REPORT ON

PATTERN OF INFERTILITY, ASSOCIATED RISK FACTORS, AND PREEXISTING FERTILITY TREATMENT AMONG PATIENTS ATTENDED AT ASSISTED REPRODUCTIVE CLINIC AT BENJAMIN MKAPA HOSPITAL IN 2023: AN ANALYTICAL CROSS-SECTIONAL STUDY.

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DECLARATION AND CERTIFICATION

We declared that this report was entirely our original idea and that the proposed research report has not been presented or conducted elsewhere in a similar manner for either award or as a research project. We followed all the ethical principles in the preparation of this research. We affirmed that we cited and referenced all other authors' ideas and words used in the work

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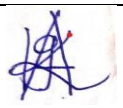
Anna Gideon Kasililika	MD, MSc-Reproductive Biology		*Annarosemary04@gmail.com*
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ABSTRACT

Introduction: Infertility is a global health problem, affecting 1 out of 6 couples worldwide, and it has been associated with various negative impacts on quality of life. Assisted reproduction technologies are recommended for treating infertility. Several studies have reported different patterns of infertility, risk factors, and preexisting fertility treatments. However, there remains a lack of clarity regarding the specific patterns of infertility, associated risk factors, and preexisting fertility treatments among patients seeking care at Benjamin Mkapa Hospital in Dodoma Region, Tanzania.

Methods: This hospital-based analytical cross-sectional study aimed to determine the pattern of infertility, associated risk factors, and the preexisting fertility treatment among 385 male and female patients with infertility who attended the Assisted Reproductive Clinic at Benjamin Mkapa Hospital in Dodoma. A structured clinical proforma containing information on socio-demographic characteristics, associated risk factors, and previous fertility treatment was used to collect specific data through patient interviews. Data analysis involved descriptive statistics conducted using the Statistical Package for Social Science (SPSS) version 25. A p-value of < 0.05 was considered statistically significant.

Results: The findings indicated that the dominant pattern of infertility was secondary infertility, accounting for 59.00% (228).The multivariable logistic regression analysis for both male and female patients revealed associated risk factors for infertility were older age (38-43 years, AOR 5.068,95% CI 1.573-16.33, P = 0.007), a frequency of sexual intercourse less than three times a week (AOR 0.554, 95% CI 0.348-0.883, P = 0.013), Among female patients, a previous history of cesarean section was also identified as a risk factor (AOR 1.152, 95% CI 0.0418-0.553, P = 0.004). Findings regarding preexisting fertility treatments for male and female patients with infertility indicated that 42% (162) had used herbal medications, while 4.94% (19) had undergone Assisted Reproduction technologies. Among male patients, 95.72% (176) had never received surgical treatment, and 70.68% (130) had never received medical treatment for infertility.

Conclusion: Secondary infertility emerges as the dominant pattern in this study with advanced age, prolonged duration of cohabiting/marriage, infrequent sexual intercourse, and a history of cesarean section as risk factors. The findings also highlight the suboptimal management of male infertility, the extensive use of herbal medications among female patients, and the limited accessibility of Assisted Reproduction Technologies (ART) services. The study recommends developing institutional treatment guidelines for both male and female infertility and the establishment of ART services in public hospitals throughout Tanzania.

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ABBREVIATIONS

ART	Assisted Reproduction Technologies
BMI	Body Mass Index
ET	Embryo Transfer
GIFT	Gamete Intrafallopian Transfer
HIV/AIDS	Human Deficiency Virus/Acquired Immunodeficiency Syndrome
ICSI	Intracytoplasmic Sperm Injection
IVF	In Vitro Fertilization
MAR	Medically Assisted Reproduction
PID	Pelvic Inflammatory Disease
PGT	Pre-implantation Genetic Testing
TVU	Transvaginal Ultrasound
UDOM	University of Dodoma
WHO	World Health Organization
ZIFT	Zygote Intrafallopian Transfer

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background information

Infertility is a disease of male and female reproductive system defined by the failure to establish clinical pregnancy after 12 months of regular unprotected sexual intercourse. Infertility may present as a primary or secondary disease. Primary infertility occurs when a woman has never diagnosed with (or a man has never initiated) a clinical pregnancy and meets the criteria of being classified as having infertility. Secondary infertility occurs when a woman is unable to establish (or a man who is unable to initiate) a clinical pregnancy but who has previously been diagnosed with (initiated) a clinical pregnancy (Zegers-Hochschild et al., 2017).

Infertility is a global health problem affecting 1 in 6 people worldwide. Infertility associated with various negative impact on quality of life of the patients including verbal and physical abuse, social stigma, (Bakhtiyar et al. 2019; Abebe, Afework, and Abaynew 2020; Monga et al. 2004) sexual dysfunction (Warchol-Biedermann 2021), marriage divorces, risk of multiple partners, sexual transmitted diseases including HIV/AIDS (Favot et al. 1997) showing the urgent need to increase access to affordable, high-quality fertility care for those in need

Different studies reported on different pattern of infertility for instance the studies in Iran (primary infertility 69.5% and secondary infertility 30.5%) (Masoumi & Yavangi, 2015), Ethiopia(primary infertility 14.4% and secondary infertility 13.2%) (Akalewold et al., 2022) and Kenya (primary infertility 55.6 % and secondary infertility 44.3%) (Otwori, 2013) reported the prevalence of primary infertility was higher than secondary infertility whereas the studies in China (primary infertility 6.54 %, secondary infertility 18.04%) (Liang et al., 2021) and Moshi, Tanzania (primary infertility 37.1% and secondary infertility 62.9%) (Larsen et al., 2006a) reported the dominance of secondary infertility.

Although previous studies (Akalewold et al., 2022; Cong et al., 2016; Kasililika et al., 2021; Liang et al., 2021) reported on the risk factors for infertility, these kind of studies were not done in Dodoma. The female risk factors observed were; age, age at marriage, high level of education, dysmenorrhea, irregularity of menses, obesity (Kasililika et al., 2021; Liang et al., 2021), as well as previous use of contraception (Akalewold et al., 2022), previous history of pelvic inflammatory

disease, fibroid. The male risk factors included obesity, drug abuse, working environment and trauma(Cong et al., 2016).

Fertility treatment is normally initiated after 12 months however there are cases where treatment may be required to start earlier based on patient's medical history, physical findings and diagnostic testing (Kamel, 2010). Fertility treatment includes medically assisted reproductions (MARs). MARs are various interventions, procedures, surgeries and technologies in treating different forms of infertility. These are ovarian stimulation, ovulation induction; intrauterine insemination with semen of husband or donor and all assisted reproductive technologies (ART).(Zegers-Hochschild et al., 2017)

Assisted reproductive technologies are all interventions that include the in vitro handling of both human oocytes and sperm or of embryos for the purpose of reproduction. These interventions include in vitro fertilization (IVF) and embryo transfer (ET), intracytoplasmic sperm injection (ICSI), embryo biopsy, pre-implantation genetic testing (PGT), assisted hatching, gamete intrafallopian transfer (GIFT) zygote intrafallopian transfer (ZIFT) ,gamete and embryo cryopreservation, gamete and embryo donation and gestational carrier cycles.(Zegers-Hochschild et al., 2017)

Although ART are recommended method for treating infertility and many patient with infertility are willing to seek (Akande et al., 2019; Liang et al., 2021; Zhou et al., 2018), ART is not available in any public hospital in Tanzania therefore, it is not clear which infertility care do patients with infertility do receive.

This study aimed at investigating the pattern of infertility, associated risk factors and used fertility treatment by the patients with infertility attended Assisted reproduction clinic at Benjamin Mkapa hospital.

1.2 Statement of the problem

It is more than 10 years since the study (Larsen et al., 2006a) was conducted in Moshi, Tanzania among infertile couple and found that secondary infertility was commoner than primary infertility(62.9% vs. 37.1%) and female factor infertility accounted for 65.9%. It is not clear

whether the same situation has been prevailing to date and therefore there is a need to determine the current pattern of infertility and risk factors for infertility in Tanzania.

Infertility is a public health problem associated with psychological, social, medical and financial difficulties situations. Previous studies in China(Cong et al., 2016) and Ethiopia(Akalewold et al., 2022) reported on the risk factors for infertility such as age, scant and heavy bleeding, history of gynaecological surgery ,body mass index, age, contraception use, drug abuse and duration of infertility. The information on the risk factors for infertility is limited in Tanzania which would be very important in guiding clinicians during clinical management.

Although WHO 2001 meeting on Medical, ethical and social aspects of assisted reproduction suggested that infertility should be treated as a public health disease condition and ensure that ART services are in accordance to the socio cultural solutions to infertility (Ombelet & Onofre, 2019).There are limited information on the preexisting utilization of fertility treatment among patients attended Assisted reproduction clinic at Benjamin Mkapa hospital. This study would add useful information while planning for infertility treatment modalities in Tanzania

1.3 Objectives of the study

1.3.1 General objective

To determine the pattern of infertility, associated risk factors and preexisting utilization of fertility treatment among patients attended Assisted Reproductive clinic at **Benjamin Mkapa Hospital.**

1.3.2 Specific Objectives.

1. To determine the overall pattern of infertility among patients attended Assisted reproductive clinic- Benjamin Mkapa hospital,
2. To determine risk factors associated with infertility pattern among patients attended Assisted Reproductive clinic -Benjamin Mkapa Hospital,
3. To identify the preexisting fertility treatment for patients with infertility before seeking treatment at Assisted Reproductive clinic- Benjamin Mkapa hospital

1.4 Research questions

1. .What are the patterns of infertility among patients attended at Assisted Reproductive clinic-Benjamin Mkapa Hospital?

2. What are the risk factors associated with infertility pattern among patients attended at Assisted Reproductive clinic –Benjamin Mkapa Hospital?
3. What are the preexisting fertility treatments utilized by patients with infertility before seeking treatment at Assisted Reproductive clinic-Benjamin Mkapa Hospital?

1.5 Significance of the study

This study determined the pattern of infertility, associated risk factors and preexisting utilization of fertility treatment among patients with infertility attended at Assisted Reproduction clinic at Benjamin Mkapa Hospital, of which the information on the pattern of infertility increases our understanding on the burden of the disease at our setting and in Tanzania.

Moreover, this study contributes in improving the fertility in Tanzania through sharing of the knowledge to the public on socio-demographic characteristics that are protective or harmful to fertility status and therefore strengthening reproductive health education programmes on prevention of sexual transmitted diseases, unsafe abortion practices, as well as contraceptive use and adopting health lifestyle.

This study also highlighted the possible risk factors for infertility in Tanzania since Benjamin Mkapa hospital receives patients from different parts of Tanzania. Knowing the cause of the infertility will influence provision of appropriate treatment in clinical setting; therefore contribute in reducing unnecessary financial burden to the patient.

This study determined the preexisting fertility treatment in Tanzania, of which will stimulate the need for appropriate fertility care for instance initiating assisted reproduction technologies in public hospitals, providing training to health professionals on infertility care in Tanzania.

CHAPTER TWO

2.0 LITERATURE REVIEW

This chapter consists of a review from different literatures of assessing infertility, risk factors and fertility treatment given by patients with infertility. It provides a general overview of pattern of infertility, \associated risk factors and fertility treatment used by patient with infertility. It describes the conceptual framework.

2.1 Pattern of infertility

The investigator conducted research among 765 Chinese women in the Henan province aged between20-49 and found that the prevalence of infertility was 24.58%. In addition, the investigator reported that Secondary infertility is noted to be higher than primary infertility (primary infertility contributing 6.54%, vs secondary infertility 18.04%. It is not clear if the same situation is happening at Benjamin Mkapa Hospital (Liang et al., 2021).

The cross sectional study at specialized infertility clinic of Fatemiah hospital, Hamadan, Iran was conducted among 1200 infertile couple and the researcher found that primary infertility was more prevalent 69.5% than secondary infertility (30.5%).(Masoumi & Yavangi, 2015)

The recent institutional based cross sectional study conducted in Addis Ababa, Ethiopia, investigate infertility among women of reproductive age group attending clinic for infertility /obstetric from three public hospitals and found that 27.6% women were infertile ,of which 14.4% had primary infertility and 13.2% had secondary infertility. (Akalewold et al., 2022).

In a descriptive study conducted among infertile couple attending fertility clinic and gynaecological outpatient clinic at Kenyatta National hospital, the investigator found that prevalence of primary infertility was 55.6%, secondary infertility was 44.3%.This study represented the fertility situation in Kenya and it is not clear if the same situation is happening in Tanzania. Therefore, there is a need for research in this field at Benjamin Mkapa Hospital (Otwori, 2013)

A cross-sectional study conducted in Moshi, Tanzania found that the prevalence of primary infertility was 37.1% and secondary infertility was 62.9%. This study was done ten years ago and

it is unclear if the prevalence has been the same today therefore the investigator need to investigate the current prevalence(Larsen et al., 2006b).

2.2 Risk factors associated with infertility

The cross sectional study was conducted among women and men of childbearing age group in Suizhong County, a rural site in the Northern China found that the socio-demographic factors for infertility was older age at marriage. The investigator also found that the risk factors for infertility were presence of scant or heavy bleeding, abnormal weight, lack of exercises, older age at marriage, number of abortions and for men; staying awake at night more than three times per week and working in high temperature. It is not clear on the risk factors of infertility at Benjamin Mkapa Hospital (Cong et al., 2016)

The descriptive cross sectional study in Iran among 241 married women aged between 15-49years found the socio-demographic factors were subject's age, mate's age. The investigator didn't associate between socio-demographic factors and patients with infertility. Therefore there is a need to assess the association between infertility and socio=demographic factors. (Azmoude et al., 2017)

The investigator analyzed the socio-demographic, behavioral, and reproductive factors associated with fertility rates among Brazilian women aged between 15–49 years and found that the socio demographic factors associated were being aged 20–24, residing in the North, being nonwhite, not being in paid employment, having lower education levels, having lower socioeconomic status, being in a stable union, having the first sexual intercourse before the age of 16 and having the first child before the age of 20.(Tejada et al., 2017).

The investigator conducted research among 765 Chinese women in the Henan province aged between 20-49 and found in logistic multivariate regression analyses, infertility was associated with age of marriage, age of first sexual intercourse, history of gynecological surgery, sweet food and decreased ovarian reserve (DOR). Primary infertility was associated with age of marriage, age of first sexual intercourse, long-term air-conditioning environment, decreased ovarian reserve and age. Secondary infertility was found to associated with history of gynecological surgery, decreased ovarian reserve , waist-to-hip ratio (WHR) above , delivery times and ages (Liang et al., 2021).

The cross sectional study conducted in three public hospitals in Addis Ababa, Ethiopia and patients were women of reproductive age group found that infertility was 26.7% among women who have used contraception twelve months before data collection. The investigator didn't clearly explain what methods of contraception were used since different contraception methods have different duration in delaying fertility. Further study need to be done to explained the method of contraception in relation to the delay of infertility (Akalewold et al., 2022).

2.3 Fertility Treatment options

WHO 2001 meeting on Medical, ethical and social aspects of assisted reproduction proposed that infertility should be treated as a public health disease condition, consideration of the health need for patients with infertility by policy makers, inclusion of infertility management in national reproductive health care programmes and ensure that ART services are in accordance to the socio cultural solutions to infertility Although the recommendation was for every country in the world, it is still unclear which treatment do patients with infertility receive in Tanzania before attending Assisted Reproduction Clinic at Benjamin Mkapa Hospital. (Ombelet & Onofre, 2019).

The investigator conducted a population based cross sectional study of 25270 couples with infertility from eight provinces in China. The investigators found that only 55.2% were willingly sought for infertility care. The investigator has not clearly stated which infertility treatment was sought .Therefore there is a need to understand what are the available treatment of infertility particularly in Tanzania (Zhou et al., 2018)

A descriptive cross sectional study of 202 married persons attending fertility services at Adeoya Maternity centre in Ibadan, Nigeria reported that some infertile person would prefer IVF as treatment of infertility. It is not clear which treatment are available for infertility and therefore the investigator need to document on the all available treatment of infertility in the country (Akande et al., 2019).

Previous cesarean section has been associated to infertility due to presence of cesarean section defects and its complication. Previous studies in Taiwan, Austria, Netherlands (Hsu et al. 2022; Ahamed et al. 2022; Hinterleitner, Kiss, and Ott 2021; Vissers et al. 2020) have also explained on this relationship. Previous cesarean sections is also related to cause infertility through hydrometra,

(Ahamed et al. 2022) and intraabdominal adhesions. Intraabdominal adhesions is known to cause anatomical and functional disturbance of fallopian tube (Hinterleitner, Kiss, and Ott 2021). Lastly intrauterine adhesions (Hinterleitner, Kiss, and Ott 2021) and consequences of uterine rupture (Hinterleitner, Kiss, and Ott 2021) are associated with cesarean sections.

Also, inappropriate dilatation and curettage following abortion is also known to associate with intrauterine adhesions such as Asherman syndrome and this was explained also in the previous study (Hinterleitner, Kiss, and Ott 2021). Intrauterine adhesions may lead to impair implantation due to endometrial trauma and therefore leading to infertility. Other studies have shown that intrauterine adhesions are also associated with tubal occlusion which cause infertility (Cenksoy et al. 2013).

2.4 Conceptual Framework for the Study

Independent **Dependent Variable**

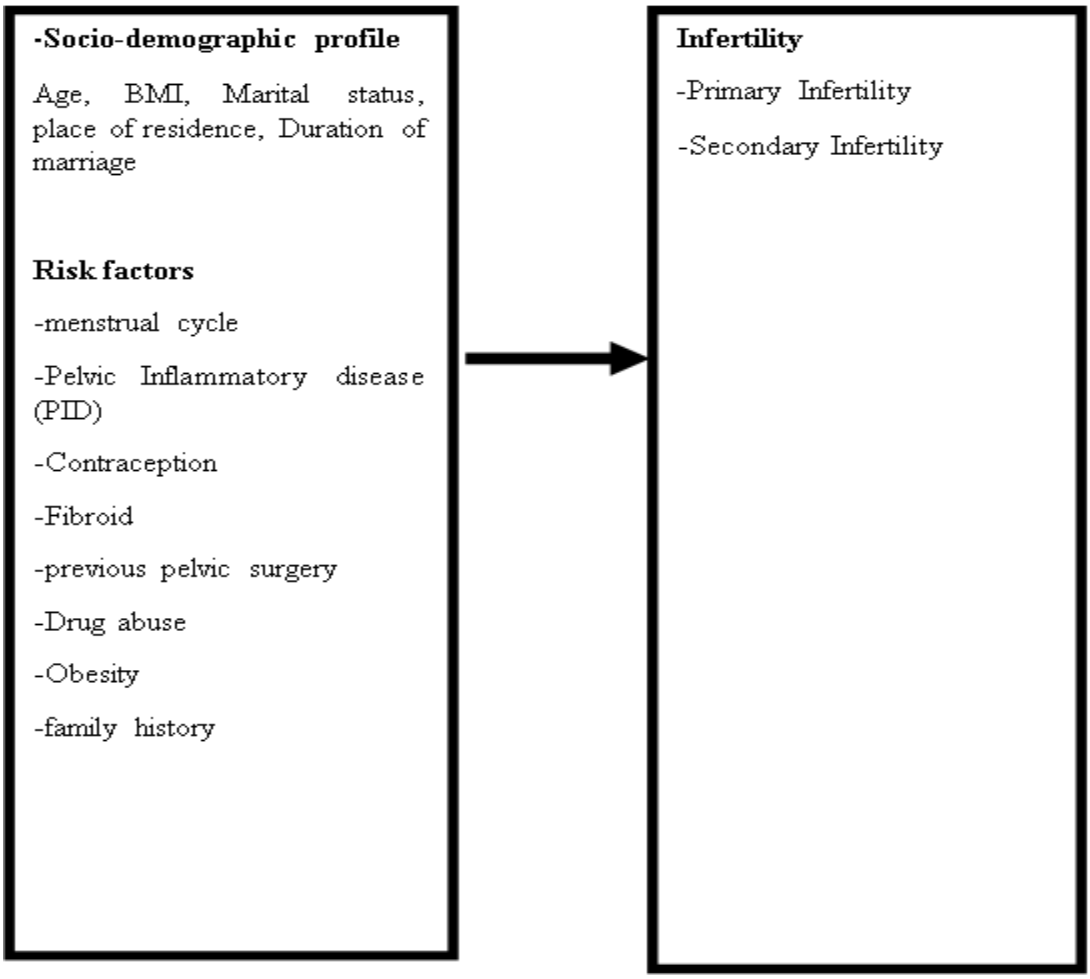

Figure 1: showing conceptual framework for the research study

CHAPTER THREE

3.0 METHODOLOGY

3.1 Location of the Study

The study was conducted at Benjamin Mkapa Hospital in Dodoma region. The Benjamin Mkapa Hospital is the first ultramodern hospital in East Africa, a specialized tertiary and teaching hospital found inside University of Dodoma (UDOM). The hospital served as a referral centre for central zone regions. The Hospital is 15km away from Dodoma town. It serves approximately 600 – 700 patients of different cases per day as outpatient. The bed capacity is about 400. The hospital is well equipped with diagnostics tools for infertility and runs Assisted Reproduction clinic within the department of Gynaecology and Obstetrics.

3.2 Study Design and Approach

The study design was hospital based analytical cross-sectional study design; and the approach was quantitative.

3.3 Study Population

The study population was patients from different part of Tanzania attended Assisted reproductive clinic. The clinic ran from Monday to Friday. The clinic attended around 15 patients per day.

3.3.1 Inclusion criteria.

- Unable to conceive /affect pregnancy after 12 months of regular unprotected sexual intercourse
- Both women & men
- Within reproductive age group 20-49yrs

3.3.2 Exclusion criteria

1. Refuse to consent

3.4 Sampling methods

3.4.1 Sample size formulae and calculations

The sample size was calculated from the formula:

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

Where:

N-was sample size required.

Z-was the desired significance level. It was 1.96 for 95% confidence interval

p- The proportion. The 50% was used because there was a limited previous study in the pattern and used fertility treatment.

d-the size of mean difference. It was 0.05.

$$N=\frac{(1.96)^2 0.5(1-0.5)}{0.05^2}$$

=384 participants.

Sample size of 384 patients determined the proportion of infertility at significance level of 5%.

3.5 Sampling procedure

A systematic sampling was used to select 385 participants. Every second patients in the list of the day was invited to participate upon consented. The second position has been calculated from the formula;

K=N/n where K was the nth selected number, N was the total population of the patients attended at either Assisted reproduction clinic. The clinics attended around 15 patients with infertility per day, making a total of 600 patients in two months from February- March 2023 and n was the sample size

K=600/385

K=1.56

K was approximately the second patients in the list.

3.6 Data collection Method and Tools

This study employed three investigators and three research assistants who helped in data collection. There were three days of training to orient research assistants with the study. The three investigators obtained ethical clearance from University of Dodoma and supervised the activity all

the time during the study to ensure accurate data was collected. Investigators requested consent from the patients prior to data collection.

The structured clinical proforma (mg.salisbury.nhs.uk/media/1343/infertility-clinic-proforma.pdf) installed in kobotool software was used to collect specific data through interviewing the patient . The clinical proforma contained information on socio-demographic characteristics, risk factors associated with infertility and the treatment used, and measuring weight and height. Data on weight and height followed the standard procedures as follows;

Assessment of Body Mass Index (BMI)

Both male and female patientswere instructed to remove their shoes and stand on standiometer to measure their height and weight according to WHO stepwise approach(WHO., 2017). Body mass index was calculated from the formula BMI=Weight in kg/height in square metres and recorded

3.7 Validity

Validity refers to the degree in which an instrument measures what it is supposed to be measuring (Golafshani, 2003). Content validity of the research tool was checked by the statistician with good experience in quantitative research method. The expert was asked to review each question to determine if it addressed the research objectives. The feedback from expert was analyzed and compared to determine the degree of content validity for each question. Any modification suggested was considered before pre-testing and data collection. In addition, all instrument for measuring weight and height were calibrated to minimize error while measuring.

3.8 Reliability of the instrument

An instrument can be said to be reliable if its measures accurately reflect the true measures of the attribute under investigation (Golafshani, 2003). Pre-test to check reliability of the tool was done with respondents with similar criteria as the study sample and appropriate modifications were made. The data collection tool was pre-tested at Benjamin Mkapa hospital with a small number of patients (10% of the sample size which was 39 patients). The purpose of pre-testing was to verify the adequate collection of desired information as well as ensuring consistence of the questions. On pre-testing process, minor corrections were made before data collection.

3.9 Variables Definition and Measurements

3.9.1 Variables Definition

Objective one

Dependent variable; Infertility,

Independent variable; pattern of infertility

Objective two

Dependent variable; Infertility

Independent variable; Associated risk factors- sociodemographic profile- age, duration of marriage, BMI, place of residence and marital status**,** menstrual cycle, parity, sexual history, PID, Contraception, Fibroid, previous pelvic surgery, Drug abuse, Obesity, family history

Objective three

Dependent variable; Infertility

Independent variable; Herbal treatment, surgical procedures, Medical treatment, ART

3.9.2 Variable Measurement

Independent variables

Pattern of infertility

Participants were asked whether they have ever conceived or not in their lifetime.

Risk factors;

Participants were asked the following questions;

- Socio-demographic profile; age, sex, high level of education, occupation, place of residence, marital status
- PID; history of PID in her life time
- Fibroid; presence of fibroid
- Contraception; type used
- Drug abuse; type of drug, duration
- menstrual cycle; irregularity, flow volume ,dysmenorrheal, amenorrhea
- sexual history; number of sexual partner, frequency, timing fertility period
- Parity; number of live children, abortions

- Previous pelvic surgery; appendicitis, cesarean section, myomectomy, salpingectomy, cystectomy, ovarian drilling, laparascopy, herniorrhapy, urethroscopy.
- Family history; infertility
- Medical history; Human Immunodeficiency Virus infection, (HIV), Diabetes Mellitus (DM), Hypertension (HTN)

Fertility treatments

Participants were asked the following;

- Herbal treatment; whether the patient have used or not herbal medication and when was the last time taken.
- Surgical procedures; type done (laparascopy, hysteroscopy, hydrotubation, myomectomy, ovarian drilling) and when was it done
- Medical treatment; type used (oral drugs and injectable drugs,) and when was the last time taken.
- ART procedure done; (Intrauterine insemination, in vitro fertilization) and whether or not have done cryopreservation.

Dependent Variable

Infertility was categorized as primary infertility and secondary infertility based on their parity. Primary infertility was identified to participants who presented with inability to conceive or affect pregnancy within 12months of regular non contraceptive sexual intimacy.

Secondary infertility was identified to a participant who presented with inability to conceive or affect pregnancy despite previous ability within 12months of regular non contraceptive sexual intimacy.

3.10 Data analysis

Data analysis was conducted using the statistical package for social science (SPSS) version 25 and statistical software (STATA) version 15. The coded data entered and cleaned in the SPSS and STATA. The analysis involved descriptive and inferential statistics; for descriptive statistic it described the sample population and relevant proportions in frequency tables and inferential statistic for cross tabulations between independent and dependent variables; Logistic regression

was determined association between type of infertility and risk factors. P-value of < 0.05 was considered statistically significant. All the analysis was based on the stated study objectives and summarized in the table 1.

Table 1: Data Analysis of the research study

	Objectives	**Model of analysis**	**Presentation of the results**
1	To determine the overall pattern of infertility among patients attended Assisted Reproductive clinic at Benjamin Mkapa hospital	Descriptive	Frequency and Percentage (%)
2	To determine the risk factors associated with infertility pattern among patients attended Assisted Reproductive clinic-Benjamin Mkapa hospital.	Descriptive	Frequency and percentage(%), COR, AOR
3	To identify the type of infertility treatment used by patients with infertility attended Assisted Reproductive Clinic-Benjamin Mkapa hospital.	Descriptive	Frequency and percentage

3.11 Ethical considerations

The ethical approval for this study was obtained from the University of Dodoma (UDOM). Permission to conduct the study was approved by Executive Director of Benjamin Mkapa Hospital who assigned Directorate of training and research to provide permission letter to the investigators to conduct the study.

Participants were asked to provide written informed consent before interviewing**.** No penalty or mistreatment was applied on the participants who refused to participate or who decided to withdraw somewhere in the middle of the study. The consent form contained full explanation about the benefits and risks of the study to participants and assurance of voluntary participation

(participants was allowed to refuse to participate at any time during the interview) and the consent form provided assurance of confidentiality by maintaining anonymous.

Research Ethics considered in the course of conducting this study include:

Ethical consideration: Before conducting this study, an ethical clearance was obtained from the University of Dodoma

Written Informed Consent was requested before data collection. Participation in this study was voluntary and any one was allowed to drop from the study at any point they wished to withdraw. Informed consent was one of the means by which a respondent's right to autonomy was protected; thus, no one was forced to participate in research.

Beneficence: The research was of benefit, and do not harm the respondent. It promoted the welfare of our constituents.

Anonymity and Confidentiality: Anonymity condition was taken care through the identity of individual subjects not to be known by the researcher. However, in confidentiality, the researcher protected the identity of the participants. Names were not asked in order to observe confidentiality and the information gathered was kept confidential

Respect and privacy: Private information was respected and not shared to others unless there was agreement with the respondent.

Respect for intellectual property: Acknowledgements of other researchers in the contributions to this research was done to avoid plagiarism.

3.12 Dissemination

The final report of this study will be disseminated to the Executive Director, directors, healthcare providers and patients with infertility attending at Benjamin Mkapa Hospital, along with presenting in the different scientific conferences as well as publishing in a reputable journal

CHAPTER FOUR

4.0 RESULTS

4.1 Introduction

This chapter presents the findings on the overall pattern of infertility, associated risk factors, and used fertility treatment among 385 patients who attended assisted reproductive clinics at Benjamin Mkapa Hospital.

4.2 Socio-demographic characteristics of the patients (female and male) with infertility

The study population consisted of a total of 385 male and female patients, out of which females were 201(52. 21%). The average age of the patients was 34.69 years. 285(74.03%) patients were married. 320 patients (83.12%) had a duration of more than ten years in cohabiting or marriage, and 253 patients (65.71%) had received a university or college education.

Patients resided across different geographic zones of Tanzania with the central zone having the highest representation of 275(71.43%) and patients 307(79.74%) lived in urban areas. 53 (13.77%) were working in teaching. The distribution of patients based on BMI status revealed that 178(46.23%) were overweight. Table 2 provides an overview of the socio-demographic characteristics of patients visiting the Assisted reproduction clinic at Benjamin Mkapa Hospital.

Table 2: Distribution of male and female Patients Who Visited the Benjamin Mkapa Hospital Assisted Reproduction Clinic (N=385).

Variables	Frequency (%)
Age of the patients (years) *M±SD*	34.69±5.89
20-25	18(4.68%)
26-31	106(27.53%)
32-37	141(36.62%)
38-43	89(23.12%)
44-49	31(8.05%)
Sex	
Female	201(52.21%)
Male	184(47.79%)

Marital status	
Cohabiting	100(25.97%)
Married	285(74.03%)
Level of education	
No formal education	1(0.26%)
Primary	41(10.65%)
Secondary	90(23.38%)
University/college	253(65.71%)
BMI Status	
Obese (more than 30.0)	61(15.84%)
Overweight (25.0-<30.0)	178(46.23%)
Normal (18.5-<25.0)	138(35.84%)
Underweight (less than 18.5)	8(2.08%)
Place of residence	
Rural	78(20.26%)
Urban	307(79.74%)
Zones	
Lake zone	15(3.90%)
Central zone	275(71.43)
Coastal zone	39(10.13%)
Northern zone	25(6.49%)
Southern highland Zone	23(5.97%)
Western zone	5(1.30%)
Zanzibar	3(0.78%)
Occupation	
Military	43(11.17%)
Finance	15(3.90%)
Healthcare	32(8.31%)
Teaching	53(13.77%)
Others	242(62.86%)

Duration of marriage/cohabiting	
Less than 10 (years)	65 (16.88%)
>10	320(83.12%)

4.2.1 Sociodemographic characteristics of female patients with infertility

The study population consisted of a total of 201 female patients, the average age of the patients was 33.59 years. 153(76.12%) patients were married. 165 patients (82.09%) had a duration of more than ten years in cohabiting or marriage, and patients 122 (60.70%) had received a university or college education.

Patients resided across different geographic zones of Tanzania with the central zone having the highest representation 150(74.63%) and patients 156(77.64%) lived in urban areas.31 (15.42%) were working in teaching. The distribution of patients based on BMI status revealed that 87(43.28%) were overweight. Table 3 provides an overview of the socio-demographic characteristics of female patients who attended the Assisted reproduction clinic at Benjamin Mkapa Hospital.

Table 3: Distribution of female Patients Who attended the Benjamin Mkapa Hospital Assisted Reproduction Clinic (N=201).

Variables	**Frequency (%)**
Age of the patients (years) *M±SD*	33.59±6.02
20-25	15(7.46%)
26-31	67(33.33%)
32-37	63(31.34%)
38-43	43(21.39%)
44-49	13(6.47%)
Marital status	
Cohabiting	48(23.88%)
Married	153(76.12%)
Level of education	

No formal education	1(0.50%)
Primary	26(12.94%)
Secondary	52(25.87%)
University/college	122(60.70%)
BMI Status	
Normal (18.5-<25.0)	74(36.82%)
Obese (more than 30.0)	34(16.92%)
Overweight (25.0-<30.0)	87(43.28%)
Underweight (less than 18.5)	6(2.99%)
Place of residence	
Rural	45(22.39%)
Urban	156(77.61%)
Zones	
Lake zone	9(4.48%)
Central zone	150(74.63%)
Coastal zone	11(5.47%)
Northern zone	12(5.97%)
Southern highland Zone	16(7.96%)
Western zone	1(0.50%)
Zanzibar	2(1.00%)
Occupation	
Military	12(5.97%)
Finance	3(1.49%)
Healthcare	21(10.45%)
Teaching	31(15.42%)
Others	134(66.67%)
Duration of marriage/cohabiting	
Less than 10 (years)	36(17.91%)
>10	165(82.09%)

4.2.2 Sociodemographic characteristics of male patients with infertility

The study population consisted of a total of 184 male patients. The average age of the patients was 35.88 years. 132(71.74%) patients were married. 155 patients (84.24%) had a duration of more than ten years in cohabiting or marriage, and patients 131 (71.20%) had received a university or college education.

Patients resided across different geographic zones of Tanzania with the central zone having the highest representation 139(75.54%) and patients 151(82.07%) lived in urban areas.29 (15.76%) were working in the military. The distribution of patients based on BMI status revealed that 91(49.46%) were overweight. Table 4 provides insights of the socio-demographic characteristics of male patients who attended the Assisted reproduction clinic at Benjamin Mkapa Hospital.

Table 4: Distribution of male Patients who attended the Assisted Reproduction Clinic at Benjamin Mkapa Hospital (N=184)

Variables	Frequency (%)
Age of the patients (years) *M±SD*	35.88±5.51
20-25	3(1.63%)
26-31	39(21.2%)
32-37	78(42.39%)
38-43	46(25%)
44-49	18(9.78%)
Marital status	
Cohabiting	52(28.26%)
Married	132(71.74%)
Level of education	
No formal education	0(0.00%)
Primary	15(8.15%)
Secondary	38(20.65%)
University/college	131(71.20%)
BMI Status	
Normal (18.5-<25.0)	64(34.78%)

Obese (more than 30.0)	27(14.67%)
Overweight (25.0-<30.0)	91(49.46%)
Underweight (less than 18.5)	2(1.09%)
Place of residence	
Rural	33(17.93%)
Urban	151(82.07%)
Zones	
Lake zone	9(4.89%)
Central zone	139(75.54%)
Coastal zone	11(5.98%)
Northern zone	10(5.43%)
Southern highland Zone	14(7.61%)
Western zone	0(0.00%)
Zanzibar	1(1.00%)
Occupation	
Military	29(15.76%)
Finance	9(4.89%)
Healthcare	10(5.43%)
Teaching	27(14.67%)
Others	109(59.24%)
Duration of marriage/cohabiting	
Less than 10 (years)	29(15.76%)
>10	155(84.24%)

4.3 Pattern of infertility among patients attended Assisted reproductive clinic- Benjamin Mkapa Hospital.

4.3.1 Descriptive results of Pattern of infertility among patients attended Assisted Reproductive Clinic- Benjamin Mkapa hospital.

Figure 2 illustrates the descriptive findings regarding infertility patterns among patients (both male and female) who sought treatment at the Assisted Reproduction Clinic at Benjamin Mkapa Hospital. Among 385 patients, 59.00% (228) experienced secondary infertility.

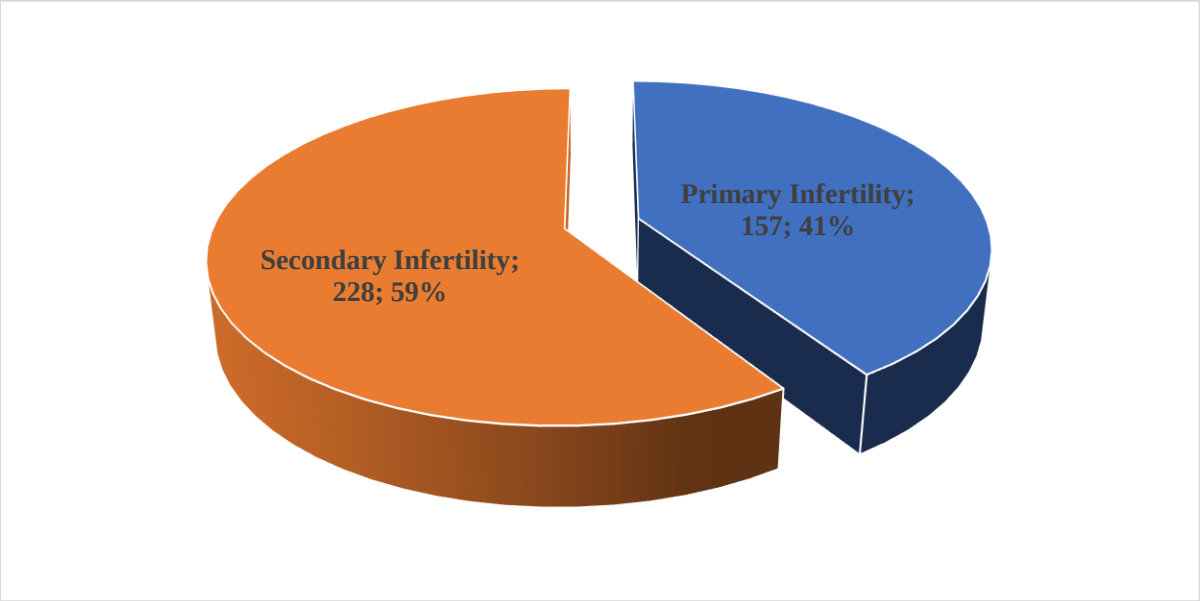

Figure 2: Pattern of infertility among male and female patients attended Assisted Reproduction Clinic at Benjamin Mkapa Hospital (N=385)

4.3.2 Descriptive results of Pattern of infertility among female patients attended Assisted reproductive clinic- Benjamin Mkapa hospital.

Figure 3 presents the descriptive results showing the infertility patterns among 201 female patients who sought treatment at the Assisted Reproduction Clinic at Benjamin Mkapa Hospital. Within this group, 126 females (62.69%) were diagnosed with secondary infertility. infertility.

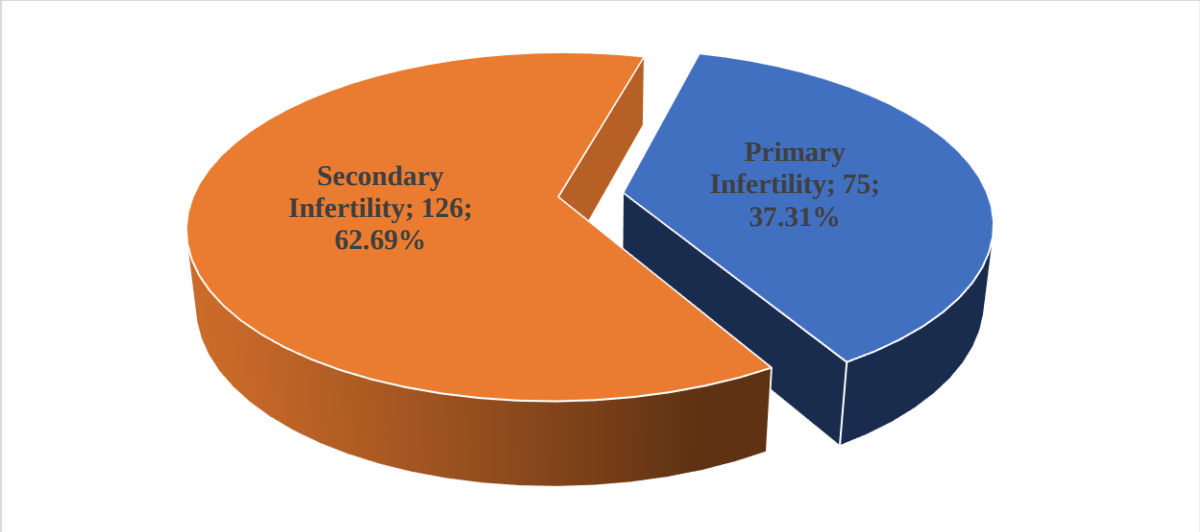

Figure 3: Pattern of Infertility Among female patients Who Visited the Benjamin Mkapa Hospital Assisted Reproduction Clinic (N=201).

4.3.2 Descriptive results of Pattern of infertility among male patients attended Assisted reproductive clinic- Benjamin Mkapa hospital.

The infertility pattern among the 184 male patients who attended the Benjamin Mkapa Hospital's assisted reproduction clinic is provided in Figure 4. In this, 102 people (55%) experienced secondary infertility.

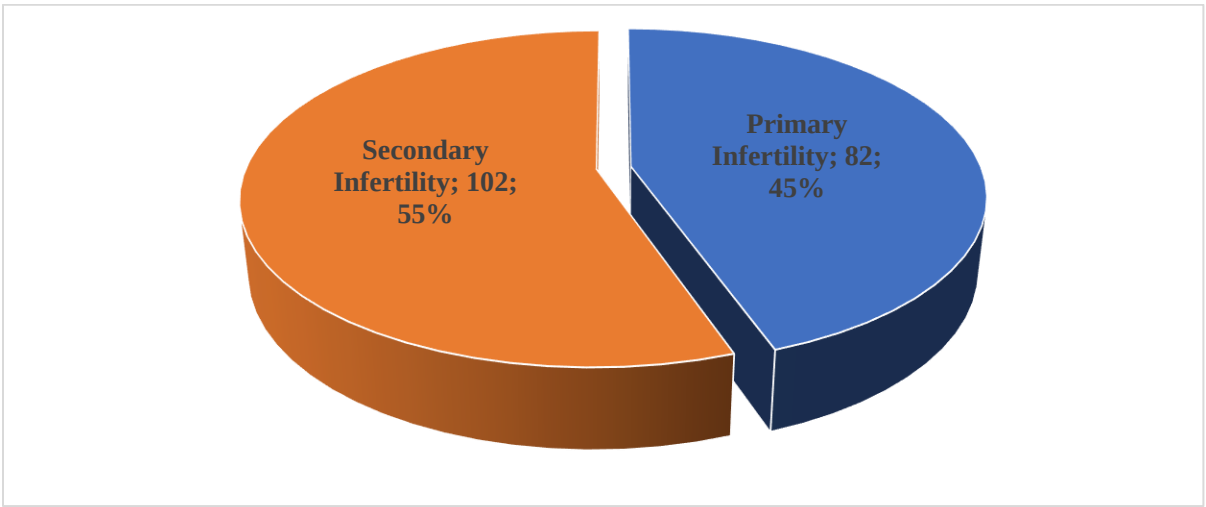

Figure 4: Pattern of Infertility in Male Patients Who Visited the Assisted Reproduction Clinic at Benjamin Mkapa Hospital (N=184)

4.4 Risk factors associated with infertility among patients attended Assisted Reproductive clinic -Benjamin Mkapa Hospital

A. (For both Male and Female patients)

4.4.1 Descriptive results of the risk factors for infertility among patients (male and female) attended Assisted Reproductive clinic -Benjamin Mkapa Hospital

The descriptive findings of the risk factors of infertility among patients (male and female) attended Assisted reproductive clinic is summarized in Table 5. Amount of 235(61.04%) of patient use below 3 days in a week in having intercourse without using any form of birth control method; 235(61.04%) of clients had below number of 5 sexual partners in their life time; Most of the clients they did not have family history of infertility by the amount of349 (90.65%).Also most of the clients they don't abuse drugs by the amount of 247 (64.16%)

Table 5: Descriptive- Risk factors for infertility among patients attended at Assisted Reproduction Clinic at Benjamin Mkapa Hospital (N=385)

Variable	Frequency (%)
Days in a week having intercourse without using any form of birth control	
below 3day	235(61.04%)
above 3 days	150(38.96%)
Number of sexual partner in life time	
Below 5 Partners	235(61.04%)
Above 5 Partners	150(38.96%)
being diagnosed with any STI	
No	272(70.65%)
Yes	113(29.35%)
Family history of infertility	
No	349(90.65%)
Yes	36(9.35%)
When was the surgical procedure done	
Less than 5 years	75(19.48%)

Above 5 years	23(5.97%)
Kind of drug ever abused	
Alcohol	97(25.19%)
Alcohol and Smoking	23(5.97%)
None	247(64.16%)
Smoking	18(4.68%)
Frequency of drug abuse	
Daily	23(5.97%)
Weekly	53(13.77%)
Monthly	14(3.64%)
Occasionally	47(12.21%)
NA	248(64.42%)
Duration of medical treatment	
Less than 5 years	358(92.99%)
Above 5 years	27(7.01%)
History of medical condition	
Communicable Diseases	10(2.60%)
Non-Communicable Diseases	23(5.97%)
None	352(91.43%)
BMI Status	
Obese	61(15.84%)
Overweight	178(46.23%)
Normal	138(35.84%)
Underweight	8(2.08%)

4.4.2 Relationship of the Risk Factors with Infertility among patients (male and female) attended Assisted Reproductive clinic -Benjamin Mkapa Hospital

This study showed that the relationship between risk factors and infertility among male and female patients attended the Assisted Reproductive Clinic at Benjamin Mkapa Hospital (N=385). The factors that were statistically significant related include age ($p = 0.002$) and the duration of marriage/ cohabiting ($p < 0.001$), number of days in a week having intercourse without using birth control ($p < 0.001$), the kind of drug abuse ($p = 0.019$) and the frequency of drug abuse and infertility status ($p = 0.015$).

Table 6: Relationship between risk factors and infertility among Male and Female patients attended Assisted Reproductive clinic -Benjamin Mkapa Hospital (N=385)

Variable	Infertility Status		Chi2	P-Value
	Primary Infertility	Secondary Infertility		
Age in Group			**16.53**	**0.002**
20-25	12(66.67%)	6(33.33%)		
26-31	51(48.11%)	55(51.89%)		
32-37	61(43.26%)	80(56.74%)		
38-43	25(28.09%)	64(71.91%)		
44-49	8(25.81%)	23(74.19%)		
Sex			2.092	0.148
Female	75(37.31%)	126(62.69%)		
Male	82(44.57%)	102(55.43%)		
Marital status			0.432	0.511
Cohabiting	38(38%)	62(62%)		
Married	119(41.75%)	166(58.25%)		
Place of residence			0.32	0.572
Rural	34(43.59%)	44(56.41%)		
Urban	123(40.07%)	184(59.93%)		
Occupation			14.5161	0.1234
Military	20(48.78%)	21(51.22%)		
Finance	8 (66.67%)	4(33.33%)		
Healthcare	4 (12.90%)	27(87.10%)		
Teaching	23(39.66%)	35(60.34%)		
Other	102(41.98%)	141(58.02%)		
Zones			12.891	0.452
Lake	4(22.22%)	14(77.78%)		
Central	135(46.71%)	154(53.29%)		

Coastal	5(22.73%)	17(77.27%)		
Northern	8(36.36%)	14(63.64%)		
Southern	5(16.67%)	25(83.33%)		
western zones	0(0%)	1(100%)		
Level of education			1.825	0.61
No formal education	1(100%)	0(0%)		
Primary education	16(39.02%)	25(60.98%)		
Secondary education	39(43.33%)	51(56.67%)		
University/college	101(39.92%)	152(60.08%)		
Duration of marriage/cohabiting(years)			**18.43**	**< 0.001**
10 years and above	11(16.92%)	54(83.08%)		
below 10 years	146(45.63%)	174(54.37%)		
Number of days in a week having intercourse without using any form of birth control			**12.81**	**<0.001**
below 3day	79 (33.62%)	156(66.38%)		
above 3 days	78(52.00%)	72(48.00%)		
sexual partner you had in your life time			1.7189	0.19
Below 5 Partners	146(41.83%)	203(58.17%)		
Above 5 Partners	11(30.56%)	25(69.44%)		
being diagnosed with any STI			2.4834	0.115
No	104(38.24%)	168(61.76%)		
Yes	53(46.90%)	60(53.10%)		
have any family history of infertility			0.013	0.909
No	142(40.69%)	207(59.31%)		
Yes	15(41.78%)	21(58.33%)		
kind of drug have ever abuse			**9.901**	**0.019**
Alcohol	29(29.90%)	68(70.10%)		
Alcohol and Smoking	14(60.87%)	9(39.13%)		
None	108(43.72%)	139(56.28%)		
Smoking	5(33.3%)	12(70.59%)		
Frequency of drug abuse			12.41	0.015
Daily	12(52.17%)	11(47.83%)		
Weekly	24(45.28%)	29(54.72%)		
Monthly	2(14.29%)	12(85.71%)		
Occasionally	11(23.40%)	36(76.60%)		
NA	108(43.55%)	140(56.45%)		
History of Medical Condition			0.5035	0.777

Communicable Diseases	4(40.00%)	6(60.00%)		
Non-Communicable Diseases	11(47.83%)	12(52.17%)		
None	142(40.78%)	210(59.22%)		
BMI Status			0.6955	0.874
Obese	27(44.26%)	34(55.74%)		
Overweight	71(39.89%)	107(60.11%)		
Normal	55(39.86%)	83(60.14%)		
Underweight	4(50.00%)	4(50.00%)		
Undergo surgical procedure			3.595	0.058
Yes	32(32.7%)	66(67.3%)		
No	125(43.6%)	162(56.4%)		

4.4.3 Association of the Risk Factors with Infertility among patients (male and female) attended Assisted Reproductive clinic -Benjamin Mkapa Hospital

The multivariable logistic regression analysis was done to check the association between the risk factors and type of infertility among patients attended assisted reproductive Clinic-Benjamin Mkapa Hospital. The analysis results are presented in table 7

The results indicate that patients with aged38-43 (AOR=5.068, 95% CI 1.573–16.33), in years were more likely to have infertility compared to those with aged 20-25 years and this association was statistically significant.

Patients with the duration of marriage or cohabiting less than ten years were less likely to have infertility compared to those whose duration of marriage or cohabiting is greater than or equal to ten years (AOR=0.406, 95% CI 0.189, 0.873) and this association was significant statistically.

Those who practice sexual intercourse in the above three days a week are less likely to have infertility in comparison to those who have sexual intercourse in below three days (AOR 0.554, CI 0.348, 0883) this association was significant statistically.

Table 7: Risk factors associated with infertility among male and female patients who attended at Assisted Reproduction Clinic at Benjamin Mkapa Hospital. (N=385)

Variable	COR at 95%	P-value	AOR at 95%	P-value
Age in Group				
20-25	Ref.			
26-31	2.157(0.754,6.172)	0.152	2.445(0.823,7.266)	0.108
32-37	2.623(0.932,7.384)	0.068	2.887(0.982,8.491)	0.054
38-43	5.12(1.733,15.13)	0.003	5.068(1.573,16.33)	**0.007**
44-49	5.75(1.618,20.432)	0.007	3.844(0.986,14.987)	0.052
Years of marriage/cohabiting				
10 years and above	Ref.			
below 10 years	0.243(0.122,0.481)	< 0.001	0.406(0.189,0.873)	**0.021**
Number of days in a week having intercourse without using any form of birth control				
below 3day	Ref			
above 3 days	0.467(0.307,0.710)	< 0.001	0.554(0.348,0.883)	**0.013**
kind of drug have ever abuse				
Alcohol	Ref			
Alcohol and Smoking	0.274(0.107,0.704)	0.007	0.423(0.139,1.287)	0.11
None	0.549(0.332,0.907)	0.19	0(0,)	1
Smoking	0.853(0.292,2.492)	0.771	0.979(0.272,3.524)	0.672
Frequency of drug abuse				
Daily	Ref			
Weekly	1.3182(0.4944,3.5149)	0.007	4.012(0.635,25.345)	0.14
Monthly	6.5455(1.1887,36.0426)	0.007	656559129.931(0,)	1
Occasionally	3.5702(1.236,10.3132)	0.771	2.218(0.632,7.791)	0.214
NA	1.4141(0.6009,3.3278)	0.19	1.267(0.418,3.845)	0.676

B (For Female Only)

4.5 Descriptive results of the risk factors for infertility among female patients who attended Assisted Reproductive Clinic -Benjamin Mkapa Hospital

The table 8 and 9 summarizes the descriptive findings for the risk factors of infertility among 201 female patients who attended Assisted Reproduction Clinic at Benjamin Mkapa Hospital. Cycle length, menstrual flow, dysmenorrhea, amenorrhea, fibroid, awareness of fertility period, previous pelvic surgery and history of contraception use were noted.

Table 8: Risk factors for infertility among female patients attended at Assisted Reproduction Clinic at Benjamin Mkapa Hospital (N=201)

Variable	Frequency (%)
Cycle length	
21-35days	125(62.19%)
<21days	2(1.00%)
>35days	15(7.46%)
Irregular	52(25.87%)
None	7(3.48%)
Menstrual flow	
Heavy	34(16.92%)
None	9(4.48%)
Normal	127(63.18%)
Scanty	31(15.42%)
Feature suggesting dysmenorrhea	
Mild	63(31.34%)
Moderate	66(32.84%)
None	45(22.39%)
Severe	27(13.43%)
Had amenorrhea in the past six months	
No	158(78.61%)
Yes	43(21.39%)
Identify suggesting fibroid symptoms	
No	172(85.57%)
Yes	29(14.43%)
Aware of fertility period	
No	60(29.85%)
Yes	141(70.15%)

Table 9: Risk factors for infertility among female patients attended at Assisted Reproduction Clinic at Benjamin Mkapa Hospital (N=201)

Variable	No	Yes
Awareness of fertility period S\symptoms		
Increased sexual desire	147(73.13%)	54(26.87%)
Increased basal body temperature	155(77.11%)	46(22.89%)
Midcycle lower abdominal pain	140(69.65%)	61(30.35%)
Watery sticky discharge	132(65.67%)	69(34.33%)
Use of calendar	122(60.70%)	79(39.30%)
previous pelvic surgery		
Myomectomy	177(88.06%)	24(11.94%)
Caesarean section	170(84.58%)	31(15.42%)
Cystectomy	183(91.04%)	18(8.96%)
Laparoscopic	348(173.13%)	37(18.41%)
Dilatation and curettage	195(97.01%)	6(2.99%)
Hysteroscopy	200(99.50%)	1(0.50%)
Urethroscopy	200(99.50%)	1(0.50%)
History of contraception used in life time		
Barrier method	187(6.47%)	13(6.47%)
Oral Contraception Drugs	157(21.89%)	44(21.89%)
Injectables	182(9.45%)	19(9.45%)
IUCD	194(3.48%)	7(3.48%)
Never use any contraceptive	77(61.69%)	124(61.69%)

4.5.1 Relationship of the Risk Factors with Infertility among female patients attended Assisted Reproductive clinic -Benjamin Mkapa Hospital

The relationship of infertility among 201 female patients attending the Assisted Reproductive Clinic at Benjamin Mkapa Hospital was found significantly with the age ($p < 0.001$), duration of Marriage/Cohabiting ($p < 0.001$), Occupation among those working in healthcare ($p = 0.046$), the cycle length ($p = 0.048$), Previous Pelvic Surgery especially Cesarean section ($p < 0.001$), and

Dilatation and curettage also showing significance (p = 0.018). Also Contraception Use particularly Oral Contraception Drugs (p = 0.024), Injectables (p = 0.011), IUCD (p = 0.038), and Never using any contraceptive (p < 0.001).

Table 6 presents the relationship between various risk factors and infertility among female patients in the clinic.

Table 10: Relationship between risk factors and infertility among female patients attended Assisted Reproductive clinic -Benjamin Mkapa Hospital (N=201).

Variable	Infertility Status		Chi2	P-Value
	Primary Infertility	Secondary Infertility		
Age in Group			**28.2262**	**<0.001**
20-25	11(73.33%)	4(26.67%)		
26-31	36(53.73%)	31(46.27%)		
32-37	19(30.16%)	44(69.84%)		
38-43	7(16.28%)	36(83.72%)		
44-49	2(15.38%)	11(84.62%)		
Marital status			0.0970	0.755
Cohabiting	17(35.42%)	31(64.58%)		
Married	58(37.91%)	95(62.09%)		
Place of residence			0.0053	0.943
Rural	17(37.78%)	28(62.22%)		
Urban	58(37.18%)	98(62.82%)		
Level of education			3.4751	0.324
No formal education	1(100.00%)	0(0.00%)		
Primary education	10(38.46%)	16(61.54%)		
Secondary education	23(44.23%)	29(55.77%)		
University/college	41(33.31%)	81(66.39%)		
Duration of marriage/cohabiting(years)			**10.29**	**<0.001**
10 years and above	5(13.89%)	31(86.11%)		

below 10 years	70(42.42%)	95(57.58%)		
Occupation			9.8178	0.046
Military	3(25.00%)	9(75.00%)		
Finance	1(33.33%)	2(66.67%)		
Healthcare	2(9.52%)	19(90.48%)		
Teaching	11(35.48%)	20(64.52%)		
Other	58(43.28%)	76(56.72%)		
Zones			10.9111	0.091
Lake	1(11.11%)	8(88.89%)		
Central	65(43.33%)	85(56.67%)		
Coastal	2(18.18%)	9(81.67%)		
Northern	4(33.33%)	8(66.67%)		
Southern	3(18.75%)	13(81.25%)		
western zones	0(0.00%)	1(100.00%)		
Zanzibar	0(0.00%)	2(100.00%)		
Cycle length			**9.5923**	**0.048**
21-35day	40(32.00%)	85(68.00%)		
<21days	2(100.00%)	0(0.00%)		
>35days	7(46.67%)	8(53.33%)		
Irregular	25(48.08%)	27(51.92%)		
None	1(14.29%)	6(85.71%)		
Nature of the menstrual flow			0.5319	0.912
Heavy	11(32.35%)	23(67.65%)		
None	3(33.33%)	6(66.67%)		
Normal	49(38.58%)	78(61.42%)		
Scanty	12(38.71%)	19(61.29%)		
Feature suggesting dysmenorrhea			0.9865	0.805
Mild	21(33.33%)	42(66.67%)		
Moderate	27(40.91%)	39(59.09%)		
None	16(35.56%)	29(59.09%)		

Severe	11(40.74%)	16(59.26%)		
You had amenorrhea in the past six months			0.4835	0.487
No	57(36.08%)	101(63.92%)		
Yes	18(41.86%)	25(58.14%)		
Feature that identifies suggesting fibroid symptoms			0.5712	0.450
No	66(38.37%)	106(61.63%)		
Yes	9(31.03%)	20(68.97%)		
Aware of fertility period			0.038	0.845
No	23(38.33%)	37(61.67%)		
Yes	52(36.88%)	89(63.12%)		
Awareness of fertility period symptoms				
Increased sexual desire			1.6052	0.205
No	51(34.69%)	96(65.31%)		
Yes	24(44.44%)	30(55.56%)		
Increased basal body temperature			1.7733	0.183
No	54(34.84%)	101(65.16%)		
Yes	21(45.65%)	25(54.35%)		
Mid-cycle lower abdominal pain			0.0057	0.940
No	52(37.14%)	88(62.86%)		
Yes	23(37.70%)	38(62.69%)		
Watery sticky discharge			1.7072	0.191
No	45(34.09%)	87(65.91%)		
Yes	30(43.48%)	39(56.52%)		
Use of calendar			1.7876	0.181
No	50(40.98%)	72(59.02%)		
Yes	25(31.65%)	54(68.35%)		
previous pelvic surgery ever done				
Myomectomy			0.7733	0.379

No	68(38.42%)	109(61.58%)		
Yes	7(29.17%)	17(70.83%)		
Cesarean section			**11.968**	**< 0.001**
No	72(42.35%)	98(57.65%)		
Yes	3(9.68%)	28(90.32%)		
Cystectomy			0.021	0.885
No	68(37.16%)	115(62.84%)		
Yes	7(38.89%)	11(61.11%)		
Laparoscopic			1.1809	0.277
No	145(41.67%)	203(58.33%)		
Yes	12(32.43%)	25(67.57%)		
Dilatation and curettage			**5.5997**	**0.018**
No	70(35.90%)	125(64.10%)		
Yes	5(83.33%)	1(16.67%)		
Hysteroscopy			0.5982	0.439
No	75(37.50%)	125(62.50%)		
Yes	0(0.00%)	1(100.00%)		
Urethroscopy			1.688	0.194
No	74(37.00%)	126(63.00%)		
Yes	1(100.00%)	0(0.00%)		
Contraception you have used in your life time				
Barrier method			0.0287	0.866
No	144(40.91%)	208(59.09%)		
Yes	13(39.39%)	20(60.61%)		
Oral Contraception Drugs			**5.1238**	**0.024**
No	65(41.40%)	92(58.60%)		
Yes	10(22.73%)	34(77.27%)		
Injectables			**6.4371**	**0.011**
No	73(40.11%)	109(59.89%)		

Yes	2(10.53%)	17(89.47%)		
IUCD			**4.317**	**0.038**
No	75(38.66%)	119(61.34%)		
Yes	0(0.00%)	7(100.00%)		
Never use any contraceptive			**12.386**	**< 0.001**
No	17(22.08%)	60(77.92%)		
Yes	58(46.77%)	66(53.23%)		

4.5.2 Association of the Risk Factors with Infertility among female patients attended Assisted Reproductive clinic -Benjamin Mkapa Hospital

The multivariable logistic regression analysis was done to check the association between the risk factors and type of infertility among female patients who attended assisted reproductive Clinic-Benjamin Mkapa Hospital. The analysis results are presented in Table 11, Female patients with history of previous cesarean section (AOR=1.152, CI 0.0418, 0.553, P=0.004) were more likely to have infertility compared to those with no history of cesarean section and this is statistically significant.

Female patients with a history of using oral contraception drugs (AOR=1.5311, CI 0.453, 5.175) p=0.493) were more likely to have infertility compared to those with no history of using oral contraception drugs however this association is not statistically significant.

Female patients with history of using injectable (AOR=2.691 CI 0.503, 14.4156, p=0.185) were more likely to have infertility compared to those with no history of using injectable however this association was not statistically significant

Women with history of being performed dilatation and curettage (AOR =1.0301, CI 0.4202,2.525, P=0.948 were more likely to have secondary infertility compared to those with no history of being performed dilatation and curettage however this association was not statistically significant

Table 11: Risk factors associated with infertility among female patients attended at Assisted Reproduction Clinic at Benjamin Mkapa Hospital. (N=201)

Variable	COR at 95%	P-value	AOR at 95%	P-value
What is your cycle length				
21-35day	**Ref.**			
<21days	0(0, .)		0(0, .)	
>35days	0.538(0.182,1.586)	0.261	0.380(0.1103,1.312)	0.126
Irregular	0.508(0.262,0.984)	0.046	0.392(0.1877,0.820)	0.013
None	2.824(0.329,24.242)	0.344	3.1712(0.3479,28.907)	0.306
Cesarean section				
No	**Ref.**			
Yes	**1.1458(0.043,0.498)**	**0.002**	**1.152(0.0418,0.553)**	**0.004**
Dilatation and curettage				
No	Ref.			
Yes	1.1428(0517,2.528)	0.742	1.0301(0.4202,2.525)	0.948
Oral Contraception Drugs				
No	Ref.			
Yes	**2.402(1.108,5.209)**	**0.026**	1.5311(0.453,5.175)	0.493
Injectables				
No	Ref.			
Yes	**5.693(1.277,25.3815)**	**0.023**	2.691(0.503,14.4156)	0.248
IUCD				
No	Ref.			
Yes	1.587(1.188,2.118)	0.002	0(0,.)	
Never use any contraceptive				
No	Ref.			
Yes	0.322(0.169,0.6138)	0.001	0.572(0.193,1.7002)	0.315

C. (For Male Only)

4.6 Descriptive results of the risk factors for infertility among Male patients attended Assisted Reproductive Clinic -Benjamin Mkapa Hospital

The descriptive findings for the risk factors of infertility among male patients who attended the Assisted Reproduction Clinic at Benjamin Mkapa Hospital were previous pelvic surgery and history of contraception use

Table 12: Descriptive -Risk factors for infertility among male patients who attended at Assisted Reproduction Clinic at Benjamin Mkapa Hospital (N=184)

Variable	No	Yes
previous pelvic surgery		
Prostate surgery	183(99.46%)	1(0.54%)
Testicular biopsy	181(98.37%)	3(1.63%)
History of contraception used in life time		
Barrier method	164(89.13%)	20(10.87%)
Never use any contraceptive	20(10.87%)	164(89.13%)

4.6.1 Relationship of the risk factors for infertility among Male patients attended Assisted Reproductive clinic -Benjamin Mkapa Hospital

This study found that among male patients attending the Assisted Reproductive Clinic at Benjamin Mkapa Hospital (N=184), there was significant relationship between infertility and

Duration of Marriage/Cohabiting: (Chi-squared = 7.9435, p = 0.005).

Table 13 summarized the relationship between risk factors and infertility among male patients attended Assisted Reproduction clinic at Benjamin Mkapa hospital.

Table 13: Relationship between risk factors and infertility among Male patients attended Assisted Reproductive clinic -Benjamin Mkapa Hospital (N=184).

Variable	Infertility Status		Chi2	P-Value
	Primary Infertility	Secondary Infertility		
Age in Group			4.9300	0.295
20-25	1(33.33%)	2(66.54%)		
26-31	15(38.46%)	24(61.54%)		
32-37	42(53.85%)	36(46.15%)		
38-43	18(39.13%)	28(60.87%)		
44-49	6(33.33%)	12(66.67%)		
Marital status			0.5128	0.474
Cohabiting	21(40.38%)	31(59.62%)		
Married	61(46.21%)	71(53.79%)		
Place of residence			0.7862	0.375
Rural	17(51.52%)	16(48.48%)		
Urban	65(43.05%)	86(56.95%)		
Level of education			0.3007	0.860
No formal education	0(0.00%)	0(0.00%)		
Primary education	6(40.00%)	22(57.89%)		
Secondary education	16(42.11%)	22(57.89%)		
University/college	60(45.80%)	71(54.20%)		
Occupation				
Military				
Finance				
Healthcare				
Teaching				
Other				
Zones			9.7642	0.082
Lake	3(33.33%)	6(66.67%)		

Central	70(50.36%)	69(49.64%)		
Coastal	3(27.27%)	8(72.73%)		
Northern	4(40.00%)	6(60.00%)		
Southern	2(14.29%)	12(85.71%)		
western zones	0(0.00%)	1(100.00%)		
Zanzibar	0(0.00%)	0(0.00%)		
Years of marriage/cohabiting			**7.9435**	**0.005**
10 years and below	6(20.69%)	23(79.31%)		
Above 10 years	76(49.03%)	79(50.97%)		
previous pelvic surgery				
Prostate surgery			0.8083	0.369
No	82(44.81%)	101(55.19%)		
Yes	0(0.00%)	1(100.00%)		
Testicular biopsy			0.1557	0.693
No	81(44.75%)	100(55.25%)		
Yes	1(33.33%)	2(66.67%)		
contraception you have used in your life time				
Barrier method			0.1893	0.664
No	74(45.12%)	90(54.88%)		
Yes	8(40.00%)	12(60.00%)		
Never use any contraceptive			0.1893	0.664
No	8(40.00%)	12(60.00%)		
Yes	74(45.12%)	90(54.88%)		

4.7 Type of preexisting fertility treatment utilized by patients with infertility prior to attend Assisted Reproductive clinic- Benjamin Mkapa hospital

4.7.1 Descriptive results of type of preexisting fertility treatment utilized by patients with infertility prior to attend at Assisted Reproductive clinic- Benjamin Mkapa hospital (N=385).

(a) Herbal

In Figure 5, it is evident that only 58% of the male and female patients who attended the Assisted Reproduction clinic at Benjamin Mkapa Hospital had never taken herbal medication as a treatment for infertility.

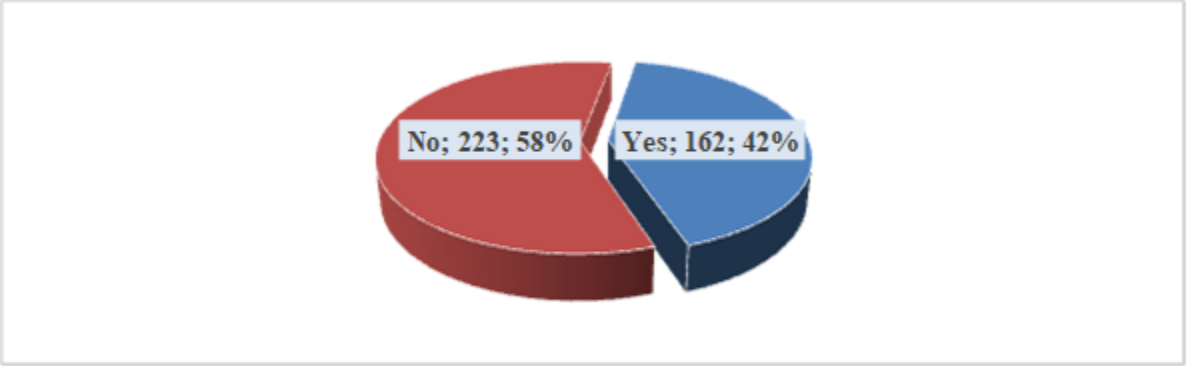

Figure 5: Herbal Medication utilized by the male and female patients as previous fertility treatment (N=385)

Out of the 201 females patients who attended the Assisted Reproduction clinic at Benjamin Mkapa Hospital, 58% (116) had history of taking herbal medication as a treatment for infertility.as portrayed in Figure 6.

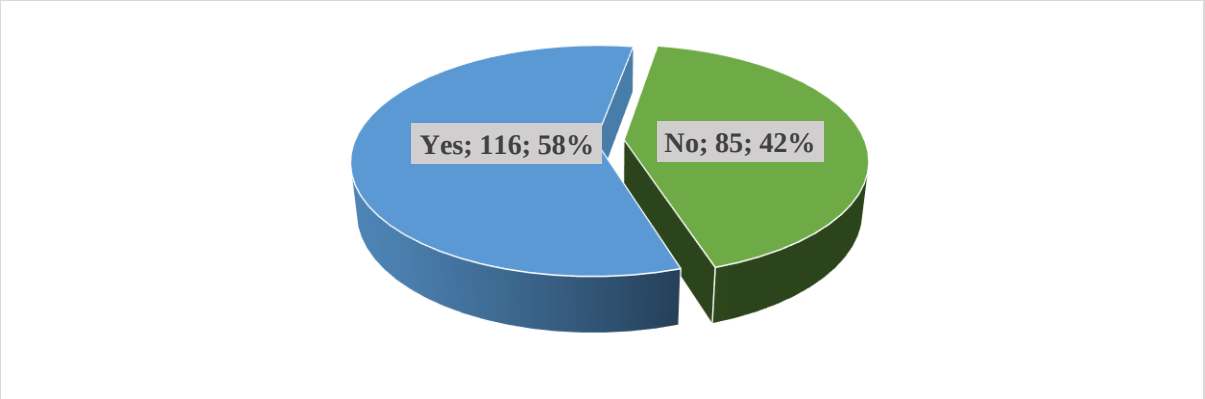

Figure 6: Herbal Medication used by the female as previous fertility treatment (N=201)

In accordance with Figure 7, among the 184 males who attended the Assisted Reproduction clinic at Benjamin Mkapa Hospital, 76% (139) have no history of taken any herbal medication as a treatment for infertility.

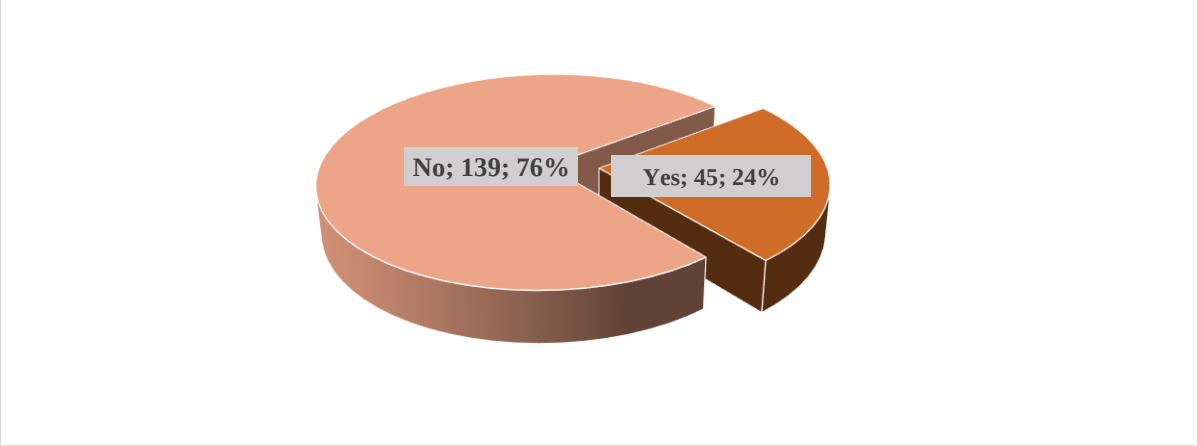

Figure 7: Herbal Medication used by the male as previous fertility treatment (N=184)

(b) Surgical Treatment

The majority of male patients who attended Assisted reproduction Clinic at Benjamin Mkapa hospital, specifically 176 (95.72%), reported that they had no history of surgical treatment for infertility as summarized in Figure 8

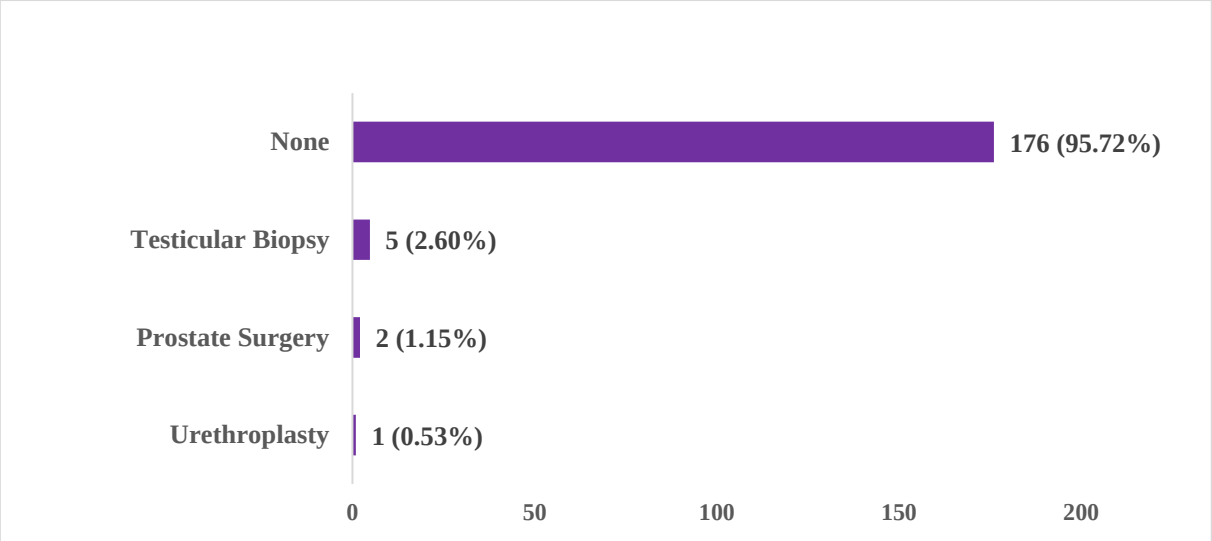

Figure 8: Male Surgical Procedures as Treatment of Infertility (N=184)

Figure 9 displays data from 201 female patients who attended the Assisted reproductive Clinic at Benjamin Mkapa Hospital for surgical procedures as a treatment for infertility. Among these participants, 90 (44.63%) had no history of surgical procedure for infertility. The study also revealed that among those patients who had surgical procedures, 16.15% (32) had laparoscopic procedures.

(c) Medical Treatment

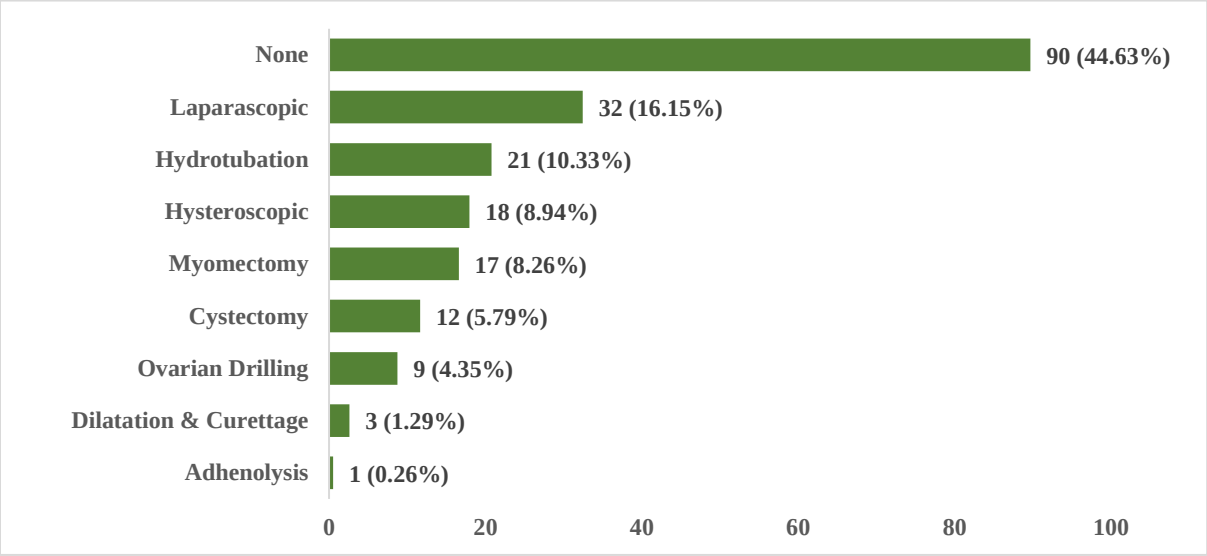

Figure 9: Female Surgical Procedures as Treatment of Infertility (N=201)

Figure 10 illustrates that the majority of male patients 130 (70.68%) had no any past medical treatment for infertility Within the group of patients who had history of medical treatment, it was found that 9.42% had used phosphodiesterase inhibitors.

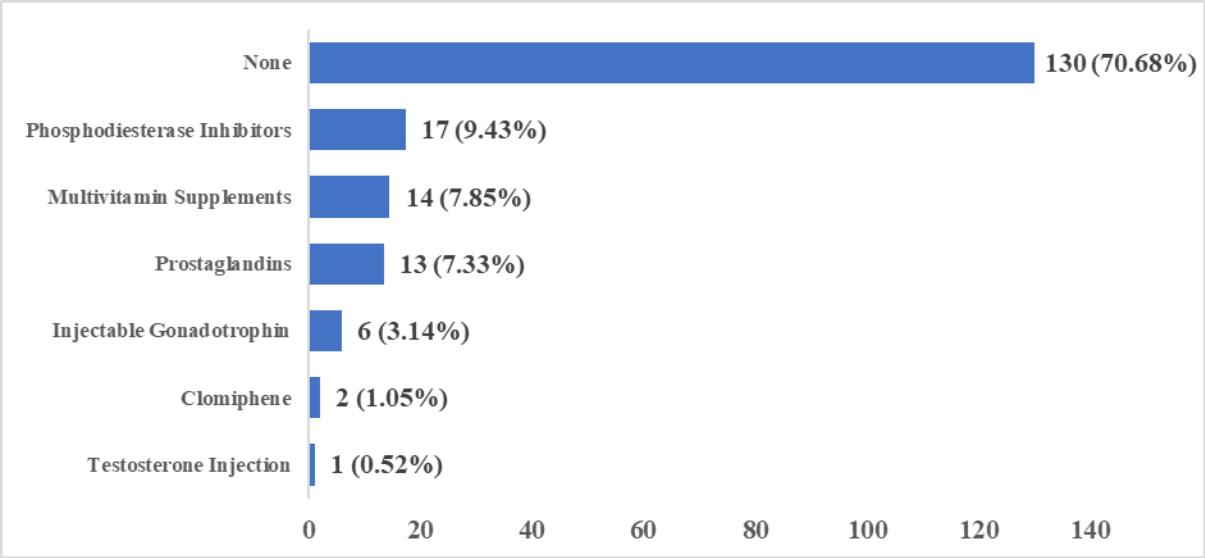

Figure 10: Male Medical Treatments as Treatment of Infertility (N=184)

In Figure 11, a graphical representation of the medical treatment for infertility among the female patients attended at the Benjamin Mkapa Hospital Clinic is presented. Remarkably, 42.57% of the female patients have used oral ovulation stimulation drugs as modality for addressing infertility in this study.

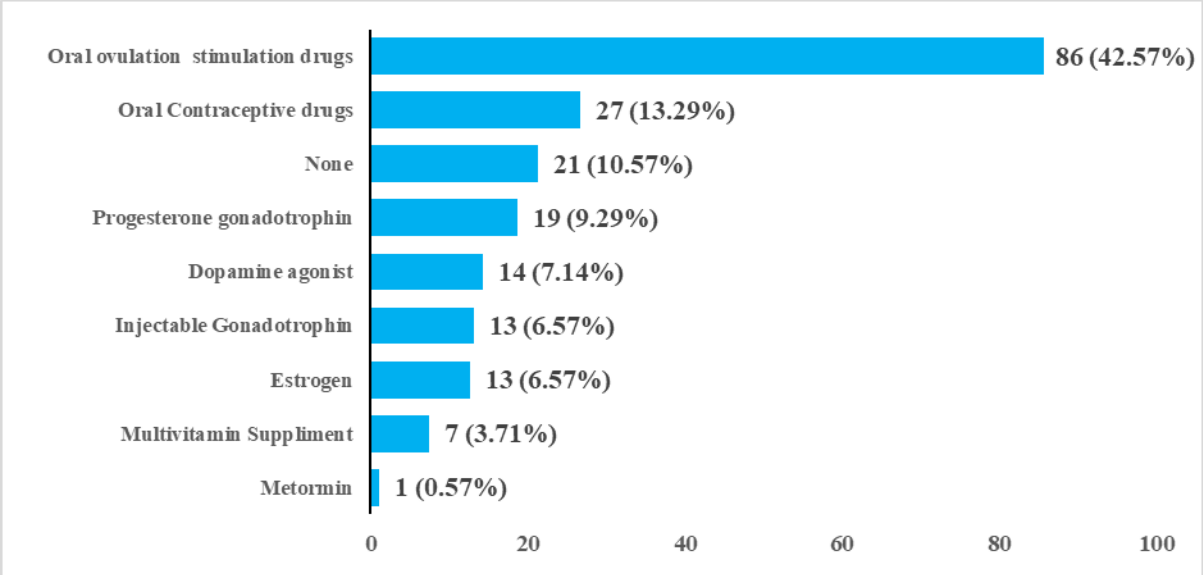

Figure 11: Female Medical Treatments as Treatment of Infertility (N=201)

(d) Previous Assisted Reproduction

4.7.2 Previous Assisted Reproduction Technologies reported by patients attended Assisted Reproduction clinic at Benjamin Mkapa Hospital

Table 8: Shows majority of the male and female patients attended Assisted Reproduction clinic at Benjamin Mkapa Hospital 366 (95.06%) reported that they had not undergone any previous Assisted Reproduction Technologies (ART).

Table 14: Previous Assisted Reproduction Technologies reported by patients attended Assisted Reproduction clinic at Benjamin Mkapa Hospital (N = 385)

ART status	Frequency (%)
Yes	19(4.94%)
No	366(95.06%)

In Figure 12, it is evident that among the male and female patients who received Assisted Reproduction technique 11 (58%) underwent In Vitro Fertilization (IVF)..

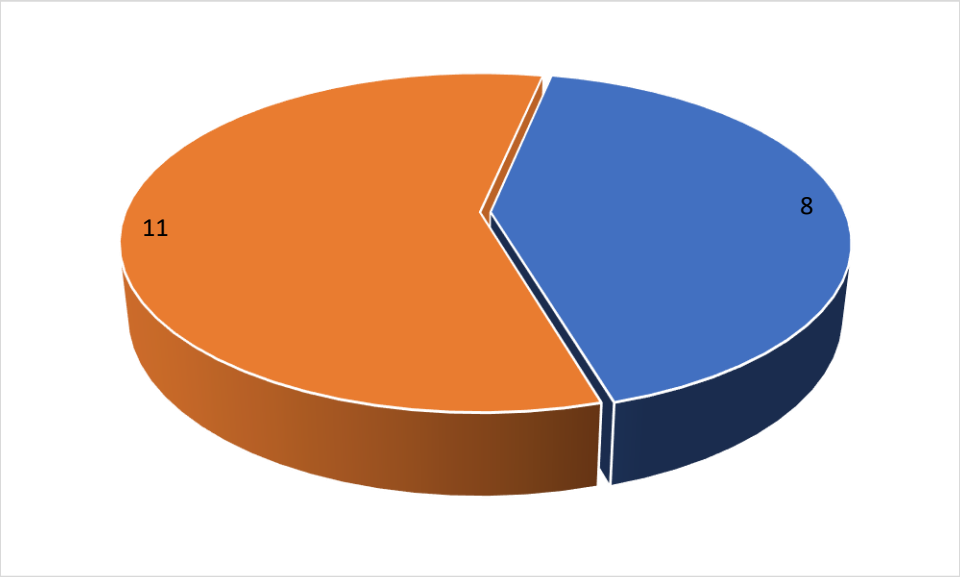

Figure 12: Previous Assisted Reproduction Technologies reported by patients prior to attend Assisted Reproduction clinic at Benjamin Mkapa Hospital (N = 19).

Figure 13 reveals that among male patients, 5 (62%) had Intrauterine Insemination (IUI).

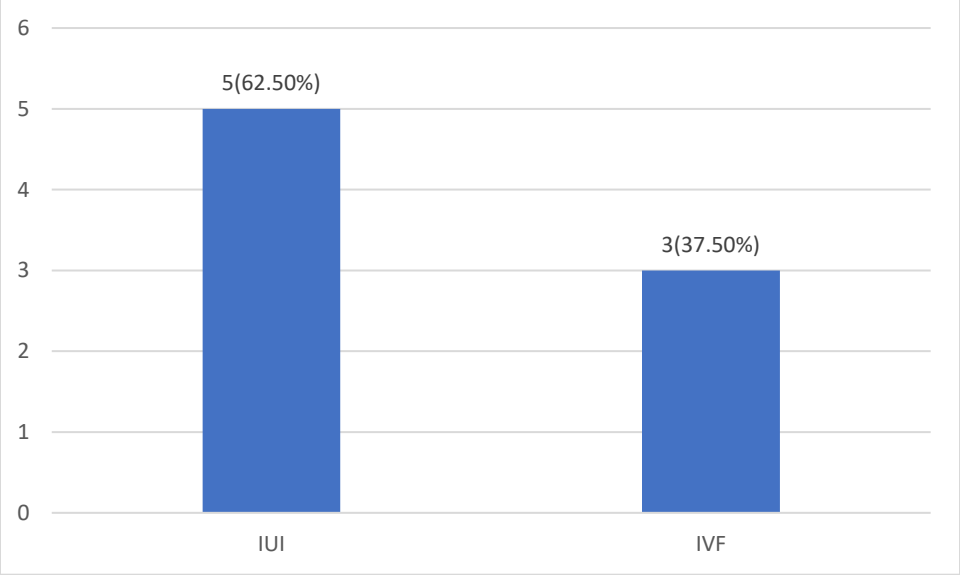

Figure 13: Previous Assisted Reproduction Technologies reported by male patients attended Assisted Reproduction clinic at Benjamin Mkapa Hospital (N = 8).

Figure 14 shows that majority of female patients 8(72.73%) had undergone In vitro Fertilization (IVF) procedure.

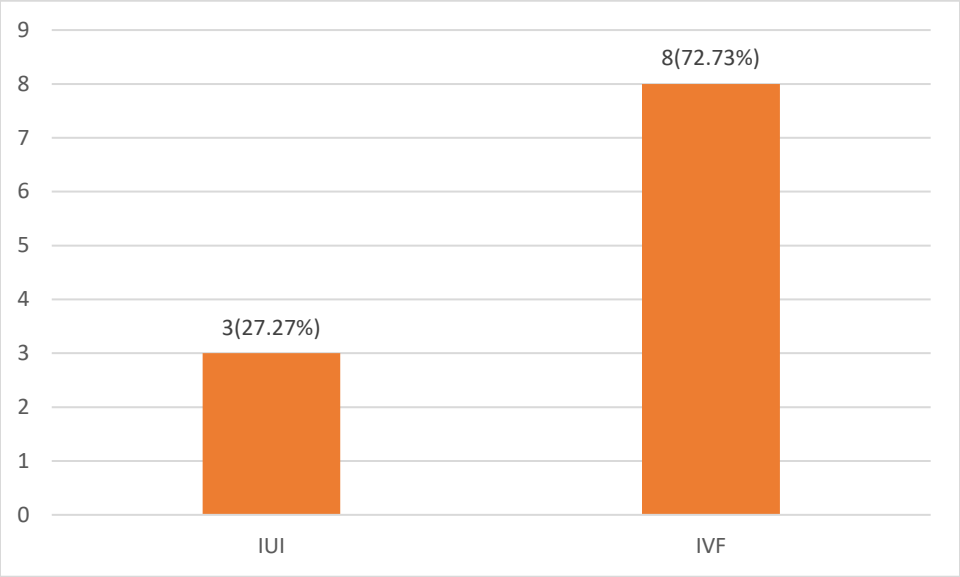

Figure 14: Previous Assisted Reproduction Technologies reported by female patients attended Assisted Reproduction clinic at Benjamin Mkapa Hospital (N = 11).

(e) Cryopreserve of gamete/embryo

Figure 15: shows that the majority of patients who attended the Clinic at Benjamin Mkapa Hospital 351(91%) had never done cryopreserve of their gamete/embryo as one of the Assisted reproductive technologies

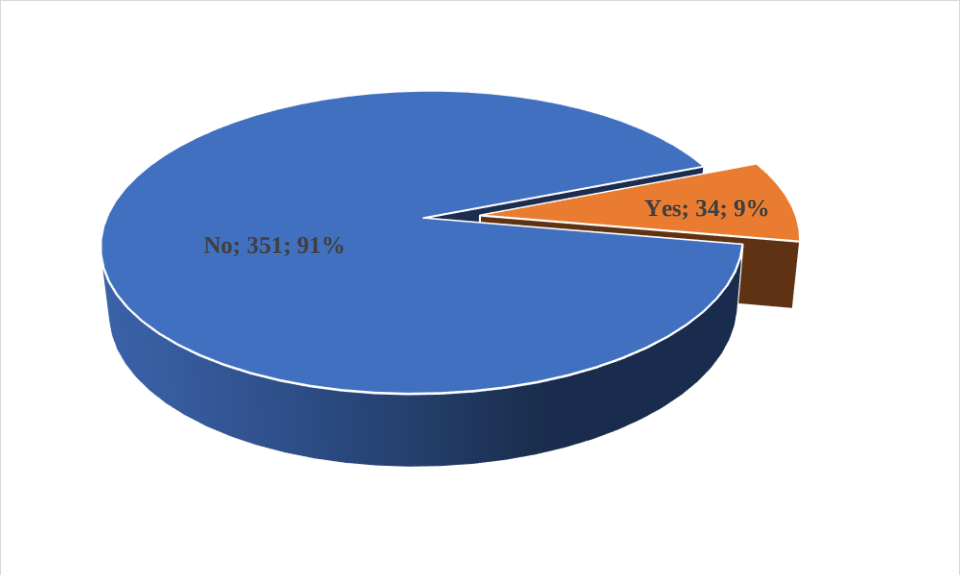

Figure 15: Previous Cryopreservation procedure reported by patients attended Assisted Reproduction Clinic at Benjamin Mkapa hospital (N=385)

Figure 16 below Indicates that majority of female who attended Clinic at Benjamin Mkapa hospital 181(90%) had no history of previous cryopreservation procedure

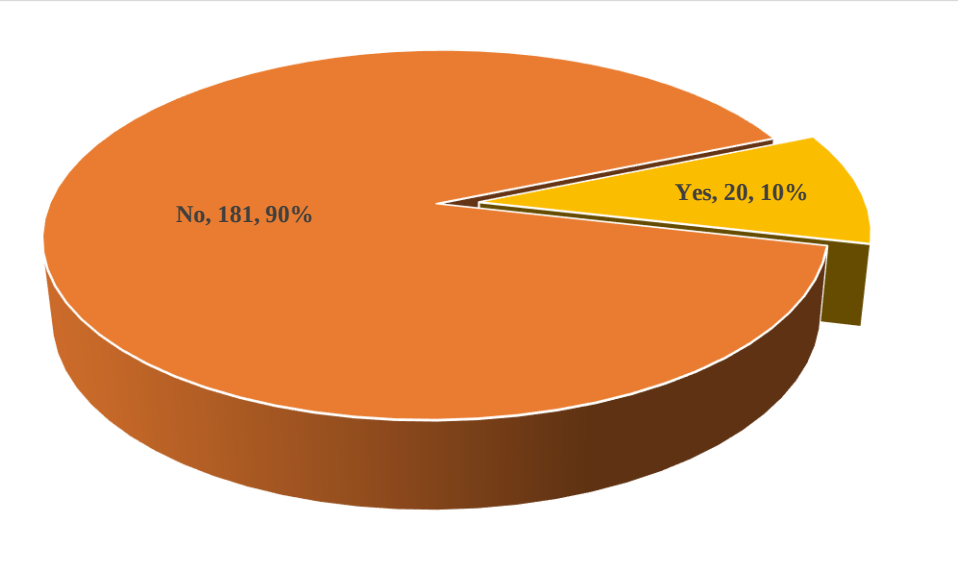

Figure 16: Previous Cryopreservation procedure reported by female patients attended Assisted Reproduction Clinic at Benjamin Mkapa hospital (N=201)

In Figure 17, it is evident that 92% of the male patients who attended the Assisted Reproduction Clinic at Benjamin Mkapa Hospital reported that they had not undergone previous cryopreservation procedure.

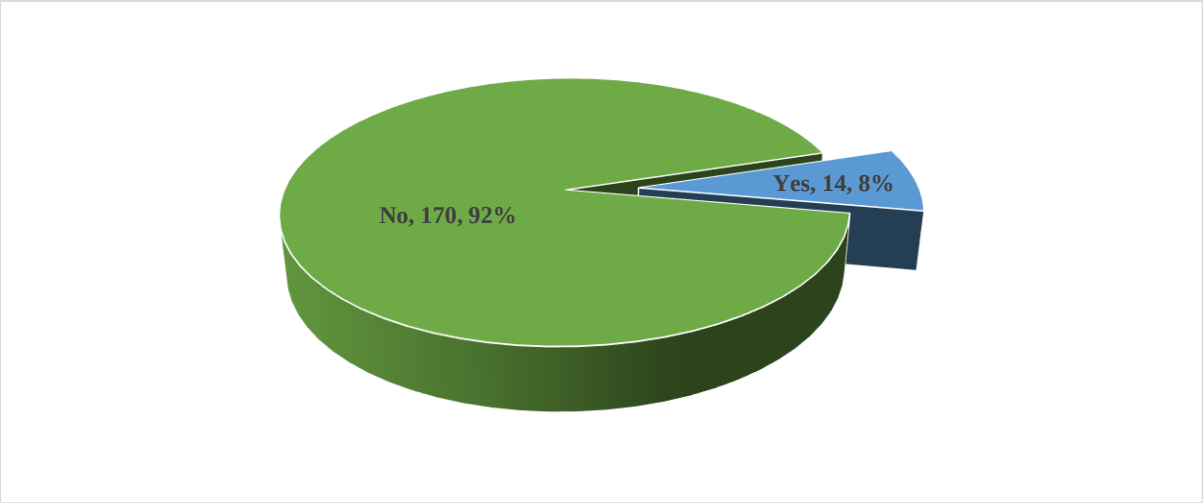

Figure 17: Previous Cryopreservation procedure reported by male patients attended Assisted Reproduction Clinic at Benjamin Mkapa hospital (N=184).

CHAPTER FIVE

5.0 DISCUSSION

5.1 Overview

This current study was conducted among 385 patients with infertility who attended the Assisted Reproduction Clinic at Benjamin Mkapa Hospital, in Dodoma region, Tanzania. The study determined the pattern of infertility, associated risk factors, and preexisting fertility treatment utilized by patients with infertility. The next sub-sections discuss the key findings concerning the research objectives. The discussion provides similarities and comparison of findings from other similar studies conducted at both the local and international levels.

5.2 Pattern of Infertility

It was found that among patients with infertility who attended at Assisted Reproduction Clinic Benjamin Mkapa Hospital, the dominant pattern of infertility was secondary infertility.

This is similar to the findings of the studies in China (Liang et al., 2021), Nigeria (Odunvbun et al., 2018), and Kenya (Otwori, 2013) while it is different from the study findings in India (Negi & Shahrawat, 2021) and in Ethiopia (Akalewold et al., 2022) where primary infertility is dominant.

Secondary infertility accounted for more than half in this study, these results might be due to abortion as reported also in the study(Larsen et al., 2006),. Previous studies found that patients with secondary infertility have low stress (Zaidouni et al., 2018). This gives promise that the patients may have a low drop-up rate during fertility treatment. In addition, patients with secondary infertility have better IUI outcomes as seen in the study (He et al., 2022) which gives hope for better results when starting medical assisted reproduction at Benjamin Mkapa hospital

5.3 Risk factors of infertility

It was found that the risk factors for infertility among patients attended Assisted Reproduction clinic at Benjamin Mkapa hospital were evidenced in this study by patients who were aged above 38years, had less than three times in a week frequency of sexual intercourse, more than ten years of duration of cohabiting/marriage and had cesarean section.

This study found that the risk of infertility among patients who attended Assisted Reproduction clinic at Benjamin Mkapa Hospital was old age. This study's findings are similar to the study findings of (Kasililika et al. 2021) where women with infertility were older than the control group. The risk of older age might be due to diminished egg reserve and the quality of the egg. This has been shown in the previous study to be associated with a decrease in the quality and quantity of eggs in women (George and Kamath 2010).

Infertility has been defined as the disease of inability to conceive in a couple who have sexually active for one year. In this study, we found that the risk factor for infertility was the frequency of sexual contact less than three times per week and this was similar to the findings from the study (Konishi et al., 2020) (Akalewold et al. 2022).

The number of sexual contact has been explained further by (Briscoe 2014) to be every 1 to 2 days making an average of 2-3 times sexual contact per week. The socio-demographic characteristics of the participants in this study such as older age, having a university education, and being employed may account for less sexual contact frequency similar to the study (Gaskins et al., 2018).

This study found that the risk of infertilityamong patients who attended Assisted Reproduction clinic at Benjamin Mkapa Hospital was more than ten years duration of cohabiting/marriage, More than ten duration of marriage is linked with poor sexual functions, fertility-related psychological stress and lastly poor quality of life; This is also explained in the study (Bose et al., 2021; Kiani et al., 2022; Yilmaz et al., 2020).

It is surprising that in this study many of the participants despite having a longer duration of infertility are seeking treatment. This is contrary to the study (Baranwal & Chattopadhyay, 2020) where a longer duration of marriage was associated with poor seeking of infertility treatment. This may be explained by the possible relationship between infertility and other diseases, which is supported by the study of (Choy & Eisenberg, 2018).

This study found that the risk of infertility among patients who attended Assisted Reproduction clinic at Benjamin Mkapa Hospital was a previous cesarean section. This study's finding is similar to the study. (Hinterleitner et al., 2021; Hsu et al., 2022) but contrary to the study (Jin et al., 2023).

(Jin et al., 2023) found that less than a quarter of women who had a prior history of cesarean section were unable to conceive.

This possible effect of the cesarean section may be due to the existence of bacteria around the cesarean section defect. (Hsu et al., 2022) , the risk of cesarean section in women with infertility (Richmond et al., 2022) , cesarean section scar (Jackman et al., 2021), and intrauterine adhesions(Yang et al., 2019).

While this study could not find that dilatation and curettage were associated with infertility, similar to the study (Tzur et al., 2021) and contrary to study findings in the studies (Hooker et al., 2020). The possible difference could be explained by a small sample of patients in this study who reported having dilatation and curettage

5.4 Preexisting Fertility treatment modalities used

This study found that half of the female patients had a history of taking herbal medication, many males with infertility hardly get any fertility treatment while less than half of the female patients had surgical and medical treatment for infertility respectively. Lastly, very few of the participants had undergone Assisted reproduction technologies.

This study established that there is a high uptake of herbal medication among female patients with infertility who attended the Assisted Reproductive unit at Benjamin Mkapa hospital , This may be accounted by socio-cultural activities where people believe on herbal medication for treatment of various disease.. This finding was also observed in the study done in Nigeria (Mohammed-Durosinlorun et al., 2019). The effect of African fertility herbal on kidney function is not known but, the study in south Africa (Monsees & Opuwari, 2017) on rats given herbal medication to improve reproductive capability found that there is association between damage of kidney function with intake of herbal.

This study has also established that males with infertility hardly get any fertility treatment probably due to African culture where infertility is mostly connected with a female partner. (Harlow et al., 2020), inadequacy of trained health staff (Leung et al., 2018). This study has posed a clinical need for the justification of why oral ovulation stimulation drug and laparoscopic surgery were more

frequent as prior medical and surgical fertility treatment modalities respectively among patients with infertility. In another study, patients had tuboplasty as infertility treatment (Afferri et al., 2022). The possible lack of appropriate national and institutional guidelines for management of infertility may have contributed to these study findings.

Except for the IVF procedure, Ovulation stimulation drugs and IUI were also reported in the study in Gambia (Afferri et al., 2022) . The difference in the provision of IVF between the two countries could be explained by differences in the sample population where this study interviewed patients who may have access to IVF services outside the Dodoma region or outside Tanzania whereas the study in Gambia interviewed the health professionals.

Access to ART fertility treatment is still low in Tanzania and this is evidenced by the high cost of fertility treatment in few ART private centres, lack of ART services in public hospitals,, limited guidelines for the management of infertility, and limited skilled health professionals(Moll et al., 2022). In systematic review study (Bahamondes & Makuch, 2014) on infertility care in poor resource areas proposed that the introducing low cost ART treatment approach would improve access to ART services among patient with ART.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The study has established that the dominance pattern of infertility among patients attended Assisted Reproduction Clinic at Benjamin Mkapa Hospital is secondary infertility

The results of the study further confirmed the possible associated risk factors for secondary infertility include age between 38-43years, frequency of sexual contact less than three days, duration of cohabiting/marriage of more than ten years and previous history of cesarean section.

This study has hypothesized that there is different type of infertility treatment given to the patients prior to attending Assisted reproduction unit at Benjamin Mkapa hospital. It is of note that male infertility is poorly managed, herbal medication is highly taken by female patients with infertility and there is limited access to ART services.

6.2 Recommendation

At national level

- Establishing of ART services in public hospitals.
- Establishing of national guideline for diagnosis and treatment of infertility

At hospital level

- Establishing institutional treatment guidelines for male and female infertility.
- Providing continuous training to health professionals on diagnosis and management of both male and female infertility
- Availability of ART services at Benjamin Mkapa Hospital.
- Educating patients on the side effect of unauthorized herbal medications
- Performing cesarean section when there is an absolute indication

At community or individual level

- Creating awareness that secondary infertility is dominant
- Creating awareness of risk factors of infertility to the public.
- Encouraging male patients to seek for fertility care

6.3 Limitation of the study

The study establishes secondary infertility as a dominant pattern; however, it is crucial to acknowledge potential limitations. The findings might be limited due to the exclusive inclusion of data from one hospital, potentially omitting valuable information from patients receiving infertility treatment at other healthcare facilities.

This study employed a cross-sectional design, measuring both the exposure and outcome at a single time point. This design presents a limitation as it makes it challenging to establish causal relationships when investigating potential risk factors for secondary infertility.

While this study provides insights into the prior fertility treatments received by patients before seeking assistance at Benjamin Mkapa Hospital, it's essential to acknowledge its limitations. The cross-sectional study design opens the possibility of patient response and recall bias when reporting their fertility treatment history.

6.4 Suggestions for further research

The study proposed in future for a multi-hospitals study to determine the dominance pattern of infertility in Tanzania.

It is also of interest in future to understand factors contributing to less frequency of sexual contact among patients with infertility also a large prospective or retrospective study could be done to assess effect of cesarean section on future fertility.

It is of interest in future to research on; the composition and effect of the herbal medication on fertility and kidney function, factor associated with poor management of male infertility and determining facilitators and barriers to establish ART in public hospitals

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APPENDIXES

Appendix 1: Consent form (English version)

THE PATTERN OF INFERTILITY, ASSOCIATED RISK FACTORS, AND USED FERTILITY TREATMENT AMONG PATIENTS ATTENDED ASSISTED REPRODUCTIVE CLINIC AT BENJAMIN MKAPA HOSPITAL IN DODOMA; ANALYTICAL CROSS-SECTIONAL STUDY.

Dear participants,

We Dr. Secilia Ngwe'shemi, The University of Dodoma, 0754690877
Dr. Anna Kasililika, The Benjamin Mkapa Hospital, 0737478868
Hindu Ibrahim, The Benjamin Mkapa hospital, 0715660103
Dr. Henry Stephen, Benjamin Mkapa hospital, 0764454870
We are carrying out a research with

UDOM Institutional Review Board, number…

1. Introduction and Purpose of the study
   Infertility is a global health problem affecting 10-15% of the couple worldwide nevertheless the pattern of infertility, associated risk factors, fertility treatment used by the patient attended at Assisted reproduction clinic at Benjamin Mkapa hospital are not known.
   This analytical cross sectional study will use detailed clinical proforma to collect information.

2. Description of the Research Include a description of what participation in the study entails.
   When you enter into the study, you will be interviewed and invited to the laboratory and radiology unit for taking fertility tests

3. Subject Participation
   We will recruit a total of 384 patients with infertility in this study
4. Potential Risks and Discomforts

   There is no known risks when involved in this study apart from minor discomfort resulted from asking sensitive question on sexual habit. .

5. Potential Benefits

   We are expecting that this study will generate useful data on pattern of infertility, associated risk factors, fertility treatment used by the patient attended at Assisted reproduction clinic at Benjamin Mkapa hospital, of which this information will be used by policy makers, clinicians and the community to improve fertility status in Tanzania

6. Confidentiality

   All information taken from the study will be coded to protect each subject's name. No names or other identifying information will be used when discussing or reporting data. The investigator(s) will safely keep all files and data collected in a secured locked cabinet in the investigators office. Once the data has been fully analyzed it will be destroyed. Your responses are completely anonymous.

   By signing this form, you authorize the use and disclosure of the following information for this research. during the course of this study for education, publication and/or presentation.

7. Compensation

   Subjects will not be compensated for participation in this study.

8. Voluntary Participation and Authorization

   Your decision to participate in this study is complete voluntary. If you decide to not participate in this study, it will not affect the care, services, or benefits to which you are entitled.

9. Withdrawal from the Study and/or Withdrawal of Authorization

   If you decide to participate in this study, you may withdraw from your participation at any time without penalty.

10. Cost/Reimbursements

    There is no cost for participating in this study. Any medical expenses resulting from participation in this study will not be reimbursed by the investigators.

I voluntarily agree to participate in this research program □ Yes □ No

I understand that I will be given a copy of this signed Consent Form.

Name of Participant

……

……Signature: Date:

Signature: Date: **Note: A copy of the signed, dated consent form must be kept by the Investigator(s) and a copy must be given to the participant.**

Appendix 2: Fomu ya ridhaa (Swahili version)

AINA YA UTASA/UGUMBA, VISABABISHI NA MATIBABU YANAYOTUMIWA NA WAGONJWA WALIOTIBIWA KLINIKI YA UPANDIKIZAJI MBEGU ZA KUIME NA MIMBA KATIKA HOSPITALI YA BENJAMIN MKAPA, DODOMA

Ndugu,

Sisi, Dr. Secilia Ngwe'shemi, Chuo Kikuu cha Dodoma, 0754690877

Anna Kasililika, Hospitali ya Benjamin Mkapa , 0737478868

Hindu Ibrahim, Hositali ya Benjamin Mkapa , 0715660103

Henry Stephen, Hospitali ya Benjamin Mkapa , 0764454870

Tunafanya utafiti wenye usajili namba kutoka chuo cha UDOM kitengo cha usajili tafiti.

11. Utangulizi na kusudi la tafiti hili.
    Utasa/Ugumba ni changamoto ya afya ya uzazi ambao unawaathiri asilimia 10-15% ya wanandoa duniani ila taaarifa za aina ya utasa/ugumba, visababishi, matibabu ya utasa/ugumba yanayotumiwa na wagonjwa Tanzania haufahamiki bado.Utafiti huu utatumia taarifa za kitabibu pamoja na vipimo.
12. Maelezo ya utafiti juu ya utafiti utakavyofanyika
    Unapokubali kuingia katikautafiti huu, utaombwa taarifa zako na kwenda maabara na chumba cha radiology kufanya vipimo.
13. Washiriki wa tafiti hii
    Utafiti huu utakuwa wa watu 384 wenye changamoto za utasa/ugumba
14. Madhara ya kushiriki utafiti huu.
    Hakuna madhara makubwa wakati wa kushiriki tafiti hii ila kuna madhara madogo kama kuulizwa maswali ya kiundani juu ya tendo la ndoa, kuchimwa sindano wakati wa kutoa damu, kutojisikia vizuri wakati wa kipimo cha ultrasound na kutoa manii.

15. Faida za kushiriki utafiti huu

    Tunategemea kuwa utafiti huu utatupa taarifa nzuri za aina ya utasa/ugumba, visababishi, matibabu ya utasa/ugumba yanayotumiwa na wagonjwa ambazo zitasaidia katika utengenezaji ya mipango kazi katika kutoa huduma ya matibabu ya utasa/ugumba Tanzania.

16. Usiri

    Taarifa zote zitakazochukuliwa wakati wa utafiti huu zitawekewa namba ili kutunza siri.Hakuna jina au kitu chochote kinachomtambulisha mtu kitatumika wakati wa kutoa taarifa ya utafiti huu.

    Watafiti watatunza taarifa zote katika kabati linalofungwa na baadae kuteketezwa.

    Hivyo kwa kusaini hii fomu unakubali taarifa zako zitumike kwa ajili ya utafiti huu katika kutoa elimu na kutoa taarifa kwa jamii.

17. Malipo

    Hakutakuwa na malipo kwa sababu ya kushiriki utafiti huu.

18. Ushiriki Voluntary Participation and Authorization

    Utaweza kushiriki tafiti hii kama ukiwa umekubali kushiriki. Endapo hutashiriki tafiti hii haitakufanya ukose huduma za matibabu ya magonjwa ya utasa/. ugumba

19. Kujitoa katika utafiti huu

    Unaruhusiwa kujitoa kushiriki tafiti hii muda wowote bila adhabu.

20. Gharama

    Hakuna gharama yoyote katika kushiriki utafiti huu na gharama za vipimo itakuwa juu ya mgonjwa.

Mimi nakubali kushiriki utafiti huu □ Ndiyo □ Hapana

Mimi nimeelewa na nitapewa nakala ya ridhaa niliyoweka saini.

Jina la mshiriki

……

Saini na tarehe.

……

Appendix 3: Clinical Proforma

https://www.chelseafertilitynyc.com/content/5-resources/7-patient forms/ASRM_Infertility_History_Form.pdf

(mg.salisbury.nhs.uk/media/1343/infertility-clinic-proforma.pdf)

https://www.fhft.nhs.uk/media/3067/fhft-gp-fertility-referral-proforma.pdf

Identification information

Mobile number;

Hospital ID;

Questionnaires Number;

Interview date;

INSTRUCTIONS

Greetings

Ask for consent.

Write or circle the response given by the patient

	SOCIO-DEMOGRAPHIC INFORMATION	
1.	**Female**	**Male**
2.	Date of birth (DD/MM/YY);	Date of birth (DD/MM/YY);
3.	Age in years;	Age in years;
4.	What is your sex a) Male b) female	What is your sex a) Male b) Female
5.	Are you married? A)YES B) NO	Are you married? A)YES B) NO
6.	Age at marriage *(yrs)*;	Age at marriage *(yrs)*;

7.	In which region are you coming from? *(region);*	In which region are you coming from? (region);
8.	Place of resident in specific region a. Urban b. Rural	Place of resident in specific region c. Urban Rural
9.	What is your occupation …….	What is your occupation …….
10.	What is the highest level of your education? a) No formal education b) Primary c) secondary d) university/college	What is the highest level of your education? e) No formal education f) Primary g) secondary university/college
	PATTERN OF INFERTILITY	
	Parity and infertility status	
	Have you ever conceived a. Yes b. No	NIL
	Number of parity……	Number of parity……
11.	What is the number of parity with your current partner?	What is the number of parity with your current partner?
12.	What is the number of parity with your previous partner?	What is the number of parity with your previous partner?
13.	How many abortion have ever had?	How many abortion have ever had?
14.	How many live children do you have?	How many live children do you have?

15.	type of Infertility suffering by the client (*Primary infertility-has neither conceive nor live birth)* *Secondary infertility-has hx of having children in the past)*	type of Infertility suffering by the client (*Primary infertility-has neither conceive nor live birth)* *Secondary infertility-has hx of having children in the past)*
16.	For how long have you had infertility? *(in month);*	For how long have you had infertility? *(in month);*
	RISK FACTORS OF INFERTILITY	
	Menstrual cycle	**NOT APPLICABLE**
1.	When was the last time you had LNMP? (Data)	
2.	What is your cycle length? a) <21days b) 21-35days c) >35days d) Others	
3.	What is nature of the menstrual flow?; a) Scanty b) Normal c) Heavy	
4.	Is there any feature suggesting dysmenorrhea? a) Mild b) Moderate c) Severe	
5.	Have you had amenorrhea in the past six months? a) Yes	

	b) No	
	Fibroid	
6.	Is there any feature suggesting fibroid symptoms (Heavy menses, dysmenorrhea, irregularity) a) Yes b) No	
	Sexual history	
7.	How many time in week have you been having intercourse without using any form of birth control?; (in week)	How many months have you been having intercourse without using any form of birth control?
8.	How many sexual partner have you had in your life time?	How many sexual partner have you had in your life time?
9.	Are you aware of fertility period? **a)** Yes **b)** No	NOT APPLICABLE
10.	How do you know your fertility period? **a)** Increased sexual desire **b)** Increased basal body temperature **c)** Mid-cycle lower abdominal pain **d)** Watery sticky discharge **e)** Use of calendar **f)** None	
	Sexual transmitted infection (STI)	
	Have you ever being diagnosed with any STI a. Yes	Have you ever being diagnosed with any STI

	b. No	a. Yes b. No
	Contraceptions	
11.	What type of contraception you have used in the past one year a) Barrier method b) Oral contraception drugs c) Injectables d) Implant e) IUCD f) None	What type of contraception you have used in the past one year a) Barrier method b) Oral contraception drugs c) Injectables d) Implant e) IUCD f) None
	Previous pelvic surgery	
12.	What previous pelvic surgery have you ever done? a) Myomectomy b) Cesarean section c) Cystectomy d) Salpingectomy e) Hydrotubation f) Dialatation and curettage g) Hysteroscopy h) Laparascopic i) Herniorrhapy j) Urethroscopy k) other l) None	What previous pelvic/ reproductive organ surgery/procedure have you ever done? a) Herniorrhapy b) Urethroscopy/cystoscopy c) Testicular biopsy d) Prostate surgery e) other f) None
	Family and social history	
13.	Do you have any family history of infertility; a) Yes	Do you have any family history of infertility; c) Yes

	b) No	d) No
	Drug abuse	
14.	What kind of drug have you ever abuse? a) Alcohol b) Smoking c) Alcohol & Smoking d) Others e) NONE	What kind of drug abuse have you ever use? a) Alcohol b) Smoking c) Others d) NONE
15.	How many times do you use drug abuse? a) Daily b) Weekly c) Monthly d) Occasionally	How many times do you use drug abuse? a) Daily b) Weekly c) Monthly d) Occasionally
	Medical conditions	
16.	Do you have the following Medical conditions a) HIV b) DM c) HTN d) Cancer e) Others f) None	Do you have the following Medical conditions a) HIV b) DM c) HTN d) Cancer e) Others f) None
	Obesity	
17.	What is your body weight in *kg*	What is your body weight in *kg*
	What is your body height in *m2*	What is your body height in *m2*
	What is the BMI; a) Underweight *(less than 18.5)*	What is the BMI; a) Underweight *(less than 18.5)*

	b) Normal *(18.5-<25.0)* c) Overweight *(25.0-<30.0)* d) Obese *(more than 30.0)*	b) Normal *(18.5-<25.0)* c) Overweight *(25.0-<30.0)* d) Obese *(more than 30.0)*
	FERTILITY TREATMENT USED	
18.	Have you ever use herbal medication for treating infertility?; a) Yes b) No	Have you ever use herbal medication for treating infertility?; a) Yes b) No
19.	When was the last time you had herbal medications as treatment for infertility?;	When was the last time you had herbal medications as treatment for infertility?;
20.	Have you ever had the following surgical procedures as treatment of infertility? a) Myomectomy b) Cystectomy c) Salpingectomy d) Hydrotubation e) Dialatation and curettage f) Hysteroscopy g) Laparascopic h) Herniorrhapy i) Urethroscopy j) other k) None	Have you ever had the following surgical procedures as treatment of infertility? a) Urethroplasty b) Prostate surgery c) Other d) None
21.	When was the surgical procedure done?	When was the surgical procedure done? (month)

22.	Have you ever taken any Medication as treatment for infertility? a) Dopamine agonist b) Oral contraceptive drugs c) Oral ovulation stimulation drugs d) Injectable gonadotrophin e) Progesterone pessaries f) Estrogen g) Other h) None	Have you ever taken any of the following medical treatment as treatment for infertility? a) prostaglandins b) Injectable gonadotrophin c) Phosphodiesterase Inhibitors
23.	For how long was the medical treatment taken in months?;	When was the medical treatment taken in months?;
24.	Have you ever underwent the any of the following assisted reproductive technical a) IUI b) IVF c) None	Have you ever underwent the any of the following assisted reproductive technical d) IUI e) IVF None
25.	How often have you tried assisted reproductive techniques ?	How often have you tried assisted reproductive techniques ?
26.	Have you ever had Cryopreservation? a) Yes b) No	Have you ever had Cryopreservation? a) Yes b) No

Appendix 4: Ethical Clearance from the University of Dodoma

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
THE UNIVERSITY OF DODOMA
OFFICE OF THE VICE CHANCELLOR

Ref. No. MA.84/261/02/14

2nd February, 2023

To: Secilia Ng'weshemi Kapatala
The University of Dodoma

RE: ETHICAL CLEARANCE

The heading above is concerned,

The Institutional Research Review Ethics Committee (IRREC) reviewed research proposal titled ***"Pattern of Infertility, Factors and Used Fertility Treatment among Patients Attending Assisted Reproductive Clinic at Benjamin Mkapa Hospital 2022;Analytical Cross Sectional Study."*** I am glad to inform you that the committee has granted ethical clearance on the submitted research proposal.

Furthermore, as the Principal Investigator of the study, the following conditions must be fulfilled: -

- Progress report is submitted to the University of Dodoma.
- Copies of final publications are made available to the University of Dodoma
- Site: **Dodoma Region.**

Best regards,

Dr. Rehema Kilonzo
For: Chairperson - Institutional Research Review Committee (IRREC)

CC: Deputy Vice Chancellor-Academic, Research and Consultancy

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