KAIRUKI UNIVERSITY

SCHOOL OF MEDICINE DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

RESEARCH REPORT

ASSOCIATION OF LIPID PROFILE WITH UTERINE FIBROID AMONG WOMEN ATTENDING GYNECOLOGICAL CLINIC IN SELECTED HOSPITALS DAR ES SALAAM TANZANIA FROM APRIL TO JUNE 2024

BY

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Dissertation submitted to the Faculty of Medicine in partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and Gynecology of Kairuki University

2025

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for examination by Kairuki University a dissertation entitled **"*Association* of lipid profile with uterine fibroid among women at gynecological clinic at Kairuki hospital, Mwananyamala, and Amana Regional referral hospitals in Dar es salaam Tanzania."** in (partial) fulfilment of the requirements for the degree **of** Master of Medicine in Obstetrics and Gynecology of Kairuki University.

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DECLARATION AND COPYRIGHT

I, **Devotha A. Shirima**, declare that this dissertation is my original work, and it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature ---------- Date ----------

ACKNOWLEDGMENT

I would like to express my heartfelt thanks to Almighty God for the invaluable gifts of good knowledge, encouragement, judgment, and good health throughout my studies. Without His wonderful support, I would not have been able to move forward with such tremendous optimism.

I am also deeply thankful to all the people who have helped me along this academic journey. Their contributions made it possible for me to accomplish this work. Specifically, I would like to regard my supervisors; Dr. Monica Chiduo and Dr. Boniphace Sylvester for their patience and guidance, and for reading and correcting my work.

I must also acknowledge the importance of experience-sharing, engagement in the activity and encouragement from my colleagues. My regards and best wishes go out to each one of them.

Lastly, I thank The Ministry of Healthy (My sponsor) for their financial support that they have made it possible for the study to be done.

DEDICATION

This work is dedicated to the people who have helped me throughout my education including my Supervisors; Dr. M. Chiduo, Dr. B. Sylvester, My beloved Husband Mr. Valentine Mado and My Son "Ethan Valentine"- born during my Study period, who gave me Strength throughout my studies.

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ABBREVIATIONS

LDL – Low-Density Lipoprotein

HDL – High-Density Lipoprotein

UF – Uterine Fibroid.

KCMC – Kilimanjaro Christian Medical Centre.

TNF – Tumor Necrotic Factor.

BMI – Body Mass Index

HIV – Human Immunodeficiency Virus

UBP – WRS; Uterine bleeding and pain Women's research study.

IGF - Insulin Growth Factor.

DEHP – di(2-ethynyl) phthalate

MEHHP - Mono (2-ethyl-5-hydroxyphenyl) phthalate

ARH – Aryl hydrocarbon receptor

OPD – Outpatient Department

CDC – Centers for Disease Control

USS – Ultrasonograph

TAH – Total Abdominal hysterectomy

WHO – World Health Organisation

SPSS - Statistical Package for Social Science

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ABSTRACT

Background: Uterine fibroids are frequent findings in gynecology wards and constitute a major concern for women's well-being worldwide due to the related increased morbidity and mortality from hysterectomy, as well as an increased risk of metrorrhagia and low birth weight.

Aim of the study: This study aimed to determine the association between serum lipid profile and the presence of uterine fibroid, among women attending gynecology clinics at Kairuki, Amana, and Mwananyamala regional referral hospitals.

Materials and methods: An unmatched case-control study design was employed in this study. It involved determining the level of serum lipid and assessing the different factors associated with uterine fibroids. Descriptive statistics, chi-square analysis, and logistic regression were used for data analysis.

Results: The study recruited 452 participants. Participants with fibroids had higher serum LDL and HDL cholesterol (71.4% and 81.3%, respectively) than those without fibroids (28.0% and 18.7%, respectively). Additionally, triglycerides were shown to modestly increase in fibroid individuals compared to those without. On the other hand, there was a significant (p value < 0.05) 2.1 chance of having UF for those with higher LDL cholesterol. Patients who had higher serum HDL cholesterol were also 2.4 times more likely to have uterine fibroids. Furthermore, Use of polished nails and lipstick, poor physical excessing, older reproductive age and education at secondary school level were the most sociodemographic factors significantly ($p < 0.05$) associating to uterine fibroid among study participants.

Conclusions: The present study found that participants with uterine fibroid had elevated serum cholesterol compared to those without fibroid. Also, there was a significant association between rise of serum cholesterol and presence of uterine fibroid. Furthermore, women at later reproductive age, those with poor physical excessing, and those educated at secondary school level were the risk to present with uterine fibroid.

CHAPTER ONE

1.0. INTRODUCTION

1.1. Background

Uterine fibroids, also known as leiomyoma or myoma, are frequent benign uterine tumors, that develop when single smooth muscle cells in the myometrium undergo neoplastic change (1). In the gynecology ward, uterine fibroids constitute a major concern due to the increased risk of menorrhagia, pelvic pain, infertility, and low birth weight among other complications, all of which hurt the well-being of women (2).

Uterine fibroids are more common findings in gynecological clinics; their frequency varies across the world and depending on the age, and the diagnostic instrument utilized among other factors (3). Eastern Europe and tropical America had the greatest age-standardized incidence rate of uterine fibroids in 2019, with a 6.87% increase in the global age-standardized incidence of uterine fibroids from 225.67 to 241.18 per 100,000 individuals between 1990 and 2019(4). In low-income countries, uterine fibroid remains also a frequent benign pelvic tumor with rates of 30.7%, 16.8%, 36.9%, and 64.6% in Nigeria, Cameroon, Ghana, and South Africa, respectively (5). In Tanzania, uterine fibroids were the most common reason for hysterectomy, accounting for 74% of elective hysterectomy cases at KCMC regional referral hospital in the Kilimanjaro region (6).

Several factors are reported to be related to the occurrence of uterine fibroid and the common ones include age, obesity, parity, smoking, and oral contraceptive drugs among others factors (3). Alternatively, the origin of uterine fibroid has been linked to growth factors, neoangiogenesis, hormonal imbalance (estrogen-progesterone imbalance), and genetic

abnormalities (7). Goodwin and Spies proposed that ovarian hormones, such as progesterone and estrogen, may play a role in the origin of uterine fibroids and stated that these hormones caused the growth of uterine fibroids (8). Hence, other authors reported the contribution of high estrogen levels in obese patients emphasizing the role of lipid change to induce uterine fibroid (9).

High serum lipid levels and the incidence of uterine fibroids were found to be significantly correlated in Russian patients with fibroid tumors, with corresponding sensitivity and specificity of 88% and 86% (9). On the other hand, it has been observed that uterine fibroids are substantially correlated with elevated serum lipids and inflammatory biomarkers in a study conducted in China (10). Moreover, there was a correlation found between the number of uterine fibroids and elevated serum triglycerides and inflammatory biomarkers (10).

Lipid profiles may constitute a reliable tool used for screening and follow-up with patients presenting with uterine fibroid. However, research on lipid profiles in patients with uterine myoma remains not well-studied in low-income countries, including Tanzania.

1.2. Problem statement

Uterine fibroids constitute a concern in the gynecology ward due to the risk of increasing morbidity and mortality related to the risk of hysterectomy, increased risk of metrorrhagia, and infertility among other complications (11). In Tanzania, UF continues to be a concern in gynecology wards, to the point that 70% of hysterectomies performed are due to UFs (6).

Identification of women at risk of developing uterine fibroid formation may help with early screening to prevent complications and burdens related to UF. Serum lipid profiles have emerged

as a dependable diagnostic and tracking tool for uterine fibroids, both in terms of size monitoring and disease progression, as observed in several studies in Western countries (13,10). The risk of uterine fibroid is higher in individuals with hyperlipidemia (13,10). This implies that lipid metabolism may be attributed to the development of tumors including uterine fibroid (10).

In practice one of the diagnostic tools is the ultrasound which is usually used in symptomatic women and hardly earlier when they are asymptomatic. In most health facilities at the district level and lower levels, ultrasound is not affordable or not available when needed. Currently, high BMI which is linked with high lipidemia and for that matter the genesis of uterine fibroids is not used for the screening of this condition.

1.3. Rationale of the study

This study is expected to determine the lipid Profile associated with uterine fibroid and the factors associated among women attending at Kairuki, Amana, and Mwananyamala gynecological clinics and wards. The findings of this study are expected to be useful in the assessment of uterine fibroid development which can be used as an initial screening tool for obese women (high BMI) and those with hyperlipidemia, who is at high risk of developing UF. Understanding the many risk factors for uterine fibroids can help with the early detection of the condition and the development of treatment plans that will lessen the burden associated with it. Future research in this area will be built upon the results of this study. This study Will be a requirement for partial fulfillment for the award of the degree of master in obstetrical and gynecology

1.4. Research questions

1. What is the lipid profile among women attending the gynecological clinic and ward at

Kairuki, Amana, and Mwananyamala regional referral hospitals?

2. What is the association between uterine fibroid and elevated serum lipid among women attending the gynecology department at Kairuki and Amana regional referral hospitals?
3. Is there any association between socio-demographic factors with uterine fibroid in women presenting with uterine fibroid in the gynecology department at Kairuki and Amana regional referral hospitals?

1.5. Objective of the study

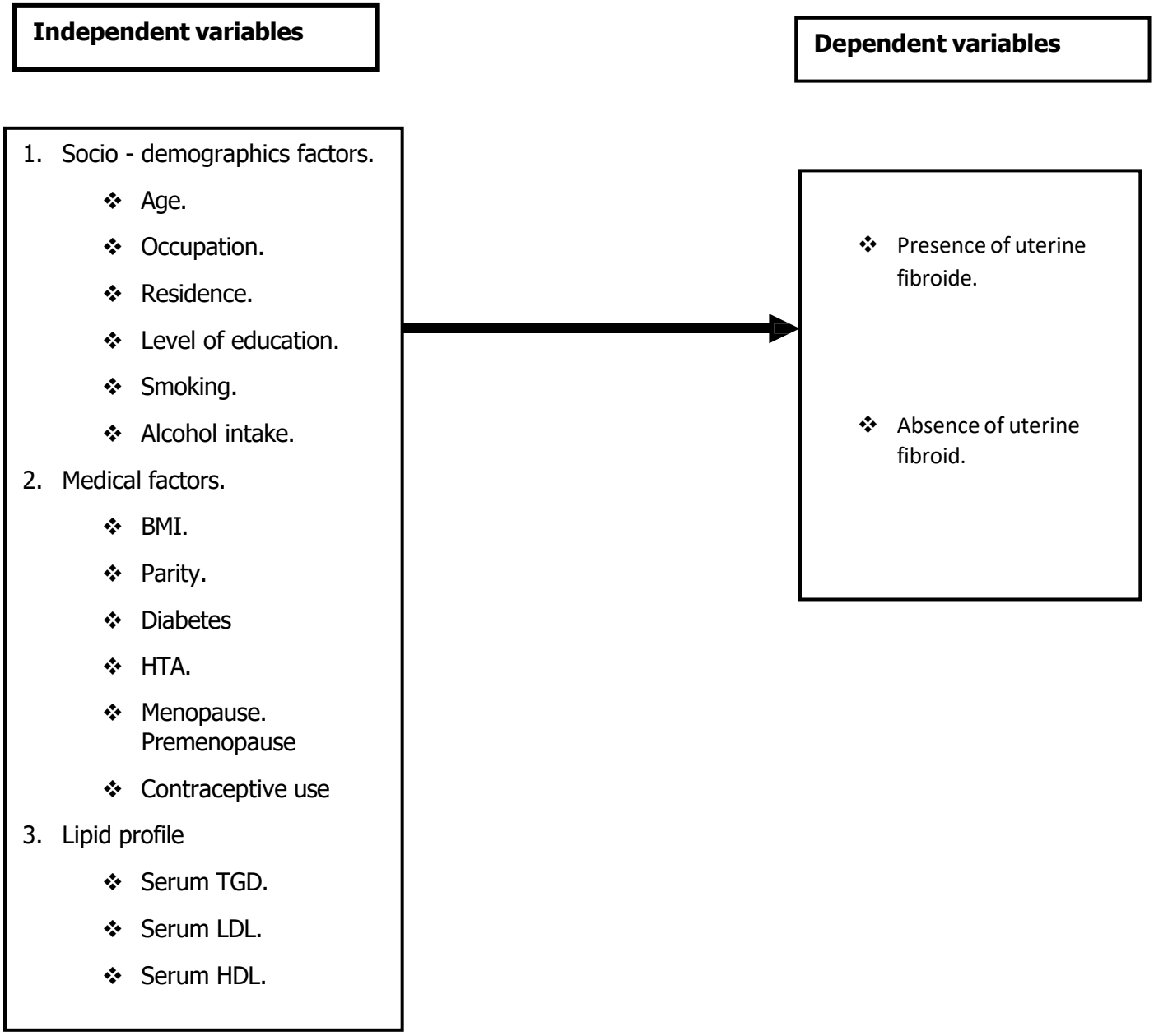
1.5.1. Main objective

To determine the lipid profile in women with uterus fibroid among women attending gynecological clinics and wards at Kairuki, Amana and Mwananyamala regional referral hospitals.

1.5.2. Specific objectives

1. To determine lipid profile among women attending the gynecological clinic and ward
2. To determine the association between uterine fibroid and elevated serum lipid among women attending gynecological clinics and wards
3. To determine socio-demographic factors associated with uterine fibroid among women attending gynecological clinics and wards.

1.6 Conceptual framework Dependent and Independent Variables Conceptual framework



CHAPTER TWO

2.0LITERATURE REVIEW

2.1 Magnitude of uterine fibroid.

Uterine fibroid is the most common benign tumor in women. According to the World Health Organization, it was estimated that between 20 and 25 percent of women worldwide suffer from fibroids and that these women account for close to 235 million cases, or 6.6% of all women globally. Uterine fibroid prevalence varies worldwide according to age, screening tools, and race, among other factors (4,17,18). In industrialized countries, the uterine fibroid is reported to have an incidence of 60% of uterine fibroids by the age of 35 years among African-American women, rising to over 80% by the age of 50 years, whereas Caucasian women had a 40% incidence by the age of 35 years and nearly 70% by the age of 50 years (16). However, the above-mentioned study selected only patients aged between 35 to 50 years.

In the other regions of Western countries, the Uterine Bleeding and Pain Women's Research Study (UBP-WRS) observed the self-reported prevalence of uterine fibroids varied widely among developed countries, with lows of 4.5% in the UK and 4.6% in France and highs of 9.8% in Italy and 9.0 % in Korea (17). However, this was the UBP-WRS, which used an online method approach to recruit participants. In addition, the study selected only participants between the ages of 18 and 49. In developing countries, the prevalence of uterine fibroids also varies region by region. In Nigeria and Ghana, a rate of 29.3% and 36% with uterine fibroid were observed among women attending gynecology departments (20,21). In the East African region, a rate of 28.2% of uterine fibroid is reported among women attending a gynecology clinic at the Mbarara Regional Referral Hospital in Uganda (20). The above-mentioned findings were hospital-based and hence their findings couldn’t reflect the general perspective of the population.

In Tanzania, there is limited literature about uterus fibroid. A study conducted in the northern Tanzanian region at KCMC referral hospital reported a rate of 74 percent of uterine fibroid among women planned for elective hysterectomy (6). However, this study, in addition to being hospital- based, recruited only patients planned for elective hysterectomy. To obtain a comprehensive view of the magnitude in the general population, a multicenter study is needed to improve the literature on uterine fibroids in Tanzania.

2.2. Association between elevated serum lipids and uterine fibroid

Several factors have been reported to be involved in the formation of uterine fibroids. Many authors are currently attempting to establish a correlation between the growth of uterine fibroids and serum lipid levels. According to a study done on Iranian women attending the Al-Zahra specialized referral hospital, uterine fibroid development has been linked to elevated serum cholesterol and low-density lipoprotein cholesterol (10). However, this was a single hospital-based study. In Nigeria, Akinlua and colleagues observed also that raised levels of serum cholesterol and triglycerides were associated with the presence of uterine fibroid growth (21). Arianna and associates in Italy observed also that there was a positive correlation between LDL-C and a negative correlation between HDL-C levels and the existence of UFs(22).On the other hand, some authors have found no association of uterine fibroids genesis and serum lipids change as in a study conducted by Fabio Parazzini and colleagues in Italy and Ratch and colleagues in the USA. However, the findings of the above-mentioned studies were based form a retrospective review of medical records(23). The mechanism by which elevated serum lipid-induced uterine fibroid formation is not well understood. However, some studies showed that ox-LDL may promote proliferation and stimulate cell migration in various types of cancer, such

as prostatic carcinoma and colorectal cancer. Prostaglandin E2, one of the COX-2 derivatives, is well-known for its potential connection to the development of cancer and chronic inflammation (24). Thus, it is conceivable that ox-LDL and the development of UFs may be connected via the same process.

2.3. Factors associated with uterine fibroid

Numerous factors, including age, race, use of contraception, obesity, and parity among other variables, have been linked to an increased risk of uterine fibroids(3). However, few research focused on the factors associated with elevated lipid levels in uterine fibroids.

On the other hand, acknowledgment of different factors associated with uterine fibroids, such as age, occupation, residence, level of education, and environmental factors, among others, may help to improve screening for uterine fibroid. Several studies have been conducted to determine the association of different factors with uterine fibroids. Numerous literatures have identified obesity as a risk factor for uterine fibroids and consequently raised serum lipid levels; however, the results vary depending on the variables that are assessed. Several authors have observed a significant correlation between Waist circumference, BMI, and uterine fibroid formation as in a study conducted in China by Ying Yang and colleagues, where high elevated BMI was significantly associated with the occurrence of uterine fibroid (25). Similar results were reported among female public school teachers and administrators in California, USA, where participants with increasing BMI were related to increased risk of presenting uterine fibroid (26) However, the above findings were from a retrospective review of medical records. Other authors in the USA reported also similar findings with increasing BMI and waist-to-hip ratio as risk factors of uterine fibroid (27).

The connection between obesity and hormone-related gynecologic diseases such as fibroid is often attributed to a hyper-estrogenic environment. Additionally, the hepatic synthesis of the insulin growth factor (IGF) binding proteins is decreased by hyper-insulinemia and insulin resistance brought on by excess weight, which raises free IGF levels (30,31,32). This later was reported to be involved in uterine fibromatosis formation.

Furthermore, due to modifications in steroid hormone metabolism and bioavailability brought on by a drop in circulating levels of sex hormone-binding globulin, obesity may impact the risk of uterine leiomyoma. Reduces in sex hormone-binding globulin may raise the fraction available for biological activity or the percentage of free estrogen(31,32).On the other hand, Balloch and associates postulated toward the close of the 1800s that African Americans were more likely to experience "fibroid processes" such as UL, keloids, and elephantiasis. However, there is a structural similarity between UL and keloids in that proliferating fibroblasts and collagen characteristic of these dermal tumors are also components of UL pathologic structure along with smooth muscle cells(15,33).The explanation for another theory was that black women experience more pelvic infections than white women and that these infections irritate the myometrium, resulting in aberrant uterine growth. Furthermore, there is proof that estradiol levels fall with rising BMI in black women but not in white women, and that premenopausal black women may have higher ovarian hormone levels than white women. These findings emphasized again that there may be differences in the impact of BMI on the risk of uterine leiomyomata between women of color and white women(33).

On the other hand, it has been noted that environmental elements such as phthalates composite

products, also referred to as plasticizers and used to make plastics more durable, increase the likelihood of uterine fibroids forming. Phthalates are constantly present in the environment because people breathe in phthalate particles from the air and consume and drink food that has been packaged with phthalates.

Uterine fibroids grew more rapidly when exposed to phthalates, especially di-(2-ethylhexyl) phthalate (DEHP). In addition, mono (2-ethyl-5-hydroxyhexyl) phthalate (MEHHP) is metabolized by DEHP (34). The mechanism of action of MEHHP is a considerable increase in cell viability and a decrease in cell apoptosis (programmed cell death) (35). MEHHP promoted the cells' absorption of tryptophan Trusted Source. The aryl hydrocarbon receptor (AHR), a ligand-activated transcription factor involved in cell proliferation, became more active as a result of this increasing kynurenine synthesis. These mechanisms promote the survival and growth of leiomyoma cells(35).

Despite the different studies conducted on uterine fibroid and their associated factors, little is known about the Tanzanian population, and yet research has shown the burden of uterine fibroid in this population.

CHAPTER THREE

3.0METHODOLOGY

3.1Research Design

This was an unmatched case-control hospital-based study carried out at a selected hospital in in Dar es Salaam. Cases included non-pregnant women confirmed with uterine fibroid by ultrasonography who attended the gynecology clinic during the study period. While control comprise non-pregnant women without uterine fibroid who attended study centers during the duration of the study.

3.2 Study area.

The study was conducted at Kairuki Hospital, Amana, and Mwananyamala Regional Referral Hospital at the gynecological clinic and in patient ward. Amana is a RRH located in Ilala urban district, Dar es Salaam. The hospital had a total bed capacity of 600 beds and serves around 3,505,598 patients per year. The study was conducted in gynecology department which receives an average of 7622 women per year. The department had 5 specialists: 40 midwife and 9 nurses. (Ministry of Health, Republic United of Tanzania). Mwananyamala RRH is located at Kinondoni district, Dar es salaam. The study was conducted at gynecological department which receive an average of 7754 women in clinic in year. The department had 3 specialists: 36 midwife nurses and 8 registered. (Ministry of Health, Republic United of Tanzania). Kairuki is also a RRH located in Mkocheni Kinondoni district, Dar es Salaam, the study was conducted at obstructs/gynecological ward and gynecological clinic, which provides outpatient and inpatient services. Ward One has 17 beds and Ward Two has 20 beds, so the total number of nurses is 22, with 12 obstetrics and gynecology doctors (Ministry of Health, Republic United of Tanzania).

3.3. Study population

All women with a history of chronic pelvic pain, dysmenorrhea, metrorrhagia, and infertility among other signs and symptoms suggestive of UFS and asymptomatic were diagnosed by USS attended the gynecology ward and clinic at Kairuki, Amana, and Mwananyamala RRH during the study period were included. Participants with uterine fibroid confirmed by ultrasonography were considered as case while those without UF were considered as controls.

3.4. Target population:

Non-pregnant Women of their reproductive age attended the gynecology ward and clinic at Kairuki Hospital, Mwananyamala, and Amana RRH.

3.4.1. Inclusion Criteria

This study included all non-pregnant women with and without uterine fibroid in reproductive age (15-49 years).

3.4.2.Exclusion Criteria

The following were excluded from the study:

- A patient who refuses to consent.
- Patients in menopause.
- The patient is on steroid drugs.
- Current or prior history of malignancies.
- Patient with a history of lipid-lowering agent treatment at the time of the study.
- Diabetic patient.

3.5. Eligibility criteria

3.5.1. Sampling Design

Consecutive enrollment in the study was performed until the desired sample size was obtained at the gynecological clinic and ward at Kairuki Hospital, Amana, and Mwananyamala RRH Patients with proven uterine fibroids were considered case participants, while other patients meeting the inclusion criteria served as control cases. Each case study was followed by the recruitment of a control participant.

a. Sample Size Estimation.

The sample size was calculated using open epi software.

(https://www.openepi.com/SampleSize/SSCC.htmsample size) for an unmatched case-control study Using the findings of Daniel and colleagues in Tanzania (6).

For:

Two-sided confidence level(1-alpha)	95
Power(% chance of detecting)	80
The ratio of Controls to Cases	1
Hypothetical proportion of controls with exposure	74
Hypothetical proportion of cases with exposure:	85.06
The least extreme Odds Ratio to be detected:	2.00

	Kelsey	Fleiss	Fleiss with CC
Sample Size - Cases	210	208	226
Sample Size - Controls	210	208	226
Total sample size:	420	416	452

References

Kelsey et al., Methods in Observational Epidemiology 2nd Edition, Table 12-15

Fleiss, Statistical Methods for Rates and Proportions, formulas 3.18 &3.19

The sample size in this study was 452.

Table 1: Distribution of sample size for each health facility

Facility	Proportion	Sample size for each facility	Cases	control
MWANYAMAALA	45/117 = 0.38	0.38 *452 =174	87	87
KAIRUKI	37/117 =0.32	0.38*452=142	71	71
AMANA	35/117 = 0.30	0.38*452=136	68	68
Total		452	226	226

Source hospital record. Following review of hospital record from each study center, we found that Mwanyamala, Kairuki and Amana had respectively 45, 37 and 35 patients with fibroid in the last 3 months. From this we get a total of 117 patients with fibroid in both study center. Hence, the proportion of study participants to each study center, was calculated using the ratio of patients with fibroid from study center to the total number of patients with fibroid in the study centers.

3.6 Data collection procedure

3.6.1 Recruitment of study participants

The study recruited all eligible non-pregnant women in reproductive age who attended gynecological clinics and wards at Amana, Mwananyamala RRH, and Kairuki Hospital. Participants were identified from any non-pregnant women who attended the gynecology ward or clinic in the selected study center. A screening for eligible participants was conducted in the gynecological and clinic ward and eligible participants were ~~identified and~~ enrolled in the study after obtaining their consent. The screening process involved first ruling out pregnancy by asking the last day of menstruation. Suspicious participants were referred to a deep stick urine pregnancy test to rule out pregnant. Than followed an interview to ascertain whether the patient was of reproductive

age, taking any particular medications, such as steroid, lipide-lowering medication, or having diabetes. Each participant had an abdominal ultrasound done by a radiologist to determine whether or not they had uterine fibroids. Subsequently, one woman without uterine fibroids was recruited for every woman with uterine fibroids until the required sample size was reached.

3.6.2. Collection of sociodemographic and medical factors

The research assistant or principal investigator collected data at admission by delivering a questionnaire to the participant. It contained socio-demographic factors (such as age, residence, occupation, smoking, alcohol intake, level of education, marital status, diet,) medical data (family history of UFs, use of oral contraceptive drugs, history of abortions, use of steroids, exposure to environmental pollutants, parity, among others).

Following that, anthropometric measurements and BMI were obtained for each patient during a clinical examination using the CDC standard procedure measurement (35). The patients' weight was recorded on a calibrated digital balance beam scale (without shoes, with light dressing, and in centimeters), with the subject wearing light clothing. The weight was recorded with a cutoff of the nearest 0.1kg.

The height was measured using a wall-mounted stadiometer with a cutoff nearest 0.1cm, with the subjects standing in the upright position without shoes. The body mass index (BMI) of the individuals was also computed using the formula BMI = body weight/height squared (kg/m2). The World Health Organization's standards for defining overweight (defined as 25.0 kg/m2) and obese (30.0 kg/m2) women served as the basis for the cut points for the current body mass index (BMI) categories.

3.6.3. Determination of lipid profiles

A blood sample was taken from each participant by lab assistant or nurse into a vacutainer containing citrate and sent to the laboratory Technician to measure the levels of triglycerides (mg/dL), high-density lipoprotein cholesterol (HDL-C, mg/dL), low-density lipoprotein cholesterol (LDL-C, mg/dL), and total cholesterol (mg/dL) using a standardized automated high enzymatic analysis using BS 240 spectrometer. Analysis of different serum lipids was measured using the low-density lipoprotein cholesterol (LDL-C) levels were calculated as per the Friedewald Formula: LDL-C = total cholesterol _ (HDL + TG/5) (36). Serum triglyceride levels were measured using a cutoff of less than 1.7 mmol/L as normal; and above 1.7 mmol and above as elevated (9,37). A range of 1.04-1.55 mmol was considered normal for HDL cholesterol, participants with HDL below 1.04mmol/L was considered having low HDL cholesterol. Those with serum cholesterol above

1.55 mmol was taken as high HDL cholesterol(9,37). A cutoff of 2.59 -4.11 mmol/L for LDL cholesterol was regarded as normal(9,37). LDL > 4.11 mmol/l was considered as elevated For diagnosis of uterine fibroid, all patients undergo abdominal or transvaginal sonography by a radiologist at Amana, Kairuki and Mwananyamala radiology department where the size, number, and anatomical location of UFS was determined. The diagnosis of UF was considered in presence of a well-defined solid hypo-echogenic or hyper-echogenic mass, with or without calcifications, inside the uterus.

3.7. Data collection tools

A semi-structured questionnaire (Refer to Appendix II) Was developed. It was used to assess lipide profile and factors associated with uterine fibroid among women attending a gynecological clinic at Kairuki Hospital, Mwananyamala, and Amana Regional Referral Hospitals. The tool was

designed after reviewing different literature on the correlation between lipid profile and uterine fibroid and consisted of three parts:

Part I: Socio-demographic characteristics like age, residence, occupation, and level of education.

Part II: clinical factors like type of metrorrhagia, pelvic pain, height, and weight, among others.

Part III: Investigations like serum triglyceride, serum LDL and HDL cholesterol, USS

3.8. Research Assistants.

The research assistant was selected among medical officers and residents of the gynecology department of the selected study center. Also, in each study center had a radiologist who was performing an abdominal pelvic ultrasound to all participants. The primary investigator was provided three days of training for two research assistants from each study center, who were medical officers or residents who attended the patients in the gynecological clinic or OPD, on how to use the checklist to retrieve pertinent information from patient files and during examinations. Research assistants received instructions on how to perform interviews to rule out uterine fibroids for symptomatic and asymptomatic patients and how to proceed with other anthropometric measurements needed for the study, such as height, weight, and BMI. In addition, the PE verified all the results of the experimentation for their reliability from different study centers.

3.9. Data management

3.9.1. Validity and Reliability

Before a pretest at Kairuki Hospital, Mwananyamala, and Amana RRH, the data collection underwent expert modification and review. To ensure that the questionnaires collected correct data and to improve their readability before the study starts, the instruments were changed after the pretesting exercise. The study instrument underwent an update before its start to ensure

accurate data collected and to enhance readability. The chief investigator and the research assistants was then used the new tool after receiving training on how to record and the importance of each data element.

3.9.2. Data collection in the field

After data is collected using a questionnaire, confidentiality was maintained by coding the data using the identifying codes provided on the questionnaire. Furthermore, data cleansing was conducted to guarantee the absence of superfluous and inaccurate information.

3.9.3Data coding and cleaning

Every day, the principal investigator and the research assistants had conversations to ensure the accuracy of the data obtained. After being double-entered by two data clerks, the data was also cleaned up and its accuracy was checked to ensure that it was of the highest quality.

3.9.4. Data Analysis

Data from questionnaires was managed and cleaned using Microsoft Excel 2010(37). The data was analyzed using SPSS software version 25.0(37). Continuous variables like duration of smoking, and lotion use among others were summarized as means and medians, standard deviations, and interquartile range. For categorical data like age and BMI parity, the SPSS 25 series for Windows was used to calculate proportions, percentages, and frequencies. The lipid profile was summarized as a mean in mg/dl of each type of lipid found in patients attended Kairuki Hospital, Amna and Mwananyamala regional referral hospitals. The association of elevated serum lipid and uterine fibroid was analyzed using an odd ratio. the odd ratio is equal to one, elevated serum lipids was increased the risk of developing uterine fibroid. And if the odd ratio is greater

than one, elevated serum lipids will be a risk factor for developing uterine fibroid, and if the odd less than one, elevated serum lipids will be a protective factor. P- A value of less or equal to 0.05 will be regarded as statistically significant. Socio-demographic factors associated with uterine fibroid will be determined using logistic regression in both bivariate and multivariate analysis.

Bivariate analysis will be done using binary logistic regression reporting both odds ratios and P values. Variables with P value ≤ 0.2 will be reanalyzed at multivariate using backward stepwise binary logistic regression. Variables with P ≤ 0.05 will be considered significant.

3.10 Ethical consideration

The study was conducted with ethical clearance granted by the HKMU Senate of Research and Publication Committee. At Kairuki Hospital, Amana, and Mwananyamala Referral Hospitals, permission from the appropriate authorities was requested for the collection of data. Following the patient's permission, participants were informed of the purpose, procedures, and benefits of the study and ensured that they had the opportunity to ask questions. All eligible women with uterine fibroid who attended the gynecology and clinic ward of Kairuki Hospital, Mwananyamala, and Amana RRH were enrolled.

Participants in this study may experience discomfort during the collection of blood samples for lipid profile or when abdominal pelvic ultrasound is performed to confirm the diagnosis of uterine fibroids. Nonetheless, it's crucial to remember that these procedures are commonplace in the gynecological ward and are carried out with little risk to the patient. Because these diagnostic procedures are well-established and follow sterile, professional protocols, any potential discomfort is minimized to the greatest extent feasible, putting the safety and well-being of the participants

Individuals who cannot give informed consent were not allowed to participate in this study. The patient's identity was concealed by using numbers in place of names. The obtained data was entered into a computer system and coded for documentation purposes. Security was upheld by restricting file access to researchers only. The written forms were kept private and accessible only to researchers in a locked cabinet.

CHAPTER FOUR

4.0 RESULTS

4.1. Study participants

Among the patients who visited the gynecological clinic and ward at the regional referral hospitals in Kairuki, Amana, and Mwananyamala, After being contacted, eligible subjects were progressively enrolled in the study until the desired sample size of 452 was obtained.

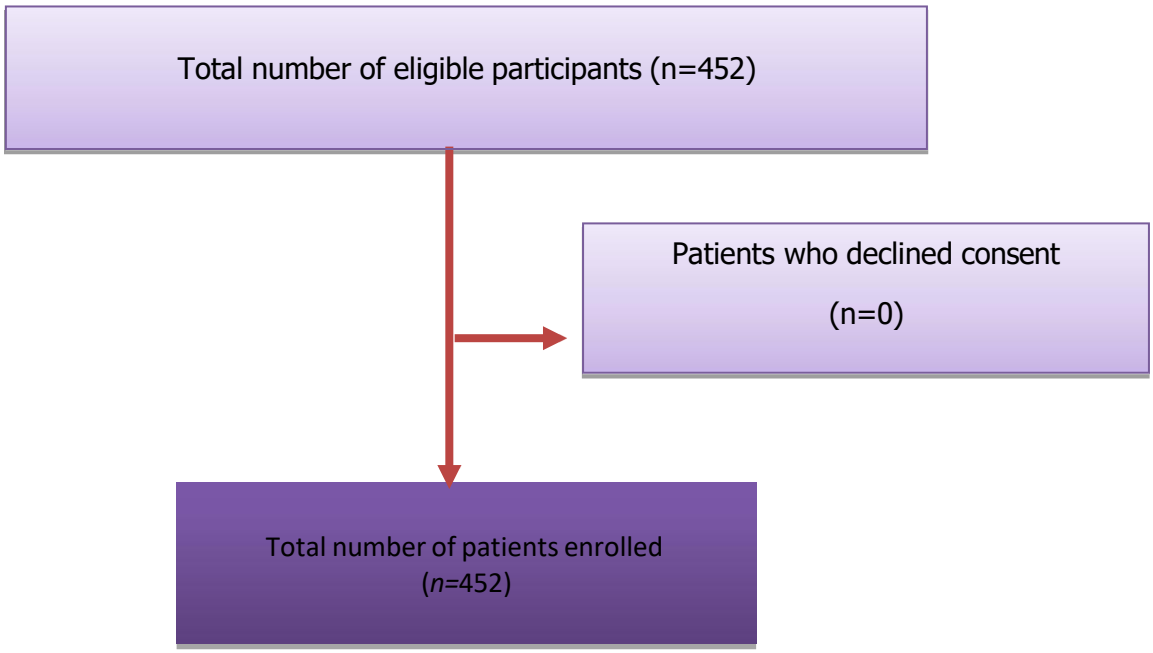


Figure 1. Study flow charts of study participants attending gyn clinic at gynecological clinic and ward at the regional referral hospitals in Kairuki, Amana, and Mwananyamala.

4.2 Sociodemographic profiles of study participants

Table 2. Sociodemographic profiles of study participants

Characteristics	Cases n=226(%)	Control n=226 (%)
Age (years)		
< 20	6(2.7)	4(1.8)
21-25	11(4.9)	27(11.9)
26-35	56(45.5)	67(54.5)
36-40	123(49.0)	128(51.0)
41-45	13(56.5)	10(54.5)
46-50	3(42.8)	4(51.2)
Level of education		
Primary	104(46)	87(38.5)
Secondary	71(31.4)	107(47.3)
University	51(22.6)	32(14.2)
Occupation		
House holder	98(43.4)	119(52.7)
Trader	39(17.3)	70(31.0)
Teacher	37(16.4)	22(4.0)
Medical stuff	41(18.1)	12(2.2)
Student	11(1.8)	3(1.3)
Smoking		
No	221(97.7)	222(98.2)
Yes	5(2.2)	4(1.8)
Alcohol intake		
No	215(95.1%)	219(96.9)
Yes	11(4.9%)	7(3.1)
Number of plastic bottles		
< 2	99(43.8)	119(52.7)
>2	127(56.2)	107(47.3)
Use of polish nail		
No	80(39)	125(55.3)
Yes	146(59.1)	101(40.9)
Use of lipstick		
No	89(42.2)	122(53.8)
Yes	137(56.8)	104(43.2)
Physical excessing		
No	105(46.5)	71(31.4)
Yes	121(53.5)	155(68.6)

In this study, majority of the participants had an age range between 26 to 35 years in both fibroid group (80.5%) and non-fibroid participants(62.8%). Also, most of the participants (43.4 % in fibroid and 52.7 % of non-fibroid) were house holder. Furthermore, 56.2 % in fibroid group and 47.3 % in non-fibroid group used more than 2 plastics bottles in a week. Others 53.5 % and 68.6% respectively in fibroid and non-fibroid group were using physical excessing. Polish nail was used in 20.8 % in fibroid and in 47.3 % in non-fibroid group.

4.3. Clinical profile of study participants

Table 3. Clinical profile of study participants

Clinical characteristics	Cases n=226	Controle n=226
Pelvic pain		
No	151(66.8%)	216(95.6%)
Yes	75(33.2%)	10(4.4%)
Dysmenorrhea		
Absent	194(85.8%)	221(97.8%)
Present	32(14.2%)	5(2.2%)
Metrorrhagia		
Absent	158(69.9%)	223(98.7%)
Present	68(30.1%)	3(1.3%)
Menorrhagia		
Absent	139(61.5%)	219(96.9%)
Present	87(38.5%)	7(3.1%)
BMI		
< 18.5	1(0.4%)	8(3.5%)
18.5-24.9	85(37.6%)	128(56.6%)
25.0-29.9	65(28.5%)	58(25.7%)
30.0-34.9	50(22.1%)	28(12.3%)
>35	25(11.1%)	4(1.7%)

In this study, pelvic pain, metrorrhagia, dysmenorrhea and menorrhagia were prevalent in participant with uterine fibroid with respectively rate of 33.2%,14.2%,30.1 % and 38.5%. In both groups, the most common BMI range was between 18.5 and 24.9 in 37.6% of participants having fibroids and 56.6% without fibroids.

4.4. Lipid profile among women attending gynecological clinic and ward at Kairuki, Amana and Mwananyamala regional referral hospitals

Table 4. Lipid profile among study participants

Serum Lipid profile	Case (n=226)	Control(n=226)
LDL Cholesterol		
Normal (2.59-4.11 mmol/l)	106(37.3%)	178(62.7%)
Elevated (>4.11 mmol/l)	120(71.4%)	48(28.8%)
HDL Cholesterol		
Low (<1.04 mmol/l)	22(11.5%)	170(88.5%)
Normal (1.04-1.55 mmol/l)	34(66.7%)	17(33.3%)
High (>1.55 mmol/l)	170(81.3%)	39(18.7%)
Triglyceride		
Normal (<1.7mm0l/l)	142(48.5%)	151(51.5%)
Elevated (>1.7 mmol/l)	84(52.8%)	75(47.2%)

χ2 = chi square test.

In the present study, LDL cholesterol was more elevated in participants with uterine fibroid in 71.4% than in those without fibroids where only 28.8% participants presented with rise serum

LDL cholesterol. Comparable distribution is noted with HDL cholesterol where 81.3% of study participants with uterine fibroids are present with high level against 18.7% without uterine fibroid. However low level of serum HDL is noticed more in participants without fibroid (88.5%) compared to those with fibroid (11.5%). 48.4 % and 43.4 % participants had respectively low and high HDL cholesterol. Triglyceride was elevated in 44% of study participants. Triglyceride was found to rise slightly in participants with fibroid compared to those without.

4.5. Association between uterine fibroid and elevated serum lipid among women attending gynecological clinic and ward at Kairuki, Amana and Mwananyamala regional referral hospitals.

Table 5. Association between uterine fibroid and elevated serum lipid among study participants

Serum Lipide profile	Case (n=226)	Control(n=226)	χ2	P value	0R (95 % CI)
LDL Cholesterol					
Normal (2.59-4.11 mmol/l)	106(37.3)	178(62.7)	49.1	0.001	2.1(1.6-2.8)
Elevated(>4.11 mmol/l)	120(71.4)	48(28.8)			
HDL Cholesterol			201.8	0.001	2.4(1.3-2.9)
Low (<1.04 mmol/l)	22(11.5)	170(88.5)			
Normal(1.04-1.55 mmol/l)	34(66.7)	17(33.3)			
High (>1.55 mmol/l)	170(81.3)	39(18.7)			
Triglyceride					
Normal (<1.7mm0l/l)	142(48.5)	151(51.5)	0.78	0.37	0.8(0.5-1.2)
Elevated (>1.7 mmol/l)	84(52.8)	75(47.2)			

Chi-square test , OR: odds ratio, P: p value, CI: confidence interval

In this study, participants with elevated LDL cholesterol had a significant (pp value < 0.05) 2.1 odd of developing UF. Like patients with elevated serum HDL cholesterol, they had 2.4 times odd to present uterine fibroid.

Figure 2: Uterine fibroid

Table 6. Association between size of uterine fibroid and serum lipid among study participants with uterine fibroids

Serum lipides	**UF < 5 cm**	**UF > 5cm**	**OR(CI 95%)**	**Chi-square**	**Sig(p< 0.05)**
LDL Cholesterol			0.8(0.4-1.4)	0.38	0.5
Normal(2.9-4.11 mmol/l)	39(44.3)	49(55.7)			
Elevated(>4.11 mmol/l)	67(48.76)	71(51.4)			
HDL Cholesterol			0.6(0.2,2.3)	0.5	0.7
Low(<1.04 mmol/l)	7(31.8)	15(68.2)			
Normal(1.04-1.55 mmol/l)	14(41.2)	20(58.8)			
High (>1.55 mmol/l)	67(39.4)	103(60.6)			
Triglyceride			1.8(1.0-3.3)	4.7	0.03
Normal(<1.7mm0l/l)	63(44.4)	79(55.6)			
Elevated (>1.7 mmol/l)	25(29.8)	59(70.2)			

In this study, there was a trend of participants with normal serum LDL, HDL and triglyceride to have smaller uterine fibroid (less than 5 cm). Howe ver, this was not statically significant ($p<0.05$).

On the other hand, participants with elevated serum triglyceride had significant 1.8 times chance to present with bigger uterine fibroid (>5 cm).

4.6. Socio-demographic factors associated with uterine fibroid among women attending gynecological clinic and ward at Kairuki, Amana and Mwananyamala regional referral hospitals.

Table 7. Socio-demographic factors associated with uterine fibroid among participants.

Characteristics	Cases n=226(%)	Bivariate analysis		Multivariate analysis	
		COR(95%CI)	Sign <0.05)	(PAOR(95 % CI)	Sign(P < 0.05)
Age (years)					
< 20	6(2.7)	Reff			
21-25	11(4.9)	3.6(0.8-15)	0.2		
26-35	56(45.5)	1.3(1.1-2.1)	0.01	1.4(1.1-1.8)	0.01
36-40	123(49.0)	2.9(0.7-11.3)	0.11		
41-45	13(56.5)				
46-50	3(42.8)				
Level of education					
Primary	104(54.5)	Reff			
Secondary	71(39.8)	1.8(1.1-2,7)	**0.005**	0.3(0.18-0.63)	0.01
University	51(61.4)	0.7(0.4-1.2)	0.4		
Occupation					
House holder	98(45.2)	Reff			
Trader	39(35.7)	1.1(0.6-1.7)	0.6		
Teacher	37(62.7)	0.3(0.2-1.6)	0.1		
Medical stuff	41(77.4)	0.6(0.2-1.5)	0.3		
Student	11(78.6)	0.3(0.3-1.3)	0.4		
Smoking					
No	221(97.7)	1.6(0.8-2.8)	0.1		
Yes	5(2.2)	Reff			
Alcohol intake					
No	215(95.1%)	1.4(0.1-1.3)	**0.3**		
Yes	11(4.9%)	Reff			
Number of plastic bottles					
< 2	99(45.4)	Reff			
>2	127(54.3)	0.7(0.4-1.0)	0.06		
Use of polish nail					
No	80(39)	Reff			
Yes	146(59.1)	3(2.0-4.6)	**0.002**	1.2(1.1-2.1)	0.45
Use of lipstick					
No	89(42.2)				
Yes	137(56.8)	6.5(4.2-10.0)	**0.001**	6.6(3.9-11)	0.001
Physical exercising					
No	105(59.6)	1.8(1.2-2.7)	**0.001**	1.8(1.2-2.9)	0.006
Yes	121(43.8)	Reff			

Binary and multivariate regression of selected sociodemographic factors. COR : crude odds ratio, AOR: adjusted odds ratio. In this study, participants whose age ranged between 36 to 40 years were significantly(p=0.01) having 1.3 times odd of having uterine fibroid. In addition, participants who used polish nail, lipstick and those who don't use to do physical excessing had significantly (p =0.001) having respectively of 1.2, 6.6 and 1.8 to present with uterine fibroid. On the other hand, participants educated at level of secondary school had significantly less chance to present with uterine fibroid.

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1. Introduction.

This was an unmatched case control hospital-based study aimed to determine the serum lipid profile, correlation between presence of uterine fibroid and elevated serum lipid and different sociodemographic factors associated with uterine fibroid among women attended gynecologic clinic at Kairuki and Amana Regional Referral, Dar es salaam, Tanzania.

5.2. Discussions.

In the present study, LDL and HDL cholesterol were observed to be elevated in participants with uterine fibroid compared to those without fibroid. Also, there it was a slight rise of serum triglycerides in fibroid participants. In addition, participants with elevated LDL cholesterol had a significant (pp value < 0.05) 2.1 odd of developing UF. Similar to patients with elevated serum HDL cholesterol, they had 2.4 times odd to present uterine fibroid. In addition, the use of polish nail, lipstick, poor physical exercise and later reproductive age were the significant socio-demographic factor associated with uterine fibroid.

There are various studies which assessed the correlation between rise serum lipide and uterine fibroids. Among them, some reported similar findings to ours, as in a study carried out in a Nigerian by Akinlua and colleagues, comparing 60 patients (with fibroid) and 60 healthy subjects (without fibroid) at University Teaching Hospital, Ado Ekiti and found that elevated serum triglyceride and cholesterol levels were linked to the development of uterine fibroid ~~growth~~(38). Another study conducted by Seyedeh Hajar and colleagues among 108 with and without fibroid women attending the Al-Zahra specialized referral hospital in Iran found that

uterine fibroid development has been linked to elevated serum cholesterol and low-density lipoprotein cholesterol(13).The rise of serum lipid in women with fibroid may be explained by the fact that adipose tissue functions as an endocrine organ, secreting pro-inflammatory, fibrotic, and angiogenic substances that can influence the tumor microenvironment through adipokines, cytokines, and chemokines
(37). As a result, women with elevated serum cholesterol have higher levels of circulating tumor necrosis factor-alpha (TNF-α), monocyte chemoattractant protein 1 (MCP-1), interleukin-6 (IL-6), IL-1β, transforming growth factor β (TGF-β), vascular endothelial growth factor (VEGF), and plasminogen activator inhibitor-1 (PAI-1) (37). These factors may be involved in the regulation, differentiation, and inflammation of tumor cell growth.

On the other side, other authors reported controversies results as in a study conducted by Fabio Parazzini and colleagues in Italy when comparing 1557 women without uterine fibroids and 843 women with uterine fibroids who attended University of Milan obstetrics and gynecology clinics(23). They found no correlation between patients' elevated serum lipid levels and the presence of uterine fibroids(25). This difference from our findings may be explained by the fact that the findings form the above mentioned studies were based on retrospective review of medical record of women attending gynecological clinic in Milan.

Furthermore, this study found that there was a trend to have a smaller uterine fibroid in participants with normal serum lipid. In addition, participants with elevated serum triglyceride had high significant risks presenting with bigger uterine fibroids. This could be explained by the fact that triglycride is essential for the synthesis of hormones that are sexually active, including estrogens. Because of these later elicit physiological reactions in their target cells upon binding

to ER- and E receptor-(ER-), it is believed that they promote the development of UFs. Compared to normal myometrium, fibroids have higher levels of ER- and ER- protein and mRNA expression(18). The formation of uterine fibroids and the physiology of the myometrium are significantly impacted by estrogens and their receptors(22). Similar findings were reported in a study conducted by Banane among 100 women with uterine fibroid attending Babylon Teaching Hospital for Maternity

and Pediatrics in IRAQ, where strong correlation was observed between dyslipidemia in form of LDL cholesterol and increase size of uterine fibroid above 5 cm(38). Scarses studies have evaluated the correlation between size of uterine fibroid and serum lipide. We didn't find published data which have observed controversies results.

There are different factors reported in literature which have been related to uterine fibroids. In the present study, participants in older reproductive age were more likely to present with uterine fibroid. Comparable results were reported by Benjamin Dabo and colleagues in a study conducted among 244 women attending three diagnostic centers in the Accra metropolis, Ghana where uterine fibroid was also prevalent among participants above 35 years(19). Similar findings were reported in Israel by S. Lurie and colleague among 799 women who underwent a gynaecologic ultrasonographic examination in a private imagining institute in central Israel(39). Zheng and colleagues in a Global burden and disease 2019 reported similar findings(40). This late reproductive age may contribute to growth of fibroid due to the fact that the ovarian hormones progesterone and estrogen have a substantial role in the development of uterine fibroids, which may explain the frequency of UF in later reproductive age groups(30). Furthermore, ovarian activity still at maximal at in later reproductive age , it is significantly lower in prepubescent and menopausal women(30). On the other hand, this prevalence in later

reproductive age might be due to the accumulation of endogenous estrogen with, change in the patient's immune system function, or continuous exposure to exogenous risk factors.

Also, in this study we found that, participants who used polish nail and lipstick were more likely to present with UF. This may be since endogenous estrogen's physiological and biochemical activities can be replicated by environmental estrogen. In humans, it can interfere with the synthesis, release, transportation, combination, and metabolism of regular endocrine compounds and alter the endocrine system's regular function; as a result, it impairs the organism's stability as well as its regulatory and feedback mechanisms. Polish nail and lipstick product contains phthalate metabolites (dibutyl phthalate) which was reported to interfere with metabolism and regulation of endogenous estrogen and hence can lead to uterine fibroid genesis(34). Comparable results were reported by Shen and colleagues among 600 women attending affiliated Zhongda Hospital of Southeast University in China where use of plastic bottle, lipstick was strongly associated with presence of uterine fibroid(41).

Furthermore, this study found that participants who did not engage in physical exercise had significantly ($p < 0.05$) higher risks of 1.5 to present with uterine fibroids. Physical Exercising is likely to affect the level of estrogen metabolism as well as growth factor and immune function, which then influences susceptibility to uterine leiomyoma(42). Comparable findings were reported among 1180 women in selected members of a health plan based in Washington where participants with less physical exercising were strongly at risk to developing uterine fibroid(42). Another study reported in the American Journal of Epidemiology found that women engaging in higher levels of physical activity had a decreased risk of developing uterine fibroids. This protective effect was observed across different racial groups, including African American and White women(43). In another cross-sectional study conducted in community-based populations

in the Yunnan Province in China reported that women who spent six or more hours per day in sedentary leisure activities had twice the risk of developing uterine fibroids compared to those with less than two hours of sedentary time(44). The risk was even higher among perimenopausal women(44). Furthermore, other authors have reported the contribution of both combined physical exercising to others factors such as life still in occurrence of uterine fibroid as in a study conducted among women attending the output patient gynecologic clinic affiliated to Zagazig University Hospital in Egypt which observed that a sedentary lifestyle, combined with certain dietary habits, may contribute to the development of uterine fibroids. The study emphasized the importance of physical activity in mitigating this risk (45).

5.3. Limitations of the study

This study was conducted in urban regions where participants could have had more risk of getting rise serum lipide. Care was taken, nevertheless, to lessen the likelihood that this would happen.

5.4. Conclusions

The present study found that participants with uterine fibroid had elevated serum cholesterol compared to those without fibroid. Also, there was a significant association between rise of serum cholesterol and presence of uterine fibroid. Furthermore, women at later reproductive age, those with poor physical exercising, and those educated at secondary school level were the risk to present with uterine fibroid.

5.5. Recommendations

The following are the recommendations of this study.

1. Screening women in their later reproductive years for the presence of uterine fibroids.

2. Screen women with elevated serum lipid for the presence of uterine fibroid.
3. Conduct health education in women in their reproductive age and improve physical exercises.

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Appendix I:

Checklist. Data collection tool.

Lipid Profile Among Women Diagnosed with Uterine Fibroid at Gynecological Clinic At Kairuki, Amana Regional and Mwananyamala Referral Hospital In Dar Es Salaam Tanzania.

Date of interview.....

PART I: SOCIAL DEMOGRAPHIC INFORMATION

1. Age of the participant in year:
2. Residence

   a). ☐ Urban

   b). ☐ Rural

3. Level of education.

a) ☐ Primary.

b) ☐ Secondary.

c) ☐ University.

4. Occupation.

1). Peasant YES ☐ No ☐

2). Housewife YES NO ☐

3). Teacher Yes ☐ NO ☐

4). Medical stuff YES ☐ NO ☐

5). Trader. N YES ☐ NO ☐

6) Student. YES ☐ NO ☐

7) Business women. YES ☐ NO ☐

8) Farmer. YE S NO ☐

5. Do you smoke cigarettes? YES NO
6. Do you drink alcohol? YES ☐ NO
7. Do you drink alcohol? YES ☐ NO
8. Number of children.
   - ❖ 0
   - ❖ 1-3
   - ❖ > 3
9. Lifestyle.

   a). use of plastic bottle for soda :
   - ❖ Not use
   - ❖ Less than 2 per week : **YES NO**
   - ❖ More than 3 a week : **YES NO**

   B). use of nail polish: **YES NO. IF yes type…….**

   c). use of lipstick: **YES NO. IF YES type**……

   d). physical excessing:
   - ❖ Not
   - ❖ Once a week. **YES NO**
   - ❖ More than 2 a week. **YES NO.**

Part II. CLINICAL INFORMATION.

1. Pelvic pain : YES ☐ NO ☐
2. Dysmenorrhea : Yes ☐ NO ☐
3. Metrorragia : Yes ☐ NO ☐
4. Menorragia : YES ☐ NO ☐
5. Height (cm) :..

6. Weight(kg) :
7. BMI :
8. Abdominal circumference (cm).

Part III. Laboratory findings.

1. Serum cholesterol :
    - ❖ LDL (mg/dl)…
    - ❖ HDL (mg/dl)..
2. Serum triglyceride.
9. Ultrasonography findings:

a) Several uterine fibroids:
b) Size of uterine fibroid(cm):
c) Location
d) Size of abdominal preperitoneal fat.
e) Size abdominal subcutaneous fat.

APPENDIX II: CONSENT FORM (ENGLISH VERSION)

Greetings Sir/Madam

My name is……. and I am a third-year postgraduate resident in Obstetrics and Gynecology at Hubert Kairuki Memorial University (HKMU). As part of my academic requirements, I am doing a study named "Association of lipid profile with uterine fibroid among women at Gynecological Clinic at Kairuki, mwananyamala, and Amana Regional Referral Hospital in Dar es Salaam Tanzania from April to June 2024."

Aim of the study:

This study aims to determine the correlation between the lipide profile and uterine fibroids.

Benefits:

Through the identification of an association between lipid profile and uterine fibroids, the results of this study will allow us to enhance the diagnostic process. In conjunction with other uterine fibroid-related characteristics, this could enhance early screening for patients who have uterine fibroid.

Risks:

It is possible for study participants to feel somewhat uncomfortable when their blood is drawn for lipid analysis. However, it is important to note that such procedures are standard and routinely conducted with minimal risk to the patient.

Study Procedures:

Structured questionnaires will be posed to you by the research assistant. You will be required to answer the questionnaires, and additional data will be collected through clinical examination. Relevant information from your hospital file will be entered into an organized clinical form.

Consent:

Enrollment in this study is completely voluntary, and consent will be sought by thumbprint or

consent form signature. Whether you participate or not won't have an impact on the treatment and supervision you or your patient receives. You are free to leave the study at any moment for any reason.

Confidentiality:

The information you provide will be treated with utmost confidentiality. Study information will be stored securely in protected computer files and paper records kept in a locked filling cabinet. Only authorized study staff will have access to this information.

Access to information:

By signing this form, you grant the research team permission to use and share the information with others involved in the study at Hubert Kairuki Memorial University.

Contact information:

For any inquiries or additional information, please contact

1. The principal investigator Dr Obstetrics and Gynecology Department, HKMU, Tel number :

   Email:
2. Supervisor Dr Senior lecturer

   Department of obstetrics and

   gynecology P.o.box 65300

   Dar es Salaam, Tanzania.
3. Co- Supervisor Senior lecturer

   Department of Pediatrics

   p.o.box 65300

   Dar es Salaam, Tanzania.

Participant Declaration

I _____have read/been explained the purpose of this study and am willing to participate in the study.

Participant Signature _____Date _____

Principal investigator Signature _____Date _____

KIAMBATANISHO 2: Idhini iliyo na taarifa (Toleo la Kiswahili)

Kichwa cha Utafiti: Profaili ya Lipid Miongoni mwa Wanawake Waliogunduliwa na Fibroid ya Uterine katika Kliniki ya Magonjwa ya Wanawake iliyopo Kairuki, Amana Mkoani na Mwananyamala Hospitali ya Rufaa Dar Es Salaam Tanzania.

Utangulizi:

Salamu! Mimi ni Dkt. Devotha Adolph SHIRIMA, mwanafunzi wa shahada ya pili anayefanya kazi ya Uzazi na Magonjwa ya Wanawake katika Chuo Kikuu cha Kumbukumbu ya Hubert Kariuki (HKMU). Kwa sasa ninaendesha utafiti wenye kichwa "Wasifu wa Lipid Miongoni mwa Wanawake Waliogunduliwa na Fibroid ya Uterine Katika Kliniki ya Magonjwa ya Wanawake Katika Hospitali ya Kairuki, Amana Mkoa na Mwananyamala Dar es Salaam Tanzania." kama sehemu ya mahitaji yangu ya masomo. naomba ushiriki wako na usaidizi katika utafiti wangu mara mimi au msaidizi wangu wa utafiti anapokukaribia. Utunzaji wako na usimamizi hautaathiriwa na uamuzi wako wa kushiriki au la. Ikiwa wewe una wasiwasi wowote kuhusu utafiti huu au huelewi kitu, tafadhali usisite kuwauliza.

Lengo la utafiti :

Kuamua wasifu wa lipid na mambo yanayohusiana na nyuzi za uterine kati ya wanawake wanohudhuria idara ya magonjwa ya wanawake katika rufaa ya Kairuki, Amana na Mwananyamala hospitali.

Faida :

Hutafaidika moja kwa moja kwa kushiriki katika utafiti huu, lakini matokeo yanaweza kuboresha utambuzi na udhibiti wa fibroids ya uterine na kuzuia shida.

Hatari :

Unaweza kupata kiwango fulani cha usumbufu katika sampuli ya utangulizi wa wasifu wa lipid na utendaji wa ultrasound; hata hivyo, kila jitihada itafanywa ili kuiweka kwa kiwango cha chini ili isiwe hivyo kuhatarisha usalama wako.

Utafiti huu unahusisha nini ?

Katika utafiti huu, mpelelezi mkuu au msaidizi wa utafiti atakuuliza wewe, au wanafamilia wako maswali yaliyopangwa. Utaulizwa kujibu maswali haya kwa kujaza dodoso iliyoandaliwa. Taarifa zaidi zitapatikana kwa uchunguzi wa kimatibabu na utafiti wa ultrasound;usimamizi utatolewa kutoka kwa faili yako ya hospitali na kuingizwa katika fomu ya kliniki iliyoundwa.

Idhini :

Unaweza kusaini fomu ya idhini ili kuonyesha kuwa uko tayari kushiriki katika utafiti, lakini ndivyo kwa hiari kabisa. Uko huru kukataa, na haitakuwa na athari kwa matibabu au uangalizi unaompa mgonjwa wako. Uko huru kusitisha kushiriki katika utafiti huu wakati wowote muda kwa sababu yoyote ile.

Usiri :

Maelezo uliyotoa yanathaminiwa sana na yatawekwa faragha kabisa. Karatasi zote mbili hati zilizowekwa katika kabati inayoweza kufungwa na faili za kompyuta zilizolindwa ndizo zitahifadhi utafiti & data. Taarifa hiyo itapatikana kwa wafanyakazi wa utafiti pekee.

Ufikiaji wa habari :

Kwa kutia saini fomu hii, unaruhusu timu ya utafiti kutumia taarifa na kuwapa wengine waliohusika katika utafiti. Timu ya utafiti inajumuisha mtafiti, wawezeshaji pamoja na wengine wanaofanyia utafiti huu katika Chuo Kikuu cha Hubert Kariuki Memorial.

Nani wa kuwasiliana naye:

Ikiwa kuna maswali yoyote kuhusu utafiti huu au maelezo zaidi, maswali, unaweza kuwasiliana na :

1. Mkurugenzi wa huduma za utafiti
   Chuo Kikuu cha Kumbukumbu ya Hubert Kariuki.

Sanduku la POSTA: 65300,

Dar es Salaam Simu :

Viambatisho IV: Dodoso

Lipid Profile Miongoni mwa Wanawake Waliogunduliwa na Uterine Fibroid katika Kliniki ya Magonjwa ya Wanawake katika Hospitali ya Kairuki, Mkoa wa Amana na Hospitali ya Rufaa ya Mwananyamala jijini Dar es Salaam Tanzania.

Tarehe ya mahojiano..... ....

SEHEMU YA I : TAARIFA ZA KIDEMOGRAFIA KIJAMII

1. Umri wa mshiriki katika mwaka :
2. Makazi
    a. ☐ Mjini
    b. ☐ Vijijini
3. Kiwango cha elimu.
    a. ☐ Msingi.
    b. ☐ Sekondari.
    c. ☐ Chuo Kikuu.
4. **Kazi.**
    a. Mama wa nyumabani :Ndiyo [ ] Hapana [ ]
    b. Mwalimu 1=Ndiyo 2=Hapana
    c. Mambo ya matibabu 1=Ndiyo 2=Hapana
    d. Mfanyabiashara 1=Ndiyo 2=Hapana
    e. Mwanafunzi 1=Ndiyo 2=Hapana

f. Mjasiriamali 1=Ndiyo 2=Hapana

g. Mkulima 1=Ndiyo 2=Hapana

5. Je, unavuta sigara ? 1=Ndiyo 2=Hapana

6. Je, unakunywa pombe ? 1=Ndiyo 2=Hapana

7. Je, unakunywa pombe ? 1=Ndiyo 2=Hapana

- 0
- 0-3

8. Idadi ya watoto

- > 3

9. Mtindo wa maisha

a) Matumizi ya chupa ya plastiki kwa soda :

- Kutotumia.
- Chini ya 2 kwa wiki: NDIYO HAPANA
- Zaidi ya 3 kwa wiki: NDIYO HAPANA

b). Matumizi ya rangi ya kucha: NDIYO [] HAPANA [ ]. Kama ndio andika…….

c). Matumizi ya lipstick:NDIYO [ ] HAPANA [ ]. Kama NDIYO andika……

d). Mazoezi ya mwili:

- Hapana
- Mara moja kwa wiki. NDIO [ ] LA [ ]

Zaidi ya 2 kwa wiki.NDIO [ ] LA [ ].

Sehemu ya II. HABARI ZA KITABIBU.

1. Maumivu ya nyonga: NDIYO [ ] HAPANA [ ]

2. Dysmenorrhea: Ndiyo [ ] HAPANA [ ]

3. Metrorrhagia: Ndiyo [ ] HAPANA [ ]

4. Dysmeno : NDIYO [ ] HAPANA [ ]

5. Urefu (cm):

6. Uzito(kg):

7. BMI:

<18 Uzito mdogo [ ]

18.5 - 24.9 Kawaida [ ]

25.0 - 29.9 Uzito kupita kiasi [ ]

30.0 - 34.9 Unene kupita kiasi (Daraja la 1) [ ]

35.0 - 39.9 Unene kupita kiasi (Daraja la 2) [ ]

>40 Unene uliokithiri (Daraja la 3) [ ]

8. Mzunguko wa tumbo (cm).[ ]

Sehemu ya III. Matokeo ya maabara

1. Cholester
   ol katika
   damu:
   LDL
   (mg/dl)
   …

- HDL (mg/dl) …

2. Serum triglyceride.

9. Matokeo ya Ultrasound:

a) Idadi ya nyuzi za uterine:

b) Ukubwa wa nyuzi za uterine (cm):

c) Mahali

d) Ukubwa wa mafuta ya tumbo kabla ya peritoneal.

e) Ukubwa wa mafuta ya chini ya ngozi ya tumbo.

Ethical clearance letter

KAIRUKI UNIVERSITY (KU)

70 Chwaku Street,
Mikocheni,
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Dar es Salaam,
Tanzania.

Tel: +255-22-2700021/4
Fax: +255-22-2775591
Email: irec@ku.ac.tz
Website: www.ku.ac.tz

Ref. No. KU/IREC/27.10/462 **1st July 2024**

Dr. Devotha Shirima,
Kairuki University,
Box 65300,
Dar es Salaam, Tanzania.

RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING HEALTH RESEARCH.

I am pleased to inform you that the research titled: **Association of Lipid Profile with Uterine Fibroid Among Women in Gynecological Clinic at Kairuki Hospital, Mwananyamala and Amana Regional Referral Hospitals in Dar Es Salaam Tanzania (Shirima D., 2024)** has been granted ethical approval.

This approval is in effect for one year from the above date. Any changes in the procedures should be reported to the Institutional Research Ethics Committee. Significant changes will require the submission of a revised request for ethical approval. You will be required to submit **study a progress report** every six months.

Permission to publish your findings should be sought from the National Institute for Medical Research (NIMR) before submission to a publisher and not concurrently.

CHAIR PERSON

Name: Prof. Fredrick Kaijage

Signature:

DIRECTOR POSTGRADUATE STUDIES AND RESEARCH INSTITUTE
HUBERT KAIRUKI MEMORIAL UNIVERSITY
P. O. Box 65300, DSM

SECRETARY

Name: Prof. Columba Mbekenga

Signature:

Permission letter

KAIRUKI HOSPITAL

Incorporated in the Kairuki Health and Education Network

Tel: *255-22-2700021/4*
+255-653723707 **(mobile)**
Fax: *255-22-2700017*

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E-mail: info@ kairuki hospital.org
web: www.kairuki hospital.org

KH/HKMU/DS/7/2024

11/7/2024

HUBERT KAIRUKI MEMORIAL UNIVERSITY (HKMU)
P.O.BOX 65300
Dar es salaam
Tanzania

RE; PERMISSION TO **DR. DEVOTHA SHIRIMA Mmed PART-2- OBSTETRICS AND GYNAECOLOGY** TO COLLECT DATA FOR RESEARCH TITLED: **ASSOCIATION OF LIPID PROFILE WITH UTERINE FIBROID AMONG WOMEN IN GYNECOLOGICAL CLINIC AT KAIRUKI HOSPITAL.**

Refer to the above heading

This is to inform you that permission to collect data for your research titled: **ASSOCIATION OF LIPID PROFILE WITH UTERINE FIBROID AMONG WOMEN IN GYNECOLOGICAL CLINIC AT KAIRUKI HOSPITAL.**

Has been granted.

Thank you for understanding and cooperation.

Emmi Masinga
HOSPITAL ADMINISTRATOR

KAIRUKI HOSPITAL
P. O. Box 65300
DAR-ES-SALAAM

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

AMANA REGIONAL REFERRAL HOSPITAL

Telegram "HEALTH", DODOMA
Phone No.: +255 026 – 2323267
Email: ps@afya.go.tz

P.O. Box 25411
DAR ES SALAAM
Phone: 022—2861903

REF. NO. MoHCDGEC/ARRH/R.1/VOL VIII/10

Date: 16/07/2024

Director, Postgraduate Studies and Research Institute,
Kairuki University,
P.O. Box 65300,
DAR ES SALAAM.

Re: PERMISSION FOR DATA COLLECTION

Refer to your letter dated 10th July, 2024 which requested us to allow **Dr. Devotha Shirima** to conduct research and collect data in our institution.

We are here to acknowledge your request with the following conditions, that she must submit the results of your research after completion of analysis in order the hospital to make use of data's to solve hospital problems.

Regards.

FOR: MEDICAL OFFICER I/C
AMANA REGIONAL REFERRAL HOSPITAL
P.O. Box 25411
DAR ES SALAAM

Dr. Rose Ntambuto
FOR: MEDICAL OFFICER INCHARGE
AMANA REGIONAL REFERRAL HOSPITAL

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

Telephone Address:

Telephone: 022-2760500

Mwananyamala Regional
Referral Hospital,
P.O.Box 61665
Dar es Salaam.

RE: NO: MA. 59/240/01/37

DATE: 22th July,2024

Director,
Hurbert Kairuki Memorial University,
P.O.BOX 65300,
DAR ES SALAAM.

RE: DR. DEVEOTHA SHIRIMA - TO CONDUCTI HIS RESEARCH IN MWANANYAMALA REGIONAL REFERRAL HOSPITAL

The captioned subject refers

2. May you be informed that your request to research Titled "***Association of lipid profile with uterie fibroid among women in gynecological clinic at Mwananyamala Regional Referral Hospital - in Dar es Salaam, Tanzania***" ***Start*** **to 22th July,2024, to 22th Augost,2024** is asserted.

3. The Institution charges **50,000/=**, as Research fee as per student spent. The payments are to be made upon reporting.

Thanks.

Atugonza Kyaruzi
RESEARCH COORDINATOR
FOR: MEDICAL OFFICER INCHARGE
MWANANYAMALA REGIONAL REFERRAL HOSPITAL

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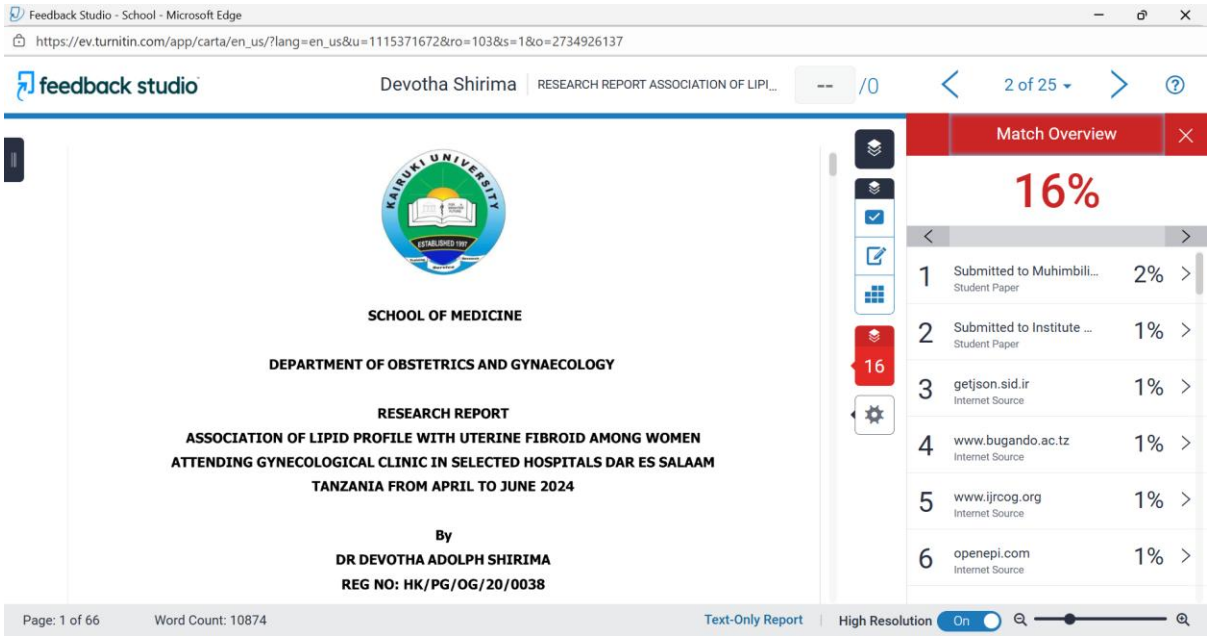
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SCHOOL OF MEDICINE
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
RESEARCH REPORT
ASSOCIATION OF LIPID PROFILE WITH UTERINE FIBROID AMONG WOMEN
ATTENDING GYNECOLOGICAL CLINIC IN SELECTED HOSPITALS DAR ES SALAAM
TANZANIA FROM APRIL TO JUNE 2024
By
DR DEVOTHA ADOLPH SHIRIMA
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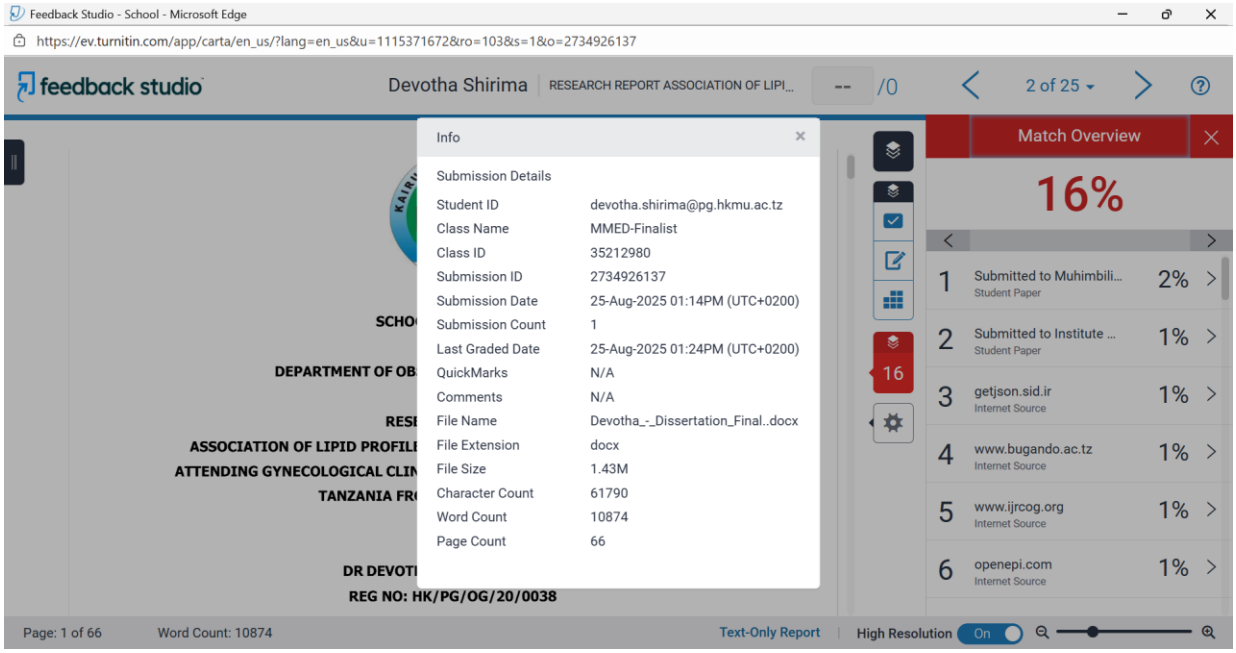
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Word count:	10,874
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