

"A Correlation of Ultrasound and Surgical Findings in Suspected Ectopic Pregnancy at Kenyatta National Hospital"

By

Dr NSHIZIRUNGU JEAN JACQUES

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"A Correlation of Ultrasound and Surgical Findings in Suspected Ectopic Pregnancy at Kenyatta National Hospital"

Dissertation submitted in part fulfillment for the award of the Degree of Masters of Medicine in Diagnostic Radiology of University of Nairobi.

By

Dr NSHIZIRUNGU JEAN JACQUES

UNIVERSITY OF NAIROBI

2009

DECLARATION

I, **Dr. NSHIZIRUNGU Jean Jacques** declare that this dissertation has not been submitted for another degree in this or any other University of Higher learning and that the views expressed herein are mine unless otherwise stated, and where such has been the case acknowledgement or reference has been quoted.

Witness my hand this...*17th*.....day of...*Sept*.....2009

Signed.....*JJ.*.....

Dr. NSHIZIRUNGU Jean Jacques.

SUPERVISORS:

Signature.....*[Signature]*.....

Date.....*18/9/09*.....

Dr N M KIMANI, MBChB, MMED (RAD)Nbi, Lecturer in the Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi

Signature.....*[Signature]*.....

Date.....*17/9/2009*.....

Dr KIHARA Anne B MBChB, MMed(Obst/Gyn)Nbi, Obstetrician Gynaecologist, Lecturer, University of Nairobi

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ABBREVIATIONS USED

B-HCG	Beta Human Chorionic Gonadotropin.
CT	Computerized Tomography
EP	Ectopic Pregnancy
HSG	Hysterosalpingography
IUCD	Intrauterine Contraceptive Device
KNH	Kenyatta National Hospital
MRI	Magnetic Resonance Imaging
NPV	Negative Predictive Value
OPD	Out- patient department
PET	Positron Emission Tomography
Post	Posterior
SPSS	Statistical Package for Social Sciences
TAS	Transabdominal Scan
TGF	Transforming Growth Factor
TVS	Transvaginal Scan
UoN	University of Nairobi
US	Ultrasound

Abstract:

This was a prospective descriptive study carried out at Kenyatta National Hospital from September 2008 to February 2009, whereby 73 patients who were diagnosed to have an ectopic pregnancy on the basis of ultrasound, later underwent laparotomy to confirm the diagnosis.

Objectives: The purpose of this study was to establish the accuracy of ultrasound, in the evaluation of a suspected ectopic pregnancy.

Methodology: Patients suspected to have an ectopic pregnancy on the basis of clinical assessment had an ultrasound examination using TAS and when TAS was inconclusive, TVS was used. The ultrasonograms were coded for: uterine size, intrauterine gestational sac, adnexal mass, adnexal ring, cul-de-sac fluid, or normal findings.

Those who had ectopic pregnancy on the basis of ultrasonographic criteria were followed and ultrasound findings were compared with surgical findings in order to establish if ultrasound is a reliable method for diagnosis of ectopic pregnancy.

Results: 112 patients were assessed by ultrasound after clinical suspicion of ectopic pregnancy. 73 of them had ectopic pregnancy on the basis of ultrasound. Among these, 72 were confirmed on laparotomy to have an ectopic pregnancy, and 1 patient had a ruptured corpus luteum cyst.

In this study, the most common site of ectopic pregnancy was the fallopian tubes.

Results confirmed on laparotomy showed that positive diagnoses by ultrasound were made in 98.6% of cases and false positive diagnosis in 1.4% of cases.

Conclusion: The results showed that pelvic ultrasound is a reliable method for diagnosis of ectopic pregnancy with a high sensitivity, specificity, positive and negative predictive value.

I. INTRODUCTION AND LITERATURE REVIEW

Ectopic pregnancy is derived from the Greek word *ektopos*, meaning out of place, and it refers to the implantation of a fertilized ovum in a location outside of the uterine cavity, including the fallopian tubes, cervix, ovary, cornual region of the uterus, and the abdominal cavity.

More than 95 percent of ectopic pregnancies occur in the fallopian tubes, another 2.5 percent occur in the cornua of the uterus, and the remainders are found in the ovary, cervix or abdominal cavity¹. Because none of these anatomic sites can accommodate placental attachment or a growing embryo, the potential for rupture and hemorrhage always exists². This failure of proper nidation is associated with ever increasing reproductive loss recorded for the last two decades³, ten times greater rise of maternal deaths than for a vaginal delivery. Moreover, prognosis for a successful subsequent pregnancy is reduced 10-15%³.

The incidence of EP has roughly doubled in the west in the past 20 years⁵. In United States, there has been a fourfold increase in the incidence during the past 15 years. Deaths from ectopic pregnancy have decreased but the percentage of all maternal deaths attributed to ectopic pregnancy has increased. Ectopic pregnancy is the second leading cause of maternal mortality⁴. A clear understanding of contributory factors responsible for ectopic pregnancy and of the effective and modern methods for earlier diagnosis is essential for maternal survival and conservation of reproductive capacity.

EP remains the great mimic of gynecology: no other pelvic condition gives rise to more diagnostic errors, since ultrasonography is capable of providing detailed images of pelvic organs, the sonologist is often asked to assist in the evaluation of patients suspected of harboring an ectopic gestation.

The use of ultrasound has revolutionised the diagnosis and evaluation of EP. The ultrasonogram can detect the intrauterine gestational sac at 5 weeks of amenorrhea or even

earlier. Thus aids in making an immediate diagnosis and prompt treatment to save the mother's life and her future reproductive capability.

The ultrasonogram can exclude ectopic pregnancy and heterotropic pregnancy at an early stage whereas no other single diagnostic modality can provide this information. Ultrasonography is also helpful in differentiating ectopic pregnancy from many other simulating conditions like; threatened abortion, incomplete abortion, torsion of ovarian cyst, appendicitis etc⁶.

TVS is the first-line investigation in haemodynamically stable women presenting with suspected ectopic pregnancy and is accurate in up to 90% of cases⁷.

A recent report by Marklad and Wright claimed that the sensitivity of ultrasonography was greater than 90% accurate in the diagnosis of ectopic pregnancy⁸.

Mansoor Ahmad, Muhammad Ali showed that positive diagnoses were made in 88.2% of cases and false positive diagnosis in 11.3% cases by ultrasound⁹.

Aleem FA, DeFazio M, Gintautas J. Showed that the detection of ectopic versus intrauterine gestation showed a high sensitivity of 95%, a specificity of 100%, and a positive predictability of 100% and a negative predictability of 97% for the TVS¹⁰.

Pederson showed a positive predictive value of 100% and a negative predictive value of 99%¹¹

Dissanayake L, Lema VM, Wanjala SH, Wachira MW, in Kenya at KNH(1988) showed , a positive predictive value of 48% and a negative predictive value of 97%¹². This can possibly have been due to the low resolution of the ultrasound machine, the lack of well trained personnel for ultrasound and the use of only transabdominal probe at that period (1988).

I.1.Ectopic pregnancy: Ectopic pregnancy (EP) is defined as implantation anywhere other than the endometrial cavity. This terminology includes both ectopic intrauterine and extra uterine pregnancies. Extra uterine pregnancy includes tubal, ovarian, and abdominal pregnancies.

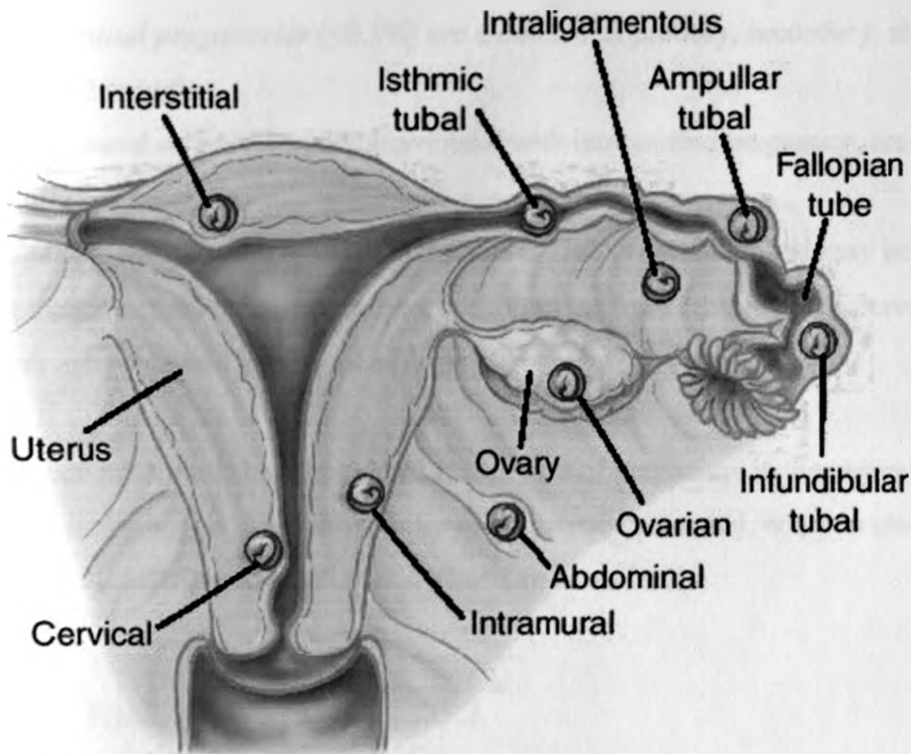


FIGURE: 1 Different sites of ectopic pregnancy.

I.1.1. Classification and Specific Incidence¹³:

- **Tubal pregnancies** account for more than 99% of total ectopic pregnancies. The locations within the tube are as follows: ampullary (55%), isthmic (25%), fimbrial (17%), interstitial (2%), bilateral, and distal with segmental absence of the tube.

- **Ovarian pregnancy** accounts for <0.5%. It may be classified as ovarian, tubo-ovarian or abdomino-ovarian.

- **Abdominal pregnancies** (<0.1%) are classified as primary, secondary, abdomino-ovarian, or tubo-abdominal.

- **Compound or heterotrophic** (combined with intrauterine pregnancy, are seen 1 in 17,000-30,000 pregnancies).

- **Cervical pregnancies** are very rare extra uterine pregnancies and may be intraligamentous, in the vesicovaginal space, and may occur following hysterectomy (in a cervical stump, in a uterine tube, in a prolapsed uterine tube [fimbria], or abdominal).

It is also possible to have abnormal placements of pregnancy in the uterus although it occurs rarely including (in descending order of occurrence): cornual, within a uterine diverticulum, in a uterine sacculation, in a rudimentary horn, or intramural.

I.1.2. Risks factors¹²:

- Prior pelvic inflammatory disease
- Prior ectopic pregnancy
- Pregnancy in a woman with an intrauterine contraceptive device (IUCD) in situ
- Pregnancy achieved by means of in vitro fertilization or fertility drugs
- Prior tubal surgery (reconstruction or tubal coagulation)
- Cigarette smoking
- Increasing age
- Prior pelvic surgery

1.1.3. Clinical Presentation and Diagnosis

Secondary amenorrhea, irregular vaginal bleeding, or lower abdominal cramping with spotting, should arouse suspicion of an EP. The classic EP triad of irregular menstrual bleeding, abdominal or pelvic pain, and palpable tender adnexal mass is found in less than 45% of patients.¹³ History and physical examination do not reliably rule out EP, because up to 9% of patients report no pain, and 36% of them lack adnexal mass.¹³⁻¹⁴ However, a detailed history can reveal the presence of risk factors that may increase the suspicion of EP, including history of a previous EP, tubal damage secondary to infection or surgery, history of infertility, treatment for in vitro fertilization, increased age, and smoking. History of pelvic inflammatory disease is especially important, because it increases the risk of EP seven fold. Although the overall risk of pregnancy in these situations is low, if a pregnancy does occur it is more likely to be ectopic.¹⁴

Several studies have assessed the efficacy of screening for EP in women who carry these risks but show no symptoms. In one study from Finland and another from the Netherlands, the incidence of EP in these risk groups was found to be 24% and 5.6%, respectively, both of which are higher than the incidence of 2% in the normal population.^{15,16} The spectrum of clinical findings in EP ranges from completely asymptomatic status to peritoneal irritation due to bleeding into peritoneal cavity or even hypovolemic shock.¹³ Early detection of EP constitutes detection before tubal rupture, which is extremely important in the prevention of maternal morbidity and mortality and the preservation of future fertility.¹⁷⁻¹⁸

It has been widely discussed whether a strict diagnostic algorithm or individual evaluation of each patient is better. A study by Mertz and Yalcinkaya¹⁹ showed that a strict algorithm is superior to individual evaluation. In a study by Gracia and Barnhart,¹⁷ six diagnostic algorithms involving combinations of clinical examination, transvaginal sonography, serum progesterone, serum B-hCG, and dilatation & curettage were compared. An algorithm using a combination of sonography and serum B-hCG yielded the most favorable outcome.

I.2 The role of Ultrasound in the diagnosis EP

Ultrasonography, both transabdominal and transvaginal, is a well-established method of examining the female pelvis. In fact, ultrasonography remains the principal initial imaging study in the work-up of gynecologic disease. It is both safe and relatively inexpensive. Currently, the potential role of US in gynecologic imaging includes lesion characterization of ovarian masses and identification of endometrial abnormalities.²¹

Regardless of clinical presentation, the primary goal of early first trimester sonographic diagnosis should be to identify the location of the gestational sac. The most important contribution of TVS in the evaluation of suspected ectopic pregnancy is its ability to identify either a normal or an abnormal intrauterine gestational sac earlier and more reliably than TAS.

Because of the low incidence of heterotopic pregnancy, sonographic demonstration of an intrauterine pregnancy reduces the likelihood of ectopic pregnancy to an almost insignificant level. Heterotopic pregnancy, however, should be suspected in the appropriate clinical setting, especially in high-risk groups. Evaluation of the adnexa should be routine in all patients, including those with documented intrauterine pregnancies.

The demonstration of a live embryo in the adnexa is diagnostic of EP. In early intrauterine pregnancy, incomplete abortion, or EP, one cannot always identify the gestational sac. In the absence of specific sonographic findings, the probability of EP can be predicted by identification of non-specific sonographic features and by correlation with the discriminatory level of the serum B-hCG²²⁻²³. The relative risk of ectopic pregnancy and the clinical status of the patient determine the need for surgical intervention or repeat sonography and conservative management.

1.2.1. Specific Sonographic Findings :

- Intrauterine Pregnancy

The intradecidual sign²⁴ can be used to demonstrate the presence of an intrauterine pregnancy before visualization of the yolk sac or embryo. Using TVS, the double-decidual sign²⁵ is usually demonstrated at approximately the same time that the yolk sac is visualized.



FIGURE: 2 Double decidual sac of intrauterine pregnancy

In patients with ectopic pregnancies, the decidua may slough, resulting in a fluid collection within the endometrial canal that is referred to as a decidual cast or pseudo gestational sac. TVS improves differentiation of the decidua that produces the pseudo gestational sac, from the choriodecidual reaction of the intradecidual and double-decidual signs²⁶. A pseudo gestational sac is a fluid collection within the endometrial canal surrounded by a single decidual layer, as opposed to a sac within the decidua abutting the endometrial canal (intradecidual sign) or the two concentric rings of the double-decidual sign. Small cysts within the decidua may appear as saclike structures in patients with EP²⁷. These decidual cysts may be distinguished from gestational sacs in that the cysts do not abut the endometrial canal and do not have an echogenic trophoblastic ring. Decidual cysts may also occur in patients with normal early intrauterine pregnancy or in non-pregnant patients. In patients with a normal intrauterine pregnancy, the decidual cyst may predate sonographic identification of the gestational sac.

The important point is that the decidual cyst should not be mistaken for an intrauterine gestational sac, an interpretation that would decrease the index of suspicion of an ectopic pregnancy²⁷.

- *Live Embryo in the Adnexa*

The sonographic demonstration of a live embryo in the adnexa is specific for the diagnosis of ectopic pregnancy²⁸. A live extra uterine fetus has been detected with TVS in 17% to 28% of patients with ectopic pregnancies²⁶⁻²⁹⁻³⁰⁻³¹, compared with approximately 10% with TAS³².

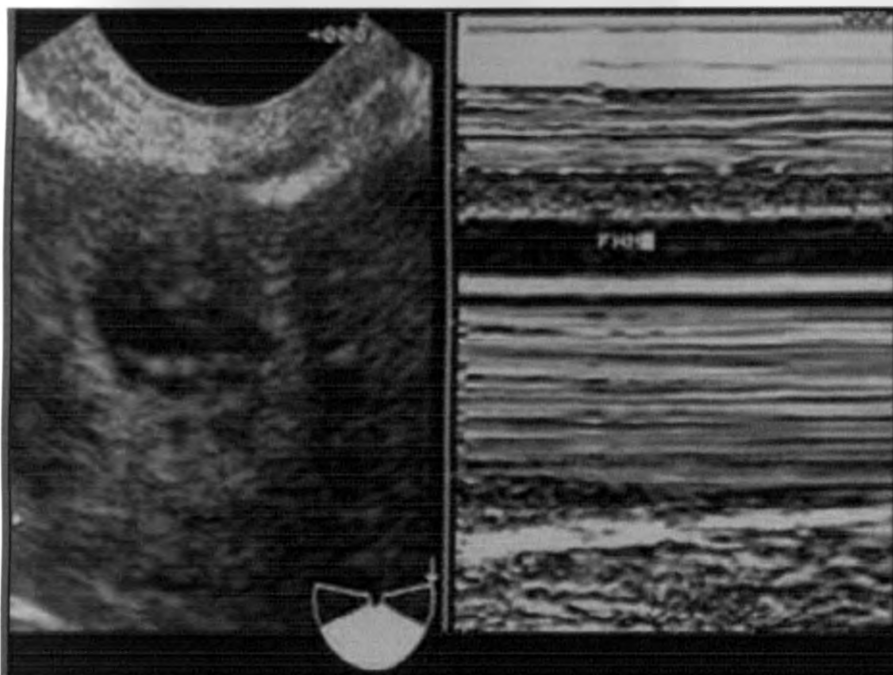


FIGURE: 3

Live tubal ectopic pregnancy with M mode showing fetal heart beat.

1.2.2. Non-specific Findings

- Adnexal Mass

An adnexal mass can be found in conditions other than EP and is therefore not diagnostic. The presence of an adnexal mass in patients with a positive B-hCG who have no sonographic evidence of an intrauterine pregnancy, however, has a positive predictive value of 70% to 75% for ectopic pregnancy²⁸.



FIGURE: 4 Transverse view of the uterus showing a non-specific mass adjacent to the left ovary and the presence of echogenic free peritoneal fluid in the pelvis.

- Tubal Ring

Fleischer and associates report finding a tubal ring in 49% of patients with ectopic pregnancy and in 68% of those with un-ruptured tubal pregnancies using TVS²⁶. A tubal ring is an echogenic adnexal ring separate from the ovary created by the trophoblast of the ectopic pregnancy surrounding the gestational sac. In the series of Nyberg and colleagues²⁸, the positive predictive value of a tubal ring for ectopic pregnancy was 100%.

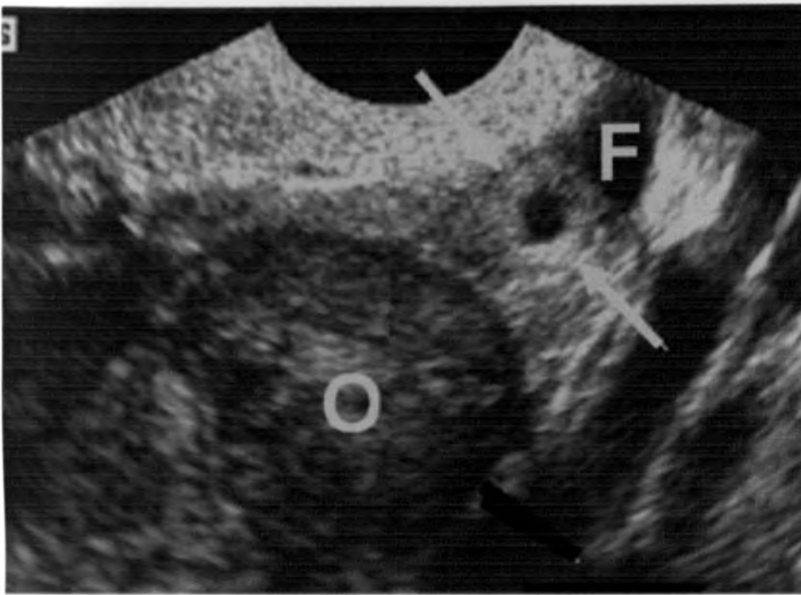


FIGURE: 5

Transvaginal transverse sonogram shows the left ovary (O) within normal limits. A tubal ring (arrows) is seen with minimal free fluid (F) surrounding it. The tubal ring is located very close to the ovary but is outside the ovarian parenchyma

- *Free Fluid in the pouch of Douglas*

The presence of free fluid is a nonspecific finding that suggests the presence of an ectopic pregnancy in the appropriate clinical setting. The amount of fluid and the echogenicity of the fluid are important clues in predicting the presence of an ectopic pregnancy.

The presence of a large amount of free fluid or of echogenic free fluid increases the positive predictive value from 63% to 86%.²⁸ Although the presence of a large amount of free fluid suggests tubal rupture, free fluid is not a specific finding because the tube may be intact in the presence of a large hemoperitoneum³³. In patients with suspected ectopic pregnancy, the combination of an adnexal mass and echogenic free fluid is associated with a 97% positive predictive value for ectopic pregnancy²⁸.

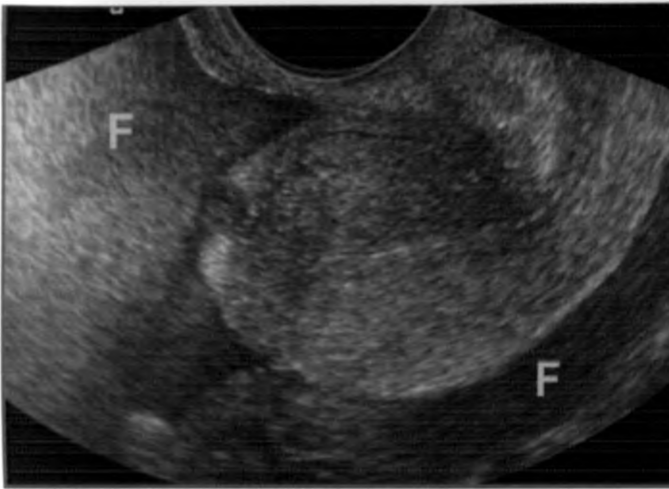


FIGURE: 5

Transvaginal sagittal sonogram shows echogenic free fluid (F) (hemorrhage) in the cul-de-sac and pelvis in a 9-week tubal ectopic pregnancy.

- *Normal Sonogram*

Patients with ectopic pregnancy may have a completely normal pelvic ultrasound examination. In the series of Nyberg and associates, 34% of patients with ectopic pregnancy had no evidence of either an adnexal mass or free fluid²⁸.

- *Endovaginal Color Flow Doppler*

EVCFD diagnosis of ectopic pregnancy is based on the identification of adnexal peritrophoblastic flow defined as high-velocity, low-resistance flow separate from the ovary³⁴. Studies demonstrate that EVCFD increases the diagnostic sensitivity for diagnosis of ectopic pregnancy compared with EVS alone³⁴⁻³⁵. Furthermore, these studies suggest that EVCFD increases the percentage of initial examinations that are diagnostic of either intrauterine or ectopic pregnancy compared with TVS alone³⁵. Although EVCFD may aid in confirming the presence of an ectopic pregnancy, its value depends on the strictness of the gray-scale criteria for diagnosis of ectopic pregnancy. Its use in diagnosing early intrauterine pregnancy may play a role in exclusion of ectopic pregnancy³⁴. Although the absence of low-resistance flow cannot exclude ectopic pregnancy, it may be related to early or dead ectopic pregnancies.

Correlation with serial B-hCG results, in the absence of placental flow pattern, may aid in conservative management of ectopic pregnancy in the future.

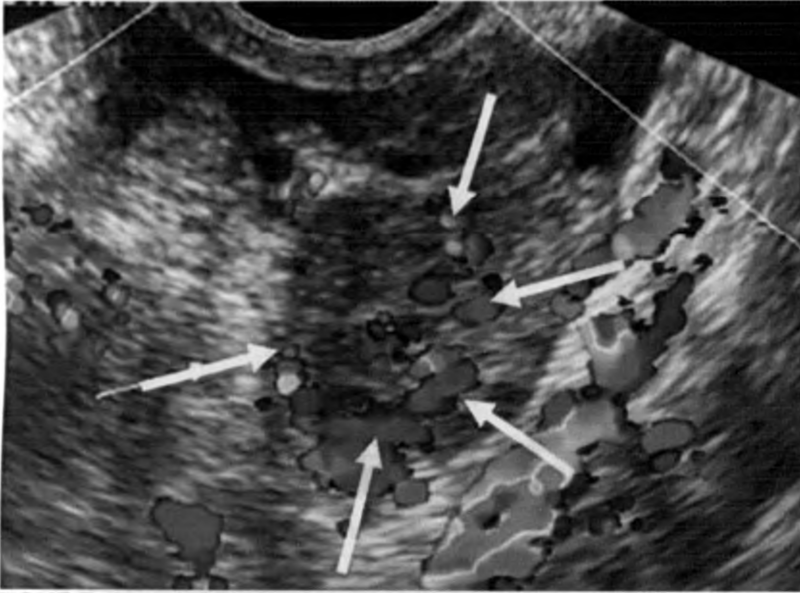


FIGURE: 6
Color Doppler sonogram shows prominent vascularization, or "ring of fire" (arrows), around the EP.

- *Interstitial (Cornual) Pregnancy*

The sonographic diagnosis of an interstitial pregnancy is suggested by an eccentric location of the gestational sac surrounded by an incomplete myometrial mantle. If the gestational sac encroaches to within 5 mm of the uterine serosa, an interstitial ectopic pregnancy should be suspected²⁶. The absence of a well-defined double-decidual sac sign and direct extension of the endometrial canal up to the midportion of the gestational sac or cornual mass improves differentiation of interstitial ectopic from eccentric intrauterine implantation. This finding is referred to as the interstitial line sign³⁶. The interstitial line sign may be helpful in the diagnosis of a cornual ectopic pregnancy even in the absence of a demonstrable gestational sac in the cornua.



FIGURE: 7

Coronal view showing a right interstitial ectopic pregnancy with the foetal pole seen within the gestational sac.

1.3. Treatment of EP

1.3.1 Medical treatment

Medical therapy involving methotrexate may be indicated in certain patients. A number of factors must be considered. The patient must be haemodynamically stable, with no signs or symptoms of active bleeding or haemoperitoneum. Furthermore, she must be reliable, compliant, and able to return for follow-up. Another factor is size of the gestation, which should not exceed 3.5 cm at its greatest dimension on ultrasound (US) measurement. She should not have any contraindications to the use of methotrexate.

1.3.2 Surgical treatment

Within the last 2 decades, a more conservative surgical approach to un-ruptured ectopic pregnancy using minimally invasive surgery has been advocated to preserve tubal function. Laparoscopy has become the recommended approach in most cases. Laparotomy is usually reserved for patients who are haemodynamically unstable or patients with cornual ectopic pregnancies. It is also a preferred method for surgeons inexperienced in laparoscopy and in patients where laparoscopic approach is difficult (for example, secondary to the presence of multiple dense adhesions, obesity or massive haemoperitoneum). In a patient who has completed childbearing and no longer desires fertility, in a patient with a history of an ectopic pregnancy in the same tube, or in a patient with severely damaged tubes, total salpingectomy is the procedure of choice.

II. JUSTIFICATION AND OBJECTIVES OF THE STUDY:

Ectopic pregnancy continues to provide a diagnostic challenge to the modern clinicians, and thus there is an increase in clinical demand for ultrasonographic evaluation of patients suspected of having EP. Although EP is more readily diagnosed due to improved testing techniques available today, it is a life-threatening condition and remains a major source of patient morbidity and mortality in developing countries. Therefore, in situations like ours where we cannot do routine expensive investigations such as serum B-hCG, we have to rely on a high degree of clinical suspicion and the use of ultrasonography with or without other laboratory aid like urine pregnancy tests.

The lack of statistically tested results of the accuracy of ultrasound in the evaluation of ectopic pregnancy in our hospital has led us to the following study.

➤ Hypothesis:

- Ultrasound is a reliable method for diagnosis of ectopic pregnancy in our setup.

➤ Broad Objective:

- To establish the accuracy of ultrasound in correlation to surgical findings in the evaluation of ectopic pregnancy.

➤ Specifics Objectives:

- To determine the sensitivity and specificity of ultrasound in diagnosing ectopic pregnancy.
- To determine which of the ultrasound findings are more likely to indicate the presence of an ectopic pregnancy.
- To determine the frequency of different localizations of ectopic pregnancy at KNH.

III. MATERIALS AND METHODS

- Study design:

It is a prospective and descriptive study.

- Study area:

This study was carried out at Kenyatta National Hospital which is a referral national hospital. The study was conducted at the Department of Radiology KNH, and the Department of Obstetrics and Gynecology (acute gynecology ward and casualty).

- Study population:

This included all patients, suspected to have an ectopic pregnancy on the basis of history and clinical examination, referred from the casualty and acute gynecology ward for pelvic ultrasound and thereafter taken to theatre for laparoscopy or laparotomy.

- Study period:

This study was conducted from September 2008 to February 2009 at KNH. It included all patients who met the following eligibility criteria.

- Eligibility criteria:

Inclusions:

- All consenting patients admitted to the acute gynecology ward with clinically suspected ectopic pregnancy and who had ultrasound as part of investigation and subsequently underwent laparotomy or laparoscopy.

Exclusions:

- Patients who did not have an ultrasound as part of investigation.
- Patients who did not have surgery to confirm ultrasound findings.
- All non-consenting patients (i.e. those who refused to give consent or very sick patients who did not have a next of kin).

- Sample size

The sampling technique was sequential.

The sample size was determined by Fisher et al (1998) formula.

$$N = p \frac{(1 - p)z^2}{d^2}$$

Where:

N= sample size

Z= standard error corresponding up to 95% level (1.96)

d= absolute precision (5%)

From studies done, the accuracy of ultrasound in diagnosis of ectopic pregnancy is between 90% and 100%¹³⁻⁴⁹.

Expected accuracy of ultrasound in our study was considered to be 95%.

P= 95 % (Expected accuracy of ultrasound)

The calculated minimal sample size was **73** patients

- Equipments and Technique:

Patients were scanned using real time unit: a PHILLIPS ultrasound machine (model SD 800), a LOGIC 7 from healthcare at KNH, and a Hewlett Packard Image Point HX machine, GE logic 5 expert machines at Department of Diagnostic Imaging and Radiation Medicine at the University of Nairobi with facilities for TAS, TVS, color Doppler, Duplex imaging and multiple frequencies.

The ultrasonograms were coded for: *uterine size, intrauterine gestation sac, adnexal mass, adnexal ring, cul-de-sac fluid, or normal findings.*

Sonography was performed by postgraduate residents in radiology under supervision of consultants. Surgery was done by consultant obstetricians and postgraduate residents in obstetric and gynecology department

- Limitation

Ultrasound is operator dependent.

- Data collection and analysis:

This was done by the researcher with help from colleagues and staff of obstetrics and gynaecology department.

The data collection form comprised of a section on patient's socio-demographic characteristics, clinical findings, ultrasound and surgical findings during the operation.

The data was entered into a microcomputer using SPSS/PC+ for windows version 11, 5 data entry and analysis program. Validation was done before analysis.

Analysis was carried out using SPSS/PC + program. The data acquired was presented in form of tables, pie charts, and graphs.

To determine concordance, cross tabulations between ultrasound and surgical findings were done.

- Testing the accuracy of ultrasound

Ideally a test should be very accurate, that is, in the presence of disease it should be able to detect it all the time and in the absence, it should always be negative. Such a test however is rare to come by, and the diagnostic tests most often used are less accurate than the ideal tests. The parameters used to gauge the performance of a test are its sensitivity and specificity. Sensitivity of a test is the proportion of people with the disease who have a positive test for the disease. In our case, it's the proportion of people with suspected EP, diagnosed to have EP by ultrasound and confirmed at surgery. Specificity of the test is the proportion of people without the disease who have a negative test. Ultrasound being a diagnostic test was evaluated using the following formula.

		<i>Disease</i>	
		<i>Present</i>	<i>Absent</i>
<i>Test</i>	<i>Positive</i>	<i>A</i>	<i>B</i>
	<i>Negative</i>	<i>C</i>	<i>D</i>

a- true positive

b- false positive

c- false negative

d- true negative

$$\text{Sensitivity} = \frac{a}{a+c}$$

$$\text{Specificity} = \frac{d}{b+d}$$

$$\text{PPV} = \frac{a}{a+b}$$

$$\text{NPV} = \frac{d}{c+d}$$

- Ethical Consideration:

1. Permission to carry out the study was sought from Ethical and Research Committee of KNH and also from authorities from the Departments of Diagnostic Imaging and Radiation Medicine and of Obstetrics & Gynecology at KNH. Commencement of the study was thus begun soon after committee approval.
2. Information obtained from the study was treated with total confidentiality and results used for academic and clinical improvement purposes only.
The study did not interfere with the management of the patients in any way.
3. Patients' names were not recorded during the study. However, only patients' hospital numbers were required for referral purposes and this helped to maintain confidentiality.
4. The results of the study will be delivered to the KNH ethical committee for future references and to facilitate any possible improvements in patient management.
5. All patients were managed at optimal standards, medically or surgically depending on their clinical state.

IV. RESULTS:

Table 1: Age distribution of the study population

The age range of the 73 patients included in this study was 18 to 49 years with a mean age of 29 years. The majority (82.2%) were between 21 and 34 years, which is also the reproductive age group.

AGE GROUP	FREQUENCY	PERCENTAGE
14- 19	3	4.1
20 – 24	16	21.9
25 – 29	18	24.7
30 – 34	26	35.6
35 – 39	7	9.6
>40	3	4.1
Total	73	100.0

Table 2: Parity distribution of the study population

The parity distribution among the study population ranged from nulliparous to a parity of 5. It shows that the majority 82.2% were of low parity (Para 2 and less.) Para 3 and above were 13(17.8%).

PARITY	FREQUENCY	PERCENTAGE
0	21	28.8
1	22	30.1
2	17	23.3
3	5	6.8
4	7	9.6
5	1	1.4
Total	73	100.0

Bar graph 1: Marital status of the study population

The majority of the study population was married 48(65.7%), 21(28%) was single and only 4(5.4%) was separated or divorced.

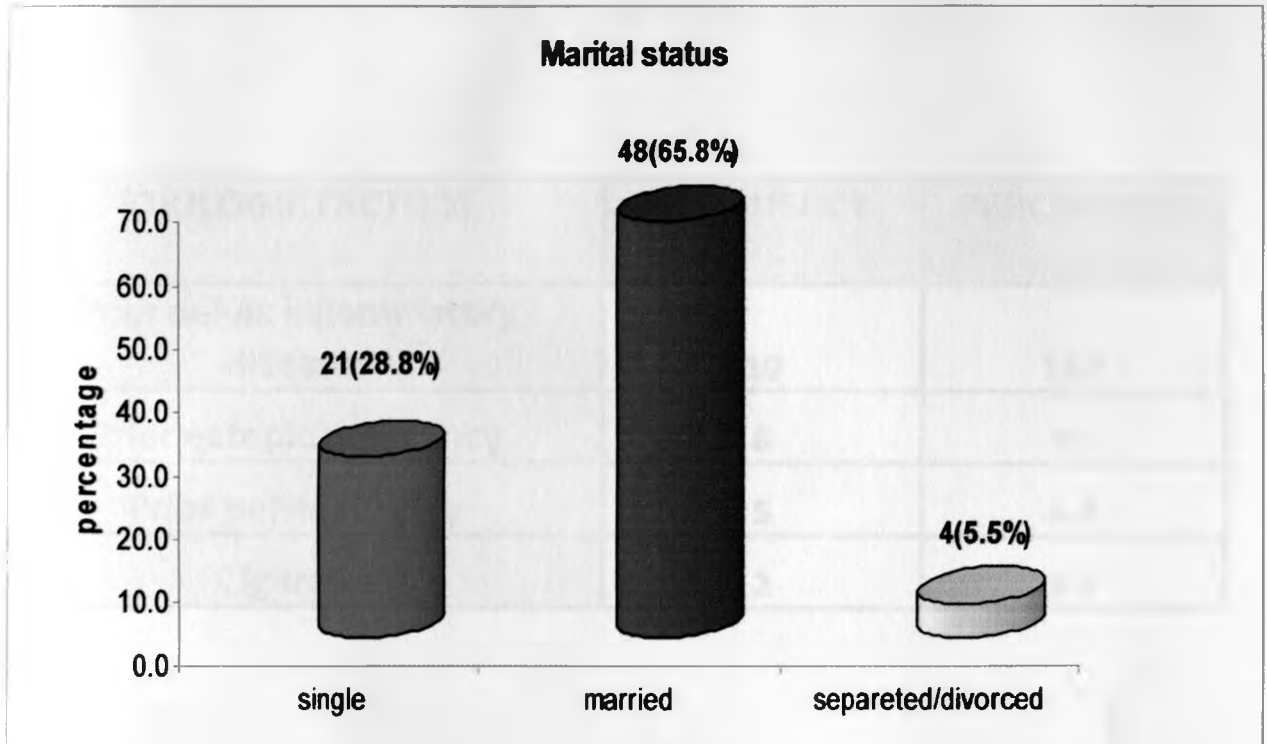


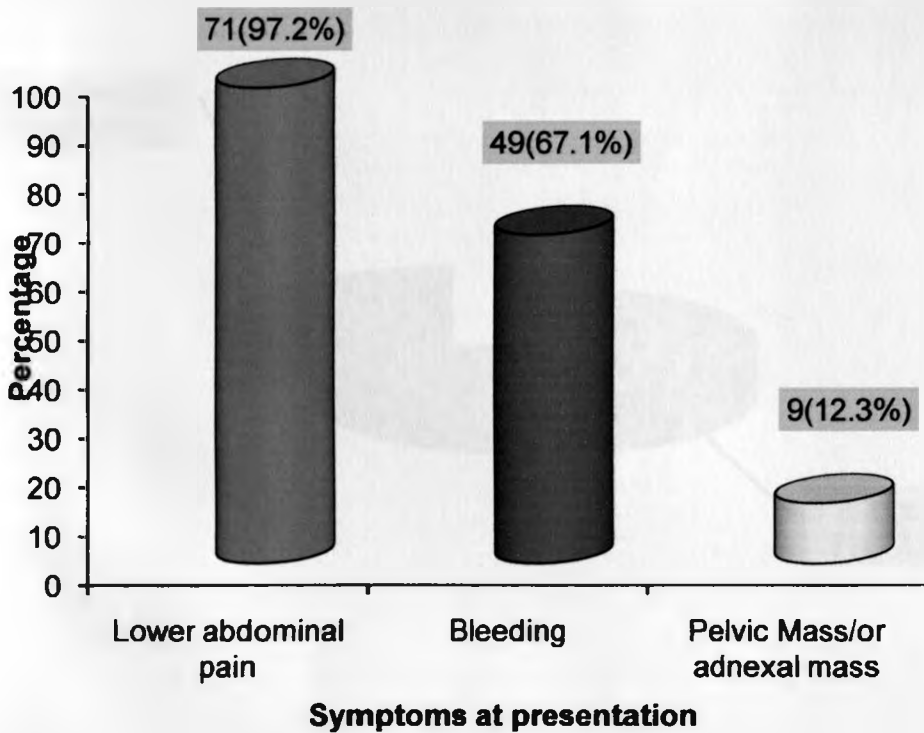
Table 3: Etiologic factors of the study population

In majority of cases (66%) there was no etiologic factor. Leading etiologic factor in our population study was prior pelvic inflammatory diseases in 10(13.7%), followed by prior ectopic pregnancy in 8(11%).

ETIOLOGIC FACTORS	FREQUENCY	PERCENTAGE
Prior pelvic inflammatory diseases	10	13.7
Prior ectopic pregnancy	8	11
Prior pelvic surgery	5	6.8
Cigarette	2	2.7

Bar graph 2: Presenting symptoms of the study population

The commonest symptom of the study population was lower abdominal pain in 71 patients (97.2%) followed by vaginal bleeding in 49 patients (67.1%) and a pelvic mass in 9 patients (12.3%).



Pie Chart1: Period of amenorrhea of the study population.

All the population in the study had a history of amenorrhea. The majority of the study population 53(72.6%) presented with a period of amenorrhea of 6 to 8 weeks.

Amenorrhoea per week

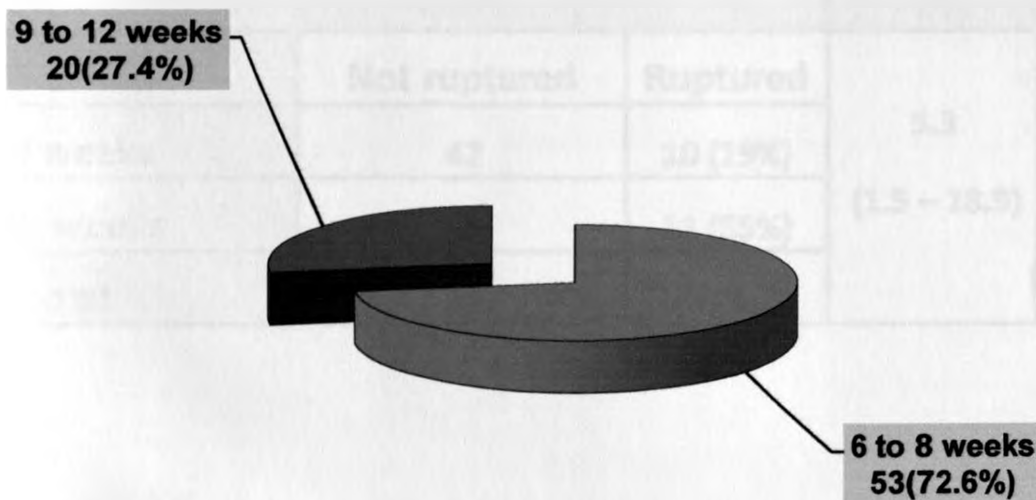


Table 4: Correlation between ruptured ectopic pregnancy and period of amenorrhea.

There is a significant association between amenorrhea and ruptured ectopic (p-value = 0.005). Patients with amenorrhea between 9 and 12 weeks are 5 times more likely to have a ruptured ectopic pregnancy.

AMENORRHOAE GROUP	ECTOPIC PREGNANCY		OR (95%CI)	P-value
	Not ruptured	Ruptured		
6-8 weeks	42	10 (19%)	5.3 (1.5 – 18.9)	0.005
9-12 weeks	9	11 (55%)		
Total	51	21		

Table 5: Criteria for ultrasound diagnosis of ectopic pregnancy.

On ultrasonography, it was observed that the single most common feature in patients suspected to have ectopic pregnancy, was the absence of a gestational sac in the uterine cavity - 73 (100%).

The presence of an extra uterine sac or a fetal pole was present in 42(57%) and was a confirmation of presence of ectopic pregnancy.

The presence of an adnexal complex mass with or without a fetal pole was seen in 56 (76.8%) of patients. Fluid in the pouch of Douglas was present in 45(61.6%) of patients. The uterus was enlarged in only 19 (26%) patients. Endometrial lining was thick in 8 (11%) of patients.

FINDINGS	FREQUENCY	PERCENTAGE
Absence Of Gestational Sac In Uterus	73	100%
Adnexal Complex Mass with or without fetal pole	56	76.8%
Fetal pole	42	57%
Fluid In Pouch Of Douglass	45	61.6%
Presence Of Extra-Uterine Sac	42	57.5%
Enlargement Of Uterus/bulky	19	26%
Thick endometrial lining or Pseudo gestational Sac	8	11%

Table 6: Site of ectopic pregnancy in study group.

The most common site for ectopic pregnancy was the fallopian tube in 70 (96 %), abdominal ectopic pregnancy seen on ultrasound was found at laparotomy to be secondary ruptured tubal ectopic pregnancy.

Cervical and cornual ectopic pregnancy were respectively 1(1.4%) each.

SITE OF ECTOPIC PREGNANCY	ON ULTRASOUND	ON SURGERY
Fallopian tube	65(87.6%)	70(96%)
Abdominal	5(6.8%)	0(0%)
Cornual	1(1.4%)	1(1.4%)
Cervical	1(1.4%)	1(1.4%)

Table 7: Disparity between ultrasonographic diagnosis and surgery (n=73)

Disparity between ultrasonographic diagnosis and surgery (n=73) was of 1.4%. The only case that was not an ectopic was seen as a complex right complex adnexal mass simulating a right ectopic pregnancy, at surgery it was a ruptured corpus luteum cyst.

DIAGNOSIS	With ULTRASOUND	Confirmed at LAPAROTOMY	DISPARITY
ECTOPIC PREGNANCY	73	72	1.4%

Table 8: Diagnostic value of ultrasound in suspected ectopic pregnancy.

Ultrasound	Ectopic		Total
	Positive	Negative	
Positive	72	1	73
Negative	0	39	39
Total	72	40	112

Sensitivity, Specificity, Positive and negative value of ultrasound in diagnosing ectopic pregnancy.

Ultrasound diagnosis of Ectopic Pregnancy	Sensitivity	Specificity	
	100%	97.5%	98.6%

Table 9: comparison of the results of this study with other authors.

This study showed a sensitivity of 100%, a specificity of 97.5%, a positive predictive value of 98.6% and a negative predictive value of 100%.

Our results and those done elsewhere, show that ultrasound alone is better in ruling out ectopic pregnancy than confirming its presence.

Authors	True positive	True negative
Pederson(1980)	100%	99%
Calvo et al(1977)	88%	100%
Markland and Wright(1978)	92%	96%
This study(2008)	98.6%	100%

Figure 8: Transverse trans-abdominal scan showing a viable abdominal ectopic pregnancy with a cardiac activity of 162 BPM at 12 weeks of gestational age. It was found at laparotomy to be secondary to ruptured tubal ectopic pregnancy.

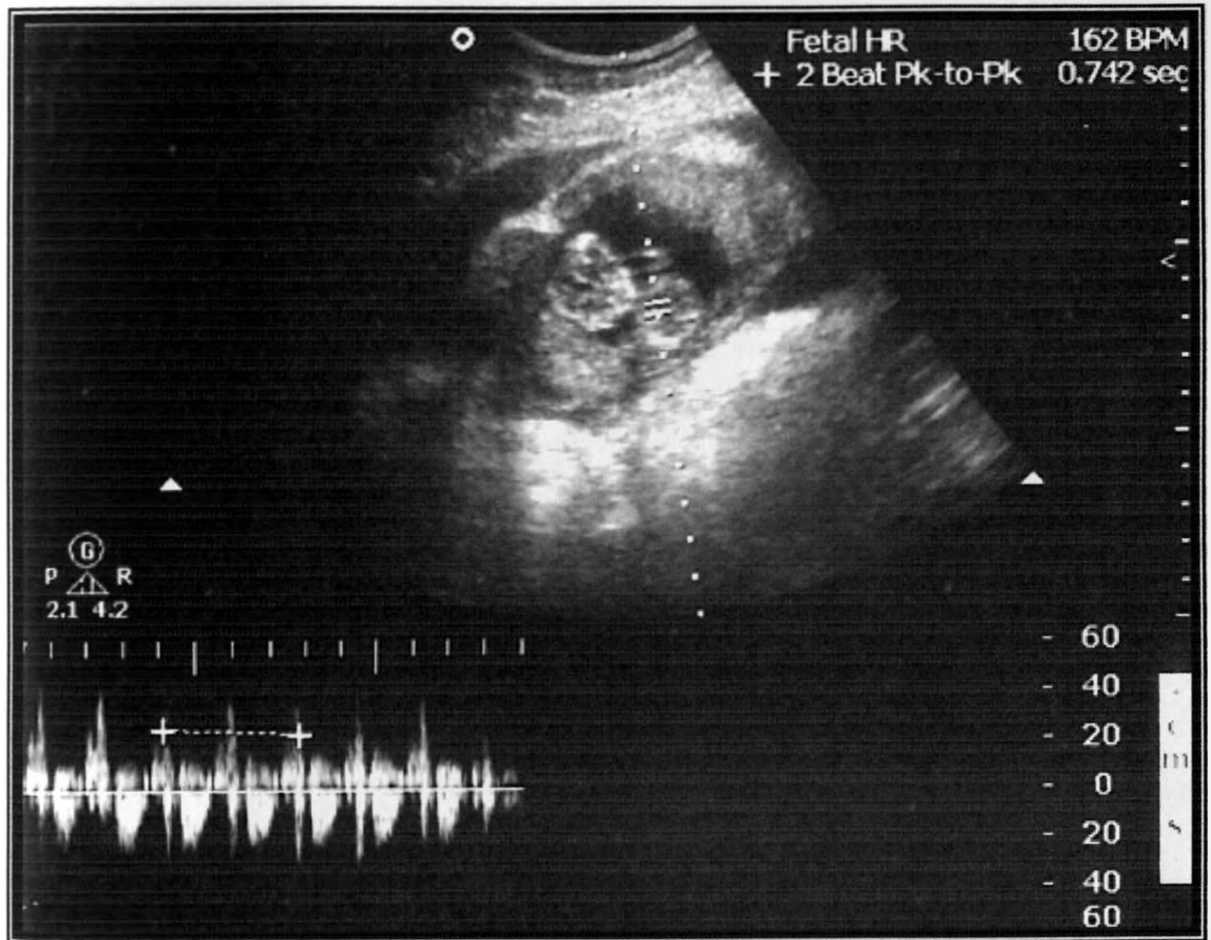


Figure 9: Trans-abdominal scans showing a cervical ectopic pregnancy at 6 weeks of gestational age in a nullipara patient. It was treated by cervical dilatation and curettage. The differential diagnosis included a spontaneous abortion in progress and a large nabothian cyst. In cases of a spontaneous abortion, the sac shape and location should change on serial imaging. A nabothian cyst usually can be distinguished from cervical EP because the cyst lacks an echogenic rim, yolk sac, and embryo.



Figure 10: Transverse scan showing a right cornual ectopic pregnancy of 7 weeks in a primipara patient. The cornual ectopic pregnancy was recognized by means of its eccentric location within the uterine lumen.

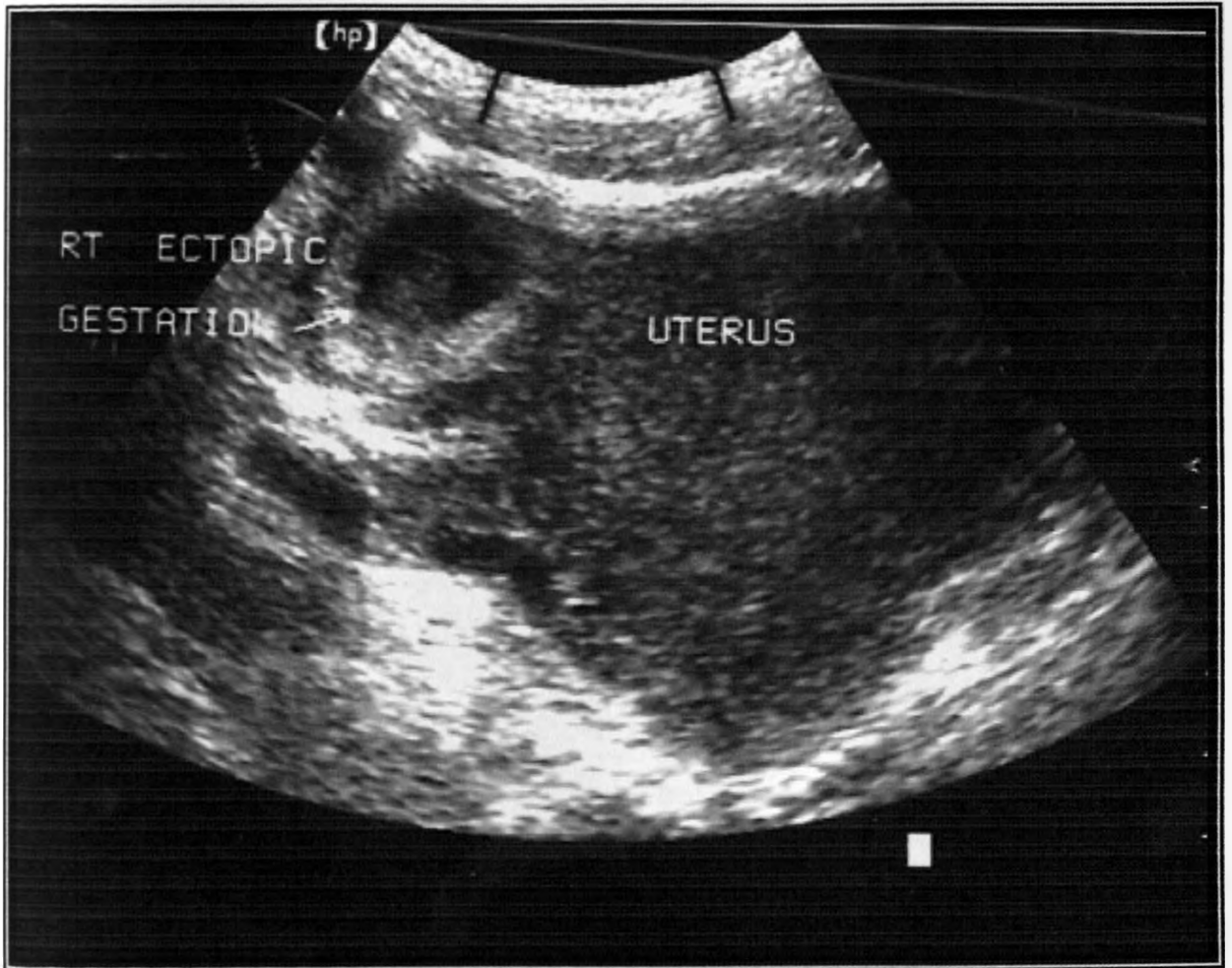


Figure 11: Transverse scan showing an ectopic pregnancy in the pouch of Douglass with free fluid. It was found at surgery to be a ruptured left tubal ectopic pregnancy at 9 weeks in the pouch of Douglass with hemoperitoneum.

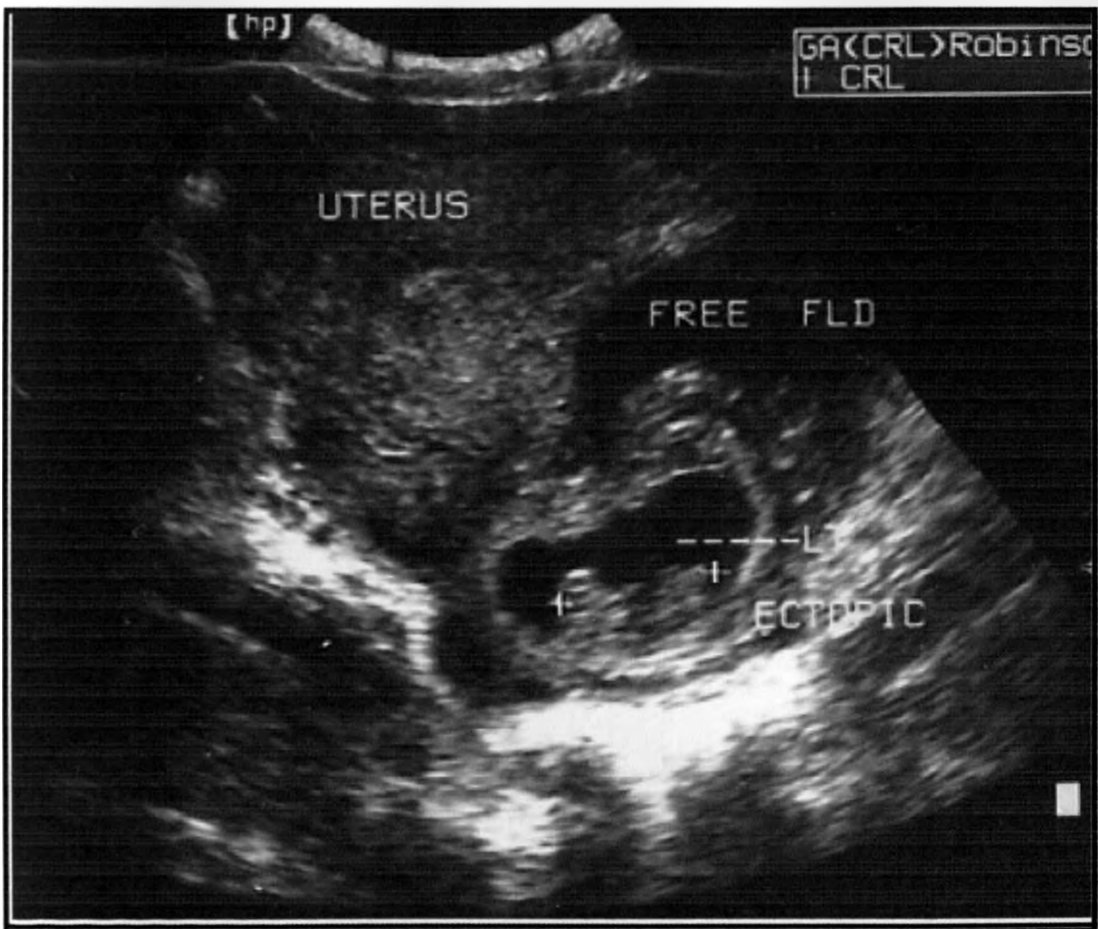


Figure 12: Transverse scan showing a complex right adnexal , with free fluid in PUD in a patient with 6weeks of amenorrhoea and pelvic pain. The mass was found at laparotomy to be a ruptured hemorrhagic corpus luteum cyst.

Corpus luteum cysts are common in normal early pregnancies; the statistical suggestion that the presence of an adnexal mass with positive pregnancy test indicates the presence of ectopic pregnancy is not always true.

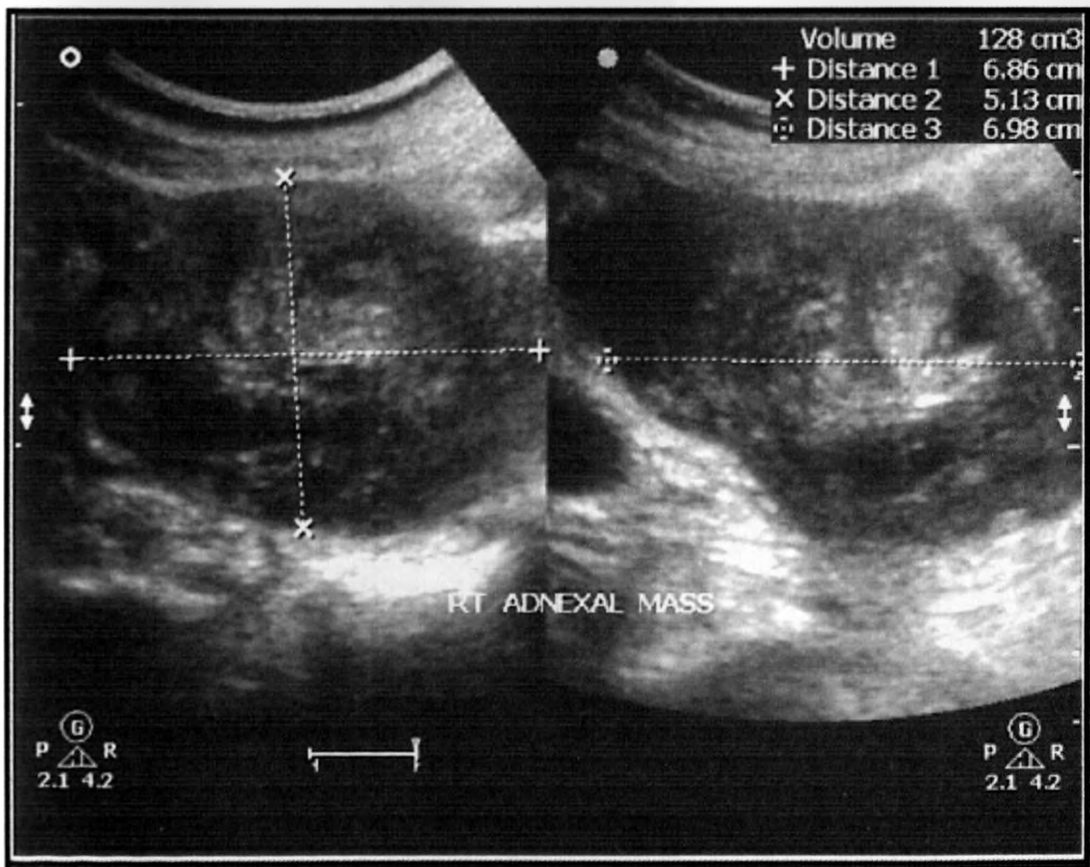


Figure 13: Parasagittal scan of a primipara presented with amenorrhea and pelvic pain, showing an unruptured tubal ectopic pregnancy which was confirmed on surgery.



V. DISCUSSION:

All women of childbearing age are at risk of having an ectopic gestation. Ectopic pregnancy is not only a diagnostic challenge but also a therapeutic emergency³⁸. Difficulty in diagnosis is because it remains asymptomatic in early weeks of gestation. If the gynecologists are better trained to diagnose ectopic pregnancy on ultrasound it would decrease the mortality and morbidity among suffering patients by reducing the time preceding active management³⁹.

Age: In this study, the majority of the patients 82.2% with suspected ectopic pregnancy were below the age of 35 years, with a mean age of 29 years. Mwathe in his study also showed that 72.9% of the patients with ectopic pregnancy were in the age group 20 to 30 years⁴⁰. This type of age distribution shows that ectopic pregnancy can occur at any time during the reproductive age of a woman, but occur much more commonly in the age group below 35 years.

Parity: With regard to parity, in this study 82.2% were para 2 or less which was similar to that of previous studies⁴⁰⁻⁴¹.

Etiologic factors: In this study, the majority of cases (66%) had no etiologic factor. Among the patients who presented with an etiologic factor, the leading etiologic factor was prior pelvic inflammatory disease in 13.7%, followed by prior ectopic pregnancy in 11%. Mwathe and Weckstein showed in their studies that ectopic pregnancy tends to occur more commonly among those with sub fertility or secondary infertility due to tubal blockage resulting from previous infections⁴⁰⁻⁴¹.

Symptomatology: All patients included in this study had a history of amenorrhea; the commonest symptom was lower abdominal pain in 97.2% followed by vaginal bleeding in 67.1% and adnexal or pelvic mass in 12.7%.

In a study done by Stabile, it was found that significantly more women with ectopic pregnancy had abdominal pain ($p < 0.05$) and irregular vaginal bleeding ($p < 0.001$)⁴². Weckstein found that significantly more women with ectopic pregnancy also presented with lower abdominal pain

($p < 0.0027$)⁴¹. This suggests that in a patient who presents with bleeding and amenorrhea especially between 5-8 weeks, the clinician should have a high index of suspecting an ectopic pregnancy as has been suggested by another study⁴⁰⁻⁴¹⁻⁴². However, many gynecological disorders in fertile menstruating women produce lower abdomen pain of acute onset.

Ultrasound criteria for diagnosis of ectopic pregnancy: In practical terms, the presence of an intrauterine gestation sac virtually excludes an ectopic pregnancy⁴⁴.

In this study, 100% of the patients with ectopic pregnancy had no intrauterine gestational sac. The presence of a gestational sac within the uterus must be definite because of the false positive diagnosis of an intrauterine pregnancy. Ectopic pregnancy can be accompanied by the picture of a pseudo gestational sac within the uterus which can be confused with a true gestational sac⁴⁵⁻⁴⁶. In this study, the presence of a live ectopic gestational sac with a fetal pole with cardiac activity allowed a definitive diagnosis of ectopic pregnancy. If a gestational sac cannot be clearly defined, a pelvic haematocele usually consisting of a complex mass with solid and cystic areas may be sought.

In this study, the most important ultrasonic abnormality in patients with ectopic pregnancy was the presence of an adnexal complex mass in 76.8% of cases.

Another aid in the diagnosis of an ectopic pregnancy is free intraperitoneal fluid and is a valuable sign in the diagnosis of ectopic pregnancy, but it may also be present in other conditions or even in the absence of any pelvic abnormality. In this study, free fluid in cul-de-sac when present was a helpful adjunct to diagnosis in 61%.

The uterus was enlarged in only 19 (26%) patients, endometrial lining was thick in 8 (11%) of patients, so these parameters were of limited value in the diagnosis of ectopic pregnancy in this study. These findings were also seen by Mansoor Ahmad et al in Pakistan⁹.

Other Studies found an enlarged empty uterus with an adjacent adnexal mass to be highly significant findings⁴⁷⁻⁴⁸. These show that the diagnosis of ectopic pregnancy on ultrasound, more than one parameter must be observed when the fetal pole or cardiac activity is not visualized, and a strong clinical suspicion of ectopic pregnancy in these patients is very important in diagnosis.

In an effort to determine the performance characteristics for these multiple criteria, a recent publication combined the results of 10 previously reported studies. The authors concluded that

for patients with a clinical suspicion of EP, the most appropriate diagnostic criterion was the presence of any noncystic, extra ovarian adnexal mass³⁷.

In this study, there was a significant association between period of amenorrhea and ruptured ectopic (p-value = 0.005). Patients with amenorrhea of 9 to 12 weeks were 5 times more likely to have a ruptured ectopic pregnancy compared to those who had amenorrhea of 6 to 8 weeks. This shows that the risk of rupture increases with the age of ectopic embryo.

Because none of the anatomic sites of ectopic pregnancy can accommodate placental attachment or a growing embryo, the potential for rupture and hemorrhage always exists².

The most common site for ectopic pregnancy in this study was the fallopian tube in 70 (97%), abdominal ectopic pregnancy seen on ultrasound was found at surgery to be secondary to ruptured fallopian tube ectopic pregnancy. Cervical and cornual ectopic pregnancy were respectively 1(1.4%) each.

Disparity between ultrasonographic diagnosis and surgery in this study was very low 1.4%. The only case which was not ectopic pregnancy was seen as a complex right adnexal mass simulating a right ectopic pregnancy on ultrasound; it was found at laparotomy to be a ruptured hemorrhagic corpus luteum cyst. This one case illustrates the potential limitation of US, as it is operator dependent; consequently, mistakes will be made. Given the fact also that corpus luteum cysts are common in normal early pregnancies, the statistical suggestion that the presence of an adnexal mass with positive pregnancy test indicates the presence of ectopic pregnancy is not always true. Mansoor Ahmad, Muhammad Ali found a discrepancy of 11.8% using only the TAS⁹.

This study showed a high sensitivity of 100%, a specificity of 97.5%, a positive predictive value of 98.6% and a negative predictive value of 100%. Our results meet those of others studies done elsewhere; and show that ultrasound alone is better in ruling out ectopic pregnancy than confirming its presence.

This high accuracy of ultrasound in this study can be partially due to the population study which was in majority patients with a period of amenorrhea of more than 6 weeks period where the embryo can be well visualized.

Treatment: majority of patient in this study had explorative laparotomy for confirmation and treatment of ectopic pregnancy. However, only one patient who had a cervical ectopic pregnancy was treated by cervical dilatation and curettage.

Great majority of cases were treated surgically immediately after ultrasound diagnosis, thus helping in rapid management of ectopic pregnancy.

With ultrasound 39 unnecessary laparotomies were avoided.

VI. CONCLUSIONS:

- 1.** This study confirmed how good ultrasound is, no doubt, however good the clinical approach is, it is of limited value.
- 2.** Ultrasound is a reliable imaging tool for diagnosing ectopic pregnancy with a high sensitivity, specificity, positive and negative predictive value.
- 3.** The presence of a complex adnexal mass associated with absence of an intra-uterine gestational sac is the ultrasound findings the more likely to indicate the presence of an ectopic pregnancy.
- 4.** The fallopian tube is the predilection site of ectopic pregnancy in majority of cases.
- 5.** Ultrasound is safe, non-invasive and quick in diagnosis EP and hence management of patients suspected to have ectopic pregnancy.

VII. RECOMMENDATIONS:

- 1.** Ultrasound should be used as a first line in the investigation of patients suspected to have an ectopic pregnancy. Paracentesis is not recommended and should not be used. Patients suspected to have ectopic pregnancy should straight away be taken for ultrasonographic examination rather than getting their pregnancy test done as a first investigation or waiting for reports to come that may worsen the condition of the patient.
- 2.** Staff in the obstetric and gynecologic department should be trained to perform ultrasound scans in order to diagnose ectopic pregnancy and ameliorate its management.
- 3.** Ultrasound aid should be available at every emergency unit dealing with obstetrics and gynecology cases for a better outcome, even at the sub district level. Also training of the doctors concerned must be specifically emphasized regarding ultrasound.
- 4.** There is a need of a similar study to be conducted for screening of early ectopic pregnancy of less than 6 weeks of gestational age, using trans-vaginal scanning and serial serum B-hCG.

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APPENDIX A: CONSENT

✓ CONSENT FORM

My name is Dr.NSHIZIRUNGU Jean Jacques, a Master of Medicine student at the Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi. I am doing a study on ectopic pregnancy, and would wish to recruit you to participate.

The information you will give and the examination findings will be handled with utmost confidentiality.

Your name will not be included, except the serial number. The results of the study will be used to improve the diagnosis and management of ectopic pregnancy. Please note that you are not obliged to participate and you have a right to decline or withdraw from the study.

If you accept to participate in this study, please sign below

Signature: _____

Date: _____

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

Dr. NSHIZIRUNGU Jean Jacques

Signature: _____

Date: _____

APPENDIX A (KISWAHILI)

✓ Maelezo Ya Kibali Cha Mgonjwa

Jina langu ni Dr NSHIZIRUNGU Jean Jacques Mimi ni daktari na pia mwanafunzi katika Chuo kikuu cha Nairobi. Ninafanya uchunguzi utafiti kuhusu mimba ya mushipa kwa kutumia mbinu ya picha ya ultrasound.

Kwa maana wewe upo hapa kupigwa picha ya tumbo , ningeomba ruhusa yako ili tuyatumie majibu yako katika uchunguzi wangu.

Majibu yoyote ambayo tutapokea kutoka kwa uchunguzi wako ni ya siri. Jina lako halitawekwa kwenye uchunguzi wetu ila nambari ya fomu tu.

Majibu ya huu uchunguzi wako na ya wengine yatasaidia kuboresha matibabu ya mimba ya mushipa.

Naelewa ya kwamba sio lazima nihusike katika huu utafiti, na pia naweza kubadili nia yangu kuhusu kuendelea kushiriki.

Asante sana kwa ushirika wako.

Kama unakubali kushiriki, tafadhali weka sahihi yako hapa chini:

Sahihi _____

Tarehe _____

Nambari _____

Ninathibitisha ya kwamba muhusika ameelewa na kukubali kushiriki kwa utafiti huu.

Daktari NSHIZIRUNGU Jean Jacques

Sahihi _____

Tarehe _____

APPENDIX B: Questionnaire: Correlation of Ultrasound and Surgical findings on patients with suspected EP.

I. Socio-demographic data:

1. Patient's number:.....
2. Patient's hospital number:.....
3. Patient's age in years:.....
4. Marital status: - Single :.....
 - Married:.....
 - Separated/divorced:.....
 - Widowed:.....
5. Level of education: None:.....
 - Primary:.....
 - Secondary:.....
 - Above secondary:.....
6. Parity:.....

II. Risk factors:

- ✓ Prior pelvic inflammatory disease:..... Y N
- ✓ Prior ectopic pregnancy :..... Y N
- ✓ Pregnancy in a woman with an intrauterine device (IUD) in place :..... Y N
- ✓ Pregnancy achieved by means of in vitro fertilization or fertility drugs:..... Y N
- ✓ Prior tubal surgery (reconstruction or tubal coagulation) :..... Y N
- ✓ Cigarette smoking :..... Y N
- ✓ Prior pelvic surgery:..... Y N

III. Clinical findings:

- ✓ Amenorrhoea: N Y
- ✓ Pain: N Y (if yes where?).....
- ✓ Bleeding: N Y
- ✓ Pelvic mass:..... N Y
- Others:.....
-
-

IV. Ultrasound findings:

- ✓ uterine size: Normal....., bulky.....
- ✓ Adnexal mass:..... N Y (If Yes Where?).....
- ✓ Intrauterine gestational sac:..... N Y
- ✓ Free fluids in the the pouch of Douglas:..... N Y
- ✓ adnexal ring:..... N Y
- ✓ normal findings..... N Y
- ✓ gestational age.....
- ✓ extrauterine gestational sac..... N Y (If Yes Where?).....

V. Surgery:

- ✓ The intraoperative approach: - laparotomy
- laparoscopy
- ✓ Surgical findings.....
- Hemoperitoneum Y N
- Site of ectopic pregnancy.....
- ✓ Any other findings.....
-
-



Ref: KNH/UON-ERC/ A/48

KENYATTA NATIONAL HOSPITAL

Hospital Rd. along, Ngong Rd.

P.O. Box 20723, Nairobi.

Tel: 726300-9

Fax: 725272

Telegrams: MEDSUP, Nairobi.

Email: KNHplan@Ken.Healthnet.org

26th August 2008

Dr. NSHIZIRUNGU Jean Jacques
Dept. of Diagnostic Imaging & Radiation medicine
School of Medicine
University of Nairobi

Dear Dr. NSHIZIRUNGU

RESEARCH PROPOSAL: "A CORRELATION OF ULTRASOUND AND SURGICAL FINDINGS IN
SUSPECTED ECTOPIC PREGNACY AT KENYATTA N. HOSPITAL" (P122/6/2008)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and **approved** your above revised research proposal for the period 26th August 2008 – 25th August 2009.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimen must also be obtained from KNH-ERC for each batch.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

DR. L. MUCHIRI

AG. SECRETARY, KNH/UON-ERC

c.c. Prof. K.M.Bhatt, Chairperson, KNH-ERC

The Deputy Director CS, KNH

The Dean, School of Medicine, UON

The Chairman, Dept. of Diagnostic Imaging & Radiation Medicine, UON

Supervisors: Dr. N.M. Kimani, Dept. of Diagnostic Imaging & Rad. Medicine, UON

Dr. Kihara Anne, Dept. of Obs/Gynae, UON