

LAPAROSCOPIC FINDINGS IN PATIENTS WITH TUBAL FACTOR INFERTILITY WITH BLOCKED FALLOPIAN TUBES ON HYSTEOSALPINGOGRAM

A dissertation submitted in part fulfilment for the award of degree of master of
Medicine in Obstetrics and Gynaecology of the University of Nairobi.

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DECLARATION

This is to declare that this research work and dissertation is my original work and that it was done with the guidance of my supervisors. It has not been submitted to any other university for the award of a degree.

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DEDICATION

This dissertation is dedicated to my lovely wife Jackie and our precious son Jeremy, for their love, patience, encouragement and tireless support during my studies. May God continue blessing them.

To my parents, Mr. Hudson Gichunuku Ngaruthi and Mrs Joyce Gichunuku. Thank you for your encouragement, support and prayers.

ACKNOWLEDGMENT

I would like to thank all the consultants, senior registrars and lectures in the Department of Obstetrics and Gynaecology, both in the UON and in KNH for their dedication and commitment in ensuring that i achieve the necessary knowledge and skills during my training at the UON.

I would like to express my sincere gratitude to my supervisors Dr Wanyoike Gichuhi and Dr John Ong'ech for their effort to see that my thesis was properly written by offering expert advice and guidance.

TABLE OF CONTENT

DECLARATION	ii
CERTIFICATION OF SUPERVISION	iii
CERTIFICATE OF AUTHENTICITY	iv
DEDICATION	v
ACKNOWLEDGMENT.....	vi
TABLE OF CONTENT	vii
OPERATIONAL DEFINITIONS.....	viii
LIST OF ABBREVIATIONS.....	ix
ABSTRACT.....	x
INTRODUCTION	1
LITERATURE REVIEW	2
STUDY JUSTIFICATION.....	12
RESEARCH QUESTION.....	12
CONCEPTUAL FRAMEWORK.....	13
OBJECTIVES	15
STUDY METHODOLOGY	16
Data collection procedure	19
Quality control of data:	19
Data management.....	19
Ethical Consideration.....	20
RESULTS	21
DISCUSSION	34
CONCLUSION.....	42
RECOMMENDATIONS	42
REFERENCES.....	43
APPENDICES	48

OPERATIONAL DEFINITIONS

Infertility: is one year of unprotected intercourse without pregnancy. Primary infertility is where by no previous pregnancy have occurred while secondary infertility a prior pregnancy, although not necessarily a live birth, has occurred.

Fecundability: is the probability of achieving pregnancy within a single menstrual cycle.

Oligoovulation: infrequent occurrence of ovulation.

Anovulation: Lack of ovulation.

Fimbrioplasty: It is the lysis of fimbrial adhesion or the dilation of fimbrial phimosis.

Neosalpingostomy: It involves the creation of a new tubal opening in an occluded fallopian tube.

Laparoscopy: It is a transperitoneal endoscopic technique that provides excellent visualization of the pelvic structures and often permits the diagnosis and management of gynaecologic disorders without laparotomy.

Hysterosalpingogram: It is a fluoroscopic study performed by instilling radio opaque dye into the uterine cavity through a catheter to determine the contour of the endometrial cavity and patency of the fallopian tubes.

Dominant group: It refers to the age group of the majority of the study participants age which was between 31 to 35 years. Twenty four (40%) of the 60 participants were within this age group.

LIST OF ABBREVIATIONS

ART – Assisted reproductive technology

PCOS – Polycystic ovarian syndrome.

MRI – Magnetic resonance imaging.

TFI – Tubal factor infertility.

CAT – Chlamydia trachomatis IgG antibody testing.

DES – Diethylstilbestrol

IVI – Intrauterine insemination.

HIV – Human immunodeficiency virus.

STD – Sexually transmitted diseases

LMP – Last menstrual period

KNH – Kenyatta National Hospital

HOCM – High osmolar contrast media

LOCM – Low osmolar contrast media

IVF – In Vitro Fertilisation

HSG – hysterosalpingogram

WHO – World health organisation

PID – Pelvic inflammatory disease

ABSTRACT

Introduction:

Infertility is a unique medical condition because it involves a couple rather than a single individual. Infertility is a complex disorder with significant medical, psychosocial and economic aspects. According to the WHO (task force on diagnosis and treatment of infertility), tubal factor as a cause of infertility contributed nearly 22% .The primary cause of tubal factor infertility is PID. The diagnosis of tubal infertility is done using HSG and laparoscopy. This lays emphasis on how important our medical institutions need to be versed with modalities of diagnosing and managing tubal factor infertility. The aim of this study is to establish the sensitivity and specificity of HSG in diagnosing tubal blockage, adhesions and hydrosalpinx..

Rationale:

To find out the concordance between HSG and laparoscopic diagnosis of tubal factor infertility since HSG is done routinely in our setup when investigating infertility. Similar study was done by Gichuhi but was not published.

Objective:

To determine the level of concordance between HSG and laparoscopy in diagnosing blocked fallopian tubes.

Methods:

This is a prospective cross-sectional study that was carried at the Kenyatta National Hospital, Nairobi, Kenya. The study population was women admitted to KNH ward 1B due tubal factor infertility secondary to blocked fallopian tubes on HSG for diagnostic/operative laparoscopy. A total of 60 patients were recruited. The main outcome measures were; proportion correctly diagnosed to have proximal and distal blockage on HSG; proportion of patients correctly diagnosed to have adhesions and proportion of patients correctly diagnosed to have

hydrosalpinx. Data was collected using a pre-tested structured questionnaire. Statistical analysis was performed using Stratgraphics Plus Version 5.

Results:

The secondary infertility was more common than primary infertility. The dominant group was between 31 and 35 years. The best sensitivity of HSG in detecting tubal blockage was 74.% and a specificity of 70% . The best sensitivity in detecting tubal adhesions was 17.9% with a specificity of 85.7%.The best sensitivity in detecting hydrosalpinx was 80% and specificity of 76% when compared to laparoscopy which is the gold standard.

Conclusion:

In this study it was found the level of sensitivity and specificity between HSG & laparoscopic diagnosis of tubal factor infertility in patients with blocked fallopian tubes compares well with similar studies carried out in various parts of the world. The women in the age of 25 to 40 years are the most vulnerable to infertility related complications and the level of education may be a factor that influence treatment seeking behaviour. Laparoscopy is an appropriate method for examining the external part of the fallopian tubes, fimbriae, the relation of fallopian tubes and the ovary and therefore HSG and laparoscopy are not alternative but complementary. HSG has a high specificity in diagnosing hydrosalpinx but of low value in detecting tubal adhesions.

Recommendations:

The following recommendations were made:

1. It is important to increase awareness of infertility related complications among the child-bearing mothers in order to increase success in reversing or stopping progression of pathologies that may lead to permanent infertility.
2. While laparoscopy is the gold standard, it is not suitable to be used as a screening test and therefore, HSG should be used as the first-line investigation.

3. Proper management of pregnancies and abortions should be done in order to reduce the risk of secondary infertility and health education on safe sexual practices to reduce STD's and PID's that may lead to primary or secondary infertility.

INTRODUCTION

Infertility is a unique medical condition because it involves a couple rather than a single individual. Both the prevalence of infertility and the number of patients seeking the treatment of this disorder are increasing and especially in the third world. Two thirds of the gynecologist's time would be spent treating infertility in the third world (28). Infertility is generally lower in the developed than in the developing countries.

Laparoscopy is a transperitoneal endoscopic technique that provides excellent visualization of the pelvic structures and often permits the diagnosis and management of gynaecologic disorders and management of gynaecologic disorders without laparotomy. The decreased morbidity and shortened hospital stay, an opportunity to diagnose and treat at the same time and a reduction in postoperative adhesion formation has led to the immense popularity of laparoscopy.

Hysterosalpingogram is a fluoroscopic study performed by instilling radio opaque dye into the uterine cavity through a catheter to determine the contour of the endometrial cavity and patency of the fallopian tubes (36)

Laparoscopy is the use of a viewing tube called a laparoscope to see the inside of the abdomen and the pelvis. The laparoscope is a long thin lighted telescope-like instrument. It is commonly inserted through an incision in the navel. Laparoscopy can be performed for the diagnosis and surgical treatment of conditions within the abdomen or pelvis.

The tubal and uterine factors can be assessed either by HSG and/or dye-laparoscopy. Diagnostic tests for tubal patency are best done during the first seven days after conclusion of the menses.

LITERATURE REVIEW

Infertility is defined as one year of unprotected intercourse without pregnancy (30). Primary infertility is where by no previous pregnancy have occurred while secondary infertility a prior pregnancy, although not necessarily a live birth, has occurred(30).Fecundability is the probability of achieving pregnancy within a single menstrual cycle. The fecundability of a normal couple has been estimated at 20% to 25%. Approximately 90% of couples should conceive after 12 months of unprotected intercourse (28) . Infertility affects 10% to 15% of reproductive age couples. Infertility is a complex disorder with significant medical, psychosocial and economic aspects (28). A WHO (task force on diagnosis and treatment of infertility found out that tubal factor as a cause of infertility contributed nearly 22% (26). Other studies have shown that tubal and peritoneal factors accounts for 30% to 40% of cases of female infertility. The primary cause of tubal factor infertility is pelvic inflammatory disease. Other conditions that may interfere with tubal transport include severe endometriosis, adhesions from previous surgery or non-tubal infection and pelvic tuberculosis (12). This emphasizes on how important our medical institutions need to be versed with modalities of investigating tubal pathology. We therefore conducted this study in order to gauge the performance of methods used in our health facility in investigating tubal factor infertility.

Prospective population-based studies have confirmed these observations and also demonstrated that between 80 to 90% of women will conceive during the first six months of attempting pregnancy (30) . These studies suggest that the diagnosis of infertility may be suspected after only twelve months of unprotected intercourse without conception. The timing of initial evaluation of infertility depends upon the couple's historical risk factors: especially the age of the female partner. As a general rule, infertility evaluation should be

undertaken for couples that have not been able to conceive after 12 months of unprotected sex and frequent intercourse. However women may experience a decline in fecundity due to ovarian aging. This correlates with increased chronological age (10). Thus delaying evaluation in a woman in her mid-thirties may condemn her to lower success rates once therapy is initiated. In addition, prospective cohort studies of fecundity (12,57) have led some researchers to propose initiation of infertility work-up after 6 months of fertility oriented intercourse without conception (12,26). In light of these data some researchers recommend initiating evaluation after 6 months of unprotected intercourse without conception in women between 35 and 40 years of age, and consider immediate evaluation in women over 40 years of age. Evaluation may also be initiated sooner if the female partner has a history of oligomenorrhoea, pelvic infection or surgery, chemotherapy and/or radiation, or endometrioses. Early evaluation of the male partner may be warranted if there is a history of a testicular trauma requiring treatment, adult mumps, impotence or other sexual dysfunction or chemotherapy and/or radiation. For a young couple (where the female partner is less than 30 years old), the initial intervention to teaching timed intercourse with the aid of a urinary ovulation predictor kit, and advise at least 12 months of attempts to conception before initiating the infertility evaluation. Several researchers have proposed a system of prognostic grading in conjunction with statements describing the couples fertility history and diagnosis in order to reduce confusing terminology and to facilitate an appropriate treatment plan (10). This system has not yet been widely accepted (27).

Factors affecting fertility in couples

These include; age of the female partner, exposure to sexually transmitted disease and to environmental and medical toxins, coexistent disease states and the specific disorder as outlined above and among them the tubal factors. The World Health Organization (WHO) task force on diagnosis and treatment of infertility performed a study of 8500 infertile couples

and utilized standard diagnostic criteria to determine the medical conditions contributing to infertility(54). In developed countries, female factor infertility was reported in 37% of couples, male factor infertility in 8% of couples, and both male and female factor infertility in 35% of couples. 5% of couples had unexplained infertility and 15% of couples became pregnant during the study. The most common identifiable female factors, which accounted for 81% of female infertility included:- ovulatory disorders (25%), endometrioses (15%), pelvic adhesions (12%), tubal blockage (11 %), other tubal abnormalities (11 %) and hyperprolactinemia (7%). In Kenya, leading causes of infertility in the female have been reported as pelvic adhesions and bilateral tubal obstruction (61%), anovulation (16%), hyperprolactinaemia (10%), ovulatory oligomenorrhoea (6%) and others (7%). Other studies in Kenya have shown that 73% of female patients with infertility had tubal occlusion secondary to pelvic inflammatory disease in which case, the leading causes of tubal occlusion have been reported as gonorrhoea, post abortal sepsis and puerperal sepsis (1,42).

Fallopian tube abnormalities/pelvic adhesions

The normal physiological function of the fallopian tube is essential for pregnancy to occur. The conformation of tubal patency does not necessarily mean that there is normal function. The endosalpinx is lined by ciliated epithelial cells and the secretory cells (30). The cilia help in propulsion of the fertilised egg towards the uterine cavity. The secretory cells provide nutrition to sperm as well as ovum in the passage across the tube. The peristaltic movements of the fallopian tube are under influence of estrogen, progesterone and prostaglandins and synchronized movements help in propulsion of sperms and fertilized egg in either direction. The ovarian fimbria spread over the ovary at ovulation and bring the ovum into fimbrial end (7,27,29,30). Therefore, the loss of any of these functions could prevent conception.

The role of pelvic inflammatory disease as a cause of tubal factor infertility

The risk of infertility after a single episode of PID is significant and increases rapidly with subsequent episodes. Indeed, the incidence of tubal infertility has been reported to be 12%, 23% and 54% after one, two and three episodes of PID respectively (29). Other conditions that may interfere with tubal transport include severe endometriosis, adhesions from previous surgery or non-tubal infection and pelvic tuberculosis(26). Patients with distal tubal obstruction may develop hydrosalpinx, which decrease the success rate of in-vitro-fertilization (IVF) when done after failure of tubal surgery to restore fertility, presumably due to embryotoxic factors contained in the hydrosalpinx fluid(12). Tubal infertility definition includes the changes due to inflammation, which affect the fallopian tubes and its relation towards the ovary in a way that it will affect ovulation, the transport of the egg, sperm, and embryo, or alter the function of the tube at the site of fertilization. Tubo- peritoneal disease may result from genital tract infection (e.g. Chlamydia) and less frequently from extratubal inflammation (e.g. appendicitis, peritonitis), previous surgery, or from endometriosis. About one half of patients with documented tubal damage have no identifiable risk factors for tubal disease most of these women are presumed to have had subclinical Chlamydia infections (16). Other causes of apparent tubal blockage include salpingitis isthmica nodosa, benign polyps within the tubal lumen, tubal endometriosis, tubal spasm, and intratubal mucous debris (18). Another special group with tubal infertility consists of those patients who desired reversal of their tubal sterilization.

Chlamydia salpingitis has been found to be the most common cause of TFI with occlusion of the fallopian tubes due to an infection by Chlamydia trachomonas or neisserra gonorrhoea. Many cases of Chlamydia salpingitis have a more or less subclinical course (16,43). The tubal infection may become chronic in spite of antibiotic therapy. Immunologic processes may continue after microbiological cure, which stresses the importance of screening for

Chlamydia in order to detect and treat carriers to hinder spread to uninfected women. The use of new species-specific antibody tests for *Chlamydia* has decreased previous specificity problems found when used to detect occlusion in work-up of women seeking treatment because of infertility (16,39).

Male factors contributing to infertility

Major causes of infertility in men can broadly be divided into testicular and post testicular. Testicular causes include chromosomal conditions like Klinefelter syndrome, XX disorder, Noonan's syndrome, vanishing Testes syndrome, and gonadotoxins (e.g. drugs or radiation). Systemic diseases that can affect spermatogenesis include renal failure, cirrhosis and sickle cell disease. Post testicular causes are broadly divided into disorders of sperm transport which could be congenital, acquired or functional, disorders of sperm motility or function due to congenital defects of the sperm tail, maturation defects, immunologic disorders or infection and the other post testicular disorder is sexual dysfunction (3,48)

The initial diagnostic test used to assess tubal patency is HSG, has a sensitivity of 85% to 100% in identifying tubal occlusion – The specificity of HSG in identifying PID and related tubal occlusion approaches 90% (53). Bilateral tubal pathology documented on HSG is associated with significant reduced fecundity rates and warrants further evaluation using fallopscopy, selective salpingography or laparoscopy.

Strategies for detecting infertility

Different screening strategies exist to estimate the risk of tubal factor subfertility, preceding laparoscopy. Three screening strategies comprising *Chlamydia trachomatis* 1gG antibody testing (CAT), high sensitivity C-reactive protein (hs-CRP) testing and HSG. In this study Hartog and colleagues concluded that CAT is proposed as first screening test for tubal factor subfertility. In CAT-negative woman, HSG may be performed because of its high specificity

and fertility – enhancing effect. In CAT-positive, women, hs-CMP seems promising whereas HSG has no additional value. Therefore, the position and timing of laparoscopy deserves critical reappraisal (19).

A study conducted by Perquin and colleagues demonstrated that routine use of HSG prior to laparoscopy and dye in the fertility workup did not result in a significant effect on the incidence of pregnancy, compared with routine use of laparoscopy without HSG (19,47). The additional value of HSG compared with laparoscopy is particularly the assessment of the uterine cavity. Uterine cavity malformations with a frequency of about 10-15% in subfertile women can be visualised by HSG (47). A related study by Tananatoe and colleagues demonstrated that diagnostic laparoscopy is needed after abnormal HSG to prevent over-treatment with IVF. In cases of bilateral abnormalities revealed by HSG bilateral pathology was confirmed by laparoscopy in at least 58 (46%) patients and they were advised to be treated by IVF after laparoscopy. It was concluded that laparoscopy is mandatory after abnormal HSG findings in the work-up prior to IUI to prevent over-treatment with IVF (57).

A study by Genvert and colleagues demonstrated that the endocervical ultrasound is a reliable alternative for detecting uterine cavity pathology (23). It can also be used in the visualization of pelvic pathogens, such as endometriosis or ovarian pathology. Ultrasonography in comparison with HSG is less invasive and easily performed in a short period without Roentgen radiation. HSG though, remains on only trustworthy method for examining tubal microsurgery (e.g. salpingostomy)(58). Albert that HSG can be better carried out after laparoscopy. The reason that HSG is performed early in the fertility workup is based more on tradition and personal preference, rather than on the demonstrated usefulness of its components. In these circumstances, oil-soluble contrast media can be used to improve pregnancy rates although HSG with oil-soluble contrast medium is associated with an

increase risk of granuloma formation and embolism; mortality in connection with embolism has been reported before (49).

CAT may replace HSG as screening test that can be used for eliminating the risk of tubal pathology prior to laparoscopy. Several studies have shown that CAT might be as accurate as HSG in diagnosing tubal pathology (59). It's the most thorough technique for diagnosis tubal and peritoneal disease. It allows visualization of all pelvic organs and permits detection of intramural and subserosal uterine fibroids, peritubal and periovarian adhesions, and endometriosis. Abnormal findings on HSG can be validated by direct visualization on laparoscopy. Chromopertubation involves the transcervical installation of a dye, such as methylene blue or indigo carmine (59).

Unlike HSG, laparoscopy allows careful assessment of the external architecture of the tubes and, in particular visualization of the fimbria. Identified abnormalities, including tubal obstruction, pelvic adhesions, and endometriosis can be treated laparoscopically at the time of diagnosis. The decreased morbidity and shortened hospital stay, an opportunity to diagnose and treat at the same time and a reduction in postoperative adhesion formation has led to the immense popularity of laparoscopy (59).

The diagnosis of tubal patency based on HSG or laparoscopic findings are not considered complete or an absolute diagnosis (16,35). As part of the basic infertility evaluation, a crucial step is the HSG that is performed after complete cessation of menses and prior to ovulation. The HSG can delineate proximal versus distal tubal occlusion, degree of tubal dilatation, integrity of the rugae, presence of salpingitis isthmica nodosa and peri adnexal adhesions. Hysterosalpingography gives an idea about the size and shape of the uterine cavity, the isthmus and the cervical canal when viewing the antero-posterior or profile films. In some cases it may be necessary to obtain an oblique view in order to analyze the uterine wall.

Starting with the intramural portion and ending with the ampulla's, the tubal morphology should be analyzed for the caliber of its lumen, presence of any mucosal folds or any sign of thickening or rigidity of the tubal wall. Finally the tubal patency can be evaluated and radio-opaque dye spills may suggest adhesion or the presence of an adnexal mass (10,61). Assessment of tubal status-A meta-analysis of 20 studies involving 4179 patients comparing hysterosalpingography (HSG) and laparoscopy with chromopertubation (the gold standard) revealed that the high specificity of the HSG (83%) makes it useful for confirming tubal patency (34). However the HSG is less sensitive (65%) for diagnosing tubal occlusion due to a high false positive rate and is not reliable in the evaluation peri tubal adhesions or endometrioses.

The HSG may also identify the abnormalities of the uterine cavity, such as submucous fibroids, a T-shaped cavity (associated with DES exposure), polyps, synechiae and congenital mullerian anomalies, although the HSG alone cannot reliably distinguish between a uterine septum and bicornuate uterus. Abnormalities found on HSG may require follow-up evaluation by laparoscopy and/or hysteroscopy. Several studies support chlamydia trachomatis antibody testing as a simple inexpensive and noninvasive method of testing for tubal disease with a higher positive predictive value than HSG (35,61). Testing for trachomatis antibody has not yet come into widespread use. Laparoscopy is invasive and expensive and does not usually alter the treatment of the infertile couple, particularly in couples where the HSG is normal. This is especially true if the clinician plans to recommend IVF relatively early in the couples treatment plan, such as in cases of severe male factor or complete bilateral proximal tubal obstruction. Generally, Laparoscopy is indicated in women with otherwise unexplained infertility and a suspicion of endometriosis or pelvic adhesions due to a 'history of pelvic pain and/or previous surgery or infection (16). The use of laparoscopy to obtain a diagnosis in cases of unexplained infertility also affords the

opportunity to treat any existing pathology. Laparoscopy provides useful information on the external aspect of the uterus, its size, shape and the appearance of the serosa suggesting the presence of a former inflammatory process. The cornua should be inspected very carefully looking for signs of rigidity abnormal surface vessels, thickening of the cornua or isthmic part of the tube either to endometriosis or post infectious changes (10,35,61). Tuboscopy by antero-grade or retrograde route is under evaluation in several centers. Its usefulness in the evaluation and even treatment of tubal disease has been evident even if technical problems remain to be solved before introducing it as a routine tool.

Sensitivity and specificity of HSG

Sensitivity and specificity of an HSG are normally approximately 65% and 85% respectively (36). Indications of HSG include: infertility, recurrent miscarriages, following tubal surgery, assessment of the integrity of a Caesarean uterine scar. It contraindicated in pregnancy, when there is a purulent discharge on inspection of the vulva or cervix, or diagnosed PID in the preceding 6 months, recent dilatation and curettage or abortion, immediately post-menstruation and contrast sensitivity

While the diagnostic usefulness of the HSG is established, its value - as- a therapeutic - procedure in infertility is a subject of some controversy. Whitelaw and colleagues found no increase in the pregnancy rate following HSG (60), whereas Palmer reported that 75% of patients having an HSG showing tubal patency, and whose husbands had normal sperm counts, became pregnant within I year of the procedure (46). This was 3 times the pregnancy rate found by the same author among patients when had not had an HSG. Speculation concerning the precise mode of therapeutic action of the procedure has included the following: It may effect a mechanical lavage of the tubes, dislogging mucus plugs, It may straighten the tubes and thus break down peritoneal adhesions, it may provide a stimulatory effect for the cilia of the tube,it may improve the cervical mucus, the iodine may exert a

bacteriologic effect on the mucous membranes, ethiodol decreases in vitro phagocytosis by peritoneal macro-phages (7).If the same effect occurs in vivo it could decrease phagocytosis of sperm and thus aid fertility.

If an HSG does enhance fertility, is the effect seen with both oil and water-soluble dyes? Gillespie reported a conception rate of 41.3% within I year of an HSG with oil media, whereas the rate was only 27.3% .when water-soluble agents were employed (25). This is in accord with other reports where the great majority of pregnancies which followed HSG occurred within 7 months of the procedure(25,38). A review of the question of oil versus aqueous dye noted that in every retrospective study in which increased pregnancy rates were noted after HSG, an oil dye was used (53). Similarly, a prospective, controlled study showed oil contrast media was followed by a higher pregnancy rate (7 of 9 patients) compared to water dye (1 of 10 patients) when the cause of the infertility was unknown (25,51). With known infertility factors, there was no difference in groups having oil or water based HSG, Whereas the case for a fertility enhancing effect for Ethiodol seems strong, one group recently has found, in a prospective study, no difference in pregnancy rates between those individuals having HSG with oil or with water dye (2). Beyond its possible value in enhancing fertility, Ethiodol produces a better film image and a lower incidence of pain on injection compared to water-soluble dyes.

The use of an oil medium has been criticized on grounds that it is only slowly absorbed and may cause granuloma formation. Granulomas are found very infrequently and they also may follow the use of water dyes). An additional fear with oil dye is embolization. Bateman et al reported that there were 13 cases of dye intravasation in 533 HSG's performed with Ethiodol (5). Six of these women had embolization of the dye but there were no symptoms and no morbidity was noted. The authors emphasized that when fluoroscopy is used, venous or lymphatic intravasation can be detected immediately and injection of dye halted.

STUDY JUSTIFICATION

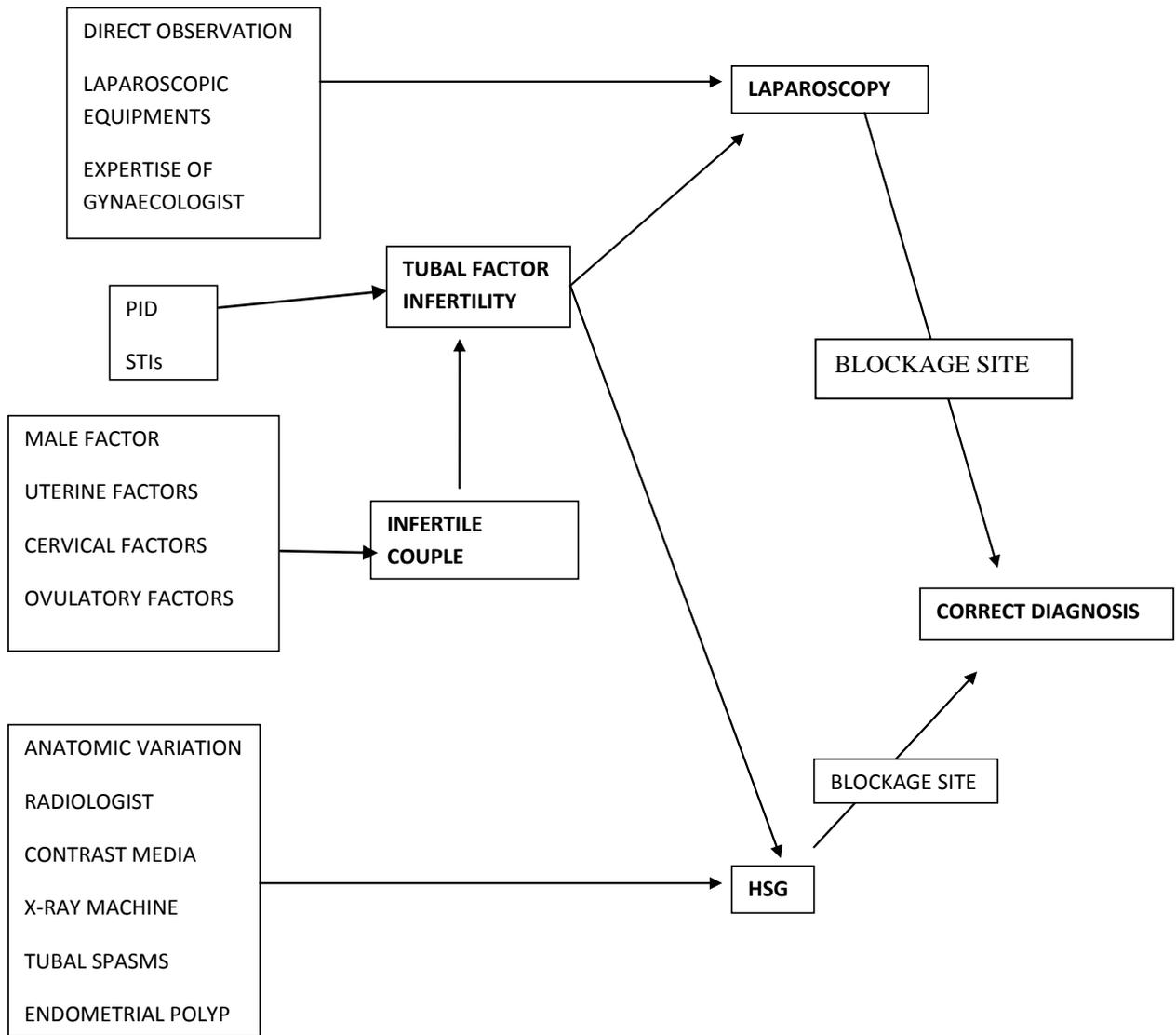
Infertility in general is on the upward trend and tubal factor is one of the leading causes in Kenya. It is therefore important to compare HSG findings with the laparoscopic findings as a form of investigating tubal factor infertility which is the leading cause of infertility in KNH and the country as a whole. The study will be a feedback on the sensitivity of HSG on diagnosing blocked fallopian tubes and possible shortcomings. A similar study was done in KNH by Gichuhi comparing laparoscopic findings with HSG findings in patients with blocked fallopian tube on HSG but there is no published data on the same(24). HSG is affordable and accessible and can be easily done in most of the hospitals unlike laparoscopy.

Kenya's provincial general hospitals and other level five hospitals had been equipped with laparoscopic equipments by JHPIEGO. This study will help carry the debate forward on the importance of diagnostic laparoscopy in the investigation of infertility hence the worth in investing in both the equipment and training surgeons on how to use it.

RESEARCH QUESTION

What is the level of concordance between HSG and laparoscopic diagnosis of tubal factor infertility in patients with blocked fallopian tubes.

CONCEPTUAL FRAMEWORK



NARRATIVE

Infertility affects 10% to 15% of reproductive age couples. It's a complex disorder with significant medical, psychosocial and economic aspects. Tubal factor infertility contributes nearly 22% of infertility. The primary cause of tubal factor infertility is PID.

The study involved doing diagnostic/operative laparoscopy in patients on follow up in KNH infertility clinic with blocked fallopian tubes on HSG.

Tubal factor infertility can be investigated by HSG which is widely available in the Districts and provincial hospitals in Kenya versus Laparoscopy which is not widely accessible but is considered the gold standard due to the fact that you can visualise the cause of infertility and treat at the same time in theatre.

We wanted to find out the sensitivity and specificity of HSG in diagnosing the blockage of fallopian tubes, the sites of obstruction, the diagnosis of adhesions and the hydrosalpinx and compare the findings with laparoscopic findings in the same study participants.

The findings of HSG can be affected by the contrast media used, the quality of x-ray machine used , the expertise of the person doing the HSG and also interpreting the HSG.

The findings of the laparoscopy can be affected by the quality of laparoscopic machine, the expertise of the gynaecologist doing the procedure, it's subjective , for example when reporting on the extent of adhesions what may look severe to one gynaecologist might be classified as moderate by some else.

OBJECTIVES

Broad objective

To compare the laparoscopic findings with HSG findings in patients with infertility due to tubal factor with blocked fallopian tubes on HSG.

Specific objectives

1. To determine the relative sensitivity and specificity of HSG compared to laparoscopy in diagnosing patients with proximal or distal tubal blockage.
2. To determine the relative sensitivity and specificity of HSG compared to laparoscopy in diagnosing patients with adhesions correctly.
3. To determine the relative sensitivity and specificity of HSG compared to laparoscopy in diagnosing patients with hydrosalpinx.

STUDY METHODOLOGY

Study Design

This was a prospective cross-sectional study.

Study Area And Study population

Study area

The study was conducted at the Kenyatta National Hospital. This is the national referral hospital and also serves as the University of Nairobi teaching hospital. It is the largest public hospital in the country located 3 kilometers north of Nairobi city centre. The hospital is the training centre for postgraduate students in Obstetrics and Gynaecology among other undergraduate and postgraduate degree training programmes. It has a bed capacity of 2,000 and serves a population of more than 2.5 million people living in Nairobi and its environs.

The hospital's Division of Obstetrics and Gynaecology is managed by staff employed by both KNH and the University of Nairobi. The Department is housed in the hospital complex and consists of a labour ward, 3 antenatal and postnatal wards, an emergency gynaecology ward, and one cold gynaecology ward. Recently a private maternity wing has been introduced in the hospital to cater for private patients. The staff also manage the gynaecology, antenatal and postnatal out-patient clinics. There also other special clinics such as infertility and oncology. The family planning clinic and the high risk adolescent clinic are also part of the Department of Obstetrics and Gynaecology. Patients who undergo laparoscopic surgery are first seen in the gynaecology out patient clinic or the family planning clinic. Here they are clerked by a senior house officer where the presenting medical history, the past medical history, family and social history are recorded. A physical examination is performed and the findings recorded. Relevant laboratory and radiological examinations are ordered and once they are satisfactory then the patient is scheduled for theatre. The senior house officer then liaises with the consultant running the laparoscopy theatre and an operation day is then scheduled. In

theatre the time the operation begins and the time it ends is recorded. The procedure notes are then documented after the operation. The operation is then recorded in the theatre registry book. There after the patient's progress in the ward postoperatively is noted in the file. The nurses also document the patient's progress in the nurses' cardex. A discharge summary is then written by the senior house officer. Patient's files are then kept in the central records department where they can be retrieved

The study population

The study population was women admitted to KNH with a diagnosis of infertility secondary to tubal factor with blocked fallopian tubes on HSG for diagnostic/operative laparoscopy.

Sample size estimation

Participants would allow an estimation of the concordance between HSG and laparoscopy within a $\pm 10\%$ margin of the estimated concordance of 80% with 95% confidence. Evidence from published literature indicates that concordance ranges from (70% to 90%). The sample size was calculated using the formula below (36)

Sample size calculation

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

Where:

n = Minimum sample size

Z = Z statistic for a level of 95% confidence level (1.96)

P = Estimate concordance between HSG and laparoscopy

δ = Margin of error of ± 0.1

$$N = \frac{1.96^2 \times 0.8(1-0.8)}{0.1^2} = 60$$

Inclusion criteria

- Patients who gave informed consent.
- Patients with a diagnosis of primary or secondary infertility due to tubal factor as evidenced by blocked fallopian tubes on HSG admitted for diagnostic/operative laparoscopy.

Exclusion criteria

The following categories of patients were excluded:

- Patients with blocked fallopian tubes on HSG who decline to give informed consent.
- Patients admitted due to tubal factor infertility for open tuboplasty.

Study Limitations

1. Surgeons expertise and experience in laparoscopic surgery.
2. The duration between HSG and laparoscopy is not standardized. Due to scarcity of resources, there is usually a gap of up to 1 year between when the HSG is performed and when the laparoscopy is performed. This may complicate the relative comparison between the findings of the two techniques
3. HSG were performed in different hospitals and reported by different radiologists while laparoscopy was also performed by different gynaecologists.

Mitigation of study limitations

It would have been possible to mitigate some of the above limitations if the study was designed in such a way that the duration between when the HSG is done and when laparoscopy is done is standardized. Since KNH is a referral hospital it was not possible to standardize the duration between when the HSG is done and the laparoscopy is done. It was

also not possible to do all the HSG in KNH and have them reported by the same radiologist, since KNH receives patients from all parts of Kenya.

Outcome Measures

1. Proportion correctly diagnosed to have proximal and distal blockage on HSG.
2. Proportion of patients correctly diagnosed to have adhesions.
3. Proportion of patients correctly diagnosed to have hydrosalpinx.

Data collection procedure

Data was collected by the principal researcher and two assistants. A pre-tested structured questionnaire was used to collect the data. The inpatient numbers were obtained from the admission register in the ward. The patients were interviewed and the information so given entered into a structured questionnaire. The admission, discharge and operating theatre notes were scrutinised and information entered in a structured questionnaire. The questionnaire included both open-ended and closed-ended questions. Data was collected for a period of six months after approval from the ethics committee.

Quality control of data:

Two research assistants were trained on interviewing, information retrieval and filling the questionnaire. In order to avoid double participant recruitment, the participants' admission (in-patient) numbers were entered into a register upon recruitment for serialization. This register was counter-checked on a daily basis for any double entries and if it so discovered, one of the questionnaires was withdrawn and discarded and the serialization rectified before recruitment was continued.

Data management

All the raw data in this study was collected by the principal investigator or his trained assistants. These was filed in suitable box files which were stored in a lockable filing drawer in the supervisor's office. All sheets were checked for completeness by the principal

investigator prior to filing. Dichotomous variables were analyzed with the χ^2 test. Odds ratios were considered when determining associations between variables. Results were considered significant within 95% confidence intervals (CIs). The null hypothesis was rejected for tests returning a p value of ≥ 0.05 . Statistical analysis was performed using Statgraphics plus Version 5 (StatPoint Technologies, INC, Warrenton, VA, USA)

Ethical Consideration

Information was collected via a questionnaire from patients attending infertility clinic in KNH who freely volunteered to join the study after giving an informed consent. It was their choice whether to participate or not. There were no risks or side effects associated with participating in the study. The information collected in this study will be confidential, all the information collected has a number but not the participants name to make sure it's confidential. The knowledge we get from the study will be shared with the policy makers, the Ministry of Medical services, and other doctors through publication and conferences. Confidential information will not be shared.

The patients attending the infertility clinic had a right to choice whether or not to enrol in the study. They had a right to withdrawal from the study and this did not affect their treatment at KNH in any way.

They did not receive any direct benefits from participating in this study. Their participation will be helpful in improving the way we diagnose infertility.

RESULTS

This section presents the data of 60 participants that were investigated between June 2011 and February 2011. The participants were recruited from the infertility clinic in KNH.

Social demographic and clinical data of patients investigated

Table 1 shows the age, marital status, occupation and the education level of the patients investigated in this study. The majority of patients were in the age bracket of 25 to 35 years and were married.

Table 1. Social demographic data

	<u>All patients</u> <u>(n-60)</u> <u>No.</u>	<u>%</u>
Age		
21-25	3	5
26-30	17	28
31-35	24	40
>35	16	27
Marital status		
Single	4	7
Married	52	87
Separated	4	7
Level of education		
Not educated	2	3
Primary level	17	28
Secondary level	30	50
Tertiary level	11	18
Employment		
Unemployed	8	13
Self-employed	42	70
Salaried employment	10	17

In table 1 majority of the participants were self employed and had at least a secondary school level of education. Majority of these participants indicated that they had not used any form of contraceptive. Further analysis revealed that the dominant set of the patients investigated in this study were in the ages of 31 to 35 years. Majority of women in the dominant group were married and had at least a secondary school level of education. The use of contraceptives in this group was also low with only 7 (29%) and 3 (13%) using the pill and injectables respectively. Regardless of the type of infertility, over 50% of the patients were diagnosed to have severe adhesion of the right and the left tube.

Table 2. Clinical characteristics

	Total number of patients (n=60)			
	<u>No.</u>	<u>%</u>		
History of PID				
History of PID	12	(20)		
Type of infertility				
Primary Infertility	29	(48)		
Secondary infertility	31	(52)		
Location of occlusion				
	<u>HSG</u>		<u>Laparoscopy</u>	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Right Proximal	30	(50)	27	(45)
Right Distal	28	(47)	22	(37)
Left Proximal	24	(40)	29	(48)
Left Distal	32	(53)	19	(32)

Detection of tubular occlusions using HSG and laparoscopy

Data relating to the detection of occlusion in the proximal or distal section of the fallopian tube using HSG and laparoscopy is also shown table 2. The data shows that HSG reported more patients as having any form of occlusion than the laparoscopy. The greatest disparity was among those identified to have a distal obstruction in the left tube in which case HSG detected 53% of patients compared to a 32% by laparoscopy.

Detection of hydrosalpinx using HSG and laparoscopy

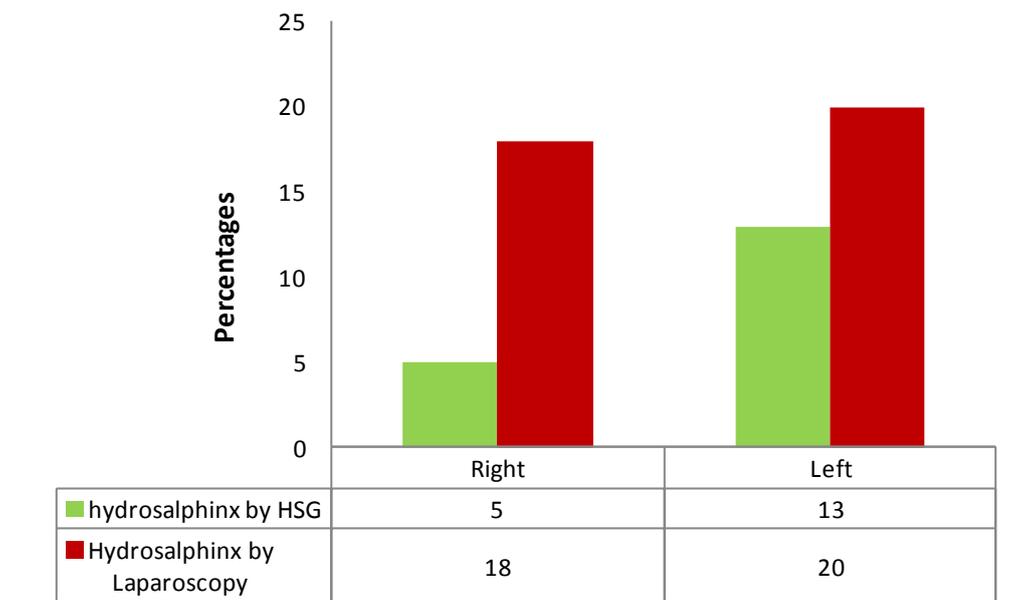
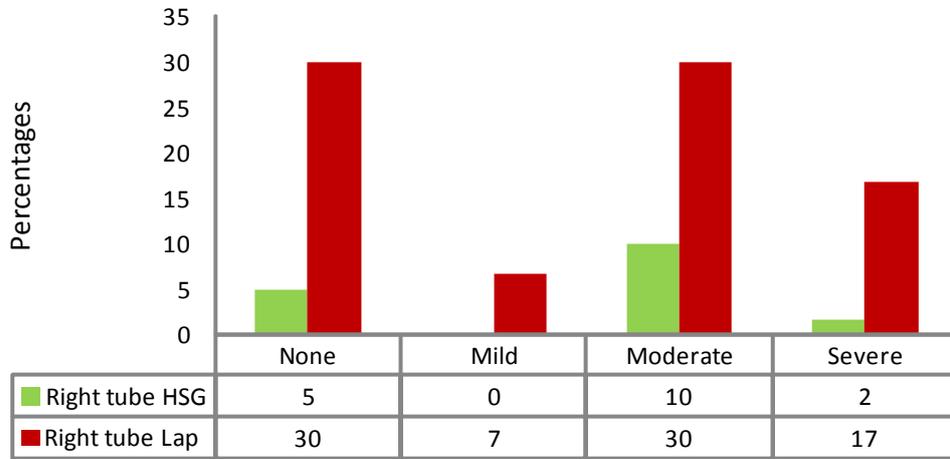


Figure 1. Figure showing percentage of patients diagnosed with hydrosalpinx using the HSG and laparoscopy.

The HSG detected fewer cases of hydrosalpinx compared to laparoscopy on both the right and left fallopian tube. The HSG only detected 5% as compared to 18% cases using laparoscopy in the right fallopian tube while on the left side, 13% of patients were categorized as having hydrosalpinx compared to 20% detected using laparoscopy.

A

Detection of adhesions using HSG and Laparoscopy on the right tube



B

Detection of adhesion using HSG and Laparoscopy on the left tube

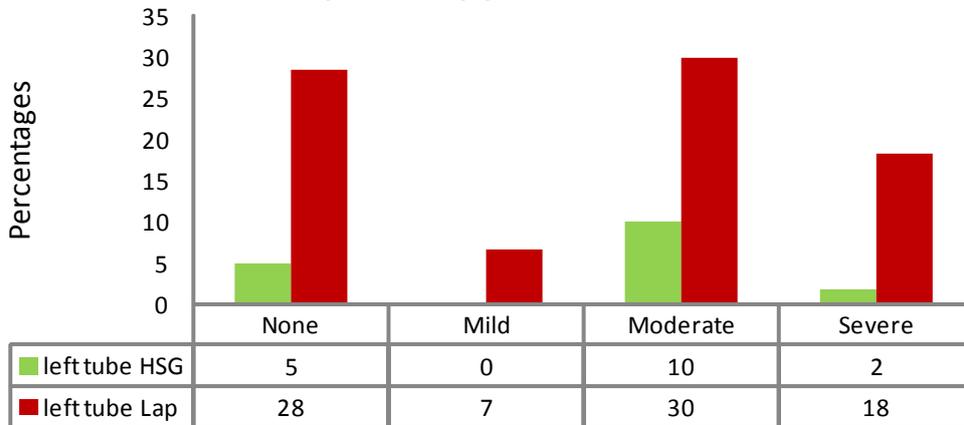


Figure 2A and 2B shows the detection of fallopian tube adhesions. The data however revealed that the HSG was less effective for detection of adhesions (χ^2 , $p=0.021$). The location of the adhesion and the side on which the fallopian tube was located did not influence the accuracy of HSG or laparoscopy.

Degree of adhesion as detected using HSG and laparoscopy

The degree of adhesions was determined using the HSG and laparoscopy and categorized into none, mild, moderate and severe, table 3.

Table 3. Degree of tubular adhesion

	<u>HSG</u>		<u>Laparoscopy</u>	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Right None	3	(5)	21	(35)
Left none	3	(5)	20	(33)
Right Mild	0	(0)	4	(7)
Right moderate	6	(10)	18	(30)
Right Severe	1	(2)	11	(18)
HSG left moderate	6	(10)	24	(40)
Left severe	1	(2)	12	(20)
Left mild	0	(0)	4	(7)

Women with secondary infertility were more likely to have some degree of adhesion in either tube than those with primary infertility (χ^2 , p=0.031). The HSG was found to be less effective in determining the degrees of severity of these adhesions compared to laparoscopy. For example, the HSG failed to detect 11 of the 12 cases categorized as severe adhesions using laparoscopy

Analysis of performance of HSG against laparoscopy for detection of occlusions, hydrosalpinx and adhesion

The performance of HSG was compared against that of the gold standard, laparoscopy, using 2x2 tables to determine sensitivity and specificity of this test. This was done by comparing the cases categorized as positive by HSG and those confirmed as true positives using the laparoscopy. The negative results as determined using HSG were also validated against the true negatives using laparoscopy. The following tables present the validation tests for the detection of occlusions, hydrosalpinx and adhesions.

Suitability of HSG for detection of obstruction in the right fallopian tube

Table 4. Comparison of HSG as a diagnostic method for detection of obstruction in the proximal section of the right fallopian tube against the use of laparoscopy (the gold standard)

Diagnostic techniques	Total confirmed (%)	Total not confirmed by Lap (%)	Validation	Value	95% confidence intervals
HSG positive/Lap positive	a 20 (74%)	b 10 (30%)	Positive predictive value	67%	48.8 to 80.8
HSG positive/Lap negative	c 7 (26%)	d 23 (70%)	Negative predictive value	77 %	59.1 to 88.2
Total (%)	e 27 (100)	f 33 (100)	Positive likelihood ratio	2.44	1.39 to 4.29
			Negative likelihood ratio	0.37	0.19 to 0.73

Table 4 presents the summary of comparative analysis between use of HSG and laparoscopy as the methods of detecting obstruction within the proximal section of the right fallopian tube. The sensitivity of HSG was calculated to be 74% (by dividing the value in cell “a” with that in cell “e”). The specificity of this method was calculated to be 70% (by dividing the value in cell “d” with that in cell “f”).

These results further show that the HSG was likely to over-report blockage in proximal section of the right fallopian tube by a factor of almost 2.5. The test was also likely to under-report 30% of patients with a proximal blockage as patent (not blocked).

Similar analysis was carried out in order to determine the suitability of HSG for detection of obstruction in the distal section of the right fallopian tube. Table 5 shows that the sensitivity of HSG was at 73% and a specificity of 68 %. This test was therefore likely to report negative cases as positive by a factor of 2.3 and report 30% of patients without an obstruction as having a distal right tube blockage.

Table 5. Comparison of HSG as a diagnostic method for detection of obstruction in the distal section of the right fallopian tube against the use of laparoscopy (the gold standard)

Diagnostic techniques	Total confirmed (%)	Total not confirmed by Lap (%)	Validation	Value	95% confidence intervals
HSG positive/Lap positive	^a 16 (73%)	^b 12 (32%)	Positive predictive value	57%	39.1 to 73.5
HSG positive/Lap negative	^c 6 (27%)	^d 26 (68%)	Negative predictive value	81.3 %	64.7 to 91.1
Total (%)	^e 22 (100)	^f 38 (100)	Positive likelihood ratio	2.3	1.35 to 3.9
			Negative likelihood ratio	0.39	0.19 to 0.81

Table 5 shows that the sensitivity of HSG was at 73% and a specificity of 68 %. This test was therefore likely to report negative cases as positive by a factor of 2.3 and report 30% of patients without an obstruction as having a distal right tube blockage.

Table 6. Comparison of HSG as a diagnostic method for detection of obstruction in the proximal section of the left fallopian tube against the use of laparoscopy (the gold standard)

Diagnostic techniques	Total confirmed (%)	Total not confirmed by Lap (%)	Validation	Value	95% confidence intervals
HSG positive/Lap positive	a 14 (48.3%)	b 10 (32%)	Positive predictive value	58.3%	38.8 to 75.5
HSG positive/Lap negative	c 15 (52%)	d 21 (68%)	Negative predictive value	58.3 %	42.2 to 72.9
Total (%)	e 29 (100)	f 31 (100)	Positive likelihood ratio	1.49	0.79 to 2.82
			Negative likelihood ratio	0.76	0.49 to 1.71

Suitability of HSG for detection of obstruction in the left fallopian tube

Tests were carried out to determine if HSG was effective for detection of blockage in the left fallopian tube, table 6. The specificity of this method for the detection of obstruction at the proximal section of left fallopian tube was found to be 48% and a specificity of 68%, table 6. Therefore, this method was likely to miss the proper identification of patients with obstruction in the left tube compared to the right. However, the specificity values of this method for both the right and the left side were closely compared at 70% and 68% for the right and the left tube respectively.

Table 7. Comparison of HSG as a diagnostic method for detection of obstruction in the distal section of the left fallopian tube against the use of laparoscopy (the gold standard)

Diagnostic techniques	Total confirmed (%)	Total not confirmed by Lap (%)	Validation	Value	95% confidence intervals
HSG positive/Lap positive	a 14 (73.7%)	b 18 (43.9%)	Positive predictive value	43.8%	28.2 to 60.7
HSG positive/Lap negative	c 5 (26.3 %)	d 23 (56.1%)	Negative predictive value	82.1 %	64.4 to 92.1
Total (%)	e 19 (100)	f 41 (100)	Positive likelihood ratio	1.67	1.08 to 2.60
			Negative likelihood ratio	0.47	0.21 to 1.04

The HSG reliability for the diagnosis of obstruction of the distal side of the left fallopian tube was investigated. The results of these tests are shown in table 7. We found a sensitivity of 74% and a specificity of 56%. Therefore, these results further indicated that there was a difference in the performance of this method depending on the section of the blockage and the side the fallopian tube is located.

Suitability of HSG for detection of hydrosalpinx in the right fallopian

Table 8. Comparison of HSG as a diagnostic method for detection of hydrosalpinx in the right fallopian tube against the use of laparoscopy (the gold standard)

Diagnostic techniques	Total confirmed (%)	Total not confirmed by Lap (%)	Validation	Value	95% confidence intervals
HSG positive/Lap positive	8 (80%)	12 (24%)	Positive predictive value	40%	21.9 to 61.3
HSG positive/Lap negative	2 (20.0%)	38 (76%)	Negative predictive value	95%	83.5 to 98.6
Total (%)	10 (100)	50 (100%)	Positive likelihood ratio	3.333	1.86 to 5.96
			Negative likelihood ratio	0.263	0.07 to 0.91

The reliability of HSG for the diagnosis of hydrosalpinx of the right fallopian tube was investigated. The results of these tests are shown in table 8. We found a sensitivity of 80% and a specificity of 76%. Therefore, these results further indicated that there was a difference in the performance of HSG and the laparoscopy.

Suitability of HSG for detection of hydrosalpinx in the left fallopian

Table 9. Comparison of HSG as a diagnostic method for detection of hydrosalpinx in the left fallopian tube against the use of laparoscopy (the gold standard)

Diagnostic techniques	Total confirmed (%)	Total not confirmed by Lap (%)	Validation	Value	95% confidence intervals
HSG positive/Lap positive	3 (50.0%)	11 (20.4%)	Positive predictive value	21.4%	7.6 to 47.6
HSG positive/Lap negative	3 (50.0%)	43 (79.6%)	Negative predictive value	93.5%	82.5 to 97.8
Total (%)	6 (100%)	54 (100%)	Positive likelihood ratio	2.455	0.941 to 6.4
			Negative likelihood ratio	0.628	0.279 to 1.414

The reliability of HSG for the diagnosis of hydrosalpinx of the left fallopian tube was evaluated. The results of these tests are shown in table 9. We found a sensitivity of 50 % and a specificity of 79%. Therefore, as was the case with the right fallopian tube, these results further indicated that there was a difference in the performance of HSG and the laparoscopy.

Suitability of HSG for detection of adhesions

Table 10. Comparison of HSG as a diagnostic method for detection of adhesions against laparoscopy (the gold standard)

Diagnostic techniques	Total confirmed (%)	Total not confirmed by Lap (%)	Validation	Value	95% confidence intervals
HSG positive/Lap positive	^a 3(14.3%)	^b 7(17.9%)	Positive predictive value	70%	39.7 to 89.2
HSG positive/Lap negative	^c 18 (85.7%)	^d 32 (82%)	Negative predictive value	36%	24.1 to 49.9
Total (%)	^e 21 (100)	^f 39 (100)	Positive likelihood ratio	1.25	0.36 to 4.36
			Negative likelihood ratio	0.95	0.76 to 1.20

The reliability of HSG for the diagnosis of adhesions was evaluated. The results of these tests are shown in table 10. The sensitivity was found to be 14% and a specificity of 82%. Therefore, HSG was found to perform poorly as far as detection of adhesions are concerned.

DISCUSSION

Socio-demographic and clinical details of the patients,

This study shows that the majority of participants seeking medical help due to infertility were between 31 and 40 years. A study conducted elsewhere showed that the dominant group seeking similar treatment was in the age group of between 26 and 30 year (6,31,37). The difference between the finding of our studies and these other past studied may partially be due to differences in treatment-seeking behaviour, availability of health institutions offering this kind of treatments and, knowledge differences in fertility among the populations in the two countries. The women in the age of 26-40 years are expected to be within the child-bearing age and are therefore more likely to seek help if they experience symptoms that suggest infertility. The majority of participants (50%) had attained at least some secondary education while 70% and were self-employed. The education level among our study subjects was higher than the national average of 23% and 48% among rural and urban women respectively while the employment level was above the national average of 58% (6). While we suspect that the level of education and employment status are not linked to complications leading to infertility but some degree of education may be a factor that contributes to treatment seeking behaviour in which case, informed women are more likely to seek treatment.

The data shows that 3.3% of participants had been treated for Chlamydia. This is consistent with a study carried out in Rwanda (43). In that study, the prevalence of Chlamydia trachomatis infection in fertile and sub-fertile women was low and did not differ significantly among sub-fertile (3.3%) and fertile women 3.8%. Nesseria gonorrhoea and Chlamydia trachomatis are the primary cause of PID but this condition may be under-reported among the patients we investigated because a good proportion may have suffered these infections without proper diagnosis or treatment. This is likely to be the case considering that secondary infertility was commoner (53.3%) than primary infertility. These

results are in agreement with that conducted in Uganda (6,31) and another one conducted in Ethiopia that found a prevalence of 53% of secondary infections among women suffering from infertility (32).

It was found that majority of women in this study did not use contraceptives. The role of contraceptive in ameliorating or aggravating sub-fertility has not been properly investigated. A past study found that while abnormal uterine bleeding was predictive of abnormalities that may cause infertility, prior use of oral contraceptives correlated negatively with pelvic pathology. We however feel that our study group under-reported the use of contraceptives given that majority of the participants were married, educated and working.

The history of PID was almost equal among patients with primary and secondary infertility and there was no major difference in major clinical presentations (χ^2 , $p=0.91$). However, among the participants with primary infertility, approximately 42% had obstructions in the distal section of the left fallopian tube compared to 25% of those with secondary infertility. Regardless of the type of infertility, over 50% of the patients were diagnosed to have severe adhesion of the right and the left tube.

In table 2, Using the HSG, only 34% compared 56% of patients were identified as having an obstruction in the distal section of the left tube. The clinical data relating to the obstruction of the left or right tube did not differ significantly among these women (χ^2 , $p=0.076$). A huge difference was observed between the diagnostic ability of HSG compared to that of laparoscopy. For example, while HSG estimated the proportion 53% of women within this age group to have a distal obstruction in the right fallopian tube, the laparoscopy returned a lower value of 29%. Similarly, HSG estimation of distal blockage of the left tube at 63% while laparoscopy returned a value at 35%. This group was also reported to have a high degree of adhesion for both the right and left tubes in which case over 70% of these patients were categorised to have adhesion in either tube.

While HSG is of a relatively lower value for absolute diagnosis and treatment of sub-fertile women, a study conducted in Italy showed that the conventional use of this technique may increase the time required to find an adequate treatment by which to achieve a successful pregnancy (11)

Sensitivity and specificity of HSG

In Sub-Saharan Africa, 75% of female infertility is attributed to tubo-peritoneal causes. HSG finds extensive use because it is relatively affordable, has well established therapeutic advantages and is associated with low frequency of complications. In many cases, this method is recommended for use in cornual occlusions, where genital tuberculosis is ruled out. This method is also recommended in patent tube as an ameliorating measure awaiting laparoscopy (33). Our study shows that the sensitivity of HSG in diagnosing proximal tubal blockage was 74 % and specificity of 70%. This compares well with those published by Kumar and colleagues who indicated that the sensitivity and specificity of HSG are approximately 65% and 85% respectively (36). However, the sensitivity in the left fallopian tube was 48% and specificity of 68 %. This concurs with the findings by Swart and colleagues who conducted a study to find out the impact of patient characteristics such as female age, duration of sub-fertility, and a clinical history without risk factors for tubal pathology. From their study, they estimated that the pooled sensitivity and specificity of HSG were 53% and 87% respectively for any tubal pathology (56). Similar data has been published by Broeze and colleagues (8). In our study HSG had a sensitivity of 80% and a specificity of 76% in the diagnosis of hydrosalpinx of the right fallopian tube. This finding concurs with those by Streda and colleagues who found that HSG had a high specificity of diagnosing proximal tubal occlusion or hydrosalpinx and low sensitivity in cases with peritubal adhesions (55).

Another study investigated 30 patients for endometriosis using different methods. Compared to laparoscopy, HSG diagnosis revealed a sensitivity of 55.5%, a specificity of 75%, a positive predictive value of 77%, and a negative predictive value of 53%. This study also showed that the anatomy of the patient may influence the accuracy of HSG. For example, in the presence of clinical pathologic uterosacral ligaments and/or sterility, the specificity of HSG may be 100%, but the sensitivity falls below the 40%. It has therefore been recommended that in patients with chronic pelvic pain, HSG is not a first choice diagnostic tool but may be useful in patients with infiltrative endometriosis of the uterosacral ligaments (13).

In yet another study, the HSG was found to have a relatively high specificity for detection of proximal obstruction, albeit with a low sensitivity (41). This method was particularly poor in the detection of distal obstruction, complications arising from hydrosalpinx and tube adhesions. The reproducibility of HSG-based detection was also found to be particularly low and the likelihood ratio for the presence of hydrosalpinx was found to be high. Using this method, proximal tubal obstruction detected on HSG was found to change the pre-test probability from 16 to 50% while proximal tubal patency detected on HSG was shown to change the pre-test probability from 16 to 9%. This study therefore concluded that HSG is of limited use in diagnosing distal tubal obstruction and hydrosalpinx, and has no value in the detection of peritubal adhesions (41)

Despite the apparent low comparability of HSG with laparoscopy, a study conducted in the Netherlands to assess the specificity of HSG in the detection of tubal pathology found that this method returns similar results in all sub-groups of patients except for women without risk factors. Therefore the study suggest that HSG is a useful tubal patency screening test for all infertile couples (9).

The best sensitivity of HSG was observed in the detection of proximal tubal occlusion on the right fallopian tube (74.1%). Our findings are consistent with the findings of a recent study (4). In that study, the investigators found that the possible causes of differential diagnosis of tubal occlusion between HSG and laparoscopic examination might be due to at least five factors that include the interval from the time the HSG is done and when the laparoscopy is carried out. In regard to our patients, we particularly note that due to limited resources in Kenya, majority of patients seeking treatment may take up to one year before laparoscopy is conducted. This raises the possibility of new pathological progressions in the reproductive system. The second factor that may compromise the quality of is that while laparoscopy is done under anaesthesia, HSG is not. Performing the HSG procedure may therefore cause spasms that may be interpreted as symptoms of tubal occlusion. Other factors include erroneous interpretation of the results due to inadequate experience by the clinician, different properties of contrast media used during HSG or anatomic variations in the width of the fallopian tubes. It is therefore possible that the false positive reported in this study might be due to tubal spasm and endometrial polyp in the area of the uterine opening of the tubes.

HSG for detection of tubal adhesion

Our study also showed that patients with secondary infections were more likely to have tubal adhesion. Most of the participants (18/60) tested negative on HSG but had moderate adhesions confirmed by laparoscopy. The sensitivity of HSG in diagnosing adhesions in the right fallopian tube was estimated to be 17.9% and specificity of 85.7%. These findings are consistent with those by Swart *et al.* These researchers conclusion was that although HSG is of limited use for detecting tubal patency because of its low sensitivity, its high specificity makes it a useful test for ruling in tubal obstruction. Some of the factors associated with tubal adhesion include infection with Chlamydia and we therefore suspect that the role of PID in secondary infertility was under-reported in this study (14). HSG has been evaluated as a method for testing for tubular adhesions and found that a combination of detection of

Chlamydial induced IgG antibodies and HSG can help identify patients at increased risk of pelvic pathology. However, in this past study, even patients with negative IgG and negative HSG had a 48% incidence of pelvic adhesive pathology (14). In a past *Chlamydia trachomatis* IgG antibody testing (CAT) was proposed as first screening test for tubal factor sub-fertility (20). In CAT-negative women, HSG may be performed because of its high specificity and fertility-enhancing effect. In CAT-positive women, high-sensitivity C-reactive protein (hs-CRP) seems promising, whereas HSG has no additional value (20). Another study suggests that the type of contrast media may affect the sensitivity of HSG in which case, water-soluble contrast media has better results and also has a therapeutic effect comparable to the oil-soluble contrast media (15)

HSG for detection of hydrosalpinx

The data suggested that HSG was likely to over-report hydrosalpinx by a factor of 3.3. These results were similar regardless of the clinical and social background of the patients investigated in this study. No association was found between the age of the patients and the probability of having hydrosalpinx in the right fallopian tube (χ^2 p=0.059) or the level of education (χ^2 p=0.67). Majority of patients with hydrosalpinx did not report a history of PID and majority did not use contraceptives

The data shows that laparoscopy is a superior technique as far as detection of hydrosalpinx is concerned. The data is in agreement with that from a past study that analysed the diagnostic value of laparoscopy in patients with tubal infertility. In that study tubal infertility diagnosed by laparoscopy accounted for 32.8% of infertile patients and the major causes of hydrosalpinx were pelvic tuberculosis and nonspecific inflammatory disease (NSID). The tuberculosis lesions were further classified into miliary ascites, adherent masses, adhesions and calcification types and nodular sclerosis. The hydrosalpinx was particularly associated with the NSID group and in 70% of cases with NSID had complete tubular occlusions. This study therefore concluded that laparoscopy examination is a valuable procedure for the

etiological diagnosis of tubal infertility. We therefore recommend that the causes and types of hydrosalpinx in Kenyan patients should also be investigated in future studies.

Alternative methods to HSG

We found that the sensitivity of HSG is below that of laparoscopy. What are alternative methods that may replace this technique? Despite the apparent low value of HSG, another study concludes that the method is still essential in ruling out pelvic diseases in sub-fertile women (21). In this study, no significant correlation was found between age of patient, duration, type of infertility and HSG findings. In that past study, 59.87% of cases detected using HSG were confirmed using laparoscopy. Therefore, although somewhat insensitive, the high specificity of HSG makes it very helpful for ruling out tubal disease, even where endoscopic evaluation is available (21). The use of HSG has also been found favourable over newer methods such as Hysterosalpingo-contrastsonography (HyCoSy). This method had been advanced as a replacer technique for assessing tubal patency using transvaginal ultrasound. However, when HyCoSy was compared with HSG using laparoscopy as a gold standard, the likelihood ratios of HyCoSy were slightly inferior to those obtained for HSG (22). Another study was conducted with the view to compare the sensitivity of a newer method known as three-dimensional saline sonohysterosalpingography (3D-SHSG) against X-ray hysterosalpingography (X-HSG) for the evaluation of the uterine cavity and fallopian tubes HSG (50). This study found that although the 3D-SHSG method was good for visualization of the uterine cavity and myometrial walls in three orthogonal planes, it does not diagnose tubal occlusion and does not depict architecture of the fallopian tube as accurately as X-ray HSG (50). This study therefore concluded that patients at high risk for tubal disease by history or with suspected tubal occlusion, the use of X-HSG or laparoscopy with chromopertubation is far much better than the 3D-SHSG. Further improvements of three-dimensional technology and contrast materials is however expected make this method comparable to X-ray HSG in future (50)

Should HSG continue to be used?

Our study showed that HSG has reduced predictive values compared to laparoscopy. These findings are in agreement with a past study conducted in South Africa (52). In this past study, laparoscopy only confirmed 15 (40.5%); 13 (35.1%) and five (13.5%) cases of HSG-diagnosed bilateral proximal, bilateral distal and mixed (i.e. one side proximal and the other distal) tubal occlusion respectively. Despite such findings, the South African study still recommended the use of HSG as a primary technique for investigating tubal occlusions. In another study conducted in Nigeria, HSG gave a false negative rate of 30.4% that were comparable to our findings (45). However the study concluded that this procedure is complementary in the evaluation of infertile couples.

Proximal tubal obstruction, either unilateral or bilateral, is a frequent finding on (HSG). Another study recommends the use of HSG as a companion technique in opening up blocked proximal tubes. The distinction between true pathologic occlusion and either spasm or plugging is crucial in determining therapy. Approximately two-thirds of the fallopian tubes resected for proximal tubal obstruction reveal an absence of luminal occlusion. The favourable results, lack of complications and low costs seem to justify the recommendation to use selective salpingography and fallopian tube recanalization as the first intervention in patients with obstruction of the proximal fallopian tube (40). Laparoscopy has however been found to be more sensitive in diagnosis of non-tubal factors and proximal tubal occlusion than HSG and therefore laparoscopy should be the first procedure in the investigation of tubal infertility and only followed by HSG if the results show some abnormality (44). Hysteroscopy cannulation of the fallopian tube has also been found to be a safe diagnostic procedure that can be used to identify those patients with true proximal occlusion, and may also serve as a therapeutic procedure in some of these patients (17).

CONCLUSION

A few conclusions can be drawn from the findings of this study:

- 1.The women in the age of 25-40 years are the most vulnerable to infertility-related complication and the level of education may be a factor that influence treatment-seeking behaviour.
- 2.Laparoscopy is a superior method for the evaluation of tubal and pelvic pathologies in the evaluation of infertility. It is an appropriate method for examining the external part of fallopian tubes, fimbriae, the relation of fallopian tubes and ovary , adhesions and other pathologies. It is therefore clear that these two methods are complimentary.
- 3.It was found that HSG has a high specificity in diagnosing hydrosalpinx but of low value in detecting tubal adhesion. It is therefore important to use the two methods in diagnosis and treatment of women with various levels of infertility.

RECOMMENDATIONS

Based on the findings from this study, we make the following recommendations: -

1. It is important to increase awareness of infertility-related complications among the child-bearing women in order to increase success in reversing or stopping progression of pathologies that may lead to permanent infertility.
2. Proper management of pregnancies and abortions should be done in order to reduce the risk of secondary infertility and health education on safe sexual practices to reduce STD's and PIDs that may lead to primary or secondary infertility.
3. Tubal assessment should also be made an integral part of female fertility evaluation. While laparoscopy is the gold standard, it is not suitable to be used as a screening test and therefore, HSG should be used as the first-line investigation.

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APPENDICES

APPENDIX I: CONSENT

INFORMED CONSENT FORM FOR LAPAROSCOPIC FINDINGS IN PATIENTS WITH TUBAL FACTOR INFERTILITY WITH BLOCKED FALLOPIAN TUBES ON HYSTEOSALPINGOGRAM

This Informed Consent Form has two parts:

- Information Sheet (to inform you about the research)
- Certificate of Consent (for signatures if you agree to take part)

PART I: Information Sheet

Introduction

My name is Dr. Josphat Gikundi Gichunuku. I am a doctor who is studying to specialize in the field of Obstetrics and Gynecology. I'm currently conducting research that is titled **"LAPAROSCOPIC FINDINGS IN PATIENTS WITH TUBAL FACTOR INFERTILITY WITH BLOCKED FALLOPIAN TUBES ON HYSTEOSALPINGOGRAM"**. I'm conducting a study to understand how these two techniques that are use for determining if a woman has infertility due to blockage of the fallopian tubes.

I am going to give you information and invite you to be part of this research. You do not have to decide now whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the doctor attending to you or the nursing staff.

Type of Research

In this study we will invite women who come to ward 1B I will collect information from the women who accept to join this research by interviewing them and filling a questionnaire. All the women who will be invited into this study will be 60. .

[Please stop me and ask me any question if you do not understand]

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital for your condition, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

If you agree to be part of this study, I will ask you some questions and fill a questionnaire, then I will..... You shall receive the exact same services whether or not you part of this research.

Side Effects

There are no side effects expected in this process.

Risks

There are no risks in participating in this study.

Benefits

You will not receive any direct benefits from participating in this study. Your participation will be very helpful in improving the way we diagnose fertility.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone. We will not be sharing the identity of those participating in the research.

Sharing the Results

The knowledge that we get from doing this research will be shared with the policy makers in this hospital and Ministry of Medical Services. And other doctors through publication and conferences. Confidential information will not be shared.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this hospital. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Dr. J. Wanyoike
Office telephone number: +254-020-2727682

This proposal has been reviewed and approved by Kenyatta National Hospital Ethics Committee, which is a committee whose task it is to make sure that research participants are protected from harm.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

If Non -literate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____

AND

Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent



I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that an interview will be conducted to collect information.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/yea

APPENDIX II: QUESTIONNAIRE

LAPAROSCOPIC FINDINGS IN PATIENTS WITH TUBAL FACTOR INFERTILITY WITH BLOCKED FALLOPIAN TUBES ON HSG

Date Serial No.....

Interviewers code

SOCIAL-DEMOGRAPHIC DATA PF THE PATIENTS

1. Age in years
2. Marital status
 - (a) single
 - (b) married
 - (c) separated
 - (d) divorced
 - (e) widowed
4. Education level
 - (a) none
 - (b) primary: standard
 - (c) secondary: form
 - (d) tertiary
5. Religion
 - (a) Christian
 - (b) Muslim
 - (c) Other (specify)
6. Occupation
 - (a) unemployed (housewife)
 - (b) self employed
 - (c) Salaried employment
 - (d) casual

Obstetrics/gynaecological history

1. Parity
2. Menstrual history
 - (a) LMP
 - (b) Menarche
 - (c) Duration of flow
 - (d) cycle length

3. Family planning method
 - (a) pills
 - (a) injectables
 - (b) Implant (e.g. Norplant)
 - (c) Iud
 - (d) condoms
 - (e) Natural method

4. Any history of PID?
 - (a) Yes
 - (b) No

5. Any history of sexually transmitted infections
 - (a) gonorrhoea
 - (b) chlamydia
 - (c) other (specify)

6. Type of infertility
 - (a) primary
 - (b) secondary.

7. Any previous surgery
 - (a) gynaecological
 - (b) obstetrical
 - (c) surgical
 - (d) Specify what was done.....

Diagnosis of proximal and distal blockage

8. Blocked fallopian tube on HSG code for yes =01 no =02
 - (a) Right - proximal obstruction
 - distal obstruction.
 - (b) Left - proximal obstruction
 - distal obstruction.

8. Blocked fallopian tube on laparoscopy
 - (a) Right - proximal obstruction
 - distal obstruction.
 - (b) Left - proximal obstruction
 - distal obstruction.

Diagnosis of adhesions

10. HSG findings
 - (a) Right fallopian tube
 - (b) Left fallopian tube

11. Laparoscopic findings
 - None
 - Mild

-Moderate
-Severe
Diagnosis of hydrosalpinx

12. HSG

(a)Right fallopian tube
(b)Left fallopian tube

13. Laparoscopy

-present
-absent