

**FACTORS ASSOCIATED WITH OBSTETRIC FISTULA REPAIR FAILURE AMONG
WOMEN ADMITTED AT GYNOCARE WOMEN'S AND FISTULA HOSPITAL IN
KENYA, 2012-2016: A CASE CONTROL STUDY**

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A thesis submitted to the Institute of Tropical and Infectious Disease, College of Health Science in partial fulfilment of the requirements for the award of the master's degree in Medical Statistics of University of Nairobi.

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DECLARATION

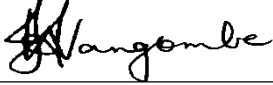
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DEDICATION

I dedicate this work to my wife Helen and children Susan and Nelson, for their immense support, devotion and understanding and to my parent Ms. Susan Mwangi, siblings: Nelson, Ann, Jane and Mary for their encouragement.

ABSTRACT

Background: Obstetric fistula is an abnormal hole that connects a woman's vagina and bladder or rectum or both leading to continuous leakage of urine and/or stool. It is estimated to affect about 2 million women in the world, with Kenya contributing about 3,000 incidences each year. Currently surgery is the main treatment option. However, surgical failure rate remains a major challenge.

Objective: The study aimed at determining factors associated with obstetric fistula repair failure at Gynocare Women's and Fistula Hospital in Kenya.

Methodology: A case control study design was adopted to investigate factors influencing the probability of fistula repair failure. Study population comprised of obstetric fistula patients who underwent fistula repair at Gynocare Women's and Fistula Hospital and repair outcomes at discharge known between January, 2012 to December, 2016 and a sample size of 357 (119 cases and 238 controls) was used. Simple random sampling was used to select the cases and controls using a computer generated random numbers. STATA 13 SE was used to code, clean and analyze data. For categorical variables frequencies and proportions were reported and presented in tables. Continuous variables were summarized using measures of central tendency (mean/median) and dispersion (standard deviation/inter-quantile range); summaries were presented in tables and distribution in histograms/box plots. Bivariate analysis was done to check for association between variables; Chi-square/Fisher's Exact test and Independent samples t-test/Mann-Whitney U test were used respectively for categorical versus categorical and categorical versus numerical variables. Logistic regression model was used to evaluate the adjusted odds ratio at alpha significance level of 0.05.

Results: On average age at development of fistula was 21 years (IQR 17, 28) but 30 years (IQR 21, 40) at the time of repair with an average fistula time period of 4.3years(IQR 06, 16.1). Study participants were mostly (62.2%) married with low or no formal education (90.1%) women. Delivery that led to fistula development occurred in the hospital for 85.2% of the study participants and 66.7% resulted into C/S. Only 1/3 (n = 120) had previous repair(s), while patients classified to have vesicovaginal fistula class IIA were 20.5%, class IIB were 35.0% and class III were 9.2%, the rest (35.3%) were classified as vesicovaginal fistula class I. The odds of failure were 2.9 times more among those with previous repair attempts compared to those with no previous repair attempts. Women with vesicovaginal fistula class IIB were 4 times more likely to develop failure. While women who attained at least secondary education level were 77% less likely to have fistula repair failure.

Conclusion: After controlling the effects of age, marital status, comorbidities, parity, time to repair, and post-operative complications: having not attained at least secondary education level, having previous repair attempts, and vesicovaginal fistula class IIB were found to be independent predictors of closure failure. Further studies required to investigate other factors not included in this study and probably extend the follow-up period beyond hospital discharge.

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ACRONYMS AND ABBREVIATIONS

C/S	- Caesarian Section
FIGO	– International Federation of Gynaecology and Obstetrics
GDP	- Gross Domestic Product
HMIS	- Health Management Information System
OF	– Obstetric Fistula
RVF	– Rectovaginal Fistula
SVD	- Spontaneous Vertex Delivery
TBA	- Traditional Birth Attendant
UNFPA	–United Nations Population Fund
VVF	– Vesicovaginal fistula
WHO	–World Health Organization

DEFINITION OF TERMS

Amenorrhoeic–Abnormal absence of menstruation

Necrosis–is a form of cell injury that results in the premature death of cells in living tissue

Obstetric fistula –Obstetric fistula is a medical condition in which a fistula (hole) develops either between the rectum and vagina (rectovaginal fistula) or between the bladder and vagina (vesicovaginal fistula).

Primiparous– Giving or having given birth for the first time

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Obstetric fistula has been defined as an abnormal hole that connects a woman's vagina and bladder or vagina and rectum through which urine and/or fecal matter leaks continuously (Lewis & Bernis 2007; Semere & Nour 2008; Delamou et al. 2016). The smell of urine and/or faeces that result, subject these women to isolation by their spouses, relatives and friends, subjecting them into poverty and depression (Wall 2006; Delamou et al. 2016).

Obstetric fistula is predominantly caused by obstructed labor that would take several days before the woman receives emergency obstetric care. In developing countries, it mainly affect the poor and marginalized women who are unable to access basic health care due to among other things, weak health systems and the three-delay model (Roka et al. 2013; Thaddeus & Maine 1994; Lewis & Bernis 2007; Delamou et al. 2016). Early marriages, hence becoming pregnant at tender age, harmful traditional practices like female genital mutilation, assault, and surgical trauma are other underlying causes of obstetric fistula (Mabeya 2004; Lewis & Bernis 2007; Harris & Garthwaite 2010).

There are two treatment options for obstetric fistula, that is, conservative and surgical intervention. Conservative treatment is spontaneous closure of defect (fistula) after catheterization or via use of fibrin-based glue injection (Harris & Garthwaite 2010). Conservative management is rarely used since it is only applicable to very small fistulas. Surgical treatment option is the most commonly adopted method of fistula treatment, and the closure rates vary from one center to another. The

rates of closure varies depending on: the denominator used to calculate the rate, fistula characteristic, surgeon expertise, repair technique, and post-op care among other factors.

Vesico-vainal fistula classification are as old as fistula surgery itself (Arrowsmith 2007), many researchers (Sims 1852; McConnachie 1958; Lawson 1968; Hamlin & Nicholson 1969; Waaldijk 1995; Goh 2004) have come up with different classification and almost all are based on description of anatomical locations and size. Currently there is no internationally acceptable classification of obstetric fistula. Therefore, since this study was based on review of records, we adopted the classification that was in use at the hospital. That is, Kees Waaldijk fistula classification, defined in details on appendix II.

1.2 Statement

It is estimated that about 2 million women in the world have obstetric fistula and majority of them living in Sub-Saharan Africa and South Asia (WHO 2014; UNFPA 2016; Mselle et al. 2011). In Kenya about 3,000 women develop obstetric fistula each year (Dworkin et al. 2016; Roka et al. 2013) with an estimated prevalence of 0.9% among women aged 15-49 years (Tunçalp et al. 2015) and only 7.5% have access to treatment and care (Dworkin et al. 2016).

Women play a big role in the socio-economy of our modern day society as they are pillars of families and contribute greatly to the country's GDP (Gross Domestic Product). However, when women develop obstetric fistula they are isolated, deprived of their dignity and become a burden in the society because they are unable to carry out their usual activities. If left untreated, obstetric fistula has a debilitating effect in a woman's life as in most cases its formation is more common

in young primigravida women starting or about to start a family (Semere & Nour 2008; Mselle et al. 2011).

Surgical repair is the mainstream treatment option, however the rates of failure of obstetric fistula repair have been reported to range between 5-20% (Dworkin et al. 2016) which correspond to a number between 150 and 600 per year who fail surgical repair. This yearly accumulation of women lead to a public health problem and it varies from one centre to another. This failure rate remains one of the challenges in management of obstetric fistula.

1.3 Justification

Studies have been done to investigate factors influencing the failure rate; but a number of them have not found significant result or have estimates with wide confidence interval perhaps due to the small sample size or their adopted study design. This study essentially used an elevated sample size and case control study design which had not been used in any of the reviewed literature.

Repeat surgery for a fistula that has not been closed represents an additional social and economic burden for the woman and fistula care programs as well as reduced likelihood of successful closure with subsequent repair attempts. Results from this study aim at ascertaining the non-randomness of the failure and identify some factors associated to it.

In addition, Gynocare hospital being the leading fistula referral hospital in Kenya, with the highest case load in the country and handles diverse cases the year round, the facility has recorded several episodes of failed repair. It's on this basis that this study sought to establish the factors influencing outcome of fistula repair among women who undergo repair at the hospital. The information obtained from this study can be used by the management of Gynocare and other fistula centers

across the country and at a global level to improve on the outcome of surgical repair of obstetric fistula. These findings can also be used for policy making on management of obstetric fistula and as a guide for further research.

1.4 Research Question

What are the factors associated with repair failure among women who underwent obstetric fistula repair at Gynocare Women's and Fistula Hospital in Kenya between January, 2012 and December, 2016?

1.5 General Objective

To determine factors associated with repair failure among women who underwent obstetric fistula repair at Gynocare Women's and Fistula Hospital in Kenya between the years 2012-2016.

1.6 Specific Objectives

1. To describe socio-demographic characteristics of women undergoing obstetric fistula repair at Gynocare Women's and Fistula Hospital with obstetric fistula.
2. To describe the obstetric characteristics of women undergoing obstetric fistula repair at Gynocare Women's and Fistula Hospital with obstetric fistula.
3. To evaluate the influence of obstetric and socio-demographic characteristics of women undergoing fistula repair on obstetric repair failure.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Obstetric fistula (OF) has been defined as a communication between vagina and rectum or between vagina and bladder. Which leaves the woman leaking urine, stool or both, and often leads to chronic medical problems, depression, social isolation and deepening poverty (UNFPA 2016). In most cases it results from prolonged obstructed labour, without access to timely, quality health care (UNFPA 2016; WHO 2014; Fistula foundation 2017). Other causes of vesicovaginal fistula are: trauma, sexual assault, malignancies, radiotherapy, and congenital anomalies (Harris & Garthwaite 2010).

About 2 million women lives with untreated fistula in Asia and Sub-saharan Africa, and each year about 50, 000 to 100, 000 women are affected by obstetric fistula worldwide (WHO 2014). Of this number about 15, 000 women receives fistula repair surgery per year, this means that, for every one women who receives surgical repair, 50 more women go without. Since many women who are affected by obstetric fistula are unable to access care, these figures may be an under estimate of the true burden. In their study, Semere & Nour (2008) found 1 million women to be affected by obstetric fistula in Nigeria alone. Maheu-Giroux et al. (2015) in their study found a lifetime prevalence of 3.0 cases (95% credible interval 1.3–5.5) per 1000 women of reproductive age. However the figure come down to 1.0 case (0.3–2.4) per 1000 women of reproductive age after they imputed missing data.

The sloughing of necrotic tissue results in a defect between organs, and these women experience uncontrolled leakage of urine and/or faeces.

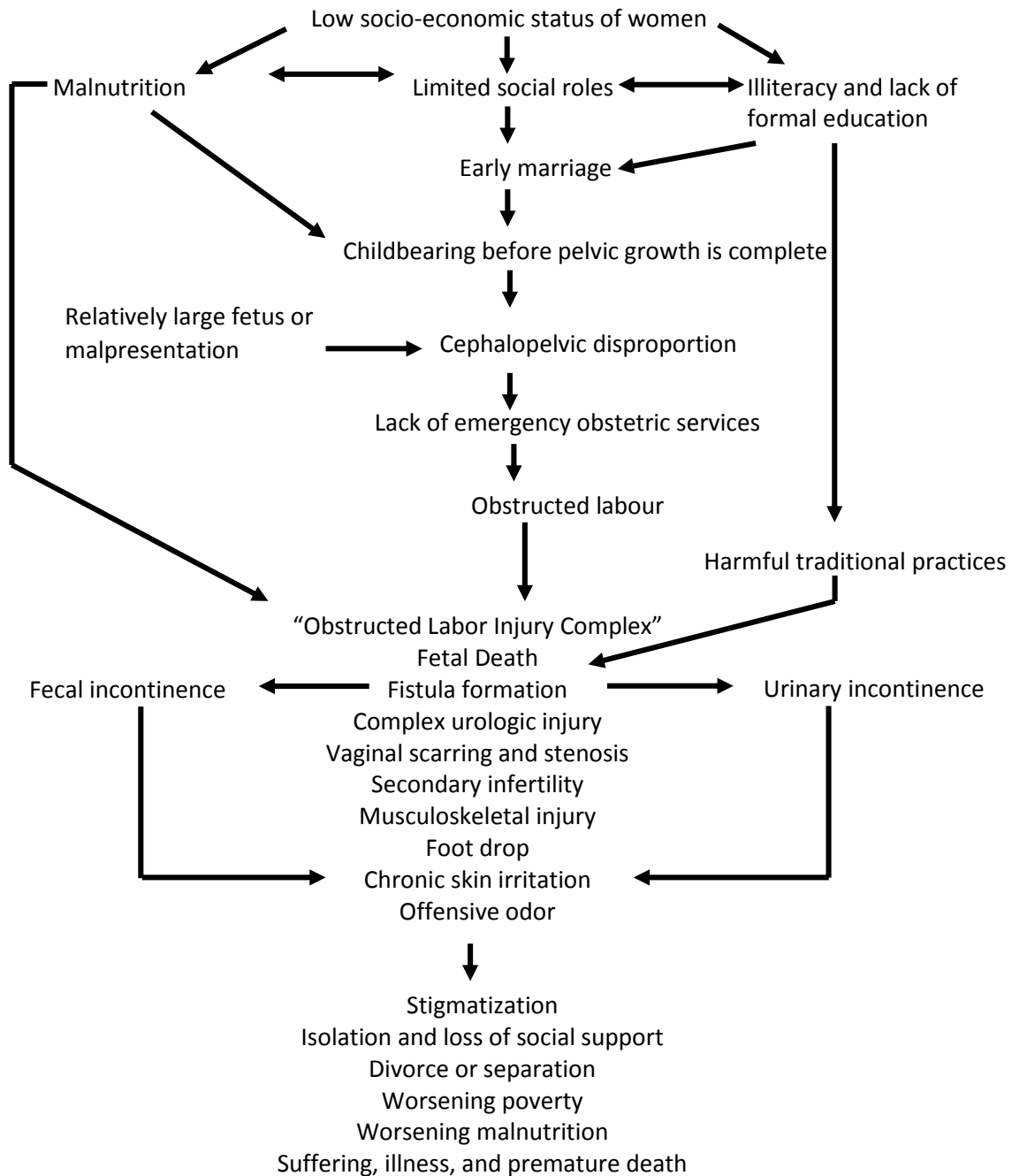
2.2 Etiology of Obstetric Fistula

Prolonged obstructed labor is estimated to account for 76% to 97% of obstetric fistula. As the fetus descends by uterine contractions, the foetal skull exact pressure on the soft tissue around the vagina and the bladder and/or rectum cutting off blood supply. Without access to emergency obstetric care, tissues damaged and ischaemic injury occur. As the necrotic tissues sloughs off it leaves a hole between bladder and vagina or between rectum and vagina (Wall 2006; Semere & Nour 2008). In addition to genital sores caused by the constant flow of urine, cervical injuries and nerve damage may result in infertility and foot-drop. General exhaustion and poor health also leave women unable to perform household tasks, thus reducing their value in the community (Lombard et al. 2015).

A complex interplay of socio-economic and biological factors are responsible for the higher prevalence of obstetric fistula in sub-Saharan Africa. For example, Cephalopelvic Disproportion (CPD) may be more likely due to narrow pelvic structure arising from individual biology, early childbearing or malnutrition (Wall 2006). In addition, lack of skilled attendance at birth and the 3 delays (delay in seeking help, delay in reaching health facility and delay in receiving high-quality emergency obstetric care) may increase risk of developing obstetric fistula (Tebeu et al. 2012; Lombard et al. 2015).

Wall et al. (2005) summarized in a pictorial form, the causes and effects of obstetric fistula and called it obstetric fistula pathway as shown below in figure 2.1.

Figure 2.1 The Obstetric Fistula Pathway: Origins and Consequences



Source: Wall et al. (2005) *The Obstetric Vesicovaginal Fistula in the developing world. Obstetrical & Gynecological Survey.*

2.3 Obstetric fistula patients' characteristic

According to Nour (2006) women affected by obstetric are usually young, primiparous, uneducated, poor, and unable to access quality obstetric care. Child marriage remain common in some countries, which puts young girls at high risk of premature childbearing and CPD (cephalopelvic disproportion), that increase risk of obstructed labor. For example in Ethiopia, about 25% of girls get married and give birth at the age of 18 years, in Uganda and Mali the proportions stood at 42% and 45% respectively (Semere & Nour 2008) .

According to Barone et al. (2012), almost all 70.7% (901/1274) of their study participants were healthy women with no other apparent medical conditions during admission. Many studies (Mcfadden et al. 2011; Kayondo et al. 2011; Goh et al. 2008; Barone et al. 2012; Munoz et al. 2012; Frajzyngier et al. 2012; Delamou et al. 2016) have shown that majority of women affected by obstetric fistula are usually married with limited education rural residents who relied on their partners for support financially. Their average age ranging from 24 – 35 years.

Among their study participants Barone et al. (2012), >1/4 were found to have had small bladder, and approximately 1/3 had some involvement of urethra, while 28.7%(363/1266) of fistulas were classified as simple. Delamou et al. (2016) in their study found lower 389(51.6%) proportion of women with intact urethra, while 44.4% (335) were reported to have had previous repair attempt.

According Munoz et al. (2012) the mean duration of leakage was found to be 9.6 with a range of 3 months – 28 years in Liberia and 33% had previous repair attempt with 10% having >1 previous repairs. The abdominal route of repair was done for 15% (6/40) while 34/40 (85%) underwent VVF repair through vaginal route.

In Ethiopia, the average time to repair from obstetric injury was found to be 48.5 months (range 1.5 – 600; mode = 3, median = 11 months). Where 18% had undergone caesarean section following obstructed labor, 51.6% (509/987) delivered at home, while 296 (30%) delivered spontaneously at a government institution. Only 6.7% (66/987) delivered live-born of which 12 died in the neonatal period (Goh et al. 2008).

In a study done in Uganda by Kayondo et al. (2011) 45% (33/65) of fistulas were classified as Type I according to Waaldijk classification with only 1 patient being classified to having Type III. Almost all 89.6% (69/77) women had VVF, 2 (6.5%) had both VVF and RVF, 2 (2.6%) had RVF while 1 (1.3%) had ureteral fistula.

A study in MTRH, Kenya by Mcfadden et al. (2011) found age at first pregnancy for women with fistula to be 10-19 years among 67% of the respondents with a mean of 18.5 years (SD 3.2), and a mean duration of incontinence of 2.8 years (SD 4.0) where most 29(35%) had lived with incontinence for 1-5 years. Mode of delivery at the development of fistula was 41(52%) where 73% (56) of the deliveries resulted in still birth. Most 70 (81%) of the repairs were done through transvaginal approach.

2.4 Management of Obstetric Fistula

Reconstructive surgery is main treatment option. Unfortunately, majority of women and girls affected by obstetric fistula often do not know treatment exist, cannot afford it or they cannot reach the facilities where the treatment it is available. Tragically, most girls and women living with obstetric fistula today will die before they get treated. Small vesicovaginal fistula can be managed

conservatively by spontaneous closure of defect during catheterization period or through injection of a fibrin-based glue into the fistula tract (Harris & Garthwaite 2010).

The goal of surgical repair is to restore normal function of the lower urinary tract and other pelvic structures (Frajzyngier et al. 2012). Although most fistulas are reparable, success depends on the severity and characteristics of the fistula, skills of the surgeon and surgical method used (Mselle et al. 2011). Despite successful repair, stress incontinence occurs in 16–32% of patients due to residual damage (Frajzyngier et al. 2012). Many women may remain amenorrhoeic, experience intrauterine and/or vaginal scarring and cervical damage that may be associated with pelvic inflammatory disease (Arrowsmith et al. 1996).

Due to social consequences of fistula, counselling and other forms of support – such as livelihood literacy, skills, job training and health education – may be necessary to help women reintegrate into their communities, rebuild their lives and regain their dignity and hope after they have been treated. In addition, follow-up usually help in ensuring they do not develop the injury again during subsequent births and helping to protect the survival and health of both mother and baby (UNFPA 2016).

Left untreated, obstetric fistula causes chronic incontinence and can lead to a range of other physical ailments, including frequent infections, kidney disease, painful sores and infertility. The physical injuries can also lead to social isolation and psychological harm: Women and girls with fistula are often unable to work, and many are abandoned by their husbands and families, and ostracized by their communities, driving them further into poverty (UNFPA 2016).

2.5 Outcome (rate of closure)

At 3 months post-repair Barone et al. (2012) found the overall fistula closure to be 81.7% (1041/1274; 95% CI: 79.5% - 83.7%), though it varied from 59.7 – 97.5% among the various sites. However, among women who had closed fistula about 20% had residual incontinence with a variation from 9.9 – 47.1%. However, in a study done in Guinea by Delamou et al. (2016), the rate of successful closure by the time patients were leaving the hospital was 85.5% (645/754) slightly higher than that of Barone et al. (2012), however overall 17.5% (132/754) were still leaking urine either continuously or from time to time. Of 646 (86.5%) women who had vvf, 87(13.5%) had unsuccessful repairs and 23 (3.5%) remained incontinent. Goh et al. (2008) in their study found success rate of fistula closure to be as high as 97.3% and urinary continence of 76.1%.

The rate of closure in a study done in Uganda was found to be 79.7% (55) among participants with VVF and 76.2% (42) had successful repair with continence (Kayondo et al. 2011). Mcfadden et al. (2011) in their study found incontinence rate of 37 (45%) before discharge from the hospital. In addition, septic surgical sites were reported in 10% of the patients and 6% reported urethral stenosis.

2.6 Factors associated with outcome of fistula repair

Barone et al. (2012) in their multi-country prospective cohort study found prior repair, urethral involvement and severe vaginal scarring predictors of incontinence at 3 month post-operation after controlling for other contextual, patients and fistula factors. Likewise, after adjusting for other fistula, contextual and patient factors only prior repair, small bladder size, urethral involvement and severe vaginal scarring were found to predict failure of fistula closure at 3 months post-operation. However a study by Delamou et al. (2016) found mean age at presentation, vaginal

scarring, mode of delivery and status of urethra to be statistically associated with fistula repair outcome. Though using multivariate analysis only status of urethral and mode of delivery were independently associated with outcome of fistula repair. Women who delivered vaginally had a higher chance of experiencing fistula repair failure (AOR: 1.9; 95% CI: 1.0-36) compared to those who delivered through caesarian section.

Though the choice of route of repair have been shown to be associated with surgeon experience, and urethra involvement. Munoz et al. (2012) found vaginal route of fistula repair to be associated with 1.42 (95% CI: 1.11-1.8) times higher chances of failure of fistula closure compared to abdominal route. Previous fistula repair attempts were found to be significantly associated with continent status, where those women with previous repair were less likely to be continent ($p=0.004$; AOR=0.07; 95% CI: 0.005, 0.83). In a study by Kayondo et al. (2011) in Uganda type IIB fistula and previous unsuccessful repair were found to be independently associated with successful repair with residual stress incontinence (OR 4.024, 95% CI 2.77 – 5.83) and (OR 38.69, 95% CI 2.13 – 703.88)

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study site

The study was carried out at Gynocare Women's and Fistula Hospital, which is located in Eldoret town, Uasin Gishu County. The hospital was established in June 2011 as a fistula surgery center with a bed capacity of 24 beds and by early 2014 over 1000 fistula surgeries had been performed at the center. In October 2014 the International Federation of Gynaecology and Obstetrics (FIGO) recognized Gynocare Fistula Centre as the first Fistula Training Center in Kenya. In October 2016, the hospital relocated to a bigger full-fledged Hospital with a bed capacity of 100 and modern equipment. To date the Hospital has performed over 1900 fistula surgeries. Gynocare was chosen purposely because it has the highest case load in the country and handles diverse cases the year round. Also it is the only specialized and leading fistula referral hospital in Kenya.

3.2 Study design

Hospital based case control study design was adopted to investigate factors associated with obstetric fistula surgical repair failure.

Cases comprised of obstetric fistula patients whom after surgery still had leaking fistula (failed closure) at the end of observation period (hospitalization period \cong 14 days). Controls comprised of obstetric fistula patients whom after corrective surgery had no leaking fistula (successful closure) at the end of observation period.

The study evaluated multiple exposures that included; co-morbidities, fistula classification (*see appendix 2 for classification*), number of previous fistula repair attempts, age, time from injury to repair, among others.

3.3 Study population

Obstetric fistula patients who underwent surgical repair at Gynocare Women's and Fistula Hospital and repair outcomes at the end of observation period (14 days) known between 2012 January to December 2016.

3.4 Sample size determination

Sample size was determined using the formula (Kelsey et al. 1986) for case control studies.

$$n \geq \frac{\bar{P}(1 - \bar{P}) \left(1 + \frac{1}{c}\right) (Z_{\alpha} + Z_{\beta})^2}{(P_1 - P_0)^2}$$

n is estimated minimum sample size for cases

$$\bar{P} = \{(P_1 + P_0)/(1 + C)\}$$

C is the ratio of controls to cases = 2:1

Z_α is the critical value at α-level of significance (Type I error (α) = 0.05; Z_{α/2} = 1.96)

Z_β is the critical value for the desired power (Type II error (β) = 0.2; Z_β=0.84)

P₁ is the proportion of exposure (Type IIB) among cases ($P_1 = (P_0 * OR) / [1 + P_0(OR-1)]$)

OR is the expected odds ratio (how many times exposure is expected to increase the risk of having closure failure) = 1.8

P₀ = Proportion of exposed among controls = 0.293 (based on a study done in a regional referral hospital in Mbarara, Western Uganda (Kayondo et al. 2011)).

Using the above formula, the minimum sample size was 357 (119 cases and 238 controls).

3.5 Sampling technique

A complete list of patients (with known repair outcomes) within the study period was extracted chronologically and serialized separately for cases and controls. Thereafter simple random sampling was used to select cases and controls using computer generated random numbers.

3.6 Recruitment criteria

3.6.1 Inclusion criteria

All VVF patients who underwent surgical repair at Gynocare Women & Fistula Hospital and repair outcomes at the end of observation period known between 1st January 2012 and 31st December 2016.

3.7 Data collection

A list of all women who underwent surgical repair of VVF was obtained from the hospital's Health Management Information System (HMIS) and recorded on a yearly basis. This was further separated into those who had successful and unsuccessful repair. Data was extracted from patients' records using a structured data extraction tool and stored in MS Access. Data collection was done during the month of October 2017.

3.8 Data management and analysis

3.8.1 Univariate analysis

Data was imported to STATA 13, coded, cleaned and analyzed. Categorical variables were tabulated in form of frequencies and proportions. Results were displayed in tables and bar graphs. For continuous variables (age, hospitalization period, parity, years with fistula, number of previous fistula repairs, catheterization period), data distribution was assessed by use of histogram and

Shapiro-Wilk W test. This was done to determine if the sample data was drawn from a normally distributed population, and therefore make decision on the statistical tests to use (whether parametric or non-parametric tests).

Shapiro-Wilk W test, tests the null hypothesis that a sample x_1, \dots, x_n came from a normally distributed population.

$$W = \frac{(\sum_{i=1}^n a_i x_{(i)})^2}{\sum_{i=1}^n (x_i - \bar{x})^2}$$

Where

$x_{(i)}$ (with parentheses enclosing the subscript index i) is the i th order statistic, i.e., the i th-smallest number in the sample.

$\bar{x} = (x_1 + \dots + x_n)/n$ is the sample mean;

the constants a_i are generated from the means, variances and covariances of the order statistics of a sample of size n from a normal distribution given by:

$$(a_1, \dots, a_n) = \frac{m^T V^{-1}}{(m^T V^{-1} V^{-1} m)^{1/2}}$$

Where

$$m = (m_1, \dots, m_n)^T$$

and m_1, \dots, m_n are the expected values of the order statistics of independent and identically distributed random variables sampled from the standard normal distribution, and V is the covariance matrix of those order statistics.

Thereafter measures of central tendency (mean/median) and dispersion (standard deviation/inter-quartile range) were used where appropriate; summaries were presented in tables and box plot.

3.8.2: Bivariate analysis

Bivariate analysis was carried out to check for association between variables; Chi-squares/Fisher's Exact tests and Independent samples t-test/Mann-Whitney U tests were used respectively for categorical versus categorical and categorical versus numerical variables.

Chi square test was used to test a null hypothesis that observed distribution of two categorical variables is not significantly different from the expected values and it is given by:

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

Where $E(\text{expected value}) = (C_T + R_T)/n$

O = observed value

To test the difference in means at the same point in time, Independent Samples t-test was used and it is given by:

$$t = \frac{\bar{x}_1 - \bar{x}_2}{SE_{(\bar{x}_1 - \bar{x}_2)}} = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{\left(\frac{1}{n_1} + \frac{1}{n_2}\right) \frac{(n_1-1)S_1^2 + (n_2-1)S_2^2}{n_1+n_2-2}}} \sim t(n_1 + n_2 - 2)$$

To test the difference in medians at the same point in time, Mann Whitney U test was used and it is given by:

$$U_2 = n_1 n_2 + \frac{n_i(n_i + 1)}{2} - R_i$$

3.8.3 Multivariate analysis

Logistic regression was used to measure association, predict outcome, and control for confounding variables effects. Predictors included in the model were those that had a p-value of ≤ 0.20 at bivariate level.

The final model was in form of:

$$\ln\left(\frac{p}{1-p}\right) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \dots + \beta_k X_k$$

$$y_2 = \begin{cases} 1 & \text{if failed fistula repair (cases)} \\ 2 & \text{if successful fistula repair (controls)} \end{cases}$$

$$P_i = P(y_i = 1)$$

Where:

- ❖ $\beta_1, \beta_2, \dots, \beta_k$ = partial regression coefficients
- ❖ X_1, X_2, \dots, X_k = predictors which included: fistula type, fistula classification, time taken from injury to surgery, age, education level, number of previous attempt, technique used, other comorbidities.
- ❖ P = probability of surgical repair failure
- ❖ $1 - P$ = probability of surgical repair success

Significant of model fit was assessed using likelihood ratio statistic by comparing fitted model to the null model, with following hypotheses:

H_0 : the null model is a better fit than the fitted model

H_1 : the fitted model is a better fit than the null model

Significance of predictors was assessed using confidence interval obtained for odds ratio by testing these hypotheses.

$$H_0 : O.R = 1 \text{ vs. } H_1 : O.R \neq 1$$

Given by:

$$e^{(\log(OR) \pm [1.96 \times SE(\log(OR))])}$$

$$\text{Where, } SE(\log(OR)) = \sqrt{\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}}$$

Effect modification was modelled by fitting interaction terms in logistic regression, if not significant the model was fitted without it, however where significant only interaction effect was interpreted and not the main effect.

All test statistics were done at alpha significance level of 0.05.

3.9 Quality Assurance

Supervisors reviewed the data collection tool and made their inputs where necessary. The data collection tool was developed through Access database with masking structures following the objectives. Data collection was done by the researcher himself to reduce inter observer bias.

3.10 Ethical considerations

The researcher sought and obtained ethical clearance to carry out the study from the Ethical Review Committee of Kenyatta National Hospital/University of Nairobi (KNH/UoN), and the Management of Gynocare Women's and Fistula Hospital. Waiver of consent from the patients was sought from the Ethical Review Committee (ERC).

CHAPTER FOUR

4.0 FINDINGS

PART A: DESCRIPTIVE ANALYSIS

4.1 INTRODUCTION

The results presented here are based on 119 cases (patients who had unsuccessful repair) and 238 control (patients with successful repair) giving a total of 314.

4.2 SOCIO-DEMOGRAPHIC CHARACTERISTICS

Table 1: Social demographic characteristic

Variable	Categories	Cases n(%)	Controls n(%)	Totals
Marital status (n=331)	Married	65 (56.5)	141 (65.3)	206(62.2)
	Single	26 (22.6)	47 (21.8)	73(22.1)
	Divorced/Separated	13 (11.3)	11 (5.1)	24(7.2)
	Widowed	11 (9.6)	17 (7.9)	28(8.5)
Education level (n=254)	None	43 (48.3)	46 (27.9)	89(35.0)
	Primary	42 (47.2)	98 (59.4)	140(55.1)
	Secondary/College	4 (4.5)	21 (14.5)	25(9.9)
Top five Counties of residence (n=288)	Kakamega	13 (11.02)	28 (12.44)	41(11.9)
	Busia	13 (11.02)	28 (12.44)	41(11.9)
	Migori	13 (11.02)	23 (10.22)	36(10.5)
	West pokot	15 (12.71)	18 (8.00)	33(9.6)
	Bungoma	8 (6.78)	24 (10.67)	32(9.3)
	Others	56 (47.46)	104 (46.22)	160(46.8)

Married women were more (65.3%) among the controls compared to cases (56.5%), however the proportion of single, divorced and separated was high among cases than controls. The proportion of those who had attained high education level (secondary and college) was higher (12.7%) among the controls than cases (4.5%). Apart from West Pokot and Bungoma counties that seemed to have a higher proportional difference in cases and control, the rest of the counties almost had the same proportions.

4.3 OBSTETRIC CHARACTERISTICS/HISTORY

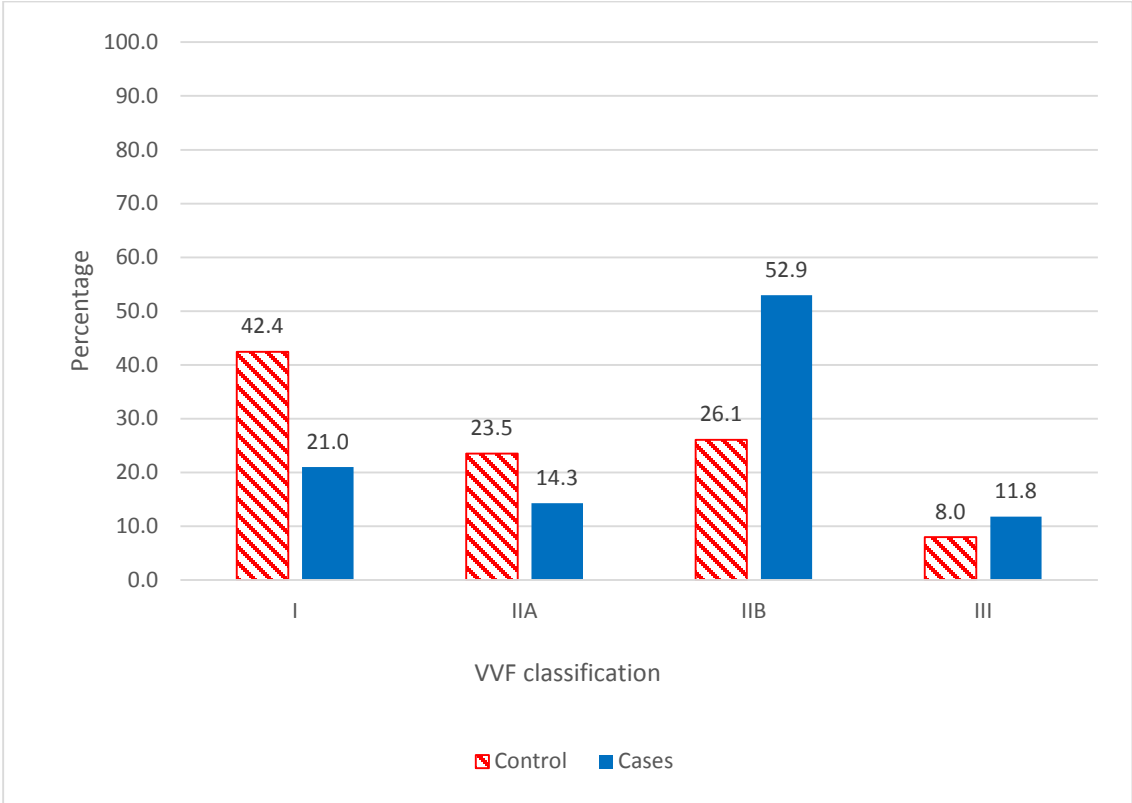
Table 2: Obstetric characteristics/history (A)

Variable	Categories	Control n (%)	Cases n (%)	Total
Presence of other comorbidities (n=357)	No	211 (88.7)	99 (83.2)	310(86.8)
	Yes	27 (11.3)	20 (16.8)	47(13.7)
Serology (HIV) status (n=357)	Negative	219(92.0)	101(84.9)	320(89.6)
	Positive	19(8.0)	18(15.1)	37(10.4)
Place of birth at development of fistula (n=351)	Hospital	203 (86.4)	96 (82.8)	299(85.2)
	Home	32 (13.6)	20 (17.2)	52(14.8)
Parity	1	111 (53.1)	54 (51.9)	165 (52.7)
	2	26 (12.4)	18 (17.3)	44 (14.1)
	3	16 (7.7)	14 (13.5)	30 (9.6)
	4-11	56 (26.8)	18 (17.3)	74 (23.6)
Type of delivery at development of fistula (n=351)	C/S	158 (67.0)	76 (66.1)	234(66.7)
	SVD	53 (22.5)	23 (20.0)	76(21.6)
	Assisted	25 (10.6)	16 (13.9)	41(11.7)
Previous repair attempts (n=357)	No	177 (74.4)	60 (50.4)	237(66.4)
	Yes	61 (25.6)	59 (49.6)	120(33.6)
Place of previous repair (n=99)	Private hospital	24 (50.0)	34 (66.7)	58(58.6)
	National hospital	9 (18.7)	6 (11.8)	15(15.2)
	County hospital	8 (16.7)	6 (11.8)	14(14.1)
	Faith based hospital	7 (14.6)	5 (9.8)	12(12.1)
VVF classification (n=357)	I	101 (42.4)	25 (21.0)	126(35.3)
	IIAa	56 (23.6)	17 (14.3)	73(20.5)
	IIBb	62 (26.0)	63 (52.9)	125(35.0)
	III	19 (8.0)	14 (11.8)	33(9.2)

Whether patients had other comorbidities, there was a difference of 5% among the control and cases. A higher proportion (86.4%) of control delivered at the hospital, while cases had a higher

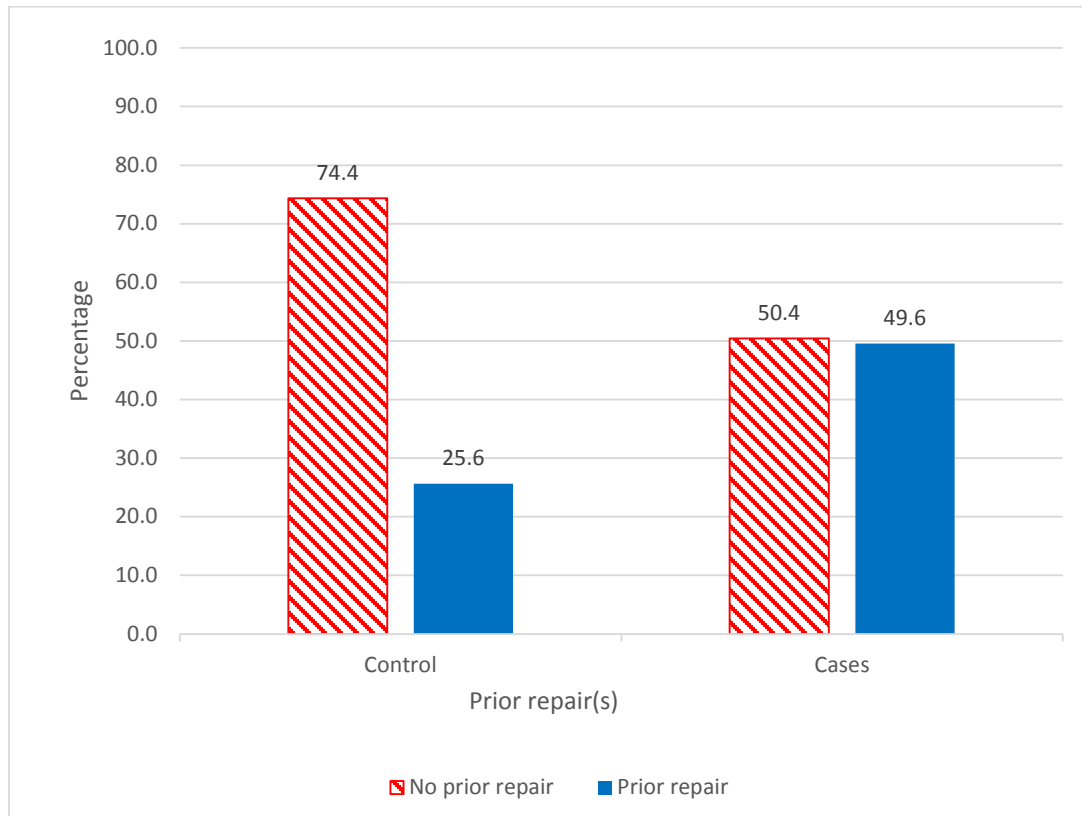
proportion (17.2%) of those who delivered at home compared to controls (13.6%). Types of delivery seemed to have almost equal proportions among control and cases. While only 25.6% of the control had prior repair(s) compared to 49.6% among the cases. In addition, proportion of those with VVF class IIB was high (53%) among cases than control (26%).

Figure 4.1: Distribution of VVF classification among cases and controls



The above figure shows the distinct difference in proportions among cases and control on each VVF classification.

Figure 4.2: Distribution of prior repair attempt among cases and controls



The above figure shows equal proportion of those who had prior repair and those who did not have prior repair among cases, however the proportions were not equal among the controls.

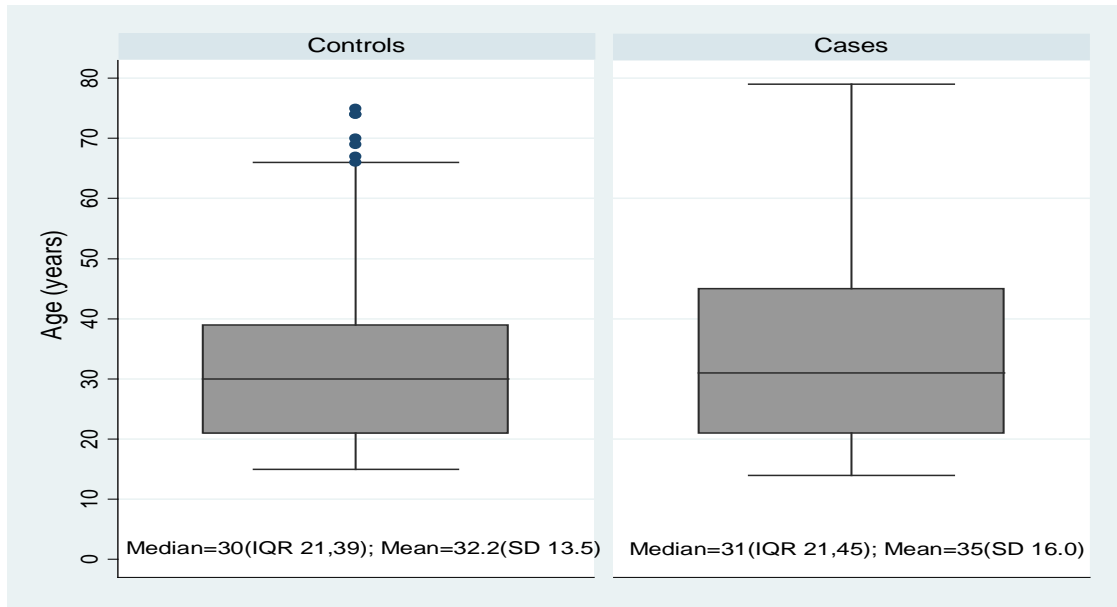
Table 3: Obstetric characteristics (B)

Variable		Shapiro-Wilk			
		Test(p-value)	Median(IQR)	Min	Max
Parity at development of fistula	Control (n=209)	0.878(<0.001)	1(1, 4)	0	11
	Cases (n=104)	0.791(<0.001)	1(1, 3)	1	11
	Overall	0.877(<0.001)	1(1, 3)	1	11
Age at repair	Controls (n=234)	0.908(<0.001)	30(21, 39)	15	75
	Cases (n=113)	0.904(<0.001)	31(21, 45)	14	79
	Overall	0.906(<0.001)	30(21, 40)	14	79
Years with fistula	Control (n=232)	0.791(<0.001)	3.8(.5, 15.8)	0.09	48.6
	Cases (n=115)	0.780(<0.001)	5.6(1.1, 17.1)	0.09	46.8
	Overall	0.789(<0.001)	4.3(0.6, 16.1)	0.08	48.6
Age at development of fistula	Control (n=230)	0.936(<0.001)	21(17, 29)	12	42
	Cases (n=109)	0.926(<0.001)	21(17, 27)	12	47
	Overall	0.935(<0.001)	21(17, 28)	12	47
Number of previous repair	Control (n=238)	0.808(<0.001)	0(0, 1)	0	6
	Cases (n=119)	0.863(<0.001)	0(0, 2)	0	7
	Overall	0.843(<0.001)	0(0, 1)	0	7

The distributions of parity at development of fistula, age at repair, years with fistula, age at development of fistula, and number of previous repairs were tested using Shapiro Wilk test and none of the 7 variables had data that assumed a normal distribution as shown in table 3 above. Therefore, median and interquartile range were reported instead of mean and standard deviation.

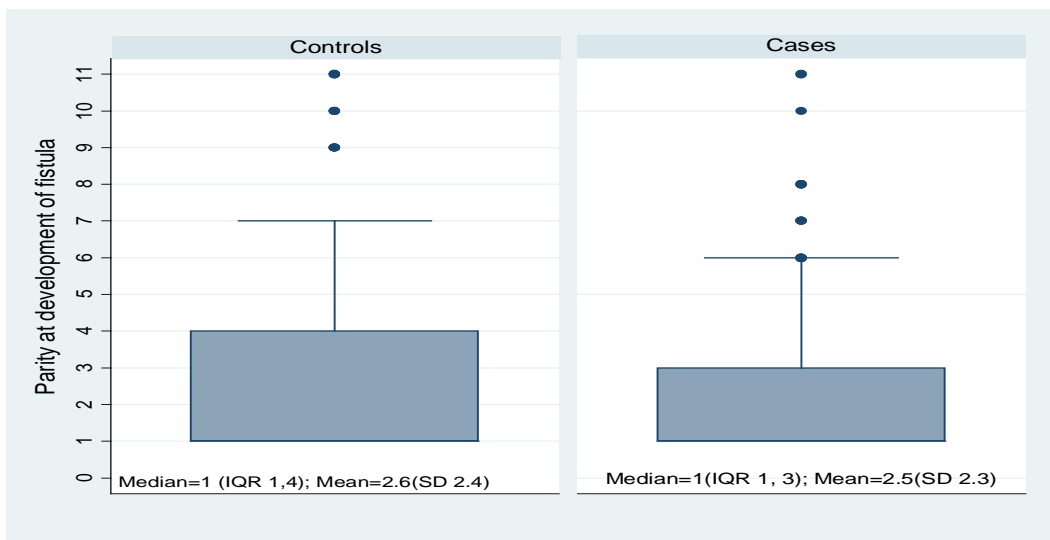
Women developed fistula during their 1st pregnancy, while at a tender age of 21 years on average for both controls and cases. However on average age at repair of fistula was 30 years for controls and 31 for cases with a longer average fistula period in cases of 5.6 years compared to control (3.8 years).

Figure 4.3: Distribution of age (in years) at time of repair



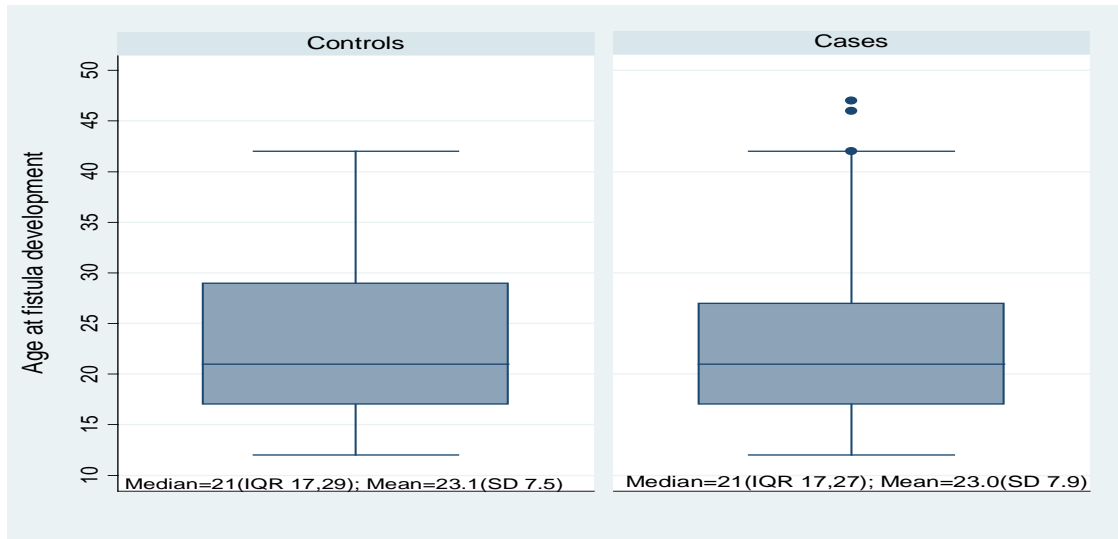
Though the average (median) age at the time of fistula repair was almost the same for control and cases, controls had ages that were more close to each other particularly for the 1st, 2nd, and 3rd quartile compared to cases.

Figure 4.4: Parity distribution at fistula development



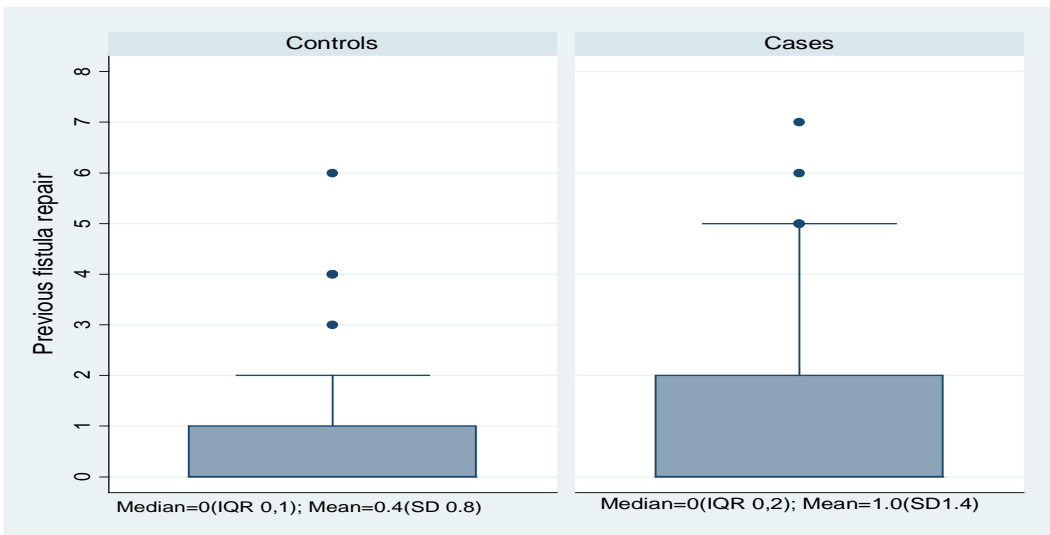
Majority of the patients had a parity of 1 which constituted the average for both controls and cases, however controls had values for the upper 50th quartile that more sparsely distributed compared to cases.

Figure 4.5: Distribution of age (in years) at fistula development



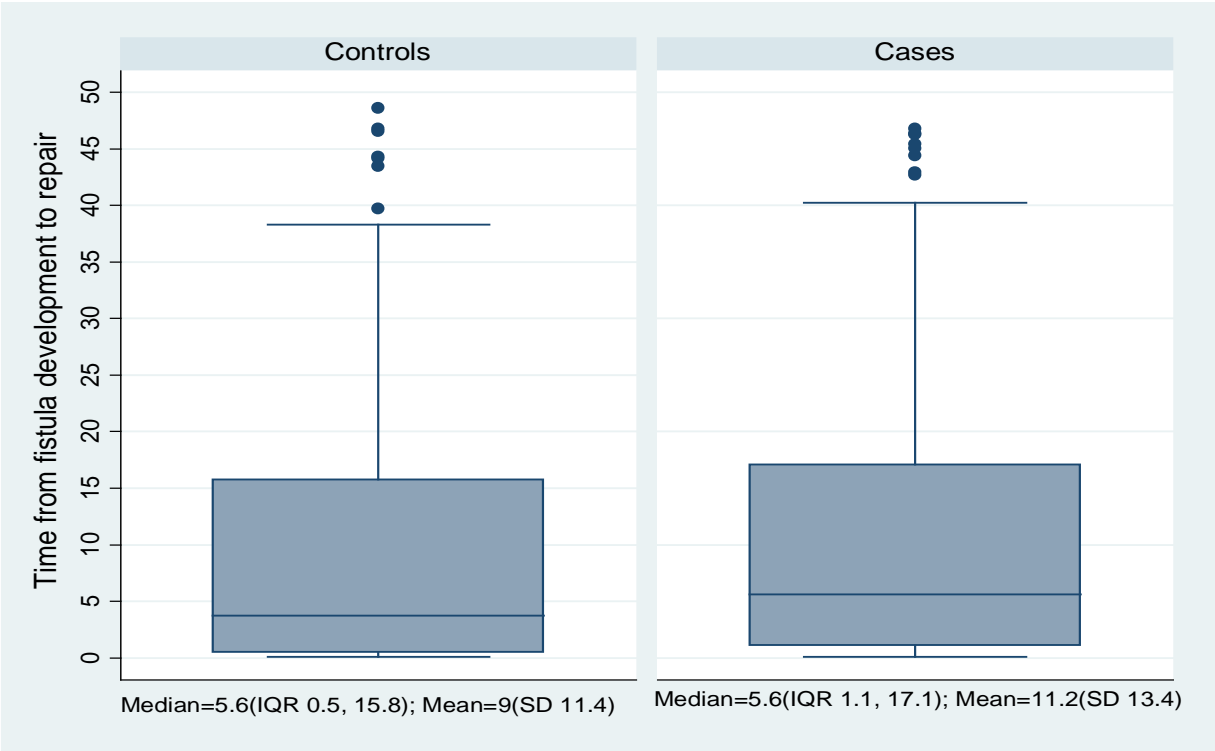
Both controls and cases had the same average age at fistula development. Distribution was skewed to the right with cases showing a number of outliers.

Figure 4.6: Distribution of number of previous repair attempts



Majority of the patients had no previous attempts hence the average was 0 for both controls and cases. However cases seemed to have more patients with more sparse data than controls where 7 was the highest number of previous attempts.

Figure 4.7: Distribution of time (in years) from fistula development to repair



The shortest time taken from fistula development to repair was 0.0877 years (32days) and a maximum of 48 years both in controls. On average controls took slightly shorter time than cases.

4.4 TREATMENT AND OUTCOME

Table 4: Treatment and outcome (A)

Variable	Categories	Controls	Cases	Total
		n(%)	n(%)	n(%)
Technique of repair(n=357)	Transvaginal	205 (86.13)	97 (81.51)	302(84.6)
	Transabdominal	33 (13.87)	22 (18.51)	55(15.4)
Post-op complication(n=357)	None	232 (97.48)	111 (93.28)	343(96.1)
	Infection	4 (1.68)	5 (4.20)	9(2.5)
	Hemorrhage	1 (0.42)	2 (1.68)	3(0.8)
	Others	1 (0.42)	1 (0.84)	2(0.6)

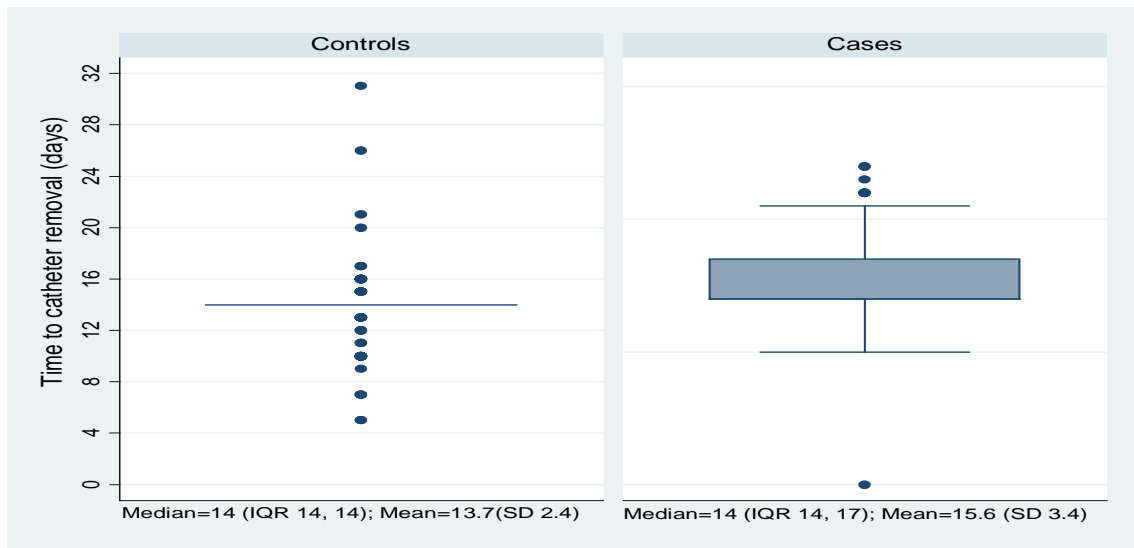
Transvaginal repair route was the most preferred compared to transabdominal in both controls and cases, most of the post-op complication captured was infections where cases had higher proportion (4.2%) compared to controls (1.7%).

Table 5: Treatment and outcome (B)

Variable	Category	Shapiro-Wilk			
		Test(p-value)	Median(IQR)	Min	Max
Time to removal of catheter	Control (n=238)	0.804(<0.001)	14(14, 14)	5	31
	Cases (n=119)	0.877(<0.001)	14(14, 17)	0	24
	Overall	0.872(<0.001)	14(14, 14)	0	31
Length of hospitalization	Control (n=238)	0.898(<0.001)	17(16, 20)	7	36
	Cases (n=119)	0.888(<0.001)	21(18, 25)	6	57
	Overall	0.899(<0.001)	18(16, 21)	6	57

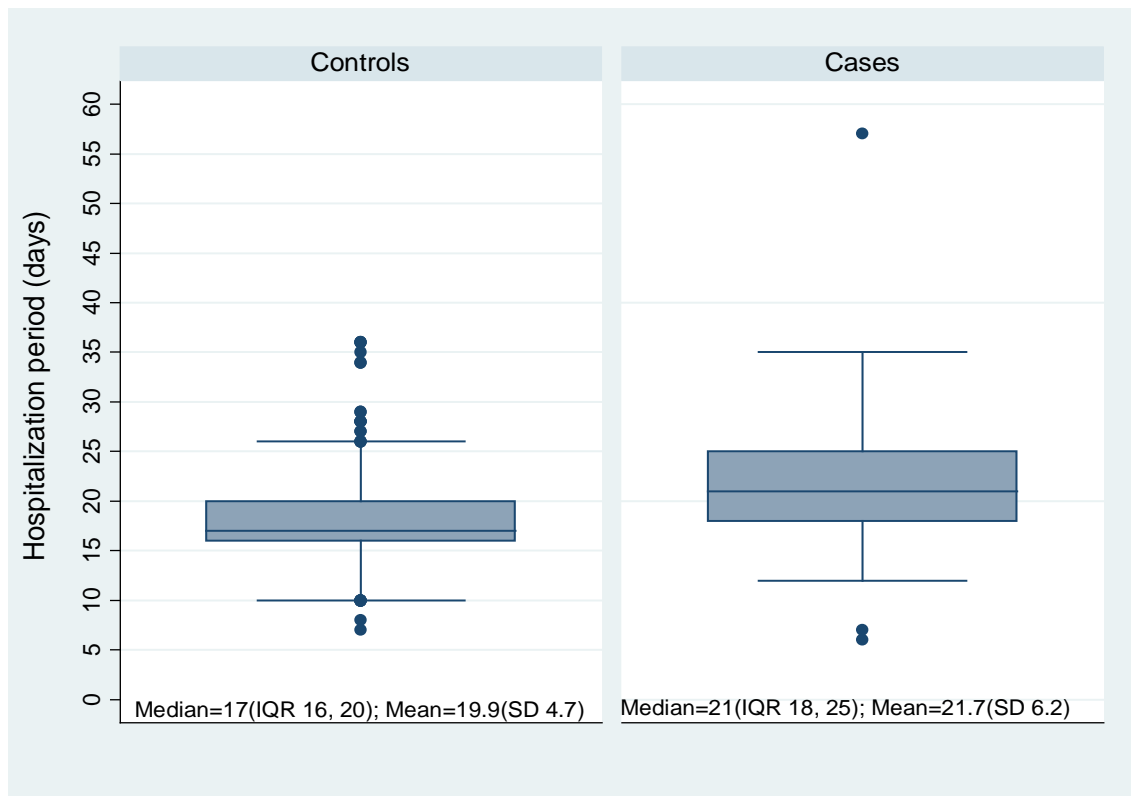
On average catheter was removed on day 14 post-operation for controls and cases, whereas the average length of hospitalization was 17 days for controls and 21 days for cases.

Figure 4.8: Distribution of catheterization period



The median period taken before catheter is removed was 14days (IQR 14, 14) for cases and controls, where minimum was 0 days and a maximum of 31 days. For controls, almost all patients had their catheter removed on 14th day any other day was an outlier.

Figure 4.9: Distribution of hospitalization period



Median hospitalization period was 17 days (IQR 16, 20) for controls and 21(IQR 18, 25) for cases.

PART B: BIVARIATE ANALYSIS

Table 6: Association between social demographic characteristic and treatment outcome

Variable	Categories	Cases n(%)	Controls n(%)	p-value
Marital status (n=331)	Married	65 (56.5)	141 (65.2)	0.158
	Single	26(22.6)	47(21.8)	
	Divorced/Separated	13(11.3)	11(5.1)	
	Widowed	11(9.6)	17(7.9)	
Education level (n=254)	None	43 (48.3)	46 (27.9)	0.002
	Primary	42 (47.2)	98 (59.4)	
	Secondary/College	4 (4.5)	21 (12.7)	
Top five Counties of residence (n=343)	Kakamega	13 (11.02)	28 (12.44)	0.642
	Busia	13 (11.02)	28 (12.44)	
	Migori	13 (11.02)	23 (10.22)	
	West pokot	15 (12.71)	18 (8.00)	
	Bungoma	8 (6.78)	24 (10.67)	
	Others	56 (47.46)	104 (46.22)	

Chi square test

Association between education level of patients and outcome of treatment was statistically significant ($\chi^2 (2) = 12.43, p=0.002$) where proportion of highly educated (secondary/college) was higher among the controls (12.7%) compared to cases (4.5%). Though not statistically significant, the proportion of married women was higher among control compared to cases but the proportions of single, divorced, and widowed were higher among cases than controls.

Table 7: Association between obstetric characteristics/history and outcome

Variable	Categories	Control n (%)	Cases n (%)	p-value
Presence of other comorbidities (n=357)	No	211 (88.7)	99 (83.2)	0.150
	Yes	27 (11.3)	20 (16.8)	
Place of birth at development of fistula (n=351)	Hospital	203 (86.4)	96 (82.8)	0.369
	Home	32 (13.6)	20 (17.2)	
Delivery mode at fistula development (n=351)	C/S	158 (67.0)	76 (66.1)	0.621
	SVD	53 (22.5)	23 (20.0)	
	Assisted	25 (10.6)	16 (13.9)	
Previous repair attempts (n=357)	No	177 (74.4)	60 (50.4)	<0.001
	Yes	61 (25.6)	59 (49.6)	
Place of previous repair (n=99)	Private hospital	24 (50.0)	34 (66.7)	0.415
	National hospital	9 (18.7)	6 (11.8)	
	County hospital	8 (16.7)	6 (11.8)	
	Faith based hospital	7 (14.6)	5 (9.8)	
VVF classification (n=357)	I	101 (42.4)	25 (21.0)	<0.001
	IIA	56(23.5)	17(14.3)	
	IIB	62(26.1)	63(52.9)	
	III	19 (8.0)	14 (11.8)	
Parity at development of fistula	1	111(53.1)	54(51.9)	0.099
	2 (low multipara)	26(12.4)	18(17.3)	
	3 (multipara)	16(7.7)	14(13.5)	
	4-11(grand multipara)	56(26.8)	18(17.3)	
Repair technique (n=357)	Transvaginal	205 (86.1)	97 (81.5)	0.254
	Transabdominal	32 (13.5)	20 (16.8)	
Post-op complication(n=357)	No	232 (97.5)	111 (93.3)	0.054
	Yes	6 (2.5)	8 (6.7)	

Chi square test

There was a significant association between having a previous repair attempt and outcome of repair $\chi^2 (1) = 20.39, p < 0.001$, where the proportion of those who had previous repair attempts was high (49.6%) among cases compared to among the controls (25.6%). In addition VVF classification was also found to be significantly associated with treatment outcome $\chi^2 (1) = 16.00, p < 0.001$.

Table 8: Association between obstetric characteristics and treatment outcome

Variable	Study groups	Median(IQR)	p-value
Age at repair	Controls (n=234)	30(21, 39)	0.178
	Cases (n=113)	31(21, 45)	
Years with fistula	Control (n=232)	3.8(.5, 15.8)	0.081
	Cases (n=115)	5.6(1.1, 17.1)	
Age at development of fistula	Control (n=230)	21(17, 29)	0.777
	Cases (n=109)	21(17, 27)	
Time to removal of catheter	Control (n=238)	14(14, 14)	<0.001
	Cases (n=119)	14(14, 17)	
Length of hospitalization	Control (n=238)	17(16, 20)	<0.001
	Cases (n=119)	21(18, 25)	

Wilcoxon rank-sum (Mann-Whitney U) test

On average cases took relatively longer time before repair (5.6, IQR 1.1, 17.1) compared to controls (3.8; IQR: 0.5, 15.8) although this difference in median time was not statistically significant. However cases took significantly longer time with catheter in situ and also longer time in the hospital before discharge ($p < 0.001$) compared to controls.

PART C: MULTIVARIATE ANALYSIS

Table 9: Association between factors/covariates and treatment outcome (fistula closure)

Factor	Category	Fistula closure (0=yes, 1=no)				
		Crude OR	p-value	95% CI	Adj OR	95% CI
Age at repair	Covariate	1.01	0.068	0.99, 1.02	0.98	0.92, 1.06
Marital status	Married	1			1	
	Single	1.20	0.525	0.68, 2.10	1.09	0.49, 2.42
	Divorced/separated	2.56	0.031	1.09, 6.02	1.68	0.56, 4.98
	Widowed	1.40	0.414	0.62, 3.16	0.48	0.08, 2.51
Education level	None	1			1	
	Primary	0.45	0.006	0.26, 0.79	0.49	0.23, 1.04
	Secondary +	0.20	0.007	0.06, 0.64	0.23	0.05, 0.99
Comorbidities	No	1			1	
	Yes	1.57	0.153	0.84, 2.95	0.89	0.31, 2.49
Parity	1	1			1	
	2 (low multipara)	1.42	0.312	0.71, 2.81	1.95	0.73, 5.22
	3 (multipara)	1.79	0.144	0.81, 3.95	3.19	0.85, 11.99
	4-11 (grand multipara)	0.66	0.192	0.35, 1.23	1.43	0.38, 5.38
Time to repair	Covariate	1.01	0.159	0.99, 1.03	1.01	0.94, 1.09
Previous repair attempts	No	1			1	
	Yes	2.85	0.000	1.79, 4.53	2.91	1.46, 5.80
Classification	I	1			1	
	IIA	1.22	0.566	0.61, 2.46	1.40	0.48, 4.06
	IIB	4.10	0.000	2.34, 7.19	4.08	1.74, 9.54
	III	2.97	0.009	1.31, 6.74	2.31	0.68, 7.88
Post-op complication	No	1			1	
	Yes	2.78	0.063	0.94, 8.22	2.12	0.39, 11.35

Model significance test LR Chi2 (13) = 44.15, p<0.001 (compared to a null model)

Education level, previous repair attempts and VVF classification were considered as the main factors. While age at repair, marital status, presence of comorbidities, parity, time to repair, and post-operative complications were used to adjust effect of the main factors on treatment outcome.

We tested if VVF classification was an effect modifier for previous repair attempts by fitting a model with interaction term between VVF classification and previous repair attempts. The interaction term was not significant ($p > 0.05$), hence the final model was fitted without the interaction term as shown in table 9. Reason for doing the interaction was logical, we suspected that, some VVF classification were severe hence are expected to have high failure rate.

After controlling the effects of other factor/covariate, having attained at least secondary education level, having previous repair attempts, and VVF class IIB were found to be significantly associated with closure failure ($p < 0.05$). However, a model with only education level as the main factor (i.e. excluding previous repair attempts and VVF classification) was found not to be significant (Log-likelihood = -130.6, LR chi2 = 17.5, p-value = 0.0622). But models with either previous repair attempts or VVF classification as the only main factor separately, were found to be significant with; Log-likelihood = -164.1, LR chi2 = 27.7, p-value = 0.0011 and Log-likelihood = -165.6, LR chi2 = 24.7, p-value = 0.0058 respectively.

Controlling for age at repair, marital status, education level, comorbidities, parity, time to repair, VVF classification and post-op complications women with previous repair attempts were 2.9 times more likely to have fistula closure failure compared to a woman who had no previous repair.

Women with VVF class IIB were 4 times more likely to develop closure failure compared to those classified to have VVF class I after adjusting for age at repair, marital status, education level, comorbidities, parity, time to repair, previous repair attempts, and post-op complications.

Adjusting for age at repair, marital status, comorbidities, parity, time to repair, previous repair attempts, VVF classification and post-op complications a woman who had attained at least secondary level of education was 78% less likely to have fistula closure failure compared to a woman who did not attend formal education.

CHAPTER FIVE

5.0 DISCUSSION

The findings on demographic characteristics of women with obstetric fistula in this study which includes; (73.5%) being under 40 years and (47.8%) between 14 – 29 years, and majority (90.2%) having no formal education/primary level education were consistence with other studies (Barone et al. 2012; Sjøveian et al. 2011; Delamou et al. 2016). However married women were majority with a minority indicating to have been divorced or separated. Though Delamou et al. (2016) found the same proportion (61%) to be married women, another study (Kayondo et al. 2011) found otherwise. We found, as others have, (Delamou et al. 2016; Munoz et al. 2012; Kayondo et al. 2011; Mcfadden et al. 2011) no relationship between demographic characteristics such as age, marital status and failure of fistula closure. However education level was found to be independently associated with outcome of fistula repair in our study.

This study adds on to the literature (Barone et al. 2012) evidence of no significant association between comorbidities and fistula closure failure. This could be an indication of independence of fistula repair outcome from other comorbidities, and gives equal grounds of successful repair regardless of the associated medical conditions. In addition our study found higher proportion of women who delivered in the hospital at the time of fistula development which mostly resulted into either Caesarian Section (C/S) or assisted delivery compared to Mcfadden et al. (2011) study. Though not confirmed, this would be because of long hours of labor at home or under the help of Traditional Birth Attendant (TBA) and only sought help at the health facility when Spontaneous Vertex Delivery (SVD) seemed impossible.

A third of the study population had at least 1 prior repair which was not successful, this is comparable to Munoz et al. (2012) study. Prior repair significantly predicted failure of fistula repair as supported by other studies (Sjøveian et al. 2011; Mcfadden et al. 2011; Barone et al. 2012; Munoz et al. 2012). Arguably this could be because of reduced viable tissues and scarring after the initial repair. Also interference with closing mechanism during repair could be a probable explanation.

Frajzyngier et al. (2012) found vaginal route of repair to be associated with an increased risk of failure of fistula closure, but in this study, no significant association was found between fistula closure and route of repair. However we found a significant association (not shown) between the route of repair and fistula classification, where fistulas not involving closing mechanism (III & I) were more likely to be repaired through abdominal route in comparison to those involving closing mechanism (II) which were more likely to be repaired through vaginal route. Consequently many studies (Sjøveian et al. 2011; Kayondo et al. 2011; Barone et al. 2012) have found evidence on the role of closing mechanism in predicting failure to closure after fistula repair of which our study adds on to this literature. This study found fistula classification II to significantly predict failure of fistula repair. Further analysis indicated that, compared to classification I, fistula classified as IIB (IIBa and IIBb) were there ones predicting closure failure).

CHAPTER SIX

6.0 CONCLUSIONS

Obstetric fistula formation majorly occurred in women with no/low education level, married, of tender age (12 – 23 years) and at their first pregnancy. Where majority delivered at a hospital through C/S.

Few (1/3 n = 120) had had previous repair, and the same proportion were classified as VVF class III, where the preferred route of repair was transvaginal for VVF class II & class I and transabdominal for VVF class III but almost all had the catheter removed on the 14th day post-operation.

Having not attained at least secondary education level, having previous repair attempts, and VVF class IIB were found to be independent predictors of fistula repair failure.

6.1 RECOMMENDATIONS

Caution should be made when women present for repair with VVF class IIB or previous repair attempt(s) as it was shown to be associated with high probability of failure. In addition, further studies needed to explore other factors that were not included in our study and probably consider longer follow-up periods since in this study repair success was assessed on discharge. There is need to improve on documentation at the hospital by probably adopting standardized medical forms.

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APPENDIX I

DATA COLLECTION TOOL

Social Demographic information

Serial number

1. Age of the patients (in)years
2. DoB (dd.mm.yyyy)
3. Marital status
 - a. Single
 - b. Married
 - c. Divorced
 - d. Separated
 - e. Widowed
4. Highest education level achieved
 - a. None
 - b. Primary
 - c. Secondary
 - d. Middle level college
 - e. University
5. County of residence

Obstetric history

6. Other comorbidities
 - a. No
 - b. Yes

If Yes (specify)
7. Parity at development of fistula
8. Current parity
9. Age at first birth years
10. Age at development of fistula years
11. Place of birth at development of fistula

- a. HomeHospital

12. Type of delivery at development of fistula

- a. SVD
- b. C/S

13. Time lapse from fistula development to repair years

14. Number of previous attempt of fistula repair

15. Place of previous repairs (name of the hospital).....

Fistula management

16. Date of admission (dd.mm.yyyy)

17. Date of surgery(dd.mm.yyyy)

18. Date of discharge(dd.mm.yyyy)

19. Fistula type

- a. Vesico vaginal fistula (VVF)
- b. Recto vaginal fistula (RVF)
- c. Both VVF & RVF

20. Classification of the fistula

- a. Type I
- b. Type IIAa
- c. Type IIAb
- d. Type IIBa
- e. Type IIBb
- f. Type III

21. Technique used to repair

- a. Transvaginal
- b. Transabdominal
- c. Others (specify).....

22. Post-op complications

- a. Infection
- b. Hemorrhage
- c. Need for re-operation before discharge
- d. Others (specify).....

23. Number of days to catheter removal after fistula repair days

24. At the time of catheter removal, was closure achieved?

- a. No
- b. Yes

25. At the time of catheter removal, was continence achieved?

- a. No
- b. Yes

26. Length of hospitalization days

APPENDIX II

FISTULA CLASSIFICATION BY KEES WAALDIJK




- **Type I** - fistulas not involving the urethral closing mechanism
- Type II - fistulas involving the urethral closing mechanism
 - A - without (sub)total urethra involvement
 - ❖ a - without a circumferential defect
 - ❖ b - with a circumferential defect
 - B - with (sub)total urethra involvement
 - ❖ a - without a circumferential defect
 - ❖ b - with a circumferential defect
- Type III - ureter and other exceptional fistulas.

Classification according to size

- Small < 2 cm
- Medium 2 – 3 cm
- Large 4 – 5 cm
- Extensive \geq 6 cm

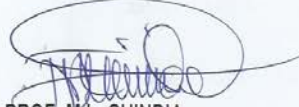
APPENDIX III

KNH/UON ERC APPROVAL LETTER

 <p>UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES P O BOX 19676 Code 00202 Telegrams: varsity Tel:(254-020) 2726300 Ext 44355</p>	 <p>18 OCT 2017 KNH/UoN ERC P.O. Box 20723-00202-NRB.</p>	 <p>KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202 Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi</p>
<p>Ref: KNH-ERC/A/312</p>	<p>KNH-UON ERC Email: uonknh_erc@uonbi.ac.ke Website: http://www.erc.uonbi.ac.ke Facebook: https://www.facebook.com/uonknh_erc Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC</p>	
<p>Henry Ruiru Mwangi Reg. No. W62/81286/2015 Institute of Tropical and Infectious Diseases (UNITID) College of Health Sciences University of Nairobi</p>	<p>18th October, 2017</p>	
<p>Dear Henry,</p>		
<p>REVISED RESEARCH PROPOSAL –DETERMINANTS OF OBSTETRIC FISTULA REPAIR FAILURE AMONG WOMEN ADMITTED AT GYNOCARE WOMEN AND FISTULA HOSPITAL IN KENYA (P334/06/2017)</p>		
<p>This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above proposal. The approval period is from 18th October 2017 –17th October 2018.</p>		
<p>This approval is subject to compliance with the following requirements:</p>		
<ul style="list-style-type: none">a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.c) 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.d) 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.e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (<i>Attach a comprehensive progress report to support the renewal</i>).f) Submission of an <i>executive summary</i> 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.		
<p>Protect to discover</p>		

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 Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chairperson, KNH-UoN ERC
The Director, Institute of Tropical and Infectious Diseases (UNITID), UoN
Supervisors: Ms. Ann Wang'ombe (UoN), Dr. Hillary Mabeya (Moi University),
Dr. Hillary Kipruto (WHO, Kenya)

Protect to discover

APPENDIX IV

STUDY SITE APPROVAL LETTER



GYNO CARE WOMENS & FISTULA HOSPITAL

Uganda ROAD KAHOYA (Mti Moja Opp. Kenya Pipeline Eld)

P.O Box 2326-30100
ELDORET, Kenya
Tel : 053-2062764
Mobile : 0708-576330

Website : [www.gynocare fistula center .org](http://www.gynocarefistulacenter.org)
Email : gynocarecenter@yahoo.com
hmabeya@yahoo.com
mabeya4@gmail.com

19th October 2017

Henry R Mwangi,
Institute of Tropical and Infectious Diseases (UNITID),
College of Health Sciences,
University of Nairobi,
P.O. Box 19676 – 00202,
Nairobi – Kenya.

Dear Henry

RE: APPROVAL TO CONDUCT RESEARCH AT GYNOCARE

Following approval from KNH/UoN Ethics & Research Committee (KNH-UoN ERC) to conduct your research titled:

“Factors associated with obstetric fistula repair failure among women admitted at Gynocare Women’s and Fistula Hospital in Kenya, 2012-2016: A case control study”

You are hereby permitted to carry out your research at Gynocare Women’s and Fistula Hospital.

DR. HILLARY MABEYA
CHIEF EXECUTIVE OFFICER
GYNO CARE WOMEN AND FISTULA HOSPITAL

