

## Developing a Simple Proof of Concept Clinical Decision-Making Tool for Predicting Surgical Outcomes after Obstetric Fistula Repair in a Developing Country

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### Abstract

**Introduction:** Obstetric fistula is a serious injury resulting from obstructed labor causing significant maternal morbidity in women in developing countries. In order to maximize probability of successful surgical repair, it is important to identify women at-risk for poor surgical outcomes so that they can be given appropriate care. The goal of this study is to explore additional factors associated with fistula repair outcomes, as well as determine whether statistical modeling can be used to create a clinical decision-making tool for predicting a successful repair.

**Methods:** Medical records for 82 patients surgically treated for obstetric fistula in Benin were retrospectively reviewed to collect demographic and clinical information related to their condition and procedure. Individuals were grouped into 3 main outcomes: successful closure with continence, successful closure with residual incontinence, and failed repair.

A backwards stepwise selection methodology and logistic regression were used to select factors and examine their associations with the surgical outcomes. Structural equation modelling was used to develop a prediction tool for successful repair.

**Results:** Location of fistula (vesicovaginal, vesicouterine, ureteroalvaginal, ureterouterine, and rectovaginal) (OR=7.6 (2.39, 24.36)), being married (OR=3.45 (1.09, 10.90)), parity of 1 to 3 (OR=2.99 (0.94, 9.49)), duration of fistula less than 10 years (OR=2.07 (0.88, 8.25)), and no previous repair attempt (OR=2.40 (0.79, 7.25)) were found to favor a successful closure with continence. We developed a prediction tool to sort women with obstetric fistula into 5 different categories based on probability of success. Our model suggests that marital status affects successful repair through a mediating factor not yet identified.

**Conclusion:** This study classified fistulous women into clinically relevant categories based on the probability of a successful repair. The results from the present study may inspire further research on identifying fistulas with poor prospect of success, which might benefit from more specialized care.

**Keywords:** Obstetric; Fistula; Repair; Outcomes; Prediction

### Introduction

Obstetric fistula (OF) is a major obstetric injury resulting from obstructed labor [1]. During an obstructed labor, timely care is critical for both the health of the mother and the child. However, in many developing countries women cannot readily access emergency obstetric care [2-5]. When an obstruction remains unrelieved, the baby may die, and the constant pressure of the fetal presenting part against the soft tissues surrounding the vagina, bladder or rectum may cause ischemic necrosis. This results in an opening known as a fistula in the tissue of the birth canal approximately 3-5 days after the obstruction [6,7]. Fistulas can develop between the vagina and bladder (vesicovaginal

fistula) and/or the rectum (rectovaginal fistula) and result in continual leakage of urine and or stool, which emits an offensive odor [6,7]. The consequences of this obstetric injury are devastating: the uncontrollable leakage of urine and or stool excoriates the genital areas, causes vaginal stenosis, bladder calculi, and infection. Additionally, women affected by fistulas are frequently deserted by their husbands and family, as well as stigmatized by society [7-9]. Divorce rates due to fistula are 55% in Nigeria and more than 50% in Ethiopia [9]. Substantial evidence suggests several factors that predispose childbearing women to OFs including young age at marriage, first delivery, prolonged labor, poverty, illiteracy, living in rural areas lacking emergency obstetric care, delivery at home, being small and short in stature, and certain cultural practices such as female genital cutting [1,9-14].

OF remains a significant cause of maternal morbidity in women in developing countries. The prevalence of this condition is not known, mainly because affected women are isolated within their communities and ashamed of seeking treatment. Estimates suggest that there are more than 2 million women living with a fistula and 50,000 to 100,000 new cases developing each year, most of which are in sub-Saharan Africa and South Asia [10,15,16].

Given the impact of OF on women's health, it has been recognized as a significant public health problem, which prompted the launching of the 2003 campaign by the United Nations Population Fund (UNPFA) and its partners to end this condition. The campaign focuses on prevention, treatment, and rehabilitation. The treatment includes performing surgery to repair fistulas. In Benin, OF repair is routinely performed by local surgeons but the majority of patients are treated during obstetric fistula camps sponsored by UNPFA. During those camps, visiting surgeons with expertise in fistula repair, train local surgeons in fistula treatment because repair often poses a challenge to surgeons.

An important step in maximizing the probability of a successful repair is to identify fistula women with poor surgical outcomes so that they can be given appropriate and specialized care. Studies have reported that the size, location, duration of the fistula, one or more previous treatment attempts, and vaginal fibrosis are associated with surgical outcomes [17-23]. These variables are important predictors of repair outcomes, and would not be difficult to use in clinical practice to group, assess, and treat fistula women based on the probability of a success. A better understanding of the heterogeneity in surgical outcomes will provide greater insight for improving management of women with obstetric fistulas. Therefore, the aim of this study was to explore factors associated with surgical outcomes after obstetric fistula repair and to assess the heterogeneity in repair outcomes using new analytic approaches. This analysis may enable the identification of fistula women who might benefit from more specialized care. This study may inspire newer approaches to enhance traditional obstetric fistula care and may spark further discussion and research on fistulas with poor prospects for surgical closure.

## Methods

### Study population and data collection

From January 2009 to December 2013, the Hospital of Bembereke (Republic of Benin) hosted 2 obstetric fistula repair missions. A total of 82 patients (Benin: N=74; Nigeria: N=5; Niger: N=1; Burkina-Faso: N=2) were surgically treated for obstetric fistula during the two missions. Pre-operatively all women were assessed using a speculum and fistulas were located by inserting a transurethral catheter and injecting a solution of methylene blue to trace the path of urine leakage. Recto-vaginal fistulas were assessed by performing a thorough rectovaginal examination. All patients operated for fistulas remained in the surgery department for 10-21 days with an indwelling urinary catheter and were followed up daily until discharge for evidence of persistent leakage or surgery complications. Medical records of patients operated were reviewed and data were collected on socio-demographic characteristics (age, religion, district of residence, marital status, occupation, gravidity and parity), obstetric history (antenatal care attendance, time spent in labor, place of delivery, mode of delivery, outcome of delivery, parity at fistula development, time spent with fistula and previous repairs) and physical examination findings (height, weight, size, location of fistula, level of vaginal scarring and outcome of

repair at discharge). The outcome of repair was classified as either successful closure with continence, successful closure with residual incontinence or failed repair at the time of hospital discharge. Continence was assessed upon removal of the urinary catheter. A woman could be dry or wet following the removal of the catheter. If a woman was dry, the outcome status was successful closure with continence. A postoperative dye test was performed on wet patients to determine whether the fistula was closed or not. If the fistula was closed, the outcome was successful closure with residual incontinence; otherwise the outcome was failed repair. A recto-vaginal repair is successful when the fistula is closed and the woman is continent.

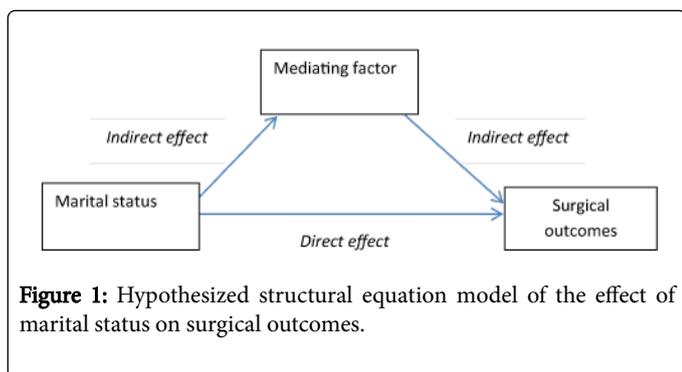
The scientific community is not in consensus agreement on the definition of a successful repair. While some researchers believe success should be defined as closure of the fistula [24-26], others argue that dryness or continence after repair should be called success [27]. For this study, we defined success as a continent closure because the expectation of a woman with fistula is to get dry. Thus, incontinence resulting from an obstructed labor must be corrected in order to label an outcome as successful. Based on our definition, a closed fistula with continence (dryness) is labeled as success whereas closure with incontinence and unclosed fistulas are labelled as failure.

### Statistical methods

Characteristics of the study population are presented as frequency distributions over the patients' age groups. Chi-square tests (or a Fisher exact test if more than 20% of cells have a count less than 5) were used to examine the relationship between demographic characteristics, clinical factors and age groups. A backwards selection procedure with  $p < 0.2$  was used to identify important variables associated with surgical outcome. We chose  $p < 0.2$  to allow the procedure to include more variables for study. The backward selection method incorporated the following predictors: age, duration of the fistula, size of the fistula, location of the fistula, previous repair attempt, vaginal fibrosis, marital status, parity, body mass index (BMI), and genital mutilation. The following variables were retained: fistula location, marital status, parity, duration of the fistula, and previous repair attempt. We then used logistic regression to examine the relationship between these variables and surgical outcome.

We developed a prediction tool using a classification and regression tree method [28]. This analytical approach predicts group membership of the classes of a categorical dependent variable from one or several predictors. The dependent variable was success (continent fistula closure) or failure (closed fistula with residual incontinence or unclosed fistula). Starting at the tree root, a classification and regression tree method searches through each predictor to find a value of a single variable that best splits the data into two groups. These two resulting groups are called child nodes. For each child node, the process is repeated until a classification tree is created. The tree is then pruned if necessary.

Our initial analysis, found marital status to be a significant predictor of a successful repair outcome, therefore, we fitted a structural equation model (SEM) to further examine whether marital status affects surgical outcomes via a mediating variable, as hypothesized in Figure 1. We hypothesize that unmarried women may be stunted or malnourished due to isolation and lower resources. Our analysis specifically tested a mediational effect of nutritional factors using body mass index (BMI) as a proxy variable.



**Figure 1:** Hypothesized structural equation model of the effect of marital status on surgical outcomes.

We used a multivariate imputation method [29] to impute variables with missing data: age (N=3), duration of fistula (N=1), fistula size (N=19), weight (N=12), height (N=18), marital status (N=5), genital mutilation (N=6), vaginal fibrosis (N=1), and fistula location (N=2). Variables incorporated into the imputation model included: age, gravidity, parity, marital status, duration of the fistula, size of the fistula, location of the fistula, weight, height, surgical route, presence/absence of menstruation, genital mutilation, vaginal fibrosis, duration of obstructed labor, delivery mode of obstructed labor, location of delivery of the obstructed labor, hysterectomy at the time of delivery, vital status of baby, per-operative outcome prediction by operating surgeon, surgical procedure, and ethnicity. Logistic regression and structural equation modeling were conducted using SAS and the classification and regression tree method was performed in R.

## Results

Descriptive statistics are shown in Table 1. Patients had elementary or no formal education, and were either housewives or farmers. One in five women with obstetric fistulas was underweight (BMI<18.5). About 4 of 10 women were not married (single, divorced, or separated) and 53.7% were grand multiparous (4 or more deliveries). More than half of the women (54.9%) had genital mutilation. More than half (51.2%) of the fistulas were 10 years or older. About 4 in 10 women had a previous repair attempt and 40.2% of the fistulas were 2 centimeters or larger. Most fistulas were vesicovaginal (50%) and about a third exhibited urethral involvement (32.9%). Nearly half of the fistulas were fibrotic. The vast majority of the fistulas were operated via the vaginal route (84.1%). Fistula closure occurred in 73.2% of patients, and postsurgical continence was achieved in 62.2% of patients (62.2% were closed with continence, 11% were closed with residual incontinence, and 26.8% failed). Older women (40 years or older) were more likely to have old fistulas (10 years or more), were more likely to be farmers and grand multiparous. Age was not statistically related to body mass index, marital status, previous repair attempt, fistula size, fistula location, vaginal fibrosis, surgical route, and treatment outcome.

Variables	Age			P-value
	<40 years N (%)	≥40 years N (%)	All N (%)	
<b>Educational attainment</b>				
None	52 (88.1)	23 (100.0)	75 (91.5)	0.1822
Elementary	7 (11.9)	0 (0.0)	7 (8.5)	
<b>Occupation</b>				

Housewives	22 (37.3)	0 (0.0)	22 (26.8)	0.0006*
Farmer/Others	37 (62.7)	23 (100.0)	60 (73.2)	
<b>Marital status</b>				
Married	37 (62.7)	14 (60.9)	51 (62.2)	0.8772
Single/Divorced/Separated	22 (37.3)	9 (39.1)	31 (37.8)	
<b>BMI</b>				
<18.5	15 (25.4)	4 (17.4)	19 (23.2)	0.7309
18.5-25	31 (52.6)	13 (56.5)	44 (56.6)	
≥25	13 (22.0)	6 (26.1)	19 (22.2)	
<b>Parity</b>				
1-3	31 (52.5)	7 (30.4)	38 (46.3)	0.0713
≥4	28 (47.5)	16 (69.6)	44 (53.7)	
<b>Genital mutilation</b>				
No	23 (39.0)	14 (60.9)	37 (45.1)	0.0736
Yes	36 (61.0)	9 (39.1)	45 (54.9)	
<b>Duration of fistula (Years)</b>				
<10	39 (66.1)	1 (4.3)	40 (48.8)	<0.0001*
≥10	20 (33.9)	22 (95.7)	42 (51.2)	
<b>Fistula size (centimeters)</b>				
<2	36 (61.0)	13 (56.5)	49 (59.8)	0.7092
≥2	23 (39.0)	10 (43.5)	33 (40.2)	
<b>Fistula location</b>				
Vesicouterine/ ureterovaginal/ ureterouterine/rectovaginal	11 (18.6)	3 (13.0)	14 (17.1)	0.7019
Vesicovaginal	30 (50.9)	11 (47.8)	41 (50.0)	
Vesicovaginal with involvement of urethra	18 (30.5)	9 (39.2)	27 (32.9)	
<b>Scarring/fibrosis of vaginal tissue</b>				
No	31 (52.5)	10 (43.5)	41 (50.0)	0.4608
Yes	28 (47.5)	13 (56.5)	41 (50.5)	
<b>Previous attempt of fistula repair</b>				
No	37 (62.7)	13 (56.5)	50 (61.0)	0.6057
Yes	22 (37.3)	10 (43.5)	32 (39.0)	
<b>Surgical Route</b>				
Vaginal	48 (81.4)	21 (91.3)	69 (84.1)	0.3339
Abdominal	11 (18.6)	2 (8.7)	13 (15.9)	
<b>Surgical outcomes</b>				
Closed fistula with continence	39 (66.1)	12 (52.2)	51 (62.2)	0.3926

Closed fistula with residual incontinence	5 (8.5)	4 (17.4)	9 (11.0)
Unclosed fistula	15 (25.4)	7 (30.4)	22 (26.8)
*Significant at p<0.05			

**Table 1:** Selected socio-demographic characteristics and clinical factors stratified by age group.

Table 2 shows the results from the logistic regression model.

Variables	OR (95% CI)
<b>Location</b>	
Vesicouterine/ureterovaginal/ureterouterine/rectovaginal/vesicovaginal	7.63 (2.39, 24.36)*
Vesicovaginal with involvement of urethra	1.00 (Ref)
<b>Marital status</b>	
Married	3.45 (1.09, 10.90)*
Single/Divorced/Separated	1.00 (Ref)
<b>Parity</b>	
1-3	2.99 (0.94, 9.49)
≥4	1.00 (Ref)
<b>Duration of fistula (Years)</b>	
<10	2.07 (0.88, 8.25)
≥10	1.00 (Ref)
<b>Previous repair attempt</b>	
No	2.40 (0.79, 7.25)
Yes	1.00 (Ref)
Model performance: C-statistic=0.82	
*Significant at p<0.05	

**Table 2:** Multivariate odds ratios and 95% confidence intervals of the associations between selected variables from backward procedure and successful repair with continence.

Location of the fistula, marital status, parity, duration of the fistula, and previous repair attempt were important predictors of surgical outcomes, and this model achieved a C-statistic of 0.82. After accounting for other variables in the model, vesicovaginal, vesicouterine, ureteroalvaginal, ureterouterine, rectovaginal fistulas were 7.6 times more likely to close with continence compared with vesicovaginal fistulas with urethral involvement (OR=7.63, 95% CI=2.39-24.36). Married women were 3.5 times more likely to have a fistula closure with continence compared to non-married women (OR=3.45, 95% CI=1.09-10.90). Women who had 1 to 3 deliveries were 3 times more likely to have a continent fistula closure compared to grand multiparous women (OR=2.99, 95% CI=0.94-9.49). Fistulas less than 10 years old were 2 times more likely to close with continence compared with fistulas 10 years or more (OR=2.07, 95% CI=0.88,

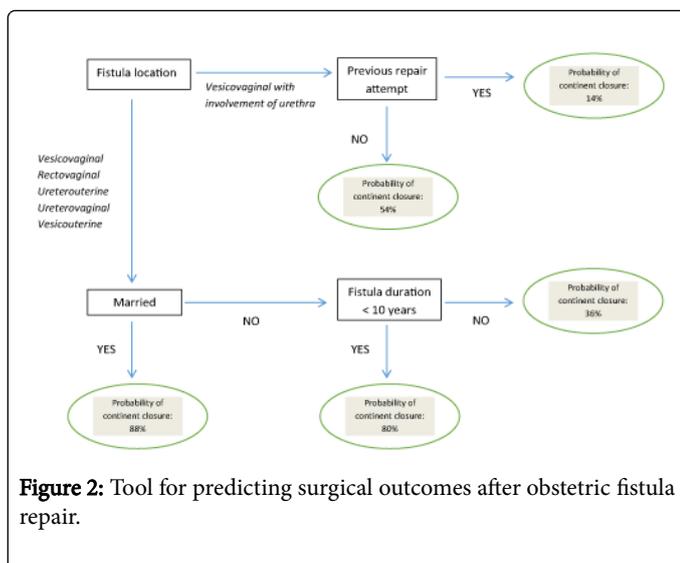
8.25). Fistulas not previously operated were 2.4 times more likely to close with continence compared to those that had a prior OF surgery (OR= 2.40, 95% CI=0.79-7.25).

Table 3 shows the estimates from the structural equation model. The direct effect of marital status on repair outcome is 0.00565 (p-value=0.9467), suggesting that marital status does not directly affect surgical outcomes. The indirect effect is 0.1645 (p-value<0.0001), implying that the effect of marital status on repair outcomes is indirect. We tested the mediational effect of nutritional factors using BMI as a proxy but it was not significant (p-value=0.8600). This suggests that marital status does not affect surgical outcomes via BMI.

Path	Parameter estimate	Standard error	t-value	P-value
Marital status→Surgical outcomes	0.00565	0.08447	0.06684	0.9467
Marital status→Mediating factor	0.33971	0.04091	8.30486	<0.0001*
Mediating factor→Surgical outcomes	0.48423	0.023	21.05115	<0.0001*
Direct effect	0.005646	0.0845	0.0668	0.9467
Indirect effect	0.1645	0.0256	6.4357	<0.0001*
Effect of marital status on surgical outcomes via BMI				
Marital status→Surgical outcomes	0.17101			
Marital status→BMI	0.25826			
BMI→Surgical outcomes	-0.00333	0.00966	-0.34517	0.73
Direct effect	0.171	0.1094	1.5626	0.1182
Indirect effect	-0.000861	0.004882	-0.1764	0.86
*Significant at p<0.05				

**Table 3:** Structural equation model (SEM) estimation results.

The results of the classification and regression tree method are shown in Figure 2, which is formatted as a proof of concept decision-making tool for predicting obstetric fistula repair outcomes. Using the predictors retained from a backward stepwise selection procedure, the classification and regression tree method further retained four important variables for the tree: fistula location, marital status, duration of the fistula, and previous repair attempt. The tree begins in upper left corner. A woman with a fistula passes through the tree in directions determined by her answers to the questions at each branch, until ending in a terminal node. The probability of success is shown at any terminal. For example, when a fistula is vesicovaginal, vesicouterine, ureteroalvaginal, ureterouterine, or rectovaginal, and the woman is married, the probability of success is 88%.



## Discussion

This study found that location of the fistula (vesicovaginal, vesicouterine, ureteroalvaginal, ureterouterine, and rectovaginal), being married, having delivered 1 to 3 times, recency of the fistula, and absence of a previous repair attempt favor a successful closure with continence. We also found that marital status has an indirect positive effect on surgical outcomes. We have developed a simple proof of concept decision-making tool that clinicians can use to predict obstetric fistula repair outcomes. This tool sorts women with obstetric fistula into 5 different categories and reports for each category the probability of success.

The results we present here are in line with those of previous studies showing that women affected with obstetric fistula are most likely to be of very low socio-economic status [9-14]. Women in our sample had elementary or no formal education, were housewives or farmers, and tended to be malnourished (1 in 5 women were underweight). Strikingly, 51.2% of women in our study who sought treatment had lived with their fistula for 10 years or more. In a study conducted in Burundi, 31% of patients had lived with their fistula for more than 10 years [30]. The relatively longer time living with fistula may be due to lack of repair services, lack of knowledge that fistula can be repaired, or the complexity of the lesion leading to repeated surgical failure. It could also be explained by the social consequences of the disease such as isolation. Our data showing that vesicovaginal fistulas are the most frequent type of obstetric fistulas is consistent with what other studies have reported in the literature [31-35].

Fistula closure occurred in 73.2% of patients, and postsurgical continence was achieved in 62.2% of patients. In a large study conducted in Nigeria, a closure rate of 84.1% was reported and a 70.5% continence rate was found in the patients [36]. The slightly lower continence rate of 62.2% in the current study may be due in part to a high proportion (51.2%) of fistulas in place 10 years or more. In a series of 454 women operated in Burundi, 87% were discharged with a closed fistula, of which 76% were continent. In a series of 65 patients operated in Niger, closure was successful in 57% of these patients, of whom 22% had post-closure stress incontinence. In general, fistula closure rates range from 70 to 95% [9,17,37,38]. Differences in reported surgical outcomes may be due to differences in patients

regarding injury severity, duration, fistula location, surgeon experience, surgical technique used, or clinical diligence in rigorously ascertaining continence status after fistula closure.

In addition to known factors associated with surgical outcomes, our data show that grand multiparity is associated with decreased odds of success, although the association was not statistically significant. The association between parity and surgical outcomes seems biologically plausible. Grand multiparity has been shown to be associated with tissue alterations in urethral and vaginal walls in animal studies [39]. This may explain the decreased odds of success observed among grand multiparous women. Perhaps the most striking finding was the significant relationship observed between marital status and fistula repair outcomes. Controlling for potential confounders, married women were 3.7 times more likely to have a closed fistula rather than a failed one. The structural equation modeling suggests that marital status affects surgical outcomes via a mediating variable. The mediational effect of nutritional factors examined using BMI was not significant. Thus, the factor by which marital status affects surgical outcomes remains to be determined. However, it is possible that marital status affects repair outcomes via psychological distress because unmarried women may experience higher level of distress compared to married women, as those who are not married are often rejected by their husbands, family, and society. Studies have shown that psychological stress can affect wound healing from injury and surgical procedures. High levels of stress prior to surgery have been associated with longer hospital stays, postoperative complications, and higher rates of rehospitalization [40,41]. The interpersonal stress associated with divorce can impede wound healing. In a study on wound healing, non-fistula women who were going through a divorce or separation had delayed skin barrier recovery following the tape stripping procedure, compared to women who were not [42]. Wound healing is a process where inflammation plays an important role early in the process. Pro-inflammatory cytokines protect against infection and prepare injured tissue for recovery through recruitment and activation of phagocytes [43]. Substantial evidence has shown that physiological stress responses can delay the initial inflammatory phase of wound healing [44]. In fact, psychological stress leads to the activation of the hypothalamic-pituitary-adrenal and the sympathetic-adrenal-medullary axes [45]. This results in enhancement of glucocorticoids and catecholamine production, which can impair several components of the wound healing process.

The limitations of this study include a small sample size, missing data on important variables such as fistula size, and lack of data on surgeon experience. Although this study included only 82 patients, it is larger than a previous study sample of 65 patients conducted in Niger, but smaller than a study in Burundi which included 454 women [30,34]. We believe this sample size is adequate in providing proof of concept for the utility of a clinical decision-making tool for predicting successful fistula repair outcomes, however additional research should be conducted to identify if there is a mediating factor between marital status and surgical outcomes. Incomplete and missing information on important variables such as fistula size, surgeon experience, and/or techniques used during surgery were major limitations of study and subsequent predictive model. Fistula repairs were conducted by different surgeons with varying experience and surgical techniques, which if known could potentially account for a large amount of variability within our model. Future studies should work to collect more thorough information on surgical experience and procedures.

## Conclusion

We have developed a simple proof of concept decision-making tool used to predict surgical outcomes after an obstetrical fistula repair. We used the tool to identify a subset of fistula women with poor surgical outcomes. This study suggests that marital status affects surgical outcomes via a mediating variable not yet identified. Further research work should be directed at innovating new approaches for identifying and treating fistula women with poor surgical outcomes.

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## Disclosure Statement

The authors have no financial or any other kind of personal conflicts with this paper.

## Author Contributions

Bio Tamou Sambo, Celestin Missikpode, and Kabibou Salifou conceived the study. Bio Tamou Sambo provided the data. Celestin Missikpode analyzed the data and Christian Johnson assisted with the analysis. Celestin Missikpode and Bio Tamou Sambo wrote the initial draft of the manuscript and revised it. Kabibou Salifou, Adrien Hodonou, Emile Mensah, Alexandre Allode, Christian Johnson, Audrey Saftlas and Robert Wallace interpreted the data, provided critical feedback, and revised the manuscript. Senior researchers Audrey Saftlas and Robert Wallace supervised the work.

## Ethics Approval

There was no ethics committee or institutional review board available at the University of Parakou. However, the authors took necessary steps to protect the study participants' privacy and confidentiality.

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