huu haitakuletea madhara yoyote.

Haki ya kujiondoa

Iwapo ungependa kujiondoa wakati wowote upo uhuru kufanya hivyo.

Ukiwa na maswali yoyote unaweza kujumuisha wafuatao:

Dkt Linda Kamathi Nguu 0720718338 lindanguu@gmail.com

Asante

SEHEMU YA MGONJWA

Mimi..... nimetoa kibali changu kushiriki katika utafiti huu. Nimeelezwa juu ya manufaa ya utafiti huu, vilevile kuhusu madhara yanayoweza kutokea na nimekubali kushiriki kwa hiari yangu.

Nimeahidiwa kuwa habari zozote nitakazotoa na ujumbe itakayopatikana itabakia siri. Ni na uhuru wa kujiondoa kwenye utafiti huu wakati wowote na kufanya hivyo hakutabadili kwa vyovyote vile, matibabu nitakayopokea.

Sahihi..... Tarehe.....

SEHEMU YA MTAFITI

Mimi mtafiti nimemweleza mshiriki kwa kina kuhusu utafiti huu, manufaa na madhara yote bila kuficha habari zozote. Pia nimemweleza kuwa ujumbe itakayopatikana itabakia siri na kwamba ana uhuru wa kujiondoa kwenye utafiti huu wakati wowote bila dhuluma na kufanya hivi hakutabadili kwa namna yoyote matibabu atakayopokea.

Jina.....

Sahihi..... Tarehe.....

Kwa taarifa/habari zaidi, masuala au ufafanuzi zaidi unaweza kuwasiliana na:

Dk. Nguu Linda. Nambari ya simu – 0720718 338 au

Dk. Mark Gacii. Nambari ya Simu- 0733709953

KNH / UON - Kitengo cha Maadili na Kamati ya Utafiti. Nambari ya simu - 2726300-9

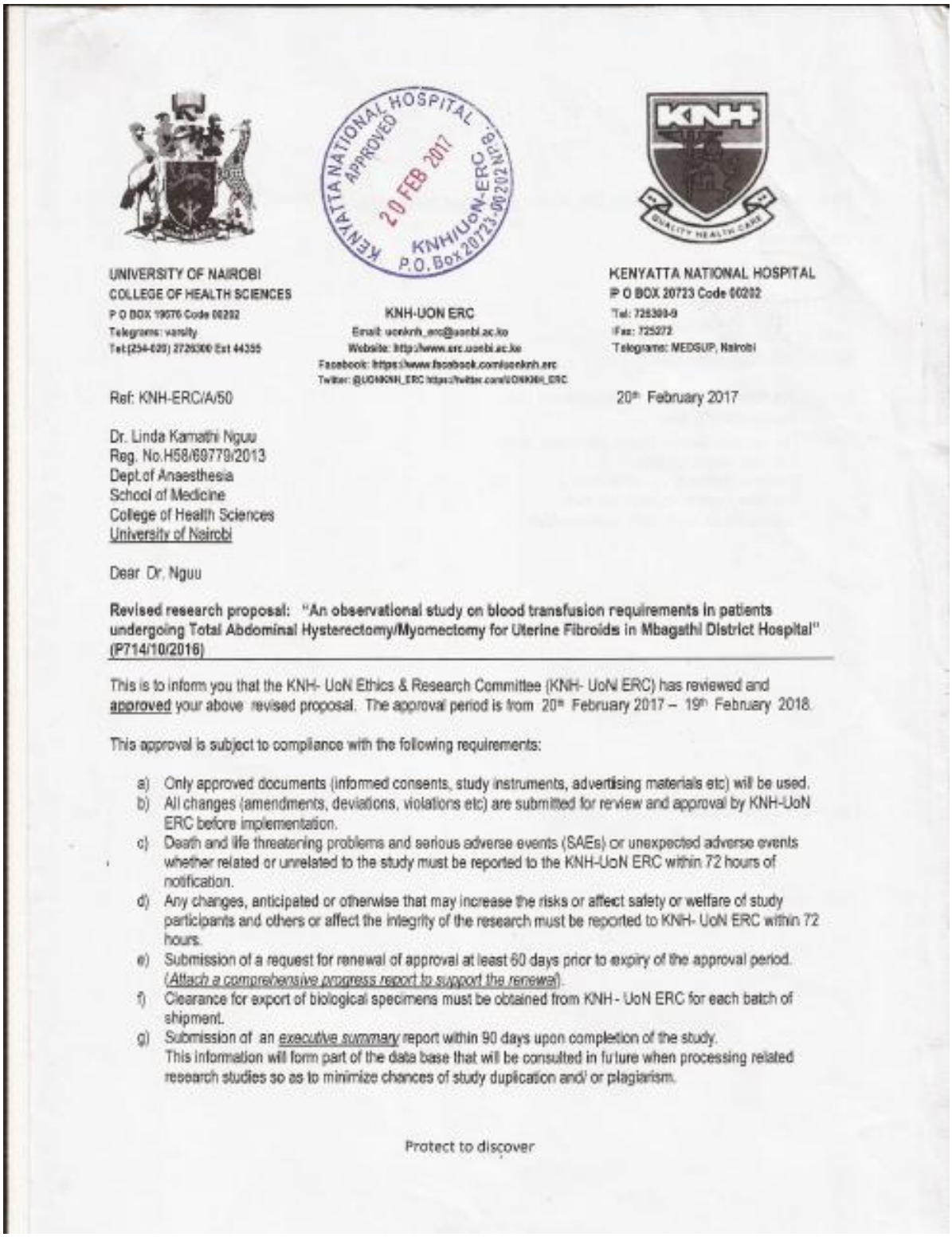
APPENDIX III: RESEARCH BUDGET IN KENYA SHILLINGS

CONCEPT/ITEM	**QUANTITY**	**UNIT COST**	**TOTAL (KSH.)**
Stationery (pens, note books, pencils)	-	-	5000
Printing & photocopying	12 copies	800	9600
Binding	12 Copies	150	1800
KNH/UON ethics & research processing fee	1	2000	2000
Statistician	1	50000	30,000
Training and allowances for Research assistants	2	10000	20,000
Hb levels	170	150	25,500
Contingency			10,000
TOTAL			**103,900**

APPENDIX IV: PROPOSED TIME FRAME

ACTIVITY	**PERIOD**
Proposal writing	December 2015 - March 2016
Proposal Discussion with supervisors	March - May 2016
Proposal Presentation to the department	May - June 2016
Seeking Ethical approval	September - December 2016
Data collection	January – February 2017
Data analysis and report writing	March 2017
Discussion of results with supervisors	March 2017
Presentation of study findings to the department	April 2017

APPENDIX V: ETHICAL APPROVAL FORM



KENYATTA NATIONAL HOSPITAL APPROVED 20 FEB 2017 KNH/UoN-ERC P.O. Box 20723-00202 Nrb

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/50

20th February 2017

Dr. Linda Kamathi Nguu
Reg. No.H58/69779/2013
Dept of Anaesthesia
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Nguu

Revised research proposal: "An observational study on blood transfusion requirements in patients undergoing Total Abdominal Hysterectomy/Myomectomy for Uterine Fibroids in Mbagathi District Hospital" (P714/10/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above revised proposal. The approval period is from 20th February 2017 – 19th February 2018.

This approval is subject to compliance with the following requirements:

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

Protect to discover

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 Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH-UoN ERC
The Dean, School of Medicine, UoN
The Chair, Dept. of Anaesthesia, UoN
Supervisors: Dr. Mark Gacii, Dr.Emma Mutio

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH-UoN ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
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KENYATTA NATIONAL HOSPITAL APPROVED 18 SEP 2017 KNH/UoN-ERC P.O. Box 20723-00202 NRB.

Ref: KNH-ERC/ Mod&SAE/228

18th September 2017

Dr.Linda Kamathi Nguu
Reg. No H58/69779/2013
Dept. of Anaesthesia
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Nguu

Re: Approval for modification – study titled 'An observational study on blood transfusion requirements in patients undergoing Total Abdominal Hysterectomy/Myomectomy for uterine fibroids in Kenyatta National Hospital' (P714/10/2016)

Refer to your communication of September 12, 2017.

Upon review, the KNH-UoN ERC has approved modification to change the study site to Kenyatta National Hospital due to challenges in data collection in the counties.

The changes are reflected in the revised proposal and are acceptable.

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Director CS, KNH
The Chair, KNH-UoN ERC
The Dean,School of Medicine,UoN
The Chair,Dept. of Anaesthesia, UoN
Supervisors: Dr. Mark Gacii, Dr. Emma Mutio

Protect to discover

APPENDIX VI: ANTIPLAGIARISM CERTIFICATE

Observational study on blood transfusion requirements in patients undergoing Total Abdominal Hysterectomy /Myomectomy for Uterine Fibroids in Kenyatta National Hospital

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