

**COMPARISON OF TRANSABDOMINAL ULTRASONOGRAPHY AND
SURGICAL FINDINGS IN PATIENTS WITH ECTOPIC PREGNANCY SEEN IN
MOI TEACHING AND REFERRAL
HOSPITAL, ELDORET KENYA**

BY

KIYENG K. GILBERT

Reg. No. SM/PGR/01/13

**A RESEARCH THESIS PRESENTED TO THE SCHOOL OF MEDICINE IN
PARTIAL FULFILLMENT FOR THE AWARD OF THE DEGREE OF MASTER
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DECLARATION

I declare that this thesis is my original work written in partial fulfillment for the degree of Master of Medicine in Radiology and Imaging and has not been presented in any other university or institution for an award of a degree or any academic credit. No part of this work may be reproduced or transmitted in any form without prior permission from the author or Moi University.

KIYENG Gilbert Kiplagat

REG No SM/PGR/01/13

Dept of Radiology and Imaging, Moi University

Signature _____

Date _____

Supervisor's Declaration

This thesis has been submitted for consideration with our approval as university supervisors.

Dr. Kimutai E.C

Consultant Radiologist

Moi Teaching and Referral Hospital

Signature _____

Date _____

Dr. Tonui P.K

Lecturer, Department of Reproductive Health, School of Medicine, Moi University

Signature _____

Date _____

DEDICATION

I would like to dedicate this study to my loving wife Joan Kiyeng for her unending support. To my son Lester Kimutai for he is a source of joy and laughter even in tough times. To my parents and my siblings for their unlimited support and love, and above all the almighty God who has seen me through my entire life. I will always love you and am grateful for everything.

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LIST OF ABBREVIATIONS:

TVS	Transvaginal sonography
TAS	Transabdominal sonography
IREC	Institutional Research and Ethics Committee
MTRH	Moi Teaching and Referral Hospital
EP	Ectopic pregnancy
GS	Gestational sac
US	Ultrasound
HCG	Human Chorionic Gonadotrophin
CDC	Centre for Disease Control
IUCD	Intrauterine contraceptive device
BTL	Bilateral tubal ligation
IUP	Intrauterine pregnancy
MRI	Magnetic Resonance Imaging
HB	Hemoglobin
POD	Pouch of Doglous
NPV	Negative Predictive Value
PPV	Positive Predictive Value
USA	United States of America
UK	United Kingdom
CT	Computed Tomography

ABSTRACT

Background: Ectopic pregnancy is a condition in which a fertilized ovum is implanted outside the uterine cavity. It's one of the conditions that is an emergency in gynaecology and causes major morbidity and mortality. Globally its incidence has been rising over the last 20 years. Early sonographic diagnosis decreases morbidity, mortality and provides management options which promote modern treatment methods including expectant treatment, medical or conservative laparoscopic surgeries.

Objective: To describe ultrasonography and surgical findings of patients with ectopic pregnancy and assess level of agreement between ultrasound and surgery in diagnosing ectopic pregnancy.

Methods: A cross-sectional study was done between October 2014 to August 2015. A total of 84 participants were included, pelvic scan was done and later laparotomy performed. Data was collected using structured questionnaire and entered in computer data base. Data on patient's demographic, clinical presentation, ultrasound findings, and surgical outcomes were collected and level of agreement calculated. Analysis was done using software for data analysis known as R (R core Team, 2015). Descriptive statistics such as frequencies, means and standard deviations, and median and interquartile range were used to summarize the data.

Results: The mean age was 22.8 ± 5.8 years. Majority 82% (n=69) of the participants were from Uasin Gishu County and 42.9% (n=36) were nulliparous. Amenorrhoea was reported in 73% (n=61) with average duration of 7 weeks. The most common ultrasound finding was complex adnexal mass at 69.9% (n=58) with majority 55% (n=46) located on the right adnexa. Ruptured tubal pregnancy with haemoperitoneum was reported in 97% (n=82) of the participants. One participant had advanced abnormal pregnancy at 25 weeks gestation as per ultrasound but was found to be a normal intrauterine pregnancy in a bicornuate uterus after laparotomy. The observed level of agreement was 81.7% while the expected level of agreement was 47.3%. This gives a Kappa value of 0.653. This value shows that the level of agreement was substantial according to Viera et al, 2005 who classified it between 0.61 – 0.80.

Conclusion: Complex adnexal mass was the most common ultrasound finding while ruptured tubal ectopic pregnancy with haemoperitoneum was the commonest surgical findings. The observed level of agreement was 81.7% while the expected level of agreement was 47.3%. This gives a Kappa value of 0.653. This value shows that the level of agreement was substantial.

Recommendations: The level of agreement of ultrasound and surgery to diagnose ectopic pregnancy is substantial and therefore all patients suspected to have the gynaecological condition are encouraged to have an ultrasound done to assist in diagnosis.

1.1 Background Information

Ectopic pregnancy is a condition in which a fertilized ovum is implanted outside the uterine cavity. The most common site is the fallopian tube but can occur in the ovary, cervix and abdomen. In the fallopian tube (95%) of ectopic pregnancies implant within the ampullary or isthmic portions of the fallopian tube. Approximately 2-4% of ectopics implant within the intramural (interstitial) portion of the tube as it traverses the uterine wall(Brant, 2001). Cervical, abdominal, and ovarian implantations are rare with each accounting for less than 1% of ectopic pregnancies. The risk factors(Patapuro, 2013) are mainly previous pelvic surgery, pelvic inflammatory disease, ovulation induction, previous ectopic pregnancy, previous abortion, intrauterine device use and assisted reproductive therapy(Al-Turki, 2012) .The ectopic pregnancy is prone to rupture with hemorrhage that may be fatal. Ectopic pregnancy is responsible for approximately 15% of maternal deaths(Brant, 2001) . Globally its incidence has been rising but its actual prevalence is not known because of non-standardized denominator for calculation of rates(P. de Rosnay & L. M. Irvine, 2012). Various researchers have been able to measure number of ectopic pregnancies using either per number of deliveries, number of gynecological admissions or total number of patients admitted in a particular period.

The incidence/ prevalence vary from one country to another and from one facility to the other. In USA Cain found out different prevalences in different states New York (2.38%), California(2.07%) and Illinois(2.43%)(Cain & Stulberg, 2013).In a study done between 2000 and 2003 in UK Mavrelos D et al found out a prevalence of 2.9%(Mavrelos et al., 2013) .In African countries the trend is the same with varied incidences & prevalences

reported. In Nigeria Akaba et al found ectopic pregnancy to be 6.86% of all gynaecological admissions with overall incidence of 2.7%(Akaba, Agida, & Onafowokan, 2012) while in Ethiopia in a study done by Yoseph S from 1981 to 1987 ectopic pregnancy cases had an incidence of 8 per 1000 deliveries(Yoseph, 1990). Kenyan study done in Kenyatta National Hospital in October 2002 by Awori M N in all patients presenting with acute abdominal pain, he found out that in females who eventually ended up undergoing laparotomy, 65.3% had ectopic pregnancy(Awori & Jani, 2005) while 66 patients out of 10,000 deliveries had ectopic pregnancies in a study done by Ruminjo JK (Ruminjo & Nuwagaba, 1990).In MTRH ectopic pregnancy cases were 103 in the year 2013 and it constituted 3.9% of all gynaecology admissions.

The most common presentation of ectopic pregnancy is a triad of amenorrhea, abdominal pain and vaginal bleeding (Akaba et al., 2012) but other symptoms may be present depending on presence of complications or not. The most feared and life threatening complication is internal haemorrhage with subsequent hypovolemic shock and death if timely intervention is not put in place.

Previously before the development of ultrasound, gynecologists used clinical assessment to make a diagnosis of ectopic pregnancy with use of positive paracentesis used to confirm a ruptured ectopic. Now with availability of ultrasound its quite easy to confirm suspected ectopic with pelvic ultrasound. Ultrasound in combination with positive beta human chorionic gonadotrophin (HCG) gives a sensitivity of up to 97% with equivalent specificity and positive predictive value (Brant, 2001).Advantages of ultrasound are easily available, cheap and no ionizing radiation among others while the main disadvantage is that ultrasound is user dependent and well trained sonographers are important for quality results

to be acquired(Brant, 2001). Early sonographic diagnosis decreases morbidity & mortality and provides management options which promotes modern methods including expectant, medical or laparoscopic surgeries(Casikar, Reid, & Condous, 2012; Winder, Reid, & Condous, 2011b)

Ultrasound findings of ectopic pregnancy with associated degree of risk(Brant, 2001) include:

- Extra uterine gestational sac containing yolk sac is diagnostic of ectopic pregnancy Risk (100%).
- Extra uterine gestational sac containing living embryo is diagnostic of ectopic pregnancy Risk (100%).
- Extra uterine "tubal ring," an echogenic thick-walled, ring-like mass separate from the ovary, represents a gestational sac with surrounding trophoblastic reaction Risk (95%).
- Complex cystic or solid adnexal mass without distinguishing features. This finding is consistent with tubal rupture and clotted blood Risk (86%) while small volume of anechoic-free intraperitoneal pelvic fluid Risk (normal finding), is not predictive of ectopic pregnancy.
- Moderate or large volume of free intraperitoneal fluid, particularly if the fluid is echogenic Risk (70%)(Brant, 2001).

More than 95% of patients with ectopic pregnancy will undergo laparotomy but in some cases use of methotrexate or conservative care can be employed with good success reported(Rabemanantsoa, Randriamahavonjy, Rabemazava, & Andrianampanalinarivo, 2010). The bulk of cases are ruptured ectopic pregnancies (Akaba et al., 2012) with the

commonest site being at the ampulla and isthmus. In Niger Delta in a 11 year study found that 9.5 % of all gynaecological admissions were due to EP with 95.3% being ruptured(Igberase, Ebeigbe, Igbekoyi, & Ajufoh, 2005) (Igberase et al 2005).The most performed surgical procedure is salpingectomy (Shetty, Gowda, & Muralidhar, 2014).

This study will be able to compare the findings of the ultrasound and surgical findings (gold standard) and in essence test the extend of agreement of the two sets of results. Early detection and management of ectopic pregnancy will reduce maternal morbidity and mortality and will also promote conservative management options which will preserve fertility and therefore not jeopardise future ability to conceive(Casikar et al., 2012; Winder, Reid, & Condous, 2011a).

1.2 Problem Statement

Ectopic pregnancy is one of the major causes of maternal morbidity and mortality. It's incidence has been rising over the years and it's two to three times higher than 20 -25 years ago. In a study done by de Rosnay P it shows the international trends of ectopic pregnancy has been generally increasing(P. de Rosnay & L. M. Irvine, 2012). The number of cases varies from one country to another and also from one facility to another. There are a good number of cases seen in Moi Teaching and Referral Hospital (MTRH) in a year with varied level of presentations, complications or no complications. Quick and accurate diagnosis is crucial for urgent intervention to be initiated to minimize complications and eventually morbidity and mortality. Through proper history taking , physical examination, beta HCG test and ultrasonography, sensitivity is up to 97%(Madani, 2008).Ultrasound has shaped diagnosis and definitive management of ectopic pregnancy and its currently considered the gold standard(T. Bignardi, Alhamdan, & Condous, 2008) and through it more modern

treatment methods like methotrexate injection, expectant treatment or laparoscopic surgeries are being practiced (Casikar et al., 2012; Winder et al., 2011b) with conservation of future fertility the main advantage. The bulk of the cases are managed through open surgical intervention (Baldvinsdottir, Gudmundsson, & Geirsson, 2013) but there is a shift towards using modern treatment methods with US enabling proper diagnosis and appropriate selection of the most convenient method. If this is done in good time most of the patients will survive unless they arrive when they have adverse complications.

1.3 Purpose of the Study

The purpose of this study was to find out and compare ultrasound and surgical findings (gold standard) in patients presenting with ectopic pregnancy in MTRH.

1.4 Research Questions

1. What are the ultrasound findings of patients presenting with ectopic pregnancy in MTRH?
2. What are the surgical findings for patients who will undergo surgery?
3. What is the level of agreement between ultrasound and surgery in diagnosing ectopic pregnancy?

1.5 Research Objectives

1.5.1 Main objective

To describe ultrasonography and surgical findings of patients presenting with ectopic pregnancy and assess level of agreement between ultrasound and surgery in diagnosing ectopic pregnancy.

1.5.2 Specific Objectives

1. To describe ultrasound findings of patients with ectopic pregnancy at Moi Teaching and Referral Hospital.
2. To find out surgical findings of patients who have undergone surgery.
3. To assess the level of agreement between ultrasound and surgery in diagnosing ectopic pregnancy.

1.5.3 Null Hypothesis

Ultrasound findings of ectopic pregnancy patients are the same as surgical findings.

1.6 Justification

Ectopic pregnancy(EP) has been one of the major causes of morbidity and mortality and its incidence has been increasing over the years(P. de Rosnay & L. M. Irvine, 2012). Previously, gynaecologists have been relying on history, physical examination and paracentesis to make a diagnosis of EP. Over time ultrasonography has become a very important imaging modality of confirming this problem giving sensitivity of up to 97%(P. de Rosnay & L. M. Irvine, 2012). This has revolutionized the management of EP with US giving very detailed information for example it can demonstrate as small as 10 mm size lesion within the adnexa , ruptured or unruptured and presence of haemoperitoneum or not. The impact of this is that the modern treatment options of EP will be utilized with subsequent reduction in morbidity and mortality and conservation of the fallopian tubes hence avoidance of infertility complication in the future(Casikar et al., 2012).There is no published data of a similar study in the region and therefore data obtained will contribute to the generation of data which can be utilized in the future by other researchers.

CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology of Ectopic Pregnancy

Ectopic pregnancy (EP) is a condition in which a fertilized ovum is implanted outside the uterine cavity. The most common site is the fallopian tube but can occur in the ovary, cervix and abdomen. In the fallopian tube, 95% of ectopic pregnancies implant within the ampullary or isthmic portions of the fallopian tube, while approximately 2-4% of ectopic pregnancies implant within the intramural (interstitial) portion of the tube as it traverses the uterine wall (Brant, 2001). Cervical, abdominal, and ovarian implantations are rare with each accounting for less than 1% of all ectopic pregnancies. The prevalence of EP vary from country to country and from one health facility to another but generally there has been an increase in cases over the last 20 years or so (P. De Rosnay & L. Irvine, 2012). In Saudi Arabia prevalence is 1.3% (Al-Turki, 2012) while in United Kingdom prevalence is 2.9% (Mavrelos et al., 2013) in a study done between 2008 to 2011. The overall rate of EP in USA according to Centre for Disease Control (CDC) in 2012 is 1-2 % (Centers for Disease & Prevention, 2012) of all pregnancies while prevalences vary in different states in USA, New York (2.38%), California (2.07%) and Illinois (2.43%) in a study done between 2000-2003 (Cain & Stulberg, 2013). Meanwhile in Iceland in a study done by Baldvinsdottir between 2000 and 2004 the incidence of EP was 5.6 per 10,000 deliveries and between 2005 and 2009 it was 12.9 per 10,000 deliveries (Baldvinsdottir et al., 2013). In India ectopic pregnancies form 1-2 % of all pregnancies with incidence of 2.46 per 1,000 deliveries according to study by Gupta R et al (Gupta, Porwal, Swarnkar, Sharma, & Maheshwari, 2012) whereas in China Tsai HD in 1995 found out that in every 52 deliveries there is one ectopic pregnancy (Tsai, Chen, & Yeh, 1995). African studies shows

the same variability whereby in Nigeria Akaba et al found EP to be 6.86% of all gynaecological admissions with overall incidence of 2.7%(Akaba et al., 2012) while Osaheni et al found that EP was 4.5%(Lawani, Anozie, & Ezeonu, 2013) of all gynaecological admissions with incidence of 2.1%. Musa J et al found a prevalence of 1.74%(Musa, Daru, Mutahir, & Ujah, 2009) in a study done between 1997 and 2000 in northern Nigeria. Ikeme AC found out that there were 136 EP out of 6,003 deliveries giving a rate of 2.2 %(Ikeme & Ezegwui, 2005) in Enugu Nigeria, while Igberase et al in Niger Delta in a 11 year study found that 9.5 % of all gynaecological admissions were due to EP with 95.3 % being ruptured(Igberase et al., 2005). In Conakry Guinea in a study done by Sy et al showed a prevalence of 1.4 %(Sy et al., 2009) while in south Africa in a study done by Amoko DH EP incidence was 11 per 1000 of reported pregnancies(Amoko & Buga, 1995). Yoseph S did a study in Ethiopia between 1981 to 1987 where EP had an incidence of 8 per 1000 deliveries(Yoseph, 1990) while in Younde in a study done by Leke RJ et al in the year 2000 he found that incidence of EP was 0.79%(Leke, Goyaux, Matsuda, & Thonneau, 2004). In Bangui, Central African Republic in a study done by Sepou et al incidence was 1 case of EP per 61.8 deliveries(Sepou et al., 2003). In Kenya 66 patients out of 10,000 deliveries(Ruminjo & Nuwagaba, 1990) had EP in a study done by Ruminjo J.K in a periurban setup whereas in a study done in KNH in October 2002 by Awori MN whereby he reviewed all patients presenting with acute abdominal pain, and he found out that in females who eventually ended up undergoing laparotomy 65.3%(Awori & Jani, 2005) had ectopic pregnancy.

2.2 Ultrasound diagnosis of ectopic pregnancy

Pelvic ultrasound has revolutionized the diagnostic process of ectopic pregnancy and is now considered the gold standard for the diagnosis of ectopic pregnancy (T. Bignardi et al., 2008). It can demonstrate masses in the adnexa as small as 10 mm in diameter and can provide more detail about the character of the mass and at the same time evaluate the contents of the endometrial cavity and assessment for the presence of free peritoneal fluid. In the adnexa, a live embryo, gestational sac, or complex mass can be demonstrated. Free intraperitoneal fluid is reported in more than 60 % of cases with echogenic or particulate fluid corresponding to hemoperitoneum. The most common location of EP is tubal (Shetty et al., 2014) with complex adnexal mass the predominant US feature (Adhikari, Blaivas, & Lyon, 2007; Shetty et al., 2014). Majority are ruptured with associated haemoperitoneum (Lawani et al., 2013).

Complex cystic or solid adnexal mass without distinguishing features is a finding which is consistent with tubal rupture and clotted blood (Brant, 2001). Rupture is more common if implantation occurs in the narrower portion of the tube which is the isthmus or may occur in the anti-mesenteric border of the tube which usually leads to profuse bleeding into the peritoneum. If rupture occurs in the mesenteric border of the tube a broad ligament haematoma will occur (Elmowafi, March 2016). It's very difficult for US to characterize the exact location of EP within the tube unless its located in the interstitial part which normally has sonographic features which includes: an empty uterine cavity, products of conception located outside of the endometrial cavity and surrounded by a continuous rim of myometrium. An 'interstitial line' is often seen consisting of a thin echogenic line that

extends from the central uterine cavity to the periphery of the interstitial sac and presumably represents the endometrial canal of the interstitial part of the Fallopian tube (Kirk & Bourne, 2009). In a study done by Adhikari et al 61% of the cases had complex adnexal mass while 13% of the cases had live ectopic (Adhikari et al., 2007). This is comparable to the findings of this study although slightly on the lower side in terms of the number of cases of complex adnexal. The number of live ectopics in this study were less in comparison with other studies which could be explained by the fact that majority were ruptured hence tubal abortion took place with loss of viability in most of them. Shetty et al reported that 60% of the cases showed a complex adnexal mass with majority of them located on the right adnexa (Shetty et al., 2014), this is comparable to the findings of this study while Condous et al reported 78% of them had complex adnexal masses with 13.2% demonstrating embryo with or without a cardiac activity (Condous et al., 2005). Casikar et al all reported that 80% of the cases had adnexal masses which ranged from inhomogenous mass to ones that appear as hyperechoic ring and 13% of the cases were having obvious gestational sac (Casikar et al., 2012). The number of adnexal masses found by Casikar & Condous are more in comparison with this study which can be attributed by the fact that most of the participants in their studies had ruptured ectopics. This is supported by the fact that they had less cases of visualized gestational sac (13%) in comparison with this study which found 27% had visualized gestational sac with or without cardiac activity.

Visualization of a gestational sac with yolk sac or fetal pole implies an intact fallopian tube with a pregnancy that is likely to be growing while visualization of an inhomogeneous mass might well be a collapsed sac, which is less likely to contain active trophoblastic tissue. More recently it has been suggested that visualization of an inhomogeneous mass

may represent either an early developing ectopic pregnancy (before a gestational sac is visualized) or a failing ectopic pregnancy. A total of 27% of the participants had a GS with only 5% of them having gestational age determination possible. This is occasioned by inability to clearly identify the parameters for age determination which may result from tubal abortions or early rupture with deformation of the GS with absent cardiac activity in majority of the cases(Elmowafi, march 2016) .Different studies have shown varied findings with Adhikari et al reporting that13% of the cases were demonstrating presence of live ectopic embryos ,same as Condous et al & Casikar et all who both reported 13% presence of embryo with or without cardiac activity(Condous et al., 2005) & obvious presence of gestational sac(Casikar et al., 2012) respectively.

2.3 Surgical Findings

The mainstay of treatment of ectopic pregnancies is surgery but there is role of methotrexate injection but limited use is reported despite high success rate of treatment noted recently(Rabemanantsoa et al., 2010). Laparoscopy is preferred to laparotomy because of advantages that include short hospital stay, less chance of infections, minimal adhesions formations among others(Taran et al., 2015). Rupture and haemoperitoneum form the bulk of surgical findings (Thonneau, Hijazi, Goyaux, Calvez, & Keita, 2002).In India Majhi found that 95% of the EP are tubal EP and 70% were ruptured with majority undergoing salpingectomy (Majhi, Roy, Karmakar, & Banerjee, 2007).There is increased use of laparoscopy in comparison with laparotomy & methotrexate injection is giving very good outcomes hence the trend of management of EP is changing day by day.

In a study done by Sherrin after review of 113 patients who had ectopic pregnancies, 94.6% underwent salpingectomy while another 3.5% had cornual excision done (Sherrin, 1966) while Sy T in 2009 found out that 80% of all cases had salpingectomy done (Sy et al., 2009) and in Madagascar 90.7% had salpingectomy (Randriambololona et al., 2012) while in India its at 90%, (Shetty et al., 2014) .

Multiple studies done have shown that over 90% of the EP are tubal and they are already ruptured at the time of surgical intervention. In a study done by Lawani et al 95.6% of the participants had ruptured cases while Musa et al & Thonneau et al found 96.9% (Musa et al., 2009) & 93% (Thonneau et al., 2002) respectively. Cornelius et al reported 99% ruptured cases (Cornelius et al., 2013) while Ruminjo et al had 78.8% (Ruminjo & Nuwagaba, 1990) & Shetty reported 48% (Shetty et al., 2014) both are lower percentages which could be because of difference in health seeking behaviour whereby the group with less ruptured cases probably sought medical attention early before rupture took place. Majority of the participants had haemoperitoneum consistent with the ruptured cases. Cornelius et al had 99% haemoperitoneum while Thonneau et al had 89.5%. In terms of whether it's the right side or the left is involved studies have shown variations.

2.4 Level of agreement between ultrasound and surgery in diagnosis of ectopic pregnancy.

There is little published data which shows level of agreement between ultrasound and surgery in the diagnosis of ectopic pregnancy. In a study done by Timmerman et al in subjective assessment of adnexal masses with the use of ultrasound, the level of agreement was almost perfect agreement (kappa value of 0.85) (Timmerman et al., 1999).

The difference with this study is that they looked at all adnexal masses in general with diagnosis made on ultrasound and later confirmed on histology, the limitation is that there are differences in interobserver agreement in studies highlighted. Most of the studies which are published looked at sensitivity and specificity of ultrasound in diagnosing ectopic pregnancy. Both sensitivity and specificity was found to be 100% in a study done by Shetty et al to determine the role of US in management of EP patients(Shetty et al., 2014).

Ultrasound has enabled early diagnosis to be possible with choice of modern treatment options like expectant treatment, laparoscopic surgeries or methotrexate injection being practiced and encouraged (Casikar et al., 2012; Rabemanantsoa et al., 2010)

2.5 Classification of Ectopic Pregnancy

Ectopic pregnancy is broadly classified into two groups- **tubal** and **non- tubal**. Each of the two is then subclassified into subgroups.

2.5.1 Tubal ectopic pregnancy

Tubal pregnancy occurs when implantation takes place within the fallopian tube. The commonest site is at the ampulla (80%), isthmus (12%), fimbrial end (5%) and interstitial (2%) (Brant, 2001).

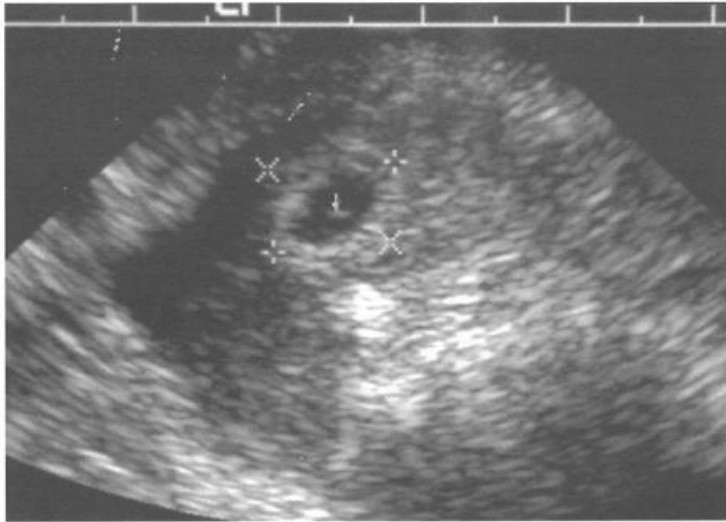


Figure 6.24 Ectopic Gestational Sac Containing Yolk Sac. An extrauterine sac (between cursors, +, x) shows a tubal ring sign with thick echogenic wall and contains a yolk sac (arrow). The presence of the yolk sac is diagnostic of extrauterine gestation.

Image 1: A Tubal pregnancy with a well demonstrated gestational sac

Adapted from: Ultrasound core curriculum by William E Brant 2001

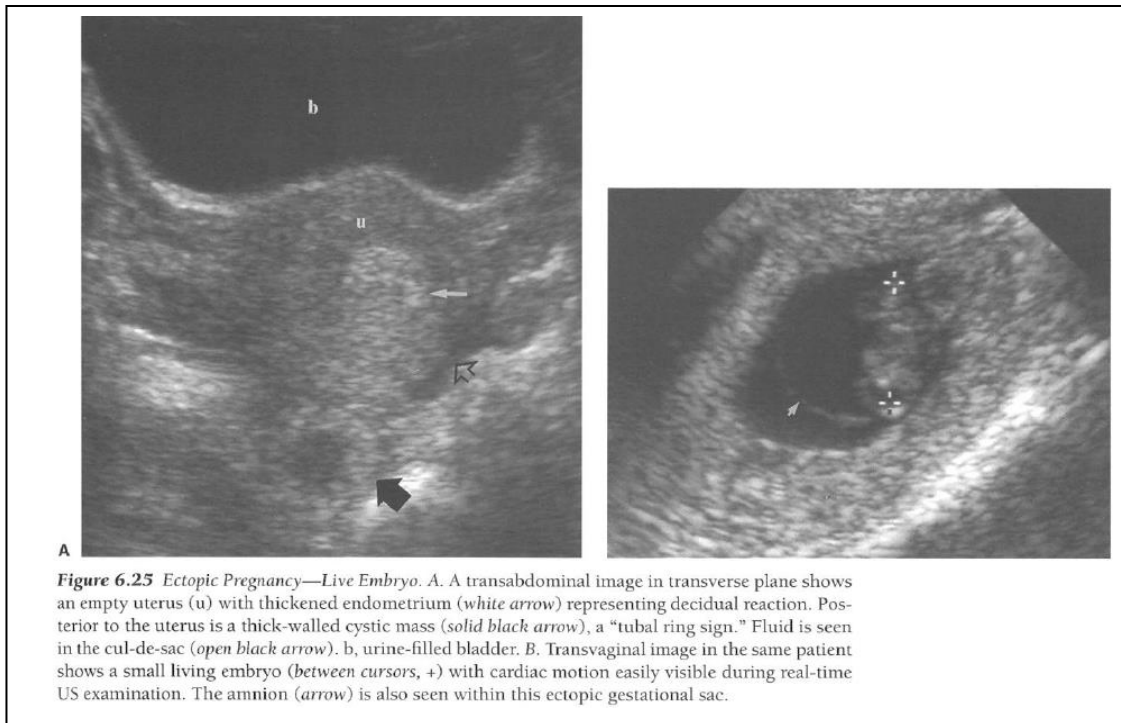


Figure 6.25 Ectopic Pregnancy—Live Embryo. A. A transabdominal image in transverse plane shows an empty uterus (u) with thickened endometrium (white arrow) representing decidual reaction. Posterior to the uterus is a thick-walled cystic mass (solid black arrow), a “tubal ring sign.” Fluid is seen in the cul-de-sac (open black arrow). b, urine-filled bladder. B. Transvaginal image in the same patient shows a small living embryo (between cursors, +) with cardiac motion easily visible during real-time US examination. The amnion (arrow) is also seen within this ectopic gestational sac.

Image 2: A Gestational sac with embryo and an empty uterus

Adapted from: Ultrasound Core Curriculum by William E Brant 2001

Tubal EP can be either **ruptured** or **non-ruptured** with the bulk being the former hence most patients will be having haemoperitoneum and can present with shock. Most patients will undergo salpingectomy(Shrestha & Saha, 2012) when they have ruptured type and when its unruptured they will undergo salpingiotomy but the problem is that it can lead to development of persistent EP due to continued trophoblastic growth arising from deeply embedded unremoved tissue and it leads to persistently high HCG (Elmowafi, march 2016).



Image 3: TAS: Right ruptured ectopic pregnancy in a 29 year old.

2.5.2 Non-tubal pregnancy

Ovarian ectopic pregnancy

Ectopic pregnancy implantation on the ovary is rare. Most ovarian masses discovered in a pregnant woman are corpus luteum cysts or preexisting ovarian lesions such as benign cystic teratoma or cystadenoma. A GS is implanted on the ovary.



Image 4: Ovarian ectopic pregnancy

Adapted from: BMJ best practice.

Cervical ectopic pregnancy

Patients usually present with painless vaginal bleeding at 6- 12 weeks of pregnancy. Implantation in the less vascular cervical tissue provides insufficient blood supply for the pregnancy to progress. The GS is implanted abnormally low within or near the cervical canal. Differentiation from an aborting GS in the cervix may be difficult and live embryo

within a normal-appearing GS is found with a cervical ectopic pregnancy. An aborting sac appears misshapen and contains an embryo without a heartbeat. A large Nabothian cyst may simulate a cervical ectopic pregnancy(Brant, 2001)



Image 5: Cervical ectopic pregnancy

Adapted from: ("Ectopic Pregnancy in the Cervix: A Case Report," 2011; Mohebbi, Rosenkrans, Luebbert, Hunt, & Jung, 2011)

Abdominal Pregnancy

Abdominal pregnancies are associated with fetal mortality as high as 90% and maternal mortality of 6-14%. Despite its importance this diagnosis is commonly missed. The pregnancy may implant anywhere in the abdominal cavity but is most common in the pouch of Douglas, the posterior uterine wall, and the anterior abdominal wall(Elmowafi, march 2016)

US features include:

- No myometrium is present around the fetus or the GS. However, this seemingly obvious finding may be difficult to recognize because trophoblastic tissue and the mothers abdominal wall may simulate the myometrium.
- An empty uterus is identified. The uterus may be squashed deep in the pelvis and is difficult to identify, particularly if the pregnancy is large. The endometrium is thickened due to decidual reaction.
- The location of the fetus is unusual.
- The presentation of the fetus is unusual. Persistent transverse lie is common.
- The lower uterine segment and cervix are not clearly identified.
- Magnetic resonance imaging may be definitive when the US diagnosis is uncertain.(Elmowafi, march 2016)

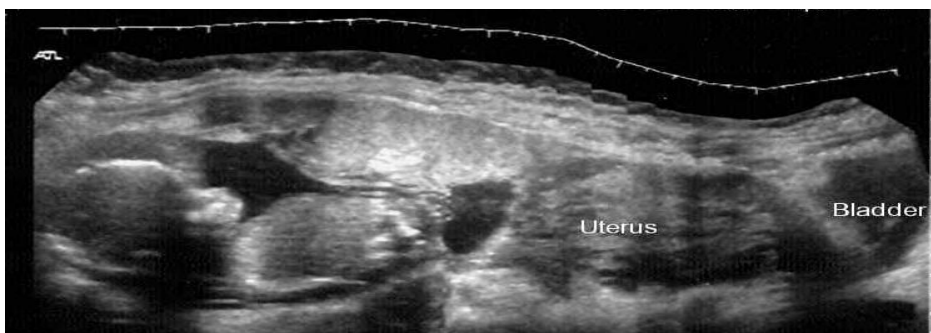


Image 6: Abdominal Pregnancy

Adapted from:(Amanda Cotter, Luis Isquierdo, & Fernando Heredia, 2002)

Heterotopic pregnancy

The simultaneous presence of intrauterine and ectopic pregnancy has become increasingly common with the use of in vitro fertilization as treatment for infertility. In some reports, heterotopic pregnancy is as common as 1-in-100 pregnancies in this population. This fact stresses the need for detailed examination of the adnexa, even when an intrauterine pregnancy(IUP) is documented.

US features include:

- An IUP is present.
- Signs of one or more ectopic pregnancies are also present(Brant, 2001)

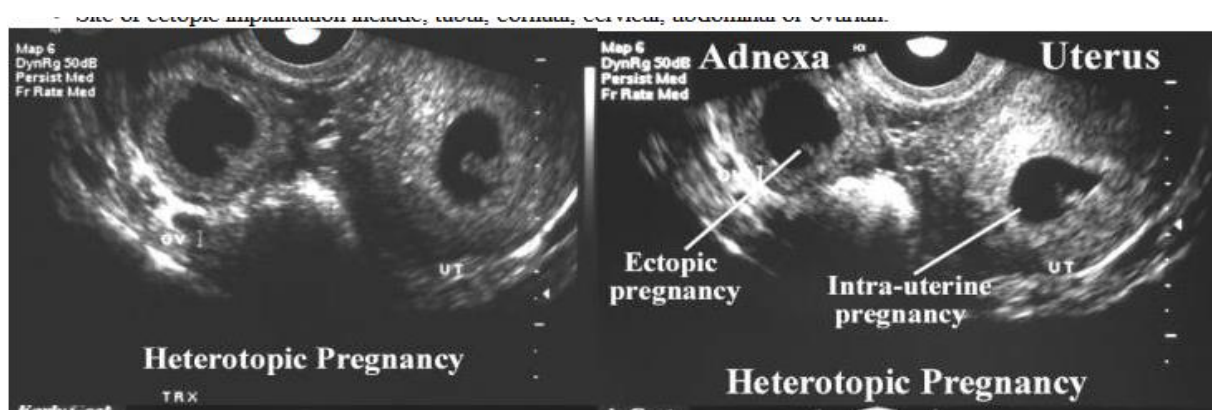


Image 7: Heterotopic pregnancy

Adapted from: Ultrasound core curriculum by William E Brant 2001

Differential diagnosis of ectopic pregnancy(Lozeau & Potter, 2005)

- Abortion
- Ovarian torsion
- Acute appendicitis
- Ruptured ovarian cyst
- Renal stone
- Pelvic inflammatory disease.

ULTRASOUND (US)

Is an imaging technology that uses high-frequency (20Kilohertz-20Megahertz) sound waves to characterize a tissue. It is a useful and flexible modality in medical imaging, and often provides additional or unique characterization of tissues, compared with other modalities such as conventional radiography or CT.

Ultrasound relies on properties of acoustic physics (compression/rarefaction, reflection, impedance, etc) to localize and characterize different tissue types. The frequency of the sound waves used in medical imaging is in the range of millions of cycles per second (megahertz, MHz). In contrast, the upper range of audible frequencies for human is around 20 thousand cycles per second (20 kHz)(Brant, 2001)

Advantages

1. Ultrasound is a non-ionizing imaging modality not been associated with carcinogenesis. This is particularly important for evaluation of fetal and gonadal tissue.
2. In most centers, ultrasound is more readily available than more advanced cross-sectional modalities such as CT or MRI.
3. Ultrasound examination is less expensive to conduct than CT or MRI.
4. There are few (if any) contraindications to use of ultrasound, compared with MRI or contrast-enhanced CT.
5. The real-time nature of ultrasound imaging is useful for the evaluation of fetal heart rate.

Disadvantages

1. Findings are operator dependent.
2. Ultrasound is not capable of evaluating tissue types with high acoustical impedance e.g. bone, air. It is also limited in evaluating structures encased in bone (e.g. cerebral parenchyma inside the calvaria).
3. The high frequencies of ultrasound result in a potential risk of thermal heat or mechanical injury to tissue at a micro level. This is of most concern in fetal imaging.
4. Ultrasound has its own set of unique artifacts (US artifacts), which can potentially degrade image quality or lead to misinterpretation.
5. Some ultrasound exams may be limited by abnormally large body habitus.

The two types of ultrasound methods which can be used to investigate ectopic pregnancy are:

- Transvaginal ultrasound (TVS)
- Transabdominal ultrasound (TAS)

PROCEDURE OF TRANSABDOMINAL ULTRASOUND (TAS)

Patient preparation

- Inform the patient about the procedure
- Seek consent
- Bladder should be full
- Maintain confidentiality and privacy

Requirements

- Ultrasound machine
- coupling gel
- 3.5- 5 MHZ probe

Positioning

- Patient wears hospital gown
- Patient in supine position
- Expose from the waist upwards

Imaging procedure

Through nonseptic technique the ultrasound probe which is lubricated with coupling gel is placed at the suprapubic area and both long and short axial planes images are acquired with any abnormalities noted and images produced sequentially{MTRH, 2010 #121}

Ultrasound features of ectopic pregnancy

- Extauterine gestational sac with yolk sac or fetal pole is definitive
- Complex adnexal mass
- Free fluid in the cul de sac
- Empty uterus in a patient with positive qualitative beta HCG (urine)
- Free peritoneal fluid which could suggest hamoperitoneum

CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

3.1 Study Design

This was a cross - sectional study involving use of quantitative techniques. Data was collected by performing and reviewing ultrasound findings and reviewing surgical notes for findings in patients with ectopic pregnancy seen in MTRH over a specified period of time of the study.

3.2 Study Site

The study was conducted at the Radiology and Imaging department, and Reproductive health department, Moi Teaching and Referral Hospital.

The Hospital is located in Eldoret town, which is 311 kilometers northwest of the capital Nairobi. MTRH is a referral health facility serving as a teaching hospital for Moi University School of Medicine, School of Nursing, School of Public health and School of Dentistry. Others include Kenya Medical Training College (KMTC) Eldoret campus and University of Eastern Africa Baraton School of Nursing. MTRH is also a training center for medical, clinical and nursing officer interns. It is the referral hospital for the Western part of Kenya and North rift and has a catchment population of approximately 13 million people. The facility has several departments including Surgery, Pediatrics and Radiology and Imaging among others.

3.3 Study Population

The study population were women admitted at Moi Teaching and Referral Hospital with suspected ectopic pregnancy.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

1. Women presenting with signs and symptoms of ectopic pregnancy e.g amenorrhea, abdominal pain and vaginal bleeding.
2. Positive qualitative (urine) beta HCG.
3. Diagnosis of ectopic pregnancy based on transabdominal ultrasound.
4. Signed written consent from the participant, guardian/parent for under 18 years.

3.4.2 Exclusion Criteria

1. Those who underwent surgery without pelvic ultrasound being done because of the unstable state which may warrant urgent surgery based on clinical findings of ectopic pregnancy.
2. Those who had medical treatment instead surgical treatment

3.5 Sampling Techniques

3.5.1 Sampling Method

Consecutive sampling was used in this study whereby every woman clinically diagnosed with ectopic pregnancy was approached and consent sought. This was done until the desired sample size was reached. This was based on the small number of patients with EP seen in the hospital in the previous year.

3.5.2 Sample Size

In order to be 95% sure that the proportion of participants with ectopic pregnancies occurring in the ampulla is within plus or minus 5% of the population value of 55%, a sample size was calculated using the following formula (Cochran, 1963). The other regions

where the ectopic pregnancy could occur are isthmus (25%), fimbriae (17%), and the abdominal cavity, ovary, and cervix (3%) (Lozeau and Potter).

$$\begin{aligned} n &= \left(\frac{Z_{1-\alpha/2}}{\delta} \right)^2 P(1-P) \\ &= \frac{1.96^2}{0.05^2} 0.55(1-0.45) \\ &= 381 \end{aligned}$$

Where P is the population proportion of participants with ectopic pregnancy that occurred in the ampulla, $\delta = 5\%$ is the margin of error. $Z_{1-\alpha/2}$ is the standard normal deviate corresponding to $(1-\alpha) \times 100\%$ of the standard normal distribution.

This sample size was corrected for finite population size. Thus we ended up with

$$\left(\frac{381}{1 + \frac{381}{101}} \right) = 80 \text{ as the required number of study participants. The population size was}$$

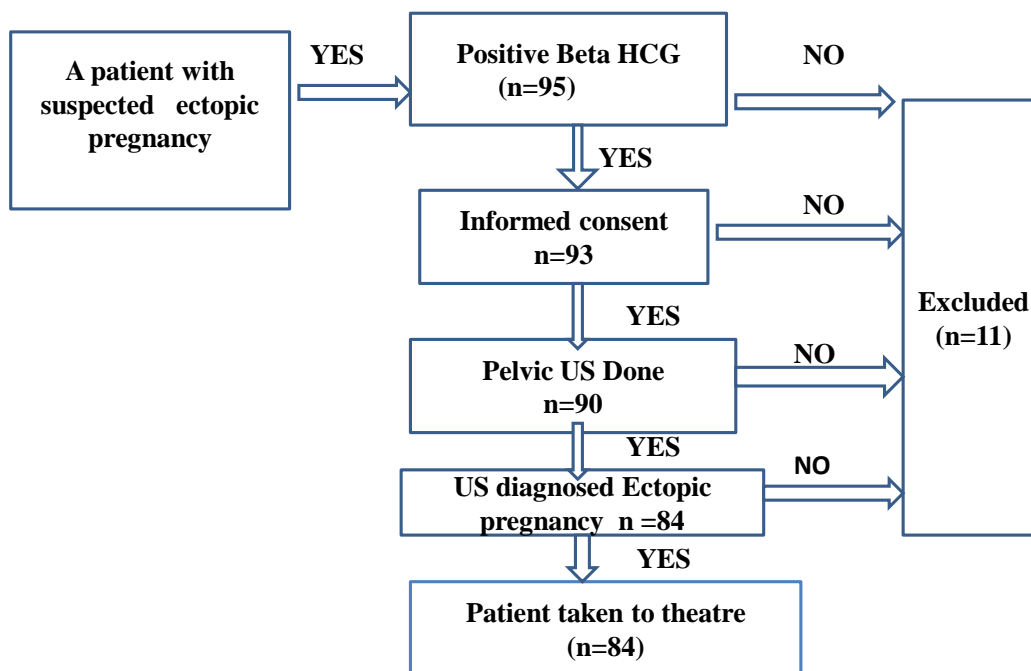
obtained from the records in Moi Teaching and Referral Hospital (MTRH) for the participants seen during the year 2013.

3.6 Study Procedure

Women presenting with suspected ectopic pregnancy based on clinical signs and symptoms, a positive qualitative beta HCG test and referred for transabdominal ultrasound were recruited after consenting. Transabdominal ultrasound (TAS) was done using either Aloka prosound Alpha 7 or Philips HD 11xe machines with images reviewed by at least

two consultant radiologists. The TAS procedure was done as per the protocol outlined in the department (consent was sought, supine position, pelvic area exposed, urinary bladder full, transverse and longitudinal images acquired using curvilinear 3.5-5 MHZ). Those participants who had negative ultrasound findings were returned to the clinician for alternative treatment while those who had ultrasound diagnosis of ectopic pregnancy were referred to the gynaecologist for review and appropriate initiation of treatment. All participants who underwent surgical treatment were noted and surgical findings were obtained through reviewing the theatre notes and recording of the results done in a structured questionnaire. Any participants who had alternative treatment or did not undergo surgery as a treatment were excluded. All data collected were recorded in a structured questionnaire which were kept confidential and locked in a safe place to ensure that access is only to authorized persons.

Recruitment schema



3.7 Data Collection and Management

3.7.1 Data Collection

Data was collected between October 2014 and August 2015. Participant demographics, clinical presentation, ultrasound and surgical findings among others was collected. Entry was made in the questionnaires and later transferred to a computer database. Double entry was used to ensure accuracy of the data. All participant details were kept confidential and data was available to the investigator and the supervisors via password protection. Participants had a copy of their results and had autonomy over who else had the results disclosed to. Serial numbers were used in order to protect participant's identity. At the end of each day data collection forms were verified for completeness and coded (assigning numerical meanings).

3.7.2 Quality Control

The ultrasounds were done in MTRH ultrasound unit as per protocol for performing TAS. The images were reviewed by at least two consultant radiologists with results appropriately recorded after agreement on the diagnosis was reached. The findings of the surgical procedures were obtained from the gynaecology ward after review of the theatre notes. The results were documented accordingly and comparison between the two was done and recorded appropriately.

3.7.3 Data Analysis and presentation

Data analysis was done using software for data analysis known as R (R core Team, 2015). Descriptive statistics such as frequencies, means and standard deviations, and median and interquartile range were used to summarize the data. Continuous variables were assessed for Gaussian assumptions and those that had the assumptions holding were summarized using mean and the corresponding standard deviation while those that violated the assumptions were summarized using median and the corresponding inter quartile range (IQR). Results were presented in tables and graphs.

3.8 Ethical Considerations

Approval to carry out the study was sought from the Institutional Research and Ethics Committee (IREC) and the Director of Moi Teaching and Referral Hospital. All patients were informed about the study and how the investigator will go about performing the TAS and the surgical intervention/ medical treatment needed. They were informed about the procedures involved in the study and the benefits of doing them. They were informed that the procedure is generally safe with no potential risks. Regarding the necessity of the investigation for management of the patient, consent was sought from the hospital

management and IREC to allow studying of the images of the patients who have undergone ultrasound. All patients received medical attention as necessary regardless of their willingness or unwillingness to participate in the study. No incentives or inducements were used to convince patients to participate in the study. Patients were informed of their results and appropriate standard treatment given. Confidentiality was maintained throughout the study. The data collection forms used did not contain the names of the patients nor their personal identification numbers. Data collecting material was kept in a locked cabinet in the office of the principal investigator during the study period.

The results of the study were presented to the Hospital's management and the university's department of Radiology and Imaging for use as necessary. It will also be available for academic reference in the College of Health Sciences Resource Centre. The results of this research shall be availed for publication in a reputable journal of medicine for use by the wider population in the general improvement of patient management and as a reference for future studies.

CHAPTER FOUR: RESULTS

4.1 Age Distribution

A total of 84 participants were included in the study. The mean age \pm SD was 22.8 ± 5.8 years with the youngest participant at 16 years while the eldest is 44 years. The peak age is 20-25 years followed by 25-30 years.

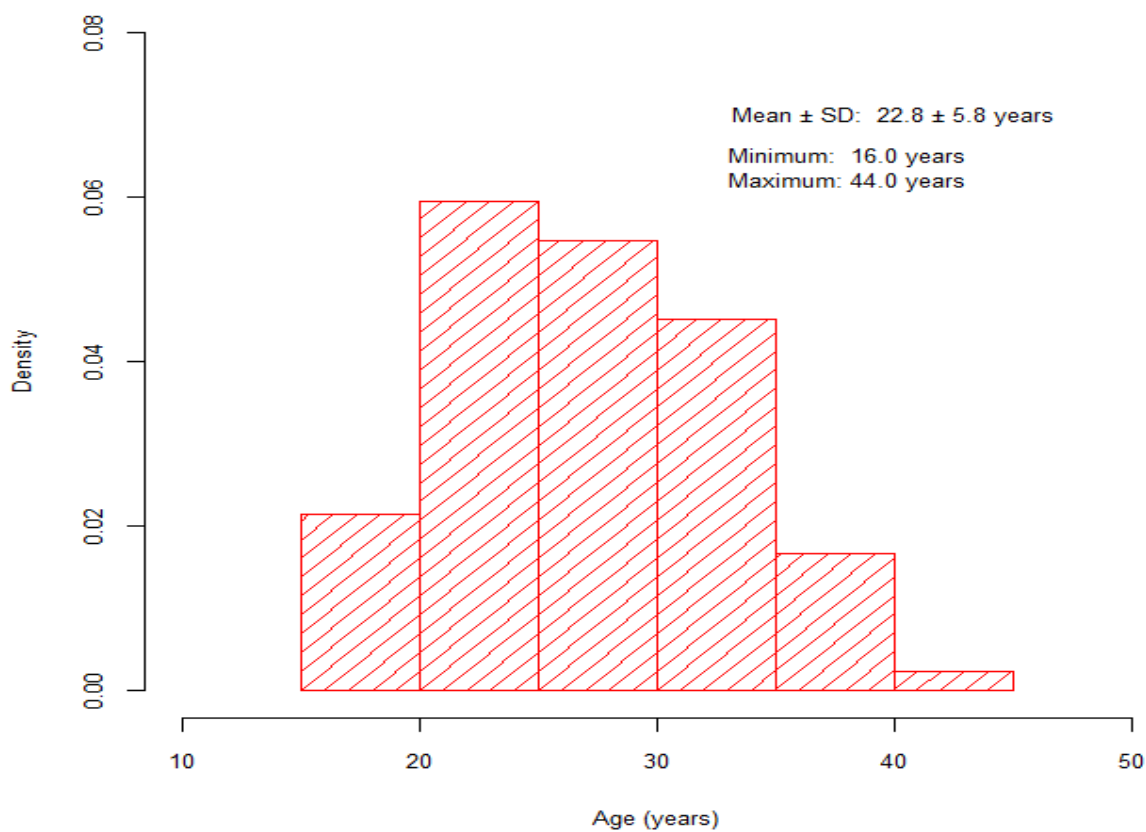


Figure 1: Age distribution

4.2 Distribution as Per Parity

Nulliparous participants were 42.9 % (n=36) while parity of 1-2 were 34.5 % (n=29) and parity of 3-6 22.6 % (n=19). Maximum parity observed was 6.

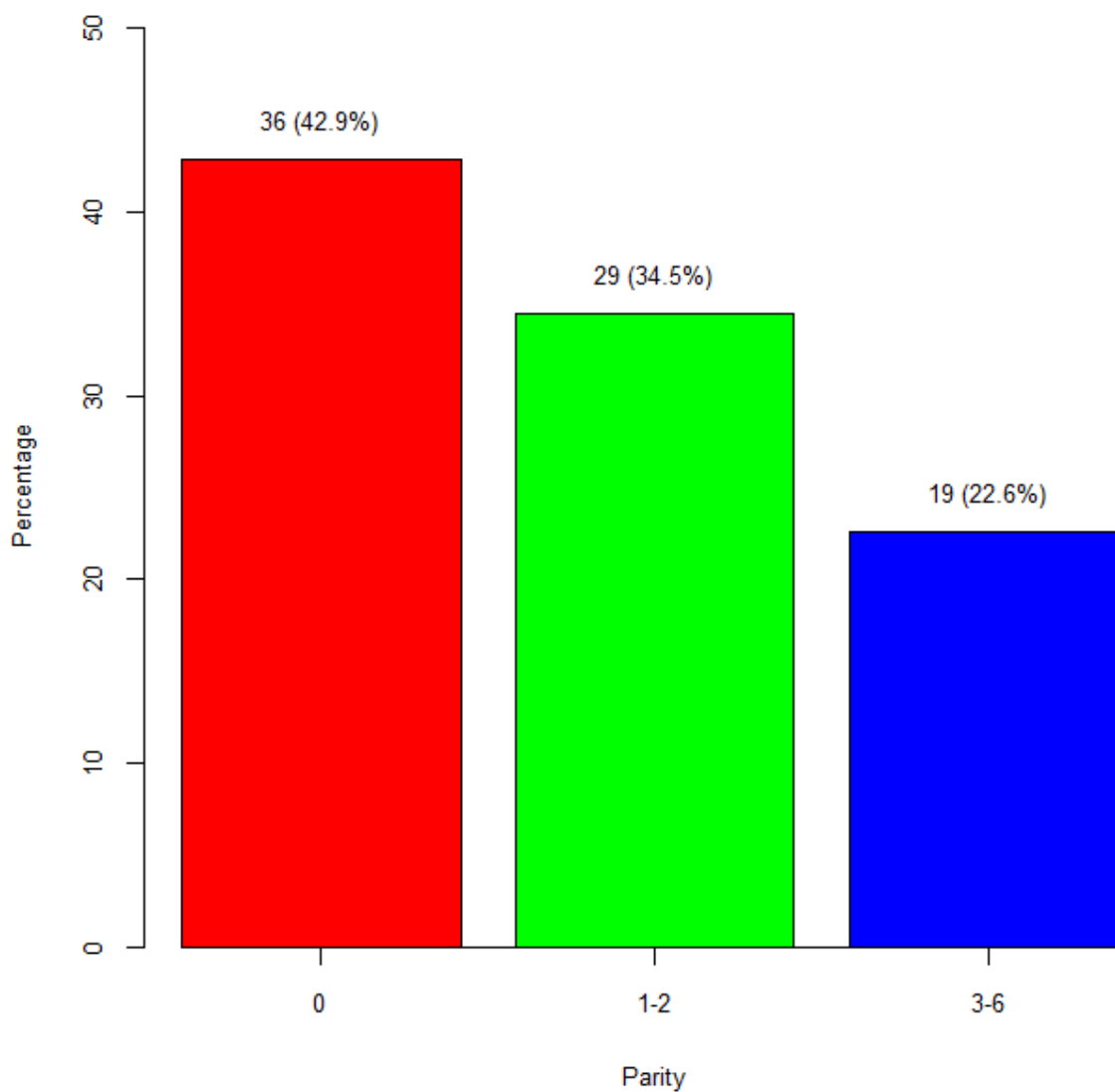


Figure 2: Parity distribution

4.3 Duration of Amenorrhea

A total of 72.6%(n=61) participants had amenorrhea with the median period of 7 weeks(IQR 6.0,8.0) minimum duration was 4 weeks and maximum of 24 weeks

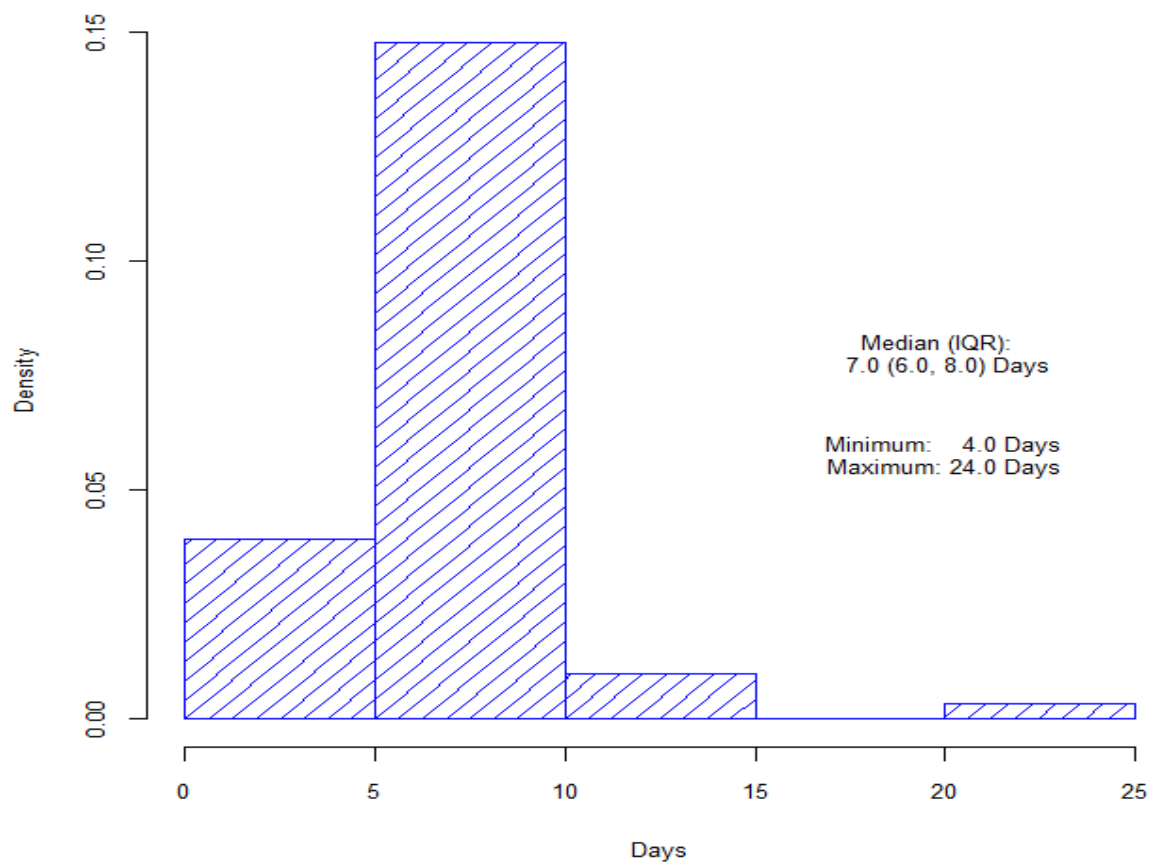


Figure 3: Duration of amenorrhea

Table 1: Clinical Presentations

Presentations	n (%)
Abdominal pain	83 (98.8%)
Missed menses	60 (71.4%)
Vaginal bleeding	57 (67.9%)
Others	11 (13.1%)

Almost all the participants presented with abdominal pain with n= 60 (71.4%) having missed their menses. Two thirds, n=57 (67.9%), presented with vaginal bleeding. while n=11(13.1%) of the participants presented with other symptoms. The symptoms were not isolated, they presented in combination with each other. There were n=38 (45.2%) who presented with a combination of abdominal pain, missed menses, and vaginal bleeding, n=15 (17.9%) who presented with a combination of abdominal pain as well as missed menses, and another n=15 (17.9%) who presented with a combination of abdominal pain and vaginal bleeding. Missed menses together with vaginal bleeding was reported by one participant. The joint occurrence of the symptoms was as seen below.

Table 2: Ultrasound findings

Ultrasound findings	n (%)
Complex adnexal mass	58 (69.9%)
Extrauterine sac with yolk	6 (7.2%)
Extrauterine sac with embryo	17 (20.5%)
Free fluid in the cul De sac	60 (72.3%)
Presence of free peritoneal fluid	73 (88.0%)

There were 69.9 % (n=58) participants who were diagnosed with complex adnexal mass, 7.2 % (n=6) with gestational sac with yolk and 20.5 % (n=17) who were diagnosed with gestational sac with embryo. Over 80% had leaking ectopic gestation with 72.3 % (n=60) having free fluid in the cul de sac and free peritoneal fluid was observed in 88.0 % (n=73) of the participants.



Image 8: TAS: GS with yolk sac and “tubal ring” sign on the left adnexa in a 23 year old.

Note the empty uterine cavity



Image 9: TAS: Right adnexa complex mass with free POD fluid and empty uterus in a 29 year old.



Image 10: TAS: Right tube ruptured ectopic showing haemoperitoneum in the Morrison's pouch and pelvic area in a 29 year.



Image 11: TAS: Left adnexal ectopic at 9 weeks gestation. Patient had an IUCD in situ in a 37 year old.



Image 12: TAS: IUCD in situ in a 37 year old. There is a left adnexa ectopic pregnancy as shown in image 11.



Image 13: TAS: A Left complex adnexal mass with free peritoneal fluid in a 31 year old.



Image 14: TAS: showing free fluid in the Morrison's pouch and other areas.



Image 15: TAS: GS on the right adnexa. Doppler showed a “ring of fire” around it in a 24 year old.



Image 16: TAS: Pouch of Douglas GS with yolk sac in a 32 year old.



Image 17: TAS: A Right abdominal pregnancy at 25 weeks. Laparotomy done found bicornuate uterus with a pregnancy on the right horn while the left horn was empty and rudimentary.



Image 18: TAS: Empty uterus on the left and a pregnancy on the right side in the same case as image 17.

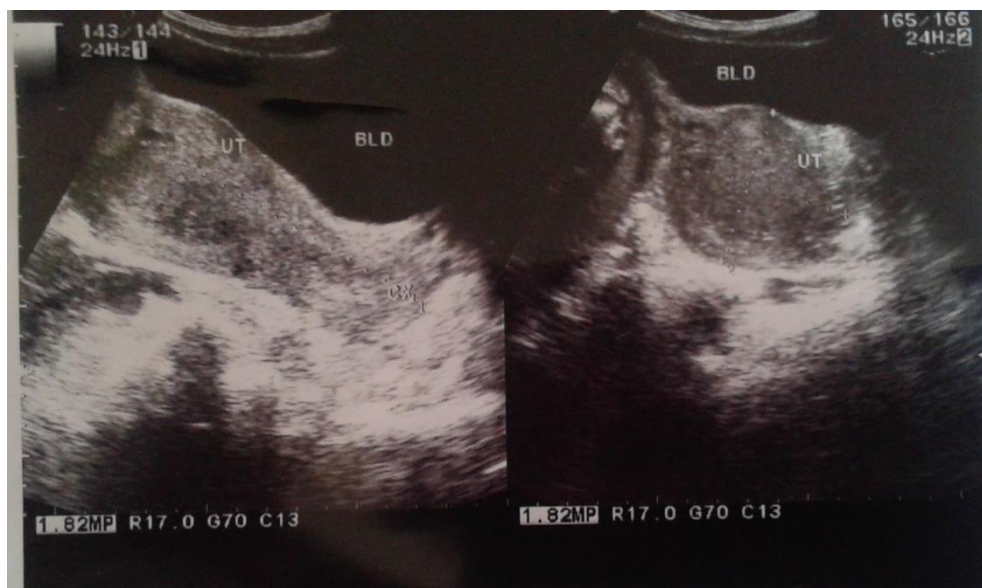


Image 19: TAS: Images showing empty uterus both on longitudinal and axial plane in the same case as image 17.

4.4 Gestational age determination by ultrasound

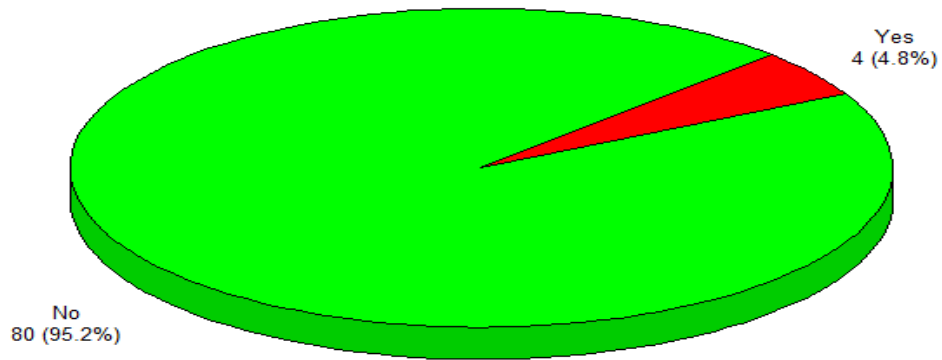


Figure 4: Gestational age determination

Less than 5% of the participants had gestational age of the ectopic pregnancy determined by ultrasound.

4.5 Location of ectopic pregnancy as per ultrasound

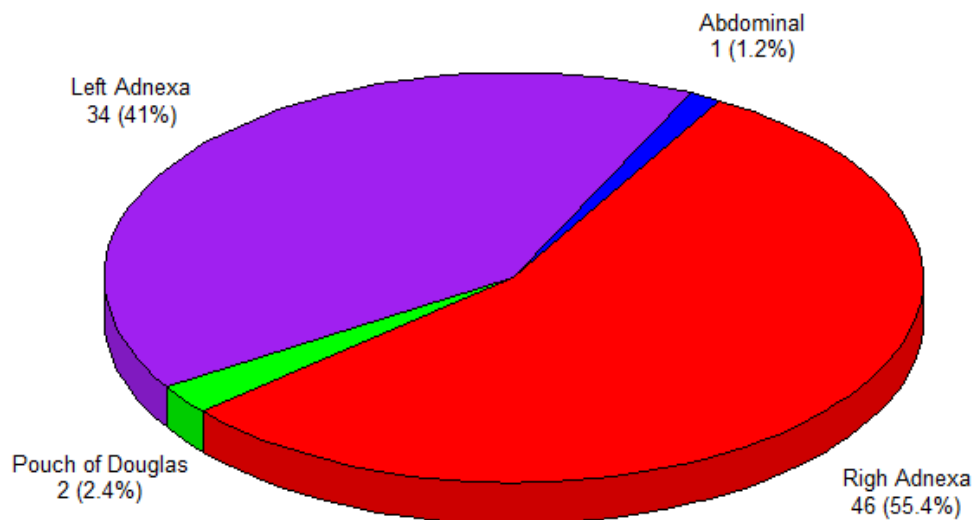


Figure 5: Ultrasound locations

More than half of the participants had EP right adnexa 55.4 % (n=46), and 41% (n=34) had left adnexa. Two participants had pouch of Douglas EP and one abdominal.

4.6 Surgical findings

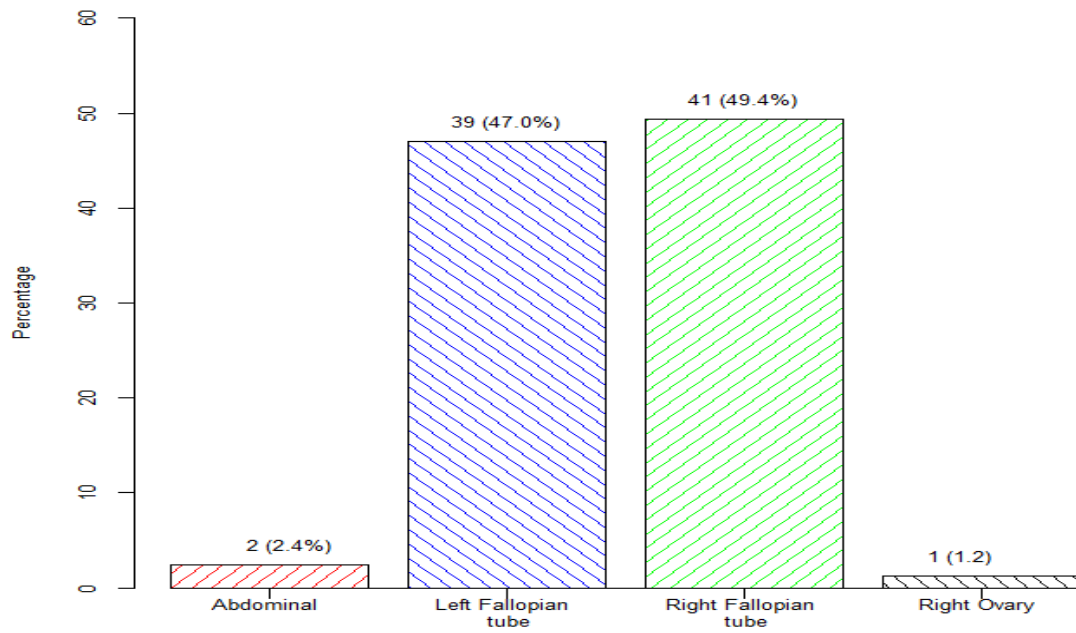


Figure 6: Surgical Findings

Main surgical findings were the right 49.4% (n=41) and the left 47.0% (n=39) fallopian tubes. 2.4% (n=2) had abdominal pregnancy, 97.6% (n=82) had ruptured ectopic pregnancy.

4.7 Other surgical findings include:

	n	%
Adhesions &absent left tube	1	3.4
Adnexal inflammatory features with live embryo	1	3.4
Calcified lesion on the left round ligament	1	3.4
Ectopic left kidney	1	3.4
GS visualized intraoperative	1	3.4
Hydrosalpinx left tube	1	3.4
Hydrosalpinx of left tube & adhesions	1	3.4
Left hydrosalpinx & adhesions	1	3.4
Left ovarian cyst 5 cm	3	10.3
Left ovarian cyst & adhesions	1	3.4
Left ovarian cyst/absent left tube	1	3.4
Bicornuate uterus with normal pregnancy on the right horn and the left horn is empty	1	3.4
R ovarian cyst/ left tube not visualized	1	3.4
Right hydrosalpinx noted	1	3.4
Right megasalpinx	1	3.4
Right ovarian cyst/ subserosal fibroids/absent left tube	1	3.4
Total	29	99%

4.8 Distribution of haemoperitoneum

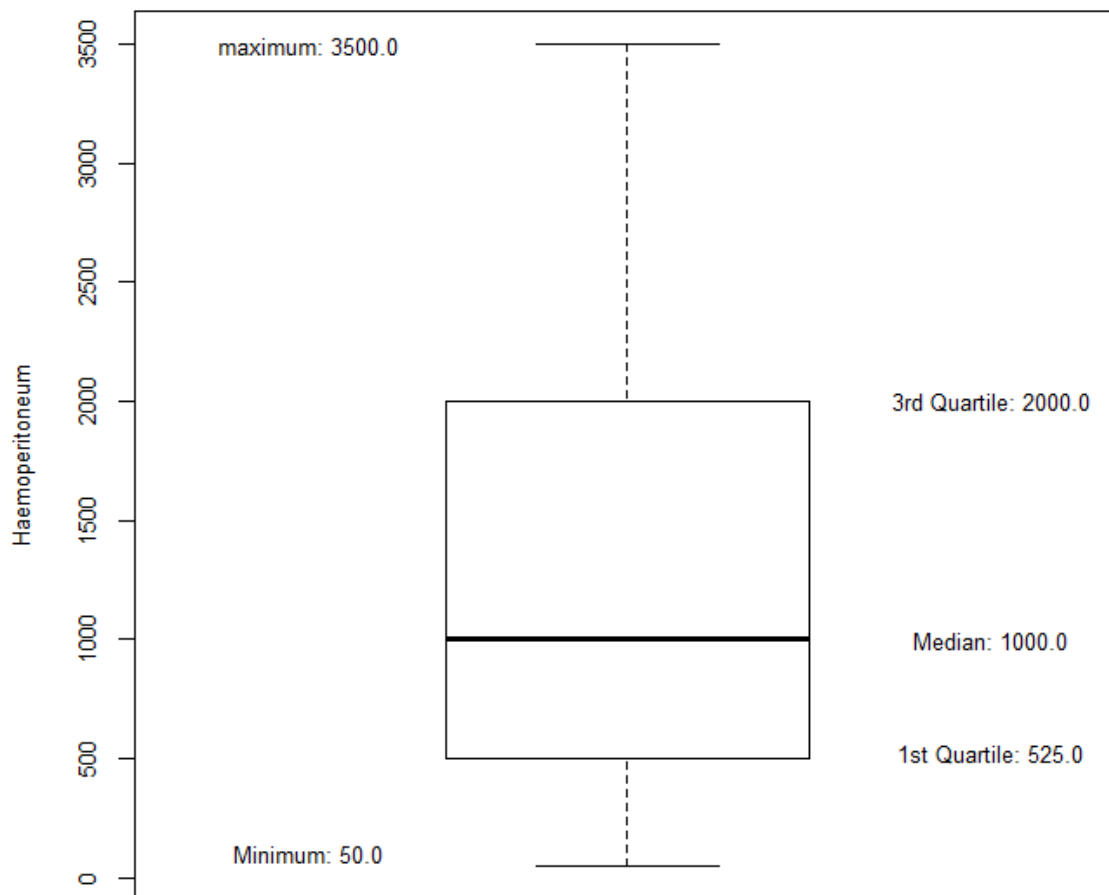


Figure 7 : Distribution of haemoperitoneum

The median (IQR) haemoperitoneum was 1000.0 (IQR: 525.0, 2000.0) with a minimum and a maximum of 50.0 and 3500.0 respectively.

Table 3: Test for agreement between surgical and ultrasonography findings

		Surgical Findings				Total
		Abdominal	RFT	LFT	RO	
Ultrasonography Findings	Right Adnexa	0	38	7	1	46
	Left Adnexa	2	3	29	0	34
	Pouch of Douglas	0	0	2	0	2
	Total	2	41	38	1	82

Observed level of agreement = 81.7%

Expected level of agreement = 47.3%

Kappa = 0.653, Z = 6.51, P - Value < 0.0001

RFT – Right Fallopian Tube; LFT – Left Fallopian Tube; RO – Right Ovary

The observed level of agreement was 81.7% while the expected level of agreement was 47.3%. This gives a Kappa value of 0.653 with Z statistic of 6.51, and P – Value <0.0001. That is, the Kappa value is significantly different from zero. This value shows that the level of agreement was substantial according to Viera et al, 2005 who classify it between 0.61 – 0.80.

Table 4: Test for agreement between surgical and ultrasonography findings

		Surgical Findings		
		Right Fallopian Tube	Left Fallopian Tube	Total
Ultrasonography Findings	Right Adnexa	38	7	45
	Left Adnexa	3	29	32
	Total	41	36	77
	Observed level of agreement = 87.0%			
Expected level of agreement = 50.6%				
Kappa = 0.737, Z = 6.51, P - Value < 0.0001				

Similar findings were obtained when we restricted our assessment of agreement to correctly classifying right fallopian tube and left fallopian tube findings.

CHAPTER FIVE: DISCUSSION

5.1 Age Distribution

The mean age of the study participants was 22.8 with SD of 5.8 years. The youngest was 16 years while the eldest was 44 years. This is important because EP is more common in the older age group in comparison with younger age group. This is attributed to cumulative effect of multiple risk factors with older age(35-45 years) and therefore higher chances of ectopic implantation (Taran et al., 2015). Several studies have shown increased risk with older maternal age and low parity(Ehsan & Mehmood, 1998). However in this study majority of the participants were in the age group 20-25 years followed closely by 26-30 years. In a study done by Lawani et al the mean age was 27 years(Lawani et al., 2013) while Shetty et al found majority to be in age bracket of 26-30 yrs(Shetty et al., 2014) same as Ehsan et al(Ehsan & Mehmood, 1998) and Majhi et al(Majhi et al., 2007).Musa et al used a larger age bracket and found out that majority of the participants(53.8%) were in the age group 20-29 years (Musa et al., 2009) same as what was reported by Sepou et al(Sepou et al., 2003) in Central African Republic while in Kenya Ruminjo et al found out that 56% (Ruminjo & Nuwagaba, 1990)were in the age group23-27 years which is comparable to the findings of this study.

5.2 Parity

The bulk of the participants were nulliparous (43%) followed by those between Para 1-2 (34.5%) and 3-6(22.6%). In a study done by Musa et al majority of the participants were nulliparous followed closely by primiravidas (Musa et al., 2009) and Cornelius et al found out that majority are nulliparous (Cornelius, Onyegbule, Uchenna, & Duke, 2013) while Majhi found out that majority of the sufferers of EP in his study to be primigravidas (Majhi et al., 2007). As per Ehsan findings, majority of the participants are of low parity and older age group (Ehsan & Mehmood, 1998) which is supported by Ruminjo study that found that 88% of the participants were para 0-2 (Ruminjo & Nuwagaba, 1990).All this are comparable to what was found on this study while on the other hand some studies have found that women of higher parity were the majority affected category. In contrast studies done by Shetty et al and parashi both found out that the most affected group were at least para 2 (Parashi, Moukhah, & Ashrafi, 2014) & (Shetty et al., 2014) same as what was reported by Tsai where majority were multiparous (Tsai et al., 1995).

5.3 Duration of Amenorrhea

A total of 72.6% of the participants had amenorrhea and the median duration was 7 weeks. The minimum was 4 weeks while the maximum was 24 weeks.

Majority had clinical features by 7 weeks post last menstrual period because by this time most of the tubal pregnancies will have ruptured due to the fact that the small lumen cannot accommodate the rapidly increasing pregnancy and therefore they present with abdominal pains, vaginal bleeding among other features depending on whether there are complications or not.

The early presentation of 4 weeks can be explained by isthmal location of the EP which is known to have a narrow lumen in comparison with the others parts hence early rupture and therefore present early clinically(Aghera). In this study majority of them were reported after surgery to be located in the isthmus.

The 24 weeks period of amenorrhea had been diagnosed as a case of viable right abdominal EP with gestational age of 25 weeks as per ultrasound. A corroborative obstetric MRI was recommended but the patient declined for it to be done. Laparotomy was done and it showed a bicornuate uterus with pregnancy on the right horn and the left horn was empty and rudimentary. The abdomen was closed and the pregnancy was allowed to continue .The participant was later taken for emergency caesarean section after developing lower abdominal pains at 34 weeks gestation where a normal baby was delivered.

In a study done by Ehsan et al (Ehsan & Mehmood, 1998) 80.6% of the participants had amenorrhea while Majhi et al found 76%(Majhi et al., 2007).This is comparable to the findings of this study. In terms of the duration of the amenorrhea, Taran et al found out that majority of the participants in his study had missed menses for 6-9 weeks (Taran et al., 2015).This is comparable to the findings of this study of 7 weeks. Usually tubal pregnancy do not progress beyond 8-10 weeks before rupture because of lack of decidual reaction in the tube, the thin wall of the tube, the inadequacy of tubal lumen & bleeding in the site of implantation as trophoblast invades the tissues(Aghera).

5.4 Clinical Presentations

A total of 98 % of the participants complained of abdominal pain while 71% had vaginal bleeding and two thirds missed menses. This confirms that the most common reason why the sick seek medical attention is because of pain. Pain occurs as a result of distention of the fallopian tube or rupture with damage of the tube or pooling of blood in the abdomen which cause pressure on the diaphragm rectum and nerves, producing symptoms such as shoulder pain and sharp abdominal pain .About 97.5% had tenderness on abdominal palpation. This is explained by the fact that there is peritoneal irritation by haemoperitoneum and ruptured area response on palpation hence tenderness is elicited (Elmowafi, march 2016)

In a study by Weekes et al 100% of the participants had abdominal pain while 90% of them had amenorrhea (Weekes, 1981) meanwhile Hamura found out that the most common complaint was abdominal pain(Hamura et al., 2013) while Sy et al reported 92% and 62% had abdominal pain and vaginal bleeding respectively(Sy et al., 2009) and Ehsan reported that 100% of the participants had abdominal pain(Ehsan & Mehmood, 1998). All of these findings are comparable with the findings of this study. In contrast Shaikh had 77% (Shaikh, Shaikh, & Shaikh, 2014) of the participants complaining of abdominal pain which is a lower percentage in comparison with this study and other studies. This could be explained by differences in health seeking behavior of the participants.

5.5 Ultrasonography Findings

A total of 70% of the participants had complex adnexal mass while GS with embryo and GS with yolk sac contributed to 20% and 7% respectively. About 88% of the participants had free peritoneal fluid while 72% had fluid in the POD.

Complex cystic or solid adnexal mass without distinguishing features is a finding which is consistent with tubal rupture and clotted blood(Brant, 2001). Rupture is more common if implantation occurs in the narrower portion of the tube which is the isthmus or may occur in the anti-mesenteric border of the tube which usually leads to profuse bleeding into the peritoneum. If rupture occurs in the mesenteric border of the tube a broad ligament haematoma will occur(Elmowafi, march 2016) .It's very difficult for US to characterize the exact location of EP within the tube unless its located in the interstitial part which normally has sonographic features which includes: an empty uterine cavity, products of conception located outside of the endometrial cavity and surrounded by a continuous rim of myometrium .An 'interstitial line' is often seen consisting of a thin echogenic line that extends from the central uterine cavity to the periphery of the interstitial sac and presumably represents the endometrial canal of the interstitial part of the Fallopian tube (Kirk & Bourne, 2009).In a study done by Adhikari et al 61% of the cases had complex adnexal mass while 13% of the cases had live ectopic(Adhikari et al., 2007).This is comparable to the findings of this study although slightly on the lower side in terms of the number of cases of complex adnexal. The number of live ectopics in this study were less in comparison with other studies which could be explained by the fact that majority were ruptured hence tubal abortion took place with loss of viability in most of them. Shetty et al reported that 60% of the cases showed a complex adnexal mass with majority of them

located on the right adnexa(Shetty et al., 2014),this is comparable to the findings of this study while Condous et al reported 78% of them had complex adnexal masses with 13.2% demonstrating embryo with or without a cardiac activity(Condous et al., 2005). Casikar et al reported that 80% of the cases had adnexal masses which ranged from inhomogenous mass to ones that appear as hyperechoic ring and 13% of the cases were having obvious gestational sac(Casikar et al., 2012). The number of adnexal masses found by Casikar & Condous are more in comparison with this study which can be attributed by the fact that most of the participants in their studies had ruptured ectopics. This is supported by the fact that they had less cases of visualized gestational sac (13%) in comparison with this study which found 27% had visualized gestational sac with or without cardiac activity.

Visualization of a gestational sac with yolk sac or fetal pole implies an intact fallopian tube with a pregnancy that is likely to be growing while visualization of an inhomogeneous mass might well be a collapsed sac, which is less likely to contain active trophoblastic tissue. More recently it has been suggested that visualization of an inhomogeneous mass may represent either an early developing ectopic pregnancy (before a gestational sac is visualized) or a failing ectopic pregnancy. A total of 27% of the participants had a GS with only 5% of them having gestational age determination possible. This is occasioned by inability to clearly identify the parameters for age determination which may result from tubal abortions or early rupture with deformation of the GS with absent cardiac activity in majority of the cases(Elmowafi, march 2016) .Different studies have shown varied findings with Adhikari et al reporting that 13% of the cases were demonstrating presence of live ectopic embryos ,same as Condous et al & Casikar et al who both reported 13% presence

of embryo with or without cardiac activity(Condous et al., 2005) & obvious presence of gestational sac(Casikar et al., 2012) respectively.

In terms of whether it's located in the right adnexa or the left adnexa 55% were on the right while the rest were on the left. There is no evidence of any predisposition of either side to EP. It looks like both sides have a equal chance of EP developing .Shetty et al found out that majority of the cases were on the right adnexa which is comparable with the findings of this study but other studies have showed variation in locations and percentages with no specific pattern demonstrated (Babu, Roy, Das, & Banerjee, 2014; Daisley, 1989; Gharoro & Igbafe, 2002; Musa et al., 2009)

Free fluid in the peritoneum and pouch of Douglas was reported in 88% and 72% respectively. Echogenic or particulate fluid correlates with hemoperitoneum. After tubal rupture takes place haemorrhage occurs with accumulation of blood in the most dependent site first (Morrison's pouch) then if it's a lot it will extend to other areas like the pelvic, iliac and subdiaphragmatic recesses(Brant, 2001).Free fluid in Morrison's pouch indicates that there is a minimum of 670 mls in the peritoneum(Casikar et al., 2012) & it's important because it predicts need for operative intervention in suspected ectopic pregnancy(Moore, Todd, O'Brien, & Lin, 2007).However there are studies which have shown that patients with haemoperitoneum can still be managed conservatively(T Bignardi & Condous, 2009).

5.6 Surgical Findings

A total of 96 % of the participants had tubal EP while there were two cases of abdominal & one case of intrauterine pregnancy. There were slightly more right tube cases in comparison with the left. Fertilization normally takes place in the fallopian tube with subsequent migration to implant in the uterus. If migration of the fertilized ovum to the uterus fails to take place then implantation occurs at the point of entrapment along the tube. The most common location is the ampulla followed by the isthmus(Brant, 2001).Tubal abortion can occur with subsequent reimplantation within the abdomen with development of abdominal abortion or there can be entrapment of fertilized ovum during transperitoneal migration a very rare occurrence(Elmowafi, march 2016) . There was a single case of intrauterine pregnancy that was detected on TAS as a viable right abdominal pregnancy at 25 wks gestation with no signs of rupture and an empty uterus noted next to it. A corroborative obstetric MRI was advised to be done by the obstetrician but it was not done because the patient refused to give consent. Laparotomy was done and a bicornuate uterus was found with a normal pregnancy on the right horn and an empty left horn. This implies that what was imaged and concluded to be a right sided abdominal pregnancy was normal intrauterine pregnancy on the right horn while the demonstrated empty uterus was the left horn. The obstetric MRI which was not done would have been very valuable in detecting the congenital anomaly and therefore avoiding surgical intervention. The two cases of abdominal EP were not detected on ultrasonography (ultrasound demonstrated complex mass within the adnexa and did not further show that its implanted outside the fallopian tube).Evidence shows that it's very difficult to demonstrate it whether on abdominal or transvaginal imaging(Brant, 2001).Almost all participants(97.6%) had ruptured EP with

accompanying haemoperitoneum of varying amounts ranging from the lowest (50mls) to the highest(3500mls).The rupture is due to expansion, weakening and finally bursting of the tube by the growing embryo within it aided by trophoblastic penetration which results in disruption of vessels and bleeding into the peritoneum (DiaaEl Mowafi, 2016).

Multiple studies done have shown that over 90% of the EP are tubal and they are already ruptured at the time of surgical intervention. In a study done by Lawani et al 95.6% of the participants had ruptured cases while Musa et al & Thonneau et al found 96.9%(Musa et al., 2009) & 93%(Thonneau et al., 2002)respectively. Cornelius et al reported 99% ruptured cases(Cornelius et al., 2013) while Ruminjo et al had 78.8%(Ruminjo & Nuwagaba, 1990) & Shetty reported 48%(Shetty et al., 2014) both are lower percentages which could be because of difference in health seeking behaviour whereby the group with less ruptured cases probably sought medical attention early before rupture took place. Majority of the participants had haemoperitoneum consistent with the ruptured cases. Cornelius et al had 99% haemoperitoneum while Thonneau et al had 89.5%.In terms of whether it's the right side or the left is involved studies have shown variations. Musa et al had 66% (Musa et al., 2009)on the right & on the left 34% while Babu et al found right(42.3%) & left(56.4%)(Babu et al., 2014).Meanwhile Gharoro found right(54%) and left(36%)(Gharoro & Igbafe, 2002) and Daisley et al right(56%),left(44%)(Daisley, 1989).There is no obvious trend to demonstrate common location whether its right or left supported by the variations in the outcomes of each study done. All the findings found in this study are comparable to what was reported by other researchers in various parts of the world.

5.7 Level of Agreement between Surgical and Ultrasonography Findings

The observed level of agreement between ultrasound and surgery was found to be at 81.7%. The expected level of agreement was 47.3%. This gives a Kappa value of 0.653. This value shows that the level of agreement was substantial according to Viera et al, 2005 who classify it between 0.61 – 0.80 (Vieira, Kaymak, & Sousa, 2010). This value was obtained after considering all the reported surgical findings like right tube, left tube ovarian and abdominal ectopic pregnancy. When the two commonest surgical findings (right and left tube ectopic pregnancy) were analysed the observed level of agreement was 87.0% while the expected level of agreement was 50.6%. The kappa value was 0.737 (substantial agreement). There is very little literature of previous published studies looking at the level of agreement between ultrasound and surgery in diagnosing ectopic pregnancy. In a study done by Timmerman et al the kappa value was 0.85 (almost perfect agreement) but the difference is that they studied all cases of adnexal masses with histology as the gold standard (Timmerman et al., 1999). Based on the findings of this study with substantial agreement level, it means that the test is fairly accurate in detecting the abnormality (Vieira et al., 2010) which in this case that ultrasound use in diagnosing ectopic pregnancy.

CHAPTER SIX: CONCLUSION AND RECOMMENDATION

6.1 Conclusions

1. The most common ultrasound finding of EP is complex adnexal mass with associated free peritoneal or pouch of Douglas fluid.
2. Tubal ruptured EP pregnancy with haemoperitoneum is the commonest surgical finding.
3. The level of agreement between surgery and ultrasonography in the diagnosis of ectopic pregnancy is substantial.

6.2 Recommendation

Agreement between surgery and ultrasound in the diagnosis of ectopic pregnancy is substantial and therefore all patients suspected to have this gynaecological condition are encouraged to have a pelvic ultrasound done to assist in diagnosis.

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APPENDICES

Appendix I: Consent Form

English Version

Investigator: My name is Dr. Gilbert Kiyeng . I am a qualified doctor, registered with the Kenya Medical Practitioners and Dentists Board. I am currently pursuing a Masters degree in Radiology and Imaging at Moi University. I would like to recruit you into my research which is entitled **Comparison of transabdominal ultrasonography and surgical findings in patients with ectopic pregnancy seen in Moi Teaching and Referral Hospital, Eldoret Kenya.** This study has been approved by the Institutional Research and Ethics Committee (IREC) of Moi University and Moi Teaching and Referral Hospital.

Purpose: The purpose of this study is to find out and compare ultrasound and surgical findings (gold standard) in patients presenting with ectopic pregnancy in MTRH.

Procedure: Women with suspected EP who meet the criteria will be recruited after consent. TAS will be done using either Aloka prosound Alpha 7 or Philiphs HD 11xe machines with images reviewed by at least two consultant radiologists. The gynaecologist will then be informed about the patient for review and appropriate initiation of treatment. Patients who will undergo surgery will be followed up and theatre notes will be scrutinized and surgical findings recorded. Comparison of the ultrasound and surgical findings will be done.

Risks: There are no anticipated risks to the participants attributable to this study.

Confidentiality: All information obtained in this study will be treated with utmost confidentiality and shall not be divulged to any unauthorized person.

Rights to Refuse: Participation in this study is voluntary, there is freedom to refuse to take part or withdraw at any time. In the event you do not agree to take part, you shall be evaluated along with other patients but your result/information will not be included in the list of those who consent. Under eighteen years participants will have consent given by the parents / guardians.

Sign or make a mark if you agree to take part in the study

I allow the minor to participate

Name..... Relationship: Parent/Guardian:

SignDate:

I agree to take part (adults)

Name.....

SignDate:

Investigator Part

Name

Sign..... date

Appendix II: Cheti Cha Ruhusa

Kiswahili Version

Cheti cha Ruhusa

Kiswahili Version

Mpelelezi: jina langu Daktari Gilbert Kiyeng . Mimi ni daktari aliyehitimu na kusajiliwa na bodi ya Kenya ya Madaktari na Madaktari wa meno. Kwa sasa natafuta shahada ya uzamili katika Radiology na Imaging katika Chuo Kikuu cha Moi. Ningependa kukuajiri katika utafiti wangu ambao ni wa kulinganisha matokea ya ultrasound na upasuaji kwa wagonjwa walio na mimba ya mshipa, wanaosuru hospitali ya Rifaa Ya Moi. . Utafiti huu umepitishwa na Utafiti wa Taasisi na Kamati ya Maadili (IREC) ya Chuo Kikuu cha Moi na Hospitali ya Rufaa.

Kusudi: Utafiti huu utajaribu kulinganisha matokeo ya picha ya ultrasound na Upasuaji kwa wagonjwa wanaopatikana na shida ya mimba ya mshipa.

Utaratibu: Wagonjwa wote ambao wana shida ya mimba ya mshipa , watashirikishwa kwenye utafiti huu ikiwa watakubali. Data zitakusanywa kwenye fomu za ukusanyaji data. Hifadhi zitakazo tumika katika ukusanyaji wa data zitawekwa katika kabati iliyofungwa katika chumba cha mpelelezi mkuu kwa kipindi cha utafiti.

Faida: Kutakuwa hakuna faida moja kwa moja ya kushiriki katika utafiti huu. Wanaofanyiwa utafiti watakuwa na haki ya kupewa matibabu sawa na wale ambao hawatahusishwa kwenye utafiti huu.

Hatari: Hakuna hatari ya kutarajia kwa washiriki kutokana na utafiti huu.

Usiri: habari zote zilizopatikana katika utafiti huu wa kutibiwa zitawekwa kwa usiri mkubwa na wala haitatolewa kwa mtu yeyote asiye husika na utafiti.

Haki ya kukataa: Kushiriki katika utafiti huu ni hiari yako, kuna uhuru wa kukataa kushiriki au kujiondoa wakati wowote.

Na iwapo hautakubali kujumuishwa kwenye zoezi hili, bado hutachunguzwa kama wale wengine, kulingana na kanuni za hospitali hii, lakini matokea haitajumuishwa katika utafiti huu. Mgonjwa alieye chini ya miaka kumi na minane, mzazi/ mlezi atamtilia sahih. Iwapo mtotot huyo atakataa, kuhuzishwa basi hatajumuishwa.

Weka sahihi au alama kama umekubali kushiriki katika utafiti.

Mzazi / Mlezi: Mpelelezi:

Tarehe:

Namruhusu kujumuishwa

JinaUhusiano : Mzazi/mlezi :

SahihiTarehe :

Nakubali kujumuishwa

Jina

Appendix III: Questionnaire

Demographics

Date:..... Serial Number.....

Age

County of Residence.....

LMP.....Parity.....

Presentation

Abdominal Pain Yes No

Vaginal Bleeding Yes No

Missed Menses Yes No

Others.....

History

Is There Any Historical Of Pelvic Surgery? Yes No

Have You Ever Had an Abortion ? Yes No

Have Had Any Historical Of Assisted Reproductive Therapy Or In Vitro Fertilization?

Yes No

Have You Had Any History Of PID? Yes No

Have You Ever Have a History Of IUCD Use? Yes No

Have Been Diagnosed To Have Ectopic Before? Yes No

Emergency Contraceptives? Yes No

History of Infertility? Yes No

General Examination

Pallor Jaundice Edema Dehydration

Lymphadenopathy

Vital Signs

BPMmg Pulse Min.....

Chest Examination Normal Abnormal

Heart Examination Normal Abnormal

Abdominal Examination Normal Abnormal

Nervous System Examination Normal Abnormal

Other Findings

.....

Ultrasonography

Complex adnexal Yes No

Extra uterine gestetational Yes No

Sac with yolk Yes No

Sac with embryo Yes No

Location of EP Yes No

Free fluid in cul de sac Yes No

Presence of free peritoneal fluid Yes No

Any intrauterine pregnancy Yes No

Ovaries visualized

Yes No

Normal Yes No

Cervix Normal

Yes No

Open

Yes No

Any Other Findings

.....

Surgical Findings

Location of the EP.....

Ruptured or non-Ruptured.....

Presence of Haemoperitoneum Ye No

Surgical Procedures Done.....

Others

Appendix IV : MTRH Formal Approval Letter



MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
 Fax: 61749
 Email: director@mtrh.or.ke

P. O. Box 3
 ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

19th September, 2014

Dr. Kiyeng K. Gilbert,
 Moi University,
 School of Medicine,
 P.O. Box 4606-30100,
ELDORET-KENYA

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:

"Ultrasonography Findings in Correlation with Surgical Findings in Patients with Ectopic Pregnancy seen in Moi Teaching and Referral Hospital."

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

John Kibosia
DR. JOHN KIBOSIA
DIRECTOR

MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
 - Chief Nurse
 - HOD, HRISM



Appendix V : Formal Approval Letter



MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 334711/2/3
Reference: IREC/2014/134
Approval Number: 0001250



MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
19th September, 2014

Dr. Kiyeng K. Gilbert,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.



Dear Dr. Kiyeng,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Ultrasonography Findings in Correlation with Surgical Findings in Patients with Ectopic Pregnancy seen in Moi Teaching and Referral Hospital."

Your proposal has been granted a Formal Approval Number: **FAN: IREC 1250** on 19th September, 2014. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 18th September, 2015. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	Director - MTRH	Dean - SOP	Dean - SOM
	Principal - CHS	Dean - SON	Dean - SOD