Body Mass Index (BMI) and Testosterone Influence on Male Partner Infertility based on Semen Parameters in Kenyatta National Hospital Infertility and Urology clinics in 2021.

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H58/12307/2018

A Thesis Submitted to University of Nairobi, Department of Obstetrics and Gynecology in Partial Fulfillment for the Award of Master of Medicine in Obstetrics and Gynecology 2021

DECLARATION

This thesis is my original work and has not been submitted for any academic award or published in any other university or any other institution of higher learning for the award of a degree.

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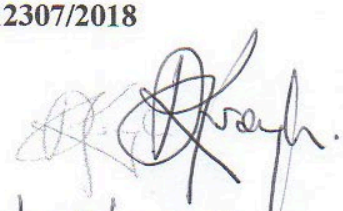
Signature: 

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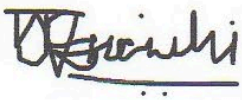
Signature:  **Date:** 24/08/2022

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Indeed, the list is endless and for all those who played a part in my academic life, you are also highly appreciated. May the Almighty give us strength and wisdom to continue being a blessing in the lives of other people.

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TABLE OF CONTENTS

ABBREVIATIONS

AR ……. ……Androgen Receptors

FSH ……. Follicle-stimulating Hormone

HPV …… ……..…. Human Papilloma Virus

ICMART……..... International Committee for Monitoring Assisted Reproductive Technology

KNH ……. Kenyatta National Hospital

LH …… ……Luteinizing Hormone

PTM ……. Peri-Tubular Myoid

SERMs …… ……. Selective Estrogen Modulators

SHBG ……...Sex Hormone-Binding Glogulin

STDs ……. Sexually Transmitted Diseases

UoN …… ……. University of Nairobi

WHO …… ……World Health Organization

DEFINITION OF TERMS

Infertility - Not being able to get pregnant despite having frequent, unprotected regular sex for at least 12 months for most couples.

Male infertility – Patients who had abnormal semen analysis parameters

Secondary Infertility - This is the inability to become pregnant or to carry a baby to term after previously giving birth to a baby.

Sperm quality – is a measure of male fertility, a measure of the ability of sperm in semen to accomplish fertilization.

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ABSTRACT

Background: Globally, the rate of infertility is increasing rapidly with over forty-eight million five hundred couples experiencing infertility. Male infertility has been increasing with approximately 50% of couples with infertility issues being attributed to male infertility. However, male infertility has been associated with different factors. Obesity and testosterone levels among men have been associated with the development of male infertility in different settings. Thus, this study aims at investigating these factors within a Kenyan context.

Aim of the study: To compare the influence of BMI and testosterone levels between fertile and infertile male partners based on Semen Analysis in Kenyatta National Hospital Infertility and Urology clinics.

Methodology: This was a case-control study including clients with normal semen analysis (controls) and abnormal semen analysis (cases). The study was conducted in infertility and urology Clinics at Kenyatta National Hospital where men attending these clinics for fertility evaluation were recruited. A consecutive sampling technique was used where 22 cases and 22 controls were recruited. A structured study questionnaire was used to obtain information from the participants. The clients were required to undergo a semen analysis test, evaluation of height and weight as well as extraction of 5 ml of blood to test free testosterone and FSH levels.

Results: The findings revealed that 17(77%) of controls were of normal weight compared to 7(27%) of the cases. The difference was not significant. There was no difference between the cases and controls based on marital status, monthly income, HIV status and presence of sexually transmitted diseases. There was a significant difference in testosterone levels between cases and controls (cases, 4.53(SD±1.93, controls, 6.38(SD±2.27, $p = 0.006$, OR =1.556). The FSH levels were higher in cases as compared to controls although the difference was not statistically significant, (cases, 7.76(SD±8.06) cases vs 4.36(SD±2.07) controls. There was no significant relationship between testosterone levels and body mass index ($r = 0.291$, $p = 0.055$).

Multivariate analysis model revealed that smoking, body mass index and Testosterone level were independent predictors of male infertility based on semen analysis. Respondents who were not smokers were 92% less likely to be a case compared to being a control, (aOR = 0.081, (95%CI, 0.014, 0.478), $p = 0.002$). With every 1 kg/m² increase in BMI, the odds of being a case were 21% higher compared to being a control (aOR = 1.206, (95%CI, 1.036, 1.403), $p = 0.016$). Similarly, in every 1 ng/ml increase in testosterone level, the odds of being a case were 56% higher compared to being a control (aOR = 1.559, (95%CI, 1.099, 2.211), $p = 0.013$).

Conclusion: The findings have shown that smoking, body mass index and testosterone levels have a significant influence on abnormal semen parameters hence there is a need to develop clear approaches to improve fertility levels through regular review of weight management to control the increased risk of abnormal semen parameters among male partners and regular physical exercises to reduce the risk of abnormal semen parameters among men.

1. CHAPTER ONE: INTRODUCTION

1.1.Background

Reproduction is defined by the level of fertility among individuals. Infertility has been recognized globally as a key healthcare problem by different health organizations including World Health Organization and the International Committee for Monitoring Assisted Reproductive Technology (ICMART) (1). These two international health organizations define infertility as the inability to achieve pregnancy after 12 months of regular and unprotected sex. Tests should be performed assessing clinical evaluation on women within the reproductive age who are unable to conceive after one year (2).

The experience of infertility is associated with adverse outcomes to individuals leading to personal distress and financial strain considering the treatment costs that are incurred. It may also lead to discrimination and ostracism. Globally, the rate of infertility is increasing rapidly with over forty-eight million five hundred thousand (48.5) couples experiencing infertility (3). However, the global prevalence of infertility varies significantly due to various reasons including no agreement or consistent definition of infertility. About 20-35% of couples are infertile in Africa. The “infertility belt”, geographical regions in Africa cut across West, through Central to East Africa with high infertility prevalence (4). Different studies encompass different parameters that are utilized in measuring the prevalence of infertility. There is an increasing trend of delayed timing of first birth as observed in developed as well as developing countries. A resultant effect of postponement of parenthood has impaired fertility.

The introduction of National treatment guidelines in most countries has led to increased detection of infertility at primary care centres considering that more awareness has been developed. Determining infertility in men is based on the evaluation of infertility concerns

from their spouses (4). There are few populations based on the experience of infertility as well as its determinants for men. According to a study conducted in Britain focusing on men and women seeking professional medical help, it was determined that male factor infertility was increasingly prevalent.

Male infertility from a global perspective affects 15% of couples who have unprotected intercourse (5). However, studies have determined that it is difficult to determine the exact regional prevalence of male infertility because the surveys conducted are those who have a concern regarding the fact that they are unable to conceive and want children. This is a specific group within the larger population who are willing to seek medical care to address their worries involving infertility (6). Thus, data from individuals who might be infertile but do not actively seek medical care is not included.

The rate of male infertility in developing countries has been on the rise in the recent past. According to a survey conducted by the World Health Organization on infertility, it was identified that one in four families is affected by infertility with a specific emphasis on the responses from women (1). The burden for infertility in men has been increasing in the recent past which means that there is a need to integrate better mechanisms to identify the underlying risk factors.

In African societies, reproduction is highly valued and infertility is considered as a curse or serious deficiency that can limit individual influence in the society (7). Women are majorly stigmatized and accused of being barren without tests being performed on both partners. In Sub-Saharan African, infertility rates are as high as 30%. The high rate of infertility has been associated with sexually transmitted infections, increasing obesity, and lower testosterone levels (8). However, few studies have been done focusing on understanding infertility in men.

In Kenya, infertility is a major reproductive health concern which creates a different level of emphasis on the need to understand better interventions to engage individuals. A national infertility survey that was conducted in 2005/2006 identified that approximately 30% of infertility cases are determined at the referral level, 27% in county hospitals, 15% in sub-county hospitals and 2% was detected in dispensaries (9). Infertility in Kenya is a major community problem leading to divorce and domestic violence. The assessment conducted showed that infertility was majorly pegged to women because of the difficulty in engaging men (10). The National reproductive health policy in Kenya (2009) recognizes infertility as a major healthcare problem in the country with few men opting to undergo tests. Engaging men in infertility tests is essential in understanding the extent to which infertility in men affects relationships. Understanding the extent of infertility in men will provide a basis under which it would be possible to understand the underlying predictors.

Infertility is becoming a major global health concern considering that approximately forty-eight million five hundred couples globally are affected by this condition. About 40% to 50% of infertility cases are a result of male factors (8). However, despite the high prevalence of infertility in men, there has been less emphasis on different factors that are likely to influence the infertility rate. Testosterone levels and body mass index have been considered as key factors influencing infertility in men. Previous research has shown that infertility in men is associated with a varying number of factors such as weight and alterations in testosterone levels, sex hormone-binding globulin, alcohol, presence of sexually transmitted diseases as well as smoking. The consideration that infertility in men is a crucial health concern means that there is a need to understand the development of male infertility and the underlying factors that are likely to influence infertility. There is limited research highlighting the association between body mass index and testosterone levels on the rate of infertility in males. Therefore, this study aimed at determining the influence of body mass index,

testosterone levels, and other risk factors such as alcohol and smoking associated with infertility.

2. CHAPTER TWO: LITERATURE REVIEW

2.1.Pathophysiology of male infertility

Understanding the predictors of infertility in males requires an understanding of the development of infertility in males which provides a crucial understanding of important processes that help define an improved level of reproduction (11). Spermatogenesis is defined as the process by which the male gamete, the spermatozoa is formed (12). This process starts during the early stages of puberty and occurs in the seminiferous tubules of the testes, where development and maturation occurs. This is a continuous process similar to oocyte maturation in females. The seminiferous tubules are the anatomical requirement for spermatogenesis to occur and are developed during puberty in the presence of Follicular stimulating hormones (FSH) (13). FSH secreted by the anterior pituitary gland binds to the Sertoli cells triggering the production of various chemical mediators which in turn stimulate spermatogenesis. There are four development stages. These stages include Type A, Type B spermatogonia, primary and secondary spermatocytes.

Different changes occur across different stages. Type B spermatogonia are formed as a result of further mitotic division, leaving the basal membrane to the luminal end. The primary spermatocyte is formed from Type B spermatogonia and then approach the seminiferous tubules (14). Two meiotic divisions result from the DNA replication which at this point, they are referred to as secondary spermatocytes. Spermatozoa creation is a process that is greatly dependent on testosterone. It consists of a head and a tail. The head mainly includes the nucleus covered by the acrosome(15). The acrosome is a cap-like structure that contains enzymes that are crucial at a later stage in breaking down the outer membrane of the ovum which is essential in the fertilization process (16).

The development of spermatozoa takes between 60 and 70 days from the undifferentiated germ cells which is a continuous process (17). Averagely, an adult male produce around 700

million spermatozoa daily. The storage of the sperm is done within the epididymis located adjacent to the testes in the scrotal sac (18).

2.2.Hormones Influencing the Male Reproductive System.

Different hormones influence the male reproductive system and are crucial in influencing male fertility. Androgenic and gonotrophic hormones form the major male hormones which are crucial in the male reproductive system. Testosterone is developed in the Leydig cells and it is also an androgen hormone (19). The pituitary gland is responsible for the formation of Luteinizing Hormone (FH) and Follicle Stimulating Hormone (FSH). These hormones are vital in female hormonal balance although in men they affect the tissues of the testes (20). Thus, both LH and FSH form a crucial role in sperm production as well as testosterone formation (21).

Infertility in men is caused by different factors although the other existing risk factors in male infertility are associated with low sperm count or immotile sperm can cause infertility (22). Around 30% of the sperm per ejaculate is supposed to be formed normally while at least 50% are expected to be mobile (23). The presence of any abnormalities is a clear indicator of underlying infertility. However, it is also essential to understand that sperm quality decreases after the age of 35. Male partner infertility has been on the rise attributing to approximately 40% of infertility cases (8).

2.3.Body mass index and male infertility

Obesity is rapidly increasing worldwide which has led to the development of other associated healthcare concerns among individuals. Additionally, weight is not only associated with an increase in chronic disease but has a detrimental influence on reproduction as well. The adverse effects in reproduction can be reversed through weight loss. In a case-controlled study conducted in Pakistan aimed at investigating the association between male infertility

and obesity, the results found that increase in BMI by every 1kg/m^2 was associated with a 6% increase in odds of male infertility. Having a previous medical condition was associated with an increased risk of infertility among cases than controls. The study further stressed that previous medical conditions such as a history of sexually transmitted diseases and a higher level of formal education were significant predictors of male infertility (24). Additionally, in another case-controlled study conducted in Iran, the findings revealed that an increase in BMI was associated with an increased risk of male infertility (25).

In addition, a case-controlled study conducted to investigate the factors influencing male infertility found that there was a significant difference in sperm concentration, motility, volume, and PH levels with body mass index levels (26). Thus, the results from the study identify that high body mass index was associated with decreased semen quality which specifically affects the volume, concentration as well as motility.

However, it is less clear whether male reproduction is influenced by excess weight. A sex hormonal imbalance can have a detrimental influence on male reproduction. According to a study conducted by Barratt et al. (2017) in determining the changes in testosterone levels based on BMI, it was found that there was a substantial reduction of testosterone to estradiol ratio among overweight and obese men in comparison to men with lower BMI (27).

According to a retrospective cohort study conducted by Nguyen et al. (2007), the study sought to conduct an assessment on BMI among men with infertility as well as the extent to which the effect of BMI can be controlled by altered sexual function. In men, an increase in weight can have a detrimental influence on estradiol and testosterone levels, poor semen quality, and infertility. The finding from the study revealed that smoking habits were associated with infertility. There was also a high chance of infertility in male partners with

high BMI based on the assessment of the odds ratio. Thus, it was concluded that men with high BMI weight are at increased risk of infertility.

According to Sermondade et al. (2013) in a meta-analysis assessment of case-controlled studies focusing on the relationship between BMI and sperm count, it was noted that the increasing global obesity epidemic is having a detrimental influence on semen quality. The association between obesity and sperm parameters remains largely unexploited based on the existing guidelines. Thus increase in BMI was linked to a higher prevalence of azoospermia or oligozoospermia (28).

Chavaro et al. (2010) sought to determine the underlying relationship between body weight and male reproductive potential parameters. The results showed that body mass index was positively associated with estradiol levels. An increase in BMI was associated with a reduction in the total testosterone levels as well as SHBG hormone levels. The results also showed that there was a strong negative relationship between BMI and inhibin B levels. BMI was not related to sperm concentration or morphology. The ejaculate volume reduced with increasing weight among men. Men who had a BMI of 35 or greater had a very low sperm count reducing the chances of fertility. Therefore the results from the study showed that despite the existing differences in reproductive hormone levels, an increase in BMI can only influence male reproductivity potential at extreme levels (29).

Hajshafiha et al. (2013) highlighted that obese men were 3.5 times more likely to have oligospermia than men with normal BMI. There was no correlation between hormone levels, luteinizing hormone, and follicle-stimulating hormone. The results highlighted that there was statistical significance between BMI and estradiol, testosterone level, and SHBG ratio. These findings indicated that an increase in BMI has been associated with a reduction in testosterone level and SHBG ratio (30).

Studies have found that obesity has been associated with Hypogonadotropic hypogonadism (HH). A clinical review conducted in 2019 by Fernandez et al. revealed that obesity-induced increase in levels of leptin, insulin, proinflammatory cytokines and oestrogen can cause functional hypogonadotropic hypogonadism with the defect present at the level of the hypothalamic gonadotrophin-releasing hormone (GnRH) neurons (31). There is a bidirectional relationship between obesity and hypogonadism. Population-based studies have shown that obesity is the single most essential factor resulting in testosterone deficiency. In addition, testosterone deficiency can cause increased adipogenesis and visceral obesity as evidenced by rapid weight gain observed in men following androgen deprivation therapy (32).

2.4.Testosterone levels and male infertility

Testosterone is an androgen that is a steroid hormone that plays a key role in the male reproductive function. Mutation of the androgen receptors is common in patients having male reproductive disorders. Androgen receptors are essential in the development of male infertility. Thus, the androgen function through the androgen receptors as well as it signaling in the testis for spermatogenesis. AR exerts significant influence in the development of germ cell lineage. The signaling role of AR has been essentially evaluated in rodent models which have shown suppression of the testosterone levels with the transgenic disruption process (33).

Studies focusing on assessment of semen quality are less which highlights the selection bias of participants which is likely to have a detrimental influence on the outcomes. The fact that hormones create and maintain spermatogenesis, means that they can also serve as surrogates of semen quality. Meeker et al. (2007) in a retrospective cohort study focusing on data from 1999 and 2003, highlighted that FSH and LH had an inverse influence on sperm concentration, motility, and morphology. The Inhibin B and T4 hormones were positively associated with sperm concentration. Therefore based on an overall assessment of the

findings, it was concluded that FSH, testosterone, and free T 4 levels, LH and Inhibin B are associated with human sperm parameters (34).

According to Rambhatla et al. (2016), estradiol is a normal female hormone although it plays a key role in men through influencing different physiologic functions including metabolism, testicular function, and cardiovascular health. Thus, due to its high influence on men, it has formed the basis of male reproductive and sexual medicine specialists in treating infertility and hypogonadism (35).

2.5.Smoking and male infertility

Smoking has been considered a major factor in predicting infertility in men. Different studies have been conducted which provide crucial information regarding the development of infertility due to smoking. In a cohort study conducted by Künzle et al. (2003) to determine the effect of cigarette smoking in men, a standard clinical semen analysis was performed. The findings from the study identified that cigarette smoking was associated with a decrease in

sperm density, total sperm count, citrate concentration as well as a total number of motile sperms. In addition, Mahboubi et al (25) also found that cigarette smoking was associated with an increased risk of male infertility.

Past studies have shown that there are specific body systems that are affected by the hazardous implications of cigarette smoking especially respiratory and cardiovascular systems. Mostafa (2010) conducted a review of literature aimed at understanding the relationship between smoking and male infertility. The results found that cigarette smoking was associated with reduced sperm creation, motility, and sperm fertilizing ability. However, the assessment also highlighted that there were studies reviewed that did not find an association between semen parameters and smokers as well as non-smokers (36). A prospective study by Hosseinzadeh Colagar et al. found that men who were smokers had a

low sperm count, impaired sperm motility and reduced volume (37). Studies assessing male infertility showed that an increased BMI was associated with reduced testicular volume, a low sperm count, impaired sperm motility, increased sperm DNA fragmentation, increased infertility, a low serum testosterone level, reduced libido, and erectile dysfunction. Obesity is now an epidemic in both men and women worldwide, resulting in compromised physical and psychological well-being (38). Further, much is known about the negative impact of obesity on pubertal sexual maturation resulting in hypogonadism (39). Underweight or overweight may lead to a low sperm count and infertility, and overweight men generally have less sex than do non-overweight men (40). A National Institute of Environmental Health Sciences (NIEHS) study showed that a 3-point increase in BMI increased the risk of infertility by 10s% in men (41).

2.6.Sexually transmitted diseases and male infertility

According to WHO, there is a high prevalence of STDs globally with approximately 1 million people becoming infected every day with the common four curable STDs including syphilis, gonorrhea, trichomoniasis, and chlamydia. Despite the high global prevalence, STDs research remains one of the less researched areas which offer fewer solutions to the existing health concerns. In developed countries, chlamydia has remained the most common sexually transmitted bacterial infection regardless of the widespread testing as well as recommendations (42).

STDs are mainly caused by bacteria, viruses or parasites that are transmitted through venereal contact. In males, these STDs may either be asymptomatic or cause urethritis, epididymitis, orchitis, vasiculitis, and prostatitis (43). Most of these infections have been shown to affect male fertility by affecting semen parameters like sperm count, motility, and morphology; however, their exact mechanism of action is still not known. The presence of infection(s) on

sperm and/or in the seminal plasma causes their horizontal transmission to sexual partners and vertical transmission to offsprings (44).

According to a case-control study conducted by Moghimi et al., it was found that there was a statistically significant association between Human Papillomavirus (HPV) and infertility in men. The finding from the study further revealed that, there is increased prevalence of HPV infertile men as compared to fertile men (45). Folkvord et al. conducted a cross-sectional descriptive study that sought to understand the influence of STDs on infertility in Zimbabwe. The findings from the study determined that there was a significant association between Human Immuno-Deficiency virus (HIV) and infertility in men. The majority of the study subject who had male infertility attributed it to stress and reported signs of mild depression with a significant number seeking traditional methods. A higher percentage of men blamed infertility on women (46).

The HIV has also been associated with an increased risk of infertility among men. Dulioust (2002) conducted a study aimed at assessing semen quality and infertility in men with HIV-1. The findings revealed that there were high semen alterations in HIV infected men with increased non-spermatic cells compared with the controls (47).

2.7.Alcohol consumption and male infertility

A case-control study conducted in Nigeria by Okonofua et al (2005), sought to evaluate predictors of infertility in men. The findings from the study showed that infertile men were heavily linked to excessive alcohol consumption and smoking. The semen analysis conducted also revealed that male infertility was associated with bacteria in semen cultures (48).

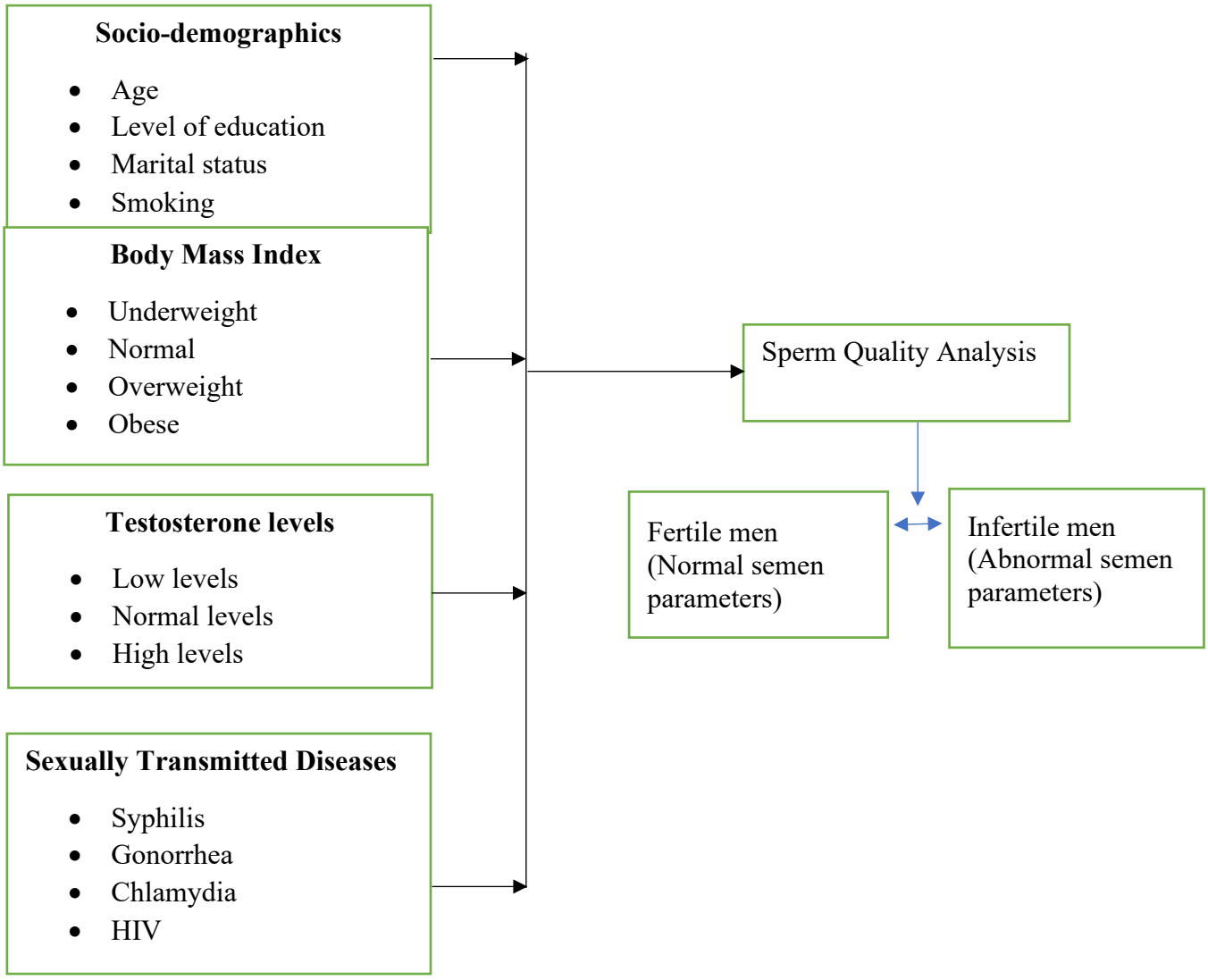
Another case-control study was conducted by Prazzini et al. (1993) focusing on the underlying risk factors in men infertility in Italy, the results provided a comparative analysis of those who have consumed alcohol and those who did not. The results identified that there

was an increased risk of infertility in men who consumed alcohol as compared to those who did not. Alcohol has been a major factor in creating a limit that influence improved outcomes (49).

2.8.Conceptual Framework

Independent variables

Dependent/outcome variables



Source (Songu, 2022)

Figure 2.1: Conceptual Framework

2.9.Justification of the study

Male infertility is a serious reproductive issue that has not been conclusively discussed which creates a difficult situation under which better interventions can be considered to improve individual reproductivity. In African societies, women have been considered as being infertile at the expense of men leading to significant family issues such as polygamy, divorce, and domestic violence. Within the Kenyan perspective, there has been a low focus on male partner infertility despite the increasing prevalence of male partner infertility in the county. Kenya just like any other African setting, infertility has been seen as a female issue with fewer men having knowledge about their fertility issues. Thus, it is essential to enhance knowledge and understanding of male infertility as a challenge that needs to be assessed. Body mass index and testosterone levels have been observed in other settings to have a significant influence on male partner infertility. Therefore, the emphasis of this study is to understand the predictors of infertility in men that will provide a greater assessment of important information that can improve care. There is limited data or studies on this in Kenya and Sub-Saharan Africa, doing such studies will act as an eye-opener in addressing the problems of male infertility.

2.10. Research question

What is the effect of Body Mass Index (BMI) and Testosterone level on male infertility based on semen parameters at the gynaecology infertility and urology clinics at the Kenyatta National Hospital?

2.11. Hypothesis

Ho1: There is no statistically significant association between body mass index and male infertility based on semen parameters as seen at the gynaecology infertility and Urology Clinics at Kenyatta National Hospital.

Ho2: There is no statistically significant association between testosterone levels and male infertility based on semen parameters as seen at the gynaecology infertility and Urology Clinics at Kenyatta National Hospital.

2.12. Objectives

2.12.1. Broad objective

To determine and compare the BMI and testosterone levels and their association with the semen parameters of fertile and infertile male partners seen at Kenyatta National Hospital Infertility and Urology clinics.

2.12.2. Specific objectives

1. To determine the association between body mass index and abnormal semen parameters among male partners in Kenyatta National Hospital Infertility and Urology Clinics.
2. To investigate the association between Testosterone levels and abnormal semen parameters among male partners in Kenyatta National Hospital Infertility and Urology Clinics.
3. To determine the association between body mass index and testosterone level among male partners in Kenyatta National Hospital Infertility and Urology Clinics.

2.12.3. Secondary objective

1. To investigate the influence of smoking and alcohol use on abnormal semen parameters among male partners in Kenyatta National Hospital Infertility and Urology Clinics.

3. CHAPTER THREE: METHODOLOGY

3.1.Study design

This was an unmatched case-control study. The study sought to assess the exposure to male infertility by independently assessing testosterone levels and body mass index. The case-control study design approach was efficient in assessing rare diseases (outcomes) as well as its cost-effectiveness. The cases are infertile males' partners and controls are fertile male partners based on semen parameters.

3.2.Study site

The study was conducted at the gynecology infertility and urology clinics at Kenyatta National Hospital. The hospital is the major referral hospital in the country with a bed capacity of 1800 and is located approximately 3km from the Central Business District in Nairobi, Kenya. The hospital has a well-structured outpatient system where different patients are engaged based on their healthcare needs. The gynecology infertility clinic operates on Mondays only and receives approximately 7 couples with infertility issues per clinic day. The urology clinic operates on Monday, Tuesday, and Wednesday and reviews around 6 patients with infertility issues on weekly basis. The standard of care in the infertility clinics at KNH begins with female spouses who seek care regarding fertility issues. The female spouses are requested to bring their male partners for further assessment where semen analysis is conducted to determine male partner fertility status.

3.3.Study population

The study population included men attending gynecology infertility and urology clinics with fertility issues as well as men taking semen analysis tests at the Kenyatta National Hospital.

3.4. Inclusion/exclusion criteria

3.4.1. Inclusion criteria

1. Male partners who are seeking fertility care at infertility and urology clinics
2. Male partners of couple who have had a regular unprotected sex for last 12 months without conception.
3. Male partners who are conducting semen analysis at KNH andrology lab.
4. Male partners who consent to participate in the study

3.4.2. Exclusion criteria

1. Male partners presenting with semen analysis from other hospitals
2. Male partners who had conditions like varicocolles, undescended testicles because they might affect the results of semen analysis
3. Male partners who refuse to consent

3.5 Sample size determination

The sample size was determined as specified by Kelsey, Jennifer L et al. (1996)

As $n_1 = \frac{(Z\alpha+Z\beta)^2 pq(r+1)}{r(P_1-P_2)^2}$

$n_2 = rn_1$

$P_1 = \frac{P_2 OR}{1 + P_2(OR - 1)}$

$p = \frac{P_1 + rP_2}{r + 1}$

In the formulas;

n_1 is the number of cases,

n_2 is the number of controls,

P_1 is the proportion of cases with infertility,

P_2 is the proportion of controls with infertility. A study conducted in Nigeria investigating the proportion of male infertility based on semen analysis revealed that 38.2% among couples visiting infertility clinic were infertile (50).

Zα = 1.96 (for 95% confidence level);

Zβ = 0.84 (required for power of 80% required in the study);

r = 1 is ratio of controls to cases

The odds ratio of ratio risk of male infertility is estimated at 7 of controls to cases)

Therefore:

$$P_1 = \frac{P_2 OR}{1 + P_2(OR - 1)}$$

$$P_1 = \frac{0.382 * 7}{1 + 0.382(7 - 1)}$$

$$P_1 = \frac{2.485}{3.13} = 0.79$$

$$p = \frac{P_1 + rP_2}{r + 1}$$

$$p = \frac{0.79 + 1 * 0.382}{1 + 1} = 0.57$$

q = 1 – 0.57 = 0.43

Using the formula.

$$n_1 = \frac{(1.96+0.84)^2 0.57*0.43(1+1)}{1(0.79-0.382)^2} = 20$$

Thus $n_1 = 20$

$n_2 = 1(20) = 20$

The sample size was 40. However, a non-response rate of 10% was calculated hence

10% of 40 is 4 therefore, the sample size was 40+4 = 44

Therefore, the sample size was 44 where 22 cases and 22 controls.

3.6 Sampling technique

A consecutive sampling technique was used. The principal investigator with the help of three research assistants consecutively sampled the target population while identifying those who

meet the inclusion criteria until the sample population is achieved at the gynecology infertility and urology clinics.

3.7 Study flow chart

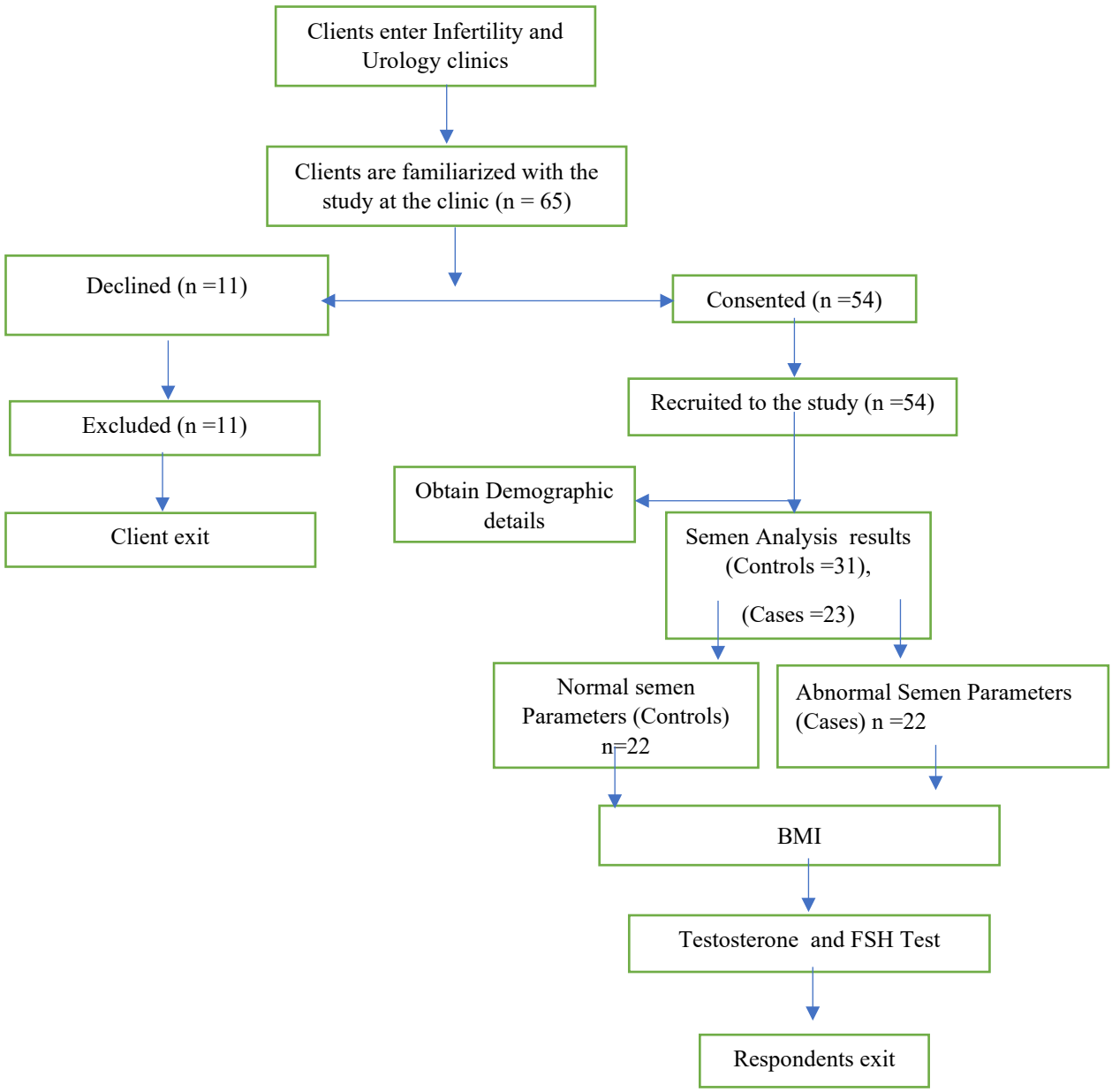


Figure 3.1:Study flowchart

3.8 Study variables

Table 3.1:Variables of the study

Objective	Exposure variables	Outcome	Source of data
To compare patient characteristics between fertile and infertile male partners	**Demographic characteristics** Age, Education level, Income, Marital status, Religion	Semen analysis parameters (fertile, infertile)	Patient files. Semen analysis test
	Clinical characteristics Cigarette smoking, alcohol use, HIV status, Presence of Chronic STDs		
To compare BMI levels between fertile and infertile male partners	Height and Weight	Semen analysis parameters (fertile, infertile)	Measurement scale, Semen analysis
To compare testosterone levels between fertile and infertile male partners	Testosterone levels	Semen analysis parameters (fertile, infertile)	Testosterone test Semen analysis

3.9 Research Assistants

The principal investigator recruited 2 nurses and 1 laboratory assistant to help in the data collection process. The research assistants recruited were required to have experience in the functioning of the urology and infertility clinic to make it easier in approaching and handling the study participants with a high level of professionalism. All research assistants will be required to abide by the study ethical guidelines.

As the principal investigator, oversaw the data collection and ensured that the nurses and laboratory assistants who were research assistants collected quality data through successful engagement with participants in the study. Expert obstetrician and Gynecology consultant also reviewed the filled questionnaire to ensure completeness. The three research assistants were present at the clinic on daily basis engaging potential participants and ensuring that they

consent before data collection. The two nurse research assistants were involved with the recruitment of study participants while the laboratory assistant extracted blood, analyzed the blood samples for testosterone as well as retrieved the semen analysis results for study use.

3.10 Consenting process

The principal investigator (PI) with the help of the recruited research assistants approached potential participants waiting for semen analysis laboratory test. The PI familiarized the study to all those who were seeking infertility review at the clinics in ensuring that they understand the study before recruitment. The key elements of the familiarization process included the purpose of the study, benefits of participating in the study, the risks involved, the level of privacy and confidentiality that was accorded to them if they agree to participate. Only those who agreed to consent were recruited into the study. After consenting, a copy of the consent was produced and given to the participant for their reference.

3.11 Data collection procedure

The data collection process began after approval from KNH – UoN Ethics Committee and permission to conduct the study from the KNH administration. The study was done at infertility and urology Clinics at Kenyatta National Hospital. The researcher with the help of research assistants engaged the potential participants waiting for the semen analysis lab test at the clinic to seek consent. Once the patients agree to participate in the study, the researcher retrieved a copy of the semen analysis to identify cases and controls. The results of semen analysis were grouped into cases and controls. Respondents with abnormal sperm quality were considered as cases and those with normal sperm quality were considered as controls. The researcher engaged the respondents when coming to collect their semen analysis. At this point, the researcher obtained patient demographic details, height, and weight for body mass index as well as extracted 5mls for blood for free testosterone analysis.

3.12 Measurements

Semen, free testosterone and FSH tests were conducted at the UoN/KNH andrology and biochemistry laboratories which are ISO certified.

The laboratory research assistant educated clients about abstaining for 3-5days before semen was collected for semen analysis and a copy of the result was used to categorize participants as cases or controls.

In obtaining the patient testosterone levels, the laboratory researcher assistant extracted 5mls of blood which were stored in clearly marked test tubes to avoid any confusion, and a blood sample run was done to obtain testosterone level.

The measurement of the respondent's body weight was done using a digital portable weighing scale. Respondents were required to wear light clothing with no shoes, jackets, or any additional clothing or anything that could increase weight significantly. The weight was recorded in kilograms (Kg). The height for respondents was measured using the portable stadiometer. Respondents were required to wear no shoes while standing in the Frankfurt position. The shoulders, buttocks, and heels touched the vertical stand. The height measurement was recorded to the nearest 0.1cm and then converted to meters (M) for BMI calculations.

3.13 Research tool

A research questionnaire was used to collect information as presented by the participants to ensure that the findings were unbiased and accurate based on the underlying research objectives being evaluated.

3.14 Data analysis methods

The data collected using questionnaires and forms were checked regularly for completeness by the researcher. Collected data were entered into Epi-Data 3.1 database then analyzed using the SPSS computer package, version 25.

The consent forms and questionnaires were given in a confidential manner and respondents did not have to include their names on them. Once they were filled, they were locked up in a safe cupboard. A statistician was employed to enter, clean, and store the data successfully. A laptop was used to enter and store in an Epi data file format. The consent forms and questionnaires will be safely stored for five years after which they will be destroyed.

The study integrated both descriptive and inferential analysis. Descriptive analysis was grouped into either categorical or continuous. Categorical data such as Marital status, Level of education were analyzed using frequencies (n) and percentages (%) and presented in tables and charts. Continuous data such as age and monthly income were analyzed using mean and standard deviation.

3.15 Ethical Consideration

Authorization to undertake this study was sought from Kenyatta National Hospital/ University of Nairobi Ethics Research Committee (KNH/UON ERC). Participation in the study was voluntary where every individual from the target population who was willing to participate in the study was required to fill an essential consent form. All information was kept confidential.

3.16. Dissemination Plan

The findings from the semen analysis were included in the files of all patients where they were informed about them and appropriate measures were advised on treatment plan. The findings were also shared with Kenyatta National administration. The findings from this study will be published in a peer reviewed journal to share local findings with international audience.

4. CHAPTER FOUR: RESULTS

4.1.Table 4.1:Socio-demographic and clinical characteristics of male partners of women seen at fertility clinic at Kenyatta National Hospital

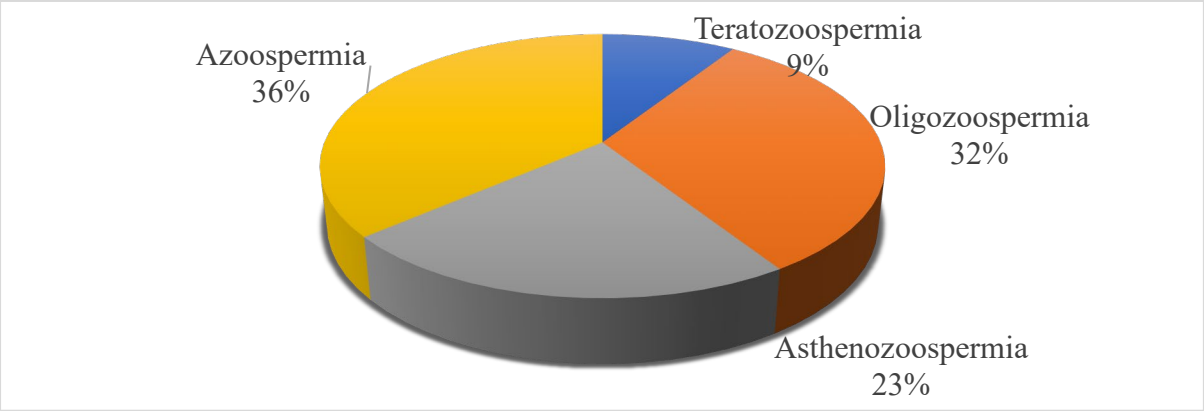
	Total	With normal semen parameters n (%)	With abnormal semen parameters n (%)	OR (95% C.I)	P-value
Age (years) (Mean±2SD)		33.4(8.51)	32.3(7.08)	1(0.561 - 2.541)	0.633*
Highest level of education					
Primary	9 (20.5)	5(23)	4(18)	Ref	
Secondary level	20(45.5)	10(46)	10(46)	0.7(0.245 - 1.412)	0.674
Tertiary Level	15(34.0)	7(31)	8(36)	0.9(0.561 - 1.891)	0.845
Marital status					
Single	16(36.0)	9(41)	7(32)	Ref	
Married	28(64.0)	13(59)	15(68)	0.7(0.341 - 1.251)	0.706
Monthly income (Mean±2SD)	44 (100)	22,659 16262.32	20,181 17798.51	1(0.561 - 2.251)	0.625*
Religion					
Christian	39(88.6)	19(86)	20(91)	1.5(1.151 - 3.211)	0.523^
Muslim	5(11.4)	3(14)	2(9)		
Smoking					
Yes	17(38.6)	4(18)	13(59)	Ref	
No	27(61.4)	18(82)	9(41)	0.15(0.091 - 0.671)	**0.008**
Alcohol					
Yes	21(47.7)	6(27)	15(68)	Ref	
No	23 (22.3)	16(73)	7(32)	0.2(0.091 - 0.89)	**0.007**
HIV status					
Negative	40 (90.1)	20(91)	20(91)	1(0.671 - 2.671)	0.697^
Positive	4(9.9)	2(9)	2(9)	Ref	
Presence of STD					
Yes	4 (9.9)	3(14)	1(5)	3.3(2.561 - 5.671)	0.303^
No	40(90.1)	19(86)	21(96)	Ref	

*Independent samples t-test. ^ Fischer's exact test, OR: Odds Ratio

The average age between cases, 32.3 years (SD±7.08) and controls 33.4 years (SD±8.51) was comparable and the difference was not significant. Forty-six percent of both cases and controls had secondary level education. On marital status, 13(59%) of the controls were married compared to 15(68%) of the cases. The average monthly income among controls was Ksh. 22659 (SD±16262.32) compared to Ksh.20181(SD±17798.51) among cases. Smoking

(p=0.008, OR = 0.154) and alcohol use (p=0.007, OR =1.00) were significantly higher in cases compared to controls as shown in Table 4.1.

Figure 4.1:Types of male infertility in male partners seen with abnormal semen analysis at the Kenyatta National Hospital.



The findings from the study revealed that 8(36%) of the cases were azoospermic, 7(32%) were oligozoospermic, 5(23%) were asthenozoospermic, while 2(9%) of the respondents were teratozoospermic as shown in Figure 4.1.

4.2.Table 4.2:Body mass index and male infertility based on semen parameters among male partners seen at Kenyatta National Hospital

	Total	With normal semen analysis n (%)	With abnormal semen analysis n (%)	OR (95%CI)	P-value
BMI (Kg/m^2)					
Underweight	2 (4.5)	1(4.5)	1(4.5)	0.6(0.241 - 0.914)	0.018
Normal weight	23(52.3)	17(77.4)	6(27.3)	Ref	
Overweight	9(20.5)	1(4.5)	8(36.4)	3.4(1.451 - 6.541	0.024
Obese	10(22.7)	3(13.6)	7(31.8)	2.3(2.511 - 5.71	0.33
BMI recategorized					
<24	26(59.1)	18(82)	8(36)	Ref	
≥24	18(41.9)	4(18)	14(64)	7.9(2.671 - 10.512)	0.009

The findings revealed that there was a significant difference in Body mass index between cases and controls (cases, 26.76(SD±5.29, controls, 22.93(SD±3.86, p = 0.009). The majority,

77% (n =18) of the controls were of normal weight compared to 27.3% in cases. Respondents who were overweight or obese were 8 times more likely to be cases than controls as shown in Table 4.2.

4.3.Table 4.3:The association between Testosterone levels, FSH and male infertility based on semen parameters seen at Kenyatta national hospital

	With normal semen parameters	**With abnormal semen parameters n (%)**	**OR (95%CI)**	**P-value**
Testosterone (ng/mL) (Mean)	**4.53(1.93)**	**6.38(2.27)**	2.3(1.51 - 3.67)	**0.006**
Testosterone levels				
Normal Testosterone	20(91)	19(86)	Ref	0.013
High Testosterone	2(9)	3(14)	1.6(1.10 - 3.61)	
FSH (mIU/mL)	4.36(2.07)	7.76(8.06)		0.063
FSH levels				
Normal FSH	22(100)	18(82)	Ref	
High FSH	0	4(18)	1.2(0.91 - 3.56)	0.102

The results showed that there was a significant difference in testosterone levels between cases and controls (cases, 4.53(SD±1.93, controls, 6.38(SD±2.27, p = 0.006, OR =1.556). The results further show that 9% (n =2) of the controls and 14% (n =3) had high levels of testosterone levels.

The FSH levels were higher in cases as compared to controls although the difference was not statistically significant (cases, 7.76(SD±8.06), controls, 4.36(SD±2.07, p = 0.063, OR =1.16) as shown in Table 4.3.

4.4.Table 4.4: The association between body mass index and testosterone level among male partners seen at Kenyatta National Hospital

	Testosterone level (ng/mL)			
BMI (Kg/m^2)	Normal Levels	Abnormal levels	OR (95%CI)	P-value
<24	23(59)	2(40)	2.2(0.323,14.410)	0.428
≥24	16(41)	3(60)	Ref	

The study also investigated the relationship between body mass index and testosterone level among male partners as shown in Table 4.4. The findings showed that there was no significant relationship between testosterone levels and body mass index (p = 0.055).

4.5.Table 4.5: Independent factors associated with male infertility based on semen parameters at the Kenyatta National Hospital.

	aOR (95%CI)	P-value
Smoking		
Yes	Ref	
No	0.1(0.014 - 0.478)	0.002
Alcohol		
Yes	Ref	
No	0.1(0.017 - 0.51)	0.065
BMI	1.2(1.036 - 1.403)	0.016
Testosterone level	1.6(1.099 - 2.211)	0.013

Smoking, alcohol use, body mass index and testosterone levels were included in the multivariate model. The findings revealed that smoking, body mass index and Testosterone level were associated with increased risk of abnormal semen parameters. The odds of respondents who were not smokers being a case was 92% lower compared to those who smoke, (aOR = 0.081, (95%CI, 0.014, 0.478), p = 0.002). With every 1 kg/m² increase in BMI, the odds of being a case were 21% higher compared to being a control (aOR = 1.206, (95%CI, 1.036, 1.403), p = 0.016). Similarly, in every 1 ng/ml increase in testosterone level,

the odds of being a case were 56% higher compared to being a control (aOR = 1.559, (95%CI, 1.099, 2.211), p = 0.013) as shown in Table 4.5.

CHAPTER FIVE: DISCUSSION

The present study sought to examine the effect of body mass index and testosterone level on male partner infertility based on semen parameters at the Kenyatta national hospital. The findings from the study revealed that the average age for the cases was 32 years compared to controls with 33 years. However, the difference between the cases and controls was not statistically significant. These findings are comparable to a case-control study conducted in Pakistan~~i~~ by Zahid et al. (2015) investigating male infertility. The study found that both controls and cases had similar age patterns. However, these findings contrast a study conducted by TJ and Thaddeus (2016) in Nigeria which found that the average age of infertile obese men was 38 years which is higher than the present study. The difference could be associated with the target population. In our study, the target population included both infertile and fertile men across different body mass index groups while their study included obese male participants.

The findings from the present study also revealed that there was no difference between the cases and controls based on marital status, monthly income, HIV status and presence of sexually transmitted diseases. These findings are comparable to a case control study conducted in Turkey by Mahboubi et al. (2014) which identified that there was no relationship between male infertility and marital status and respondent monthly income. However the findings from the present study contrast those from Kushnir and Lewis (2012) who found that there was higher rate of male infertility in HIV positive patients (51). Further, early studies in sub-Saharan Africa showed that fertility was 25– 40% lower in HIV-1 infected women than uninfected controls (52). This was the first suggestion that HIV/AIDS was associated with fertility defects. This difference could be attributed to the small sample size in the current study where only two infertile respondents were HIV positive.

Our study found that alcohol use and cigarette smoking were associated with male infertility based on semen analysis. The likelihood of male infertility was higher in cigarette smokers and alcohol users. These findings are consistent with Mahboubi et al. who found that smoking and alcohol abuse are associated with increased risk of male infertility. In addition, a study conducted in United States investigating smoking and male infertility by Kovac et al. (2015) in the United States found that men who smoked more than 20 cigarettes per day experienced a 19% reduction in sperm concentration as compared to non-smokers leading to infertility. Additionally, a systematic and meta-analysis review conducted by Bundhun et al. (2019) examining human semen found that tobacco smoking was associated with negative

influence on semen parameters resulting in infertility. Zahid et al. (2015) in a study conducted in Pakistan also revealed that cigarette smoking was associated with increased risk of male infertility.

The findings from the present study found that 17 (77%) of controls were of normal weight compared to 7(27%) of the cases. Similarly, it was also identified that 4(18%) of the controls were either overweight or obese while 14(64%) of the cases were either overweight or obese. Thus, the findings reveal that majority of the respondents who were infertile were either obese or overweight. The difference was statistically significant. The findings from the present study further asserted that, respondents who were overweight or obese were eight times more likely to be cases than controls. The multivariate analysis conducted also revealed that with every 1 kg/m² increase in BMI, the odd of being a case were 21% higher compared to being a control. These findings are in line with Zahid et al. (2015) in a study conducted in Pakistan which found that with every 1 kg/m² increase in BMI the odds of being a case was 6% higher as compared to being a control. Another study conducted by Mahboubi et al. in 2014 investigating 268 men attending infertility clinic found that an increase in the body mass index was associated with increased risk of male partner infertility (25). Engin-Ustun et al in a study conducted in 2018 examining male infertility among 159 men found that, high body mass index was associated with lower sperm concentration, motility and volume which contribute to decreased sperm quality (26). Nguyen et al. also found that body mass index negative influences male fertility because of reduced oestradiol levels (48).

The results from the present study also revealed that, 20(90%) of the controls had normal testosterone levels compared to 19(86%) of the cases. Further, the present study also found that, 2(9%) of the controls vs 3(14%) of the cases had high testosterone levels. The difference was significant. The findings showed that respondents who had high testosterone were 2 times likely to be cases compared to controls. The multivariate analysis found that, with every 1 ng/ml increase in testosterone level, the odd of being a case were 56% higher compared to being a control. These findings are in line with a cross sectional study conducted in Rwanda by Mapira Tendayi et a. (2020) in assessing 62 men attending infertility clinic who found that there was a statistically significant association between male infertility and testosterone levels. The study further stressed that there was a strong positive relationship between testosterone levels and sperm count (49). Another study conducted in the United States by Trussell et al. in 2019 among 781 men found that testosterone levels was associated with male fertility. Lower total testosterone in their study was assessed at less than 264 ng/dL

where men with TT <264 ng/dL were less likely to have normal (≥4% strict Kruger) morphology. The findings from the study also found that, there was no association between low total testosterone levels and semen volume (50). However, in a study assessing low testosterone levels and semen parameters in male partners by Di Guardo et al. (2020), in 853 men patients, it was found that Semen volume, sperm cell count, progressive (A + B) motility and morphology (≥4% strict Kruger) were lower in the low TT group but not significantly different between low and normal TT groups. Multivariable regression analysis revealed that low TT and free T levels had no significant effect on the aforementioned semen parameters (51)

The results from the present study found that there was no significant difference in FSH between cases and controls. These findings however were contrasting a cross sectional study conducted in Rwanda by Mapira Tendayi et al. (2020) who found that there was significant negative relationship between FSH , LH and sperm count (49). Further, Ehala-Aleksejev and Punab in a study conducted in 2018 among 2642 men in Estonia found that there was negative relationship between FSH and semen analysis parameters (52). The difference could be associated with skewed data distribution where he FSH values obtained included outliers hence affecting the distribution and the underlying relationship.

The findings from our study identified that, there was no significant association between testosterone levels and body mass index. The results are in line with Adebayo et al. (2020) assessing the relationship between Body Mass Index (BMI) and testicular and hormonal parameters of sexually active male greater cane rats. The findings revealed that BMI/LI, both of which followed the same pattern, neither correlate with testicular parameters nor with serum testosterone, progesterone, LH and FSH concentrations but had low correlations with serum estradiol concentration ($r^2 = 0.2$; $p = 0.0023$) (53). So, these relationships may provide clue on obesity and its effect on reproductive performance and strengthened the possibility of the characterized BMI/LI as obesity marker for breeding selection in male cane rat.

These findings are contrast to most studies which have found an inverse association between body mass index and testosterone level. A study conducted by Eriksson et al. (2017) in Denmark, Sweden and Germany investigating the direction and causality of the relationship between body mass index (BMI) and serum testosterone. The results showed that, for a body weight reduction altering the BMI from 30 to 25 kg/m^2, the effect would equal a 13% increase in serum testosterone. No association was seen for genetically instrumented

testosterone with BMI, a finding that was confirmed using large-scale data from the GIANT consortium (54).

CHAPTER SIX: CONCLUSION AND RECOMMENDATION

6.1.Conclusion

The findings also showed that (77%) of controls were of normal weight compared to 7(27%) of the cases.

The findings have showed that majority of those with abnormal semen parameters were either overweight or obese. The results showed that there was significant difference in testosterone levels between cases and controls. The results further show that those with abnormal semen parameters had higher testosterone levels compared to those with normal semen parameters. The findings showed that, there was no significant relationship between testosterone levels and body mass index ($r = 0.291$, $p = 0.055$).

Multivariate analysis model revealed that smoking, body mass index and Testosterone level were independent predictors of male infertility. Respondents who were not smokers were 92% less likely to be a case compared to being a control, (aOR = 0.081, (95%CI, 0.014, 0.478), $p = 0.002$). With every 1 kg/m² increase in BMI, the odd of being a case were 21% higher compared to being a control (aOR = 1.206, (95%CI, 1.036, 1.403), $p = 0.016$). Similarly, in every 1 ng/ml increase in testosterone level, the odd of being a case were 56% higher compared to being a control (aOR = 1.559, (95%CI, 1.099, 2.211), $p = 0.013$).

6.2.Recommendation

- Create increased awareness on the adverse implications of cigarette smoking and its influence on semen parameters in male fertility.
- Emphasize on regular review of weight management to control increased risk of male infertility based on semen parameters among male partners.
- Advocate for regular physical exercises to reduce the risk of infertility among men

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APPENDICES
Appendix I: Consent form

Title of the study: Body Mass Index (BMI) and Testosterone Influence on Male Partner Infertility as seen at the Kenyatta National Hospital Infertility and Urology clinics.

Researcher: Dr. Komba Songu – M'Briwa

Introduction to the study: You are requested to participate in the study which is voluntary and will be conducted in the Department of Obstetrics and Gynecology at Kenyatta National Hospital.

The Purpose of the study: To determine how Body Mass Index (BMI) and testosterone influence on male partner infertility as seen at the infertility and urology clinics at Kenyatta National Hospital.

Procedures: If you agree to participate in the study, your demographic details, height and weight will be taken. You are also requested to allow access of your medical data as documented in the file to obtain your medical history. In addition to the semen analysis test that you are currently undertaking I will request you to consent to an additional test which is a testosterone test will also be administered. I will also require to measure your height and weight for the purpose of computing Body Mass Index.

Time: The study is simplified and will not consume much of your time with approximately 15 minutes required to finish the whole process.

Benefit of the study: The researcher will pay for the testosterone test you will be required to undergo thus you will not incur any additional cost for involvement in this study.

Risks, stress and discomfort: Considering the nature of study and condition being evaluated, it might cause you a slight discomfort. In extracting blood, you will feel slight pain. However, the researcher is experienced in the field and will guide you and provide you with any information pertaining your condition for high quality and expert management. In addition, you have the right to decline giving information.

Cost and risk of loss of Confidentiality: There will be no additional direct cost incurred by you neither will you receive any money for participating in this study. Information that you will provide is mainly for academic purposes and at no point in time will you be required to provide personal information unwillingly. Your data will be labeled with your unique identity and your name concealed maintaining confidentiality when taking part in the study. Furthermore, your name will not appear in any report or publication of the research and all your personal information will be handled with a high level of confidentiality.

Voluntary Participation and withdrawal: Remember, your participation is entirely voluntarily. Should you consider changing your mind midway, you have the right to do so and you shall not suffer any consequence whatsoever. Incase you reach this conclusion after specimen and medical data has been collected, your inclusion into the study will not be considered and thus you will be excluded from the study entirely and collected information discarded.

Sharing of results: The results of this study may be presented during scientific and academic forums and may be published in scientific medical journals and academic papers.

Participants consent

I confirm that the researcher has explained fully the nature of the study and the extent of activities which I will be asked to undertake. I confirm that I have had adequate opportunity to evaluate and ask questions about this study. I understand that my participation is voluntary and that I may withdraw at any time during the study, without having to give a reason. I agree to take part in this study by filling in the proforma.

Signed: by participant…… Date…….

In case of any issues or challenges related to this study, please contact me on **0**757614776 or Dr. Wanyoike on 0722522234, Dr. Diana Ondieki on 0722246101 or /UON ERC Secretariat on Tel.2726300 ext 44102, uonknherc@uonbi.ac.ke

Thank you for sparing your precious time dedicated to participating in this study exercise.

Researcher's statement

I certify that the purpose, potential benefits and possible risks associated with participating in this research have been explained to the above participant and the individual has voluntarily consented to participate.

Signature_____ Date_____

Appendix II: Questionnaire

Questionnaire No……

Section A: Patient demographic details

1. Age (in years) …….
2. Level of education

   Primary

   Secondary level

   Tertiary
3. Monthly income (average in Ksh.) …….
4. Marital status

   Single [ ]

   Married [ ]
5. Religion

   Christian [ ]

   Muslim [ ]

   Hindu [ ]
6. Do you smoke?

   Yes [ ] No [ ]
7. Do you take alcohol?
8. Yes [ ] No [ ]

Part B: Clinical characteristics

9. HIV status

Negative [ ] Positive [ ]

10. Have you had chronic sexually transmitted disease in the past 1 year?

Yes [ ] No [ ]

11. If yes, Which one? ……

Part C: Body Mass Index

12. Height (in cm) ……

13. Weight (in kg) …….

Part D: Testosterone test

14. Testosterone level (ng/mL) …….

15. FSH (mIU/mL) …….

Part E: Semen analysis

Parameter	Measurement
16. Sperm volume (ml)	
17. Sperm concentration (ml)	
18. Total sperm count	
19. Sperm progressive motility (A+B) %	
20. Sperm morphology (%)	
21. Sperm morphology (%)	
22. Sperm DNA fragmentation (%)	
23. Non-sperm cells (ml)	

24. Semen analysis status: Normal [ ] Abnormal [ ]

Appendix III: Fomu ya idhini

Kichwa cha utafiti: Faharisi ya molekuli ya mwili (BMI) na Testosterone Ushawishi juu ya Ugumba wa Washirika wa Kiume kama inavyoonekana katika Kliniki za Hospitali ya Taifa ya Kenyatta na kliniki za Urology.

Mtafiti: Dkt. Komba Songu - M'Briwa

Utangulizi wa utafiti huo: Unaombwa kushiriki katika utafiti huo ambao ni wa hiari na utafanywa katika Idara ya Ukunga na jinekolojia katika Hospitali ya Kitaifa ya Kenyatta.

Madhumuni ya utafiti: Kuamua jinsi Faharisi ya molekuli ya mwili (BMI) na testosterone ushawishi juu ya ugumba wa mpenzi wa kiume kama inavyoonekana katika kliniki za ugumba na urology katika Hospitali ya Kitaifa ya Kenyatta.

Taratibu: Ikiwa unakubali kushiriki katika utafiti, maelezo yako yanayokuhusu demografia, historia ya matibabu itachukuliwa iwapo utakubali kushirii. Mbali na mtihani wa uchambuzi wa shahawa kwamba kwa sasa unafanya nitakuomba mtihani wa kuongeza idhini ambayo ni mtihani wa testosterone pia utasimamiwa. Pia nitahitaji kupima urefu wako na uzito kwa lengo la computing Mwili Misa Index.

Muda: Utafiti umerahisishwa na hautatumia muda wako mwingi na takriban dakika 15 zinazohitajika kumaliza mchakato mzima.

Faida ya utafiti: Mtafiti ni mtaalamu katika ugumba wa kiume na hivyo ushiriki unakuhakikishia utunzaji wa ziada na kuzingatia zaidi tatizo lako katika ngazi ya kibinafsi. Mtafiti pia atalipia mtihani wa testosterone utahitajika kufanyiwa hivyo huwezi kupata gharama yoyote ya ziada ya kuhusika katika utafiti huu.

Hatari, mfadhaiko na usumbufu: Kwa kuzingatia asili ya utafiti na hali inayotathminiwa, inaweza kukusababishia usumbufu kidogo. Katika kuchimba damu, utahisi maumivu kidogo. Walakini, mtafiti ana uzoefu uwanjani na atakuongoza na kukupa habari yoyote inayohusu hali yako kwa usimamizi wa ubora wa juu na mtaalam. Kwa kuongezea, una haki ya kukataa kutoa habari.

Gharama na hatari ya kupoteza Usiri: Hakutakuwa na gharama ya ziada ya moja kwa moja iliyopatikana na wewe wala hutapokea pesa zozote za kushiriki katika utafiti huu. Maelezo ambayo utatoa ni hasa kwa madhumuni ya kitaaluma na wakati wowote utahitajika kutoa habari binafsi bila kutaka. Data yako itaandikwa na utambulisho wako wa kipekee na jina lako limefichikwa kudumisha usiri wakati wa kushiriki katika utafiti. Zaidi ya hayo, jina lako halitaonekana katika ripoti yoyote au uchapishaji wa utafiti na maelezo yako yote ya kibinafsi yatashughulikiwa na kiwango cha juu cha usiri.

Ushiriki wa hiari na uondoaji: Kumbuka, ushiriki wako ni wa hiari kabisa. Na mkiona baya, basi yaliyo juu yake ni aliyo bebeshwa, na yaliyo juu yenu ni mliyo bebshwa nyinyi.

Kushiriki matokeo: Matokeo ya utafiti huu yanaweza kuwasilishwa wakati wa vikao vya kisayansi na kitaaluma na inaweza kuchapishwa katika majarida ya matibabu ya kisayansi na karatasi za kitaaluma.

Ridhaa ya washiriki

Ninathibitisha kuwa mtafiti ameelezea kikamilifu asili ya utafiti huo na kiwango cha shughuli ambazo nitaombwa kufanya. Ninathibitisha kwamba nimepata fursa ya kutosha ya kutathmini na kuuliza maswali kuhusu utafiti huu. Ninaelewa kwamba ushiriki wangu ni wa hiari na kwamba ninaweza kujiondoa wakati wowote wakati wa utafiti, bila kutoa sababu. Ninakubali kushiriki katika utafiti huu kwa kujaza proforma.

Imesainiwa: na mshiriki..... Tarehe.....

Katika kesi ya masuala yoyote au changamoto zinazohusiana na utafiti huu, tafadhali **wasiliana**nami juu ya0 757614776 au Dk. Wanyoike juu ya 07225222234, Dk. Diana Ondieki juu ya 0722246101 au Maadili ya KNH-UON ERC kupitia nambari ya simu.2726300 ext 44102, au barua pepe uonknherc@uonbi.ac.ke

Asante kwa kuachia muda wako wa thamani uliojitolea kushiriki katika zoezi hili la utafiti.

Kauli ya Mtafiti

Mahojiano : Ninathibitisha kwamba kusudi, faida zinazowezekana na hatari zinazowezekana zinazohusiana na kushiriki katika utafiti huu zimeelezwa kwa mshiriki hapo juu na mtu amekubali kushiriki.

Signature_____ Date_____

Appendix IV: Dodoso

Nambari ya dodoso.....

Sehemu A: Maelezo ya idadi ya watu ya mgonjwa

1. Umri (katika miaka)....
2. Kiwango cha elimu

   Msingi

   Ngazi ya sekondari

   Tertiary
3. Mapato ya kila mwezi (wastani katika Ksh.) .....
4. Hali ya ndoa

   Single []

   Ndoa [ ]
5. Dini

   Kikristo [ ]

   Waislamu [ ]

   Kihindu [ ]
6. Unavuta sigara?

   Ndiyo [ ] Hapana [ ]
7. Unatumia pombe?
8. Ndiyo [ ] Hapana [ ]

Sehemu B: Sifa za kliniki

9. Hali ya VVU

Hasi [ ] Chanya [ ]

10. Je, umewahi kuwa na ugonjwa sugu wa zinaa katika mwaka wa 1 uliopita?

Ndiyo [ ] Hapana [ ]

11. Kama ndiyo, Ni ipi? .....

Sehemu C: Kielezo cha Misa ya Mwili

12. Urefu (katika cm) .....

13. Uzito (kwa kilo)....

Sehemu ya D: Mtihani wa Testosterone

14. Kiwango cha Testosterone (ng / dL)....

15. Kiwango cha FSH (mIU/mL)……

Sehemu E: Uchambuzi wa shahawa

Parameta	Kipimo
16. Kiasi cha mbegu za kiume (ml)	
17. Wingi wa mbegu za kiume (ml)	
18. Jumla ya hesabu ya mbegu za kiume	
19. Motisha ya mbegu za kiume (A +B) %	
20. Mbegu za kiume (%)	
21. Mbegu za kiume (%)	
22. Mbegu za kiume DNA kugawanya (%)	
23. Seli zisizo za mbegu za kiume (ml)	

24. Hali ya uchambuzi wa shahawa: Kawaida [ ] Isiyo ya kawaida [ ]

Appendix V: Letter to Ethics

Dr. Komba Songu – M'Briwa
Resident Obs/Gynae
University of Nairobi
NAIROBI.

To
The Chair
The Research and Ethics Review Committee, KNH/UoN
PO BOX 20723- 00202
NAIROBI,

Dear sir,
RE: REQUEST FOR AUTHORITY TO CONDUCT RESEARCH IN KNH.
I am a student at University of Nairobi Undertaking a Master of Medicine (M.Med) in the department of Obstetrics and Gynecology.
I am requesting for your authorization to carry out research on the Body **Mass Index (BMI) and Testosterone Influence on Male Partner Infertility as seen at the Kenyatta National Hospital Infertility and Urology clinics** as part of my academic requirements.
Attached is a copy of my research proposal for your perusal.

Thank you in advance

Yours faithfully;

Dr. Komba Songu – M'Briwa

H58/12307/2018

Appendix VI: Workplan

Activity/Year	**Mar – July 2020**	**July– Nov 2020**	**Dec 2020**	**Jan – Mar 2021**	**March - July 2021**	**July - Aug 2021**	**Aug - Sept**	**Oct 2021**
Concept paper Development								
Proposal Development								
Proposal Presentation								
Approval								
Data collection								
Data Analysis								
Report Writing								
Thesis Submission								

Appendix VII: Budget

Item Description	Unit Cost (Kshs.)	Quantity	Total (Kshs.)
Proposal and questionnaire development			
Files	**500.00**	**2**	**1000.00**
Pens	**200.00**	**6**	**1200.00**
Flash Disk	**2000.00**	**3**	**6,000.00**
Internet	**5,000**	**3**	**15,000.00**
Printing	**10.00**	**50**	**500.00**
Photocopying	**5.00**	**50*5**	**1,250.00**
Binding	**250.00**	**5**	**1,250.00**
Sub-total			**26,200**
Data Collection and Analysis			
Research assistant	**30,000.00**	**3**	**90,000.00**
Data entry and cleaning	**15,000.00**	**1**	**15,000.00**
Statistician	**60,000.00**	**1**	**60,000.00**
Sub-total			**165,000**
Thesis Development			
Printing	**10.00**	**100**	**1,000.00**
Binding	**500.00**	**5**	**2,500.00**
Photocopying	**5.00**	**100**	**2,500.00**
Sub-total			**6,000**
Other Expenses			
Testosterone and FSH tests **Semen analysis**	**1,500** **1000**	**44** **44**	**66,000** **44,000**
Airtime	**100.00**	**50**	**5,000.00**
Sub-total			**115,000**
Sum-Total			**312,200**
Contingencies (15%)			**46,830**
Grand Total			**359,030**

Appendix VI: Plagiarism Report

Body Mass Index (BMI) and Testosterone Influence on Male Partner Infertility in Kenyatta National Hospital Infertility and Urology clinics in 2021.

ORIGINALITY REPORT

14%	10%	11%	3%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	hwbdocuments.env.nm.gov Internet Source	1%
2	"Male Infertility", Springer Science and Business Media LLC, 2020 Publication	1%
3	"Poster Presentations", International Journal of Gynecology & Obstetrics, 2015. Publication	1%
4	www.ncbi.nlm.nih.gov Internet Source	1%
5	academic.oup.com Internet Source	1%
	Albert Salas-Huetos, Leila Maghsoumi-	