OBSTETRIC OUTCOMES IN WOMENWITHUTERINE FIBROIDS AT KENYATTA NATIONAL HOSPITAL:A PROSPECTIVE COHORT STUDY

PRINCIPAL INVESTIGATOR:

DR. JOSEPH MAMBO MUTUA

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SENIOR HOUSE OFFICER

SUPERVISORS:

1. **DR. ONESMUS GACHUNO MBCHB, M.MED (OBS/GYN), PGDRM.**

SENIOR LECTURER, DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY,

CONSULTANT, OBSTETRICIAN AND GYNECOLOGIST,

UNIVERSITY OF NAIROBI.

2. **DR. ALFRED OSOTI MBCHB, M.MED (OBS/GYN), MPH, PhD**

SENIOR LECTURER, DEPARMENT OF OBSTETRICS AND GYNAECOLOGY,

CONSULTANT, OBSTETRICIAN AND GYNAECOLOGIST,

UNIVERSITY OF NAIROBI.

A DISSERTATION, SUBMITTED TO THE UNIVERSITY OF NAIROBI, DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY IN PARTIAL FULFILMENT OF THE REQUIREMENTS, FOR THE AWARD OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY.

DECLARATION

I declare that this dissertation is my original work done underthe guidance of my supervisors.

Dr. Joseph M. Mutua MBCHB

Department of Obstetrics and Gynecology

University of Nairobi.

Signature:…… Date:…….

CERTIFICATE OF SUPERVISION:

This proposal has been presented with our full approval as supervisors

1. **Dr. Onesmus Gachuno, MBCHB, M.MED (OBSGYN), PGDRM**
   Senior Lecturer, Department of Obstetrics and Gynaecology,
   Consultant, Obstetrician and Gynecologist, University of Nairobi.

   Signature:…… Date:…….

2. **Dr. Alfred Osoti, MBCHB, M.MED (OBS/GYN), MPH, PhD**
   Senior Lecturer, Department of Obstetrics and Gynaecology,
   Consultant Obstetrician and Gynaecologist, University of Nairobi.

   Signature:…….. Date:……

CERTIFICATE OF AUTHENTICITY:

This is to certify that this dissertation is the original work of **Dr. Joseph Mambo Mutua,** Master of Medicine student in Department of Obstetrics and Gynaecology, registration number **H58/76665/2014,** University of Nairobi. The research was carried out in the Department of Obstetrics and Gynecology, School of Medicine, College of Health Sciences.It has not been presented in any other university for award of a degree.

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

Professor Omondi Ogutu

Associate Professor, Department of Obstetrics and Gynecology,

Consultant, Obstetrician and Gynaecologist,

Chairman, Department of Obstetrics and Gynaecology,

University of Nairobi.

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LIST OF ABBREVIATIONS

APGAR	Appearance, Pulse, Grimace, Activity, Respiration
APH	Antepartum hemorrhage
C/S	Caesarean section
CI	Confidence interval
DM	Diabetes mellitus
EBL	Estimated blood loss
IBM	International Business Machines Corporation
IUGR	Intrauterine growth restriction
KNH	Kenyatta National Hospital
OR	Odds Ratio
PPH	Postpartum hemorrhage
PPROM	Preterm premature rapture of membranes
RR	Relative Risk
SD	Standard deviation
SGA	Small for gestational age
SPSS	Statistical package for social sciences
SVD	Spontaneous vertex delivery

ABSTRACT

Background

Uterine fibroids are the most common benign tumors in women, with an estimated prevalence of 0.1-4% in pregnancy. Prevalence rates vary with race, and are most common in Africanwomen.

Uterine fibroids have been associated with adverse pregnancy outcomes such as preterm labour and delivery, preterm premature rupture of membranes, placental abruption, fetal malpresentation, postpartum hemorrhage, and high cesarean section rates.

Despite the high prevalence of fibroids reported among African women, there is limited data on obstetric outcomes in pregnant women with fibroids.Previous studies done on the subject have reported inconsistent findings.

Objective

To determine the effect of uterine fibroids on obstetric outcomes from 28 weeks.

Methods

This was a prospective cohort study ofpregnant women who had routine obstetric ultrasonography by 28 weeks of gestation at Kenyatta National Hospital. Seventy onewomenwith uterine fibroids detected by ultrasonography and seventy two women without fibroids were followed up monthly until delivery. Maternal, fetal and early neonatal outcomes were recorded as the women progressed to delivery and compared between the two groups.

Results

Presence of fibroids was associated with advanced maternal age. No significant difference was observed between the two groups with regard to preterm premature rupture of membranes, preterm labour and delivery, small for gestational age infant, antepartum haemorrhage, mode of delivery, duration of labour, postpartum hemorrhage, fetal presentation and neonatal outcomes ($p > 0.05$).

Conclusion

Pregnant women with fibroids are not at an increased risk of adverse obstetric outcomes compared to women without fibroids.

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

Introduction

Uterine leiomyomas (fibroids) are benign tumours of the myometrium. They are the most common benign tumours of the female reproductive tract with a prevalence rate of 20-50% of women in the reproductive age(1–3).The actual prevalence is difficult to determine as approximately 50% of the women with fibroids are clinically asymptomatic.Pathologic examination of post hysterectomy uterine specimens has previously detected a prevalence rate of 77%(4). There is scanty data on uterine fibroids in Kenya and Africa, thus making it difficult to estimate the prevalence(5–7).

The prevalence of uterine fibroids varies with age and race and is estimated to be higher among blacks than whites and in the latter half of the reproductive age compared to other age brackets(8,9).

The pathogenesis of uterine fibroids remains unclear. Estrogen and progesterone are the key regulators of fibroid growth and havebeen shown to promote growth of leiomyomas(10,11).Others factors thought to be involved in the growth of fibroids include growth factors such as insulin-like growth factor, epidermal growth factor, transforming growth factor and basic fibroblast growth factor (12,13).

Risk factors associated with fibroids include age (late reproductive years), black race, nulliparity and obesity. Low parity has been shown to be a risk factor for fibroids.

The reduced risk after menopause is thought to be due to reduced hormonal influence (12).Additional risk factors include metabolic factors such as diabetes, polycystic ovarian syndrome and hypertension (3,10). Literature on the effect of hormone replacement therapy and oral contraceptives on the development and growth of fibroids has reported inconsistent findings(12).

Fibroids are commonly classified as submucosal, intramural or subserosal based on their location relative to the layers of the uterus.Submucousleiomyomas are those that distort or are in contact with the uterine cavity. Subserous fibroids are those that distort the external contour of the uterus while intramural lie within the myometrium, neither distorting the contour nor cavity (14).

The European Society of Hysteroscopy further classifies the submucosal type into three subtypes: Type 0, Type I and Type II. Type 0 submucosal myomas are pedunculated and without intramural extension; Type I are sessile with less than 50% intramural involvement; and Type II are sessile with an intramural extension of50% or more (1).

Uterine leiomyomas vary in location as described above, size and numbers. Thisvariation may influence the reproductive function of a woman in different ways, ranging from alterations in fertility and conception, to effects on pregnancy outcomes(15).

Reviewof literature has shown that uterine fibroids have an impact on fertility. The general consensus is that submucosal fibroids lower fertility rates and their removal improve rates of conception and live births.

Subserosal fibroids have not been shown to have detrimental effects on fertility. The effect of intramural fibroids on fertility is unclear, and the benefit of their removal has not been shown (15–17).

The prevalence of fibroids in pregnancy reported in earlier studies ranges from 0.1 to 3.9% (18–20). The prevalence may be higher than this because of the difficulty in diagnosing fibroids during pregnancy, as they are difficult to differentiate from the normal physiological thickening of the myometrium by ultrasound (21). Due to the current pattern of delaying childbearing until later in life and the advent of assisted reproductive technology that has enabled more women with sub fertility to conceive, the prevalence of fibroids during pregnancy is likely to increase.

Literature review

Available literature shows that uterine leiomyomas are associated with various complications during pregnancy. Prenatal complications associated with fibroids include pain, increased rate of spontaneous miscarriage, threatened miscarriage, first trimester bleeding, preterm labour, preterm delivery, preterm premature rapture of membranes (PPROM), intrauterine growth restriction (IUGR), placenta previa and placental abruption(15). Complications reported during labour and delivery include labour

dystocia, caesarean delivery, postpartum hemorrhage (PPH), peripartum hysterectomy and retained placenta(15).

The influence of fibroids on pregnancy outcomes is not clearly understood. This is because studies done have reported mixed findings on the effect of uterine fibroids on obstetric outcomes of pregnant women with fibroids. Some studies have shown positive association of fibroids with a particular adverse event while others have reported no association with the same complication(15).

Abdominal pain most common prenatal complication of fibroids reported(15,21–24). Admission is necessary for pain control in cases where the pain is severe(17). The pain is caused by red degeneration of the fibroids, and this has been theorized to result from: Infarction and necrosis secondary to tissue anoxia due to growth of the fibroids ;ischemia followed by necrosis secondary to reduced blood supply to the fibroid resulting from the growing uterus; edema and bleeding into the fibroid and prostaglandins released from cellular damage in the fibroids (21,22).

Although rapid fibroid growth has been proposed as a cause of pain, a number of studies have failed to show significant growth of fibroids during pregnancy(15,25–27). Katz et al reported that pain appeared to be unrelated to the size of the fibroids (22). Location of the fibroid may have an influence on the pain. One study reported that

fibroids located in the posterior wall of the uterus were associated with more pain than anteriorly located fibroids (21).

Uterine fibroids have been associated with an increased risk of spontaneous miscarriage(16,28,29). Benson et al reported an increased rate of spontaneous pregnancy loss in the first trimester of pregnancy in women with fibroids, which was almost twice the rate in women without fibroids. The rate of pregnancy loss was higher in women with multiple fibroids, but it was not associated with the fibroid size or location(28). Fibroid location may be important. In astudy comparing anteriorly located fibroids with posteriorly located fibroids, a higher rate of miscarriage was found in women with posteriorly located fibroids (21).

In one study, the risk of miscarriage in women with fibroids was not increased compared to those without (24). A systematic review reported a higher rate of spontaneous miscarriage in women with intramural fibroids with pregnancies resulting from IVF compared with women with no fibroids (15). The frequency of threatened abortion has also been shown to be higher in women with uterine fibroids (24,27,30).

The association between fibroids and preterm labor and delivery has been well studied. Most studies report that compared to women without fibroids, women with fibroids had a significantly higher risk of preterm births or delivery at an earlier gestational age(18,26,31–37). In contrast, some studies done earlier did not show a positive

association between fibroids and preterm delivery (24,38,39). A systematic review with cumulative data from these studies showed an increased risk of preterm labor and delivery among women with fibroids during pregnancy (15).

Studies have shown that patients with fibroids are not at a higher risk of developing preterm premature rapture of membranes(PPROM) during pregnancy (18,19,24,29,38,39). Cumulative data from a systematic review of these studies showed a reduced risk of PPROM among patients with uterine fibroids (15). Morerecent studies have contradicted the previous findings, showing a higher risk of PPROM in patients with fibroids, especially in women with large fibroids greater than 5 cm in diameter(27,31,34).

Fetal growth seems not to be affected by the presence of uterine fibroids in pregnancy. Literature has consistently shown that the rate of IUGR is not higher among women with fibroids compared to those without(15,19,20,24,30,34,38). Only one population based study showed a small but significant risk of SGA infants in women with uterine fibroids(33).Though rare, fetal deformities may arise due to compression especially by a large submucosal fibroid, as has been reported in some case studies (35,40).

Studies have reported conflicting results on the risk of abruptio placenta in pregnant women with fibroids (15). Some studies have shown a positive association between abruption placenta and fibroids, and the risk was found to be higher in patients with

retro-placental or sub mucosal fibroids(19,20,24,36,41). Three studies found no correlation between fibroids and abruptio placenta(18,34,38).

The potential risk of placental abruption in this population should always be kept in mind while managing these patients because of its association with intrauterine fetal demise.

Two studies reported higher rates of placenta previa in patients with leiomyoma (18,20). This association remained even after controlling for confounders such as prior caesarean section and my omectomy (18). Other studies have shown no correlation between fibroids and placenta previa(34,38,41).

Various complications have reportedly been associated with uterine fibroids during labour and delivery. Adequate studies have reported an increased risk of fetal malpresentation in patients with uterine fibroids(15,22,27).Breech presentation is the most common malpresentation reported(20,34,41,42).Large fibroids have been shown to have a higher risk of malpresentation(18)(19)(43). Presence of multiple fibroids is also associated with a higher risk (30,34).

Leiomyomasare thought to cause labour dystocia due to interference with uterine contractions, but the few studies that have investigated this association have produced different results(15). A large retrospective study compared rates operative vaginal delivery and duration of labor between women with fibroids and those without and found no difference(18). In contrast, in another large retrospective cohort study, no association

was found between large fibroids and dysfunctional labor(42). In a large population based series, uterine fibroids were found tobe associated with dysfunctional labor(41).

Most studies have determined the influence of fibroids on the mode of delivery.

Evidence from these studies shows that fibroids cause an increased rate of caesarean delivery (15,18,41,42,19,28,30,32,34,36,38,39). The risk seems to be higher among women with larger fibroids(38,42,44), and also in those with multiple fibroids (34).Fetal mal-presentation appears to be the most common cause of higher rates of caesarean deliveries (15,18,19,41).Stout et al and Verganiet al showed an increased risk of caesarean delivery even after controlling for fetal mal-presentation and placenta previa(37,42). Two studies did not demonstrate an increased risk of caesarean delivery among women with fibroids(24,27).Despite the increased risk of caesarean delivery, most authors recommend trial of labour since studies have shown the rates of vaginal deliveries to be higher among the labour-eligible women(18,42).

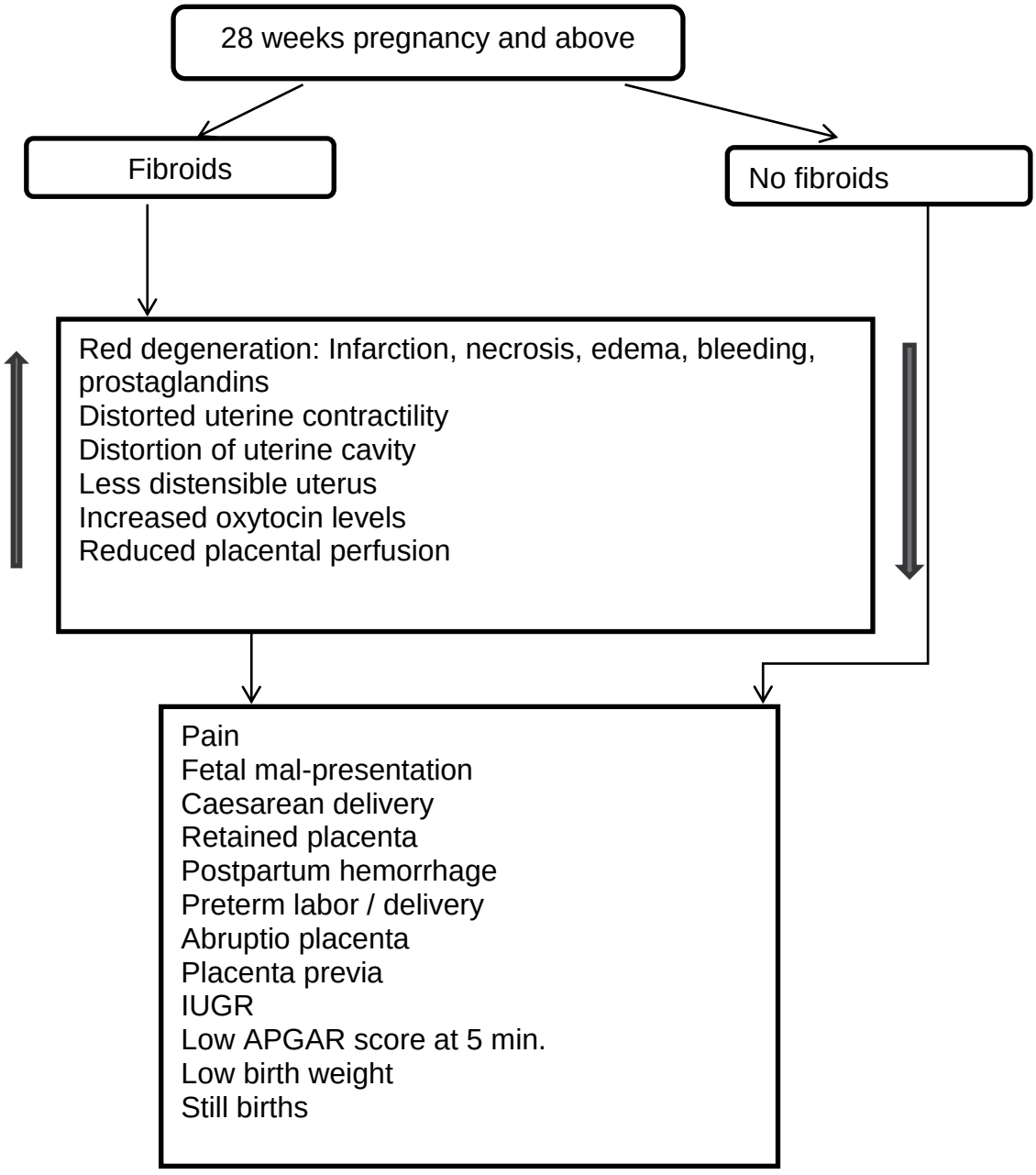
During the postpartum period, most studies report a higher incidence of postpartum haemorrhage among patients with uterine fibroids(15,18,32,42). This could be due to distorted uterine contractility attributed to uterine fibroids(45). Two studies found an increased need of emergency hysterectomy to control postpartum haemorrhage (19,24). Other studies have not shown an increased risk of PPH in patients with fibroids (38,39,41).

There is scanty literature on the link between fibroids and other postpartum adverse events such as retained placenta and postpartum endomyometritis. Two studies reported an increased incidence of endomyometritis in patients with fibroids(22,24). One study found no association after controlling for PPH(18).

The association between fibroids and retained placenta is inconclusive. One study reported no increased risk in women with fibroids (38), but a recent study reported a slightly higher incidence of retained placenta in women with fibroids compared with controls (32).

Most studies have reported no difference in neonatal outcomes such as birth weight, admission to new born intensive care unit and APGAR scores between women with fibroids and those without(15,19,27,32).

CONCEPTUAL FRAMEWORK



Key: Increased Risk   Decreased Risk

Figure 1: conceptual framework

Conceptual framework: Narrative

Pregnancies complicated by uterine fibroids are at risk of various complications. Painis the most common complication and is thought to be as a result of red degeneration within the fibroids.The proposed mechanisms for the pain associated with red degeneration are ischemia and infarction due to increased growth of the fibroids and changes in blood supply in the growing fetus; edema and release of prostaglandins from cellular damage within the fibroids.

Reduced placental perfusion is thought to be as a result of retroplacental location of submucosal fibroids. This may cause a bruptio placentae and placenta previa and may lead to IUGR, small for gestational infants, low birth weight, perinatal asphyxia or still birth.

Distortion of the uterine cavity by large fibroids may result in mal-presentation and subsequently increased operative delivery. Fibroids interfere with normal uterine contractility, which could lead to dysfunctional labour and postpartum haemorrhage.

Proposed mechanisms of preterm labor and delivery are increased oxytocin levels within the fibroids and a less a less distensible uterus caused by the fibroids.

JUSTIFICATION

Uterine fibroids have been reported to be more common among African women. To the best of our knowledge, no studies had been done in Kenya to determine the influence of fibroids on maternal and perinatal outcomes.

Globally, previous studies done to determine the association between uterine fibroids during pregnancy and obstetric outcomes have reported mixed findings.

The incidence of fibroids is expected to rise because of the current trend by women to delay childbearing. As a result of increased access to routine ultrasonography, more mothers with fibroids will present to the obstetrician seeking preconception and prenatal care.

This study sought to add more knowledge to the available local and globalliterature on outcomes and provide opportunities for counseling.

RESEARCH QUESTION

What is the effect of uterine fibroids on obstetric outcomes of women seen at Kenyatta National Hospital between 28 weeks of gestation and 24 hours after delivery?

NULL HYPOTHESIS

There is no difference in maternal and perinatal outcomes between pregnant women with fibroids and without fibroids seen at Kenyatta National Hospital from 28 weeks of gestation until 24 hours after delivery.

OBJECTIVES

Broad objective

To determine the effect of uterine fibroids on obstetric outcomes of women seen at Kenyatta National Hospital from 28 weeks of gestation until 24 hours postpartum.

Specific objectives

Among pregnancies of women seen at Kenyatta National Hospital with and without uterine fibroids from 28 weeks of gestation until 24 hours postpartum, to compare:

1. Maternal outcomes
2. Fetal and early neonatal outcomes

CHAPTER 2: METHODS

Study design

This was a prospective cohort study that included women with singleton gestations who had undergone routine first or second trimester obstetric ultra sonography during the antenatal period. The exposure of interest was the presence of uterine fibroids identified on ultra sonography. Pregnant women with fibroids noted on ultra sonography and a control group of pregnant women without fibroids were followed up from 28 weeks until 24 hours after delivery. Data on obstetric outcomes was obtained as the patients progressed to delivery and compared between the two groups. Maternal outcomes assessed were PPROM, APH (abruptio placenta; placenta previa), preterm labor, caesarean delivery, retained placenta and PPH. Fetal outcomes were fetal mal-presentation and SGA. Early neonatal outcomes were preterm delivery, live or still birth, APGAR score at 5 minutes and birth weight.

Study site and setting

The study was conducted at the Kenyatta National Hospital's (KNH) labour ward, antenatal clinic, antenatal and postnatal wards. KNH is Kenya's main referral and teaching hospital. It also serves as a primary hospital for people living within the capital city of Nairobi.KNH is the training facility for postgraduate and undergraduate students of the college of health sciences at the University of Nairobi. It is also used by Kenya Medical Training College (KMTC) to train students undertaking various diploma courses in the medical field.

Study population

Pregnant women who hadroutine first or second trimes terobstetric ultrasonography at KNH formed the study population. Pregnant women with at least one uterine fibroid noted onultrasonography were compared with pregnant women without uterine fibroids noted on obstetric ultrasonography.

***Inclusion criteria*:**

- Pregnant mothers withan obstetric ultrasound scan done during the first or second trimester.
- Gestational age between 28 and 36weeks.
- Women who gave written informed consent.

***Exclusion criteria*:**

- Multiple pregnancies.

- Previous caesarean section or myomectomy scar.

Sample size

The main outcome of this study was the proportion of pregnancies with adverse outcomes among women with fibroids as compared to similar women without fibroids. In a recent review, women with fibroids had a 48% cesarean section rate while those without fibroids had 13% cesarean section rate.

We postulated that in our setting women without fibroids may have a higher baseline CS rate of 15% and 40% for those with fibroids. Therefore for us to detect a 25% difference in the CS rates between the two groups we estimated using the sample size formula

$$n = \frac{2\left(z_{1-\alpha/2}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_c(1-p_c)+p_a(1-p_a)}\right)^2}{(p_c-p_a)^2}$$ [Allan Donner; Stat. Medicine(1984)] (46)that we would need to study a total of 120 women in total (60 per group) to achieve a 80% power to detect the stated difference of 25% at a two-sided alpha=0.05 level of significance. Where we define p_c= 15% and p_a= 40% to be the proportions of pregnant

women with fibroids and without fibroids respectively and $\bar{p} = (p_C + p_a)/2$ ($Z_{0.05}$=1.960, and $Z_{0.8}$ =0.842). We assumed a 10% loss to follow-up or incomplete data, producing a total of 136 women (68 per group).

Sampling procedure:

Consecutive sampling was conducted. Patients who met the eligibility criteria and gave consent were enrolled until the desired sample size was achieved.

Sources and methods of recruitment

Study participants were recruited in the antenatal clinic and labor ward. Recruitment was done by the principal investigator with the assistance of a trained research assistant at the antenatal clinic. Pregnant women who had undergone obstetric ultrasonography were assessed for eligibility. A written informed consent was obtained from those who voluntarily agreed to participate. Questionnaires were filled at recruitment, during antenatal follow up and after delivery.

Study procedure

Patients were recruited between 28 and 36 weeks of gestation. After recruitment, they were followed up every 4 weeks while attending their routine ANC scheduled visits.

They would also be contacted at any time they were admitted, at delivery and 24 hours after delivery which was the end point for the study. Patients who did not deliver within KNH were be traced via their telephone contacts or that of their next of kin. The questionnaire was filled by the principal researcher and the research assistant at these points.

Study flow chart

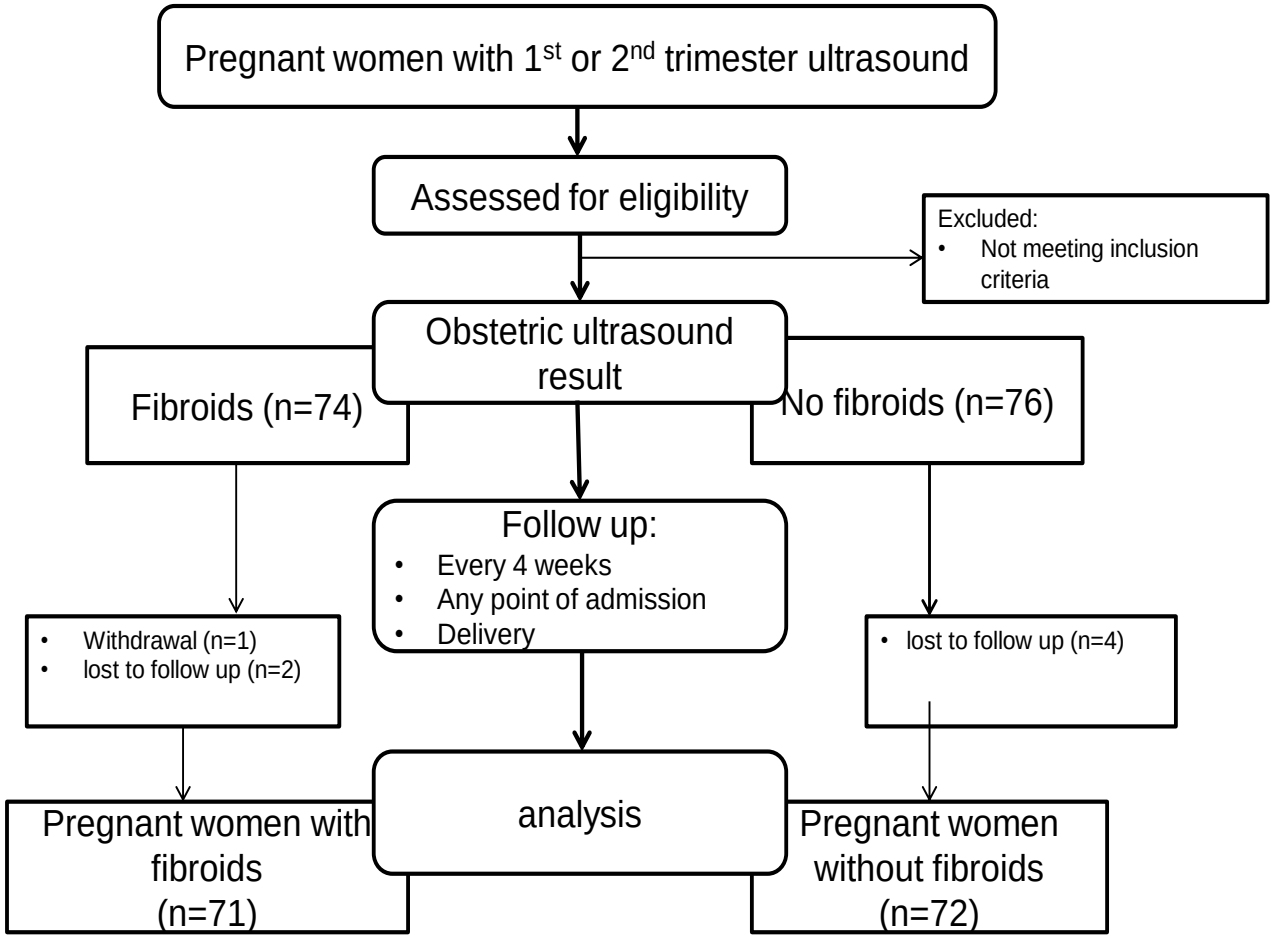


Figure 2 : study flow chart

Data variables

Table 2.1: Data variables

	Independent	Dependent
	Sociode mographic characteristics: • Maternal age • Parity • Marital status • Occupation • Educational level	
	Inter-pregnancy interval	
	Fibroids characteristics: • Size • Number • Type • Site • Location	
		PPROM
		Preterm labor
		APH (Abruptio placenta /Placenta previa)
		Duration of labor (for SVD)
		Caesarean delivery
		Retained placenta
		Postpartum hemorrhage
objective 2		Fetal malpresentation
		Small for Gestational age
		Preterm delivery
		Immediate neonatal outcome: live or still birth
		APGAR score at 5 min.
		Birth weight

Data collection and management

Data was collected using a structured questionnaire shown in appendix 1. The questionnaire was administered to patients who had consented by the principal investigator aided by a research assistant. The radiology department,residents and nursing staff working in the reproductive health unit were briefed on the study before commencement.

The research assistant, a reproductive health nursing officer working at the antenatal clinic, underwent training by the principal investigation bout the study, the study procedures and proper filing of the questionnaires 3 days prior to commencement of data collection. Using the questionnaire, we obtained data on sociodemographic and clinical characteristics of patients, characteristics of fibroids if present, maternal and perinatal outcomes as the participants progressed to delivery. Patient's ANC booklet and files were also used to retrieve any additional information required.

Data was then entered and cleaned using SPSS database. Backup data was securely stored in an external hard drive. Data was only accessible to the principal investigator, statistician and supervisors.

Quality control

The research assistant was trained by the principal investigator on patient recruitment and proper administration of the questionnaires. Pretesting of the questionnaire was done by the principal investigator and research assistant. Information entered into the questionnaires was double checked after filling to ensure completeness.

Data analysis

Statistical analysis was conducted using IBM SPSS version 21.

Descriptive statistics were conducted by calculating means and standard deviations for continuous variables such as age. Percentages and frequencies were calculated for categorical variables.

Inferential statistics were performed. Continuous demographic and clinical variables between women with fibroids and those without were compared using the Student *t* test. For categorical demographic and clinical data, comparison of percentages in the two groups wasdone using the Pearson's chi-square test.

For maternal and fetal outcomes, a primary comparison of caesarean section rates between women with fibroids and those without was done using the chi- square test. A Relative Risk (R.R) with 95% confidence intervals (CI) was calculated to determine the magnitude of effect. The other maternal and fetal outcomes including, PPROM, APH, preterm labour, PPH, retained placenta, fetal malpresentation and IUGR were similarly compared between the two groups.

Perinatal outcomes including preterm delivery, live births, still births, Apgar score at 5 minutes and birth weight between women with fibroids and those without fibroids were also compare dusing the chi-square test. R.R with 95% CIs was calculated.

A *P*- value < 0.05 was considered statistically significant.

Ethical considerations

The proposal was reviewed and approved by the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee. Permission to conduct the study was alsosought and granted by the management of KNH. Information obtained from the patients' files was kept confidential. Names and any data identifying particular patients were not recorded on the data collection instruments. Data collected was only used for the purposes of this study.

Study limitations

Some patients who delivered outside KNH were lost to follow up. We could not ascertain the accuracy of the outcome data such patients gave over the telephone for those we were able to trace. However, this had been eliminated by adding the attrition rate to the sample size.

Ascertainment bias may have occurred if the fibroids were identified after complications such as pain had developed. This was minimized by recruiting patients who had fibroids identified on antenatal routine obstetric scan.

The study relied on obstetric ultrasound scans done by different sonographers. To mitigate this, standard operating procedures for details required such as location, number and size of fibroids were provided to the sonographers. Despite this, a number of obstetric ultrasounds did not report on some fibroid characteristics. This data was captured as unspecified on the questionnaires.

CHAPTER 3: RESULTS

A total of 143 women with singleton gestations were included in the final analysis. Of these, 71 had uterine fibroids documented on obstetric ultrasonography, while the other 72 had no sonographically identified uterine leiomyoma.

Table 3. 1: Sociodemographic characteristics of pregnant women at KNH with uterine fibroids compared with pregnant women without fibroids

	Fibroids (N = 71)	**No fibroids (N = 72)**	**RR (95% CI)**	**P value**
Maternal age (y), mean ± SD	33.7 ± 4.9	30.1 ± 6.8	1.05(1.01-1.08)	<0.001
	n (%)	**n (%)**		
Maternal age				
18-24 years	3(4.2)	16(22.2)	1	
25-29 years	9(12.7)	14(19.4)	2.48(0.78-7.91)	0.105
30-34 years	30(42.3)	23(31.9)	3.58(1.23-10.44)	0.007
35-45 years	29(40.8)	19(26.4)	3.83(1.32-11.12)	0.004
Marital status				
Married	62(87.3)	62(86.1)	1	
Single	9(12.7)	10(13.9)	0.95(0.57-1.57)	0.931
Education				
None	1(1.4)	1(1.4)	1	
Primary	13(18.3)	14(19.4)	0.96(0.23-4.09)	0.959
Secondary	26(36.6)	33(45.8)	0.88(0.21-3.65)	0.862
Tertiary	31(43.7)	24(33.3)	1.13(0.28-4.62)	0.868
Occupation				
Self employed	31(43.7)	28(38.9)	1	
Formal	17(23.9)	10(13.9)	1.20(0.82-1.75)	0.349
Casual	2(2.8)	4(5.6)	0.63(0.20-2.03)	0.442
Unemployed	21(29.6)	30(41.7)	0.78(0.52-1.18)	0.243

Women with fibroids were more likely to be of advanced maternal age compared to women without fibroids (Table 3.1). The mean age of the women with fibroids was 33.7 ± 4.9 years and those without fibroids 30.1 ± 6.8. The difference was statistically significant ($p < 0.001$). There was a progressive increase in risk of fibroids with increasing age, as women between 30-34years and 35-45 years were 3.5 and 3.8 times more likely to have fibroids compared to women between 18-24 years respectively.

No significant differences in the other sociodemographic characteristics including marital status, educational level and occupation were observed between the two groups.

Table 3.2: Obstetric characteristics of pregnant women at KNH with uterine fibroids compared with pregnant women without fibroids

	Fibroids (N = 71)	**No fibroids (N = 72)**	**RR (95% CI)**	**P value**
	n (%)	**n (%)**		
Parity				
Nulliparous	30(42.3)	28(38.9)	1	
1	16(22.5)	18(25.0)	0.91(0.59-1.41)	0.671
2	13(18.3)	14(19.4)	0.93(0.58-1.48)	0.763
>= 3	12(16.9)	12(16.7)	0.97(0.60-1.55)	0.888
Duration since last pregnancy (years), mean ± SD	1.4 ± 0.5	1.2 ± 0.4	1.004(1.0004-1.01)	0.03

There was no significant difference in parity between the two groups.

With regards to the mean interpregnancy interval, the difference was too small to derive a conclusion despite a p value of 0.03.

Table 3.3: Characteristics of fibroids in women with uterine fibroids at KNH.

meansize of the fibroids was 53.4 mm (SD 29.5) range 18 to 164 mm.		
	Frequency (n)	**Percent (%)**
Number of fibroids		
Single	32	45.1
Multiple	39	54.9
Fibroid type		
Intramural	45	63.4
Subserosal	13	18.3
Mixed intramural subserosal	9	12.7
Submucosal	4	5.6
Site		
Anterior	40	56.3
Posterior	10	14.1
Lateral	2	2.8
Other	19	26.8
Location		
Corpus	28	39.4
Fundal	23	32.4
Lower uterine segment	7	9.9
Cervical	2	2.8
Other	11	15.5

The mean size of the fibroids was 53.4 mm (SD 29.5) range 18 to 164 mm.

Majority of the womenhad more than one fibroid seen on ultrasound (54.9%).

Of the fibroids whose type could be determined on the basis of sonographic images, most were found to be intramural (63.4%) and the remainder were noted to have sub serosal (18.3%) or sub mucosal (5.6%) extension.

Most fibroids were detected on the anterior (56.3%) and posterior (14.1%) uterine walls. The rest were lateral (2.8%), in multiple mixed locations (23.8%) and in 3% of the women the location was not specified (Table 3.3).

The commonest location of myomas was at the uterine corpus (39.4%), followed by the fundus (32.4%) and the lower uterine segment (9.9%). Only 2 women (2.9%) had cervical fibroids noted on ultrasound.

Table 3. 4: Maternal outcomes for pregnant women at KNH with uterine fibroids compared with pregnant women without fibroids

	Fibroids (N = 71)	**No fibroids (N = 72)**	**RR (95% CI)**	**P value**
	n (%)	**n (%)**		
PPROM	4(5.6)	4(5.6)	1.01(0.26-3.92)	0.200
Preterm labor	7(9.9)	2(2.8)	3.55(0.76-16.6)	0.107
Antepartum haemorrhage	2(2.8)	1(1.4)	2.03(0.19-22.1)	0.561
Gestational age at delivery, mean ± SD (wk)	38.2 ± 2.5	38.7 ± 2.5		
<37 weeks	10(14.1)	6(8.3)	1	
≥37 weeks	61(85.9)	66(91.7)	0.94(0.83-1.05)	0.275
Mode of delivery				
Vaginal	34(47.9)	45(62.5)	1	
CS	37(52.1)	27(37.5)	1.39(0.96-2.02)	0.084
Mean (±SD) duration of 1st stage in min	536.1(±184.9)	477.3(±191.6)	1.001(1.0-1.002)	0.207
Mean (±SD) duration of 2nd stage in min	20.6(±10.3)	21.5(±22.3)	1.0(0.99-1.01)	0.800
Mean (SD) estimated blood loss in ml	399.3(±222.2)	340.3(±181.7)	1.00(1.0001-1.001)	0.037
PPH	1(1.4)	1(1.4)	0.99(0.06-15.6)	0.992

There was no significant increased risk of PPROM, preterm labor, APH or PPH in women with uterine fibroids compared with women without fibroids ($p > 0.05$).

There was no significant difference in mode of delivery between the two groups. The CS rate was found to be higher among women with fibroids (52.1%) compared to women without fibroids (37.5%). However, this difference did not reach statistical significance (RR 1.39, 95%CI 0.96- 2.02, p=0.084).

We found no statistical differences in the gestational age at delivery, mean EBL and mean duration of the first and second stages of labor between the two groups.

None of the women in both groups had a hysterectomy performed after delivery.

Table 3.5: Fetal outcomes for pregnant women at KNH with uterine fibroids compared with pregnant women without uterine fibroids

	Fibroids (N = 71)	**No fibroids (N = 72)**	**RR (95% CI)**	**P value**
	n (%)	**n (%)**		
Small for Gestational Age (SGA)	8(11.3)	3(4.2)	2.74(0.76-9.96)	0.125
Fetal presentation				
Cephalic	63(88.7)	68(94.4)	1	
Malpresentation	8(11.3)	4(5.6)	2.02(0.64-6.46)	0.232

Fetal outcomes including small for gestational age and fetal presentation were not statistically different between the two groups.

Table 3.6: Neonatal outcomes for pregnant women at KNH with uterine fibroids compared with pregnant women without fibroids.

	Fibroids (N = 71)	**No fibroids (N = 72)**	**RR (95% CI)**	**P value**
	n (%)	**n (%)**		
Preterm delivery	10(14.1)	6(8.3)	1.69(0.65-4.42)	0.284
Immediate outcome				
Live birth	70(98.6)	72(100.0)	1	
Stillbirth	1(1.4)	0(0.0)	NA	NA
Median (range]) APGAR score at 5 min.	9(0.0-10.0)	10(5.0-10.0)	0.92(0.86 to 0.998)	0.044
Mean (+/-SD) birth weight (g)	3067.7(±608.5)	3212.5(±618.6)	1.0(1.0-1.0001)	0.144

We did not find significant differences in women with fibroids compared to those without fibroids with respect to preterm delivery, immediate neonatal outcome and mean birth weight ($p > .05$).

CHAPTER 4: DISCUSSION

The aim of this study was to compare obstetric outcomes between women with singleton pregnancies complicated by uterine fibroids and pregnant women without fibroids.

Similar to what has been reported in other studies, presence of fibroids was associated with advanced maternal age (8,12,14,36).The increase in prevalence of fibroids with age could be due to increased growth or symptomatology ofpreviously existing fibroids. Alternatively, the apparent increase in the latereproductive years may represent many years of progressive stimulation by estrogen and progesterone(12).

Several studies have shown an inverse relationship between parity and the risk of fibroids(12). We found no association between fibroids and parity. A large retrospective cohort study by Qidwai et al also reported the same finding.

Mean size of the fibroids was 53.4 ± 29.5mm (range 18 -164 mm).This is comparable to that reported by Deveer at al. of 57.44 ± 23.62 (30 - 132) mm in a retrospective study of 84 pregnant women(21).

Anterior located fibroids (56.3%) were more frequent than posterior (14.1%) and lateral (2.8%).Deever et al reported similar findings and gave a possible explanation that this could be because ultrasound evaluation of posterior fibroids in pregnancy is more difficult and less accurate than evaluation of anterior fibroids.

Types of fibroids described in order of frequency were intramural (63.4%), subserosal (18.3%) and submucosal (5.6%). Thisis consistent with findings by Shavelle et al- intramural (55.6%),subserosal (36.1%) and submucosal (8.3%).

We did not find significant differences in women with fibroids compared to those without fibroids with respect to maternal outcomes includingPPROM, preterm labor, APH, gestational age at delivery, mode of delivery, mean duration of labor, estimated blood loss and PPH. Similarly there was no statistical difference in fetal outcomes including fetal presentation and risk of delivery of a small for gestational age infant. As described in a systematic review by Klatsky et al, data from previous studies regarding the association between fibroids and these outcomes is highly inconsistent (15). Therefore, our findings agreed with some previous reports but were also inconsistent with findings of other studies.

Numerous studies have shown that uterine fibroids are a risk factor for cesarean delivery. The most common cause of the higher cesarean rates in those studies appears to be malpresentation (15). In our study, there was a trend towards increased rate of CS in pregnant women with fibroids but it did not reach statistical significance. We also found no significant association between uterine fibroids and fetal malpresentation. A large retrospective cohortstudy comparing 454 pregnant women with fibroids and 11,387 without fibroids, similarly observed no significant difference in caesarean or vacuum delivery rates between the two groups (24).

There were no significant differences in preterm birth, immediate birth outcome (live vs. still birth), APGAR score at 5 minutesand birth weightbetween the two groups.

This confirmed findings fromprevious studies that have reported no difference in neonatal outcomes between pregnant women with fibroids and those without (15,19,32).

Our study had several limitations. Due to the small number of outcomes, it was difficult to do further sub analysis to determine the effect of size or number of fibroids on obstetric outcomes. Secondly, evaluation of fibroids during pregnancy may beinaccurate especially posterior fibroids. In addition, because the ultrasound scans were performed by different sonographers, interobserver variability may have been introduced. We attempted to mitigate this by ensuring that the scans were all done at our institution. Lastly, our findings were limited to pregnancies in the third trimester and therefore conclusions regarding the effect of fibroids in the first and second trimesters of pregnancy cannot be made from the study.

The main strength of the study was that it was a prospective cohort study and this enabled us acquire most of the data we required from our study participants.

These findings will be useful during preconception and antenatal counseling of women with fibroids

CONCLUSION

Pregnant women with fibroids are not at a significant increased risk of adverse maternal, fetal and early neonatal outcomes compared to women without fibroids.

RECOMMENDATIONS

Pregnant women with uterine fibroids should be advised that adverse obstetric outcomes between women with fibroids and those without fibroids are comparable. The outcome of their pregnancies is generally expected to be good.

Because other studies have shown increased risk in some adverse outcomes, follow up should be individualized for every patient and appropriate management instituted in case any complications arise.

We recommend further studies to validate our findings on the association between uterine fibroids and adverse obstetric outcomes. These studies should have larger sample sizes with adequate power to determine the effect of size and number of fibroids on obstetric outcomes.

TIMELINES

Table 4.1: Timelines

	2017			**2018**		
	Jan-Aug	**Sep**	**Oct- Apr**	**May -Oct**	**Nov**	**Dec**
Proposal development						
Proposal presentation						
Ethical approval						
Data collection						
Data analysis						
Report writing & presentation						
Submission to department						

BUDGET

Table 4.2: Budget

Items	**Unit Cost Kshs**	**Units**	**Total Kshs**
Research assistant per diem/ administration of questionnaires	100	150	15000
Stationery	5000	1	5000
Printing	500	10	5000
Photocopy	25	400	10000
Binding	500	4	2000
Communication/ Airtime	5000	1	5000
Data analysis/ statistician	30000	1	30000
Miscellaneous	10000	1	10000
TOTAL			**82000**

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APPENDICES

Appendix 1: Questionnaire

Date _____

Serial number _____

Obstetric ultrasound scan result: ☐fibroids ☐ No fibroids

SECTION A: socio-demographic and clinical characteristics

1. Age _____ years.

2. Marital status
   a) Single☐
   b) Married☐

3. Educational level
   a) Tertiary☐
   b) Secondary☐
   c) Primary ☐
   d) None ☐

4. Occupational level
   a) Formal ☐
   b) Casual☐
   c) Self employed ☐
   d) Unemployed☐

5. Parity
   a) Nulliparous ☐
   b) 1☐
   c) 2☐
   d) ≥3☐

6. If multiparous, duration since the last pregnancy _____ months.

SECTION B: Fibroid characteristics (if present)

7. Fibroid size (largest diameter) _____ mm.

8. Number of fibroids
   a) 1 ☐
   b) 2 ☐
   c) 3 ☐
   d) ≥4☐

9. Fibroid type (location within layers of the myometrium)
   a) submucosal ☐
   b) intramural ☐
   c) subserosal ☐
   d) mixed ☐

10. Fibroid site on the uterine walls
   a) Anterior ☐
   b) Posterior ☐
   c) Right lateral ☐
   d) Left lateral ☐

11. Fibroid location on the uterus
   a) Fundal☐
   b) Corpus☐
   c) Lower uterine segment ☐
   d) Cervical ☐

12. Re-troplacental
   a) Yes ☐
   b) No ☐

SECTION C:Maternal outcomes

13. Abdominal pain requiring admission

    a) Yes☐
    b) No☐

14. PPROM
    a) Yes☐
    b) No☐

15. Preterm labor
    a) Yes ☐
    b) No☐

16. Ante partum haemorrhage
    a) Yes ☐
    b) No☐

    If yes
    a) Placenta previa☐
    b) Abruptio placentae☐
    c) Others (specify) _____

17. Gestational age at delivery : _____ weeks

18. Mode of delivery
    a) Vaginal delivery☐
    b) Assisted vaginal delivery☐
    c) Caesarean section☐

19. If caesarean
    a) Emergency☐
    b) Elective☐

20. Duration of labor (for SVD)

    a) 1st stage _____ min.

    b) 2nd stage _____ min.

21. Retained placenta
    a) Yes☐
    b) No☐

22. Estimated blood loss after delivery: _____ mls.

23. Postpartum haemorrhage
    a) Yes☐
    b) No☐

24. Need for hysterectomy
    a) Yes ☐
    b) No ☐

SECTION D: Fetal outcomes

25. Fetal presentation

    a) Normal cephalic ☐

    b) Malpresentation ☐

26. IUGR
    a) Yes ☐
    b) No ☐

SECTION E: Neonatal outcomes

27. Preterm delivery
    a) Yes ☐
    b) No ☐

28. Immediate neonatal outcome
    a) Live birth☐
    b) Still birth ☐

29. Apgar score at 5 min. _____/10.

30. Birth weight _____ grams.

Appendix 2: Informed consent.

Study title: Outcome of pregnancies in women with uterine fibroids at KNH.

Principal investigator: Dr. Joseph Mambo Mutua

Introduction:

My name is Joseph Mutua, a postgraduate student at the Department of Obstetrics, University of Nairobi. I am conducting a study to determine the effect of uterine fibroids on pregnancy from 28 weeks of gestation. You are hereby requested to participate in the study.

This information will help you make a decision on whether to participate in the study or not. You may ask any questions about the study or anything in this form that is not clear.

Purpose of the study:

Uterine fibroids are noncancerous growths in the uterus. More fibroids are being discovered during pregnancy due to increased access to routine obstetric ultrasonography during antenatal follow up.

This study will compare pregnancy outcomes between expectant mothers with uterine fibroids and others without uterine fibroids at KNH. It aims to establish whether fibroids during pregnancy pose a risk to the health of the mother and the baby.

Benefits:

By participating in the study, you will help us to know whether uterine fibroids during pregnancy are associated with more adverse pregnancy outcomes or not. This will enable usanticipate any problems that may occur in your future pregnancies in case you have the condition and attempt to prevent them. You will also receive information about this common condition affecting women such as its symptoms and how it can be managed, and any questions you might have regarding the condition will be answered.

Possible risks:

There are no risks involved by your participation in the study. You will receive the standard of care accorded to other patients in the hospital. No invasive procedures will be conducted on you. The risks being investigated such as preterm delivery, threatened miscarriages, postpartum haemorrhage and so forth are possible risks of pregnant women with fibroids and are not due to your participation in the study.

Voluntarism:

Participation in this study is voluntary. If you choose to participate in this study, you are allowed to leave the study at any time if you wish to do so. The care you receive from the hospital will not be influenced by the decision you make.

Compensation:

No compensation will be offered for participation in the study.

Procedure:

If you agree to participate in the study, the principal investigator or his research assistant will interview you and fill the responses in a questionnaire. The interviewer may also obtain some additional information from your medical records. The research team will regularly follow you up during your antenatal visits until after your delivery. You are advised to contact the primary investigator in case you are admitted during this period.

Confidentiality:

The information that you will provide will be kept confidential. Names or any information identifying you will not be included in the questionnaires or final report

Contact information:

For more information on the research you can contact the following:

Principal investigator, Dr. Joseph M. Mutua

Department of Obstetrics and Gynaecology, University of Nairobi

P.O.Box 19676-00202, Nairobi.

Telephone no. 0722753217.

Or

The chairperson,

KNH/UON Ethics and Research Committee

P.O. Box 20723-00202, Nairobi.

Telephone number: (254-020) 2726300-9 Ext 44355

Email:uonknh_erc@uonbi.ac.ke

Consent:

I _____, the undersigned, acknowledge that I have been provided with adequate information about the study by Dr. /Mr. /Mrs. /Ms. _____. I have read the information, or it has been read to me. I have had the opportunity to ask questions, which have been answered to my satisfaction. I voluntarily agree to participate in the study.

Signature of Participant _____ Date _____

Signature of Researcher/ Assistant _____ Date _____

Appendix 4: Consent form- Kiswahili

Kichwa cha kifani: Matokeoyaujauzitomiongonimwawanawakewalionauvimbewamfukowauzazi.

Mtafiti Mkuu: Dk. Joseph Mambo Mutua

Utangulizi:

Jinalanguni Joseph Mutua, mwanafunziwashahadaya kwanza katikaIdaraya Obstetrics, Chuo Kikuu cha Nairobi.
Ninafanyautafitiilikuamuaatharizauvimbewamfukowauzazikuanzia wiki 28 zaujauzito. Unaulizwakushirikikatikautafiti.

Taarifahiiitakusaidiakufanyauamuzijuuyakushirikikatikautafiti au la.Unawezakuulizamaswaliyoyotekuhusuutafiti auchochotekatikafomuhiiambachohukielewi.

Kusudi la utafiti:

Uvimbe wamfuko wa uzazini ukuajiusionakansa.
Shidahiihujulikanasnawakatiwaujauzitowakati mama mjamzitoanpigwapichayatumbo..

Utafitihuuutafananishamatokeoyaujauzitokatiwanawakewalionauvimbekwamfukowauzazinawenginebilauvimbekatika KNH.
Inalengakuonyeshakamakamauvimbewamfukowauzaziwakatiwaujauzitohuwahatarikwa afyaya mama namtoto.

Faida:

Kwa kushiriki katika utafiti huu, utatusaidia kujua kamauvimbe wa mfuko wa uzazi wakati wa ujauzito unahusishwa na matokeo mabaya au la. Hii itatuwezesha kutarajia matatizo yoyote ambayo yanaweza kutokea katika ujauzito wako wa baadaye ikiwa una hali hii na kujaribu kuyazuia. Utapata pia habari kuhusu hali hii inayoathiri wanawake wengi kama vile dalili zake na jinsi inavyoweza kutibiwa, na maswali yoyote unaweza kuwa nayo kuhusu hali hii yatajibiwa.

Hatarizilizowezekana:

Hakunahatarizinazohusikanaushirikiwakokatikautafitihuu. Utapokeakiwango cha utunzajikamawagonjwawenginekatikahospitali.
Hakunataratibuzauvamizizitafanyikakwako.Hatarizinazochunguzwakama vile kupotezamimba, kuvujadamubaadayakujifunguanakadhalika ni

hatarizinazohusishwanawanawakewajawazitowalionauvimbewamfukowauzazinasiokuto kananaushirikiwakokatikautafitihuu.

Ushiriki:

Kushirikikatikautafitihuunikwahiari.
Ikiwaunachaguakushirikikatikautafitihuu,unaruhusiwakuondokawakatiwowoteikiwaunata kakufanyahivyo.Utunzajiunaopokeakutokahospitalihauwezikuathiriwanauamuziunaofany a

Fidia:

Hakunafidiaitatolewakwakushirikikatikautafitihuu.

Utaratibu:

Ikiwaunakubalikushirikikatikautafitihuu, mchunguzimkuu au msaidizi wake wautafitiatawahojiwewenakujazamajibukatikamaswali.
Msaidizianawezapiakupatamaelezoyaziadakutokakwakumbukumbuzakozamatibabu.
Timuyautafitiitafuatiliamarakwamarawakatiwaziarazakozaujauzitompakabaadayakujifun gua.

Usiri:

Taarifautakayatoaitahifadhiwakwasiri. Majina au maelezoyoyoteyakukutambulishahayatakuwakwaripotiyamwisho

Maelezoyamawasiliano:

Kwahabarizaidijuuyautafitiunawezakuwasiliananawafuatao:

Mtafitimkuu, Dk. Joseph M. Mutua

Idaraya Obstetrics na Gynecology, Chuo Kikuu cha Nairobi

P.O. Sanduku 19676-00202, Nairobi.

Nambayasimu. 0722753217.

Au

Mwenyekiti,

KNH / UON KamatiyaMaadilinaUtafiti

P.O. Sanduku 20723-00202, Nairobi.

Nambariyasimu: (254-020) 2726300-9 Ext 44355

Baruapepe: uonknh_erc@uonbi.ac.ke

Idhini

Mimi _____, aliyeandikwachini, nakubalikwambanimepewataarifazakutoshakuhusuutafitihuuna Dk. / Mr. /Bi. / Bi. _____. Nimesomaidhinihii, au nimesomewa.Nimekuwananafasiyakuulizamaswali, ambayoyamejibiwakwakuridhikakwangu. Mimi kwahiariyangunakubalikushirikikatikautafitihuu.

SahihiyaMshiriki _____ Tarehe _____

SainiyaMtafiti / Msaidizi _____ Tarehe _____