ABSTRACT

Objective: To determine the association between access to health care among pregnant women in Malawi and occurrence of obstetric vesicovaginal fistula (VVF).

Methods: This was a case-control study using data obtained from patients’ records documented by the ‘Fistula Care Center-Bwaila Hospital’ in Malawi. Socio-demographic characteristics of women with VVF (study arm, n=1046) and perineal tear (control arm, n=37) were examined. A composite variable called “Malawi Healthcare Access Index” (MHAI) was created through summation of scores related to three factors of access to care: (1) walking distance to closest health center; (2) presence of trained provider at delivery; and (3) receipt of antenatal care. Binomial logistic regression models were built to determine the association between the MHAI and presence of VVF.

Results: Obstetric VVF was more common in women from rural areas, mothers delivering at extremes of age, those with less education, and patients with long labor (>12 hours). In adjusted models, women with “insufficient” health access based on the MHAI were at greater risk (OR = 2.64, 95%CI = 1.07 – 6.03) of obstetric VVF than women with “sufficient” score on the MHAI.

Conclusion and Global Health Implications: Inadequate access to essential obstetric care increases the risk of VVF.

Key words: • Health care index • Obstetric complications • Vesicovaginal fistula • Poverty • Malawi • Malawi Healthcare Access Index

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1. Introduction

1.1. Background of the Study

Obstetric vesicovaginal fistula (VVF) is a devastating outcome of childbirth which occurs almost exclusively in women living in extreme poverty in developing countries.\(^1\)

Eradicated in industrialized nations, obstetric VVF results from failure to provide women with adequate access to obstetric health services and, most essentially, safe cesarean delivery. Obstructed labor, or when there is failure of delivery to occur in a normal time period, is thought to occur in about four percent of births worldwide, impacting over six million women annually with the vast majority of cases occurring in developing countries.\(^2\) For those women surviving the labor, one of the worst long-term consequences is the development of a VVF.

Obstetric VVF is a condition in which a connection occurs between the vagina and the bladder resulting in uncontrolled leakage of urine.\(^3\) It is most frequently caused by obstructed labor when prolonged fetal head compression leads to ischemia of tissues of the vagina and the urinary tract which eventually sloughs off creating a “hole” in the vagina and bladder.\(^4,5\) This abnormal connection causes continuous leakage of urine from the vagina, which frequently sets off a downward social and economic spiral. These extremely vulnerable women, often at the extremes of reproductive age, usually suffer the devastating outcome of stillbirth during the delivery in addition to fistula formation.\(^6\) The combination of continuous odor from uncontrolled urine and loss of a child leads to stigma, powerlessness, isolation, and often ultimately results in total abandonment of a woman by her spouse, family and community.\(^6,7\) It is estimated that well over 2 million women suffer from untreated obstetric fistulas in Asia and sub-Saharan Africa, with 50,000-100,000 new cases occurring annually.\(^8\)

In Malawi, the prevalence of fistula is estimated to be 1.6 per 1000 women.\(^9\) Though 85-95% of obstetric fistulas are correctable through surgical repair, access to centers of treatment is limited, requires extended hospital stays and staff with advanced training.\(^10-12\) While efforts to repair those affected are being made, prevention of new cases is required to eradicate fistula. As the development of functional health systems capable of providing quality maternity care including widespread access to cesarean delivery in developing countries is decades away at best, interim solutions must be sought through targeting of modifiable risk factors.

Moreover, commonly discussed risk factors for development of obstetric fistula include delivery outside of a health center, absence of skilled birthing attendant, prolonged duration of labor, early age at time of marriage, and lack of prenatal care.\(^13-15\) However, risk factors vary significantly by country and patient population.

This study sought to identify risk factors for development of obstetric fistula for women seeking care for fistula in Lilongwe, Malawi, in hopes of assisting in the development of effective prevention strategies for this patient population.

2. Methods

2.1. Study Variables

This was a case-control study using data obtained from patient records at the Fistula Care Center at Bwaila Hospital in Malawi, a facility which primarily serves fistula patients but which also attends to patients with some other more common complications of labor, including perineal tears. The Fistula Care Center patient record database was created to capture information on patients with reported urine leakage associated with pregnancy or childbirth. Those with leakage arising from VVF underwent one or more fistula closures or repair surgeries. The database contains patient demographic information, their past medical and social histories, information from a physical examination conducted by a doctor at the hospital, pre-operative, operative and post-operative notes and the information from up to three follow-ups that were conducted after surgery.

2.2. Statistical Analysis

We limited our analysis to women with VVF (study arm) and those with perineal tear only (control arm). Patients with perineal tear were used as the
control group as the occurrence of perineal tear was presumed not to be dependent on healthcare access. Women with both conditions were excluded from the study. The exposure of interest was access to health care and the primary outcome (or cases) was VVF. Access to health care was defined as a composite variable using the following three indicators: (1) number of hours of walking to the hospital; (2) person assisting the delivery; and (3) receipt of antenatal care. Number of hours of walking to the hospital was categorized into: (i) ≤4 hours; (ii) >4 hours; or (iii) missing. Person assisting the delivery was categorized into: (i) formally trained professionals like doctors, nurses, midwives; (ii) untrained individuals like relatives or traditional birth attendants; or (iii) missing. Receipt of antenatal care was classified as (i) yes; (ii) no; and (iii) missing. A missing value was assigned a score of 0 regardless of the variable; a score of 1, which indicated limited access, was assigned to the following: > 4 hours of walking to hospital; person other than doctors, nurses or midwives assisting the delivery and no access to antenatal care; and 2 for the best access to health care: <= 4 hours of walking to hospital; doctor, nurse or midwife assisting the delivery and access to antenatal care.

We then created a composite variable called ‘Malawi Healthcare Access Index’ (MHAI) by summing the scores. The least possible score was a 0 for all missing values and the highest possible score was a 6, which denotes the best possible access to health care. A variable called ‘MHAI grade’ was created and a score of 4 or less was graded as ‘Insufficient’ category, which designated inadequate access to health care while a score of greater than four was designated as ‘Sufficient’ grade, which designated adequate access to health care. The indexing and grading was performed after removing records with missing information in any of the three exposure variables from the dataset.

We compared women who had VVF with women who had perineal tear based on socio-demographic and behavioral characteristics that included age, country, tribe, religion, place of residence, living arrangement, education, marital status, roof type of the house they lived in, occupation, HIV status, smoking, and alcohol consumption. Prevalence estimates for each socio-demographic and behavioral characteristic were computed and compared between cases (VVF) and control (perineal tear). We then conducted a similar bivariate comparison based on factors related to delivery that caused the leakage. These factors were maternal age at delivery, type of delivery (i.e. cesarean or vaginal), length of labor, intended place of delivery when the labor began, actual place of delivery, duration between labor onset and arrival at the hospital, number of hours of walking to the hospital, person attending the labor, person assisting the delivery, if the uterus was removed, condition of baby (i.e. alive or stillborn), and receipt of antenatal care. Pearson’s chi-square tests were conducted to detect differences between the strata of women (VVF vs. perineal tear) with respect to socio-demographic factors and factors related to delivery that was associated with the leakage. For variables containing more than 25% of the expected cell values of less than 5, we conducted Fisher’s exact test instead of Pearson’s chi-squared test.

We created an adjusted binomial logistic regression model to assess the association between MHAI grade and presence of VVF, with the reference group being women with perineal tear while adjusting for maternal place of residence, age, and marital status. All tests of hypothesis were two-tailed with a type I-error rate at 5%. All statistical analyses were performed using R (version 3.5.1) and RStudio (Version 1.1.423).16

2.3. Ethical Approval
The Malawian National Health Science and Research Committee (CID 1116 Protocol number 929), and Institutional Review Board of Baylor College of Medicine (H37617) approved this study.

3. Results
3.1. Sociodemographic Characteristics
A total of 2,268 women were entered into the patient database from 2011 to 2019. After limiting our data to women with either VVF or perineal tear, and removal of the records with missing values, we were left with a total of 1,083 records. Among these, 1,046 (96.6%) women had a VVF occurring at the time of a delivery and 37 (3.4%) women had a
### Table 1: Comparison of selected socio-demographic characteristics of women hospitalized for VVF (vesicovaginal fistula) versus those with perineal tear

| Socio Demographic Factors | Perineal Tear | VVF Because of Delivery | p-value |
|---------------------------|---------------|-------------------------|---------|
|                           | Count | Percentage | Count | Percentage |         |
|                           | n=37   | %=3.4       | n=1046 | %=96.6     |         |
| **Age group**             |       |             |         |            | 0.0902  |
| <20 years                 | 2     | 5.4         | 97     | 9.3        |         |
| 20-29 years               | 12    | 32.4        | 295    | 28.2       |         |
| 30-39 years               | 16    | 43.2        | 290    | 27.7       |         |
| >=40 years                | 7     | 18.9        | 364    | 34.8       |         |
| **Country**               |       |             |         |            | 0.0037* |
| Malawi                    | 27    | 73.0        | 682    | 65.2       |         |
| Mozambique                | 0     | 0.0         | 139    | 13.3       |         |
| Zambia                    | 0     | 0.0         | 2      | 0.2        |         |
| Don’t know/Missing        | 10    | 27.0        | 169    | 16.2       |         |
| **Tribe**                 |       |             |         |            | 0.1260* |
| Yao                       | 1     | 2.7         | 131    | 12.5       |         |
| Chewa                     | 27    | 73.0        | 568    | 54.3       |         |
| Lomwe                     | 2     | 5.4         | 106    | 10.1       |         |
| Tumbuka                   | 2     | 5.4         | 124    | 11.9       |         |
| Others                    | 5     | 13.5        | 109    | 10.4       |         |
| Don’t know/Missing        | 0     | 0.0         | 8      | 0.8        |         |
| **Religion**              |       |             |         |            | 0.3200  |
| Christian                 | 35    | 94.6        | 871    | 83.3       |         |
| Muslim or others          | 2     | 5.4         | 143    | 13.7       |         |
| Don’t know/Missing        | 0     | 0.0         | 32     | 3.1        |         |
| **Residence**             |       |             |         |            | < 0.0001* |
| Urban                     | 9     | 24.3        | 14     | 1.3        |         |
| Rural                     | 28    | 75.7        | 1031   | 98.6       |         |
| Don’t know/Missing        | 0     | 0.0         | 1      | 0.1        |         |
| **Living arrangement**    |       |             |         |            | 0.0886* |
| Living alone              | 3     | 8.1         | 158    | 15.1       |         |
| Living with husband       | 31    | 83.8        | 673    | 64.3       |         |
| Living with family/friend | 3     | 8.1         | 214    | 20.5       |         |
| Don’t know/Missing        | 0     | 0.0         | 1      | 0.1        |         |
| **Education**             |       |             |         |            | < 0.0001 |
| Less than secondary       | 24    | 64.9        | 929    | 88.8       |         |
| Secondary or more         | 13    | 35.1        | 115    | 11.0       |         |
| Don’t know/Missing        | 0     | 0.0         | 2      | 0.2        |         |
| **Marital Status**        |       |             |         |            | 0.0025* |
| Single/never married      | 2     | 5.4         | 14     | 1.3        |         |
| Married                   | 31    | 83.8        | 684    | 65.4       |         |
| Separated/divorced/widowed| 4     | 10.8        | 348    | 33.3       |         |

(Contd....)
There were 9 women who had both perineal tear and VVF and were excluded from the analysis. Table 1 summarizes results of comparison with respect to socio-demographic characteristics between women who developed VVF versus those with perineal tear. The vast majority (98.6%) of women with VVF were from rural areas, versus 75.7% in the control group. VVF patients were less likely to be married than the perineal tear group (65.4% vs 83.8%), and were more likely to live in a house with a grass or no roof as opposed to metal, wood, cement roof (79.5% vs 56.8%). Over 91.3% of VVF patients were peasant farmers compared to 54.1% of control subjects. Nearly 90% of women with VVF had less than secondary education, contrasting with 65.4% of controls. About 6.3% of women with VVF were HIV positive compared with 10.8% of women with perineal tear.

Table 2 shows factors related to the delivery resulting in urinary leakage or perineal tear. VVF occurred in deliveries at extremes of reproductive age (<20, and over 40) over 55% of the time, while perineal tear occurred at these ages approximately 24% of the time. Women with VVF ended up requiring a cesarean section 43.4% of the time versus 8% of the time in the reference group. Over 70% of the women with VVF had labor that lasted more than 12 hours compared with 57% of women with perineal tear. More women in the VVF group than the reference

| Socio Demographic Factors | Perineal Tear | VVF Because of Delivery |
|---------------------------|--------------|-------------------------|
|                           | Count | Percentage | Count | Percentage | p-value |
| Roof Type                 |       |            |       |            |         |
| Grass/none                | 21    | 56.8       | 832   | 79.5       |         |
| Metal/wood/cement         | 16    | 43.2       | 214   | 20.5       |         |
| Occupation                |       |            |       |            | < 0.0001* |
| Peasant farmer            | 20    | 54.1       | 955   | 91.3       |         |
| Commercial farmer         | 0     | 0.0        | 3     | 0.3        |         |
| Student/pupil             | 0     | 0.0        | 9     | 0.9        |         |
| Unemployed                | 1     | 2.7        | 9     | 0.9        |         |
| Civil servant/teacher     | 3     | 8.1        | 1     | 0.1        |         |
| Housewife/caretaker       | 9     | 24.3       | 13    | 1.2        |         |
| Small business owner      | 4     | 10.8       | 52    | 5.0        |         |
| Casual laborer            | 0     | 0.0        | 3     | 0.3        |         |
| Don’t know/Missing        | 0     | 0.0        | 1     | 0.1        |         |
| HIV Status                |       |            |       |            | 0.0789  |
| Yes                       | 4     | 10.8       | 66    | 6.3        |         |
| No                        | 33    | 89.2       | 899   | 85.9       |         |
| Don’t know/Missing        | 0     | 0.0        | 81    | 7.7        |         |
| Smoking                   |       |            |       |            | 0.3730* |
| Yes                       | 0     | 0.0        | 28    | 2.7        |         |
| No                        | 37    | 100.0      | 1018  | 97.3       |         |
| Alcohol                   |       |            |       |            | 0.4170* |
| Yes                       | 0     | 0.0        | 44    | 4.2        |         |
| No                        | 37    | 100.0      | 1001  | 95.7       |         |
| Don’t know/Missing        | 1     | 2.7        | 1     | 0.1        |         |

*represents p-values from Fisher’s exact test. Otherwise p-values are obtained from Pearson’s chi-square test.
Table 2: Demographic data for factors related to the delivery leading to vesicovaginal fistula (VVF) or perineal tear

| Factors Associated with delivery that caused leakage | Perineal Tear | VVF Because of Delivery | p-value |
|-----------------------------------------------------|---------------|-------------------------|---------|
|                                                     | Count | Percentage | Count | Percentage |         |
|                                                     | n=37   | %=3.4 | n=1046 | %=96.6 |
| Age at delivery that caused leakage                 |       |        |        |          |
| <20 years                                           | 7     | 18.9  | 230    | 22.0     | <0.0001 |
| 20-29 years                                         | 15    | 40.5  | 246    | 23.5     |         |
| 30-39 years                                         | 11    | 29.7  | 124    | 11.9     |         |
| >=40 years                                          | 2     | 5.4   | 341    | 32.6     |         |
| Don't know/Missing                                  | 2     | 5.4   | 105    | 10.0     |         |
| Type of delivery                                    |       |        |        |          |
| Vaginal                                             | 3     | 8.1   | 589    | 56.3     | <0.0001*|
| Cesarean section                                    | 34    | 91.9  | 454    | 43.4     |         |
| Missing                                             | 0     | 0.0   | 3      | 0.3      |         |
| Length of labor                                     |       |        |        |          |
| <=12 hours                                          | 16    | 43.2  | 309    | 29.5     | 0.0188* |
| >12 hours                                           | 21    | 56.8  | 734    | 70.2     |         |
| Missing                                             | 0     | 0.0   | 3      | 0.3      |         |
| Place of delivery                                   |       |        |        |          |
| Central hospital                                    | 2     | 5.4   | 67     | 6.4      | <0.0001 |
| District/Mission/Private hospital                   | 17    | 45.9  | 690    | 66.0     |         |
| Health center                                       | 10    | 27.0  | 156    | 14.9     |         |
| Home/TBA                                           | 8     | 21.6  | 122    | 11.7     |         |
| Other                                               | 0     | 0.0   | 1      | 1.1      |         |
| Duration between labor onset and hospital arrival   |       |        |        |          |
| <=5 hours                                           | 22    | 59.5  | 622    | 59.5     | 0.5090  |
| >5 hours                                            | 7     | 18.9  | 280    | 26.8     |         |
| Missing                                             | 8     | 21.6  | 144    | 13.8     |         |
| Number of hours of walking to the hospital          |       |        |        |          |
| <=4 hours                                           | 32    | 86.5  | 905    | 86.5     | <0.0001 |
| >4 hours                                            | 5     | 13.5  | 141    | 13.5     |         |
| Place of intended delivery when labor began         |       |        |        |          |
| Central/District/Mission/Private hospital            | 15    | 40.5  | 319    | 30.5     | 0.1940  |
| Others                                              | 22    | 59.5  | 727    | 69.5     |         |
| Person attending the labor                          |       |        |        |          |
| MO/CO                                               | 0     | 0.0   | 51     | 4.9      | 0.3850  |
| Curse/midwife                                       | 29    | 78.4  | 788    | 75.3     |         |
| Others                                              | 8     | 21.6  | 207    | 19.8     |         |
| Person assisting the delivery                       |       |        |        |          |
| MO/CO                                               | 17    | 45.9  | 809    | 77.3     | <0.0001 |
| Nurse/midwife                                       | 12    | 32.4  | 104    | 9.9      |         |
| Others                                              | 8     | 21.6  | 133    | 12.7     |         |

(Contd....)
group intended to deliver at a facility other than a hospital (69.5% vs 59.5%). In the VVF group, 15.8% of women ended up with a hysterectomy, compared with 2.7% of women with perineal tear. Before controlling for co-variables, both groups had a similar rate of living over 4 hours of walking distance from the closest hospital (13.5%), and similar rates of attendance at delivery by unskilled provider (21.6% vs 19.8%). Consistent with prior reports on birth outcomes of fistula patients, 81% of the women with VVF had a stillbirth compared with 16.2% of perineal tear patients. Interestingly, 16% of the women with perineal tear did not receive any antenatal care, which was higher than the VVF group of 12.4%.

### 3.2. Healthcare Access and VVF

Table 3 displays the results generated from the binomial logistic regression models examining the association between health care access using MHAI grade and likelihood of having a VVF while adjusting for place of residence, marital status and education. We found a statistically significant negative association between health care access and occurrence of VVF. That is, women who had ‘insufficient’ grade health care access had almost three times the likelihood (OR = 2.64, 95%CI = 1.07 – 6.03) of suffering from VVF as compared to women with ‘sufficient’ health care access. For the covariates, it was found that rural women were 8 times more likely to have a VVF as compared to their urban counterparts. Also, women with less than secondary education were 3.85 times as likely (95% CI= 1.66 – 8.49) to suffer from VVF as compared to those with more than secondary education. Unexpectedly, women who were married at the time of the interview were more likely to have a VVF as compared to single or unmarried women.

### 4. Discussion

#### 4.1. Discussion

This study examined demographic factors of patients with obstetric VVF receiving care in Malawi compared to those in a reference group (perineal tear) and association of VVF with access to health care and found that women living in poverty in rural areas, with lower levels of education, and less access with essential health services were more likely to suffer from an obstetric VVF. Among the study population, obstetric VVF was more common in women from rural areas living in poor housing- as identified by roof type, who worked as peasant farmers, and those with less than secondary school education. These characteristics generally indicate extreme poverty among women in Malawi. Furthermore, VVF tended to occur in women at extremes of reproductive age. After controlling for covariables, VVF was significantly more likely in women with poor access to health care (living far from a health facility, no skilled provider at delivery, and no antenatal care).
Table 3: Adjusted binomial logistic regression model estimates to quantify the likelihood of VVF (vesicovaginal fistula) using the Malawi Healthcare access index (MHAI) as predictive marker of the association between VVF and MHAI with perineal tear used as the reference group

|                         | OR   | 95% CI     | p-value |
|-------------------------|------|------------|---------|
| Malawi Healthcare Access Index Grade |      |            |         |
| Sufficient              |      | Reference  |         |
| Insufficient            | 2.64 | (1.07,6.03) | 0.03    |
| Residence               |      |            |         |
| Urban                   |      | Reference  |         |
| Rural                   | 8.1  | (3.47,18.24) | <0.0001 |
| Marital Status          |      |            |         |
| Single/never married    |      | Reference  |         |
| Married                 | 4.37 | (1.19,15.18) | 0.02    |
| Separated/divorced/widowed | 5.79 | (1.54,20.60) | 0.01    |
| Education               |      |            |         |
| Secondary or more       |      | Reference  |         |
| Less than secondary     | 3.85 | (1.66,8.49)  | <0.0001 |

These findings highlight the marked disparities within the health care delivery system, evidenced by the fact that obstetric VVF is most likely to occur in the most vulnerable populations least equipped to deal with the resulting significant personal and health ramifications.

Though other studies have focused on physical and clinical factors including height, parity, weight of the baby, age of mother, and adequacy of pelvis in evaluating risk for obstetric VVF, we focused our analysis on demographic and health access measures.\(^{17,18}\) Compared to other studies looking at education, our findings were consistent that higher levels of education are protective against VVF formation.\(^{17}\) In addition, similar to past studies we found that factors contributing to delay in care during labor (distance from health facility, attempted delivery at home) were associated with higher incidence of VVF.\(^{19}\)

4.2. Limitations

This study has some important limitations. Because the reference population, or number of patients with isolated perineal tears, for this study was so small given that the hospital from which the data were collected specializes in fistula care, it was not possible to achieve tight confidence intervals for association models. This database was mainly developed from the records of women with fistula and with small numbers of patients presenting solely with perineal tear and no VVF which made our reference group very small further affecting the association model. Further studies are needed to more clearly elucidate the true incidence of obstetric fistula to better inform the development and implementation of fistula prevention strategies. Furthermore as the push to expand access to basic obstetric services is underway, future studies should measure the impact that such efforts are having on obstetric fistula formation.

5. Conclusion and Global Health Implications

Illustrated by its nearly complete eradication in developed countries, obstetric VVF is a preventable complication of labor which results from women having inadequate access to essential maternal health services. Given the increasing number of obstetric VVF cases and the limited treatment centers, focus must be shifted from treatment of obstetric VVF to prevention. As current capacity to repair obstetric VVF is far below the incidence of VVF, the number of preventable fistula cases is rapidly increasing.\(^{20,21}\) It is imperative that strategies targeting the most
vulnerable populations- those living in poverty, from rural regions, with low levels of education, far from adequate healthcare resources, must be implemented to reduce the likelihood of preventable, stigmatizing, and life-altering health outcome of obstetric VVF.

Compliance with Ethical Standards

Conflicts of Interest: The authors have no conflicts of interest to disclose. Financial Disclosures: The authors have no financial disclosures to discuss. Funding/Support: The study was supported through protected research time allotted by Baylor College of Medicine. Ethics Approval: The Malawian National Health Science and Research Committee (CID 1116 Protocol number 929), and Institutional Review Board of Baylor College of Medicine (H37617) approved this study. Acknowledgments: The authors would like to acknowledge the instrumental support of the Freedom from Fistula Foundation in partnering with Baylor College of Medicine to provide excellent care for fistula patients in Lilongwe, Malawi.

Key Messages

• Obstetric vesicovaginal fistula (VVF) in Malawi is more common in women from rural areas, mothers delivering at extremes of age, those with less education, and women with long labor (>12 hours).
• Obstetric vesicovaginal fistula (VVF) is most likely to happen to marginalized women who are least equipped to deal with the long term consequences of fistula formation.

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