# PREDICTORS OF FISTULA HEALING; A STRUCTURED LITERATURE REVIEW.

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## ABSTRACT

**Introduction:** Obstetric fistula is defined as an abnormal communication between two epithelial surfaces. It is a preventable maternal morbidity that results from prolonged and obstructed labor. Often, the condition is characterized by continuous urine or stool leakage. In East Africa, the condition is common. In recent years, health workers have scaled up access to fistula repairs in an attempt to restore the dignity of affected woman. However, little is known about the number of women who gain full continence after surgery. In addition, factors that affect or promote fistula healing are scanty. The aim of this review was to describe predictors of fistula healing in these settings.

**Methodology:** Methods Structured review system to literature compilation was used. Explicit methodology was utilized to identify, select, and critically evaluate results of the studies to be included in the literature review. Authors developed a pre-defined eligibility criterion and a specific research question which guided the search process. Papers which focused on predictors of fistula healing were reviewed. The following Keywords were used in the search: Vesicovaginal Fistula (VVF), Vaginal Fistula (VF), urogenital fistula (UGF), Obstetric fistula (OF), Female Genital fistula (FGF) and Treatment outcomes. Hawkers tool was used in scoring selected papers.

**Results:** A total of 23 papers were reviewed. Few papers assessed surgical outcomes in fistula surgery especially in East Africa. Predictors of poor surgical outcomes were reported, these include: Scarring tissue, repeat repairs and large fistulas.

**Conclusion:** Factors that predict outcomes in fistula surgery are far more than those reported. There is limited evidence of mixed methods study designs in this field of surgery. As such, further inquiry is required to explore a wider range of factors and develop holistic approaches to fistula management.

**Keywords:** Vesico Vaginal Fistula and Predictors of Surgical Outcomes.

## INTRODUCTION

Literature reviews have been described as a systematic process of identifying and analyzing documents of what is already known and written down, relevant to a research topic (Robson, 2011). Specific methodologies exist for searching, appraising and synthesizing findings of primary studies. In this paper a structured literature review approach was preferred because the approach is ranked high in the hierarchy of evidence (Clarke and Stewart 1994: National Institute for Health and Care Excellence, 2005). The sound methods used in appraising literature contributes to the high-ranking of these reviews.

In this type of review, the reviewer develops pre-defined eligibility criteria and a specific research question to answer. The review is well structured and planned to respond to the specific research question:

it uses a systematic and explicit methodology to identify, select, and critically evaluate results of the studies to be included in the literature review. The structured process helps minimize biases, thereby producing valid and reliable search outcomes (Higgins and Green, 2009). Because of this, structured reviews are considered more credible since they are less biased than expert opinions. They are also flexible and more pragmatic than systematic reviews, but still follow a systematic approach. The outcomes are also presented in an organized way, clearly addressing well-articulated research question or series of questions. Its this systematic approach that enables the reader to follow the whole process, making such evidence a crucial component of fistula care programming.

In this context, the main aim of appraising the literature was to explore a number of knowledge sources, discover gaps and use these findings to guide clinical practice in this specialized field of Obstetric Fistula. To achieve this, the review addressed the research question: "What are the predictors of successful fistula closure in obstetric fistula women attending services in East Africa?" Studies in this review included quantitative, empirical, randomized/ non-randomized experimental and observational study designs.

## METHODOLOGY

In order to access as many relevant studies as possible to address the question; the following databases were searched, Ovid Medline, Ovid Embase, Ovid Cinahl and Ovid PsycINFO. A preliminary search revealed most of the literature within Ovid Medline(R), Cochrane database for systematic reviews, CINAHL plus and Ovid Embase. The databases were searched using the following keywords: Vesicovaginal Fistula (VVF), Vaginal Fistula (VF), urogenital fistula (UGF), Obstetric fistula (OF), Female Genital fistula (FGF) and Treatment outcome. The Boolean operators 'OR' and 'AND' were applied as shown in Table1.Each keyword was utilized to search for the literature in all four databases. Also, the reference lists and bibliographies of included papers were manually searched. All likely conforming studies were saved and then exported into Endnote after thoroughly scanning the databases. While in the endnote the duplicates were screened out leaving only single studies. These were thoroughly screened, sorted and articles that did not meet the inclusion criteria by titles were removed.

### Inclusion and Exclusion Criteria

The criterion applied for exclusion and inclusion of the papers in the review were: the population under the study, the phenomenon under study and the type of research design in favor of identification of appropriate data to adequately explain the phenomenon (Bernard 1994).

Other criteria were geographical location, year of publication and language of publication as explained by (Bettany-Saltikov, 2012b: Joanna Briggs, 2011). Women with obstetric fistula are a specific group and studies had to be restricted by gender (only women) and exclude men with fistula. It was necessary to include women of all ages as some acquired fistula when they were too young for the review to be meaningful, and findings were understood in the context of this group. The studies explored were also restricted by the aetiology of obstetric fistula and settings, hence the higher concentration of African studies. The study criteria allowed all research designs so that relevant data were not missed. It also covered the years from 1970 to July 2019, the period where much publication on the topic has happened. Table2 presents a summary of the exclusion / inclusion criteria.

The selected papers were saved and then exported into an Endnote library. Selected papers were manually assessed for relevance to the key research questions, such as predictors of fistula closure. To be eligible for full review, the paper needed to address fistula outcomes or predictors, either as a primary or secondary paper. Papers identified included search terms in the title or abstract. It was intended that this would highlight any papers where the aim or findings were significantly related to the research question. A difficulty in using vaginal wound healing as a search term is that it highlights a significant number of papers where the term is used in wound healing not specific to obstetric fistula healing. Hence, full paper searches were not carried out in connection with the terms 'fistula healing' and 'predictors'.

The review excluded Mesh headings unrelated to female genital fistula of interest such as infant fistula, fistula due to radiotherapy, renal diseases, and cancer-related fistula studies. All papers identified were reviewed for relevance. Relevant papers were then selected and downloaded and scrutinized to ensure that they were answering the research questions of the study.

**Assessment of Quality**

The quality of the papers was evaluated using the Hawker tool (Hawker et al. 2002). The tool looks at factors in a study as shown in Table 3 and scores each factor as shown in Table 4. The minimum score of 9 means inferior quality and a maximum of 36 a good study. The tool was selected because it is comprehensive but easy to understand and can be applied to different study designs. It also allows the reviewer to assign a value to various methodological elements like abstract, methods, sampling and analysis to show the rigour of the study.

## FINDINGS

The initial literature search was conducted in the year 2013 and revealed eight relevant papers. The search was updated in July 2019 which revealed additional literature. The search of literature in July 2019 produced 446 papers after removing 98 duplicates. Further screening of the 446 papers was done using titles and abstracts, which led to the exclusion of 414 papers which did not meet the inclusion criteria. A thorough repeat screening of the abstracts was performed this time with an independent assessor which yielded 32 articles.

Out of these, nine articles were eliminated at this stage either because: the fistula occurred following radiotherapy or a malignancy complication, it occurred in different settings or it was associated with Crohn's disease. The total number that met the inclusion criteria came down to 23 papers.

The full text of the 23 papers meeting the inclusion criteria was requested. The papers were mainly African studies with a concentration in West and East Africa. Papers not written in English were excluded.

**Predictors of Successful Fistula Surgery**

In the literature, various factors affecting fistula healing after surgery have been discussed, as summarised in Appendix 2.1. In Uganda, Kayondo et al. (2012) conducted a prospective study looking at some factors that influence surgical outcomes of VVF. The aims of this study were to determine the outcome of surgical repair of VVF and establish the factors that predict results of surgical repair of VVF in Mbarara, a regional referral hospital. For unknown reasons, patients presenting with fistulas of less than two months were excluded from the study, even though most patients indicated that they had given birth through caesarean section, 46 (59.7%) with a 90% perinatal mortality. This may mean that patients had been discharged from the hospital after the fistula developed following the caesarean section. Out of 77 patients who had fistula repaired, the majority (n=55, 79.7%) gained continence. However, among patients presenting with both vesicovaginal fistula and recto-vaginal fistula, 3(60%) had unsuccessful fistulae closure.

**Fistula Classification associated with poor prognosis**

Reports from Uganda also indicate that major classifications have poorer healing rates (Kayondo et al. 2012). In part, this explains why failures are attributed to extensive and multiple fistulas including a combination of VVF and RVF. The reports indicate that the presence of scarring tissue and circumferential defect are key factors in predicting fistula healing. Scarring can occur as a result of infection especially where there is a combination of VVF and RVF. The same study shows that patients who had large fistulas were more likely to have unsuccessful repair than those with small fistulae, with an odds ratio of 6.0, 95% CI 1.46 to 24.63 (Kayondo et al. 2012).

The major limitations cited in the study were: a small number of cases (77 participants), limited supplies and equipment as well as challenges in individual surgeon competencies. A conclusion that circumferential fistulae, marked vaginal scarring and patients with previous unsuccessful fistula repair are more likely to yield negative surgical outcomes has been made (Kayondo et al. 2012).

Others define predictors of fistula outcomes in terms of fistula size and pathology (Hategekimana 2005). A questionnaire was used for data collection in this prospective hospital-based study. A total of 112 patients were recruited over a five-year period (1997 to 2001) in Kigali, Rwanda. Postoperatively, patients were reviewed at months 1 and 6, a time when surgical outcomes were assessed. Symptomatic infection associated with Foley's catheter was observed in this cohort. During the immediate postoperative period, 13 (11.6%) fistulas recurred. Further, the study indicates that fistula diameter, bladder neck involvement and vaginal fibrosis are predictors of fistula failure. This observation is in agreement with their description of patient profiles where it is said that 64% of the patients presented with more complex fistulas, this may be associated with a breakdown in health systems following the 1994 genocide. The researchers have presented a background to the subject matter and described materials and methods. However, data management processes failed to pinpoint the factors that predict fistula success. Hence, the paper does not provide a conclusive statement on factors that affect fistula outcomes in this setting.

**Fistula Closure with Urinary Incontinence**

In a similar study, Goh et al. (2008) conducted a prospective study among 987 women with the aim of assessing predictors of failure of fistula closure and post-fistula urinary incontinence. The assessment for fistula closure and residual urinary incontinence was performed before the patients were discharged. The majority (n=960) had successful closure and 229 reported urinary incontinence after surgery. The highest number of urinary incontinences was reported among women whose fistulas were located closest to the external urinary meatus. Similarly, patients with significant vaginal scarring were more likely to report fistula closure and incontinence: an observation shared by Kayondo et al. (2012).

More recently, a multi-country study looking at predictors of fistula outcomes three months after surgery was conducted by Barone et al. (2012). Countries included in the study were: Bangladesh, Niger, Nigeria, Guinea and Uganda. The study focused on fistula closure and residual incontinence in women with a closed fistula. Patient and fistula characteristics and context of repair were said to be potential predictors in the study. A total of 1,274 women were recruited for study over a three-year period. The results indicated that severe vaginal scarring (adjusted RR 1.56, 95% CI 1.20-2.04), partial urethral involvement (adjusted RR 1.36, 95% CI 1.11-1.66), and complete urethral destruction or circumferential defect (adjusted RR 1.72, 95% CI 1.33-2.23) predicted failed fistula closure. Furthermore, severe vaginal scarring, partial urethral involvement, and complete urethral destruction or circumferential defect (adjusted RR 2.06, 95% CI 1.51-2.81) and previous repairs were significantly associated with residual incontinence. The researchers concluded that fistula closure is related to preoperative bladder size, previous repair, vaginal scarring and urethral involvement.

At the Jimma University in Ethiopia, 168 women were recruited in a cross-section study, Sori et al. (2016). The survey recorded a success rate of 93.4%, but it failed to evaluate the risk factors associated with failure to close the fistula. The study had minimal details in the data analysis, and the results are unadjusted. There was no new knowledge presented in this paper.

In a cohort study, Delamou et al. (2016) looked at factors associated with failure of obstetric fistula repair in 754 women in Guinea retrospectively and found that presence of urethral damage and a history of vaginal delivery in the previous pregnancy predicted failure. However, the study cautioned surgeons to exercise diligence in repair whenever they faced with patients with both factors. Also, the study proposed a mixed method design to assess further insights into these factors. Although the study gave elaborate details in the background, it had minimal details on data analysis. The sample size was adequate to measure effect size and to validate their results. In the similar settings, a retrospective study conducted by Loposso et al. (2016) failed to identify urethral damage and previous vaginal deliveries as risk factors for failed fistula closure. This study concluded that a history of previous repair, the presence of multiple repairs, the severity of the fistula, surgeon's experience and duration of the fistula were reasons for failed repair.

**Factors Associated with Fistula Recurrence**

In a retrospective cohort study of 640 women, Javed studied the factors to determine recurrence of fistula after VVF repair, Javed et al. (2015). The study described factors for VVF recurrence as the presence of multiple fistulas, pre-operative bladder size, secondary repairs and duration of fistula. The study reported no ethical clearance and appeared much like an audit of the hospital procedures. The researchers made proposals for a prospective study and standardization of terminologies in fistula for purposes of comparison of results and to determine the prognostic factors. Also noted were non-prognostic factors like age, parity, and aetiology, route of repair and location of the fistula which partially contradicts Gedik's (2015) observations on the choice of technique for VVF repair.

Studies by Loposso et al. (2016) were determined to evaluate factors to predict recurrence and successful treatment following surgical repair of VVF. This retrospective cohort study in DR Congo with a sample of 166 women went on to show that fibrosis and fistula location was a significant predictor of success and that use of Martius flap and fistula size cannot significantly predict success nor recurrence of fistula after repair. The method utilized in the classification of fistula is not entirely true, because unlike Waaldijk classification of VVF looks at anatomic/physiologic factors and fistula sizes to assess prognosis. These are different from those described by Loposso et al. (2016), which essentially compromises comparability.

A recent cohort study in Malawi, Bengtson et al. (2016) comprehensively investigated for factors to identify patients at risk of urinary incontinence after surgery. The study had a sample size of 401 women and prospectively looked at sociodemographic data, fistula factors, body mass index, and fistula classification. The researchers described a risk scoring technique that would identify women at risk of urinary incontinence following repair. The study, conducted between 2011 and 2014, used logistic regression to develop a risk score to identify women with the likelihood of residual urinary incontinence defined as grade 2-5 within 120 days of VVF first fistula repair. The study based the score on preoperative clinical and demographic characteristics (age, the number of years with fistula, human immunodeficiency p virus status, body mass index, previous surgery at an outside facility, revised Goh classification, VVF size, circumferential fistula, vaginal scarring bladder size, and urethral length). At each cut-off point, the study assessed the sensitivity, specificity, and positive and negative predictive values of the risk score. A risk score of 20 or higher had an associated increased the likelihood of residual incontinence with satisfactory sensitivity and specificity. The score had an excellent sensitivity of 82% and specificity of 63%. The negative predictive value was 91%. It recommended that validation in future with different population and data set to promote its application. This risk score is a new outcome. However, the centre run by expert surgeons only would compromise its generalizability. If validated, it could be applied by surgeons to know which clients with VVF to refer to expert surgeons.

**Use of Technology and Surgical Outcomes**

Other studies that looked at new technologies in the management of VVF concentrated on minimally invasive laparoscopic and robotic techniques on iatrogenic (VVF Tenggardjaja et al. 2013: Wang et al. 2013: Moses et al. 2017). Unfortunately, the studies were in different settings where obstetric fistula is rare. Obstetric fistula occurs in poor settings in rural Africa and South East Asia where these techniques applicability is limited owing to poor hospital infrastructure. Furthermore, the time taken for training and the expenses involved would deplete resources for many ordinary surgeons and institutions in the low-resource settings. Needless to say, that the most appropriate technologies would be those that are safe, easy to learn, easily applicable with excellent results and at minimum cost.

## DISCUSSION

The scope of review papers in East Africa is limited. There are no primary papers looking at fistula surgery and predictors of closure or healing in Kenya. A few papers (Kayondo et al. 2011, Vera et al., 2013) assessing fistula surgery and outcomes have been reported in some countries in Africa. Negative

predictive values were observed in patients with a history of previous repairs, presence of scarring tissues and size of the fistula. Larger fistulas with bladder neck involvement were mentioned more commonly as having a negative healing predictive indicator in women diagnosed with fistula. Fistula may occur during caesarean section especially where the surgeon is less experienced, when this happens the fistula is referred to as iatrogenic fistula because it develops as untoward surgical outcome. Despite this observation, the authors did not highlight the contribution of inexperienced surgeons in fistula etiologies and their contribution in fistula outcomes as evidenced by Kayondo et al. (2011).

Although there were assumptions drawn regarding presence of infection and antibiotic use, none of the studies made an attempt to measure HIV seropositivity in relation to healing predictors. Considering that HIV epidemic is highest in Africa, the authors missed an opportunity to establish its effect in fistula healing. In their three-month study, Barone, et al., (2013) reported predictors as scarring tissue and circumferential defects.

The context in which authors designed short term follow up periods indicate that they themselves consider it to be an acceptable phenomenon than long-term follow up studies. In itself, a three-month period is not enough for most patients to gain full continence. Perhaps it is for this reason that authors are reporting stress incontinence more often. Studies utilizing the abdominal route of fistula repair were associated with longer hospital stay and more likely to fail than those optimizing on vaginal route. In the researcher's view, the underpinning factors have not been discussed although authors mention some indications for abdominal surgery, this is not adequate. Further research work needs to be done to help unearth prevailing issues.

## CONCLUSION

Evidence relating to predictors of fistula closure is limited. Few studies report predictors of fistula healing over a short period of time. None of the papers reviewed adequately addressed the association between HIV seropositivity and fistula healing. There is an urgent need for expanded exploration of predictors of fistula healing in East Africa.

**Table 1: Keywords search used in the literature**

| QUANTITATIVE |
|---|
| #1 Vesicovaginal Fistula.mp. |
| #2 Vesicovaginal Fistula/ |
| #3 Urinary Bladder Fistula/ |
| #4 Urinary Fistula/ |
| #5 Vaginal Fistula/ |
| #6 Rectovaginal Fistula/ |
| #7 Obstetric fistula.mp. |
| #8 Obstetric fistula/ |
| #9 Female genital fistula.mp |
| #10 Female genital fistula/ |
| #11 Urogenital fistula.mp. |
| #12 Urogenital fistula/ |
| #13 Experimental Treatment outcomes |
| #14 Treatment outcomes |
| #15 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or10 or 11 or 12 or 13 or 14 |
| #16 14 or 15 |
| #17 16 and 17 |

**Table 2: Inclusion/exclusion criteria**

**Inclusion criteria**

- Predictors of fistula surgery related studies.
- Papers relating to any healthcare setting.
- Studies published in English.
- Primary or secondary research papers.

**Exclusion criteria**

- Papers not written in English
- Poor quality of the papers
- Case studies
- Case series
- Opinion pieces and Papers not related to female genital fistula
- Cancer and radiation-related fistula
- Fistulas in males
- Fistulas in Crohn's disease or ulcerative colitis
- Infant fistulas

**Table 3: QUANTITATIVE PAPER SCORING USING HAWKER'S TOOL**

| Authors | Abstract & Title | Introduction & Aims | Method & Data | Sampling | Data Analysis | Ethics & Bias | Results | Transfer-ability | Implica-tion | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| 1. Bodner-Adler et al. (2017) | 4 | 3 | 4 | 4 | 4 | 2 | 4 | 3 | 3 | 31 |
| 2. Moses et al. (2017) | 3 | 4 | 2 | 2 | 2 | 1 | 3 | 2 | 3 | 22 |
| 3.Sori et al. (2016) | 4 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 2 | 29 |
| 4.Loposso et al. (2016) | 4 | 3 | 4 | 3 | 3 | 2 | 4 | 4 | 3 | 30 |
| 5.Delamou et al. (2016) | 3 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 32 |
| 6. Bengtson et al.(2016) | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 35 |
| 7.Wahab et al. (2016) | 4 | 3 | 3 | 3 | 1 | 3 | 1 | 3 | 1 | 18 |
| 8.Delamou et al. (2015) | 3 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 33 |
| 9.Gedik et al. (2015) | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 21 |
| 10. Javed et al. (2015) | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 22 |
| 11.Cowgill et al. (2015) | 4 | 4 | 4 | 4 | 4 | 1 | 4 | 4 | 3 | 32 |
| 12.Loposso et al. (2015) | 4 | 3 | 4 | 3 | 3 | 4 | 3 | 4 | 3 | 31 |
| 13.Wright et al. (2015) | 3 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 25 |
| 14.Mellano et al. (2014) | 4 | 4 | 2 | 2 | 2 | 2 | 4 | 3 | 3 | 26 |
| 15.Takayanagi et al. (2014) | 3 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 2 | 28 |
| 16.Tayler-Smith et al. (2013) | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 4 | 3 | 33 |
| 17.Tenggardjaja et al. (2013) | 3 | 4 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 23 |
| 18.Wang et al. (2013) | 4 | 4 | 4 | 3 | 3 | 4 | 3 | 3 | 4 | 32 |
| 19. Barone, et al. (2013) | 3 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 33 |
| 20.Frajzyngier, et al. (2013) | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 3 | 34 |
| 21.Rafique et al. (2013) | 3 | 4 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 22 |
| 22.Kayondo et al. (2012) | 4 | 4 | 4 | 2 | 4 | 3 | 4 | 4 | 3 | 32 |
| 23.Hategekimana, (2001) | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 3 | 33 |

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