FEMALE GENITAL MUTILATION AND ADVERSE OBSTETRIC OUTCOMES AMONG PREGNANT WOMEN SEEN IN SELECT HOSPITALS IN FREETOWN, SIERRA LEONE

A Research Dissertation Submitted to the University of Nairobi, Department of Obstetrics and Gynecology in Partial Fulfillment for the Award of Master of Medicine (M. Med) Obstetrics and Gynecology

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DECLARATION

This dissertation is my original work and to the best of my knowledge, has not been presented to any university for any purpose

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Date: 01/09/2022

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CERTIFICATE OF AUTHENTICITY

This is to certify that this work of dissertation by Dr. David Jalloh is my original work in the Department of Obstetrics and Gynecology in the University of Nairobi with Registration Number H58/12313/2018. His supervisors are Dr. Francis Odawa and Professor Muia Ndavi. This research was carried out in four selected Hospital Princess Christiana Hospital (PCMH), Lumley Kingharrma Government and Aberdeen Women Hospital Freetown, Western Area Sierra Leone. It has not been presented elsewhere for the award of a Degree.

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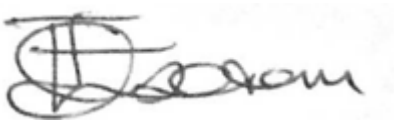
Signature:  **Date: 01/09/2022**

DEDICATION

I dedicate this dissertation to my Isatu Jalloh whose unconditional love and encouragement inspired me to complete this work.

My siblings and colleagues for their encouragement and support. To my late father and mother (Mr. and Mrs. Abdullah S. Jalloh) who have made me what I am today.

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LIST OF ABBREVIATIONS

ERC	Ethics Review committee
FGC	Female Genital Cutting
FGM	Female Genital Mutilation
NICU	Neonatal Intensive Care Unit
PCMH	Prince Christian Maternity Hospital
PHU	Peripheral Health Unit
SPSS	Statistical Package for Social Science
UN	United Nations
UNICEF	United Nations International Children Emergency Fund
WHO	World Health Organization

DEFINITION OF TERMS

FGM/C: Female Genital Mutilation and cutting (FGM/C) comprises all procedures that involve partial or total removal of the external female genitalia, or other injuries to the female genital organs for a non-medical reason

Prolonged Hospital Stay: Hospital stay longer than 72hrs

Latent phase of labor: dilatation of cervix from 0-4cm

Active phase of labor: dilatation of cervix above 4cm

Soweis: The name of traditional initiators of FGM/C in Sierra Leone

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ABSTRACT

Background: Female genital mutilation/cutting (FGM/C) is a commonly occurring exercise in most parts of the world. This practice is linked with adverse short term and long-term complications to the victims. Around 3 million women are at increased risk of FGM with more than 200 million undergoing the procedure across the globe annually. Sierra Leone is one of the countries that record very high rate of FGM with 81% in urban and 94% in rural settings. Sierra Leone has high mortality rate of around 1,165 deaths per 100,000 live births. Thus, there need to compare the occurrence of obstetric complication in women who have undergone FGM and those without FGM.

Objective: The main objective is to determine the types of Female genital mutilation and the associated adverse obstetric outcomes among pregnant women seen in a select hospital in Western Area, Freetown Sierra Leone

Methodology: The study adopted a prospective cohort design. The study targeted all women aged 15 to 49 years going for a spontaneous vaginal delivery for singleton babies in both active and latent phase of labor in Princess Christiana Maternity Hospital (PCMH), Lumley, Kingharma Road Government Hospital and Aberdeen women Hospital between age 15 to 49years. The study included 357 FGM exposed and 119 FGM non-exposed. A structured questionnaire was used for data collection. SPSS version 26 software was used for the analysis. The level of significant used to assessed was at 0.05.

Results: The mean age of the respondents was 24 years, 58.4% were married, 61.6% were Muslims. Education level analysis revealed that, 38.4% had secondary level education, 31.1% were self-employed. Majority of the respondents, 70.8% had less or equal to four antenatal visits, 95.6% (455) had between para 1 and para 4. Bivariable analysis revealed that, delivery complications (RR =2.24, 95%CI: 1.6 – 3.14, p<0.001), perineal tear, (RR =2.58, 95%CI: 1.72 – 3.85, p <0.001), cervical tear, (RR =6.00, 95%CI (1.47 – 24.54, p = 0.001), PPH, (RR =2.32, 95%CI: 1.27 – 4.19, p<0.001), outlet obstruction, (RR= 1.47, 95%CI: 1.14 – 1.91, p = 0.001). Management of outlet obstruction by episiotomy was higher among women with FGM, (RR = 2.5, 95%CI: 1.46 – 3.81, p<0.001), Duration of second stage ≥45 minutes, (RR = 1.69, 95%CI: 1.32 – 2.15, p <0.001) were significantly associated with FGM. Apgar score of less than 7 at 1st minute, (RR = 1.38, 95%CI:1.03 – 1.86, p=0.024), Apgar score less than 7 at 5th minute (RR = 2.93, 95%CI:1.63 – 5.29, p<0.001), admission to NICU, (RR = 2.14, 95%CI: 1.14 – 4.04, p = 0.009) were significantly associated with FGM.

Multivariable analysis conducted revealed that, perineal tear (aRR = 2.45, 95%CI: 1.09 – 5.6, p = 0.031), delay second stage, (aRR =2.49, 95%CI: 1.47 – 4.22, p = 0.001), Apgar score (less than 7) (aRR = 3.71, 95%CI:1.58 – 8.7, p = 0.003) were independently associated with FGM.

Conclusion and Recommendations: The findings have shown that type II was the most common type of FGM while the risk of adverse outcomes increases with increase in the severity of type of FGM. Thus, to control these adverse outcomes, it is essential to conduct clinical examination to identify women with FGM in order to advice for the appropriate mode of delivery to control adverse outcomes.

Key Words: Female Genital Mutilation/Cutting, Obstetric Complication

1. CHAPTER ONE

INTRODUCTION

1.1 Background of the Study (Definition and history)

Female genital mutilation/cutting (FGM/C) is a practice that is mainly associated with the performance of the procedure that mainly involves the causation of intentional injury or alterations on the external female genital organs for non-medical reasons (1). Female genital mutilation and cutting which occurs in African and Middle Eastern countries are mainly performed by traditional birth attendants and circumcisers who are usually not medically trained (2). There has however been the involvement of medical professionals in performing this practice but there have never been any reasons to perform this procedure (3). FGM is generally performed in many countries by specific individuals who have specific names that differ from country to country and ethnic group. In Sierra Leone, they are called Soweis (4).

Female genital mutilation/cutting is commonly performed with non-sterilized instruments without anesthesia (5). A majority of the individuals who practice female genital mutilation/cutting usually have low educational background and are commonly from areas that practice circumcision of girls and women as a tradition (6). Female genital mutilation/cutting (FGM/C) practices are commonly linked to the Islamic religion however not all Muslims justify these practices as it is not included in the Koran (7). These practices are also inconclusive with the teachings of Prophet Muhammad as it lacks credibility contrary to male circumcision. However, it is critical to point out that there are religious requirements for individuals who practice FGM/C, a practice that is also not mentioned in the bible (8).

In Sierra Leone majority of the women mostly undergo Type I and II forms of FGM however, there is variation in relation to data on the number of women and girls who have had their genitals sewn but most women (85.2%) in the country have undergone female genital mutilation by the age of 14 years with 31.7% being cut by the age of 5-9 years and the largest number being cut between the ages of 10-14 years (9). However, infibulation is still practiced throughout much of sub-Saharan Africa increasing in some regions by up to 8% in the last 30 years (10).

The promotion of FGM practices in Sierra Leone is aided/encouraged by the lack of laws that prevent these practices. The Child Rights Act also promotes these practices by encouraging girls to consent after the age of 18 years before being cut. Similarly, the anti-FGM Act by the Sowei council also states that practitioners must allow women and girls to consent to taking part in these practices (11).

This study aims to determine the obstetric outcome associated with FGM/C and the types in selected Hospital in Freetown Sierra Leone

1.2 Epidemiology

It is estimated 200 million girls and women have endured this procedure with approximately 3 million at risk of adverse obstetric outcomes on annual basis. FGM is commonly practiced in Africa where it has been effectively embedded in most of the African cultures as a rite of passage in more than 28 countries in the continent. Although there is evidence which shows FGM being practiced in other parts of the world such as Middle East and Asia (1,12).

In the United States, there is approximately 513,000 immigrants who have undergone FGM including both women and girls. This is a greater increase from the 168,000 estimates in 1990. The arrests of physicians that have been made in the United States specifically in Michigan in 2017 shows that the practice is happening in the United States (13).

There are a number of reasons for the practice of FGM, but the main reasons were for cultural and traditional practices (14). The practice of FGM has been associated with increased risk of childbirth complications such as difficult delivery, excessive bleeding and caesarian section delivery as well as neonatal deaths (15). A study conducted to assess the complications associated with FGM, it was observed that, women who underwent FGM/C were two times likely to experience dyspareunia, prolonged labor as well as episiotomy (16).

FGM is common in rural areas. In Sierra Leone, the practice of FGM is significantly high with 94% prevalence in rural areas and 81% in urban areas. The highest prevalence of female genital mutilation in Sierra Leone is in Northern province however, their prevalence of this practice is 75% which cuts across the districts in the rural and urban areas (9).

1.3 Classification of FGM

FGM occurs in four major ways. Each of the four types encompass different processes which are carried out.

Type 1 FGM mainly involve partial or complete elimination of the clitoral glans. This entails the outer visible part which is the most sensitive of the female genitals. Type 1a involve the elimination of the prepuce hood only, type 1b include both removal of the clitoral hood and glans.

Type II FGM include partial or complete elimination of the clitoral glans as well as labia manora. The different types of type II include Type IIa which include elimination of labia manora only, Type IIb involve partial and complete of the clitoral glans as well as labia minora. The clitoral hood might be affected during this type of FGM. The Type IIc involve the partial or total removal of the clitoral glans, the labia minora as well as the labia majora.

Another type of FGM is Type III that is also referred to as infibulation. It is the narrowing of the vaginal opening with the specific creation of the covering seal. The seal is majorly developed through the cutting and repositioning the labia minora or labia majora. The covering can be done with or without the removal of the prepuce. There are different types of type III FGM. The Type IIIa involve the removal and repositioning of the labia minora, Type IIIb involve the removal and repositioning of the labia majora.

Type IV involve all other harmful procedures to the female genitalia for non-medical purposes such as pricking, piercing, scraping, incising as well as cauterization.

DE infibulation involves the practice of cutting open the sealed vaginal opening of a women who has type II FGM. This is mostly done in most cases to allow sexual intercourse or facilitate childbirth and thus it is usually essential in improving the woman's healthcare (17).

1.4 Pathophysiology of the potential adverse outcomes

The human body function is aided by homeostasis between the body and the environment. Impairment to the fluid passage to the environment can result in infection. Women and Girls who have undergone FGM/C present with pelvic infection due to blockage of the vaginal passage to discharge leading to its accumulation and source for infection. It may also be caused due to the presence of vaginal stenosis or vaginal stones (18).

A hypertrophic scar is usually characterized by the development of a thick, wide wound that develops upon injury of the woman. These scars normally occur during the healing process and are normally as a result of an irregular response to tissue and injury. Keloids, on the other hand, are raised scars. These scars normally grow to a larger extent contrary to the original scar. Both Hypertrophic scar and keloid can occur after FGM/C and this can have a direct effect on the passage of the vulvar during childbirth and sexual intercourse (19).

Excessive excision of the vulvar seen in infibulation due to FGM/C can lead to narrowing of the vaginal orifice impairing the smooth passage of menstrual blood flow to the outside. This can lead to a medical condition called hematocolpos which presents as painful cyclic menstrual period and severe pelvic pain and swelling Menstrual blood is usually confined hence causing the swelling of the lower abdomen. This condition will have a long-time complication on the ability of the woman to conceive (19).

The type/severity of FGM is mostly linked to morbidity which occurs in the long or short term. The short-term complications include difficulty in passing urine, excessive bleeding, shock as well as severe abdominal pain. The long term complications which are linked to female genital mutilation include complications linked to childbirth, infertility and cervical cancer The occurrence of these complications has been found to be linked with the type of female genital mutilation (21).

2. CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This section presents the literature review on the aspects of female genital mutilation/cutting (FGM/C) and the maternal and neonatal complications associated with these practices.

2.2 Maternal outcomes

2.2.1 Obstetric Complications

Obstetric complications that women with FGM are likely to encounter during pregnancy or labor varies depending on the context. In low resource setting where there is limited knowledge and access to antenatal care, there is increased risk of complications (22). In a study investigating 28,000 women with FGM in six African countries, it was revealed that FGM was associated with increased risks of prolonged labor, caesarian section delivery as well as postpartum hemorrhage (23).

Similarly, FGM has also been associated with high risk of neonatal resuscitation, low birthrate, stillbirth as well as early neonatal deaths. FGM was associated with an extra 1 – 2 perinatal deaths per 100 deliveries. Larger systematic review study conducted in 2013 involving 3 million participants, it was observed that pregnant women with FGM were more likely to experience obstetric complications (24). Many past studies have found that there are higher rates of perineal tears (25,26) as well as higher rates of episiotomy which is higher in women with Type III FGM (27).

2.2.2 Complication during labor

Women who have undergone FGM/C especially those with type III cut usually experience soft tissue obstruction (dystocia) and delayed labor during the second stage, which is usually faster than the first stage of labor (1,28).

2.2.3 Episiotomies and perineal tears

The commonest type of complication as a result of FGM/C by women who have undergone the procedure especially type III cut is episiotomy and perineal tears. These women sustain

more perineal injury and episiotomies during birth compared to those did not undergo the cut. It was also noted that type 1 and type 2 also noted to have perineal tear (29)**.**

2.2.4 Antenatal Complications and Early Labor Complications

The post FGM/C women are less likely to visit the ANC for four times and above due to stigma compared to women who have not undergone FGM especially Type III for fear of engaging them for deinfubalation. (30). Recent studies have suggested that women with FGM were more likely to develop pregnancy related complications during child birth (31). Thus, it is crucial to ensure that these women are identified early during the ANC. In clinical practice, most unskillful clinicians have difficulty in doing vaginal examination during antenatal assessment and catheterization are very difficult hence putting the mother's and child's life in danger for women with FGM/C. Those that are most at risk are infibulated women for going through the caesarean section as compared to those with type I, II and IV than those without FGM/C (23).

2.2.5 Postpartum Hemorrhage (PPH)

Postpartum bleeding or postpartum hemorrhage (PPH) is often characterized by the loss of 500-100ml of blood after 24hours of childbirth. PPH can be primary when it occurs in the first 24hours and secondary from 24hours to 42 days. There is usually a great increase in the number of women who suffer due to PPH especially amid those who are infibulated to those who are uncut (1).

2.2.6 Maternal Death

PPH resulting from FGM/C can lead to hypovolemic shock and if not handled correctly in time or by a skilled birth attendant can result in death. Maternal deaths can also occur due to negligence on the part of the health care provider such as inappropriately handled obstructed labor caused by FGM/C (23).

2.2.7 Maternal Hospital Stay

There is a higher hospital stay among women who underwent FGM compared to those without FGM. Those who have gone through the cut and have delivered vaginally are more likely to stay in the hospital for a longer period (32).

2.3 Fetal/Neonatal Complications

Because of outlet obstruction due to FGM especially in infibulated women can lead to prolonged labor and the outcomes of the fetus are low Apgar score and pre-labor death compared to women without FGM. Overall, babies of FGM mother usually require resuscitation immediately after delivery than uncut Mothers. Additionally, babies die as a result of FGM and its related complications. According to a study conducted by prevalence of 38% was captured for women with FGM who also experienced long hospital stay, prolonged labor, and early neonatal death (33).

2.4 Problem Statement

There is no legislation that bans FGM nor prosecutions which are directed towards dealing with such practices in Sierra Leone. Similarly, there is very limited evidence that suggests that the National legislation has been used in the prosecution of FGM perpetrators (34). The international regulations which are meant to limit the occurrence of FGM are also poorly implemented and there have been isolated reports from the media in regards to FGM.

In most parts of the world including Africa, the prevalence of FGM has decreased significantly. This has been majorly associated with strict anti FGM legislations. However, the prevalence has remained significantly high. Countries such as Chad, Mali and sierra Leone which had strong adherence to FGM culture have remained active despite the legal processes that have been outlined. Infibulation is the common approach that is still being practiced in most parts. The increase in the last 30 years is approximately 8% (10).

Additionally, there is very little information which is linked to prosecutions on the FGM in Sierra Leone (35). Because of lack of legislative actions and laws banning FGM practice, the effect of FGM/C is overlooked and underestimated. Sierra Leone is one of the countries in the world that report highest maternal mortality in the world with an estimated 1,165 deaths per 100,000 live births (36). The common types of FGM practiced in Sierra Leone include Type I and Type II (37).

The national government policies and programs (Ministry of Social welfare, Gender and Children's affairs) of Sierra Leone have been significant in the enactment of laws that prevent underage initiation of FGM activities. However, there has been very little action in relation to the enforcement of these regulations. Similarly, there are a number of international and non-governmental organizations that help in mobilization of communities to end FGM in the

country in the country. These efforts are however not fully supported by the national policy and legislation to help limit the occurrence of FGM (38). Because of lack of policy to guide management of FGM/C in the Hospital

Studies done in Ethiopia and other sub-Saharan Africa countries have shown the detrimental effect that FGM has had on maternal health; it is however not clear to what effect the practice of FGM in Sierra Leone has on maternal and child health. In view of the high prevalence of the FGM practice, it is postulated that this could be a major contributor to the high reported adverse maternal and neonatal outcomes (39).

2.5 Theoretical Framework

The social convention theory presents a significant understanding on harmful traditions and cultural practices such as FGM which negative impact on the health and wellbeing of community members. Mackie and Lejeune asserted that societal disparities that sustain such behaviors, and how factors including gender, class, and a desire to increase one's access to social and economic resources may contribute to the practice's formation and perpetuation (40)Women who have been cut are seen to have kept their virginity, which is desirable for marriage in many FGM-affected cultures. As a result, the practice of cutting female genitals becomes accepted as a social standard, as no family wants to be linked with the disgrace of having a daughter deemed "unfit" for marriage (41). Because decisions about performing FGM are dependent on decisions made by other intermarrying families in the communities around them, such as having their daughters cut in order to boost their chances of finding a good marriage partner, FGM is ingrained and reinforced.

Changing behavior and adopting positive outcomes present a more straightforward emphasis on better processes which help attain improved outcomes. The model also requires that an individual develop skills and knowledge on how the necessary conditioning factors can control the participation level of a person in self-efficacy (42). Self-efficacy provides a higher evaluation of specific concepts which can help in identifying an improved concentration on specific factors which determine a high level of commitment. Thus, there is a need to provide different concepts which help in keeping positive outcomes.

2.6 Conceptual Framework

The conceptual framework as presented in Figure 2.1 explain the female genital mutilation and associated adverse obstetric outcomes. The independent variables in the study include demographic characteristics such as factors such as age, marital status, level of education, occupation, socio-economic status and clinical factors such as ANC visits and parity. The outcome variable includes obstetric complications such as Maternal (perineal tear, episiotomies, PPH, maternal death, caesarian section, labor complications, long hospital stay, episiotomy, Vulvar hematoma and neonatal complications which comprised fetal (low birth weight, low Apgar score, still birth, early neonatal death, long hospital stay. Thus, the independent and outcome variables were compared on the basis of exposed (FGM/C) and unexposed (Non-FGM/C) groups. Respondents with FGM were more likely to be single, have low education level, low socio-economic status, casual employment, less ANC visits (<4 visits) and were associated with increased risk of obstetric and neonatal complications.

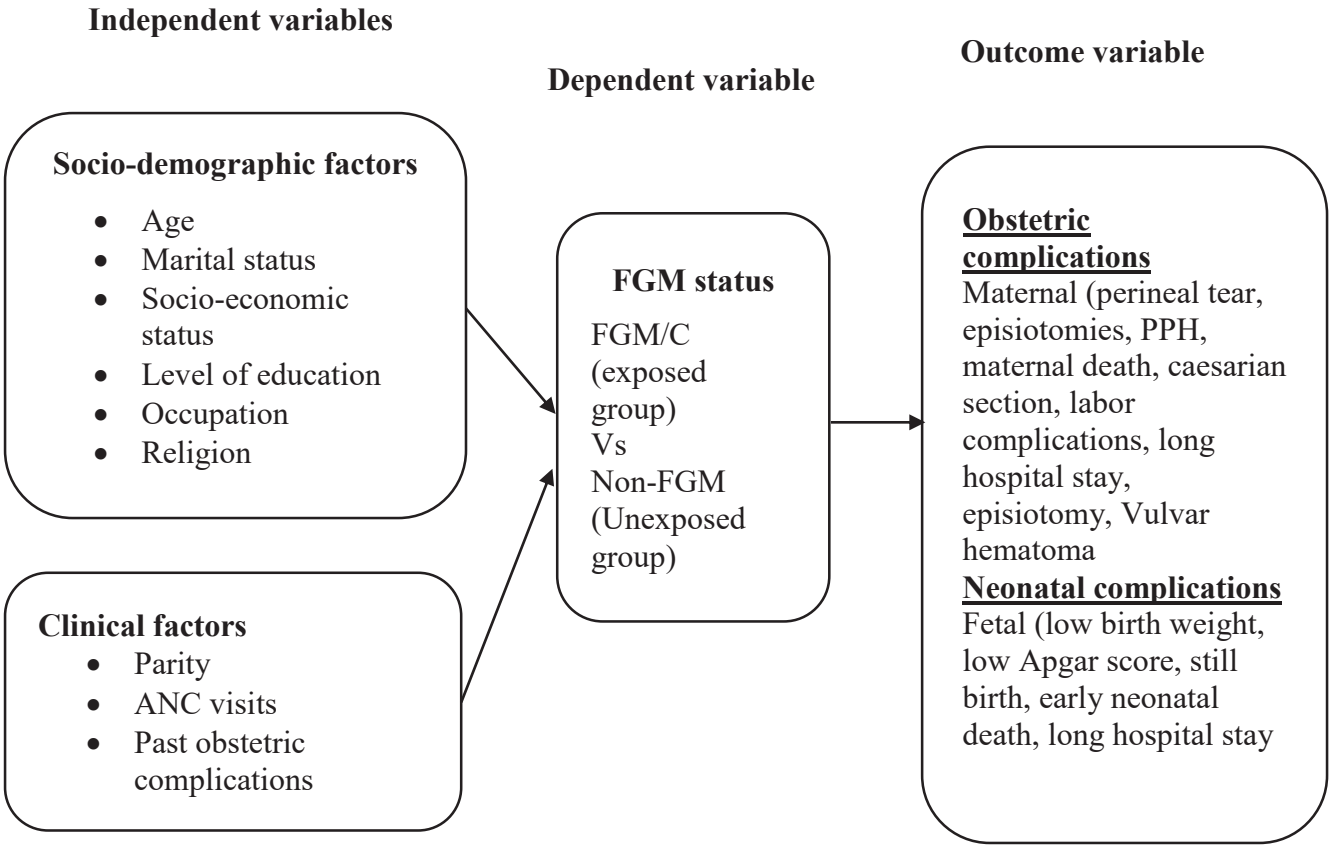

Figure 2.1 Conceptual framework

2.7 Justification of the Study

Prior studies as shown that FGM is a major risk factor in developing adverse maternal outcome such as Postpartum Hemorrhage prevalence of FGM in Sierra Leone is 94%, 81% in rural and urban area respectively. Despite the high rate of FGM in the country the Government as not implemented any guidelines or policies to control the practice. No studies have been done in Sierra Leone assessing obstetric complication associated with FGM. Then, there is need to determine the existing association between FGM and occurrence of obstetric complications in pregnant Women.

This study seeks to describe adverse maternal and neonatal complication associated with FGM and the findings will be useful to the Ministry of health especially the maternal reproductive wing for planning and strategic purposes, and as well as a policymaker and other stakeholders in order to avoid the practice of FGM. The Sierra Leone Reproductive Health Strategic plan 2017 – 2021 has effectively been defined to achieve:

- Reduction of maternal mortality ratio from 1165 per 100000 live births to 650 per 100000 live births by 2021
- Reduction of neonatal mortality rate from 39 per 1000 live births to 23 per 1000 live births by 2021
- Reduction of Still birth rate from 24 per 1000 live births to 18 per 1000 live births by 2021

2.8 Research Questions

1. What are the maternal and neonatal complications associated with Female Genital Mutilation/C among pregnant women seen in Free Town, Sierra Leone?

2.9 Hypothesis

2.9.1 Null Hypothesis (H_0)

There is no difference in obstetric outcomes between women with FGM/C and without FGM/C

2.10 Study Objectives

2.10.1 General Objective

To determine the types of Female genital mutilation and associated adverse obstetric outcomes among pregnant women seen in select hospitals in Western Area, Freetown Sierra Leone

2.10.2 Specific Objectives

1) To identify the types of female genital mutilation/c among women delivering in Free Town, Sierra Leone
2) To determine the peripartum maternal complications associated with female genital mutilation
3) To determine the neonatal complications associated with female genital mutilation.

3. CHAPTER THREE

METHODOLOGY

3.1 Study Design

The study adopted a prospective cohort study design. The study participants were inclusive of women who had undergone female genital mutilation (exposed) and women who had not undergone female genital mutilation (unexposed). The study compared the maternal and neonatal complications between the two study groups.

3.2 Study Area

The study was conducted in Freetown the capital city of Sierra Leone West Africa in four selected Hospitals in Freetown which is one of the largest cities in the country. It is one of the major urban centers in the area with a population of over 802,639 in accordance with the 2019 world population review. The four hospitals that were selected are the ones most utilized by the public and can be accessed from the East, West or Central Sierra Leone. Princess Christiana Maternity Hospital located in the East is the main Referral Maternity and Teaching Hospital in Freetown serving more than one million Pregnant women with Antenatal care of 22,300 per year. Aberdeen Women Hospital is the second busiest Maternity Hospital that also operates more than 300 fistula patient per year and antenatal care of 5,600. Lumley Government Hospital (LGH) serves as a referral hospital for the PHU'S in the west end of Freetown and their environs, thou it is secondary Hospital with a catchment population of more than 23,542 with antenatal care of more than 4,640 per year. Kingharma Road Hospital was once a secondary Hospital but has been upgraded to tertiary status and is located centrally with a catchment population of 20,000 and an annual antenatal care of 3,800.

3.3 Study Population

The study targeted all women going for a spontaneous vaginal delivery in both the active and latent phase of labor for singleton babies in Princess Christiana Maternity Hospital (PCMH), Lumley, Kingharma Road Government Hospital and Aberdeen women Hospital within the reproductive age group with FGM and non-FGM. The population is heterogeneous spanning

across middle and low classes, and hospitals cater for all ages with 62% of the women delivering in these hospitals attended by skilled birth attendance.

3.4 Selection Criteria

Table 3.1: Enrolment Criteria for the women who have undergone Female Genital Mutilation

Inclusion Criteria	Exclusion Criteria
1) All women in the reproductive age group 15-49 who go for spontaneous singleton vaginal delivery at term (37-42 weeks) in both the latent and active phase	1) All women requiring elective caesarean section 2) All women with the obstetric emergency in the active phase with exception of complication due to FGM 3) All medical obstetric emergency

Table 3.2: Enrolment Criteria for the women who have not undergone Female Genital Mutilation

Inclusion Criteria	Exclusion Criteria
1) All women in the reproductive age group 15 -49 who go for spontaneous singleton vaginal delivery at term (37-42 weeks) in both the latent and active phase in the selected group	1) All elective caesarean section within the reproductive age group will be excluded and 2) All women with an obstetric emergency in the active phase with the exception of outlet obstruction, fetal distress and Cephalo pelvic disproportion 3) All medical obstetric emergency

3.5 Sample Size Determination and Formula

The sample size was calculated using JL Fleiss (stat calc, epi – info ™) sample size calculation for cohort studies with the following assumptions from a similar study conducted in Ethiopia (39).

$$n = \left(\frac{r+1}{r}\right)\frac{(\bar{p})(1-\bar{p})(Z_{\beta}+Z_{\alpha/2})^2}{(p_1-p_2)^2}$$

n = sample size for the exposed arm

r = ratio of women who have not undergone Female Genital Mutilation (unexposed) to those who have undergone Female Genital Mutilation (exposed) (1:3) with respect to the hospitals delivery

P_1= proportion of women who had undergone Female Genital Mutilation and who developed Post-Partum Hemorrhage (11.2%)

P_2=proportion of women who had not undergone Female Genital Mutilation and who developed Post-Partum Hemorrhage (3.5%)

$\acute{P}$ =measure of variability, taken as 0.112 + 0.035 /2 = 0.074

Z_β= is the power of the study at 80%

$Z\alpha$ = Z score of 95% confidence interval at 95% (1.96)

P_1- P_2 = effect size (difference in proportions) = 0.112-0.035=0.077

Substituting these values in the equation gives us a sample size as calculated below:

Where $n = \frac{(0.33+1)\ (0.074)\ (0.926)\ (7.62)}{0.33 \qquad 0.0059}$

$= 4 * 88.7 = 357$

Therefore: sample for women who have undergone Female Genital Mutilation = **357** while those who have not undergone Female Genital Mutilation = 357/3= **119** using the ratio 1:3 as above for non-exposed and exposed

3.6 Sampling Procedure/Selection of Study Participants

3.6.1 Sampling Procedure

The study adopted multi stage sampling technique:

Stage 1: Selection of the facilities

A purposive sampling technique was used to select facilities in Freetown, Sierra Leone. There are seven major health facilities in Freetown which include two tertiary and five secondary. The study selected the two tertiary Hospital and the equivalent number among the secondary facilities with the highest number of delivery.

These four facilities formed the four strata that was used in identifying study subjects.

Table 3.3: Selection of facilities

Hospital (Strata)	Number of deliveries for the year 2018
PCMH	7805
Lumley	784
Aberdeen	3060
Kingharma	586
Total	12235

Stage 2: Selection of study participants

Thus, from the identified four strata, the researcher used proportionate sampling to ensure that each hospital has an equal representative of study subjects based on the estimated number of deliveries in each of the facilities.

Table 3.4: Selection of Participants in the facilities

Hospital	Number of deliveries for the year 2018	Proportionate Sample (Exposed)	Proportionate Sample (Unexposed)
PCMH	7805	227	75
Lumley	784	23	08
Aberdeen	3060	89	30
Kingharma	586	18	6
Total	12235	357	119

Stage 3: Recruitment of study subjects

In each of the facilities, the researcher adopted consecutive sampling based on the inclusion criteria until the sample size is achieved. All patients within the sampling frame who showed interest to participate in the study were recruited. The recruitment process stopped once the sample targeted in each facility was achieved. All the women in the maternity unit and in both the latent and active phase of labor received a verbal invitation and explanation to participate in the study. Those who accepted to participate in the study were administered questionnaire and signed the consent form; for those who opt-out, a replacement was done by picking the next qualified patient as per the inclusion criteria.

3.7 Study Variables

Table 3.5: Study Variables

Objective	**dependent variables (Exposed)**	**Outcome dependent variable**	**Source of data**
Types of FGM	FGM	Type 1, Type 2 and Type 3	Questionnaire/patient file
Immediate Post Delivery complication	FGM	Incidence of birth trauma, assisted delivery, prolonged 2nd stage, Vulva(l) hematoma PPH, perineal tear, $2^{nd(0)}$ PPH, prolonged hospital stay	Questionnaire/patient file
Neonatal complication	FGM	Apgar score, the weight of baby, respiratory infection, early neonatal death, stillbirth, birth injury, prolonged neonatal admission	Questionnaire/patient file

3.8 Quality Assurance Procedures

We ensured that the questionnaire collected information that helped answer the study questions, a 5% of the total sample size was pretested at Makeni government hospital.

During pre-testing, the questionnaire was assessed for completeness, clarity, length and efficacy.

The research assistants were fully trained on how to effectively extract information and filling the questionnaires. The research assistants were qualified medical officers who understand medical information and engaged the study subjects. The research assistants were trained in appropriate interview techniques in filling the questionnaires.

A training session was conducted to ensure that research assistants understood how to evaluate presence or absence of FGM as well as identification of the different types.

Recording of clinical findings was done only after thorough scrutiny and counter checking the data for accuracy. The study participants were assigned exclusive identifiers to ensure that they are were targeted once within the study period. This also ensured that each study subject was only targeted once. The questionnaires were checked for completeness after delivery details.

3.9 Data Collection Procedure

The study adopted an interviewer guided questionnaire and an observational checklist which were employed as data collection tools. The structured questionnaires included specific questions relating to the study objective.

The researcher employed a total of eight research assistants in the four hospitals to aid in data collection. After obtaining consent, the researcher with the help of research assistants who were qualified medical officers working in these facilities conducted clinical examination based on the WHO classification guidelines to identify FGM and non-FGM cases. This was done using a predeveloped observational checklist.

The patient socio demographic and economic characteristics as well as medical histories were captured using the pre-tested study questionnaire.

Women who underwent FGM while very young were examined and if otherwise they fall under non-exposed. The women who consented to the study were followed till delivery.

During delivery, details of the delivery including adverse obstetric outcomes were collected using the questionnaire with patient been followed till 72hrs. Birth complication were reported as concluded by a birth attendant.

3.10 Data Management

3.10.1 Data Cleaning and Entry

The data was collected using questionnaires and forms were checked for completeness by the researcher after delivery information has been captured. Collected data was entered in Epi-Data 3.1 database then exported to SPSS computer package, version 26 for analysis.

3.10.2 Data storage

The consent forms, questionnaires, and forms did not contain in personal identifiers. Unique codes were used to identify the patients throughout the study period. The unique identifier ensured that there was a clear identification of study subjects through the study period. Once they have been filled, they were locked up in a safe cupboard. The laptop that was used in the analysis of the data have a password to ensure limited access by authorized personnel only. The consent forms and questionnaires were safely stored; after which they will be destroyed after five years

3.11 Data analysis and presentation

Before analysis, Quantitative data was coded, cleaned, and edited to ensure that it was accurate. Data was analyzed through SPSS version 26.0. All comparisons were performed at 0.05 significance level. The analysis included both descriptive and inferential analysis.

Demographic characteristics

Demographic characteristics were analysed descriptively. Categorical variables were analysed using frequencies (n) and percentages (%). Continuous variables were analysed using mean (SD) and Median (IQR)

In comparing sociodemographic and clinical patient characteristics between with FGM and without FGM group, A Pearson chi-square or Fisher's exact tests was used to test for associations between categorical variables in the study and FGM. A student t-test was used to

determine whether there was statistically significant difference between FGM and without FGM group based on continuous variables included in the study.

Descriptive analysis was conducted to describe the types of female genital mutilation/c among women delivering in Free Town, Sierra Leone. Frequencies (n) and percentages (%) will be used.

A binary logistic regression will be conducted to determine the peripartum maternal complications associated with female genital mutilation. Relative risk will be computed to explain the existing association between FGM group and without FGM

Similarly, binary logistic regression was conducted to determine the neonatal complications associated with female genital mutilation. Relative risk was computed to compare the neonatal complication association between FGM group and without FGM group.

3.12 Research Ethics

The study seek approval from KNH-UON Ethics and Review Committee and the Sierra Leone Medical Research Ethics. Permission was also sought from the heads of each of the four hospitals. Consenting was done when the mothers report to the hospital. The researcher adhered to a declaration of non-disclosure of the respondent's identity in order not to breach their confidence. The purpose and benefits of the study was expounded to the respondent and only willing respondents were allowed to participate.

3.13 Study Results Dissemination Plan

The results of the study were presented to the Department of Obstetrics and Gynecology for inputs from the faculty and as part of the fulfillment of the master in Obstetrics and Gynecology. Following the revisions by both the internal and external examiners, the findings will be disseminated to the hospitals in Free town and a report submitted to the hospital management and the Ministry of Health. The study will then be published upon its completion.

3.14 Study Closure Plan and Procedure

The study was conducted in three phases: phase one entailed recruitment and data collection, followed by data analysis and presentation to the department of obstetrics and gynecology for review. The third phase entailed feedback to the key stakeholders. The recommendations from these feedback sessions will be incorporated into the final report before publication.

4. CHAPTER FOUR

RESULT

The study sought to investigate the types of female genital mutilation (FGM) and associated adverse obstetric outcomes among pregnant women seen in select hospital in Western Area, Freetown Sierra Leone. A total of 550 patients were screened including 400 women with FGM and 150 without FGM. Among those with FGM, 35 declined to consent while 8 questionnaires were incomplete. Among those without FGM, 25 declined to consent while 6 questionnaires were incomplete. This represented a 100% response rate based on predetermined sample size for exposed and non-exposed.

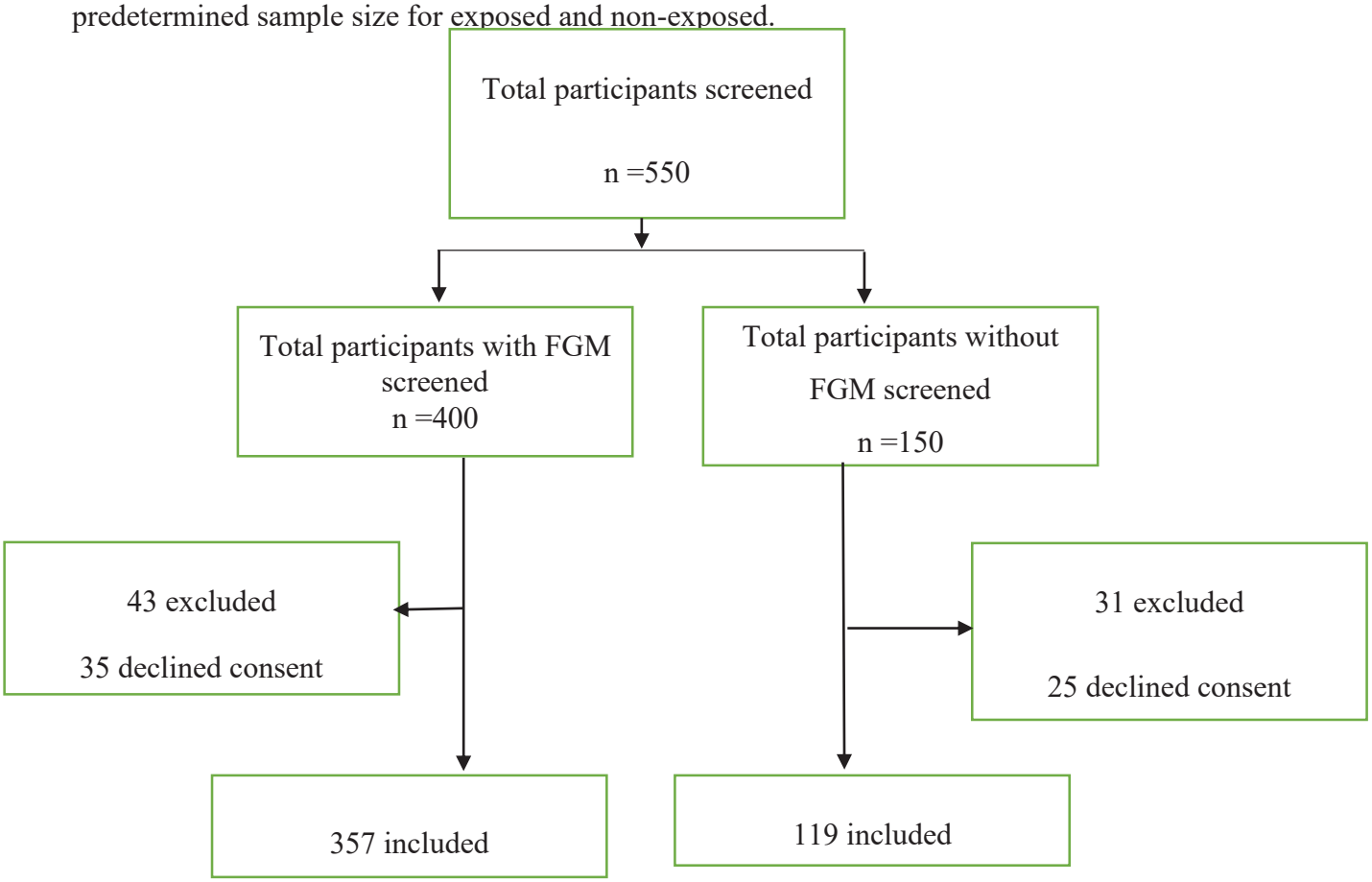

Figure 4.1: Study Description

4.1 Comparison of the Socio-Demographic Characteristics between the Exposed and Non-Exposed Groups

Table 4.1: Comparison of the Socio-Demographic Characteristics between the Exposed and Non-Exposed Groups

	Total n (%)	FGM n (%)	Without FGM n (%)	RR(95%CI)	P-value
Age (Mean± SD)	**24±5.7**				
15 - 24 years	238 (50)	174(48.7)	64(53.8)	0.91(0.74 - 1.10)	0.199
25 - 49 years	238 (50)	183(51.3)	55(46.2)	1	
Marital status					
Single	158(33.2)	113(31.7)	45(37.8)	0.84(0.64 -1.1)	0.131
Married	318(66.8)	244(68.3)	74(62.2)	1	
Religion					
Christian	**183 (38.4)**	**126(35.3)**	**57(47.9)**	**Ref**	
Muslim	**293(61.6)**	**231(64.7)**	**62(52.1)**	**1.15(1.02 -1.28)**	**0.01**
Level of education					
No formal education	122 (25.6)	102(28.6)	20(16.8)	1.7 (1.1 - 2.62)	0.192
Primary	95 (20.0)	75(21)	20(16.8)	1.25 (1.02 - 1.53)	0.02
Secondary	183 (38.4)	132(37)	51(42.9)	0.86 (0.67- 1.11)	0.328
Tertiary	76(16)	48(13.4)	28(23.5)	1	
Occupation					
Formal employment	33 (6.9)	23(6.4)	10(8.4)	0.76 (0.37 - 1.56)	0.465
Self-employment	148 (31.1)	117(32.8)	31(26.1)	1.26 (0.90 - 1.76)	0 .170
Casual	89(18.7)	62(17.4)	27(22.7)	0.77 (0.51 - 1.14)	0.197
House work	138(29.0)	112(31.4)	26(21.8)	1.44 (0.99 -2.08)	0.047
Student	**68 (14.3)**	**43(12)**	**25(21)**	**0.57 (0.37 - 0.90)**	**0.014**
Number of ANC visits					
None	15 (3.2)	12(3.4)	3(2.5)	1.36(0.33 - 4.64)	0.834
1 - 4 visits	**337 (70.8)**	**243(68.1)**	**94(79)**	**0.86(0.77 - 0.97)**	**0.013**
> 4 visits	124(26.1)	102(28.6)	22(18.5)	1	
Parity					
<2	221 (46.4)	165(46.2)	56(47.1)	0.98(0.79 - 1.23)	0.478
>=2	255(53.6)	192(53.8)	63 (52.9)	1	

The findings from the analysis as shown in Table 4.1 revealed that, women with FGM, compared to those without FGM, were more likely to be Muslim (RR = 1.15, 95%CI: 1.02 – 1.28, p=0.01), but less likely to be students (RR = 0.57, 95% CI: 0.37 – 0.9, p =0.014) and to have had 1-4 ANC visits (RR = 0.86, 95%CI: 0.77 – 0.97, p = 0.01).

4.2 The types of female genital mutilation/c among women delivering in Free Town, Sierra Leone

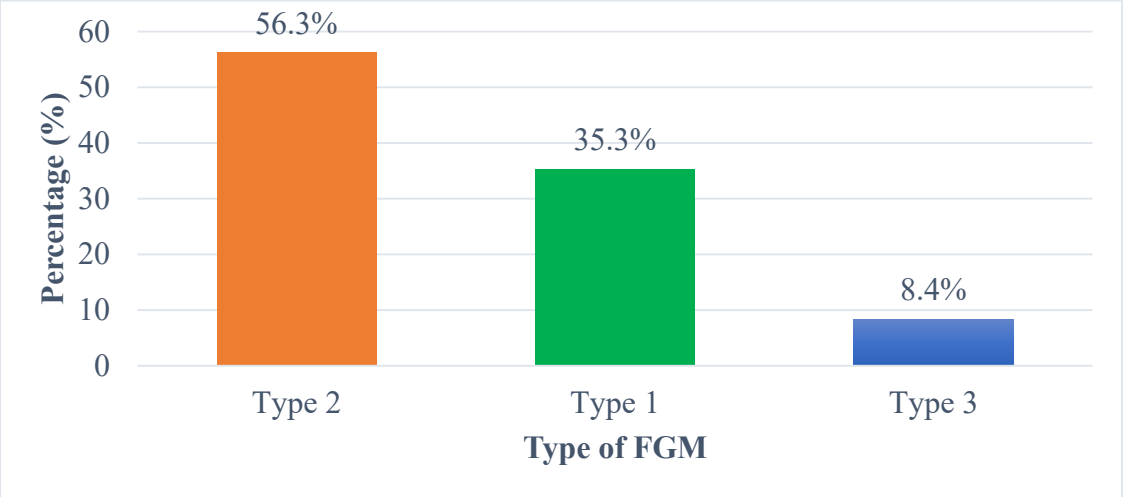

Figure 4.2: Types of FGM

The findings revealed that among respondents with FGM among women who delivered in select hospitals in Western Area Freetown, 56.3% (201) had type 2, 35.3%(126) had type 1 while 8.4%(30) had type 3 as shown in Figure 4.2.

4.3 The peripartum maternal complications associated with female genital mutilation among women delivering in Free Town, Sierra Leone

4.3.1 Current maternal and Delivery complications

Table 4.2: The peripartum maternal complications associated with female genital mutilation among women delivering in Free Town, Sierra Leone

	FGM	Without FGM	RR(95%CI)	P-value
SVD				
Yes	284(79.6)	95(79.8)	0.99(0.89,1.11)	0.531
No	73(20.4)	24(20.2)		
Delivery complication				
Yes	**188(52.7)**	**28(23.5)**	**2.24(1.6,3.14)**	**P<0.001**
No	169(47.3)	91(76.5)		
Perineal tear				
Yes	**162(45.4)**	**21(17.6)**	**2.58(1.72, 3.85)**	**P<0.001**

No	195(54.6)	98(82.4)		
Cervical tear				
Yes	**36(10.1)**	**2(1.7)**	**6.00(1.47, 24.54)**	**0.001**
No	321(89.9)	117(98.3)		
PPH				
Yes	**76(21.3)**	**11(9.2)**	**2.32(1.27, 4.19)**	**P<0.001**
No	281(78.7)	108(90.8)		
Outlet obstruction				
Yes	**190(53.2)**	**43(36.1)**	**1.47(1.14, 1.91)**	**0.001**
No	167(46.8)	76(63.9)		
Management of Outlet obstruction				
Episiotomy				
Yes	**113(31.7)**	**15(12.7)**	**2.5(1.46,3.81)**	**P<0.001**
No	244(68.3)	103(87.3)		
Emergency cs				
Yes	73(20.4)	24(20.2)	1.01(0.67, 1.53)	0.531
No	284(79.6)	95(79.8)		
Duration of second stage labour				
≥45 minutes	**228(63.9)**	**45(37.8)**	**1.69(1.32 - 2.15)**	**p<0.001**
<45 minutes	129(36.1)	74(62.2)		

According to Table 4.2, it is shown, compared to women without FGM, women with FGM were statistically more likely to develop delivery complications (RR =2.24, 95%CI: 1.6 – 3.14, p<0.001), perineal tear (RR =2.58, 95%CI: 1.72 – 3.85, p <0.001), cervical tear , (RR =6.00, 95%CI (1.47 – 24.54, p = 0.001), PPH (RR =2.32, 95%CI: 1.27 – 4.19, p<0.001), outlet obstruction (RR= 1.47, 95%CI: 1.14 – 1.91, p = 0.001), duration of second stage ≥45 minutes (RR = 1.69, 95%CI: 1.32 – 2.15, p <0.001) while the management of outlet obstruction by episiotomy was higher among women with FGM, (RR = 2.5, 95%CI: 1.46 – 3.81, p<0.001). .

4.4 The neonatal complications associated with female genital mutilation among women delivering in Free Town, Sierra Leone

Table 4.3: The neonatal complications associated with female genital mutilation among women delivering in Free Town, Sierra Leone

	FGM	Without FGM	RR(95%CI)	P-value
Delivery outcome				
Live birth	338(94.7)	115(96.6)	0.98(0.94 - 1.02)	0.277
Still birth	19(5.3)	4(3.4)	1	
Birth weight				
Less 2500	12(3.6)	7(6.1)	0.59(0.24 - 1.45)	0.17
More than 2500	326(96.4)	108(93.9)	1	
Apgar at 1st minute				
Less than 7	**146(43.2)**	**36(31.3)**	**1.38(1.03,1.86)**	**0.024**
7 or more	192(56.8)	79(68.7)	1	
Apgar score at 5th minute				
Less than 7	**95(28.1)**	**11(9.6)**	**2.93(1.63 - 5.29)**	**p<0.001**
7 or more	243(71.9)	104(90.4)	1	
Apgar at 10min				
Less than 7	26(7.7)	4(3.5)	2.2(0.79, 6.20)	0.091
7 or more	312(92.3)	111(96.5)	1	
Admitted to NICU				
Yes	**63(18.6)**	**10(8.7)**	**2.14(1.14 – 4.04)**	**0.009**
No	275(81.4)	105(91.3)	1	
Died ≤72 hours after NICU admission				
Yes	**12(19.0)**	**5(50)**	**0.38(0.17 – 0.85)**	**0.018**
No	51(81.0)	5(50)	1	

The neonatal complications associated with FGM were investigated as shown in Table 4.3. Compared with women without FGM Women with FGM were statistically more likely to deliver babies with Apgar score of less than 7 at 1st minute, (RR = 1.38, 95%CI:1.03 – 1.86, p=0.024), and Apgar score less than 7 at 5th (RR = 2.93, 95%CI:1.63 – 5.29, p<0.001)., while admission of babies born to NICU was higher among FGM (RR = 2.14, 95%CI: 1.14 – 4.04, p = 0.009). but less likely neonates who died ≤72 hours, (RR = 0.38, 95%CI: 0.17 – 0.85, p<0.018).

4.5 Multivariable analysis

4.5.1 Independent peripartum maternal complications associated with female genital mutilation among women delivering in Free Town, Sierra Leone

Table 4.4: Independent peripartum maternal complications associated with female genital mutilation among women delivering in Free Town, Sierra Leone

Complications	aRR (95%CI)	P-value
Delivery complications		
Yes	0.66(0.30 - 1.5)	0.335
No	1	
Perineal tear		
Yes	**2.45(1.09 - 5.6)**	**0.031**
No	1	
Cervical tear		
Yes	0.29(0.06 - 1.34)	0.113
No	1	
PPH		
Yes	1.17(0.53 - 2.59)	0.702
No	1	
Outlet Obstruction		
Yes	0.95 (0.56 -1.63)	0.854
No	1	
Duration of second stage		
Less 45 minutes	**2.49(1.47 - 4.22)**	**0.001**
More than 45 minutes	1	

Multivariable analysis conducted as shown in Table 4.4 it was found that, compared with parturient without FGM to those with FGM were statistically more likely to have perineal tear (aRR = 2.45, 95%CI: 1.09 – 5.6, p = 0.031). delay second stage (>45 minutes) was, (aRR =2.49, 95%CI: 1.47 – 4.22, p = 0.001).

4.5.2 Independent neonatal complications associated with female genital mutilation among women delivering in Free Town, Sierra Leone

The findings from multivariable analysis revealed that FGM was independently associated with Apgar score at 5th minute. Comparing the risk of lower Apgar score (less than 7) for

neonates born by women without FGM to those with FGM were statistically more likely, (aRR = 3.71, 95%CI:1.58 – 8.7, p = 0.003) as shown in Table 4.5

.**Table 4.5: Independent neonatal complications associated with female genital mutilation among women delivering in Free Town, Sierra Leone**

	aRR (95%CI)	p-value
Apgar at 1st minute		
Less than 7	0.92(0.55 - 1.56)	0.761
≥7 minute	1	
Apgar score at 5th minute		
Less than 7	**3.71(1.58 - 8.7)**	**0.003**
≥7	1	
Admitted to NICU		
Yes	1.03(0.42 - 2.5)	0.949
No	1	

4.6 Association between type of FGM and maternal complications among women delivering in Free Town, Sierra Leone

Table 4.6: Type of FGM and peripartum complications

Peripartum complications	Yes	No	P-value
SVD			
Type 1	100(79.3)	26(20.7)	
Type 2	161(80.1)	40(19.9)	0.538
Type 3	23(76.7)	7(23.3)	
Presence of delivery complication			
Type 1	68(53.9)	58(46.1)	
Type 2	**96(47.8)**	**1052.2)**	**0.011**
Type 3	24(80)	6(20)	
Perineal tear			
Type 1	62(49.2)	64(50.8)	
Type 2	81(40.3)	120(59.7)	**0.07**
Type 3	19(63.3)	11(36.7)	
Cervical tear			
Type 1	6(47.6)	120(52.4)	
Type 2	19(9.5)	182(90.5)	**p<0.001**
Type 3	11(36.7)	19(63.3)	
PPH			
Type 1	25(19.8)	101(80.2)	
Type 2	39(19.4)	162(80.6)	0.058
Type 3	12(40)	18(60)	
Outlet obstruction			
Type 1	66(52.4)	60(47.6)	
Type 2	94(45.8)	107(54.2)	**p<0.001**
Type 3	30 (100)	0	

Episiotomy			
Type 1	40(31.7)	86(68.3)	
Type 2	51(25.4)	150(74.6)	**p<0.001**
Type 3	2273.3)	8 (26.7)	
Emergency Caesarean			
Type 1	28(22.2)	98(77.8)	
Type 2	39(19.4)	162(80.6)	0.531
Type 3	6(20)	24(80)	
Duration of second stage labour (<45 minutes)			
Type 1	52(41.3)	74(58.7)	
Type 2	71(35.3)	13064.7)	**p<0.001**
Type 3	6(20)	24(80)	

The study also sought to compare maternal complications among Parturient with FGM based on their different types of FGM to determine whether there was significant difference in the complications that were assessed. The results revealed that there were statistical associations, type of FGM and presence of delivery complication, ($p = 0.011$), cervical tear ($p<0.001$), outlet obstruction ($p<0.001$), episiotomy ($p<0.001$) and Duration of second stage ($p<0.001$) as shown in Table 4.6.

4.7 Association between type of FGM and neonatal complications among women delivering in Free Town, Sierra Leone

Table 4.7: Association between neonatal complications and FGM

Birth outcome	**Live birth**	**Still birth**	**P-value**
Type 1	120(97.6)	3(2.4)	
Type 2	184(92.4)	15(7.6)	0.236
Type 3	29(96.7)	1(3.3)	
Birthweight	**Less 2500**	**More than 2500**	
Type 1	4(3.2)	122(96.8)	
Type 2	8(3.9)	193(96.1)	0.731
Type 3	0	30(100)	
Apgar at 1st minute	**Less than 7**	**7 or more**	
Type 1	44(34.9)	82(65.1)	
Type 2	83(41.3)	118(58.7)	x^2=6.44 0.011
Type 3	19(63.3)	11;(36.7)	
Apgar score at 5th minute	**Less than 7**	**7 or more**	
Type 1	31(24.6)	95(75.4)	
Type 2	51(25.4)	150(74.6)	0.138
Type 3	13(43.3)	17(56.7)	
Apgar at 10min	**Less than 7**	**7 or more**	
Type 1	3(2.4)	123(97.6)	

Type 2	19(9.5)	182(90.5)	x^2=7.24 0.007
Type 3	4(13.3)	26(86.7)	
Admitted to NICU	**Yes**	**No**	
Type 1	24(19.1)	102(80.9)	
Type 2	31(15.4)	17084.6)	0.188
Type 3	8(26.7)	22(73.3)	

In investigating neonatal complications, the findings revealed that type of FGM was associated with Apgar score at 1st minute ($\chi 2$ trend = 6.44, p=0.011) and Apgar score at 10th Minute ($\chi 2$ for trend =7.24, p=0.007) as shown in Table 4.7.

5. CHAPTER FIVE

DISCUSSION

The current study investigated the types of female genital mutilation and the associated adverse obstetric outcomes among pregnant women seen at select hospital in Sierra Leone. The demographic characteristics showed that the average age of the respondents was 24 years. However, half of the respondents, were aged between 15- and 24-years. Sierra Leone has one of the highest rates of teenage pregnancy in the world with around 28% of girls giving birth before the age of 18 years (43) Thus, the average age of 24 shows that majority of the study participants were young adults. These findings however higher than those from Sakeah et al.(44) in Ghana which found that 36% of the respondents were aged between 15 and 24 years. However, despite both countries being from West Africa, the difference could be explained by the sample size included in their study compare to the current study. In our study a total sample size 476 compared 830 in their study. In investigating marital status, in our study, more than half, 66.8% were married. This is however lower compared to a previous study conducted in Sierra Leone by UNICEF (45) while investigating FGM in the country. The findings from the study found that 75% of those involved in the study were married. This difference could be explained due to our small sample size. The findings from our study further identified that 62% were Muslims. Sierra Leone is a predominantly a country with many Muslims of 77% (46) which is slightly higher than our study respondents because of our small sample size. However, these findings are comparable to a study done in Ghana by Sakeah et al. (44) which found that a similar percentage were Muslims. This was however, lower compared to a study conducted in Ethiopia by Gebremicheal et al. (47) who found that 74% were Muslims. The difference as seen in this context could be as a result of the fact that almost the whole population are Muslims in Ethiopia which is higher compared to Sierra Leone. The findings from the present study further showed that almost half of the respondents, 38.4% had secondary level education. The findings also showed that 26% of the respondents had no formal education. These findings are comparable in most of the studies conducted in West Africa (44) (48) (49).

The findings from our current study established that type 2 was the most common type of FGM and was present in more than half of those with FGM, 56%. Similarly type 1 and type 3 occurred with 35% and 8% respectively. These findings reflect those from past report published in Sierra Leone which revealed that common types of FGM in the country were

type I and type II (37). These findings however were lower as compared to a study conducted by Mitike and Deressa et al. (50) in Ethiopia who found that the common types of FGM included clitoris cutting, 64% was the most common type of FGM. Further, another study conducted by Koski and Heymann (51) in a study conducted in 22 countries , it was found that majority of women had their flesh removed from their genitals corresponding to type 2 FGM. The findings from the study also established that infibulation is currently still being practiced throughout sub-Saharan Africa. Estimates of flesh removal should be treated as lower bounds given the substantial proportion of women who reported that they did not know whether flesh had been removed from their genitals (48).

The findings from our study revealed that the risk of having a delivery complication was 2.2 times higher among women with FGM. The findings further revealed that 51% of all adverse complications occurred in those with type 2 FGM. This could be explained by the fact that type 2 was the most common type of FGM and involved partial or complete removal of of the clitoral glans as well as labia minora hence more exposed to higher risk of complications than type 1 FGM. In the present study, it was determined that the risk of adverse outcomes increased with severity of type of FGM. These findings are comparable to past studies (23) (24) (27) which revealed that adverse outcomes occurred more among patients with FGM. Similarly, according to a study by World Health Organization (52) in six African countries including Burkina Faso, Ghana, Kenya, Nigeria, Senegal, and Sudan, it was found that Women with FGM are significantly more likely than those without FGM to have adverse obstetric outcomes. Risks seem to be greater with more extensive FGM.

The current study also found that the risk of perineal tear was 2.6 times higher in women with FGM. The findings further showed that 61.7% of perineal tear in women with FGM occurred in women with type II and type III. These findings are comparable to a study conducted in Ethiopia which found that the risk of perineal tear increased with severity of type of FGM. Perineal tear was also significant under multivariable model which showed that the risk of perineal tear was 2.5 times higher in women with FGM. The results are comparable to Gebremicheal et al. in Ethiopia in 2018 which revealed that the risk of perineal tear in mothers with type 3 was 4.91 times (47). However, when investigating the risk of perineal tear in other studies, a study conducted in Nigeria by Rodriguez et al. (53) in investigating obstetric outcomes in women living with type 3 FGM, it was found that type 3 was significantly associated with perineal tear. Though, we are unable to make such conclusion in our present study considering that only 8% of those with FGM had type 3 hence it is a small

sample to consider any inferential analysis. Further, another descriptive study conducted in Australia by Varol et al. (54) revealed that, there is significantly higher risk of first and second degree perineal tears were significantly common in patients with FGM.

The findings from our study revealed that, the risk of cervical tear was 6 times higher in women with FGM compared to those without. The findings from the study also found that 83% of all cervical tears in women with FGM occurred in type II and III. These findings are in line with most of previous studies which have found an increase in risk of cervical tear in women with FGM while subsequently the risk of cervical tears is significantly higher in women who had type 3 (53)(51). However, this aspect was difficult to investigate in our study considering that type 3 was least common in our present study findings.

The results from our study also showed that, the risk of outlet obstruction was 1.4 times higher among women with FGM as compared to those without FGM. These findings are comparable to a study conducted in Ethiopia by Gebremicheal et al. (47) which found that the risk of outlet obstruction was 2 times higher in women with FGM as compared to those without. The findings also revealed that, the risk of outlet obstruction increased with increasing severity of FGM. Respondents who had type II FGM were 2.3 times compared to type III which had a higher risk of 2.9 as compared to those without. Similarly, another study conducted by Klein et al. (55) revealed that the odds of outlet obstruction was 1.7 times higher in women with FGM as compared to those without.

The findings from the present study have showed that in management of outlet obstruction, the risk of episiotomy was 2.5 times higher in women with FGM as compared to those without FGM. The findings also showed that, the risk of episiotomy increased with increasing severity of FGM with 32% in type I FGM and 73% in type III. The use of episiotomy is fundamental in expediting delivery considering that it is carried out with a major goal to prevent the risk of trauma on the genital tract especially in women with type II and type III FGM which are common types of FGM (56)(49). This explains why episiotomy was common in patients with FGM type III in our current study. The risk of second stage of more than 45 minutes was 2 times higher in women with FGM compared to those without FGM. Under the multivariable model, it was found that the risk of seconds stage more than 45 minutes was 2.5 times higher among women within FGM. These findings are contrast to a study conducted in Sweden by Essen et al. (57) who found that women with FGM had

significantly shorter second stage of labour. This could be as a result of scarring from FGM which would be too delicate to be torn during the delivery.

The findings from the present study have showed that there was association between FGM and postpartum haemorrhage. However these findings compare with those from previous studies which have shown that There is high risk of PPH in women with FGM especially in women with type III FGM (52) (47). According to a study conducted by WHO (52) the risk of Postpartum haemorrhage was 1.3 times higher in women who had FGM. Further, Gebremicheal et al. (47) identified that the risk of PPH in women with Type III FGM was 6.3 times higher than other types of FGM. These findings are different from the current study mainly due to the sample size of type III FGM respondents included in the study. In our present study only 8% (18) had type III hence no meaningful inferences could be made.

The risk of women with FGM having a baby born with an Apgar of less than 7 in the 1st minute was 1.4 times higher than those without FGM. The findings also established that the risk of Apgar score of less than 7 was 3 times higher at 5th minute. The findings from the study also showed that the Apgar score at 1st minute decreased with severity of the type of FGM. The findings revealed that 63% of neonates born of mothers with type III FGM had Apgar score of less than 7. At 1st minute. However, there was no association between type of FGM and Apgar score at 5th minute and 10th minutes. These findings are comparable to Gebremicheal et al.(47) who found that the risk of Apgar score less than 7 was higher in women with FGM at 1st minute. Similarly, another study conducted in Burkina Faso by Frega et al. (58) revealed that, low Apgar score was significantly higher among women with FGM compared to those without. Suleiman et al.(59) in a study conducted in Northern Tanzania investigating the trends in FGM found that the risk of lower Apgar was higher among neonates born of mother with FGM compared to those without. The risk of low Apgar score at 5th minute was 1.6 times higher in women with FGM as compared to those without although there was no difference between the different types of FGM.

The present study also established that the risk of NICU admission was 2 times higher in women with FGM compared to those without FGM. However, this study also found that there was significant difference between types of FGM and NICU admissions. The descriptives show an increasing NICU admissions with increase in the severity of FGM type. These findings are different to a study conducted in Australia by Davis and Jellins (60) which found that there was no significant difference in neonatal nursery admission among neonates

born of mothers affected with FGM and those not affected by FGM. The difference could be attributed to the smaller sample size of women with FGM included in the study. In the present study, a total of 357 women with FGM were included compared to 147 in their study which could contribute to lack of significance between those with FGM and those without. Similarly, Varol et al.(54) also found contrasting results where there was no significant difference between neonatal admission to special care between mothers with FGM and those without FGM. This study was conducted in Australia which is a more advanced setting compared to Sierra Leone hence explains the differences in the significance. Women with FGM are managed better in Australia to control adverse outcomes.

6. CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The findings from the study revealed that,

The average age among the respondents was 24 (SD =5.7) years, 58.4% were married. In assessing religion, 61.6% were Muslims. Education level analysis revealed that, 38.4% had secondary level education, 31.1% were self-employed. Majority of the respondents, 70.8% had less or equal to four antenatal visits, 95.6% had between para 1 and para 4.

The common type of FGM was type, 56% followed by 35% and 8% in type I and type III respectively.

FGM was significantly associated with delivery complications, perineal tear, cervical tear, PPH and outlet obstruction.

Neonatal outcomes associated with FGM were also investigated. The findings revealed that FGM was significantly associated with low Apgar score at both 1st minute and 5th minute and admission to NICU.

Multivariable analysis conducted found that, FGM was independently associated with perineal tear, duration of second stage (more than 45 minutes) and Apgar score at 1st minute.

6.2 Recommendation

Based on the study the following recommendations are made:

I. Conduct clinical examination to identify women with FGM in order to advice for the appropriate mode of delivery to control adverse outcomes.
II. Ensure frequent clinical reviews in women with FGM to check the progress of their fetus and provide evidence-based care.
III. Develop protocol in management of care among women with FGM to control the risk of adverse outcomes which is high. And also engage in advocacy to Women groups, Ministry of health and sanitation, ministry of Social welfare gender and children affairs(MSWGCA) to ban the Patrice in Sierra Leone.

Area for further Research

To conduct a large study that compares adverse outcomes and management approaches in different types of FGM in Sierra Leone.

6.3 Study Limitations

1) In sierra Leone 62% of all births are attended by skilled birth attendants which implies that 38% of women who might be having FGM complications are missed since they are not delivering in the hospital
2) All multiple pregnancies who might be having FGM complications are excluded

6.4 Study Strength

This study is the first Hospital based study conducted in Sierra Leone looking at FGM and adverse obstetric outcome among pregnant women seen in Freetown

REFERENCES

1. WHO. An update of WHO's work on Female Genital Mutilation (FGM): progress report. Geneva, Switzerland: World Health Organization; 2014.

2. UNICEF. Female genital mutilation/cutting: A statistical overview and exploration of the dynamics of change. Geneva, Switzerland: United Nations International Children's Emergency Fund; 2015.

3. Elmusharaf S, Elhadi N, Almroth L. Reliability of self reported form of female genital mutilation and WHO classification: cross-sectional study. Br Med J. 2006;333(7559):124–7.

4. Mgbako C, Saxena M, Cave A. Penetrating the Silence in Sierra Leone: A Blueprint for the Eradication of Female Genital Mutilation. Harv Hum Rts J. 2010;

5. Alsibiani S, Rouzi A. Sexual function in women with female genital mutilation. Fertil Steril. 2010;93(3):722–4.

6. Pashael T, Rahimi A, Felah A. Related Factors of Female Genital Mutilation (FGM) in Ravansar (Iran). Women's Health Care. 2012;

7. Beller J, Kroger C. Differenntial effects from aspecs of religion on female genital mutilation/cutting. Psychol Relig Spiritual. 2018;

8. Koski A, Heymann J. Changes in support for the continuation of female genital mutilation/cutting and religious views on thepracice in 19 countries. Glob Public Health. 2019;14(5):696–708.

9. DHS. FGM in Sierra Leone. Demographic Health; 2014.

10. Koski A, Heymann J. Thirty-year trends in the prevalence and severity of female genital mutilation: a comparison of 22 countries. BMJ Glob Health. 2017;2(4).

11. Bangura E, Ngegba M. Female genital mutilation(FGM) in Sierra Leone: Factors influencingthe practice of in Jaiama Bongor chiefdom in Bo district. Int Res J Soc Sci Humanit. 2016;1(1):1–12.

12. WHO. Female genital mutilation [Internet]. Geneva,Swizerland: World Health Organization; 2021. Available from: https://www.who.int/health-topics/female-genital-mutilation#tab=tab_1

13. Atkinson H, Ottenheimer D, Mishori R. Public Health Research Priorities to Address Female Genital Mutilation or Cutting in the United States. Am J Public Health. 2019;

14. Doucet M, Pallitto C, Groleau D. Understanding the motivations of health-care providers in performing female genital mutilation: an integrative review of the literature. Reprod Health. 2017;14(46).

15. WHO. Female genital mutilation [Internet]. Geneva,Swizerland: World Health Organization; 2020. Available from: https://www.who.int/news-room/fact-sheets/detail/female-genital-mutilation

16. Lurie J, Weidman A, Huynh S, Delgado D, Easthausen I, Kaur G. Painful gynecologic and obstetric complications of female genital mutilation/cutting: A systematic review and meta-analysis. Plos Med. 2020;

17. WHO. Types of female genital mutilation [Internet]. Geneva,Swizerland: World Health Organization; 2018. Available from: https://www.who.int/sexual-and-reproductive-health/types-of-female-genital-mutilation

18. Rushwan H. Female genital mutilation: A tragedy for women's reproductive health. Afr J Urol. 2013;19(3).

19. Onuh S, Igberase G, Umeora J. Female genital mutilation: knowledge, attitude and practice among nurses. J Natl Med A. 2006;98(3).

20. Utz-Billing I. Female genital mutilation: an injury, physical and mental harm. J Psychosom Obstet Gyneology. 2008;29(4).

21. Osterman A, Winer R, Gottlieb G, Sy M, Dembele B, Toure P. Female genital mutilation and noninvasive cervical abnormalities and invasive cervical cancer in Senegal, West Africa: A retrospective study. Int J Cancer. 2018;114(6).

22. WHO. A Systematic review of the health complications of female genital mutilation including sequelae in childbirth. Geneva,Swizerland: World Health Organization; 2000.

23. Banks E, Meirik O, Atkande F. Female genital mutilation and obstetric outcome: WHO collaborative prospective study in six African countries. Lancet. 2006;3(367).

24. Berg R, Undeland V. Female Genital Mutilation, Cutting, or Circumcision. Obstet Gynecol Int. 2013;

25. de Silva S. Obstetric sequelae of female circumcision. Eur Jouranl Obstet Gynecol Reprod Biol. 1989;32(3).

26. Millogo-Traore F, Kaba S, Thieba B, Akotionga m. Pronostic maternel et fœtal au cours de l'accouchement chez la femme exciséeMaternal and foetal prognostic in excised women delivery. J Gynecol Obstet Biol Reprod (Paris). 2007;36(4).

27. Al-Hussaini T. Female genital cutting: types, motives and perineal damage in laboring Egyptian women. Med Princ Pr. 2003;12(2):123–8.

28. Chibber R, El-Saleh E, El-Harmi J. Female circumcision: obstetrical and psychological sequelae continues unabated in the 21st century. J Matern Fetal Neonatal Med. 2011;24(6):833–6.

29. Rodriguez M, Seuc A, Say L, Hindin M. Episiotomy and obstetric outcomes among women living with type 3 female genital mutilation: a secondary analysis. Reprod Health. 2016;13.

30. Antabe R, Sano Y, Anfaara F, Kansanga M. Antenatal Care Utilization and Female Genital Mutilation in Kenya. Sex Cult. 2019;23.

31. Lincetto O, Mothebesoane-Anoh S, Gomez P. Antenatal Care [Internet]. Geneva,Swizerland: World Health Organization; Available from: https://www.who.int/pmnch/media/publications/aonsectionIII_2.pdf

32. Suleiman I, Maro E, Shayo B. Trend in female genital mutilation and its associated adverse birth outcomes: A 10-year retrospective birth registry study in Northern Tanzania. Plos One. 2021;

33. WHO. An update on WHO's work on female genital mutilation (FGM). Geneva,Swizerland: World Health Organization; 2014.

34. Devi S. FGM in Sierra Leone. The Lancet. 2018;391(10119):415.

35. Fanthorpe R. Sierra Leone: The Influence of the Secret Societies, with Special Reference to Female Genital Mutilation [Internet]. Refworld; 2007. Available from: http://www.refworld.org/docid/46cee3152.html.

36. WHO. New report sheds light on tragic maternal death situation in Sierra Leone [Internet]. Geneva,Swizerland: World Health Organization; 2017. Available from: https://www.afro.who.int/news/new-report-sheds-light-tragic-maternal-death-situation-sierra-leone

37. UNICEF. Maternal, neonatal and child health [Internet]. UNICEF; 2020. Available from: https://www.unicef.org/sierraleone/maternal-neonatal-and-child-health#:~:text=The%20maternal%20mortality%20rate%20in,per%201%2C000%20live%20births%2C%20respectively

38. UN. Advancement of women, third committee of the United Nations General Assembly [Internet]. United Nations; 2012. Available from: http://www.ifrc.org/en/news-and-media/opinions-and-positions/speeches/2012/advancement-ofwomen-third-committee-of-the-united-nations-general-assembly/.

39. Gebremicheal K, Ewunetu H, Melaku S, Alemseged F, Tolossa D. Sequela of female genital mutilation on birth outcomes in Jijiga town in Ethiopia Somali region: a prospective cohort study. BMC Pregnancy Childbirth. 2018;

40. Abraham C, Sheeran P. The health belief model. In: Cambridge Handbook of Psychology, Health and Medicine, Second Edition. 2014.

41. Abdulah DM, Dawson A, Sedo BA. The impact of health education on attitudes of parents and religious leaders towards female genital mutilation. BMJ Sex Reprod Health. 2020;

42. Nkwam-Uwaoma A, Ojiakor IC, Onovo JC. Awareness, Knowledge and Perception of Female Genital Mutilation and Cutting (FGM/C) Radio Campaign and Practice among Women in Imo State. Arch Curr Res Int. 2019;

43. Medici Con L'Africa. Teenage pregnancy in Sierra Leone [Internet]. Medici Con L'Africa; 2016. Available from: https://doctorswithafrica.org/en/wp-content/uploads/sites/2/2020/01/teenage-pregnancy-sierra-leone.pdf

44. Sakeah E, Debpuur C, Oduro AR, Welaga P, Aborigo R, Sakeah JK, et al. Prevalence and factors associated with female genital mutilation among women of reproductive age in the Bawku municipality and Pusiga District of northern Ghana. BMC Womens Health. 2018;18(1):150.

45. UNICEF. Statistical profile on female genital mutilation/cutting [Internet]. UNICEF; 2013. Available from: file:///C:/Users/Dr.%20Victor%20Yandi/Downloads/FGMC_SLE.pdf

46. U.S department of State. Sierra Leone [Internet]. United States Department of State. 2020. Available from: https://www.state.gov/reports/2020-report-on-international-religious-freedom/sierra-leone/

47. Gebremicheal K, Alemseged F, Ewunetu H, Tolossa D, Ma'alin A, Yewondwessen M, et al. Sequela of female genital mutilation on birth outcomes in Jijiga town, Ethiopian Somali region: A prospective cohort study. BMC Pregnancy Childbirth. 2018;

48. Berg RC, Underland V. The Obstetric Consequences of Female Genital Mutilation/Cutting: A Systematic Review and Meta-Analysis. Obstet Gynecol Int. 2013;

49. Obiora OL, Maree JE, Nkosi-Mafutha N. Female genital mutilation in Africa: Scoping the landscape of evidence. International Journal of Africa Nursing Sciences. 2020.

50. Mitike G, Deressa W. Prevalence and associated factors of female genital mutilation among Somali refugees in eastern Ethiopia: A cross-sectional study. BMC Public Health. 2009;

51. Koski A, Heymann J. Thirty-year trends in the prevalence and severity of female genital mutilation: A comparison of 22 countries. BMJ Glob Health. 2017;

52. WHO. Female Genital Mutilation and Obstetric Outcome: WHO Collaborative Prospective Study in Six African Countries. Obstet Gynecol. 2006;108(2):450.

53. Rodriguez MI, Seuc A, Say L, Hindin MJ. Episiotomy and obstetric outcomes among women living with type 3 female genital mutilation: a secondary analysis. Reproductive Health. 2016.

54. Varol N, Dawson A, Turkmani S, Hall JJ, Nanayakkara S, Jenkins G, et al. Obstetric outcomes for women with female genital mutilation at an Australian hospital, 2006-2012: A descriptive study. BMC Pregnancy Childbirth. 2016;

55. Klein E, Helzner E, Shayowitz M, Kohlhoff S, Smith-Norowitz TA. Female Genital Mutilation: Health Consequences and Complications - A Short Literature Review. Obstetrics and Gynecology International. 2018.

56. Sundby J, Essén B, Johansen REB. Female Genital Mutilation, Cutting, or Circumcision. Obstet Gynecol Int. 2013;

57. Essén B, Sjöberg NO, Gudmundsson S, Östergren PO, Lindqvist PG. No association between female circumcision and prolonged labour: A case control study of immigrant women giving birth in Sweden. Eur J Obstet Gynecol Reprod Biol. 2005;

58. Frega A, Puzio G, Maniglio P, Catalano A, Milazzo GN, Lombardi D, et al. Obstetric and neonatal outcomes of women with FGM i and II in San Camillo Hospital, Burkina Faso. Arch Gynecol Obstet. 2013;

59. Suleiman IR, Maro E, Shayo BC, Alloyce JP, Masenga G, Mahande MJ, et al. Trend in female genital mutilation and its associated adverse birth outcomes: A 10-year retrospective birth registry study in Northern Tanzania. PLoS ONE. 2021;

60. Davis G, Jellins J. Female genital mutilation: Obstetric outcomes in metropolitan Sydney. Aust N Z J Obstet Gynaecol. 2019;

ANNEXES

Annex 1: Budget and Budget Justification

Item Description	Unit Cost (Kshs.)	Quantity	Total (Kshs.)
Proposal and questionnaire development			
Files	100.00	6	600.00
Pens	15.00	6	90.00
Papers	500.00	5	2,500.00
Flash Disk	2000.00	3	6,000.00
Internet			15,000.00
Printing	10.00	1000	10,000.00
Photocopying	5.00	1000	5,000.00
Binding	100.00	10	1,000.00
Sub-total			40,190
Data Collection and Analysis			
Research assistant	40,000.00	8	320,000.00
Data entry and cleaning	15,000.00	1	15,000.00
Statistician	30,000.00	1	30,000.00
Sub-total			365,000
Thesis Development			
Printing	10.00	1000	10,000.00
Binding	100.00	7	700.00
Photocopying	5.00	1000	5,000.00
Sub-total			15,700
Other Expenses			
Travelling	10000.00	8	80,000.00
Internet			15,000
Airtime	2000.00	8	16,000.00
Sub-total			111,000
Sum-Total			531,890
Contingencies (5%)			26,594
Grand Total			558,484.00

Annex 2: Consent Form

Title of the study: Female genital mutilation and adverse obstetric outcomes among pregnant women seen in select hospitals in Freetown, Sierra Leone

Researcher: David Jalloh

Introduction to the study: You are requested to participate in the study which is voluntary and will be conducted in select Hospital in Freetown, Sierra Leone

Purpose of the Study

The overall study objective is to determine the obstetric and neonatal outcomes associated with FGM among pregnant women seen in select hospitals in Western Area, Freetown Sierra Leone

Supportive aid will be provided in the event that you experience difficulties in responding to the questions. Confidentiality will be highly respected throughout the study.

Time: The study is simple and will not take much of your time with approximately 10 minutes required to finish the whole process.

Benefits of the study

This study will be useful in capturing the most common obstetric outcomes seen as a result of FGM/C practices. It will also highlight the major barriers that are associated with the prevention of these issues. Additionally, it will be critical in developing preventive strategies for dealing with poor neonatal outcomes which are associated with FGM

Sharing of results: The results of my study will be presented in an academic and scientific form and published in scientific medical journals and academic papers.

Risks, stress and discomfort: Considering the nature of study and condition being evaluated, it might cause you a slight discomfort during vaginal examination. However, you have the right to decline giving information

Voluntary participation

No form of incentive will be offered for participants recruited in the study and the participant is obliged to withdraw from the study at any point.

Confidentiality

All information provided in the study will be handled in absolute confidentiality and the information will not be shared with any other individual who is not part of the study.

Participants Consent

I confirm that the researcher has explained fully the nature of the study and the extent of activities which I will be asked to undertake. I confirm that I have had adequate opportunity to evaluate and ask questions about this study. I understand that my participation is voluntary and that I may withdraw at any time during the study, without having to give a reason. I, therefore, consent to participate in the study after reading and understanding the purpose of the study.

Sign ……. Date ……

In case of any issues or challenges related to this study, please contact me on **+254112113348 or +23278684810** or /UON ERC Secretariat on uonknherc@uonbi.ac.ke or contact Sierra Leone ethics and scientific review committee MOHS email: efoday@health.gov.sl or Tel: +23278366493

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

Researcher's statement

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

Signature_____ Date_____

Annex 3: Study Questionnaire

FEMALE GENITAL MUTILATION AND ADVERSE OBSTETRIC OUTCOMES AMONG PREGNANT WOMEN SEEN IN SELECT HOSPITALS IN FREETOWN, SIERRA LEONE

Section A: Socio-Demographic Factors

1. What is your age? _____ (in years)
2. Marital status

   Single [ ]

   Married [ ]

   Cohabiting [ ]

   Divorced [ ]
3. What is your religion

   Catholic [ ]

   Muslim [ ]

   SDA [ ]

   Protestant [ ]

   Other (specify) _____
4. Educational level [ ]

   No formal education [ ]

   Primary [ ]

   Secondary [ ]

   Tertiary [ ]
5. Occupation

   Formal Employment [ ]

   Self –Employment [ ]

   Casual Work [ ]

   House Work [ ]

   Student [ ]

Section B: Clinical History

1. Parity …….Para ____ + _____
2. Have you had FGM?

   Yes [ ]

   No [ ]

   Unaware ( )
3. Type of FGM (by clinical examination)

   Type 1 [ ]

   Type 2 [ ]

   Type 3 ( )

   Other (Specify) _____
4. Experienced any complications during past delivery

   Yes

   No

   If yes, types of maternal obstetric complications

   _____

   _____

   Types of neonatal complications

   _____

   _____
5. Number of ANC visits _____

Section C: Maternal Delivery Complications

1. Type of Delivery
   a. SVD

      Yes[ ]

      No[ ]
   b. If SVD, any assisted vaginal delivery?

      Yes [ ]

      No [ ]
   c. What assisted vaginal delivery?

      Episiotomy [ ]

      Vacuum delivery [ ]

Other (specify) _____

d. Delivery complication

Yes [ ]

No [ ]

e. Type of delivery complication?

Perineal tear [ ]

Other (Specify _____

f. Type of perineal tear

Grade 1 [ ]

Grade 2 [ ]

Grade 3 [ ]

2. Cervical tear

Yes [ ]

No [ ]

3. PPH

Yes [ ]

No [ ]

4. Outlet obstruction

Yes [ ]

No [ ]

a. What was done to manage the outlet obstruction?

Episiotomy [ ]

Caesarean section [ ]

Duration of second stage [ ]

Section C: Neonatal Complications

1. Outcome SVD

Live birth [ ]

Still birth [ ]

2. Outcome of Caesarean section

Live birth [ ]

Still birth [ ]

3. Weight of the baby _____ (In Kgs)

4. APGAR score in

   1",5",10" _____

5. Any respiratory distress

   Yes [ ]

   No [ ]

6. Was the neonate admitted to the Neonatal intensive care unit (NICU)

   Yes [ ]

   No [ ]

7. How long was the neonate admitted to the NICU? _____ (in days)

8. What was the outcome of the admission?

   _____

   _____

   _____

9. Any other clinical(?) specific on admission to NICU?

   _____

   _____

   _____

Annex 4: Study Timeline

Month/year / Activity	**June 2020**	**July 2020**	**Apr 2021**	**Apr-May 2021**	**July-Aug 2021**	**Sept 2021**	**Oct 2021**
Review and selection of the study topic							
Proposal development							
Presentation							
Proposal submission							
Collection of data							
Data analysis							
Thesis Report Writing							
Presentation of the final proposal							

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C 9 AUG 2021

9th August , 2021

Ref: KNH-ERC/A/289

Dr. David Jalloh
Reg No H58/12313/2018
Dept of Obstetrics and Gynaecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Jalloh

RESEARCH PROPOSAL: FEMALE GENITAL MUTILATION AND ADVERSE OBSTETRIC OUTCOMES AMONG PREGNANT WOMEN SEEN IN SELECT HOSPITALS IN FREETOWN, SIERRA LEONE (P266/04/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above research proposal. The approval period is 9th August 2021 – 8th August 2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
vii. Submission of an executive summary report within 90 days upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH- UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept.of Obstetrics and Gynaecology, UoN
Supervisors: Dr. Francis F.O. Odawa, Dept. of Obstetrics and Gynaecology, UoN
Prof. Patrick Muia Ndavi, Dept.of Obstetrics and Gynaecology, UoN

GOVERNMENT OF SIERRA LEONE
Office of the Sierra Leone Ethics and Scientific Review Committee
Directorate of Training and Research
5th Floor, Youyi Building Brookfields, Freetown
Ministry of Health and Sanitation

1st September, 2021

To: **Dr David Jalloh** (M.Med Student) **Principal Investigator**
Department of Obstetrics and Gynaecology
College of Health Sciences
University of Nairobi
Nairobi, Kenya
djalloh89@gmail.com

Study Title: **Female Genital Mutilation and Adverse Obstetric Outcomes Among Pregnant Women seen in Select Hospitals in Freetown, Sierra Leone**

Version: 1.0 of July, 2021

Submission Type: First protocol version submitted for review

Supervisor: **Dr Francis F O Odawa**
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Study Locations:

1. Princess Christian Maternity Hospital (PCMH)
2. Lumley Government Hospital (LGH)
3. Aberdeen Women Hospital (AWH)
4. Kingharman Road Government Hospital (KRGH)

Committee Action: Expedited Review

Approval Date: 01 September, 2021

The Sierra Leone Ethics and Scientific Review Committee (SLESRC) having conducted an expedited review of the above study protocol and determined that it presents minimal risk to subjects, **hereby grants ethical and scientific approval for it to be conducted in Sierra Leone.** The approval is valid for the period, **01 September, 2021 – 31 August, 2022.** It is your responsibility to obtain re-approval/extension for any on-going research prior to its expiration date. The request for re-approval/extension must be supported by a progress report.

For further enquiries please contact: efoday@mohs.gov.sl

GOVERNMENT OF SIERRA LEONE
Office of the Sierra Leone Ethics and Scientific Review Committee
Directorate of Training and Research
5th Floor, Youyi Building Brookfields, Freetown
Ministry of Health and Sanitation

Review Comments

- **Amendments:** Intended changes to the approved protocol such as the informed consent documents, study design, recruitment of participants and key study personnel, must be submitted for approval by the SLESRC prior to implementation.
- **Termination of the study:** When study procedures and data analyses are fully complete, please inform the SLESRC that you are terminating the study and submit a brief report covering the protocol activities. Individual identifying information should be destroyed unless there is sufficient justification to retain, approved by the SLESRC. All findings should be based on de-identified aggregate data and all published results in aggregate or group form. A copy of any publication be submitted to the SLESRC for its archive.

Professor Henry G. Morgan
Chair

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