

**SONOGRAPHIC FINDINGS IN PATIENTS WITH FIRST TRIMESTER
BLEEDING AND RELATED ASSOCIATIONS IN NAIROBI**

**A DISSERTATION SUBMITTED IN PART FULFILMENT FOR THE DEGREE OF
MASTER OF MEDICINE IN DIAGNOSTIC IMAGING AND RADIATION MEDICINE,
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DECLARATION

I, **Dr. Irene Njeri Githinji**, declare that the work contained herein is my original work and has not been presented at any other place in Kenya to the best of my knowledge.

SignatureDate.....

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DEDICATION

This work is dedicated to my family, Lewis, my husband and my sons Michael, Albert, Justin, Claver for their undying patience, understanding and support, and little Blaise who lent me an extra brain, during preparation of this book.

To my brothers and sisters for their encouragement and especially those who helped me when my computer developed problems (special thanks to James and Josemaria); and to my parents for their support and prayers.

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LIST OF ABBREVIATIONS

β- hCG	-	beta subunit of human chorionic gonadotrophin
BPD	-	biparietal diameter
BTL	-	bilateral tubal ligation
CRL	-	crown-rump length
CW	-	continuous wave
DDIRM	-	Department of Diagnostic Imaging and Radiation Medicine
ERC	-	Ethics and Research Committee
GA	-	gestational age
GBD	-	gestational age by dates
GEPC	-	gynaecological and early pregnancy complaints
GS	-	gestational sac
GTD	-	gestational trophoblastic disease
H/o	-	history of
HC	-	head circumference
IUCD	-	intrauterine contraceptive device
KNH	-	Kenyatta National Hospital
LAC	-	lower abdominal complaints
MSD	-	mean sac diameter
MHz	-	megahertz
mIU	-	milli-international units
OCPs	-	oral contraceptive pills
PDT	-	pregnancy detection test
PV	-	per vaginum
PW	-	pulsed wave
SCH	-	subchorionic haemorrhage
TAS	-	transabdominal scan
TVS	-	transvaginal scan
UON	-	University of Nairobi
YS	-	yolk sac

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ABSTRACT

INTRODUCTION

Ultrasound imaging plays a major role in evaluation of pregnancies especially in the first trimester. Vaginal bleeding in early pregnancy is a relatively common presentation in the acute gynaecological setting, and ultrasonography remains the safest and fastest way of evaluating these patients.

OBJECTIVE

The aim of the study was to determine the ultrasound findings in patients presenting with vaginal bleeding in the first trimester and their proportions.

MATERIALS AND METHODS

A cross-sectional descriptive study carried out at the University of Nairobi, Department of Diagnostic Imaging and Radiation Medicine (DDIRM, UON) and at Kenyatta National Hospital (KNH). All Patients presenting to the radiology department for ultrasound due to vaginal bleeding in the first trimester, between April and December, 2013, were evaluated with a pelvic ultrasound, either transabdominal, transvaginal or both. A data collection sheet was used to record the pelvic sonographic findings and possible predisposing factors associated with the vaginal bleeding. The data was analysed using the Stata computer software package and the results presented in the form of tables, pie charts and bar charts.

RESULTS

A total of 231 patients were recruited into the study. The age range was 16 – 47 years with a mean of 27.83 years and a median of 27 years with a standard deviation of 5.686. Most patients were in the 26 to 35 year age group (133 cases; 57.6%). All 231 patients had abnormal findings on ultrasound, but 6 of them had more than one finding, giving a total of 237 findings. The commonest finding was incomplete abortion accounting for 38.7% of cases, followed by ectopic pregnancy accounting for 28.1%, while the least common finding was uterine fibroids in pregnancy accounting for 0.4%. First trimester bleeding was associated with a high rate of pregnancy loss with 206 of the patients (89.2%) having pregnancy loss.

CONCLUSION

Vaginal bleeding during the first trimester of pregnancy was associated with high rates of pregnancy failure in the emergency setting, with incomplete abortion and ectopic pregnancy being common sonographic findings. One should therefore have a high suspicion index for these conditions and apply appropriate investigative procedures and management.

1 INTRODUCTION AND LITERATURE REVIEW

Ultrasound imaging plays a major role in evaluation of pregnancies especially in the first trimester, as it has not been found to cause any known biological side effects in the fetus at the usual diagnostic frequencies of between 2.5 to 15MHz, even after extensive use in obstetrics for about fifty years⁽¹⁾. It should, however, be used judiciously as there may be effects to the embryo which have not yet been described. Use of Doppler techniques is associated with higher intensity levels of ultrasound than the usual B- mode and M- mode pulsed wave techniques, and its use should therefore be avoided.

Obstetric ultrasound was introduced by Ian Donald in the early 1960's and has since been very important in evaluation of the mother and fetus during pregnancy⁽²⁾. It has unique features such as its non-invasive nature and the fact that it uses non-ionizing radiation, which gives it special advantage over other imaging modalities. For this reason its value has been established in those areas where these qualities are useful⁽³⁾, for example, in obstetric and paediatric imaging.

Because it is less demanding in terms of the physical infrastructure required, cost of equipment and consumables, the development and expansion of basic ultrasound services is more readily achievable than other imaging modalities⁽³⁾. The only drawback is that it is operator dependent, and diagnosis heavily relies on the expertise, technique, training and experience of the operator^(3, 4, 5).

Basically, ultrasound imaging is the use of very high frequency sound, generated in an electrically excited crystalline material, to produce images. Extensive scrutiny has established that potential biohazards including increase in tissue temperature and the formation and collapse of bubbles in liquids, which may be caused by the use of ultrasound occur at exposure durations and intensity levels that are hundreds of times above those used in diagnostic imaging. This makes ultrasound one of the safest forms of energy used in medical imaging⁽³⁾.

Ultrasonography is a dynamic study which is carried out in "real-time". Cross sectional imaging can be done in any plane the examiner chooses especially those that best demonstrate anatomy or pathology. At the same time, extended examination of another region of the body, if needed, can be carried out at the same sitting without discomfort to the patient. 3- Dimensional reconstruction can also be done to better depict anatomy or pathology.

1.1 ROLE OF ULTRASOUND IN FIRST TRIMESTER IMAGING

The first trimester is a period of rapid change that spans fertilization, formation of the blastocyst, implantation, gastrulation, neurulation, the embryonic period (weeks 6 to 10) and early fetal life⁽⁶⁾. Imaging in the first trimester of pregnancy is important in the assessment of the early gestation to confirm the presence, number, position and viability of the pregnancy. The placentation and cervix can also be assessed. Measurement of crown- rump length (CRL) and mean sac diameter (MSD) approximate the gestational age (GA). The CRL, however, is usually the most accurate way of GA determination. Late in the first trimester, dating can be performed with measurement of biparietal diameter (BPD) and head circumference (HC) rather than the CRL⁽¹⁾. The embryo can be visualized by the 6th menstrual week on transvaginal scanning (TVS). CRL is preferred for dating between 7 and 12 weeks. The standard deviation in the first trimester is about 5 days.⁽⁷⁾

Assessment of the female pelvis by transabdominal approach (TAS) is assisted by the presence of a full urinary bladder which acts as an acoustic window. TAS is limited by presence of air-containing small bowel loops in the pelvis especially when the urinary bladder is empty. It also requires the use of a low frequency transducer which reduces image resolution. The transvaginal approach (TVS) using a high frequency endocavitary transducer has the advantage of producing images of higher resolution, with early visualization of the gestational sac (GS) and its contents⁽⁸⁾ and earlier identification of embryonic cardiac activity⁽⁹⁾. A small gestational sac can be seen at about 4.5 weeks, using this technique⁽¹⁰⁾. The yolk sac is the first thing to be visualized within the normal gestational sac⁽¹¹⁾. However deep structures cannot be well visualized. In some cases, a transperineal approach is used. However, the TAS and TVS are the standards used in our setting.

The yolk sac should be visualized when the mean sac diameter (MSD) is 20mm when using the transabdominal approach⁽¹²⁾. This corresponds to about 6.5weeks gestation. Using the transvaginal approach, the yolk sac should be visualized when the MSD is 8mm⁽⁷⁾. When the CRL is greater than 3mm, the cardiac activity can usually be seen by TVS⁽¹¹⁾.



Figure 1: measurement of the fetal CRL.
(From DDIRM, UON).

1.2 DEFINITIONS AND CAUSES OF FIRST TRIMESTER BLEEDING

First trimester bleeding is any vaginal bleeding occurring during the first 12 weeks of pregnancy, and by default constitutes a threatened abortion^(13, 14) until a non-threatening cause is identified. It occurs in about a quarter of pregnancies, approximately half of whom will miscarry⁽¹⁵⁾, while the other half will stop bleeding and complete a normal pregnancy⁽¹⁶⁾.

To aid in distinguishing among the many conditions of first trimester bleeding, discriminatory criteria using TVS and the β subunit of the human chorionic gonadotrophin hormone (β -HCG) testing, are used⁽¹⁷⁾.

Possible causes of bleeding include obstetric and non-obstetric causes. Non obstetric causes include cervicitis, vaginitis, trauma, cystitis, cervical cancer or polyps. Obstetric causes include sub chorionic haemorrhage, embryonic demise, anembryonic pregnancy, incomplete abortion, ectopic pregnancy and gestational trophoblastic disease.

Some definitions of terms applied to early pregnancy loss: (taken mainly from references 13 and 14, additions from 7 and 11).

- 1 Anembryonic pregnancy: an intrauterine gestational sac measuring more than 18 mm by TVS and more than 25 mm by TAS is present without evidence of embryonic tissue (yolk sac or embryo). The previous term is “blighted ovum”. It is also termed a missed abortion,

together with embryonic demise. Other criteria includes a GS with an MSD of 8mm or more without a yolk sac on TVS.⁽⁷⁾

- 2 Ectopic pregnancy: a pregnancy situated anywhere outside the uterine cavity. The usual location is in the fallopian tubes, but it may occur in the broad ligament, ovary, cervix or abdomen.
- 3 Embryonic demise: presence of an embryo with a CRL of more than 5mm by TVS, without cardiac activity, within an intrauterine gestational sac. It is also known as a “missed abortion”.
- 4 Gestational trophoblastic disease or hydatidiform mole: it includes complete and partial moles.

Complete mole: placental proliferation is present in the absence of a fetus; most have 46XX chromosomal composition, and all are derived from paternal source.

Partial mole: presence of a molar placenta occurring with a fetus; most are genetically triploid (69XXY).

The appearance of a molar pregnancy on ultrasound is usually characteristic, and by correlating this with high levels of β -hCG, the diagnosis can be made.⁽¹¹⁾

- 5 Heterotrophic pregnancy: occurrence of simultaneous intrauterine and ectopic pregnancy. This is a rare occurrence.
- 6 Recurrent pregnancy loss: more than two consecutive pregnancy losses.
- 7 Spontaneous abortion: spontaneous loss of pregnancy before 20 weeks gestation.
- 8 Complete abortion: the complete passage of all products of conception.
- 9 Incomplete abortion: occurs when some but not all of the products of conception have passed.
- 10 Inevitable abortion: bleeding in the presence of a dilated cervix, which indicates that passage of the conceptus is unavoidable.
- 11 Septic abortion: incomplete abortion with ascending infection of the endometrium, parametrium, adnexa or peritoneum.

- 12 Subchorionic haemorrhage: findings on ultrasound of blood between the chorion and uterine wall, usually in the setting of vaginal bleeding. A subchorionic haemorrhage can be present in the presence of a live gestation. The outcome of the pregnancy can be predicted by the size of the haematoma ⁽¹¹⁾.
- 13 Threatened abortion: bleeding is present before 20 weeks gestation in the presence of an intrauterine gestational sac which contains an embryo with cardiac activity; and closed cervix.
- 14 Vanishing twin: a multifetal pregnancy is identified on ultrasound, and one or more fetuses later disappear. This occurs more often now that early ultrasound is common. If it occurs in early pregnancy, the embryo is often reabsorbed; if it occurs later in pregnancy it leads to a compressed or mummified fetus or amorphous material.

1.3 ROLE OF ULTRASOUND IN FIRST TRIMESTER BLEEDING

Early detection of pregnancy depends on transvaginal ultrasonography using a transducer frequency of 5-MHz or greater. A 5-mm sonolucent gestational sac should be visible in the endometrium at the fundus by five menstrual weeks ⁽¹⁵⁾. The normal sac of an intrauterine pregnancy consists of a central blastocyst surrounded by a double ring of echogenic chorionic villi and decidua. This distinguishes it from a pseudogestational sac associated with ectopic pregnancy.

Ultrasound has a very important role in the diagnosis of ectopic pregnancy, If an intrauterine gestation is seen on ultrasound, then it almost always excludes an ectopic gestation; however, heterotrophic pregnancies can occur, which they do in about 1 in 7000 pregnancies ⁽¹⁸⁾. One should, therefore, always look out for this when performing a first-trimester ultrasound examination. An ultrasound exam should be carried out when there is suspicion of an ectopic pregnancy. Studies have found the overall accuracy for the diagnosis of ectopic pregnancy by TVS to be 90% or better. A prospective study comparing the sonographic, surgical and serum β -hCG findings found that the most common finding suggestive of an ectopic pregnancy was a ring in the adnexa with a thickened echogenic wall, which was seen in 62% of patients with ectopic gestations. A yolk sac was seen within this ring in 15% of patients, while fetal echoes and cardiac activity were seen in 17%. In 32% of cases, a complex mass is seen ⁽¹⁹⁾.

Correlation of ultrasound findings with β -hCG levels is of great importance in the diagnosis of ectopic pregnancy^(19, 20). An MSD of between 5 and 25mm has been shown to have a linear correlation with β -hCG levels⁽²¹⁾. The level also rises in ectopic pregnancy, but more slowly. The presence of an empty uterus on TVS in the setting of a positive pregnancy test or serum β -hCG levels, is highly suspicious of an ectopic gestation. An intrauterine gestational sac should be seen on TVS when serum β -hCG level is 1000mIU/ml⁽⁹⁾. The higher the β -hCG levels in the setting of an empty uterus, the more likely the presence of an ectopic pregnancy.

A β -hCG level of less than 1000mIU/ml in the presence of an empty uterus could indicate either, a normal early IU gestation, an ectopic pregnancy or a complete abortion; and a follow up of β -hCG levels and ultrasound is recommended⁽⁹⁾, thus, initial sonography cannot always be relied on to identify intrauterine and ectopic pregnancies⁽¹⁷⁾. At 4-5 weeks gestation, β -hCG levels may be less than 1,500 mIU per mL with ultrasound findings that are non-diagnostic, in which case ultrasound may be repeated after one week in a stable patient. During this period, there is significant growth of the gestational sac or embryo, both of which should grow at the rate of 1 mm per day⁽¹⁶⁾. Serial quantitative β -hCG levels in combination with follow-up imaging are also useful. Based on a prospective study, the minimum β -hCG increase necessary for a living pregnancy over a 48-hour interval is 53 percent⁽²²⁾. If the rise is slower than this, or it plateaus, or falls, the differential diagnosis is either a failing intrauterine pregnancy or ectopic pregnancy.



Figure 2: TAS: subchorionic haemorrhage (SCH). Fetal pole (FP) and yolk sac (YS) are seen within the gestational sac. (From the Diagnostic Imaging Department, KNH, Nairobi).



Figure 3: TAS: Free pelvic fluid is suggestive of ectopic pregnancy in the setting of a positive pregnancy test and an empty uterus. (From the Diagnostic Imaging Department, KNH, Nairobi)

1.4 EVALUATION OF CASES REPORTING WITH BLEEDING PER VAGINA DURING THE FIRST 20 WEEKS GESTATION

Since vaginal bleeding during early pregnancy, is a sign of a threatened pregnancy, it calls for rapid evaluation of these patients to find the cause of bleeding, so as to institute proper and timely management.

Obore (2001) ⁽²³⁾, in a review of maternal mortality in KNH between 1995 and 1999, found that among the causes of maternal mortality, post-abortion sepsis accounted for 25.6% and ectopic pregnancy accounted for 2.5%. Haemorrhage of various causes accounted for 10.8%. This indicates that the importance of proper evaluation and timely management cannot be overemphasized.

In a descriptive study carried out in Pakistan to determine the prevalence of vaginal bleeding in pregnancy upto 20 weeks, the prevalence of bleeding was found to be 11.3%. Among these, 95.9% were abortions, 1.87% ectopic, 1.47% molar and 0.66% were due to local causes and trauma. The highest frequency of bleeding was in the first trimester at 81.7% as compared to 18.2% in the second trimester. Women between 26-35 years of age experienced more abortions. The percentage of abortion increased as the parity increased, with 42.5% and 30.3% abortions in the fourth and fifth pregnancies respectively. The previous history of abortion (44%) and the last pregnancy abortion (41.2%) were the significant factors in the past obstetric performance of the patients. The main maternal risk factors were medical problems in 21.4%, treatment for infertility in 18.47% and use of contraception in 18.5%. No cause was found in 13.9% patients ⁽²⁴⁾. In another study, it was estimated that the average rate of miscarriage was 31%, with the mean time around 11 weeks gestational age ⁽²⁵⁾. A Nigerian study whose aim was to determine the clinical pattern of gynecological and early pregnancy complaints as well as evaluate the correlation between the clinical and sonographic diagnoses, found that: Of the 253 cases, bleeding per vaginum (BPV), with or without pain, were the highest comprising 149 cases (61.6%), followed by threatened abortion, 45 cases (18.6%), and non-viable or incomplete abortions, 13 cases (5.4%). There was poor correlation between clinical impressions and ultrasound findings ⁽²⁶⁾.

Mbugua (1999) ⁽²⁷⁾, in a postgraduate dissertation on the morbidity patterns in the acute gynaecological unit in a rural district hospital in Kenya, found that the commonest complaints were abnormal vaginal bleeding (85.8%) and abdominal pain (76.4%). Various types of abortion

were the commonest diagnosis on admission, many of which were incomplete (37.8%). It was also noted that the commonest diagnosis on admission was not the commonest at the time the patients were discharged home. The above studies and others underscore the importance of ultrasound in evaluation of first trimester bleeding.

1.5 FACTORS PREDISPOSING TO SPONTANEOUS ABORTION AND ECTOPIC PREGNANCY

Factors predisposing to spontaneous abortion include: endocrine (e.g., progesterone deficiency, thyroid disease, uncontrolled diabetes), genetic aneuploidy (accounts for about half of spontaneous abortions), immunologic (e.g., antiphospholipid syndrome, lupus), infection (e.g., chlamydia, gonorrhoea, herpes, listeria, mycoplasma, syphilis, toxoplasmosis, ureaplasma), occupational chemical exposure, radiation exposure and uterine factors (e.g., congenital anomalies); while those predisposing to ectopic pregnancy include: current intrauterine device, history of ectopic pregnancy, history of in utero exposure to diethylstilbestrol, history of genital infection (including pelvic inflammatory disease, chlamydia, or gonorrhoea), history of tubal surgery (including tubal ligation or re-anastomosis of the tubes after tubal ligation), in vitro fertilization, infertility and smoking^(4,5, 28).

Akonde (1999)⁽²⁹⁾, in a postgraduate dissertation on risk factors associated with spontaneous recurrent abortion carried out at KNH, found that previous ectopic pregnancy and history of abnormal vaginal discharge were significantly associated with spontaneous recurrent abortion (Fisher's exact test = 0.017 and 0.042 respectively). There was an association between single marital status and spontaneous recurrent abortion, though not significant (O.R = 2.05, Fisher's exact test = 0.32).

In Western countries, the prevalence of ectopic pregnancy has been increasing.⁽³⁰⁾ Groups found to have a higher risk include women with previous history of pelvic inflammatory disease, those who have had tubal surgical intervention for infertility and those who have undergone in-vitro fertilization⁽⁹⁾.

1.6 OUTCOMES OF PREGNANCIES FOLLOWING FIRST TRIMESTER BLEEDING

Studies have shown that vaginal bleeding in the first trimester of pregnancy is associated with a high risk for unfavourable outcome of that pregnancy, and a risk for recurrence of first-trimester bleeding in subsequent pregnancies ^(31, 32).

In a retrospective, registry-based cohort study, women delivering in Denmark from 1978 to 2007 with a first singleton pregnancy (782,287 cases) and first and second singleton pregnancies (536,419 cases) were identified. It was found that women with first-trimester bleeding in the first pregnancy have an increased risk of complications of that pregnancy and of recurrence of first-trimester bleeding and other complications in the second pregnancy ⁽³¹⁾.

Another study carried out in Naval Medical Center, Portsmouth, Virginia to determine fetal outcomes of women with an indeterminate ultrasound who present to the emergency department during the first trimester of pregnancy, found that carrying the pregnancy to 20 weeks or more occurred in 70 patients (23.9%). Spontaneous abortion occurred in 193 women (65.9%), and 30 women (10.2%) were treated for an ectopic pregnancy. Total fetal loss incidence was 89.2% in patients presenting with any vaginal bleeding, compared to 34.7% in patients with pain only, indicating that vaginal bleeding increased the risk of fetal loss ⁽³²⁾.

Sonographic evaluation of patients presenting with first trimester vaginal bleeding was found to have significant effects on care decisions and cost ⁽³³⁾ in a study conducted to assess the outcome (to the end of the first trimester) of pregnancies with vaginal bleeding and the influence of ultrasound-acquired information on care and cost of care. The main findings included that on endovaginal ultrasonography, 44% of the pregnancies were viable, of which 86% continued to the end of the first trimester. Of the 33% of pregnancies that were nonviable, 74% successfully miscarried without intervention. About 5.4% had ectopic pregnancies, while no pregnancy was identified in the remaining 17.6%. If ultrasonography reported a nonviable pregnancy, expectant management was significantly less expensive than scheduled curettage. Spontaneous abortion, also, was significantly less expensive than scheduled or emergency evacuation for women who eventually miscarried after initial ultrasonography revealed a live pregnancy ⁽³³⁾.

Bennett, Bromley, Lieberman and Benacerraf ⁽³⁴⁾, in a study carried out on 516 patients with vaginal bleeding and ultrasound findings of subchorionic haematoma with a live fetus, found that fetal outcome is dependent on size of the haematoma, where the overall spontaneous abortion rate of 9.3% nearly doubled when the haematoma was large (18.8%) as compared with small and moderate haematomas (7.7% and 9.2% respectively). Outcome is also dependent on maternal age and gestational age.

Another study found unfavourable outcome in 71% of pregnancies with sonographic evidence of subchorionic haemorrhage which correlated well with relative and absolute size of the haematoma. The severity of vaginal bleeding, the presence of pain and change in hematoma size on follow-up examination were also found to correlate with the outcome. There was no significant correlation found between pregnancy outcome and echogenicity of the haematoma, placental margin elevation, maternal age, gravity or parity ⁽³⁵⁾.

2 STUDY OBJECTIVES

BROAD OBJECTIVE

The main objective of this study was to evaluate the ultrasound findings of patients presenting with first trimester bleeding at Kenyatta National Hospital (KNH) and their distribution.

SPECIFIC OBJECTIVES

1. To determine the most common ultrasound finding in patients presenting with first trimester per vaginal bleeding.
2. To determine the proportion of each ultrasound finding in first trimester bleeding.
3. To determine the range of predisposing factors that would be/ have been associated with the ultrasound findings in patients with first trimester bleeding.

2.1 STUDY RATIONALE AND JUSTIFICATION

Per vaginal (PV) bleeding in the first trimester constitutes, by default, a threatened abortion^(13, 14). Some causes of first trimester PV bleeding are also life-threatening to the mother. It, therefore, needs to be investigated to exclude a life-threatening cause to either mother or embryo. If a life-threatening cause is found, then management must be prompt. A proper history and physical examination may suggest the cause of bleeding, but in most cases, an ultrasound scan of the pelvis is indicated to get the diagnosis.

A history of circumstantial events may point at certain predisposing factor(s) for whatever diagnosis is found. If a cause-effect relationship can be established between certain events and the cause of bleeding, this would improve predictability of diagnosis, hence urgency of management and focused patient counseling. It may also impact on modification of behavior or treatment in an attempt to prevent recurrence of the bleeding in future especially if it is life-threatening. Currently, to the best of available knowledge, there is no local study that has been carried out in this area and there is need to have local data.

2.2 RESEARCH QUESTION

1. What is the proportion of the different sonographic findings in patients with first trimester vaginal bleeding as seen at KNH?
2. Is there any relationship between the sonographic findings and various patient variables, including patient age, parity, prior contraceptive use, infertility therapy, trauma, medical illness, previous PV bleeding during pregnancy, previous pregnancy loss, caesarian section and genital tract infection, level of education, marital status, and occupation as seen at KNH?

3 STUDY DESIGN, MATERIALS AND METHODS

The study was conducted at the Radiology department of Kenyatta National Hospital (KNH) and at the Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi (DDIRM, UON) between April and December, 2013.

This was a cross sectional descriptive study.

3.1 STUDY POPULATION

The study included patients referred for pelvic ultrasound examination for indication of early pregnancy bleeding, or vaginal bleeding with history of amenorrhoea at KNH and DDIRM, UON.

3.2 SAMPLE SIZE DETERMINATION

The sample size was calculated using the following formula:

$$n = \frac{Z^2 \times p(1-p)}{C^2}$$

Where:

Z = relative coefficient. Standard normal deviate at 5% level of significance (95% CI) is 1.96

P = prevalence of first trimester bleeding as per reference 24. (0.82)

C = margin of error (0.05)

When the above formula is applied, a sample size of 227 was obtained, as follows:

$$n = \frac{(1.96 \times 1.96) \times (0.82 \times 0.18)}{0.0025} = \frac{0.5670}{0.0025} = 226.8$$

Therefore, **n = 227**.

A sample size of **231** was used in this study.

3.3 SAMPLING METHODS

Random sampling was used to obtain subjects for the study. Randomization was done by including all those meeting the inclusion criteria during any given data collection period.

3.3.1 Inclusion criteria:

- Patients with a history of per vaginal bleeding, whatever the amount, in the setting of amenorrhoea of up to 12 weeks or known pregnancy in the first trimester (either from a urine pregnancy detection test (PDT) or β -HCG levels or from a previous ultrasound scan).
- Patients, who may have had a short period of amenorrhoea, though were not sure of their dates.

3.3.2 Exclusion criteria:

- Patients without PV bleeding.
- Patients with no amenorrhoea, or in whom pregnancy had been excluded by a urine PDT or serum β -HCG levels.
- Patients with pregnancy beyond the first trimester (greater than 12 weeks gestation).
- Patients with an indeterminate ultrasound scan both by TAS and TVS and would therefore require a follow up scan.
- Patients who decline to participate in the study.

3.4 MATERIALS AND METHODS

Both centres where the study was conducted use Phillips and GE machines.

These were all used in evaluation of selected patients. TAS examinations were carried out using curvilinear 3.5 to 5-MHz transducers while TVS examinations were carried out using endovaginal 7 to 12-MHz transducers.

Selected patients were prepared for the pelvic ultrasound examination. They were counseled on the examination they were to undergo, and consent was obtained from them. Those who were to undergo TAS pelvic examination were asked to fill their urinary bladder by drinking at least 4 to 6 glasses of plain water, or until they had the urge to void. Those who were to undergo TVS pelvic examination were asked to completely empty their urinary bladders.

The selected patients then underwent standard TAS or TVS pelvic examinations in different planes, mainly longitudinal and transverse and selected images saved and printed for reference. Assessment of the maternal uterus and ovaries was carried out. Use of Doppler techniques was avoided and fetal cardiac activity was evaluated using standard B-mode and M-mode techniques. The findings were documented. The principal investigator performed the ultrasound examination. The findings were verified by a consultant radiologist, in agreement with another consultant radiologist.

If the TAS findings were inconclusive, then a TVS examination was carried out with the patients consent. If consent was not obtained for the TVS examination, or the TVS findings were also inconclusive, then the patient was excluded from the study.

In some cases, follow up of the patient and correlation with the intra-operative findings, confirmed the ultrasound diagnosis, especially in cases of ectopic pregnancies.

4 DATA MANAGEMENT AND ANALYSIS

4.1 DATA COLLECTION

Patient history and ultrasound findings were documented on a data collection sheet, and subsequently the information was fed into a database.

4.2 DATA ANALYSIS

Once data had been collected, it was fed into a database, and the following was analysed by the statistician

- All sonographic findings and their proportions
- Ultrasound findings in relation the various variables studied

Mean, mode, median were calculated for all groups of data.

Comparison (association) was made between sonographic findings and their relation to the various variables studied. Level of significance was tested using the Chi-square test for comparing simple data and the T-test for comparing means.

Stata computer package was used for data analysis.

4.3 DATA REPRESENTATION

Subsequently, tables, pie charts and bar charts were used to present the data.

5 ETHICAL CONSIDERATIONS

Many ethical considerations were taken into account in the process of this research, including:

- Kenyatta National Hospital and University of Nairobi Ethics and Research committee approved the research.
- The study was commenced only upon approval by the ethical and research committee.
- The patients had the study and examination they were to undergo explained to them. They were only recruited once they had consented. They were required to sign a consent form as proof of their consent.
- The patient's personal information e.g. names and hospital numbers were not used in the study in order to uphold confidentiality.
- The information acquired was not used for any other purpose besides in the clinical management of patients and academics.
- No examination was carried out on the patients other than the one requested by the primary physician.

6 RESULTS

6.1 DEMOGRAPHICS

A total of 231 patients were evaluated; age range of 16 to 47 with a mean age of 27.83. The median age was 27 years with a standard deviation of 5.686. Majority were within the age of 26 to 35 years (133 cases; 57.6%), followed by the age group of between 15 to 25 years (78 cases; 33.8 %). Nineteen cases (8.2%) were between the ages of 36 to 45years, while 1 case (0.4%) was above the age of 45, as summarized in chart 1.

Seventy percent of the subjects (162) were married while 28.1% (65) were single. The remaining 1.7% (4) were either separated (3) or divorced (1).

As regards level of education, 102 of them (44.3%) had been educated up to secondary school, while 27.4% (63) had reached college level; 7.4% (17) had gone to university and 20.9% (48) had only had primary education.

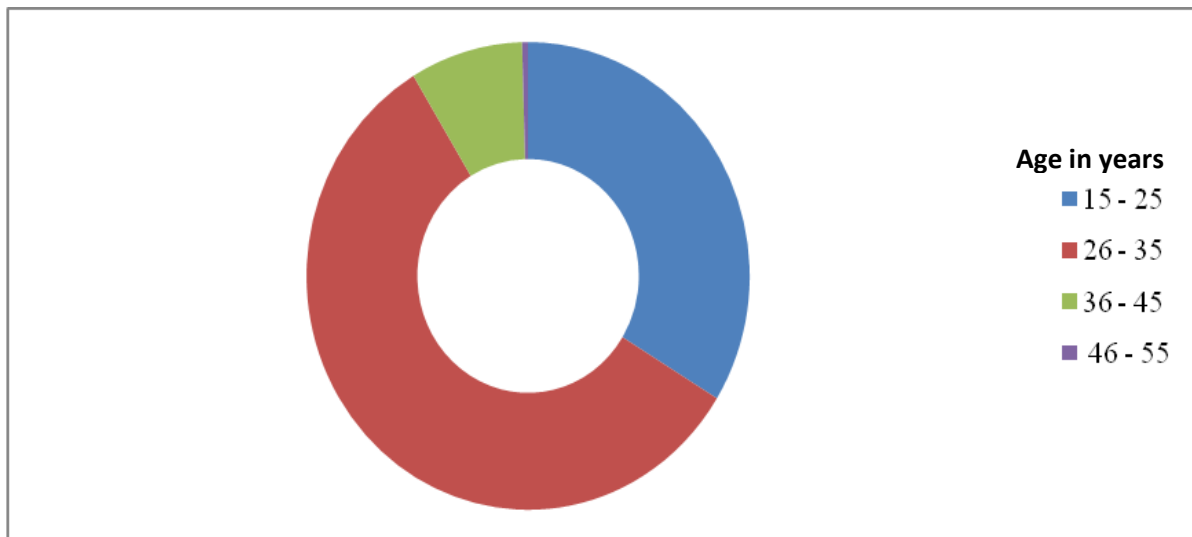


Chart 1: Distribution of study subjects by age group in years.

6.2 PRESENTING COMPLAINTS

All patients had a history of amenorrhoea and per vaginal bleeding. Of these, 150 (64.9%) reported heavy bleeding, while 81(35.1%) had spotting.

Other symptoms reported by the patients included nausea and/ or vomiting in 68 (29.4%) of respondents; fever in 38 (16.5%) and other complaints in 184 (79.7%) of patients. Lower abdominal pain was the commonest “other” complaints (167 patients; 72.3% of cases). Other complaints included headaches, dizziness and fainting episodes. One patient had jaundice.

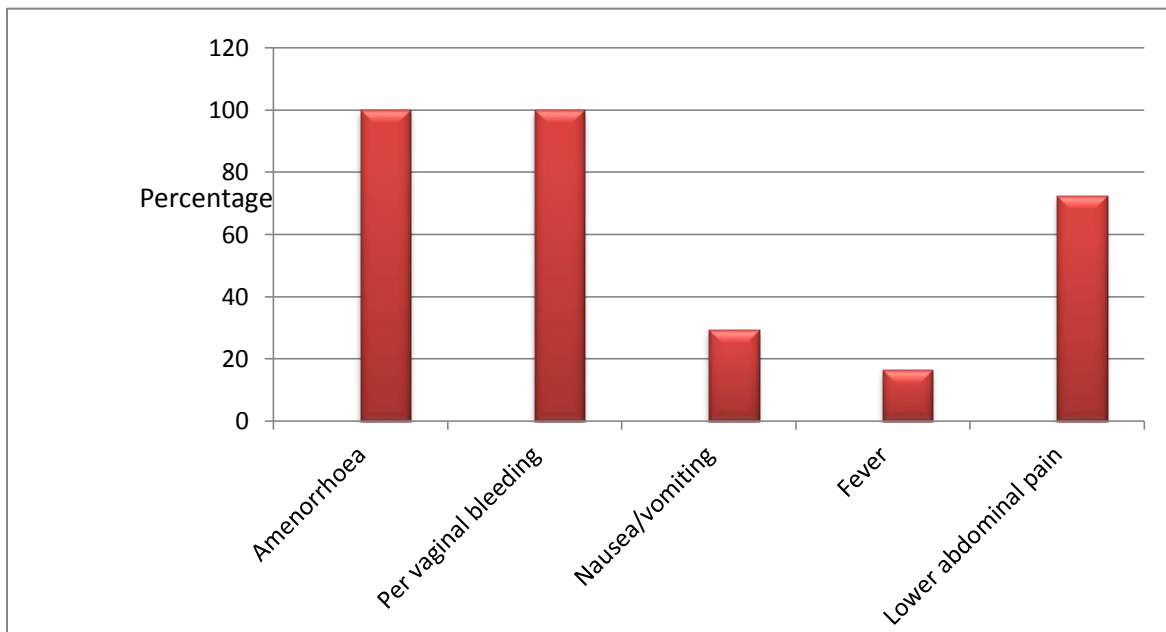


Chart 2: Distribution of presenting complaints

6.3 PREVIOUS HISTORY

Only 3% of patients reported a history of recent trauma (n=7). A high rate of contraceptive use was noted, with 70 patient (30.3%) having never used them and 161 patients (69.7%) having used them. Of these, 129 patients (55.8%) had used them more than three months prior, while 41 (17.7%) had been on contraceptives less than 3 months before presentation, that is, possibly, even after conception of the pregnancy. History of previous pregnancy bleeding was reported in 59 cases (25.5%) while 55 (23.8%) reported a previous pregnancy loss. History of previous ectopic pregnancy was reported in 4 cases (1.7%). Seven patients (3%) had been treated for

infertility; 25 (10.8%) reported previous caesarian section; 29 (12.6%) reported a history of genital tract infection. Twenty six (11.3%) had a concurrent medical illness and 105 (45.5%) had taken some form of medication during the period of amenorrhoea. This is summarized in table 1.

Table 1: Distribution of previous medical history

CHARACTERISTICS	Previous History		
	SUBCHARACTERISTICS	n	% of cases
H/o recent trauma		7	3
Contraceptive use		161	69.7
	Previous (> 3 months ago)	129	55.8
	Norplant	9	3.9
	IUCD	5	2.2
	BTL	0	0
	Depo-Provera	53	22.9
	Other contraceptives	11	4.8
	Current (< 3 months ago)	41	17.7
	Norplant	0	0
	IUCD	1	0.4
	BTL	0	0
	Depo-Provera	2	0.9
	Other contraceptive	26	11.3
H/o Previous pregnancy bleeding		59	25.5
H/o Previous pregnancy loss		55	23.8
H/o previous ectopic pregnancy		4	1.7
Treatment for infertility		7	3
	Pills	7	3
	Surgery	0	0
	Other	1	0.4
H/o previous caesarian section		25	10.8
Previous or current genital tract infection		29	12.6
H/o medical illness		31	13.4
	Hypertension	2	0.9
	Diabetes and thyroid disease	0	0
	Asthma	5	2.2
	Others	24	10.4
Medication during period of amenorrhoea		105	45.5

6.4 CONCURRENT MEDICAL ILLNESS

Thirty one (13.4%) of the patients reported having concurrent medical illness. Of these 2 (6.5%) were hypertensive, 5(16.1%) had asthma, none (0%) reported diabetes or thyroid disorder.

Twenty four (77.4%) reported having other illnesses including peptic ulcer disease (PUD) (10) 32.3%, UTI (5) 16.1%, HIV (4) 13.0%, epilepsy (1) (3.2%), migraine (1) (3.2%), allergies (1) (3.2%). One (3.2%) reported having had malaria and typhoid and 1 (3.2%) was found to have polycystic kidneys during evaluation of the PV bleeding by ultrasound.

Table 2: Distribution of illness type

Distribution of type of illness			
		N=31	N=29
Illness	n	% of responses	% of Cases
Hypertension	2	6.5%	7.00%
Diabetes, thyroid disorder	0	0.0%	0.00%
Asthma	5	16.1%	17.20%
Other	24	77.4%	82.80%
Total	31	100.0%	107.00%

Table 3: Distribution of other illnesses

Distribution of other illnesses		
Illness	n	% of responses
PUD	10	32.30%
UTI	5	16.10%
HIV	4	13.00%
epilepsy	1	3.20%
migraine	1	3.20%
malaria/typhoid	1	3.20%
allergies	1	3.20%
polycystic kidneys	1	3.20%
Total	24	77.40%

6.5 ULTRASOUND FINDINGS

6.5.1 DISTRIBUTION OF ULTRASOUND FINDINGS

As shown in table 4, all 231 patients had abnormal ultrasound findings, with 237 ultrasound findings being recorded, because 6 of them had more than one abnormal finding. Of the cases, 14 (6.1%) were found to have anembryonic pregnancy, 65 (28.1%) had ectopic pregnancy, 18 (7.8%) had embryonic demise, 9 (4.0%) had GTD, 7 (3%) were found to have a complete abortion, 89 (38.7%) had incomplete abortion, 4 (1.7%) had inevitable abortion, 24 (10.1%) were found to have SCH, 1(0.4%) had uterine fibroids in pregnancy with a live embryo at 7weeks. Two (0.8%) had placenta praevia grade 4, one of whom also had SCH. Four (1.7%) had other findings in addition to the main findings including a normal twin pregnancy with SCH (1), IUCD in-situ with a SCH (1), right ovarian cyst with a SCH, and bilateral polycystic kidneys with incomplete abortion(1). Among the single patients, incomplete abortion was the most common finding accounting for 50.8%.

Table 4: Distribution of ultrasound findings

Distribution of ultrasound findings			
		N=237	N=231
Ultrasound Findings	n	% responses	% Cases
Anembryonic pregnancy	14	5.9%	6.1%
Ectopic Pregnancy	65	27.4%	28.3%
Embryonic Demise	18	7.6%	7.8%
Gestational trophoblastic disease	9	3.8%	4.0%
Complete Abortion	7	3.0%	3.0%
Incomplete Abortion	89	37.6%	38.7%
Inevitable Abortion	4	1.7%	1.7%
Subchorionic haemorrhage	24	10.1%	10.4%
Uterine fibroids in pregnancy	1	0.4%	0.4%
Placenta praevia	2	0.8%	0.9%
Other (specify)	4	1.7%	1.7%
Total	237	100.0%	103%

As indicated in the above findings above, only 25 patients (10.8% of cases) had normal gestations sonographically, while 106 (89.2% of cases) had pregnancy losses.

6.5.2 ULTRASOUND FINDINGS AS PER AGE GROUP

Majority of findings in each category were found in the 26 -35 year age group. This was also the age group with the largest number of patients. These findings are summarized in table 5.

Table 5: Distribution of ultrasound findings as per age group

ULTRASOUND FINDINGS	AGE GROUP (YEARS)				TOTAL
	15 - 25	26 -35	36 - 45	45 -55	
anembryonic pregnancy	3 (21.4%)	10 (71.4%)	1 (7.2%)	0	14
ectopic pregnancy	20 (30.8%)	43 (66.1%)	2 (3.1%)	0	65
embryonic demise	5 (27.8%)	9 (50%)	4 (22.2%)	0	18
GTD	2 (22.2%)	6 (66.7)	0	1 (11.1%)	9
complete abortion	2 (28.6%)	5 (71.4%)	0	0	7
incomplete abortion	36 (40.4%)	45 (50.6%)	8 (9%)	0	89
inevitable abortion	0	3 (75%)	1 (25%)	0	4
SCH	9 (37.5%)	12 (50%)	3 (12.5%)	0	24
fibroids	0	1 (100%)	0	0	1
placenta preavia	1 (50%)	1 (50%)	0	0	2
others	1 (25%)	0	3 (75%)	0	4
TOTAL FINDINGS	79	135	22	1	237

6.6 DURATION OF AMENORRHOEA AND PV BLEEDING

The minimum and maximum duration of amenorrhoea was 29 days and 88 days respectively with an interquartile range (IQR) of 24. The mean duration was 63.9 days and the median was 65 days (standard deviation of 15.13). The minimal and maximum duration of vaginal bleeding was 1 day and 42 days respectively (IQR if 2), with a mean of 4.6 days and a median of 3 (standard deviation of 5.993). This is depicted in table 6.

Table 6: Duration of ammenorrhoea and vaginal bleeding

	Duration in Days	
	Amenorrhoea	P v bleeding
n	231	231
Mean	63.9	4.6
Median	65	3
Std. Deviation	15.13	5.993
Minimum	29	1
Maximum	88	42
IQR	24	2

6.7 SIGNIFICANT ASSOCIATIONS BETWEEN ULTRASOUND FINDINGS AND CLINICAL HISTORY

The following significant associations were found between the ultrasound findings and the clinical history.

1. There was a significant association between ultrasound finding of ectopic pregnancy and the amount of bleeding (Chi-square test: p value <0.001) with 67% of patients with ectopic pregnancy reporting vaginal spotting. Ectopic pregnancy was also significantly associated with the duration of amenorrhoea, with these patients having a significantly lower mean duration of amenorrhoea (55.83 days) than those without this finding (67.07 days). (T-test: p-value <0.001).
1. Embryonic demise was significantly associated with the duration of amenorrhoea, with the mean gestational age being higher (73.16 days) in these patients than in those with other findings (63.06 days). (T-test: p-value 0.005).
2. Ultrasound finding of GTD was significantly associated with the duration of vaginal bleeding (p = 0.003), with the mean duration of vaginal bleeding reported being significantly higher than those with other findings (10.44 days versus 4.36days).
3. Both complete and incomplete abortions were significantly associated with heavy vaginal bleeding, where it was reported in 100% of patients found to have a complete abortion (p-value 0.031) and 94.4% of those with findings of incomplete abortion (p-value <0.001). Incomplete abortion was also significantly associated with previous pregnancy bleeding and previous pregnancy loss (p = 0.037 and 0.049 respectively) as well a significantly greater mean duration of amenorrhoea (66.81 days) than those without incomplete abortion (62.06 days) (p=0.02); and a shorter mean duration of vaginal bleeding (3.35 days) as compared to those without (5.35 days) (p= 0.012).
4. There was a significant association between the findings of inevitable abortion and the duration of amenorrhoea, with a significantly higher gestational age reported in these patients (82.75 days) than in those without this finding (63.56 days) (p=0.012).

5. There was a significant association between subchorionic haemorrhage and spotting, with 70.8% of these patients reporting vaginal spotting (p-value <0.001).

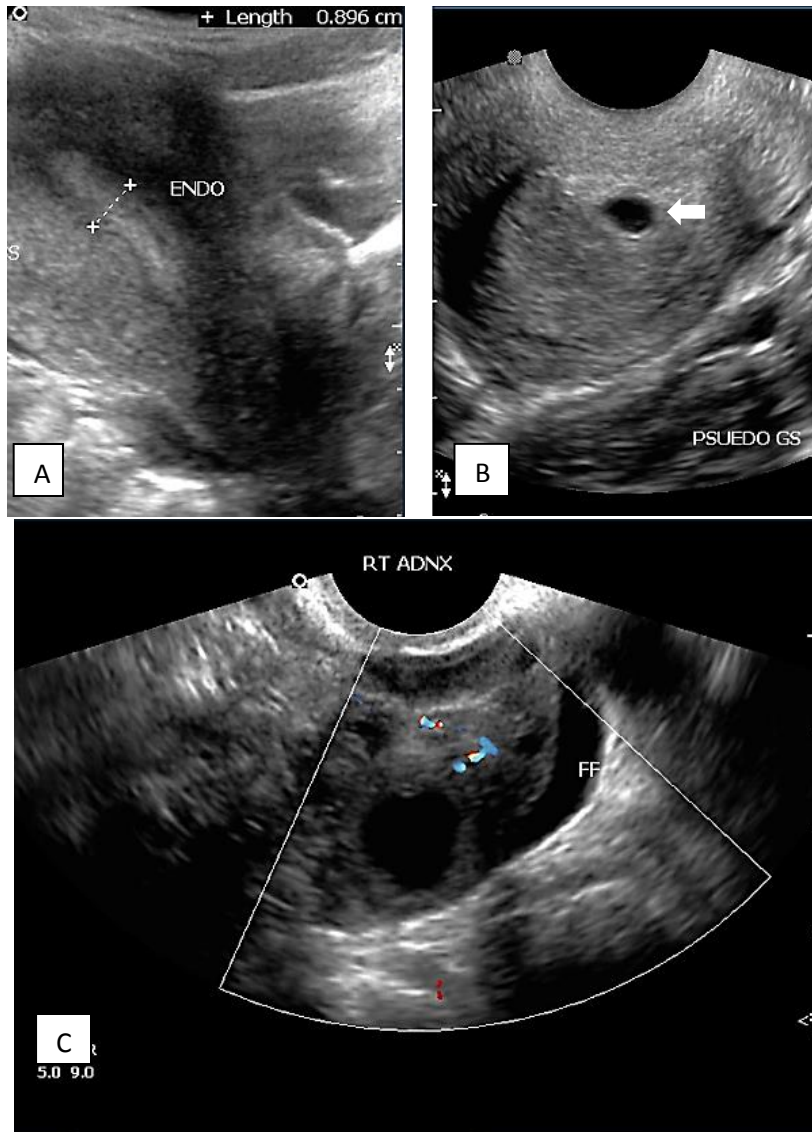
This information is summarized in table 7.

Table 7: Summary of significant associations found

Ectopic pregnancy			
Amount	No	Yes	P-Value
Spotting	34(21%)	43(67%)	<0.001
Heavy	128(79%)	22(33%)	
Duration of Amenorrhoea (mean (SD))	67.07(13.696)	55.83(15.695)	<0.001
Embryonic Demise			
	No	Yes	
Duration of Amenorrhoea (mean (SD))	63.06(15.247)	73.16(10.062)	0.005
Gestational Trophoblastic Disease			
	No	Yes	P-Value
PV bleeding Duration(Mean(SD))	4.36(5.233)	10.44(15.371)	0.003
Complete Abortion			
Heavy Bleeding	No	Yes	p-Value
Absent	154(70%)	0	0.031
Present	65(30%)	7(100%)	
Incomplete Abortion			
Amount	No	Yes	P-Value
Spotting	72(51%)	5(6%)	<0.001
Heavy	68(49%)	81(94%)	
Previous pregnancy bleeding			
No	99(70%)	73(82%)	0.037
Yes	43(30%)	16(18%)	
Previous pregnancy loss			
No	102(72%)	74(83%)	0.049
Yes	40(28%)	15(17%)	
Duration of Amenorrhoea (mean (SD))	62.06(15.208)	66.81(4.619)	0.02
PV bleeding Duration(Mean(SD))	5.38(7.268)	3.35(2.585)	0.012
Inevitable Abortion			
	No	Yes	P-Value
Duration of Amenorrhoea (mean (SD))	63.56(15)	82.75(2.9)	0.012
Subchorionic haemorrhage			
Amount	No	Yes	P-Value
Spotting	60(29.7%)	17(70.8%)	<0.001
Heavy	142(70.3%)	7(29.2%)	

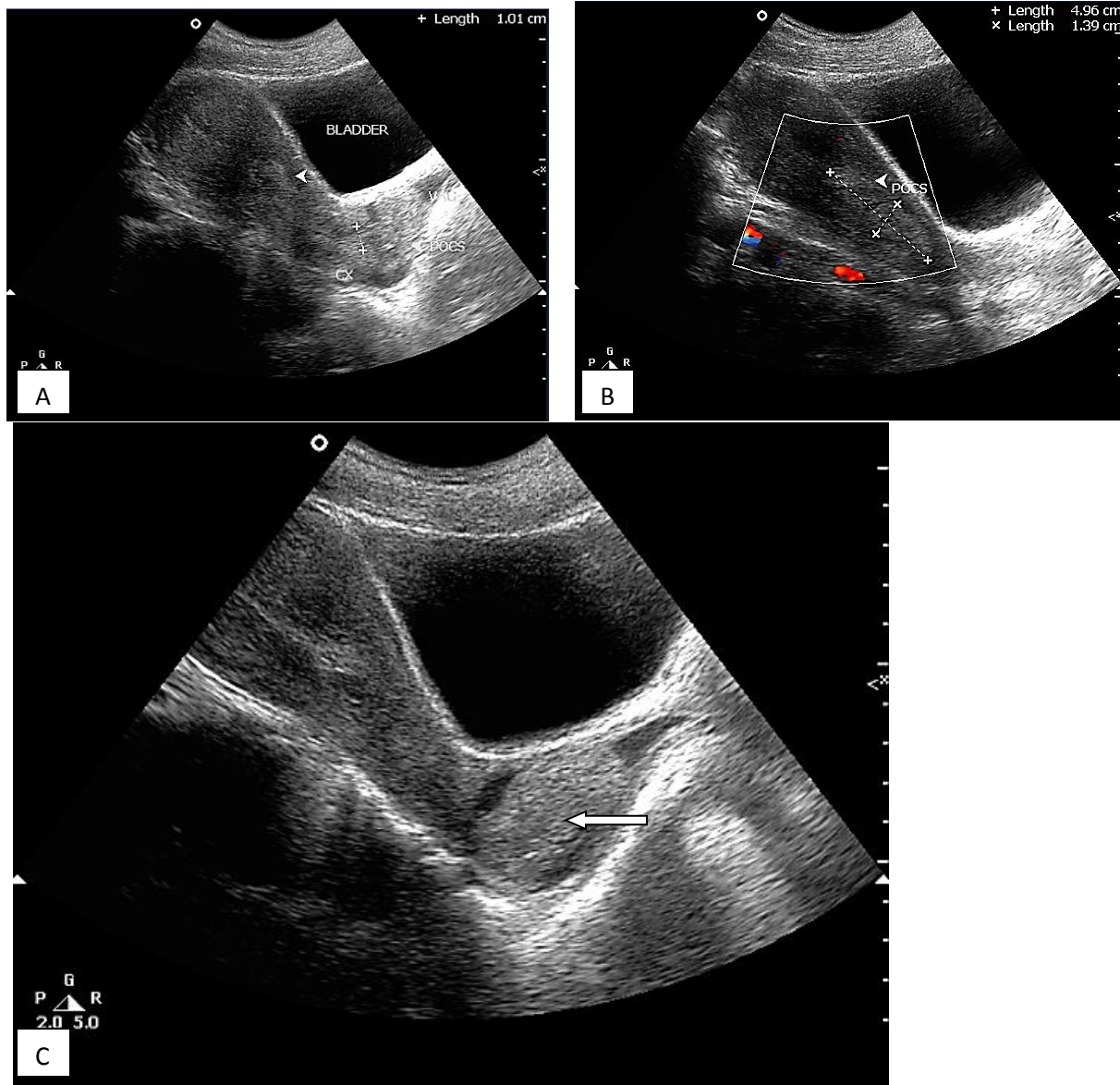
PLATES

CASE 1



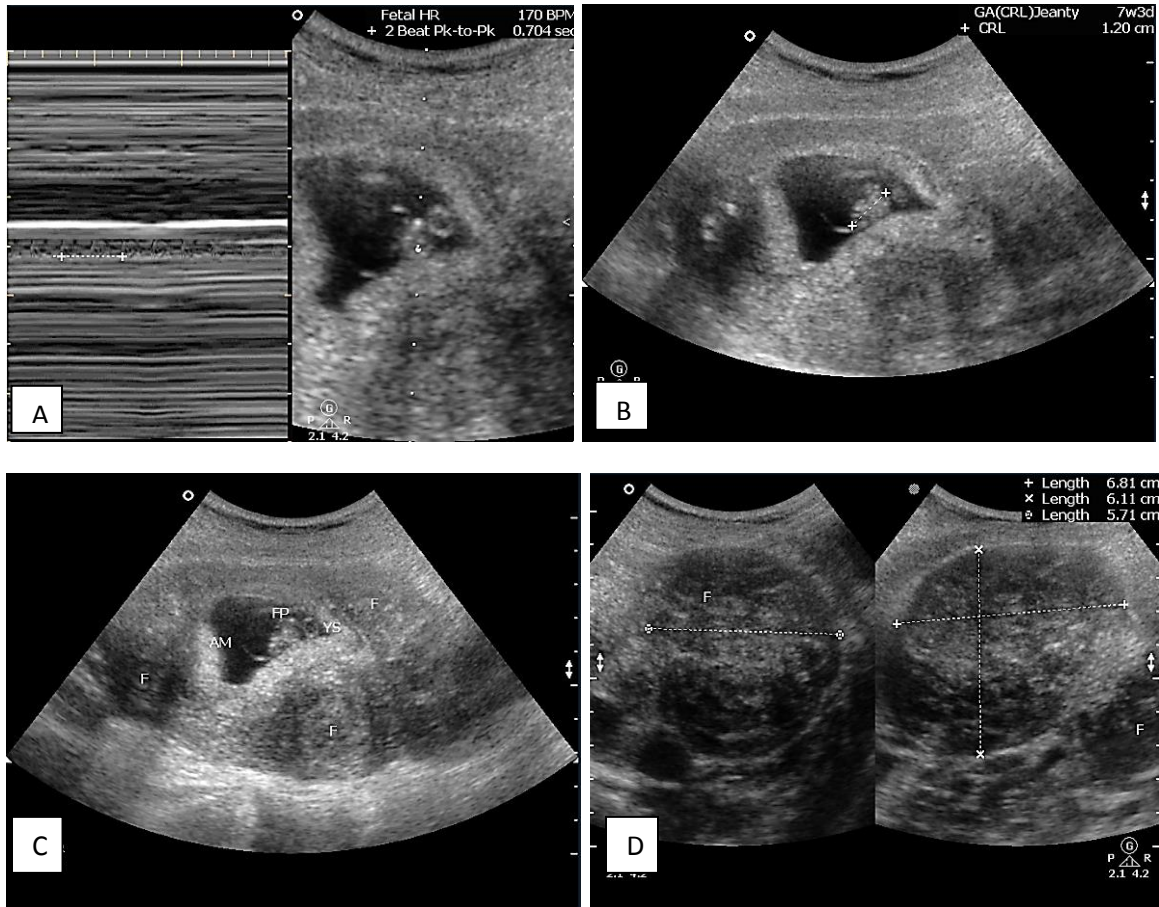
The above are images from a 23-year old Para 0+0 with an 8 week history of amenorrhoea and per vaginal spotting and lower abdominal pain for 1 day. A pregnancy test carried out was positive. On TAS an empty uterus was seen with a somewhat thickened endometrium (plate A). On further examination by TVS, a pseudo gestational sac (arrow) was seen in the uterus (plate B) and an empty, irregular gestational sac was seen in the right adnexa. It was surrounded by a complex mass and free pelvic fluid (FF) was seen, likely representing haemoperitoneum (plate C). An ultrasound diagnosis of a ruptured ectopic pregnancy was thus made.

CASE 2:



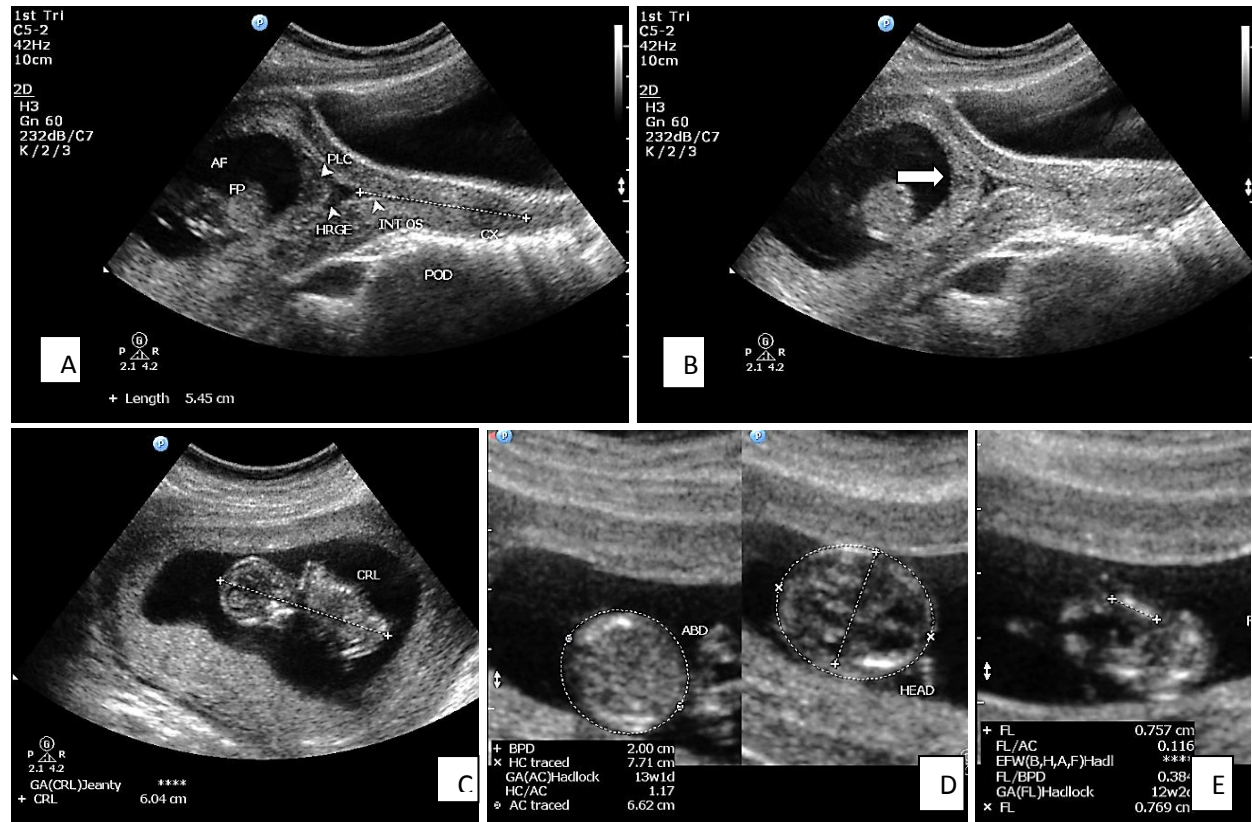
The above are ultrasound images from a 23 year old businesswoman. She was Para 0+1 with 11 weeks of amenorrhoea, who presented with a 4 day history of moderate vaginal bleeding and a 1 day history of heavy bleeding and lower abdominal pain. She had been taking analgesics for the pain. Her pregnancy test was positive. She had had previous pregnancy bleeding and loss at a gestation of about 12 weeks. TAS revealed a bulky uterus with slightly echogenic material within the endometrial cavity, which did not show any vascularity on colour Doppler, and was thought to be retained products of conception (arrowheads) (plates A and B). The cervical canal was open and similar echogenic material was seen in the vaginal canal (arrow), better seen on plate C. A diagnosis of incomplete abortion was made.

CASE 3



The above patient above was a 32 year old housewife, who was Para 0+0 with amenorrhoea for 8 weeks and moderate vaginal bleeding for 2 days. TAS showed an intrauterine live fetus with a regular heartbeat of 170b/m (plate A), and a CRL corresponding to 7 weeks 3 days (plate B). A normal yolk sac (YS) and amnion (AM) were seen, as well as multiple small uterine fibroids (F) (plate C). A large fibroid was also seen as shown (plate D). The cause of first trimester bleeding in this patient was therefore concluded to be due to the presence of multiple uterine fibroids.

CASE 4



Above are ultrasound images from a 27 year old Para 0+0 who had amenorrhoea of 12 weeks. She presented with a 1 day history of heavy vaginal bleeding. She reported having experienced bleeding during this pregnancy before; at 7 weeks gestation and that a scan done then had revealed a subchorionic haematoma. She had subsequently been treated with dydrogesterone (Duphaston[®]) and hydroxyprogesterone hexanoate (Primolut depo[®]). Previously, she had been on oral contraceptive pills. On TAS an intrauterine gestation is seen with a low-lying placenta overlying the internal cervical os (INT OS), with a subplacental haemorrhage (HRGE). The fetal pole (FP) is seen and the cervix (CX) is of normal length (plate A). The placenta is better shown in plate B. The fetal age by CRL was found to be greater than 12 weeks (plate C), therefore age was assessed by BPD, HC and FL, which gave a fetal age of 13weeks 0 days (plate D and E). The fetus was alive with a heart rate of 162b/min (not shown in the plates above). This was a case of placenta praevia in the first trimester. This patient should be followed up to assess the subsequent placental positions, as the placenta is likely to move up as the uterus grows, and may later assume a normal position.

CASE 5



The above patient was a 19 year old Para 0+1 married businesswoman. She presented with a 2 week history of spotting, mild lower abdominal pains and nausea, after a 7.5 week period of amenorrhoea. She reported a previous pregnancy loss at a gestation of about 6 weeks. On TAS, a live embryo (FP) was identified within an intrauterine gestational sac (GS), with a heart rate of 167b/min and a normal yolk sac (YS) (plate A and B). The CRL corresponded to a gestational age of 8 weeks (plate C). Besides these, there was a subchorionic haemorrhage (SCH), (arrow), which was the cause of vaginal bleeding.

7 DISCUSSION

The aim of this study was to evaluate the ultrasound findings and the proportion of each finding in patients presenting with bleeding in the first trimester of pregnancy. The relationship between the sonographic findings and various patient variables were also assessed.

A total of 231 patients were studied with an age range of 16 to 47 with a mean of 27.8 years and a median of 27 years, with a standard deviation of 5.686. Majority were within the age of 26 to 35 years consisting of 133 cases (57.6%), which is expected as this is the time when childbearing is at its highest.

The most common finding on ultrasound was incomplete abortion (89) (37.6%), followed by ectopic pregnancy (65) (27.4%) and subchorionic haemorrhage (24) (10.1%).

The highest proportion of each finding was in the 26 to 35 year age group. Similar findings were found in a Pakistan study on evaluation of cases reporting with bleeding per during the first 20 weeks of gestation ⁽²⁴⁾.

Majority of patients (206) had failed pregnancies which constituted 89.2% of cases, indicating that patients with first trimester bleeding have a high risk for poor pregnancy outcome. Patients found to have live pregnancies on ultrasound were 25 (10.8% of cases). This compares with other studies that have shown that vaginal bleeding in the first trimester of pregnancy is associated with a high risk for unfavourable outcome of that pregnancy, and a risk for recurrence of first-trimester bleeding in subsequent pregnancies ^(32, 33).

Incomplete abortion was the most common finding in this study, accounting for 89 (37.6%). Similar findings were seen in a postgraduate dissertation by Mbugua (1999) ⁽²⁷⁾ on the morbidity patterns in the acute gynaecological unit in a rural district hospital in Kenya, where it was found to be a common diagnosis on admission (37.8%).

Nationally, estimates of abortion in Kenya based on a study of women treated in public hospitals over a three month period in 2002 for abortion related complications showed that more than 300,000 abortions occur in Kenya annually (46 per 1000 women of reproductive age) ⁽³⁶⁾.

Both complete and incomplete abortions were associated significantly with heavy vaginal bleeding with 100% of patients found to have a complete abortion and 94% of those with findings of incomplete abortion reporting heavy bleeding (P-value 0.031 and <0.001, respectively). Incomplete abortion was also significantly associated with previous pregnancy bleeding and previous pregnancy loss (p=0.037 and 0.049 respectively) as well as the duration of amenorrhoea (p=0.02) and duration of vaginal bleeding (p= 0.012). This finding compares with previous studies which have shown an increased risk for pregnancy loss in patients with heavy bleeding as compared with those with light bleeding ⁽³⁷⁾.

The occurrence of ectopic pregnancy has been found in other studies to be 1.87% ⁽²⁴⁾ in patients presenting with pregnancy bleeding in the first 20 weeks gestation, and about 2% of all pregnancies ⁽³⁸⁾. It has, however, been found to be more prevalent in emergency departments, with one study finding about 13% of all pregnant emergency department patients ⁽³⁹⁾. The high incidence in this study (27.4%) may be explained by the nature of patients presenting at KNH being largely referrals, who specifically presented with pregnancy bleeding. It could also be due to higher rates of genital tract infections in our setting which may be poorly treated or not treated. These have been found to be risk factors for ectopic pregnancy ^(40, 41).

Significant associations were found between ectopic pregnancy and the amount of vaginal bleeding (Chi square test: p value <0.001) with 67% of patients with ectopic pregnancy reporting vaginal spotting; and the duration of amenorrhoea (T-test: p-value <0.001).

No association was found between use of emergency contraceptive use (levonogestrel) and ectopic pregnancy, even though it is known that after the use of these pills, there is a possibility of ectopic pregnancy ⁽⁴²⁾. A similar study by Cleland, Raymond, Trussell et al, however, found no difference in the rate of ectopic pregnancy when treatment with emergency pills fails, and the rate observed in the general population ⁽⁴³⁾.

Literature suggests that approximately 20% of women with first trimester bleeding have a subchorionic hematoma ⁽⁴⁴⁾. This was not established in this study probably because such patients are managed at peripheral facilities and are not referred to KNH.

Ninety two percent of patients with SCH (22 out of 24) were found to have live pregnancies at the time of scanning, while 2 (8%) patients had an associated embryonic demise. It has been shown, however, that the outcome of pregnancies with SCH depends on the size^(34, 35) and management⁽⁴⁵⁾. These studies have shown unfavourable outcome in most cases of SCH with large bleeds^(34, 35).

Significant association was also found between subchorionic haemorrhage and amount of vaginal bleeding with 70.8% of patients reporting vaginal spotting (p-value <0.001). This compares with other previous studies indicating that vaginal spotting in early pregnancy is less likely to be associated with miscarriage, especially if short-lived⁽³⁷⁾.

The most common presenting complaint associated with vaginal bleeding was lower abdominal pain (72.3%), followed by nausea/ vomiting (25.4%) and fever (16.5%). This compares to a post graduate dissertation on the morbidity patterns in the acute gynaecological unit in a rural district hospital in Kenya, where it was found that the commonest complaints were abnormal vaginal bleeding (85.8%) and abdominal pain (76.4%)⁽²⁷⁾.

Patients with heavy bleeding were more likely to have pregnancy loss, though spotting was also associated with ectopic pregnancy (p <0.001) which is considered a failed pregnancy. Spotting was also associated with SCH (p<0.001) in which most of the pregnancies were live. Heavy bleeding was associated with incomplete abortion (p<0.001), complete abortion (p=0.031). Similar findings were seen in a study associating first trimester bleeding with miscarriage where it was found that heavy bleeding in the first trimester is associated with a higher risk for miscarriage, especially if accompanied by pain⁽³⁷⁾.

Contraceptive use among subjects was high with 161(69.7%) of patients having used them and 70 having never used them (30.3%). One hundred and twenty nine (55.8%) had last used them more than 3 months prior while 41 (17.7%) had used them less than 3 months prior.

The overall most commonly used contraceptives were OCPs (64 + 14 = 78), followed by injectable depo preparations (Depo Provera[®]) (53 + 2 = 55). Emergency contraceptive pills ranked third (9 + 25 = 31). Norplant (9 + 0 = 9) and IUCD (5 + 1 = 6) followed, and lastly came condoms (1 + 1 = 2), herbal contraceptives (0 + 1 = 1) and BTL (0 + 0 = 0).

No association was found between contraceptive use and the sonographic findings, though other studies have shown use of levonorgestrel ⁽⁴²⁾ and IUCD as risk factors for ectopic pregnancy ⁽⁴¹⁾.

In the Kenya Demographic and Health Survey of 2008-2009, it was found that only 12-17% of the poorest and uneducated married women in Kenya use modern contraceptives, as compared to 48%-52% of the wealthiest and most educated ⁽⁴⁶⁾. One out of three of women in the reproductive age group used any contraceptive method, which is the same proportion that was found in 1998^(46, 47). The high prevalence of contraceptive use found in this study is probably due to the largely urban background of the study population.

Embryonic demise was significantly associated with a longer mean gestational age than in those without this finding. (T-test: p-value 0.005).

Ultrasound finding of GTD was significantly associated with the duration of vaginal bleeding with the mean duration of bleeding being significantly higher in these patients (p = 0.003).

There was a significant association between the findings of inevitable abortion and the duration of amenorrhoea with this patients having a higher mean gestational age as compared to those with other finding (p=0.012).

The limitation of this study was that it was difficult to examine all patients presenting during the study period due to the odd times at which most of them presented. This may have skewed the data.

In terms of the generalizability of findings, it is important to note that KNH is a referral facility, thus, most patients seen here are either very sick or have been referred from peripheral facilities. Patients with less threatening findings are less likely to present in KNH. It may not, therefore be completely accurate to generalize the findings. However, it gives a fairly accurate picture of the commonest causes of first trimester bleeding in our setting. Similar proportions of incomplete abortion have been found in a rural district hospital in Kenya ⁽²⁷⁾ which further supports generalizability of the findings.

8 CONCLUSION

The commonest cause of bleeding in the first trimester of pregnancy in our setting was found to be incomplete abortion, followed by ectopic pregnancy and subchorionic haemorrhage respectively.

The proportions of sonographic findings were as follows:

Eighty nine patients had incomplete abortion (37.6%), 65 had ectopic pregnancy (27.4%), 24 had subchorionic haemorrhage (10.1%), 18 had embryonic demise (7.6%), 14 had anembryonic pregnancy (5.9%), 9 had GTD (3.8%), 7 had complete abortion (3%), 4 had inevitable abortion (1.7%), 2 had placenta praevia (0.8%), and 1 had uterine fibroids in pregnancy with a live embryo (0.4%).

Spotting in early pregnancy was associated with ectopic pregnancy and subchorionic haemorrhage; while heavy bleeding was associated with both incomplete abortion and complete abortion.

First trimester bleeding was associated with a high rate of pregnancy loss (89.2%), possibly because those presenting to KNH are likely to have heavy bleeding rather than spotting, as it is a referral facility.

9 RECOMMENDATIONS

Any patient presenting with first trimester bleeding should have an early and timely ultrasound.

Spotting in early pregnancy should rouse a suspicion of ectopic pregnancy which should then be excluded by ultrasound.

A larger multicenter study is required to establish significant associations between the clinical history and bleeding; and associations between the ultrasound findings and the clinical history which this study may have failed to establish.

Studies relating each patient variable to the specific ultrasound findings may be useful in establishing significant associations which this study may have failed to establish.

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APPENDICES

APPENDIX A:

Patient consent form

My name is Dr. Irene Githinji, a postgraduate student in the department of Diagnostic Imaging and Radiation Medicine at the University of Nairobi. I am carrying out a study on ultrasound findings in first trimester bleeding.

This study involves carrying out an ultrasound examination on you and documenting findings of your ultrasound scan and asking important questions which may help in finding what may have led to the bleeding. You will be required to answer a few questions.

The study will involve applying gel on your lower abdomen and using a probe on the abdomen to acquire images of your internal structures. You will be required to fill your urinary bladder for this examination. It may involve examination through the birth canal. The ultrasound probe will be covered using a clean, new condom and clean gel applied to it. It will then be inserted through the birth canal so as to acquire images with better detail, and, therefore, more accurate findings. You will be required to empty your bladder completely for this examination.

Ultrasound is used to find a cause for the bleeding, and in some cases, nothing is found. It is not a form of treatment. Diagnostic ultrasound is safe to use even during pregnancy. The examination is not painful.

I would like to recruit you in this study. Information obtained from you will be treated with confidentiality. Only your hospital number will be used.

Please note that your participation is voluntary and you have a right to decline or withdraw from the study.

Patient number: _____ Signature: _____ Date: _____

I certify that the patient has understood and consented participation in the study.

Dr. Irene Githinji 0721 430071

Signature _____ Date _____

Supervisor

Dr A Aywak

Department of Diagnostic Imaging and Radiation Medicine,

University of Nairobi

ETHICS AND RESEARCH COMMITTEE.

KNH/UON-ERC

P.O. Box 20723, Nairobi

APPENDIX B

Kibali cha kushiriki katika utafiti

Jina langu ni Daktari Irene Githinji, mwanafunzi katika chuo cha udaktari, Chuo Kikuu cha Nairobi. Ninafanya utafiti kuhusu chanzo cha utokaji damu katika miezi tatu ya mwanzo ya mimba, na pia matokeo yake kutumia *ultrasound*.

Haki zako zitalindwa, habari utakayotoa au ile itakayopatikana kukuhusu, itakuwa siri wakati wote na itatumika katika utafiti huu tu.

Utafiti huu utahusu kukupima kwa tumbo kutumia mafuta na kifaa cha *ultrasound* ili kuviona viungo vyako vya ndani ya tumbo, ili kujua chanzo cha utokaji damu. Utahitajika kujaza kibofu chako cha makojoo ili upigwe picha hii. Inawezekana pia kuwa utahitaji kupimwa kwa njia ya uzazi. Kifaa cha ultrasound kita funikwa na mpira aina ya *condom*, kisha kipakwe mafuta ya *ultrasound* na kutiwa katika njia ya uzazi ili kuona viungo vya ndani ya tumbo vema zaidi. Utahitajika kutoa makojoo yote kwa kibofu ili upigwe picha hii.

Ultrasound ni aina ya picha inayotumika kutafuta chanzo cha kuvuja damu, lakini kwa wakati mwingine, sababu haipatikani. *Ultrasound* si aina ya matibabu. Picha hii ya *ultrasound* haina madhara kwako wala kwa mimba. Pia haina uchungu.

Ni muhimu kuelewa ya kwamba ushiriki ni wakujitolea, sio lazima kushiriki katika utafiti huu, na pia waweza kubadili nia yako wakati wowote kuhusu kuendelea kushiriki, bila ya kuathiri huduma zako za kiafya.

Asante sana kwa ushirikiano wako.

Nimekubali kwamba nimeelezwa kikamilifu kuhusu utafiti huu na nakubali kushiriki.

Nambariyamgonjwa: _____ Sahihi: _____ Tarehe: _____

Nimekubali kwamba nimeeleza kikamilifu kuhusu utafiti huu na mgonjwa amekubali kushiriki.

Dr. Irene Githinji 0721430071

Sahihi: _____ Tarehe: _____

Supervisor

Dr A Aywak

Department of Diagnostic Imaging and Radiation Medicine,

University of Nairobi

ETHICS AND RESEARCH COMMITTEE.

KNH/UON-ERC

P.O. Box 20723, Nairobi

APPENDIX C

QUESTIONNAIRE: DATA COLLECTION FORM

Form N^o: _____

Patient X-ray N^o: _____

Date: _____

Age: _____

Parity: _____

LMP: _____

GBD: _____ PDT/ β -HCG done? Yes

No

Results? _____

Residence _____ Occupation _____

Marital status _____ Education level _____

Presenting complaints: (tick where applicable)

- Amenorrhoea duration: _____
- Per vaginal bleeding duration: _____
Amount of bleeding: spotting heavy
- Nausea/ vomiting duration: _____
- Fever duration: _____
- Other (specify) _____ duration: _____

Previous history:

- H/o recent trauma
- Contraceptive use { Previous (> 3months ago)
 Current (< 3months ago)
Type: OCPs Norplant/ Jadele IUCD BTL
 Depo-Provera Other (specify) _____
- H/o previous pregnancy bleeding number of times at what GA * _____
- H/o previous pregnancy loss number of times GA * at loss _____
- H/o previous ectopic pregnancy number of times
- Treatment for infertility pills surgery Other(specify) _____
- H/o previous caesarian section date(year) _____
- H/o previous or current genital tract infection treated untreated
- H/o medical illness Diabetes Hypertension Asthma
 Thyroid disorder other (specify) _____
- H/o any medication during the period of amenorrhoea.
Which medication(s)? _____

*GA: gestational age

Section2: Ultrasound Findings (tick as appropriate)

Please attach a copy of the most representative image(s)

- anembryonic pregnancy
 - ectopic pregnancy
 - embryonic demise
 - gestational trophoblastic disease
 - complete abortion
 - incomplete abortion
 - inevitable abortion
 - subchorionic haemorrhage
 - uterine fibroids in pregnancy
 - Other (specify)
-

Ultrasound gestational age (GA)

by: MSD _____

CRL _____

average _____

Need for follow up scan? _____ Reason _____

APPENDIX D:**BUDGET**

ITEM	QUANTITY	UNIT PRICE (Ksh)	TOTAL (Ksh)
WRITING PENS	1 BOX	200	200
NOTEBOOKS	5 PIECES	60	300
FILES	8 PIECES	50	400
PRINTING PAPER	5 RIMS	400	2000
CARTRIDGE	1 PC	6000	6000
INTERNET SURFING	200 HRS	60	12000
FLASH DISCS	2 PCS	2000	4000
PRINTING DRAFTS AND FINAL PROPOSAL	10 COPIES	500	5000
PHOTOCOPIES OF QUESTIONNAIRES	300 COPIES	10	3000
PHOTOCOPIES OF FINAL PROPOSAL	6 COPIES	100	600
BINDING COPIES OF PROPOSAL	6 COPIES	60	360
ETHICAL REVIEW FEE	1	1000	1000
SUBTOTAL			34860
PERSONNEL			
RESEARCH ASSISTANT	2	10000	20000
BIostatistician	1	30000	30000
SUBTOTAL			50000
DATA COLLECTION, DATA ANALYSIS AND THESIS DEVELOPMENT			
PRINTING OF THESIS DRAFTS	10 COPIES	1000	10000
PRINTING FINAL THESIS	6 COPIES	1000	6000
BINDING OF THESIS	6 COPIES	300	1800
DISSEMINATION COST			10000
SUBTOTAL			27800
CONTINGENCY (10% OF TOTAL BUDGET)			11266
GRAND TOTAL			123926