UNIVERSITY OF NAIROBI

COLLEGE OF HEALTH SCIENCES

SCHOOL OF MEDICINE

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

THE PATTERN OF LAPARASCOPIC FINDINGS AND MANAGEMENT OFFERED TO WOMEN WITH INFERTILITY AT THE KENYATTA NATIONAL HOSPITAL 2009-2013

DR. GIDEON MUTISO MUTUA

THE PATTERN OF LAPARASCOPIC FINDINGS AND MANAGEMENT OFFERED TO WOMEN WITH INFERTILITY AT THE KENYATTA NATIONAL HOSPITAL 2009-2013

A RETROSPECTIVE CROSS SECTIONAL STUDY

A DISSERTATION IN PARTIAL FULFILMENT OF A DEGREE IN MASTERS OF MEDICINE IN OBSTETRICS AND GYNECOLOGY

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DECLARATION

I declare that this is my original work and has not been presented for a degree in any other university.

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List of Abbreviations

ART	Assisted reproductive technology
HSG	Hysterosalpingography
ICSI	Intra-cytoplasmic sperm injection
IHH	Idiopathic hypothalamic hypogonadism
IUD	Intrauterine device
IUI	Intra uterine insemination
IVF	In-Vitro Fertilization
KNH	Kenyatta National Hospital
LEEP	Loop electrosurgical excision procedure
MTRH	Moi Teaching and Referral Hospital
PCOS	Polycystic ovary syndrome
PCR	Polymerase Chain Reaction
PID	Pelvic inflammatory disease
POF	Premature ovarian failure
SLE	Systemic lupus erythematosus
STI	Sexually Transmitted Infection
UON	University of Nairobi
WHO	World Health Organization

LIST OF FIGURES AND TABLES

DEFINITIONS

1. **Fecundity** is the probability of achieving a live birth in one menstrual cycle.
2. **Fecundability** is the probability of being pregnant in a single menstrual cycle.
3. **Infertility** is the inability of a couple to conceive within one year of unprotected intercourse of reasonable frequency. Reasonable frequency in this context refers to sexual frequency of 2-3 times a week.
4. **Male infertility** is inability of a man to achieve a conception with his partner after 12 months of regular unprotected sexual intercourse.
5. **Primary Infertility** applies to those who have never conceived, whereas secondary Infertility designates those who have conceived at some time in the past.
6. **Sterility** is an intrinsic inability to achieve pregnancy.
7. **Sub-fertility** occurs when the couple has difficulty in conceiving because both partners have reduced fecundity.
8. **Unexplained Infertility** is the diagnosis given to couples after a thorough evaluation has not revealed a cause.

TABLE OF CONTENTS

ABSTRACT

Background

Infertility is a common condition with important medical and socioeconomic implications. Infertility affects 10 to 15 percent of reproductive-aged couples worldwide. In Kenya the exact magnitude is not known although according to the Infertility in Kenya Survey Report 2008, gynecologists spent 31% of their consultations on infertility in both Kenyatta National Hospital and Moi Teaching and Referral Hospital, the two largest hospitals in Kenya. Laparoscopy is the gold standard approach for direct inspection and assessment of pelvic pathology. It allows both diagnosis and immediate surgery for conditions such as tubal blockage, pelvic adhesions and endometriosis.

Methodology

The main objective of this retrospective cross sectional study was to describe the pattern of laparoscopic findings and management offered to women with infertility at the Kenyatta National Hospital. A total of 402 patients' records of women with infertility who underwent laparoscopy between January 2009 and December 2013 were analyzed. The information in the records was retrieved using a pre-tested and precoded data retrieval form. Data entry was made and analyzed after verification using SPSS version 21.0

Results

The mean age of the women with infertility was 32.0 years which shows an increasing age shift. The main laparoscopic finding were tubal blockage (74.40%), endometriosis (11.20%) and genital tuberculosis (5.22%). Genital Tuberculosis, pelvic adhesions and endometriosis were the intra-operative diagnoses most likely to be missed pre-operatively with kappa values of 0.0, 0.002 and 0.1 respectively. Nearly a third of all patients (29.67%) were eventually recommended to pursue Assisted Reproductive Technologies (ART) services.

Conclusion and Recommendations

There is a shift in the mean age of women with infertility therefore prompt evaluation and appropriate care is critical. Tubal blockage is an important cause of infertility as are endometriosis and genital tuberculosis. There should be a standardized way of evaluating and reporting laparascopic findings such as endometriosis since this has implications on management.The general evaluation of women with infertility should include endometriosis and genital tuberculosis.There is need for affordable low cost ART services in Kenya as envisioned in the National Reproductive Health Strategy 2009-2015 in KNH since it is not only the premier referral and teaching hospital in the country and region but also the largest hospital in eastern Africa.

INTRODUCTION AND LITERATURE REVIEW

Infertility is a common condition with important medical and socio-economic implications. In addition, infertility treatment is not covered by insurance. Infertility is defined as failure of a couple to conceive after twelve months of regular intercourse without use of contraception (1,2). Fecundability is the probability of achieving a pregnancy in one menstrual cycle (2).

Infertility can either be primary or secondary. Primary infertility refers to no prior pregnancies while secondary infertility refers to infertility following at least one prior conception (2). Infertility affects 10 to 15 percent of reproductive-aged couples worldwide (2). In Kenya the exact magnitude is not known although in a national survey, gynecologists spent 31% of their consultations on infertility in both Kenyatta National Hospital (KNH) and Moi Teaching and Referral Hospital (MTRH) (3). An earlier study by Mati et al had found that 60% of patients in the Gynecology Outpatient Clinic at KNH presented with infertility (4).

Approximately 50 % of women will be pregnant at 3 months, 75 % will be pregnant at 6 months and more than 85 % will be pregnant by 1 year (2). Globally, Secondary infertility is more common than primary infertility (2). This is also true in Kenya (5). Most couples are more correctly considered to be subfertile, rather than infertile, as they will ultimately conceive if given enough time (2). This concept of subfertility can be reassuring to couples. However, there are exceptions, such as in bilaterally obstructed tubes or azoospermia (2).

Infertility is a unique medical condition since it involves a couple and as such both need to be involved since the treatment modality would be determined by the couple's individual fertility prospects.The evaluation of a couple with infertility involves the assessment of four key aspects for fertility: the sperm (male factor), the oocyte (ovulatory factor and ovarian reserve), transport and implantation of ova (pelvic factor including fallopian tubes) and the uterus (2).

Etiology of Infertility in the Female

Successful pregnancy requires a complex sequence of events including ovulation, ovum pick-up by a fallopian tube, fertilization, transport of a fertilized ovum into the uterus and implantation into a receptive uterine cavity. In addition, sperm of adequate number and quality must be deposited at the cervix near the time of ovulation.

In general, infertility can be attributed to the female partner one third of the time, the male partner one third of the time and both partners in the remaining one third (2).

In a WHO study of 8502 infertile couples the most common factors of female infertility included; ovulatory disorders (25%), tubal blockage and other tubal abnormalities (22%), endometriosis (15%), pelvic adhesions (12%) and hyperprolactinemia (7%) (6).

In Kenya, Okumu found the causes of infertility in the female to be pelvic adhesions and bilateral tubal obstruction (61%), anovulation (16%), hyperprolactinemia (10%) and ovulatory oligomenorrhea at 6% (7).

When ovulation is infrequent (oligoovulation) or absent (anovulation) the number of oocytes available for fertilization is reduced. Women with regular monthly menses and menstrual molimina such as breast tenderness, dysmenorrhea and bloating generally have ovulatory cycles. If menses and molimina are irregular or absent, pregnancy or other conditions associated with oligoovulation/anovulation are likely to be the cause.

Ovulatory dysfunction may be caused by abnormalities in the hypothalamus, anterior pituitary, or ovaries (2). Hypothalamic dysfunction or improper migration of the hypothalamic gonadotropin-releasing hormone neurons may be inherited; such as in Idiopathic Hypothalamic Hypogonadism (IHH) or Kallman syndrome. Other hypothalamic disorders may be due to lifestyle, for example, excessive exercise, eating disorders, or stress. Thyroid disease and

hyperprolactinemia may also contribute to menstrual disturbances (2,6). Other important causes of ovulatory disorders are polycystic ovary syndrome (PCOS) and medication such as contraceptive pills.

Infertility is also linked to age due to the loss of viable oocytes with increasing age. At midgestation, a normal human female fetus has approximately seven million oocytes, which will decrease to between two and three million by birth. Ongoing atresia of nondominant follicles proceeds throughout a woman's reproductive life span, with approximately 300,000 follicles at puberty and less than 1,000 follicles at the onset of menopause (2). The rate of follicle loss accelerates after the mid-thirties (8).

Tubal and pelvic factors are important causes of infertility (2, 6). Tubal disease may be caused by pelvic infection, endometriosis or prior pelvic surgery. Adhesions can prevent normal tubal movement, ovum pick-up and transport of the fertilized egg into the uterus (2).
A history of pelvic inflammatory disease (PID), abortion and Sexually Transmitted infection (STI) is suspicious for damage to the fallopian tubes or pelvic adhesions. In their study Gachuno et al showed that a history of STI and abortion was associated with tubal infertility (9).

The most common causes of tubal disease are infection with Chlamydia trachomatis or Neisseria gonorrhea (2). Tuberculosis is a common cause of both tubal and intrauterine disease in countries with endemic infection. Tubal infertility has been estimated to follow in 12 %, 23 %, and 54 % of women following one, two, or three cases of PID, respectively (2). Conversely, a considerable number of patients have been shown to have tubal damage with no history of prior PID (2).

Endometriosis is thought to be responsible for 10-25 % of infertility (2, 6, 10,11). Endometriosis is defined as the presence of endometrial glands and stroma at extrauterine sites. These ectopic

endometrial implants are usually located in the pelvis but can occur nearly anywhere in the body (10). It is a common estrogen dependent disorder which may present with chronic pelvic pain and infertility (10). It may also be symptomless.

Endometriosis results in inflammation and chronic bleeding within implants leading to obstruction of fallopian tubes or development of severe pelvic adhesions (2, 11). The mechanism for impaired fertility may involve anatomic distortion from pelvic adhesions and endometriomas or production of substances such as cytokines which are "hostile" to normal ovarian function (10). Thus ovulation, fertilization and implantation may be impeded (10,11).

Congenital and acquired uterine abnormalities can lead to infertility. Acquired anomalies include fibroids, intrauterine polyps and Asherman syndrome (2). Congenital uterine anomalies include uterine septum, bicornuate uterus, unicornuate uterus and uterine didelphys. Septate uterus is associated with the poorest reproductive outcome (12).

Fibroids may prevent normal implantation depending on their size and location (2, 13). Fibroids may obstruct a fallopian tube, distort the uterine cavity or fill the uterine cavity. The less vascular endometrium and myometrial dysfunctional contractility contribute to lower rates of successful pregnancy (2).

Asherman Syndrome, the presence of intrauterine adhesions or synechiae can lead to infertility (2). It occurs most frequently in women with a history of uterine dilatation and curettage. Endometrial polyps are estimated to be present in 3 to 5 percent of infertile women (2). Their removal has been shown to improve pregnancy rates following intrauterine insemination (2, 14).

Abnormalities in cervical mucus production are most frequently observed in women who have undergone cryosurgery, cervical conization, or Loop Electrosurgical Excision Procedure (LEEP) for treatment of an abnormal Pap smear. Cervical infection is thought to negatively impact mucus quality (2,14,15). Causative microorganisms include Chlamydia trachomatis, Neisseria gonorrhea, Ureaplasma urealyticum and Mycoplasma hominis (2).

Other causes of female infertility include genetic disorders and autoimmune diseases.The most common aneuploidies associated with infertility are 45, X (Turner syndrome) in women and 47, XXY (Klinefelter syndrome) in men (16). The former is associated with gonadal dysgenesis while the latter is associated with primary hypogonadism in the male. Gonadal dysgenesis is the most common cause of premature ovarian failure (POF) (2).

Some women with premature ovarian failure have been found to have autoimmune diseases such as systemic lupus erythematosus (SLE), celiac disease and myasthenia gravis. Such women may have autoimmune oophoritis as part of polyglandular autoimmune failure (16).

Unexplained infertility is the diagnosis given to couples after a thorough evaluation has not revealed a cause (2). It may be due to small contributions from multiple factors such as subtle oocyte and sperm dysfunction (17).

Laparoscopic Findings and Treatment Options for Women with Infertility

Laparoscopy is the gold standard approach for direct inspection and assessment of pelvic pathology (2). It allows both diagnosis and immediate surgery for conditions such as tubal blockage, pelvic adhesions and endometriosis. Chromotubation is performed for assessment of tubal patency. A dilute dye is injected through an acorn cannula on the cervix or a balloon catheter positioned in the uterus and then tubal spill evaluated through the laparoscope (2).

Since laparoscopy is an invasive procedure, hysterosalpingography (HSG) and ultrasonography are performed as part of the initial infertility evaluation.

Laparoscopy is more superior in the diagnostic work up of infertility in addition to providing an opportunity to institute immediate treatment. Mbura and Mgaya in their study at Muhimbili Medical Centre showed that HSG has a 50% failure rate in detecting pelvic adhesions (18). Gichuhi in his study at KNH also showed that HSG demonstrated tubal patency in 44.7% of patients while laparoscopy demonstrated patency on 47% of patients. In addition, the same study showed corneal occlusion on 26.2% of patients against 31.9% by laparoscopy (19).

A stepwise approach where HSG is done first and then laparoscopy is more cost-effective (2,20). Furthermore HSG and laparoscopy tend also to be complimentary for diagnostic work up.

Laparoscopic surgery is better than laparotomy for a number of reasons: the surgery is minimal and thus shorter hospital stay, there are less adhesions which is important in infertility since adhesions contribute to infertility (2). In addition, there tends to be a fair agreement in the assessment of tubal patency and occlusion between laparoscopy and laparotomy as shown by Ouko and Ndavi in a study in KNH (5).

Lastly, direct visualization by laparoscopy is the gold standard diagnosis of endometriosis (1). Granted that laparoscopic diagnosis of endometriosis does not always correlate with the histopathological diagnosis as shown by Sikolia et al in their study at Aga Khan Hospital, negative histopathology does not rule endometriosis (21). In cases where laparoscopy does not yield sufficient access or bleeding is not adequately controlled conversion to laparotomy is done to optimize treatment. Laparoscopic surgical treatment for women with infertility includes several procedures.

Laparoscopy has also been shown to pick pathology which has been missed on HSG and therefore institute appropriate surgical treatment at once or refer patients early for other treatment options such as ART. Early referral is critical for older women since the ability to conceive in a woman diminishes with advancing age (22). Corson and his colleagues found that in a 100 patients with a negative reproductive work-up up to the point of laparoscopy, 68 had significant pathology: intrinsic tubal disease 24, peritubal adhesive disease 34, and endometriosis 43, some in combination.

In cases where uterine synechiae or submucosal fibroid is suspected, hysteroscopy can also be performed to evaluate the uterine cavity and resection done. Hysteroscopy is to be performed in cases where submucosal fibroid or polyp occupies less than 50% of the intrauterine cavity from a prior evaluation such as with HSG (2,20).

In a study of 281 women by Heise et al, 46 women (16.4%) were referred for laparoscopy after initial HSG. Eight (17.3%) of them were noted to have unilateral tubal blockage while 28 (60.8%) had bilateral tubal blockage. Unilateral and bilateral salpingectomy was done respectively during laparoscopy. Salpingolysis was performed on 7 (15.2%) women while 3 (6.7%) women had untreatable adhesions (23).

Distal tubal blockage is treated by fimbrioplasty or salpingectomy. In an evaluation of 35 women who had undergone laparoscopic fimbrioplasty, Audebert et al found the intrauterine pregnancy rate was 51%, live birth rate was 37% and ectopic pregnancy rate was 23% after two years (24).

Terminal salpingostomy is performed to relieve tubal obstruction associated with hydrosalpinx. Efficacy for improving fertility depends on ampullary dilation, presence of mucosal folds, percentage of ciliated cells in the fimbrial end, and peritubal adhesions. Salpingectomy is

recommended for significant adnexal adhesions or where hydrosalpinges are dilated more than 3 cm especially in preparation for IVF (2,20).

A Cochrane review including three randomized trials showed the odds of pregnancy were increased with laparoscopic salpingectomy for hydrosalpinges prior to IVF (OR = 1.75, 95% CI 1.07-2.86), as were the odds of ongoing pregnancy/live birth (OR = 2.13, 95% CI 1.24-3.65) (25).

Tubal anastomosis is done for reversal of sterilization, midtubal block secondary to pathology, tubal occlusion from ectopic pregnancy and salpingitis isthmica nodosa. Rock et al found that the pregnancy rate after tubal anastomosis is 75 % in women with tubal length of 4 cm or more, but only 19 % in those with shorter tubes (26).

Pelvic adhesions especially peri-adnexal adhesions are treated through adhesiolysis which has been shown to improve pregnancy rates (27). Endometriosis can be ablated or excised laparoscopically. The most effective treatment of endometriomas is excision. Medical therapy for endometriomas larger than 1 cm has been shown not to be effective (28). In addition to improving pregnancy outcomes in endometriosis, laparoscopic excision also relieves pain (28). Laparoscopic ovarian drilling is done for patients with polycystic ovary syndrome (PCOS)-related anovulatory infertility where medical treatment has failed (2).

Laparoscopy has some complications such as visceral perforation and bowel injury. Ndovi in his study in KNH found the rate of complications to be 1.2% (29). Carbon dioxide subcutaneous emphysema and carbon dioxide gas embolism may also occur as highlighted by Obura (30).

Etiology of Infertility in the Male

The evaluation of infertility needs to involve the couple as either of them or both may be the cause of infertility. In addition, involvement of the couple together from the beginning is critical for them to support each other emotionally and financially. Causes of male infertility include abnormalities of sperm production, abnormalities of sperm function and obstruction of the ductal outflow tract (2). In addition to history and physical examination, seminalysis is the core investigation in the evaluation of male infertility. Additional investigations are guided by the history and physical examination (2,6).

CONCEPTUAL FRAMEWORK

Infertility in a couple may be due to female, male, combined causes or unexpelained causes. In the evaluation of infertility the couple is evaluated together. The evaluation begins with a history and then physical examination followed by investigations and finally the appropriate treatment and care offered to the couple.

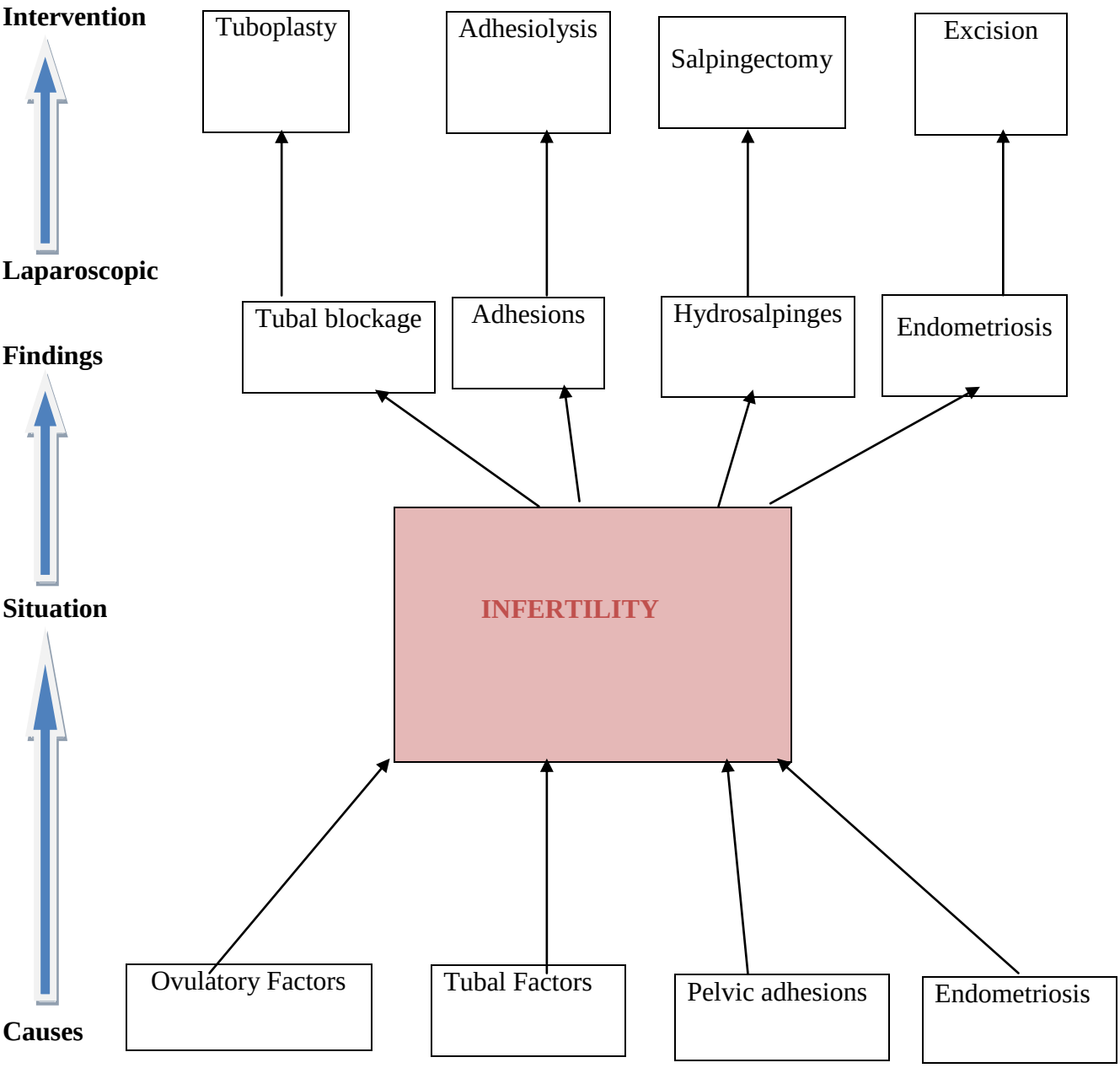
In the evalauation of the female a careful history and physical examination which then guides the investigations to be carried out is done. The investigations done should in most cases be used to confirm or build up on the diagnosis made in the history and physical examination.

The causes of female infertility may be tubal factors and ovulatory causes which may manifest as polycystic ovarian syndrome (PCOS). The other causes are endometriosis, genital tuberculosis. These causes lead to the situation of infertility as shown below in the conceptual framework.

The causes of infertility or the diagnoses may be confirmed or found at laparoscopy as tubal blockage, pelvic adhesions, polycystic ovaries, endometriosis. In addition other findings at laparoscopy may be uterine malformations or anomalies such as hypoplastic uterus and asherman syndrome seen at hysteroscopy. Tubal blockage may also manifest with hydrosalpinges and peritubal adhesions.

Once the diagnosis or impression is made at laparoscopy various procedures (interventions) are then made. These include tuboplasty for tubal blockage, adhesiolysis for pelvic adhesions, excision and ablation for endometriosis and hysteroscopy for asherman syndrome (see conceptual framework below).

CONCEPTUAL FRAMEWORK



PROBLEM STATEMENT AND JUSTIFICATION

Infertility is one of the most common reasons for gynecology visits not only globally but also in Kenya (2, 4). Infertility is unique in that it involves a couple. It cuts across all racial, religious socio-economic strata of life and has significant psychological, social and economic impact on the individual. Infertility is also one of the nine components of the National Reproductive Health Policy of Kenya (31). The implementation of this policy with regard to infertility is further elaborated in the National Reproductive Health Strategy 2009-2015 (32).

There are various studies done globally on the subject of infertility on the etiology and treatment modality at or after laparoscopy. However, there are few local studies on laparoscopic findings and management offered to women with infertility.

Lastly, advances in medical technology have brought to the fore various diagnostic and treatment options for infertility such as ART. In addition, laparoscopy techniques for both diagnosis of infertility and treatment have improved over time. The purpose of this study therefore was to fill this knowledge gap in Kenya and provide a basis for more studies in the field in future. This was a retrospective cross sectional study because of time factor. This study helped audit laparscopic services offered to gynecology patients with the aim of providing optimal services.

In addition, it is hoped that this study will help other centers in the country that have or intend to have this facility improve on the experience gained in Kenyatta National Hospital (KNH). Currently, KNH and Moi Teaching and Referral Hospital (MTRH) are the only public facilities in Kenya that offer laparoscopic services for infertility management**.**

RESEARCH QUESTION

What is the pattern of laparoscopic findings and management offered to women with infertility at the Kenyatta National Hospital?

OBJECTIVES

Main objective

To describe the pattern of laparoscopic findings and management offered to women with infertility at the Kenyatta National Hospital

Specific objectives

1. To describe the sociodemographic characteristics of women with infertility undergoing laparoscopy at the Kenyatta National Hospital.
2. To describe the pattern of laparoscopic findings in women with infertility at the Kenyatta National Hospital.
3. To compare the pre-operative and post-operative diagnosis in women undergoing laparascopy for infertility at the Kenyatta National Hospital.
4. To describe the management offered to women with infertility after undergoing laparoscopy at the Kenyatta National Hospital.
5. To describe complications in women who were done laparoscopy for infertility at the Kenyatta National Hospital.

MATERIALS AND METHODS

Study design

This was a hospital based retrospective descriptive cross sectional study where a total of 402 patient records of women who underwent laparoscopy between January 2009 and December 2013 were analyzed.

Study site and Setting

The study was carried out at Kenyatta National Hospital; located 3.5 km from Nairobi Central Business District. Kenyatta National Hospital (KNH) has a bed capacity of 1900 and is the largest hospital in East and Central Africa. It is a teaching and referral facility that serves Kenya and other neighboring countries.

Study population

The study population was women who presented with infertility and underwent laparoscopy. Patients with infertility are seen in the Gynecology Outpateint Clinic (GOPC) and the Infertility clinic at the Kenyatta National Hospital (KNH) outpatient department. The patients with an indication for laparoscopy are then admitted to ward IB for preparation for surgery.

Inclusion criteria

The following inclusion criteria was used:

- Women with infertility who underwent laparoscopy.
- Patients with complete information with regard to demographic characteristics, complete documentation on laparoscopic findings and treatment options offered.
- Women with infertility who underwent hysteroscopy as part of the fertility management.

Exclusion criteria

The following exclusion criteria was used:

- Women with infertility who were scheduled for laparoscopy but instead laparotomy was done without prior laparoscopy.
- Women with infertility who were scheduled for laparoscopy but did not undergo the procedure.

Study sample size

The sample size for the study was calculated using Fisher's formula (33) as follows:

$$N = \frac{Z^2(P)(1-P)}{D^2}$$

Where:

N= The desired sample size

Z=The standard normal deviation usually set at 1.96 which corresponds to 95% confidence interval.

P= Estimated proportion taken as 0.5 (50%). This is because there are several expectedlaparascopy findings such as tubal blockage, adhesions, endometriosis and hydrosalpinges.

D=Degree of accuracy with which P is determined set at 0.05

$$\text{Thus } N = \frac{1.96\times1.96(0.5\times0.5)}{0.05\times0.05}$$

The sample size was therefore 384.

Sampling Procedure

A total of 402 patient files were analyzed. There were 487 patients who underwent laparoscopy between January 2009 and December 2013 according to theatre records. Out of these, 51 files did not meet the inclusion criteria while 34 files were missing. Therefore the retrieval rate was 93.02%. All the files of patients who underwent laparoscopy for infertility and fulfilled the inclusion criteria were retrieved and then convenience sampling done where every consecutive file was reviewed for anaylsis.

$$\text{Retrieval rate} = \frac{\text{total number of patients done laparoscopy minus missing files} \times 100}{\text{total number of patients done laparoscopy}}$$

$$= \frac{487-34 \times 100}{487}$$

$$= \mathbf{93.02\%}$$

Data variables

The data variables included age, marital status, type of infertility, duration of infertility, pre-oprative diagnosis, intra-operative diagnosis and treatment procuderes.

Study instrument

A pre-tested and pre-coded data retrieval form was used to collect data from the patients' records.

Data collection and Management

Two research assistants were trained on the data retrieval form and then recruited to help in the collection of data from the records department of KNH. Data was collected by the principal investigator and the two research assistants. Data entry and statistical analysis were done using

the Statistical Package for Social science (SPSS) version 21.0. Data validation was carried out before analysis.

Data Analysis

Descriptive statistics were used in result presentation. Continuous data such as age was described using means, standard deviations, medians, proportions and frequency distribution. Categorical data was analyzed using percentages.Kappa statistics were used to compare the pre operative and post operative diagnoses. Analyzed data was presented in the form of tables and pie charts.In the analysis, confidence interval was set at 95% and P value below 0.05 was taken as statistically significant.

STUDY LIMITATIONS

There were four study limitations. Firstly there was incomplete data on the various data variables of the study. Secondly, the file retrieval rate was 93.02% thus information on the missing files was not reviewed and analyzed.

Thirdly, hysterosalpingography and laparoscopy are done by different radiologists and gynecologists respectively therefore introducing information bias.

Lastly, this study was carried out in one facility and even though this is the main teaching and referral hospital in Kenya, the study findings may not be generalized in the Kenyan population. Nevertheless this was a retrospective cross sectional study where there was no Hawthorne's effect and thus the findings are likely to be a true reflection of the services offered.

ETHICAL CONSIDERATIONS

The study was carried out after approval from the University of Nairobi/Kenyatta National Hospital Scientific and Ethical Review Committee and the Department of Reproductive Health, Kenyatta National Hospital.

This was a low risk study unlikely to be injurious to patients since it was a retrospective cross sectional study. In addition, the data was reviewed without any contact with the patients who had been treated.

All information obtained from the study was handled in confidence and used only for the intended purpose. The research findings will be communicated to the primary care providers of the institution through the annual Infertility Management symposium at the Kenyatta National Hospital.

RESULTS

A total of 402 files of female patients who presented with infertility and had laparoscopy done between January 2009 and December 2013 were analyzed. This was a retrieval rate of 93.02% as shown in the flow chart below.

Figure 1. Flow chart depicting retrieval of records of women with infertility who had laparoscopy done at the KNH between January 2009 and December 2013

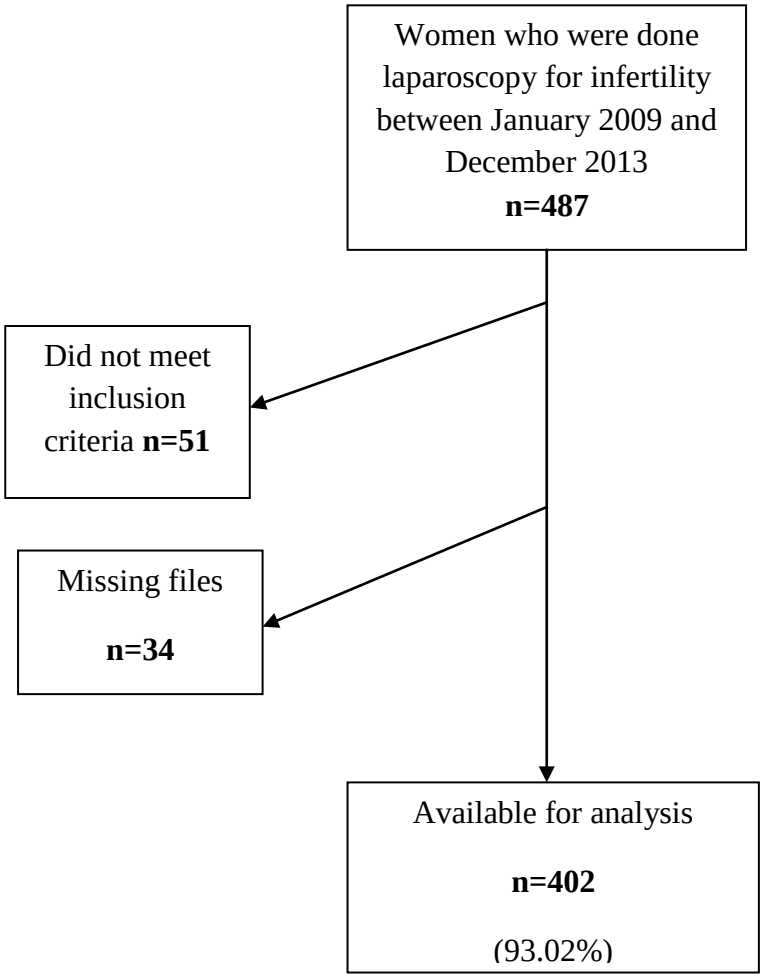


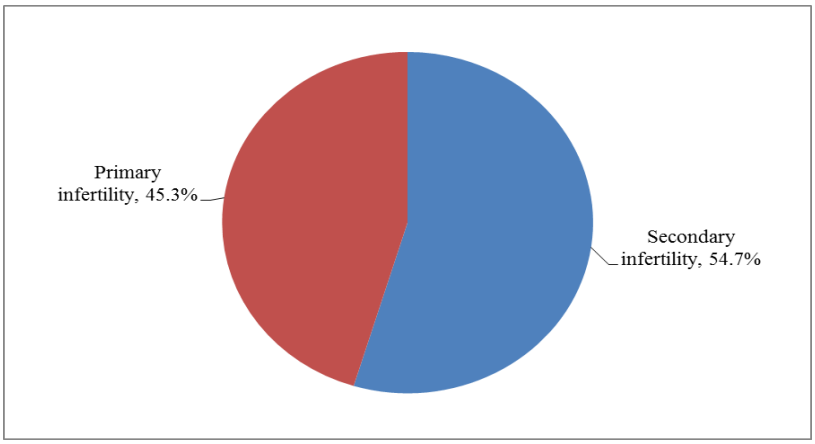
Table 1.Socio-demographic characteristics of women with infertility done laparoscopy at the KNH between Jan 2009 and Dec 2013 (n=402)

Variable	Frequency	%
Age (years)		
Mean (Standard deviation)	32 (5.0)	------
Median (Inter-quartile range)	32 (29-35)	------
Min-Max	21-51	------
Age group		
21-24	26	6.5
25-29	89	22.1
30-34	172	42.8
35-39	91	22.6
>=40	24	6.0
Marital status		
Married	372	92.5
Single	18	4.5
Divorced	4	1.0
Separated	8	0.2
If divorced or separated was infertility a contributing factor		
Yes	10	33.3
No	4	13.3
Unknown	16	53.3
Residence		
Urban	297	73.9
Peri-urban	54	13.4
Rural	50	12.4
Other	1	0.2
Educational level		
None	2	0.5
Primary	101	25.7
Secondary	227	56.5
Tertiary	102	25.3
Religion		
Protestant	290	72.1
Catholic	101	25.1
Muslim	10	2.5
African traditional	1	0.2
Occupation		
Unemployed/housewife	73	18.2
Casual worker	6	1.5
Self-employed	203	51.0
Formal employment	118	29.4

Table 1.above shows the sociodemographic characteristics of the patients. The mean age was 32.0 years. Most of the patients were married (90.5%). In the category of those who were divorced or separated, a third of them (33.3%) attributed the cause of their separation or divorce to infertility.

Type of infertility

Figure 2. Type of infertility of women who underwent laparoscopy at the KNH between January 2009 and December 2013 (n=402)



Most of the patients had secondary infertility (54.7%) as shown in the figure 1. above.

Duration of Infertility

Table 2. Duration of infertility of women who underwent laparoscopy at the KNH between January 2009 and December 2013 (n=402)

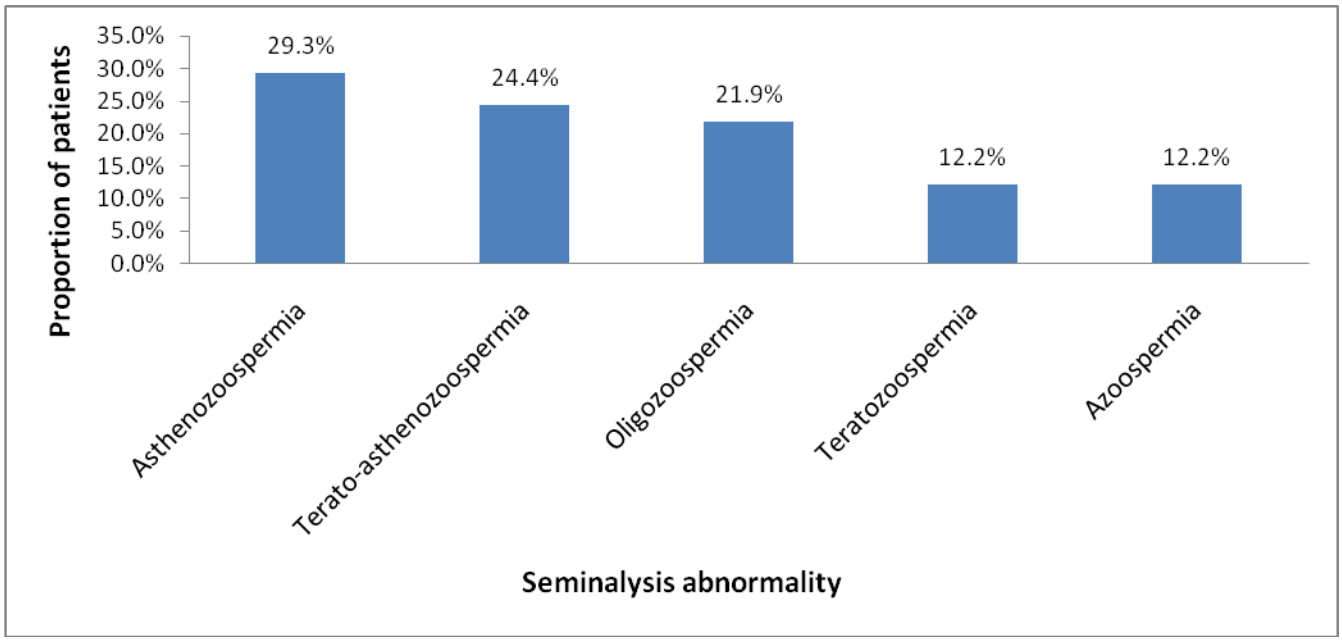
Variable	**Frequency**	**%**
Duration of infertility (years)		
Mean (SD)	5 (3-8)	------
Min-Max	1-20	------
Number of years of infertility		
1-3	119	29.6
4-6	143	35.6
7-9	65	16.2
>=10	75	18.7

SD-Standard deviation

The average duration of infertility was 5 years as shown in table 2 above.

Seminalysis Abnormalities

Figure 3: Seminalysis abnormalities of husbands of women with infertility done laparoscopy at the KNH between January 2009 and December 2013 (n=41)



Azoospermia represented 12.2% of abnormalities on seminalysis as shown in figure 2.above.

History of Presenting Illness

Table 3.History of presenting illness of women with infertility done laparoscopy at the KNH between January 2009 and December 2013 (n=402)

Variable	Frequency	%
History of Pelvic Inflammatory Disease (PID)		
Yes	156	38.8
No	228	56.7
Unkown	18	4.5
History of Sexually Transmitted Infection (STI)		
Yes	23	5.6
No	326	81.1
Unknown	53	13.2
Systemic Illness		
None	378	94.03
Diabetes	2	0.49
Hypertension	2	0.49
TB	11	2.73
Asthma	2	0.49
HIV/AIDs	5	1.24
Peptic Ulcer Disease (PUD)	2	0.49
History of Infertility treatment		
None	385	95.78
Laparoscopic tuboplasty	8	1.99
Open tuboplasty	6	1.49
In-Vitro Fertilization (IVF)	2	0.49
Intra-Uterine Insemination (IUI)	1	0.24

Slightly more than a third (38.8%) of the patients had a history of Pelvic Inflammatory Disease (PID) and 5.6% of them had history of a sexually transmitted infection (STI) as shown in table 3. above.

Pre-operative diagnosis

Table 4.Pre-operative diagnosis of women with infertility done laparoscopy at the KNH between January 2009 and December 2013 (n=402)

Diagnosis	Frequency	%
Tubal blockage	363	90.29
Pelvic dhesions	43	10.69
Polycystic ovarian syndrome (PCOS)	21	5.22
Uterine malformations	7	1.74
Endometriosis	6	1.49
Asherman's syndrome	5	1.24
Fibroids	2	0.24

NB. Some patients had multiple diagnoses and hence the total is more than 100%

Most of the patients had a pre-operative diagnosis of tubal blockage (90.29%) followed by pelvic adhesions (10.69%) as shown in table 4. above.

Laparoscopic Findings

Table 5.Laparoscopic findings of women with infertility at the KNH between January 2009 and December 2013 (n=402)

Laparoscopic Finding/Impression	Frequency	%
Tubal blockage	299	74.40
Endometriosis	45	11.20
Genital tuberculosis*	21	5.22
Polycystic ovarian syndrome (PCOS)	14	3.48
Frozen pelvis	11	2.72
Fibroids	7	1.74
Uterine abnormalities	5	1.24
Normal pelvis (No abnormality detected)	2	0.48

NB.1. The above constitute the dominant diagnosis/findings at laparoscopy

2. * Genital tuberculosiswas confirmed in 21 cases on AAFB while in total suspected (clinical) Tuberculosis was seen in 31 patients.

Tubal blockage was the most common laparoscopic finding (74.4%) followed by endometriosis (11.2%) and genital tuberculosis (5.22%) as shown in table 5. above.

Association of patient charecterists with tubal blockage

Table 6. Association of patient characteristics and tubal blockage in women with infertility who had laparoscopy done at the KNH between Jan 2009 and Dec 2013 (n=402)

Characteristics	**With tubal blockage N=299**		**Without tubal blockage N=103**		**OR (95% CI)**	**P value**
	n (%)	Mean (SD)/ Median (IQR)	n (%)	Mean (SD)/ Median (IQR)		
Age		32.1(4.6)		31.4 (5.2)		0.161
Type of infertility						
Primary	132 (44.1)		50 (48.5)		0.8 (0.5-1.3)	0.439
Secondary	167 (55.9)		53 (51.5)		1.0	
Duration of infertility		5(3-8)		4 (3-7)		0.011
PID						
Yes	149 (49.8)		59 (57.3)		0.7 (0.5-1.2)	0.192
No	150 (50.2)		44 (42.7)		1.0	
Marital status						
Married	278 (93.0)		94 (91.3)		1.3 (0.6-2.9)	0.568
Unmarried	21(7.0)		9 (8.7)		1.0	
STI						
Yes	80 (26.8)		39 (37.9)		0.6 (0.4-1.0)	0.033
No	219 (73.2)		64 (62.1)		1.0	

P value=0.05
SD-Standard deviation
IQR-Inter-quartile range
PID-Pelvic inflammatory disease
STI-Sexually transmitted infection

Patients who were married were 1.3 times more likely to have tubal blockage than those who were not married as shown in table 6.above. This was not statistically significant. (OR 1.3, p value= 0.568).

Association of patient characterists with endometriosis

Table 7. Association of patient characteristics and endometriosis in women with infertility who had laparoscopy done at the KNH between Jan 2009 and Dec 2013 (n=402)

Characteristics	**With endometriosis N=45**		**Without endometriosis N=357**		**OR (95% CI)**	**P value**
	n (%)	Mean (SD)/ Median (IQR)	n (%)	Mean (SD)/ Median (IQR)		
Age		32.8 (5.2)		31.9 (4.7)		0.531
Type of infertility						
Primary	17 (37.8)		165 (46.2)		0.7 (0.3-1.3)	0.284
Secondary	28 (62.2)		192 (53.8)		1.0	
Duration of infertility		4 (3-6)		5 (3-8)		0.149
PID						
Yes	18 (40.0)		190 (53.2)		0.6 (0.3-1.1)	0.094
No	27 (60.0)		167 (46.8)		1.0	
Marital status						
Married	37 (82.2)		335 (93.8)		0.3 (0.1-0.7)	0.012
Unmarried	8 (17.8)		22 (6.2)		1.0	
Unemployed	6 (13.3)		67 (18.8)		0.7 (0.3-1.6)	0.373
Employed	39 (86.7)		290 (81.2)		1.0	
STI						
Yes	15 (33.3)		104 (29.1)		1.2 (0.6-2.4)	0.561
No	30 (66.7)		253 (70.9)		1.0	

P value=0.05
SD-Standard deviation
IQR-Inter-quartile range
PID-Pelvic inflammatory disease
STI-Sexually transmitted infection

Patients with STI were 1.2 more times likey to have endometriosis compared to those without STI although this was not statiscally significant as shown in table 7. above (OR 1.2, p=0.561)

Comparison between pre-operative and intra-operative diagnosis

Table 8.Comparison between pre-operative and intra-operative diagnosis in women with infertility who had laparoscopy done at the KNH between January 2009 and December 2013 (n=402)

Variable	Pre-operative diagnosis n (%)	Intra-operative diagnosis n (%)	Kappa statistic, P value
Tubal blockage			
Yes	363 (90.3)	299 (74.4)	0.3, <0.001
No	39 (9.7)	103 (25.6)	
Pelvic adhesions			
Yes	43 (10.7)	222 (55.2)	0.002, 0.934
No	359 (89.3)	180 (44.8)	
PCOS			
Yes	21 (5.2)	14 (3.5)	0.7, <0.001
No	381 (94.8)	388 (96.5)	
Endometriosis			
Yes	6 (1.5)	45 (11.2)	0.1, 0.002
No	396 (98.5)	357 (88.8)	
Uterine abnormalities			
Yes	7 (1.5)	5 (1.2)	0.9,1.000
No	395 (98.5)	397 (98.8)	
Genital Tuberculosis			
Yes	0 (0.0)	21 (5.2)	0.0, <0.001
No	402 (100.0)	381 (94.8)	
Fibroids			
Yes	2 (0.5)	7 (1.7)	0.4, 0.067
No	400 (99.5)	395 (98.3)	

PCOS=Polycystic ovarian syndrome

P value=0.05

Genital Tuberculosis, pelvic adhesions and endometriosis were the intra-operative diagnoses most likely to be missed pre-operatively with kappa values of 0.0, 0.002 and 0.1 respectively as shown in table 8.above.

Management Option Offered

Table 9.Management offered to women with infertility who had laparoscopy done at the KNH between January 2009 and December 2013 (n=402)

Procedureat Laparoscopy	**Frequency**	**%**
Adhesiolysis	157	29.90
Adhesiolysis and salpingostomy	113	21.52
Adhesiolysis, fimbrioplasty	98	18.67
Excision and ablation for endometriosis	45	8.57
Salpingectomy	44	8.38
Laparoscopic ovarian drilling	33	6.29
Conversion to laparatomy (myomectomy, tuboplasty)	31	5.90
Hysteroscopy	4	0.76
Eventual management option offered		
Conceive normally with no further intervention	229	56.97
In-Vitro Fertilization (IVF)	118	29.35
Open Tuboplasty	28	6.97
Adoption	20	4.98
Intra-Uterine Insemination (IUI)	4	0.99
Interventional Radiology	3	0.75

NB: A total of 82 patients had failed tuboplasty with completely blocked tubes, 11 had frozen pelvis so no laparoscopy done. Multiple procedures were done in some patients.

Adhesiolysis alone then adhesiolysis and salpingostomy were the most common laparoscopic procedures (29.90% and 21.52% respectively). The eventual management offered to most of the patients was to conceive normally without further intervention (56.97%) while 29.35% of the patients were advised to pursue IVF as shown in table 9. above.

Complications of laparoscopic surgery

Table 10: Complications in women with infertility who had laparoscopy done at the KNH between January 2009 and December 2013 (n=402)

Complications of laparoscopic surgery	Frequency	%
None	396	98.5
Gut injury	3	0.7
Urinary tract injury	2	0.5
Wound sepsis	1	0.2

Most of the patients (98.5%) did not experience any complications from laparoscopic surgery as shown in table 10. above.

DISCUSSION

This was a retrospective cross sectional descriptive study where a total of 402 files of patients who underwent laparoscopy between January 2009 and December 2013 were analyzed. The mean age of the study population was 32.0 years (SD 5.0) (table 1). Earlier studies in KNH on infertility had shown younger ages. The mean age in a study by Nderitu in 2007 (34) was 30.0 years whereas the mean age was 27.1 years ina study by Gichuhi in 1995 (19). This shift inage could be attributed to postponement of getting children latter in life by women due to education and employment (35).

This increasing age of women with infertility has an important implication because of decreased fecundability of a woman with increasing age especially from 30 years (36). Therefore prompt and appropriate care is critical (36,37).

A third (10 out of 30) of the women in the category of those who were divorced or separated in this study attributedthe cause of divorce or separation to infertility (table 1). Dhont et al in Rwanda also found that a third of dissolution of unions was due to infertility (38). Social stigma is attached to infertility and divorce is likely especially if the woman is unemployed (3).

In this study, most of the patients (54.7%) had secondary infertility (figure 1). Okwelogu et al in Nigeria also found secondary infertility to be more common than primary infertility (39).This is also true globally (2). Women with secondary infertility are more likely to succeed in conception especially in In-Vitro Fertilization (IVF) (8). This is important since 29.35% of the patients in this study were recommended to pursue IVF.

Tubal blockage was the most common laparoscopic finding (74.40%) in this study (table 5). In Africa, tubal factor is the most common cause of female infertility whereas globally tubal

blockage and other tubal abnormalities are the second most common cause of female infertility after Ovulatory disorders (6,39).

In this study, women with PID were not more likely to have tubal blockage compared to those women without PID although it was statistically significant (OR 0.1, p=<0.001).This might be attributed to the fact that this study may not have had sufficient power to detect this association.

Endometriosis was found in 11.20% of the patients at laparoscopy but was not suspected in most of the patients before surgery (table 5). There were few cases where the severity of endemetriosis was graded. Chirchir in his study at Aga Khan Hospital here in Kenya found the prevalence of endometriosis to be 35% among Caucasians and 14% among Black Africans (40). In this study 100 % of the study population were black Africans. In an earlier study by Gichuhi in 1995 in KNH no endometriosis was found in women with infertility at laparoscopy (19). This could be due to evolving technique in diagnosis of endometriosis or there may be a difference in the two study populations.

Mboudou et al in Cameroon found the prevalence of endometriosis to be 13.53% (41). In contrast, Osefo and Okeke found the prevalence of endometriosis among the Igbo women of Nigeria to be much lower at 4.3% (42). Globally, the prevalence of endometriosis is 15% (6)

There was no association between patients' characteristics such as age, marital status, parity, type of infertility and endometriosis in this study (table 7). Endometriosis has been associated with lower parity and to be more common in causcasians and Asians than in black women (43-46). This study may not have had sufficient power to detect differences in parity. All the patients were also black women.

Genital tuberculosis was seen in 5.22% of the patients in this study (table 5) and was the diagnosis most likely to be missed before laparoscopy. These patients with TB were referred to the TB clinic at the hospital for treatment and also followed up in the infertility clinic. In india some studies have shown prevalence of 19% among women with infertility (47). The global prevalence of genital tuberculosis is 2-6% with a rising incidence, partly as a result of HIV pandemic and emergence of resistant strains (48).

Genital TB has profound implications because the multidrug therapy may adversely affect the pregnancy outcome (48). It is therefore important to probe for TB in a patient with infertility in a setting of HIV pandemic such as Kenya. In addition, a combination of methods including polymerase chain reaction (PCR) is more accurate (47-51).

Laparoscopic treatment for tubal and pelvic disease as was done in this study has been shown to avoid progression to In-Vitro Fertilization (IVF) (2,20). In their study, Levy et al found that when laparoscopy was recommended in cases with suspected bilateral tubal occlusion on HSG, it altered the original treatment plan in 30% of the patients from IVF to induction of ovulation with intra uterine insemination (IUI) (22).

Ablation and excision for endometriosis was done in 8.57% of the patients in this study(table 9). This procedure has been shown to improve fertility and pregnancy rates even in patients who may require IVF (52-54). In contrast, several randomized control trials have shown that hormone therapy for endometriosis does not improve fertility or pregnacy rates (55). Laparoscopic ovarian drilling was done in 6.29% of the patients in this study. This is associated with an ovulation rate of 80% and pregnancy rates of 82% at 24 months (56, 57).

In this study, most of the patients (56.97%) were advised to conceive without further intervention while 29.35% of the patients were advised to pursue IVF (table 9). There is certainly a great need for low cost Assisted Reproducitve Technologies (ART) in developing countries including Kenya (3,58). The provision of such services however need to be done with public education and awareness (39).

Adoption as a management option was recommended to 4.98% (20 out of 402) of the patients (table 9). Assuming the patients chose adoption, this adoption rate after infertility treatment is comparable with other studies done elsewhere. In a study of 1338 couples with infertility in USA, adoption of a child occurred in 5.9% of the couples (59). There is however a low acceptance rate of adoption in Kenya. Ondieki in her study in KNH found that 80% of couples with infertility did not favour adoption (60). The Infertility Survey in Kenya also showed that adoption was not favoured by infertile couples (3). In contrast, Wole in a rural survey in Uganda found that adoption was acceptable (61).

A small number of the patients (0.75%) were recommended for interventional radiology i.e tubal catheterization under fluoroscopic guidance (table 9). In a study of 110 infertile women on therapeutic effectiveness of tubal catheterization and fertility outcome, Papaioannou et al showed that 36.2% of the women conceived without IVF or Intra-cytoplasmic sperm injection (ICSI) after tubal catheterization (62).

The rate of complications from laparoscopy was found to be quite low in this study at only 1.5%. In contrast, Nderitu in his study at KNH in 2007 found that 8.7% of the patients had complications (34). However, in the study by Nderitu the sample size was 82 as compared to 402

in this study. Globally, complications of laparoscopy in gynecologic patients range from 0.1% to 10% (63).

CONCLUSION

There are significant findings in this study. Firstly, there is a shift in the mean age of women with infertility which calls for prompt evaluation and appropriate care. Secondly, tubal blockage was the most common laparoscopic finding and therefore appropriate management of PID and STI is important since these significantly contribute to tubal blockage and peritubal adhesions.

Thirdly genital tuberculosis and endometriosis are important causes of infertility in women. HIV/AIDS which is endemic in Kenya has been shown to increase the prevalence of tuberculosis globally (37, 54). According to the Kenya Aids Indicator Survey (KAIS) 2012, the prevalence of HIV among adults aged 15 to 64 years is 5.6% (64). Granted that in this study the link between HIV/AIDS and tuberculosis was not established. Nevertheless this calls for a high index of suspicion in the evalauation of women with infertility.

Lastly, nearly a third of the patients were recommended to pursue ART services. Therefore there is a great demand for affordable ART services in Kenya.These services need to be developed together with an effective referral system for infertility care in general. Despite the limitations of this study due to its retrospective design, it provides important knowledge and also forms a basis for other studies in the field of infertility.

RECOMMENDATIONS

1. There should be a standardized way of evaluating and reporting laparascopic findings such as endometriosis since this has implications on management.
2. The general evaluation of women with infertility should include probing for endometriosis and genital tuberculosis.
3. In cases of suspected (clinical) TB, a combination of diagnostic methods including use of Lowenstein-Jensen medium, pelvic and endometrial PCR in a TB endemic region such as Kenya to improve the diagnosis.
4. Histological evaluation of endometriosis should be done in a teaching and referral centre such as KNH.
5. There is need for affordable low cost ART services in Kenya as enviosined in the National Reproductive Health Strategy 2009-2015 especially in KNH since it is not only the premier referral and teaching hospital in the country and region but also the largest hospital in the eastern African region.

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APPENDICES

APPENDIX I:DATA RETRIEVAL FORM

A. Basic Information

1. Date ……
2. Study No …….
3. Hospital No ……

B. Socio-demographic Data

4. Age ……
5. Educational level
    1. None☐
    2. Primary☐
    3. Secondary☐
    4. Tertiary ☐
6. Religion……
    1. Protestant
    2. Catholic
    3. Muslim
    4. Other…….
7. Occupation ……
        1. Unemployed
        2. Casual worker
        3. Self employed
        4. Formal employment
8. Residence…….
        1. Urban
        2. Peri-urban

3. Rural
4. Other----------

C. History of Presenting Illness

9. Duration of Infertility (Years)……

10. Type of Infertility

1. Primary Infertility ☐
2. Secondary Infertility ☐

11. Seminalysis Done for Husband

1. Yes ☐
2. No ☐

12. Results of spouse

1. Normal ☐
2. Abnormal ☐

13. If secondary infertility, history of abortion

1. Yes ☐
2. No ☐

14. History of Prior Pelvic Inflammatory Disease

3. Yes ☐
4. No ☐

15. History of Prior Sexually Transmitted Infection (STI)

1. Yes ☐
2. No ☐

If yes, indicate type……

16. Any systemic illness

1. Diabetes ☐
2. Hypertension ☐
3. Other ☐(Indicate)…….

17. History of previous surgery

1. Yes ☐
2. No ☐

If yes indicate type of surgery ……..

D. Pre-operative diagnosis

18. What was the pre-operative diagnosis **(HSG)**

1. Tube blockage (indicate whether right or left)

Proximal ☐ Distal ☐

Unilateral ☐ Bilateral ☐

2. Uterine anomalies (Indicate type) ----------

E. Laparoscopic Findings

19. Date surgery planned…….

Date surgery done…….

20. Pelvic/Tubal Pathology (indicate whether right or left)

1. Tubal blockage

Unilateral ☐ Bilateral ☐

2. Hydrosalpinx

Unilateral ☐ Bilateral ☐

3. Pelvic adhesions

Yes ☐ No ☐

4. Endometriosis

Yes ☐ No ☐

5. Other Pelvic Pathology……..
6. No Pelvic Pathology noted ……

F. Treatment Option

21. Treatment Option given

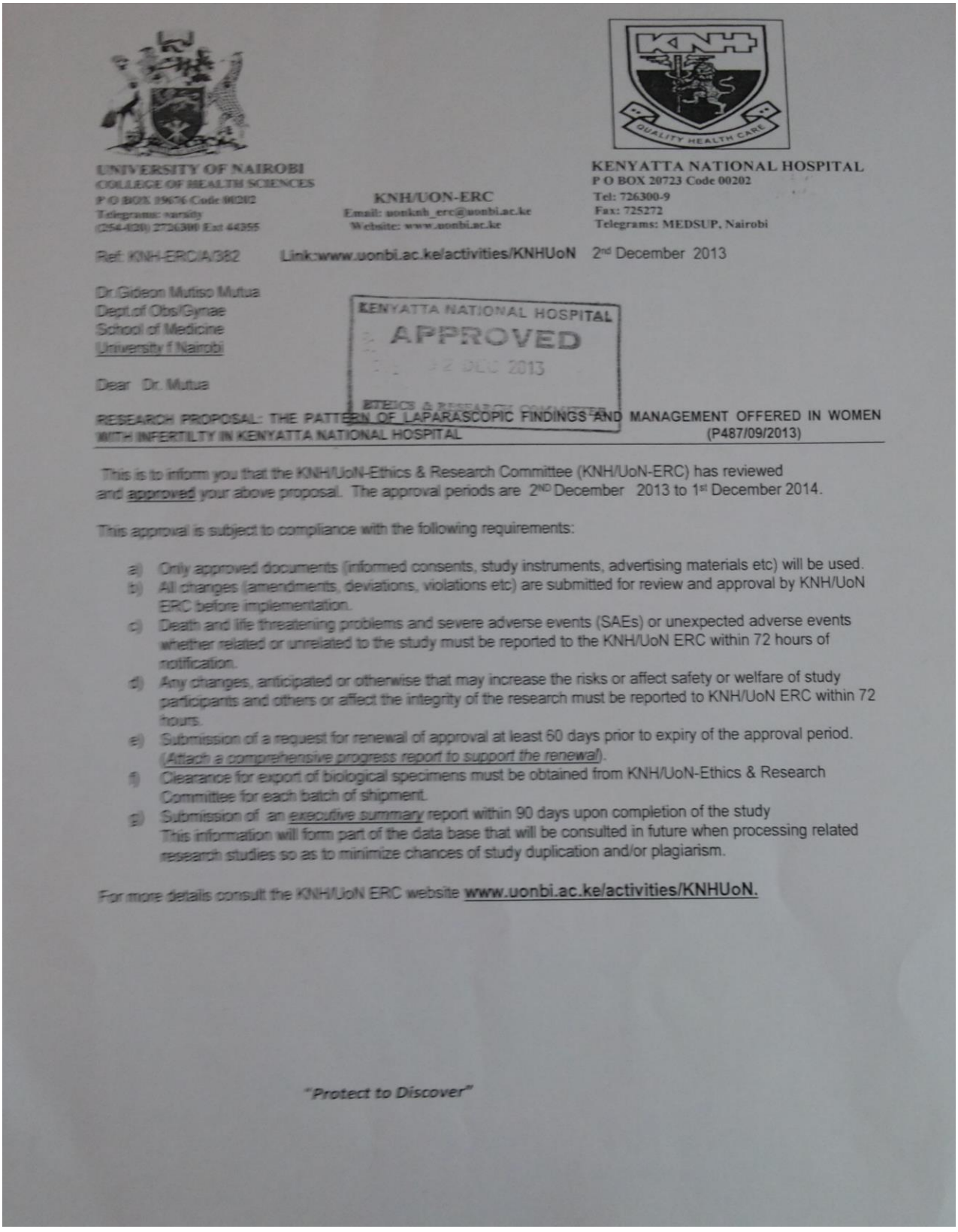
1. Salpingectomy ☐
2. Salpingostomy ☐
3. Adhesiolysis ☐
4. Fimbriolysis ☐
5. Hysteroscopy ☐
6. Conversion to laparotomy…….. (Mention procedure done)
7. Assisted Reproductive Technology (ART)----------
   (Mention whether IVF, IUI etc.)
8. Other treatment option……..... (Mention option given)

G. Complications of laparoscopy

22. Complications of laparoscopy

1. None
2. Gut injury
3. Urinary tract injury
4. Other injury (mention type……)

APPENDIX II: ETHICS APPROVAL LETTER



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Ref: KNH-ERC/A/382 Link:www.uonbi.ac.ke/activities/KNHUoN 2nd December 2013

Dr.Gideon Mutiso Mutua
Dept.of Obs/Gynae
School of Medicine
University f Nairobi

KENYATTA NATIONAL HOSPITAL
APPROVED
2013

Dear Dr. Mutua

RESEARCH PROPOSAL: THE PATTERN OF LAPARASCOPIC FINDINGS AND MANAGEMENT OFFERED IN WOMEN WITH INFERTILTY IN KENYATTA NATIONAL HOSPITAL (P487/09/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 2ND December 2013 to 1st December 2014.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

"Protect to Discover"

Yours sincerely

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. Prof. A.N.Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Dean, School of Medicine, UoN
The Chairman, Dept.of Obs/Gynae, UoN
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KNH/RH/16/Vol.1

DATE: 11th December, 2013

To

Dr. Gideon Mutiso Mutua
H58/70608/2011

RE: PERMISSION TO CONDUCT STUDY
THE PATTERN OF LAPAROSCOPIC FINDINGS AND MANAGEMENT OFFERED IN WOMEN WITH INFERTILITY IN KENYATTA NATIONAL HOSPITAL

Your letter on the above subject refers. The department of Reproductive Health has approved your study.

Please liaise with Assistant Chief Nurse Reproductive Health and In-charge clinic 18 to help you implement this.

KENYATTA NATIONAL HOSPITAL
HEAD OF DEPARTMENT
11 DEC 2013
OBSTETRICS & GYNECOLOGY
P. O. Box 20723 NAIROBI

Dr. Ndirangu Gathari
AG. SENIOR ASSISTANT DIRECTOR
REPRODUCTIVE HEALTH DEPARTMENT
KENYATTA NATIONAL HOSPITAL

CC: ACN– Reproductive Health
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