THE CAUSES AND PATTERN OF PRESENTATION OF MALE FACTOR INFERTILITY AS SEEN AT KENYATTA NATIONAL HOSPITAL

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H58/74857/2014

MBChB (UON)

A DISSERTATION SUBMITTED AS PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE (UROLOGY), UNIVERSITY OF NAIROBI

2020

DECLARATION

I certify that this dissertation is my original work and it has not been submitted for a degree in any other University.

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DEFINITIONS OF OPERATIONAL TERMS

1. **Fecundity -** This is the probability of achieving a live birth in the duration of 1 menstrual cycle.

2. **Fecundability -** This is the probability of achieving pregnancy in a single menstrual cycle.

3. **Infertility** - Referred to as the inability of a couple to conceive in 1 year of unprotected intercourse which should be of reasonable frequency. Reasonable frequency refers to a sexual frequency of 2-3 times a week.

4. **Male infertility** - Referred to as the inability of a man to achieve conception with his partner, after 12 months of regular unprotected sexual intercourse.

5. **Primary Infertility -** the inability to conceive in a patient who has never conceived in the past.

6. **Secondary Infertility** designates those who have conceived at some time in the past but currently cannot conceive.

7. **Sterility** is an intrinsic inability to achieve pregnancy.

LIST OF ABBREVIATIONS

FSH – Follicle stimulating hormone

KNH – Kenyatta National Hospital

LH – Luteinizing hormone

WHO – World Health Organisation

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ABSTRACT

BACKGROUND: Infertility is defined as the incapability of attaining a pregnancy after one year of regular unprotected intercourse. A considerable body of literature on the causes of female infertility exists, but there is a deficit of data on male factor infertility.

OBJECTIVE: To identify and describe the causes and pattern of presentation of male factor infertility at Kenyatta National Hospital.

METHODOLOGY: This was a cross sectional study conducted among patients with male factor infertility that underwent treatment at the Kenyatta National Hospital urological, gynaecological and the doctor's plaza clinics. Selection of participants was done in a nonrandomized consecutive sampling of eligible patients until the desired sample size was achieved. Informed consent was obtained from all the participants. A structured questionnaire was administered to the participants who consented to participate in the study. The collected data was uploaded to a password protected excel sheet for coding and analysis before analysis using SPSS version 22.0 software. Descriptive statistics for socio demographics such as age and smoking history were presented as proportions using pie charts and tables.

RESULTS: This study found 60.5% of male factor infertility to be due to unexplained factors, 31.6% due to varicoceles, 2.6% due to congenital factors and 5.2% due to ejaculatory duct obstruction. The mean age for the study participants was 34.7 years (standard deviation - 4.8). Most patients did not have clinical risk factors attributed towards male factor infertility. 71.5% of subjects reported a frequency of having sexual intercourse at least once weekly, 26.3% reported having sexual intercourse at least twice a month whereas only 2.6% reported of having sexual intercourse less than twice a month. Semen analysis was done on all the subjects who were included in the study. oligozoospermia was found to be the commonest

abnormality at 36.8%, azoospermia at 28.9%, asthenozoospermia at 8% and a combination of oligozoospermia and asthenozoospermia at 13.2%.

CONCLUSION: Male factor infertility is a common and distressing condition to a patient. Thus it is important to invest in diagnostic and treatment technologies locally to be able tackle this disease. Despite some limitations, the study provides a basis for further scientific research on male factor infertility in our setup.

1.0 INTRODUCTION

The International Committee for Monitoring Assisted Reproductive Technology, World Health Organization (WHO), defines infertility as a disease of the reproductive system that is defined by a failure to achieve a clinical pregnancy after 12 months (1 year) or more of regular unprotected sexual intercourse(1)(2). It is categorised as primary infertility if no previous pregnancies have taken place and secondary infertility if it took place after one or more pregnancies (3).

It is estimated that primary infertility affects 15% of couples in the reproductive age(4). Another 10 % of couples face secondary infertility(3). Approximately 35% are attributed to female factors alone, 30% to exclusively male factors, 20% due to both female and male factors, and 15% unexplained(5)(3). Therefore, male factor infertility is at least partly responsible for 50% of the cases of infertility(3). Conditions that cause male infertility are still widely underdiagnosed and undertreated.

The prevalence and pattern of presentation of infertility varies from country to country with the prevalence being more in the underdeveloped countries which have limited resources for diagnosis and treatment(6). This variance within the population is also influenced by sociocultural differences, the degree of promiscuity, prevalence of sexually transmitted infections and reproductive health behaviours(7).

Infertility should be seen as a public health problem, as it has an impact not only on the health care system but also on the social environment(6). The World Health Organization (WHO) had pronounced that where there is an infertility rate of more than 15% of couples, it should be recognized as a public health problem.

2.0 LITERATURE REVIEW

2.1 Background Information

Infertility can be described as the inability to conceive after 12 months of unprotected sexual intercourse with the same partner(8). Thus a couple should only be determined as infertile after one year of frequent sexual activity without using a contraceptive(6). For a young couple that is in a good healthy condition, the chances of achieving pregnancy per reproductive cycle is approximately 20-25%(6). The cumulative probability of conception is 60% within the first six months. This probability rises to 84% within the first year and a further 92% during the second year of fertility minded sexual activity(6).

Thus infertility is a common clinical problem that affects 13-15% of couples worldwide(6), i.e., 50-80 million people(9)(10). In one meta-analysis done, it was estimated that not less than 30 million men globally are infertile with the highest rates being found in Africa and Eastern Europe(11) Globally, the data regarding the rates of male infertility is inadequate, and it has not been precisely reported(11).

The prevalence of infertility varies throughout different countries with the prevalence found to be increased in the nations which are underdeveloped where limited resources for diagnosis and treatment exist(6). In some parts of sub-Saharan Africa infertility rates could be more than 30%(1)(12). In some countries especially Kenya, Gabon, Botswana, Zimbabwe there has been a trend towards lower fertility(1). Thus one of the most significant and least recognised reproductive health problems in developing countries is the high rate of infertility and childlessness(9).

The magnitude of infertility in Kenya remains inadequately determined, however a national infertility survey done in 2005/2006 showed that infertility cases contribute to approximately 30% of gynecological consultations at national referral hospitals, 15% of gynecological cases at district hospitals, 4% of gynecological cases in health centres and 2% of gynecological centres in dispensaries(13).

2.2 Presentation of male factor infertility

The pattern of presentation and the causes of infertility changes in various populations due to sociocultural differences and by the different levels of promiscuity, occurrences of sexually transmitted infections and the various reproductive health behaviours among these populations(14). A study done in 1982–85 involving various research institutions in collaboration with the WHO established that in 20% of infertility cases the problem was predominantly from the male partner, in 38% the problem was predominantly from the female partner whereas in 27% the problem was found in both partners. In the remaining 15% there was no obvious cause of infertility found(15). Males of a younger age represent over half of the male infertility cases within the United States of America(16). The usage of ambulatory surgery for male infertility was found to be higher amongst patients aged 25-34 years with a usage rate of 126 per 100000 compared to men aged 35-44 whose usage was 83 per 100000 while those aged 45 and older were at 20 per 100000 cases(16). A difference in the distribution of these cases was also noted in the United states of America whereby men who were living in the Western region had lower use of day care surgery compared with those in the Northeast and Midwest (29 per 100,000, 104 per 100,000 and 72 per 100,000, respectively) (16).

Globally, most cases of male factor infertility do not have an identifiable cause. The commonest cause of reversible male factor infertility is varicoceles(17). The other causes of male factor fertility in descending order of frequency are obstruction, cryptorchidism, immunologic causes, ejaculatory failure, endocrinological causes, drugs and radiation, genetic causes, testicular failure, sexual dysfunction, pyospermia, cancer, systemic diseases, infections, testicular torsion and ultrastructural defects(18). Male factor infertility in Kenya has been shown to be associated with tropical diseases such as Bancroftian microfiliarisis, leprosy, tuberculosis and schistomiasis(13).This study also showed hydrocele secondary to Bancroftian microfiliariasis to be associated with poor sperm quality and abnormal hormonal profile. There was also decreased semen quality in male with lepromatous and tuberculous leprosy(13). In another local study it was found that 49% of azoospermic males at Kenyatta National Hospital had a palpable epididymal abnormality with 11% had varicocele. A conclusion was thus made that the commonest cause of azoospermia in KNH, through the use of vasography, was obstructive lesions most likely as a consequence of urogenital infection(13). Occupation which involved riding a bicycle which is mechanical and has a nasal seat, has also been associated with erectile dysfunction in western Kenya(19). In a study conducted in southern Eastern Nigeria, the commonest abnormality found in male factor infertility was oligozoospermia (20).

Otwori et al in the analysis of causes and types of infertility amongst couples managed at KNH found that male factor infertility accounted for 13 cases (16.5%) out of 79 couples that were studied. In the analysis of semen parameters 6 of the cases had azoospermia, 38 had normal semen parameters whereas 33 had terato oligozoospermia. He also found that the mean age of males in the infertile couples was 37.1(SD 8.7) and that most of these men were

monogamous in their first marriage, most had either secondary education or collage education, most were self-employed, only 26.8% smoked and 34.5% took alcohol. Of the male patients with male factor infertility, 3 had a history purulent discharge from the urethra, 5 had a history of mumps, 5 had acute scrotal pain 6 had erectile dysfunction whereas 3 had ejaculatoty problems(13). Ondieki et al found that male participation improves the quality of care for an infertile couple. The men who accompanied their spouses for treatment of infertility were likely to be investigated. Regardless the male partner had limited knowledge on fertility, causes of infertility and treatment options compared to their spouses(10).

However, the frequency with which these causes of male factor infertility are encountered in the course of medical practice has not been well documented and this had led to a paucity of data on the causes and pattern of presentation of male factor infertility globally(18). The complication of infertility that is found in sub-Saharan Africa is that it is eclipsed by the regions high fertility rates thus giving rise to concerns of high fertility and population growth that is not in tandem with the perception of infertility as a problem(21). This is a problem that has economic, medical and psychological implications resulting in stress and trauma especially in a social set up that puts a lot of importance on child bearing(1). Male factor infertility is usually seen as an issue that no one wants to accept that it exists(21). It is usually approached with secrecy to try and protect the dignity of the male partner(21). This denial of the problem forces women to be more tenacious in seeking treatment. This leads to an unnecessary burden upon the limited reproductive health resources found in developing countries(21).

2.3 Reasons for male factor infertility underreporting in the African set up

The female partner is mostly held responsible as the cause of infertility. This leads to lack of fertility evaluation of the men, thus the underreporting. The custom of marrying more than one wife reduces discordancy and this leads to increased chances of conceiving.

Male infertility is usually considered a taboo hence some cultures allow a male relative to make pregnant the spouse of a man with male factor infertility.

For the above reasons males who present themselves to infertility clinics usually represent a small group who generally do not represent the larger population of infertile men.

2.4 Causes of male factor infertility

Male fertility depends on the production of adequate numbers of mature spermatozoa and a patent conduit for their transport into the female. Also secretions from the prostate gland and seminal vesicles act as the vehicle for the successful transportation and nourishment of the sperms. Thus the cause of infertility may be either lack of spermatogenesis or faulty transport of spermatozoa.

Infertility can be grouped as primary i.e. when there has been no conception/pregnancy ever, or it can be secondary, where there has been a pregnancy/conception previously irrespective of the outcome. Primary and secondary infertility has been established in 67%–71% and 29%–33% of infertile patients, respectively(17). Male infertility is a complex syndrome that involves a wide variety of disorders. In more than half of men with male factor infertility, the cause is known, but approximately 10% of male factor infertility is unknown(17).

The known causes of male factor infertility are many. They can be put into a variety of major classifications(17). Male factor infertility can be classified to be due to pretesticular, testicular and post-testicular factors(15). The commonest causes of male infertility are discussed as follows:

2.4.1 Varicoceles – These are the most common detectable cause of male factor infertility. It is a condition that is characterised by distended veins of the pampiniform plexus of the spermatic cord(17). They cause impaired spermatogenesis through a variety of mechanisms. These include causing hyperthermia within the testes, alterations in the testicular blood flow, increased venous pressures within the pampiniform plexus, renal/adrenal metabolic product reflux to the testes, inducing hormonal dysfunction, disruption in the blood testicular barrier leading to anti-sperm antibodies, induction of oxidative stress and impairing the acrosome reaction(22)(23).

2.4.2 Ductal Obstruction – The most commonly seen obstruction is epididymal obstruction, as a result of epididymitis with infections like tuberculosis and gonnorhea(18). The azoospermia that accompanies the obstruction can be treated by performing an epididymovasostomy. Testicular biopsy should a be done to demonstrate the presence of spermatogenesis before relieving the obstruction(24). Scrotal sonography, transrectal sonography, endorectal MRI and surgical vasography can be used in the assessment of ductal obstruction. Ductal obstruction can be treated either by microsurgical reconstruction of the vas deferens and epididymis or by transurethral resection of the ejaculatory ducts.

2.4.3 Cryptorchidism - High intra-abdominal temperatures exposes undescended testes to impaired spermatogenesis(25). Cryptorchidism also leads to abnormal gonocyte

maturation(25). It is usually a preventable cause of infertility as early intervention, orchidopexy, can reverse the damage to the testes(18). It is also true that some undescended testes are pathologic from the onset(18).

2.4.4 Immunological Causes – Gamate damage that is secondary to antisperm antibodies is a major cause of male factor infertility(17). Suspected immunological male factor infertility was seen in approximately 3% of couples in a WHO survey. They found >10% of motile spermatozoa were coated with antibody using various assays.(26).

2.4.5 Ejaculatory Failure – Anejaculation and retrograde ejaculation can contribute to male factor infertility(27). Retrograde ejaculation could be the first sign of diabetic complications e.g. neuropathy, and may be a beginning of total ejaculatory impotence. Unfortunately this cannot be corrected by careful control and treatment of the diabetes(28).

2.4.6 Endocrinological Causes – Some of these causes are due reduced of pituitary gonadotropin production and this can be remedied using gonadotropins successfully. Adrenogenital syndrome can lead to a low sperm count with poor sperm motility with an increase in the immature forms of sperms in the ejaculate. This picture can be seen in varicocele patients thus this should be ruled out by doing the 17-ketosteroid and pregnanetriol studies in those patients who have varicocele. Corticoids supplementation is usually the effective mode of treatment(18). Congenital GnRH deficiency (Kallmann syndrome), a genetically heterogeneous developmental disease with different modes of transmission can

also contribute to endrocrinological causes of male factor infertility(29). Thyroid gland diseases can also contribute significantly in male factor infertility(18).

2.4.7 Drugs and Radiation – A number of drugs and radiation can affect the normal semen parameters of an individual and they can also cause reduction in semen volume. Some of the drug categories that have been associated with this include antibiotics (amoxicillin, tetracycline, co-trimoxazole, and erythromycin), alcohol, marijuana, tobacco, steroids, cocaine, heroin and chemotherapy(30).

2.4.8 Genetic and Congenital Causes - Klinefelter syndrome is the most frequently encountered chromosomal male anomaly that is linked to male infertility. Aneuploidy is the most frequently encountered chromosomal error identified in infertile men. The most frequently encountered of these are the mixed gonadal dysgenesis, Y chromosome microdeletions, XX male syndrome and autosomal translocations. There is progressive deterioration in testicular function as testicular architecture is replaced initially by either tubular atrophy, sclerosis or maturation arrest and ultimately degenerates to fibrosis and hyalinised tissue(31). Other congenital causes of infertility include multi-organ genetic disorders (Laurence-Moon-Beidl syndrome, Prader-Willi Syndrome) and congenital GnRH deficiency (Kallmann syndrome),

2.4.9 Testicular Failure – Testicular failure can be due to germ cell aplasia, kleinfelters syndrome, mumps orchitis and also sperm maturation arrest. These can lead to various anomalies in the spermiogram, and thus contribute in male factor infertility(18).

2.4.10 Cancer Treatment – In the treatment of testicular cancer, orchiectomy with radiation therapy reduces fertility. However if the remaining testis is found to be normal, significant fertility may not be lost(18). Initially, radiation therapy causes the absence of sperms within several months. The quality of the semen usually goes back to pre-treatment levels within 3-4 years after the radiation therapy(18). Permanent azoospermia is as a common side effect of cancer chemotherapy(30).

2.4.11 Systemic Diseases – Several diseases are associated with male factor infertility, either directly indirectly as a consequence of systemic disturbance. Infertility can also arise as a result of medical or surgical intervention towards the primary disease. Some systemic diseases associated with infertility include diabetes, renal failure, hepatic failure, pituitary failure, tuberculosis, syphilis, paraplegia, bronchiectasis, Kartagener's syndrome(26).

2.4.12 Testicular Torsion/ Testicular Trauma/ Surgical Injuries - Torsion of testis should be diagnosed and treated as soon as possible so as to preserve the viability of the testis. The contralateral testis should undergo orchidopexy prophylactically otherwise a risk of losing both testes with resultant infertility may occur(18). Acute testis trauma with disruption of the tunica albuginea requires quick surgical intervention to preserve the testis. Bilateral injuries

may lead to impaired fertility(18). Testicular atrophy and vasal injury following inguinal and scrotal surgeries usually occur. Thus caution must be observed during inguinal and scrotal surgeries(18). Testicular biopsies should also be done with caution as inadvertent biopsy of the epididymis bilaterally can lead to infertility(18).

2.4.13 Occupational and Environmental Causes – The effects that occupational hazards have on male factor infertility remains debatable. Heavy metals exposures to lead, arsenic, zinc and cadmium have been reported to interfere with sperm production even though the data remains controversial. A number of herbicides and pesticides have been found to be toxic to sperm production as have some organic chemicals. The effects of occupational heat exposure with its effect on sperm production remains controversial (28). Some environmental factors are usually considered as influencing factors for infertility, e.g., alcohol use and smoking(32).

2.5 Management of male factor infertility

The management of male factor infertility is usually directed according to the cause of infertility i.e. according to testicular factors, according to ductal (obstructive) factors and finally according to hormonal and sexual factors.

Thus the pragmatic management of male factor infertility requires proper timing of suitable investigations and proper timing of the beginning of treatment to prevent both over and under treatment(2). The assessment of the male patient who has infertility is often misconstrued and

often postponed(6). Thus it is recommended that the male factor infertility patient must be methodically assessed in every investigation of an infertile couple (33).

Investigations can be started sooner when risk factors for male factor infertility exist. These can include a history of urological surgery, maternal age > 35 years, cancer, cryptorchidism, orchitis, paternal age > 45 years, varicocele, use of gonadotoxins and history of genital infections among others(6).

A reduction in the general health status within the population appears to be linked to reduction in the male reproductive health which includes a lowered concentration of sperms, a reduced total testosterone levels, and a higher FSH levels(34). In about one percent of the cases, male factor infertility may be the manifestation of a more serious or potentially fatal disease such as brain or testicular cancer, medullary spinal cancer, genitourinary malformations, endocrinopathies, systemic diseases, and certain genetic syndromes(6). Thus it is essential to have this in mind while managing male infertility patients since their health status and fertility are closely intertwined(34).

The diagnostic assessment of male factor infertility usually starts with a detailed history taking followed by physical examination and semen analysis(35). The use of genetic and hormonal assessment is usually done when indicated(35). Semen analysis is the cornerstone for evaluating male infertility(5). Up to 25% of male patients exhibit abnormal semen analysis for which there is no identifiable aetiology(36). One study has shown a decline in sperm quality over 50 years. This was shown by a pronounced reduction in the mean sperm

count and seminal volume with an even more significant reduction in sperm production and consequently a decrease in sperm density(37). This may indicate an overall reduction of fertility over time.

The fertility of a male partner also relies on a functional hypothalamic-pituitary-testicular axis to start and maintain a qualitative and quantitative normal sperm production(4). Thus the hormonal characteristics of the infertile male patient have to be studied. Up to 20% of male infertility can be attributed to endocrine disorders(38). This is important to note because most of these causes are treatable. Hormones initially evaluated for infertility in males include FSH, LH, testosterone, and prolactin(38). The treatment of male factor fertility is usually tailored to the cause.

2.6 PROBLEM STATEMENT

As earlier stated, male factor infertility is estimated to at least be partly responsible for 50% of the cases of infertility amongst couples globally. Conditions that cause male infertility are still widely underdiagnosed and undertreated. Many factors have been attributed to this problem of underreporting and underdiagnosing that has been showed to be compounded by the high fertility rates especially in sub Saharan Africa. Subsequently this has resulted in a paucity of data on the causes of male factor infertility and how the disease presents. Locally, there has been no study that has exclusively focused on causes and presentation of male factor and this study is likely to provide crucial basic information on this important subject.

2.7 SIGNIFICANCE OF STUDY

The significance of the study is that it will provide the crucial basic information on male factor infertility as this population has not yet been studied in isolation. Most of the data that is available presently is through study of this population as a couple. This can lead to formulation policy guidelines on how to manage male factor infertility. The scope of the study is to define the presentation of male factor infertility by getting to know the causes, their frequencies, associated factors and also the characteristics of the affected populations.

Assumptions are that the causes and pattern of presentation may differ from the other studies that have been done from the focus of couple e.g. In this study, there will be inclusion of patients from the urological clinic who were not captured in the study done by Otwori et al which focused on couples who had presented only in the gynaecological clinic at KNH.

Another assumption is that the burden of varicocele induced infertility may be underreported as the numbers of these patients are significant.

2.8 STUDY JUSTIFICATION

Male factor infertility contributes significantly to all cases of infertility worldwide. Testicular failure secondary to varicoceles has been found to be the commonest cause of reversible infertility amongst men. Obstruction of the vas deferens and epididymis (mostly secondary to infections), cryptorchidism and the presence of sperm autoantibodies also play a major role in male factor infertility. Most of these conditions are common in our setup and yet the incidences of male factor infertility remain low.

Regardless, there is a paucity of data on male factor infertility compared to female factor infertility. Also, conditions of the male that affect fertility are still generally underdiagnosed and undertreated.

Thus this study aims to provide crucial necessary information on male factor infertility in our local setup. It will also provide data that is necessary in planning and restructuring of the management of infertile male patients to provide services more efficiently by formulation of targeted management strategies. Furthermore, it forms a baseline for local male factor infertility situation and further scientific research on male factor infertility.

2.9 RESEARCH QUESTION

What are the causes and pattern of presentation of male factor infertility as seen at the Kenyatta National Hospital?

2.10 STUDY OBJECTIVES

2.10.1 Main Objective

- To identify and describe the causes and pattern of presentation of male factor infertility at Kenyatta National Hospital.

2.10.2 Specific Objectives

- To identify the causes of male factor infertility at Kenyatta National Hospital.
- To describe the pattern of presentation of male factor infertility at Kenyatta National Hospital.

2.11 CONCEPTUAL FRAMEWORK

Male factor infertility is associated with multiple factors which are usually interdependent in many cases. These factors include demographic, environmental, medical, personal and lifestyle factors. Lifestyle factors may include taking alcohol, smoking, taking drugs, engaging in risky sexual acts or behaviours. These can have some contribution towards male factor infertility.

Social factors which may include education level, religion, marital status, may assist in determining the cause of infertility because they may directly or indirectly influence infertility.

Medical factors that may have impact on the fertility of a male individual may include infections, chronic illnesses, anatomical defects and congenital disorders. Medical factors may be influenced by demographic or personal factors to affect male factor infertility.

Personal factors which include age, social class, and educational level may also affect male factor infertility. These factors are usually self-reported functional status showing the significance of social support. These factors may directly or indirectly cause or influence a person's fertility status.

Occupational and environmental factors such as exposures to chemicals, heavy metals, climatic conditions have an influence on a living organism in one way or another. Heavy metals have been associated with a decrease in fertility. Apart from being influenced by personal factors to influence infertility, environmental factors may also influence lifestyle to take the same course.

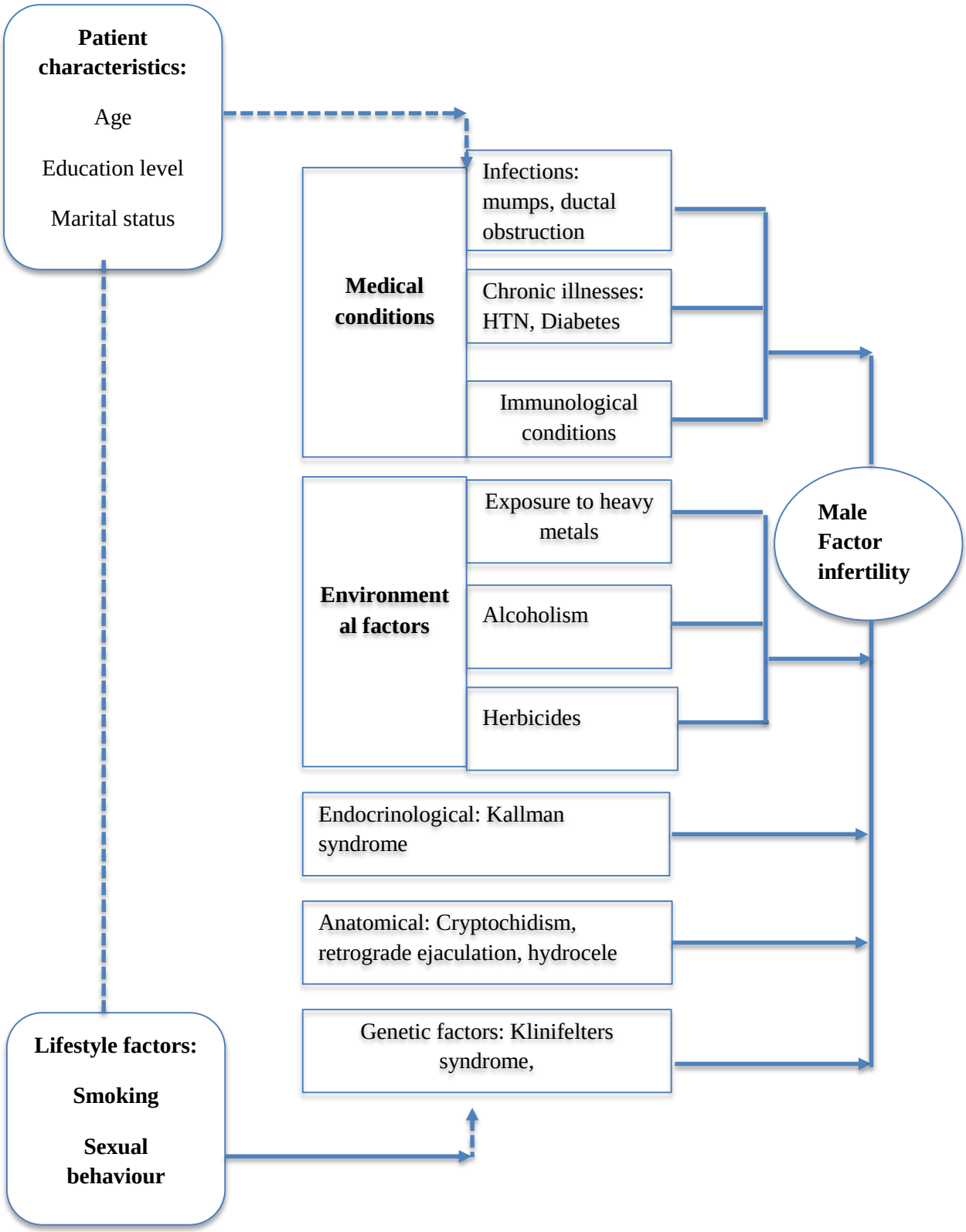


Figure 1: Conceptual Framework

3.0 METHODOLOGY

3.1 STUDY DESIGN

The study was a cross sectional study design

3.2 STUDY AREA

The study was conducted at the Kenyatta National Hospital urological clinic, gynecological clinic, and the doctor's plaza clinics. KNH is a teaching hospital for the University of Nairobi, Faculty of Medicine and visiting students from other institutions. The hospital offers comprehensive speciality services including surgical and obstetrics and gynecology departments. In addition, it has a private wing for both inpatient and outpatient services (the Doctors Plaza). These departments also run specialty clinics including fertility clinics.

3.3 STUDY POPULATION

The study population was all the patients with male factor infertility that attended the urological, gynaecological and doctors plaza clinics within the confines of Kenyatta National Hospital. The study population was taken through the consent form in a language that they best understood and in the presence of a language barrier; a translator was used to translate the message between the researcher and the study participant.

3.4 SAMPLE SIZE CALCULATION

The sample size was calculated using the formula for a descriptive study. The estimated prevalence of male infertility in sub-Saharan Africa is 2.5 to 4.8%(11). Thus the estimated prevalence of 2.5% was used to estimate the sample size.

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

Where Z = Z statistic for a level of confidence

P = expected prevalence of male infertility.

n = sample size

d = precision

In proportion of one; if 5%, d = 0.05

For the level of confidence of 95%, Z value is 1.96

$$n = \frac{1.96^2 \times 0.025(1-0.025)}{0.05^2}$$

n = 38

3.4 SAMPLING TECHNIQUE

Selection was done in a nonrandomized consecutive sampling of eligible patients until the desired sample size was achieved.

3.5 INCLUSION CRITERIA

1. All the patients with a confirmed diagnosis of male factor infertility that will have consented to participate in the study.

3.6 EXCLUSION CRITERIA

1. Patients who do not wish to partake in the study.
2. Patients who have already been treated for male factor infertility.
3. Patients who have stayed for less than a year (12 months) trying to conceive.

3.7 DATA COLLECTION

Data collection was done by the principal investigator and a research assistant who administered a pretested structured closed ended questionnaire and they also obtain more information from case notes after the patient had been attended to. The research assistant was trained in data collection and research ethics. Strict confidentiality was maintained throughout the whole process. All personal identifiers were removed from the questionnaires and assigning of questionnaire codes was done randomly. Completed questionnaires were then coded for ease of data entry. Data was cleaned and entered in IBM SPSS statistics version 22. The data was then entered into a password protected computer database by the principle investigator. In addition, the questionnaires and study records were kept in a lockable cabinet only accessible to the principle investigator and statistician.

3.8 DATA QUALITY CONTROL

The questionnaire was pretested at the KNH urology, gynaecology and doctors plaza clinics. The questionnaire was further analysed for any flaws in the design and clarifications on questions were identified and corrected before being administered to the participants. The same questionnaire was then used on all participants. So as to prevent double recruitment, the file numbers of the participants was put down into a register after being recruited for serialization purposes. Counter-checking of the register was done regularly so that if there was any double entries discovered, these records/questionnaires were removed and gotten rid of. The serialization was then rectified before recruitment continued. The quality of the data was further enhanced at all steps of data collection, entry and analysis. The quality of data was also assessed by conducting consistency checks.

3.9 DATA ANALYSIS

The collected data will be entered cleaned, coded and analysed by use of the Statistical Package for Social Sciences version 22.0 (SPSS 22.0). Continuous variables such as age were summarized by using means and standard deviations. Comparison of continuous variables was to be done using the student t-test for normally distributed variables. Categorical variables such as sex, occupation, level of school attended was to be summarized by using proportions, frequency tables and graphs where applicable. The associations of categorical variables were to be demonstrated by using the chi square tests and all statistical tests were to be performed at 5%significance level (95% confidence level). Patients' characteristics were represented in the form of tables which illustrated the distribution of social, economic demographic and reproductive health characteristics.

3.10 ETHICAL CONSIDERATIONS

Ethical approval was sought from the department of surgery (UON) and KNH Ethics and Research Committee

Pre-consent counselling was done followed by obtaining informed consent before enrolment into the study.

Patients who consent to inclusion into the study were guaranteed the utmost observance of confidentiality and were allowed to drop out at any time during the study period.

Raw data was to be destroyed pending completion of the study.

Those who decline participation were not denied treatment.

The study participants were not to incur any extra financial costs.

The principal investigator did not benefit in monetary terms from this study.

The results will be published to allow other medical practitioners to benefit from the study.

Upon approval of the study proposal by the UON-KNH ERC, permission was sought from the KNH research committee to conduct the study.

3.11 STUDY LIMITATIONS

1. Lack of uniform standards especially in semen analysis because of the use of different laboratories. This was overcome by including only those results coming from ISO certified laboratories.

2. Recall bias for patients as certain answers required recall. Patients were given ample time to answer the questions

3. Case records can be incomplete.

4. Some subjects may have had questionable sexual behaviours and may have given what they think are socially correct responses instead of the truth. This was overcome by ensuring confidentiality to the patients.

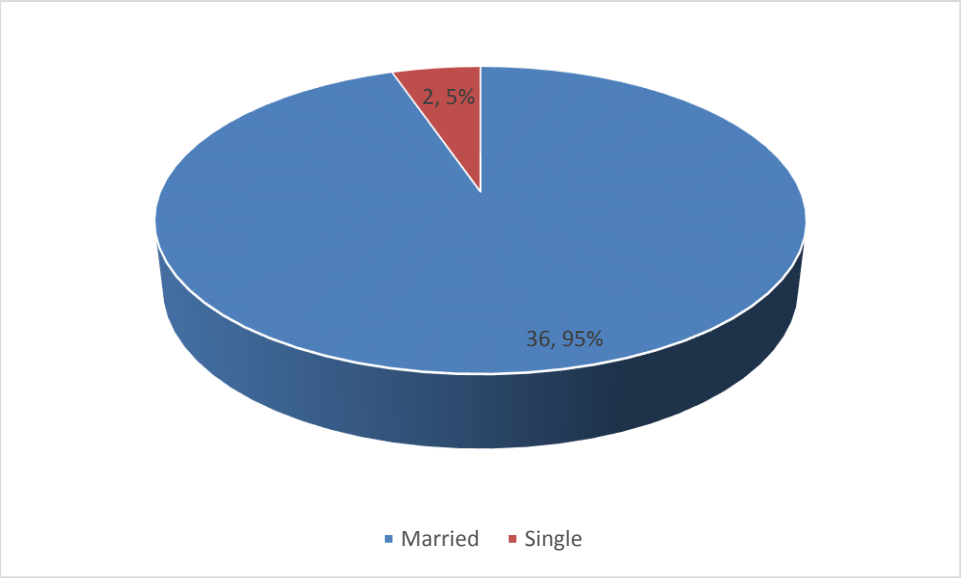
5. Patients might refuse to consent to participate in this study. The researcher overcame this challenge by sensitizing the study participants on the importance of the study, and ensured that there will be no harm to them.

6. Low turnout of patients in the clinics. This was overcome by collaborating with the staff in the clinics to disseminate information concerning the research and also by putting posters in the respective clinics such that all patients who may present themselves may be captured in the study.

4.0 RESULTS

The mean age for the study participants was 34.7 years (standard deviation - 4.8)

1. **Marital status**



A majority of the participants, 36 (95%) were married, while only 2, (5%) were single.

2. Socio Demographic and Medical Characteristics

Variable		Frequency	Percentage
Level of Education (38)	Secondary	04	10.6
	College	13	34.2
	University	21	55.2
Occupation (n=38)	Employed	24	63.5
	Self Employed	12	31.6
	Un employed	02	05.3

A majority of the participants, 21, had acquired University level of education (55.2%), followed by 13 at College level at 34.2% then 4 at Secondary level at 10.6%. In terms of employment, 24 of the participants (63.5%) had been employed, 12 (31.6%) were self-employed while 2 (5.3%) were unemployed.

3. Environmental and Social Exposures

Variable	Response	Frequency	Percentage
History of Smoking (n=38)	No	38	100
	Yes	00	00
History of Alcohol intake (n=38)	No	26	68.4
	Yes	12	31.6
History of Drug Abuse (n=37)	No	37	100
	Yes	00	00

Among the 38 respondents, none of had a history of smoking. However, 12, 31.6% had a history of alcohol intake. None of the 37 responds indicated to have used drugs of abuse

4. Clinical Characteristics: Past History of Exposure to Pre disposing factors

Variable	Response	Frequency	Percentage
Ever Impregnated	No	30	78.9
	Yes	08	21.1
History of Urethral Discharge	No	36	94.7
	Yes	02	05.3
History of Mumps	No	38	100
	Yes	00	00
History of Scrotal Swelling	No	38	100
	Yes	00	00
History of Acute testicular pain	No	38	100
	Yes	00	00
History of Trauma to the Groin	No	38	100
	Yes	00	00
History of Chronic Illness	No	38	100
	Yes	00	00
Use of Long Term Medication	No	38	100
	Yes	00	00
History of Surgery of the Groin	No	38	100
	Yes	00	00
History of Congenital Syndrome	No	37	97.4
(Zinner syndrome)	Yes	01	02.6

From the output above, out of 38 participants 08 (21.1%) ever impregnated a lady whereas 30(78.9%) did not.

The output on history of urethral discharge indicates that out of the 38 participants, those with a history of urethral discharge were 02(05.3%) whereas those without a history of urethral discharge were 36(94.7%).

The output on history of mumps shows that out of the 38 participants, those without a history of mumps were 38(100%), therefore no one had a history of mumps.

The output on history of scrotal swelling shows that out of the 38 participants, those without a history of scrotal swelling were 38(100%), therefore no one had a history of scrotal swelling.

The output on history of acute testicular pain also shows that out of the 38 participants, those without a history of acute testicular pain were 38(100%), therefore no one had a history of acute testicular pain.

The output on history of trauma to the groin indicates that out of the 38 participants, those without a history of trauma to the groin were 38(100%); therefore no one had a history of trauma to the groin.

The output on history of chronic illness shows that out of the 38 participants, those without a history of chronic illness were 38(100%), therefore no one had a history of chronic illness.

On the use of long-term medication, 38(n=38), 100% of the respondents were found of not using long-term medication. Zero respondents used long-term medication as per the analyzed data.

The output from the analyzed data also shows that none of the 38 respondents had a history of surgery of the groin as from the above output. This means that 38 out 38 respondents, 100% were free from history of surgery in the groin.

The output on history of congenital syndrome (Zinner syndrome) indicates that out of the 38 participants, those with a history of congenital syndrome were 01(02.6%) whereas those without a history of congenital syndrome were 37(97.4%).

To sum up on the analytics of clinical characteristics, a majority of the respondents did not have past history of exposure to the suspected predisposing factors (testicular pain, trauma, and swelling).

5. **Sexual Intercourse Frequency**

Variable	Frequency	Percent
At least once weekly	27	71.5
At least twice a month	10	26.3
Less than twice a month	01	02.6

A majority of the study participants, 26 (68.5%) had sex at least once per week, followed by those who had sex at least twice per month (26.3%), 1 each (2.6%) for those who had sex at least once weekly and less than twice a month respectively.

6. Physical assessment and Investigations for reduced fertility in men

Variable		Frequency	Percentage
Erection	Inadequate	06	15.8
	Normal	32	84.2
Ejaculation	Normal	38	100
	Abnormal	00	00
Varicocele	No	25	67.5
	Yes	12	32.3
Un descended testis	No	38	100
	Yes	00	00
Testicular mass	No	38	100
	Yes	00	00
Palpable Vas Deferens	No	00	00
	Yes	38	100
Seminalysis done	No	38	100
	Yes	00	00
Seminalysis Results	Asthenozoospermia	08	21.1
	Asthenozoospermia + Oligozoospermia	05	13.2

	Azoospermia	11	28.9
	Oligozoospermia	14	36.8
Hormonal profile done	No	03	07.9
	Yes	35	92.1
Specificity	Low testosterone	01	02.6
	Low testosterone	01	02.6
	Normal	31	81.6
	Slightly low testosterone	01	02.6
Testicular Biopsy Done	No	31	81.6
	Yes	07	18.4
Outcomes of the Biopsy	Few Mature Spermatozoa	01	14.2
	Maturation arrest	06	85.8
Transrectal Ultrasound Done	No	36	94.7
	Yes	02	05.3
Ultrasound Results	Ejaculatory Duct Obstruction	01	
	Left ejaculatory duct Obstruction	01	

From the output above, participants with normal erection were 36(n=38), 84.2% whereas those with inadequate erection were 06(n=38), 15.8%.

The output on ejaculation shows that all of the 38(n=38), 100.0% respondents had a normal ejaculation, and therefore no one had an abnormal ejaculation 0(n=38), 0.0%.

The output on varicocele shows that out of the 38 respondents, 12(32.3%) of them had a variocele whereas 25(67.5%) did not have (no) 38(n=38).

The output on undescendent testis shows that all of the 38(n=38), 100.0% respondents did not have an undescendent testis, and therefore no one had an undescendent testis.

The output on testicular mass shows that all of the 38(n=38), 100.0% respondents did not have a testicular mass.

The output on palpable vas deferens indicates that 38(n=38) of the participants had a palpable vas deferens whereas none of them lacked vas deferens.

The entire 38 (100%) respondents accepted seminalysis test to be done .This is as per the output on the seminalysis done.

As per the output on the test results on seminalysis, 8 respondents(n=38),21.1% had Asthenozoospermia ,5(=38) ,13.2% had both Asthenozoospermia and Oligozoospermia ,11(n=38) ,28.9%% had Azoospermia ,and lastly 14(38) ,36.8% had Oligospermia.

The output on hormonal profile indicated that 35(n=38), 07.9% had a hormonal profile done whereas 03(n=38), 92.1% participants didn't have a hormonal profile done on them.

Participants specificity was also carried out on the 38 respondents and these were the results that were obtained ,1(n=38) ,02.6% specified mild ,1(n=38) ,02.6% specified mild testosterone

,31(n=38) ,81.6% specified normal ,and last one(02.6%) respondent specified slight testosterone .

From the output on testicular biopsy done, 07(n=38), 18.4% participants had the testicular biopsy done whereas 31(n=38) participants didn't have the biopsy done on them. This was represented by 81.6%.

The output on the outcomes of the biopsy indicates that 01(n=38), 14.2% participants had few mature spermatozoa whereas 06(n=38), 85.8% had maturation arrest.

The output on transrectal ultra sound done shows that only 2(n=38), 05.3% of the participants had the transrectal test done whereas 36(n=38), 94.7% did not have the transcretal ultra sound done.

From the output on the ultrasound results, 1(n=38), 02.6% participant had ejaculatory duct obstruction, another 1(n=38), 02.6% participant had a left ejaculatory duct obstruction.

7. Causes of infertility

Among patients with fertility causes, only 15 (39.5%) had a known cause of fertility as classified below:

Variable	Frequency	Percentage
Unexplained	23	60.5
Varicocele	12	31.6
Congenital (Zinner syndrome)	1	2.6
Ejaculatory duct obstruction	2	5.2

8. Causes of infertility vs Seminalysis

	Asthenozoospermia	Asthenozosspermia + Oligozoospermia	Azoospermia	Oligozoospermia
Unexplained	6	0	5	11
Varicocele	2	5	3	3
Congenital(Zinner syndrome)	0	0	1	0
Ejaculatory duct obstruction	0	0	2	0

Unexplained fertility had 6 (27.3%) patients with asthenozoospermia, 5 (22.7%) with azoospermia and 11(50%) with oligozoospermia.

Varicocele had 2 (15.4%) patients with asthenozoospermia, 5 (38.5%) patients with both asthenozoospermia and oligozospermia, 3 (23.1%) patients with azoospermia and 3 (23.1%) with oligozoospermia.

Congenital causes (Zinner syndrome) had only 1 (100%) patient with azoospermia.

Ejaculatory duct obstruction had 2 (100%) patients with azoospermia.

9. Testosterone levels vs seminalysis results

	Asthenozoospermia	Asthenozosspermia + Oligozoospermia	Azoospermia	Oligozoospermia
Low testosterone levels	0	0	2	1
Normal testosterone levels	8	4	9	11

35 out 38 patients had hormonal profiles done, mainly testosterone levels.

3 out of 35 patients had low testosterone levels. Two of these patients had accompanied azoospermia whereas one had oligozoospermia.

33 patients had a normal hormonal profile i.e. normal testosterone levels.

5.0 DISCUSSION

A hospital based descriptive study was carried out from January to July 2019 to determine the causes and pattern of presentation of male factor infertility as seen at Kenyatta National Hospital in Nairobi, Kenya. This study found 60.5% of male factor infertility to be due to unexplained factors, 31.6% due to varicoceles, 2.6% due to congenital factors (zinner syndrome) and 5.2% due to ejaculatory duct obstruction. This compares with the global data on varicoceles as a cause of infertility whereby it has been shown that varicoceles are found in 19 to 41% of men with infertility(22). The rate of unexplained infertility appeared to be high (60.5%) as compared to a global estimate of 50%(1). This can be attributed by the fact that majority of the cases of male factor infertility are mostly caused by an intratesticular disorder(1). Also about 10% of male factor infertility is due to chromosomal translocations and this information was not available amongst the study subjects(1).

The mean age of the study population was 34.7 years. This compares well with a study done by Meacham et al whereby he found that most of the patients seeking ambulatory surgery visits for males with infertility were between the ages of 18 – 34 years(16). Most of the patients were married 95% whereas only 5% were not married. Those patients who were single had an obvious cause of reduced fertility i.e. varicocele. Most of the male factor infertility patients had primary infertility (78.9%) as opposed to (21.1%) who presented with secondary infertility. This varies as compared to a local study done by Gachara et al who found that 65% of couples had secondary infertility whereas 35 % of couples have primary infertility(13). The difference could be due to the component that the female factor infertility is involved when infertility is studied amongst a couple.

On the clinical characteristics which may implicate a risk factor towards the subject's status of infertility, only 2 patients were found to have a history of a urethral discharge (implicating

infections). None of the subjects had a history of mumps, scrotal swelling, acute testicular pains, testicular trauma, chronic illness, long term medication or surgery to the groin. This thus resulted to the high numbers of subjects with unexplained infertility (60.5%) that was discussed earlier.

Since infertility can be described as the inability to become pregnant after 12 months of regular unprotected sexual intercourse with the same partner(8), the frequency of sexual intercourse amongst the couple plays a significant factor to their fertility status. 71.5% of subjects reported a frequency of having sexual intercourse at least once weekly, 26.3% reported having sexual intercourse at least twice a month whereas only 2.6% reported of having sexual intercourse less than twice a month. In reproductive aged couples, intercourse frequency plays a significant role in determining couple fecundity(39). The median sexual intercourse frequency amongst couples trying to conceive during follow-up was found to be 6 (4–9) acts per month which compares well with our findings(39).

Semen analysis remains the single most useful and fundamental investigation in the search for the cause of male factor infertility. It is a simple test which assesses the formation and maturity of sperm as well as how the sperm interacts with the seminal fluid so it provides insight not only on sperm production (count), but sperm quality (motility, morphology) as well(5). Semen analysis was done on all the subjects who were included in the study. oligozoospermia was found to be the commonest abnormality at 36.8%, azoospermia at 28.9%, asthenozoospermia at 8% and a combination of oligozoospermia and asthenozoospermia at 13.2%. In a local study on semen characteristics on male partners of couples with infertility, 48.1% were found to have normozoospermia, 2.5% normozoospermia with agglutination, 41.8% teratozoospermia with oligozoospermia and 7.6% with azoospermia(13). This shows a contrasting picture from our findings and it may be due to the study being conducted amongst infertile couples.

Amongst the 11 subjects with azoospermia, 7 underwent testicular biopsy whereby 6 subjects had a biopsy result of sperm maturation arrest whereas one of the subjects had few mature spermatozoa seen in the biopsy. Two of the azoospermic subjects underwent transrectal ultrasound which revealed ejaculatory duct obstruction.

Other significant findings from this study were a 15.8% of males had erectile dysfunction but none had inadequate ejaculation. Hormonal levels were normal in 92.1% of the participants whereas those with abnormalities only had mildly low levels of testosterone with normal LH and FSH levels. These results clearly highlight the urgent need for an andrology unit whereby male factor infertility patients can be followed up and treated.

The main limitations of this study, however, were that it was a hospital based study hence its findings might not be generalizable and there was possible quality variability in the laboratory evaluation of semen even though results from laboratories which used the WHO guidelines were included. Also the small sample size of the study does not allow computation of any associations thus analysis was mainly on frequencies. Another limitation to the study was inadequate investigations offered to the patients e.g. all of the patients with azoospermia were not done a vasography to determine patency of the spermatozoa conduit. Also not all patients with azoospermia were done for a testicular biopsy due to lack of bouin's solution and facilities to preserve any spermatozoa if found in the biopsy. Nevertheless this study provides a basis for further scientific research.

6.0 CONCLUSION

Male factor infertility is a common and distressing condition to a patient. However, the major difficulties which exist in the accurate and meaningful diagnosis of male reproductive dysfunction serve to complicate our understanding of the epidemiology and aetiology of male infertility. This is an important point because correct treatment requires, as its basis, accurate diagnosis. Thus it is important to invest in diagnostic and treatment technologies locally to be able tackle this disease. Also health educational campaigns should be made targeting men on male factor infertility so that they may be proactive in the management of an infertile couple.

7.0 RECOMMENDATIONS

1. To establish facilities capable of diagnosing and managing of male factor infertility.
2. Further research with a multicentre and a larger sample size to allow computation of associations and allow generalisation of data.
3. To introduce Assisted Reproductive technology in Kenyatta National hospital due to the high rates of male factor infertility.
4. To increase the public health educations on male factor infertility thus create awareness in the general public on the presence of the disease and also the various management options possible.
5. To train andrologists who will be treating the male factor infertility patients.

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9.0 APPENDICES

Appendix I – CONSENT FORM (ENGLISH VERSION)

Part I: Information sheet

TITLE OF STUDY

The causes and pattern of presentation of male factor infertility as seen at Kenyatta National Hospital.

Introduction

My name is Dr. Alvin Keya Amadi, a urology postgraduate student at the University of Nairobi. I am conducting a study to assess male infertility at Kenyatta National Hospital. This will be determined by data collection through filling a questionnaire and patient examination.

Purpose of the research

The information that is obtained from this study will be used to assess the scope of male infertility at Kenyatta National Hospital. This study is also a requirement for any doctor who aspires to graduate from our college as a urologist.

Voluntary Participation/Right to Decline or Withdraw

An invitation to participate in this study is hereby extended to you. You will have the opportunity to ask questions before you decide on your enrollment into the study. You may seek clarification regarding any bit of the study from my assistant(s) or me should any part be unclear. The decision to participate in this research is entirely voluntary after you have comprehensively understood the details herein. By refusing to participate in the study, you (or

your kin) will not be denied any medical care. Furthermore, you may stop participating at any time with no consequences whatsoever.

Confidentiality

If you agree to take part in the study, you will be asked to provide personal information and other details related to your condition. All the information collected will be kept confidential, and no one but the researchers will access it. Your name will not appear in any document. The information about the participant will be identified by a number, and only the researchers can relate the identification number to the said participant. The information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC).

Risks

Your involvement in this research will be through an interview and clinical evaluation, and thus it will not expose you to any risks if you consent to participate.

Cost and Compensation

There will be no extra cost incurred by you from participation in this study, and there is also no compensation.

Sharing of information

Following authorization by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC), which is a committee whose work is to make sure research participants are protected from harm, relevant medical information yielded from this study may be shared with fellow doctors through scientific seminars, workshops, and publications. Personal information will not be disclosed whatsoever.

Whom to contact

This proposal has been reviewed and subsequently approved by the KNH/UoN-ERC, for one year; the responsibility of this committee is to make sure research participants are protected from harm. It has been submitted to them through the Chairman of the Department of Surgery at the School of Medicine, University of Nairobi, with the approval of university supervisors. The contact information of these people is given below if you wish to contact any of them for whatever reason;

The Secretary, KNH/UoN-ERC

P.O. Box 20723 KNH,

Nairobi 00202

Tel 726300-9

Email: uonknh_erc@uonbi.ac.ke

Principal researcher:

Dr. Alvin Keya Amadi, Urology Resident, Department of Surgery, School of Medicine, University of Nairobi. P.O. Box 19676 KNH, Nairobi 00202. Mobile No. 0721789949.

University of Nairobi research supervisors

1. Prof. Peter L. Nadguatha, Department of Surgery, School of Medicine, University of Nairobi, P.O. Box 19676 KNH, Nairobi 00202, Tel: 0202726300.

2. Dr. Francis Owillah, Department of Surgery, School of Medicine, University of Nairobi, P.O. Box 19676 KNH, Nairobi 00202, Tel: 0202726300.

Part ii: Consent certificate by the patient

I hereby give my written and informed consent to allow myself to participate in this study on male infertility as seen at Kenyatta National Hospital.

I have been adequately explained to about the study by Dr. Alvin Keya Amadi. I do this with the full understanding of the purpose of the study and procedures which have been explained to me. I understand that my rights will be respected, and confidentiality maintained at all times.

I also understand that the consent is voluntary, and I am at liberty to withdraw from the study without my care being affected.

Patient's signature……Patient's Name……

Signature/left thumbprint

Date……Day/Month/Year

Statement by the witness if the participant is not literate

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

Name of witness……

Signature of witness……..

Date……

Part iii: Statement by the researcher

I have accurately read out the information sheet to the participant and the best of my ability and made sure of the following;

- That the participant consent has been given voluntarily and free of duress.
- That all information given will be treated with confidentiality.
- That refusal to take part in or withdrawal from the study will not in any way compromise the quality of care and treatment given to the patient.
- That the results of this study might be published to enhance the knowledge of the subject of research.
- That I have answered all the questions asked by the participant to the best of my ability and knowledge.

- That a copy of this Informed Consent Form has been provided to the participant.

Name of the researcher taking consent ……

Signature of the researcher taking the consent ……

Date ……Day/Month/Year

Appendix II – CONSENT FORM (SWAHILI VERSION)

Sehemu ya I: Maelezo ya habari

Ukosefu wa kiume kama inavyoonekana katika Hospitali ya Taifa ya Kenyatta.

Utangulizi

Jina langu ni Dk. Alvin Keya Amadi, mwanafunzi wa mwisho wa urology katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kuchunguza ukosefu wa kiume katika Hospitali ya Taifa ya Kenyatta. Hii itatambulishwa na kukusanya data kupitia kujaza dodoso na uchunguzi wa mgonjwa.

Kusudi la utafiti

Taarifa zilizopatikana kutoka kwenye utafiti huu zitatumika kutathmini upeo wa utasa wa kiume katika Hospitali ya Taifa ya Kenyatta. Utafiti huu pia ni mahitaji kwa daktari yeyote anayependa kuhitimu kutoka chuo kikuu kama urolojia.

Kushiriki kwa hiari / Haki ya Kupungua au Kuondolewa

Mwaliko wa kushiriki katika utafiti huu unapanuliwa kwako. Utakuwa na nafasi ya kuuliza maswali kabla ya kuamua juu ya usajili wako katika utafiti. Unaweza kutafuta ufafanuzi kuhusiana na sehemu yoyote ya utafiti kutoka kwa msaidizi wangu au kutoka kwangu lazima sehemu yoyote isiwe wazi. Uamuzi wa kushiriki katika utafiti huu ni kikamilifu kwa hiari baada ya kuelewa kikamilifu maelezo hapa. Kwa kukataa kushiriki katika utafiti huo, wewe (au jamaa yako) hautakataa huduma yoyote ya matibabu. Aidha, unaweza kuacha kushiriki wakati wowote bila matokeo yoyote.

Usiri

Ikiwa unakubali kushiriki, utaulizwa kutoa maelezo ya kibinafsi na maelezo mengine kuhusiana na hali yako. Taarifa zote zinazotolewa zitashika siri na hakuna mtu lakini watafiti watazipata. Jina lako halitaonekana katika hati yoyote. Taarifa kuhusu mshiriki huyo itajulikana kwa nambari na watafiti tu wanaweza kuhusisha nambari ya kitambulisho kwa mshiriki huyo. Taarifa haitashirikiwa na mtu mwingine isipokuwa idhini ya Kenyatta National Hospital / Chuo Kikuu cha Nairobi - Kamati ya Maadili na Utafiti (KNH / UoN-ERC).

Hatari

Ushiriki wako katika utafiti huu utakuwa kwa njia ya mahojiano na tathmini ya kliniki na hivyo hakutakuletea hatari yoyote ikiwa unakubali kushiriki.

Gharama na Malipo

Hutakuwa na gharama ya ziada iliyopatikana na wewe kutoka kwa kushiriki katika utafiti huu, na hakuna pia fidia.

Ugawanaji wa habari

Kufuatilia idhini ya Kenyatta National Hospital / Chuo Kikuu cha Nairobi - Kamati ya Maadili na Utafiti (KNH / UoN-ERC), ambayo ni kamati ambayo kazi yake ni kuhakikisha washiriki wa utafiti wanalindwa dhidi ya madhara, taarifa za afya zinazofaa kutoka kwa utafiti huu inaweza kuwa kushirikiana na madaktari wenzake kupitia semina za kisayansi, warsha na machapisho. Maelezo ya kibinafsi hayatafunuliwa chochote.

Nani wa kuwasiliana

Pendekezo hili limepitiwa na kupitishwa na KNH / UoN-ERC, kwa muda wa mwaka mmoja; jukumu la kamati hii ni kuhakikisha washiriki wa utafiti wanalindwa kutokana na madhara. Imewasilishwa kwao kupitia Mwenyekiti wa Idara ya Upasuaji kwenye Shule ya Matibabu ya Chuo Kikuu cha Nairobi na idhini ya wasimamizi wa chuo kikuu. Maelezo ya mawasiliano ya watu hawa yanapewa hapa chini ikiwa unataka kuwasiliana na yeyote kati yao kwa sababu yoyote;

Katibu, KNH / UoN-ERC

P.O. Sanduku 20723 KNH,

Nairobi 00202

Simu 726300-9

Barua pepe: uonknh_erc@uonbi.ac.ke

Mtafiti mkuu:

Dr Alvin Keya Amadi, Mkazi wa Urology, Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi. P.O. Sanduku la 19676 KNH, Nairobi 00202. Simu ya Mkono Namba ya 0721789949.

Wasimamizi wa utafiti wa Chuo Kikuu cha Nairobi

1. Prof. Peter L. Ndaguatha. Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi, P.O. Sanduku la 19676 KNH, Nairobi 00202, Tani: 0202726300.

2. Dr Francis Owillah, Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi, P.O. Sanduku la 19676 KNH, Nairobi 00202, Tani: 0202726300.

Sehemu ya ii: Hati ya kibali kwa mgonjwa

Mimi hapa kutoa idhini yangu iliyoandikwa na taarifa ya kuruhusiwa kushiriki katika utafiti huu juu ya kutokuwa na ujinga wa kiume kama inavyoonekana katika Hospitali ya Taifa ya Kenyatta.

Nimeelezwa kwa kutosha juu ya utafiti na Dk. Alvin Keya Amadi. Ninafanya hivyo kwa ufahamu kamili wa kusudi la utafiti na taratibu ambazo zimeelezezwa kwangu. Ninaelewa kuwa haki zangu zitaheshimiwa, na usiri umehifadhiwa wakati wote.

Pia ninaelewa kwamba ridhaa ni ya hiari, na nina uhuru wa kujiondoa kwenye utafiti bila kujali kuathiriwa.

Sahihi ya mgonjwa ..... Jina la Mgonjwa .....

Ishara……

Tarehe ..... Siku / Mwezi / Mwaka

Taarifa ya shahidi ikiwa mshiriki hayujui

Nimeona usomaji sahihi wa fomu ya kibali kwa mshiriki, na mtu huyo amepata fursa ya kuuliza maswali. Ninathibitisha kwamba mtu huyo ametoa ridhaa kwa uhuru.

Jina la shahidi .....

Saini ya shahidi ....

Tarehe……

Sehemu ya iii: Taarifa ya mtafiti

Nimesoma kwa usahihi karatasi ya habari kwa mshiriki na kwa uwezo wangu mkubwa na ninahakikisha kuwa zifuatazo;

• Kuwa ridhaa ya mshiriki amepewa kwa hiari na bila ya kufadhaika.

• Kwamba habari zote zitapewa zitashughulikiwa kwa siri.

• Kukataa kushiriki au kuondokana na utafiti hakutapoteza ubora wa huduma na matibabu ya mgonjwa.

• Kwamba matokeo ya utafiti huu yanaweza kuchapishwa ili kuongeza ujuzi wa somo la utafiti.

• Kwamba nimejibu maswali yote aliyoulizwa na mshiriki kwa uwezo wangu wote na ujuzi wangu.

• Kuwa nakala ya Fomu hii ya Ruhusa ya Ruhusa imetolewa kwa mshiriki.

Jina la mtafiti alichukua ridhaa .....

Sahihi ya mtafiti anaidhinisha .....

Tarehe ..... Siku / Mwezi / Mwaka

Appendix III-MALE INFERTILITY QUESTIONNAIRE

STUDY NUMBER ____

DATE OF THE INTERVIEW dd-mm-yyyy __-__-____

YEAR OF BIRTH dd-mm-yyyy __-__-____

A. SOCIAL DEMOGRAPHIC FACTORS

1. What is your marital status?

- Married (Monogamous)
- Married (Polygamous)
- Single
- Cohabiting
- Others, specify _____

2. What is the highest level of education?

- Primary
- Secondary
- College/middle level
- University
- Never attended school

3. What is your occupation?

- Unemployed
- Self-employed
- Employed

- Sick/disabled and unable to work
- Student
- Other

4. Have you ever impregnated a woman?

- Yes
- No

B. HISTORY

5. Do you have any previous history of urethral/penile discharge or painful micturition?

- Yes
- No

6. Do you have any previous history of mumps?

- Yes
- No

7. Do you have any previous history of scrotal swelling?

- Yes
- No

8. Do you have any previous history of acute testicular pain?

- Yes
- No

9. Do you have any history of trauma to the groin?

- Yes
- No

10. Do you smoke cigarettes?

- Yes
- No
- If yes, how many pack years?

11. Do you drink alcohol?

- Yes
- No

12. Any previous history of drug abuse?

- Yes
- No

13. Do you suffer from any chronic illness?

- Yes
- No

14. If yes, which one?

- Specify _____

15. Are you on any long term medication?

- Yes
- No
- If yes, specify _____

16. Any previous history of surgery to the groin?

- Yes
- No
- If yes, specify _____

17. Does the patient have a congenital syndrome?

- Yes
- No
- If yes, specify the findings _____

18. On average how many times do you have sexual intercourse in a month?

- At least once weekly
- At least twice a month
- Less than twice a month

19. How many sexual partners do you have?

- 1
- More than 1
- If more than 1 specify the number_____

20. How do you describe your erection?

- Normal
- Inadequate

21. How do you describe your ejaculation?

- Normal
- Premature
- Delayed

C. EXAMINATION

22. Is there any presence of a varicocele?

- Yes
- No

23. Is there any presence of undescended testes?

- Yes
- No

24. Is there any presence of a testicular mass?

- Yes
- No

25. Are both vas deferens palpable?

- Yes
- No
- Only one is palpable.

D. INVESTIGATIONS

26. Has any seminalysis been done?

- Yes
- No
- If yes, specify the findings _____

27. Has any hormonal profile been done?

- Yes
- No
- If yes, specify the findings _____

28. Has any testicular biopsy been done?

- Yes
- No
- If yes, specify the findings _____

29. Has any transrectal ultrasound been done?

- Yes
- No
- If yes, specify the findings _____

MASWALI KUHUSU UTASA WA WANAUME

NUMBARI _____

SIKU YA MAFUNZO dd-mm-yyyy __-__-____

MWAKA WA KUZALIWA dd-mm-yyyy __-__-____

A. **MASWALI YA KIJUMLA**

1. Hali yako ya ndoa ni gani?

o Umeoa mke mmoja

o Umeoa wake wengi

o Bado kuoa

o Unaishi na mwanamke kabla ya kumuoa

o Wengine, taja _____

2. Ni kiwango gani cha juu cha elimu?

o Msingi

o Sekondari

o Chuo / katikati ngazi

o Chuo kikuu

o Sijawahi kuhudhuria shule

3. Kazi yako ni nini?

o ajira

o Kuajiriwa

o Ufanyika

o Wagonjwa / walemavu na hawawezi kufanya kazi

o Mwanafunzi

o Nyingine

4. Je! Umewai kumpa mwanamke mimba?

o Ndiyo

o Hapana

B. HISTORIA

5. Je! Una historia yoyote ya usaha kutokwa kwa njia ya mkojo?

o Ndiyo

o Hapana

6. Je! Una historia yoyote ya awali ya matone?

o Ndiyo

o Hapana

7. Je! Una historia yoyote ya awali ya uvimbe wa kinga?

o Ndiyo

o Hapana

8. Je! Una historia yoyote ya awali ya maumivu makali ya makende?

o Ndiyo

o Hapana

9.Je! Una historia yoyote ya kugongwa au maumivu katika sehemu nyeti?

o Ndiyo

o Hapana

10. Je, wewe unavuta sigara?

o Ndiyo

o Hapana

o Ikiwa ndio, ni miaka ngapi umevuta?

11. Je, unakunywa pombe?

o Ndiyo

o Hapana

12. Historia yoyote ya zamani ya matumizi mabaya ya madawa ya kulevya?

o Ndiyo

o Hapana

o Kama ndiyo ndiyo, taja madawa ya kulevya _____

13. Je, unakabiliwa na ugonjwa wowote?

o Ndiyo

o Hapana

14. Kama ndiyo

o Taja _____

15. Je, unatumia dawa yoyote kwa muda mrefu?

o Ndiyo

o Hapana

o Kama ndiyo ndiyo, taja _____

16. Historia yoyote ya awali ya upasuaji wa urolojia?

o Ndiyo

o Hapana

o Kama ndiyo ndiyo, taja _____

17. Je, mgonjwa ana ugonjwa wowote wa kuzaliwa?

o Ndiyo

o Hapana

o Kama ndiyo ndiyo, taja matokeo _____

18. Kwa wastani mara ngapi unavyofanya ngono kwa mwezi?

o Angalau mara moja kila wiki

o Angalau mara mbili kwa mwezi

o Chini ya mara mbili kwa mwezi

19. Je, una washirika wangapi wa ngono?

o 1

o zaidi ya 1

o Ikiwa zaidi ya 1 inataja idadi_____

20. Je, uume wako unasimama aje?

o kawaida

o Haitoshi

21. Je, kumwagika kwako baada ya kufanya mapenzi uko aje?

o kawaida

o kabla

o Ilichelewa

C. KUCHUNGUZWA KWA MWILI

22. Je! Kuna shida ya varicocele?

o Ndiyo

o Hapana

23. Je, kuna kuwepo kwa makende usioshuka?

o Ndiyo

o Hapana

24. Je, kuna kuwepo kwa uvimbe wa makende?

o Ndiyo

o Hapana

25. Je, vas deferens zote mbili ziko?

o Ndiyo

o Hapana

o Moja tu iko.

D. UPELELEZI

26. Je, upelelezi wowote wa shahawa umefanyika?

o Ndiyo

o Hapana

o Kama ndiyo ndiyo, taja matokeo ... _____

27. Je, maelezo yoyote ya homoni yamefanyika?

o Ndiyo

o Hapana

o Kama ndiyo ndiyo, taja matokeo ... _____

28. Je, biopsy yoyote ya makende imefanywa?

o Ndiyo

o Hapana

o Kama ndiyo ndiyo, taja matokeo ... _____

29. Je, ultrasound yoyote imefanywa?

o Ndiyo

o Hapana

o Kama ndiyo ndiyo, taja matokeo ... _____

TABLE 1 - STUDY TIMEFRAME

ACTIVITY/TIME	JANUARY 2019	FEBRUARY 2019	MARCH 2019	APRIL 2019	MAY 2019	JUNE 2019	JULY 2019
PROPOSAL DEVELOPMENT	a						
ETHICAL APPROVAL							
DATA COLLECTION							
DATA ANALYSIS							
DISSERTATION SUBMISSION							

TABLE 2 - STUDY BUDGET

ITEM	**COST**
Research fee	2000
Statistician	30000
Research Assistant	20000
Stationery and printing	20000
TOTAL	72000