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## Good clinical outcomes from a seven years holistic program of fistula repair in Guinea

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### Abstract

**Objectives:** Female genital fistula remains a public health concern in developing countries. From January 2007 to September 2013, the Fistula Care project, managed by EngenderHealth in partnership with the Ministry of Health, and supported by USAID, integrated fistula repair services in the maternity wards of general hospitals in Guinea. The objective of this article is to present and discuss the clinical outcomes of 7 years of work involving 2116 women repaired in three hospitals across the country.

**Methods:** This was a retrospective cohort study using data abstracted from medical records for fistula repairs conducted from 2007 to 2013. The study data was reviewed during the period April to August 2014.

**Results:** The majority of the 2116 women who underwent surgical repair had vesico vaginal fistula

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(n=2045, 97%) and 3% had recto vaginal fistula or a combination of both. Overall 1748 (83%) had a closed fistula and were continent of urine immediately after surgery. At discharge 1795 women (85%) had a closed fistula and 1680 (79%) were dry, meaning they no longer leaked urine and/or faeces. 115 (5%) remained with residual incontinence despite fistula closure. Follow-up at three months was completed by 1663 (79%) women of whom 1405 (84.5%) had their fistula closed and 80% were continent. 21% were lost to follow-up.

**Conclusion:** Routine programmatic repair for obstetric fistula in low resources settings can yield good outcomes. However, more efforts are needed to address loss to follow-up, sustain the results and prevent the occurrence and/or recurrence of fistula.

**Keywords:** Obstetric fistula, Guinea, Fistula Care, Operational research, SORT-IT

### Introduction

Female genital fistula is a serious medical condition in which a perforation develops either between most commonly bladder and vagina (vesico-vaginal fistula [VVF]), between rectum and vagina (recto-vaginal fistula [RVF]), or a combination of both. It occurs most commonly after prolonged labour when the head of the unborn child compresses the birth canal and leads to tissue necrosis (1;2). More rarely, fistula may be caused by genital cutting such as *yankan gichiri*, sexual violence, iatrogenic reasons (from c-section, hysterectomy or poorly performed abortions), pelvic fractures, and malignancy or radiation (3-5). Female genital fistula is no longer prevalent in the developed world, but remains a common public health concern in developing countries (6;7). There are no good estimates of the burden of fistula but the most recent estimates of its prevalence range from one to two million worldwide, based on reviews by Stanton et al and Adler et al (8;9).

In Guinea, 0.6 % of women experienced obstetric fistula in their lifetime (10). As in many other resource-limited settings, the local capacity to diagnose and to perform surgical repair is very limited. Up to 2006, only the Department of Urology of the Ignace Deen Hospital was recognized and was performing quality surgical repair for female genital fistula in Guinea. In 2007, EngenderHealth (an international reproductive health non-governmental organization) helped to establish and strengthen three additional centers for fistula management in Guinea, of which three continued to perform surgical repair up to the end of this project in 2013.

While immediate post-operative closure rates for obstetric fistula can be as high as 90% (11;12), this rate varies by repair center and other factors such as the size of fistula, surgeon's experience, pre-operative bladder size, degree of vaginal scarring, degree of urethral involvement and number of previous repairs (13;14). Although urinary continence is not always achieved immediately after surgical repair even with closure of the fistula, residual incontinence can improve or be resolved with time (15). Repair breakdown can happen as a consequence of inadequate post-operative care or poor catheter management and has been reported following hospital discharge, for reasons including heavy work, sexual intercourse, wound infections and at the subsequent pregnancy in case of prolonged labour or poor management of vaginal delivery (16).

Many published studies have reported on fistula characteristics, risk factors and outcomes of repair from different settings (11;12;17-20). However, all previous studies in West Africa either focused on outcomes at discharge and most used a relatively small sample size from one repair center (21;22). This paper assesses the characteristics of more than 2000 women and their clinical outcomes after fistula repair from three local repair hospitals across Guinea. Routine programme data could yield useful and reliable information to guide future fistula programmes in Guinea.

Using data on women who underwent surgical repair of female genital fistula at three hospitals in Guinea with repair services supported by Fistula Care, we report on: (1) the demographic and clinical characteristics of patients, (2) The number and proportion of fistula types, (3) outcomes of the treatment up to 3 months follow-up (fistula closed and dry, fistula closed with residual incontinence and fistula not closed) stratified by fistula type, number of previous repairs, duration of fistula and year of repair at the time of hospital discharge.

## **METHODS**

### **Study design**

This was a retrospective cohort study using data abstracted from medical records for fistula repairs conducted from 2007 to 2013.

## Setting

Guinea is a West African country with a population of about 12 million (6). It is among the poorest countries in the world with the majority (65%) of the population living in rural areas. Health indicators are poor including a maternal mortality ratio of 724 per 100 000 live births (10).

Fistula Care supported both prevention and treatment, with a focus on treatment at three geographically dispersed centers, as well as reintegration of fistula patients into the community. The three centres that continued with repairs during the Fistula Care project are integrated within the maternity unit of hospitals in geographically dispersed regions of Guinea (Jean Paul II Hospital in Conakry, the Regional Hospital of Labé and the Prefectoral Hospital of Kissidougou).

Building capacity included ongoing training of surgeons, training of nursing staff, counselling training, quality improvement, medical monitoring, equipment provision, and mentorship for continuous skills building (23). Surgeons from the Geneva Foundation for Medical Education and Research (GFMER) travelled to Guinea on a quarterly basis to lead training sessions and monitor progress of trainees. Sixteen Guinean local surgeons received training with support from Fistula Care. They attended an average of 22 training sessions, with 12 continuing to provide surgery after the Fistula Care ended. Each centre was staffed by two or three surgeons, an anaesthetist, a counsellor and two to four nurses all trained in fistula prevention and management. Community awareness campaigns on fistula and the availability of fistula management services were conducted regularly through collaboration with rural radio, community leaders and community volunteers (village safe motherhood committees).

The three centres collectively performed on average 300-400 surgical repair operations per year. Treatment in the centres was free and included assessment and surgical repair by a surgeon, and counselling about exercises, family planning methods, and restrictions on sexual intercourse and heavy labour during the healing period.

For each woman, surgical outcomes (fistula closed and dry, fistula closed with residual incontinence and fistula not closed) were assessed immediately after surgery, at hospital discharge and three months later. Women with a fistula that was not closed at the time of the follow-up visit were usually scheduled for another repair surgery. Patients were considered lost to follow-up if they failed to attend the follow-up appointment within six months of their discharge for reasons that included residence out of the country, death, farming, etc.

The fistula was considered not closed (immediately after surgery or in the case of initial closure breakdown within 3 months of surgery) if the woman reported an uncontrolled and continuous leakage of urine. Residual incontinence, some incontinence remaining despite fistula closure, could be urge, stress or overflow incontinence. The woman was considered dry if the fistula was closed and there was no leakage of urine or faeces.

### **Study population and participants**

We included all women who underwent fistula repair surgery in each of the three sites between January 1<sup>st</sup>, 2007 and September 30, 2013.

### **Data variables, source of data and data collection**

The socio-demographic and clinical characteristics of fistula patients were extracted from patient files and included age at admission in the repair site, marital status, age at marriage, occupation, level of education, residence (rural/urban), parity, number of previous repairs, duration of fistula, mode of delivery causing fistula, neonatal outcome at causal delivery, and type of fistula (VVF, RVF or both). Treatment outcomes (fistula closed and dry, fistula closed with residual incontinence and fistula not closed) were assessed by a dye test immediately after surgery, at the time of hospital discharge and at 3 months follow-up visit in most, but not all cases. Data was sourced from patients' files, kept at each fistula care repair hospital, using structured forms. Patient files were reviewed between April and August 2014.

### **Data analysis**

Collected data were double-entered by two independent encoders into EpiData Entry software (version 3.1, EpiData Association, Odense, Denmark). The two data files were compared and discordances resolved by cross-checking with the data collection forms. Data were analysed using STATA 13 software (STATA Corporation, College Station, TX, USA). Frequencies (%) were calculated to describe patients' characteristics and treatment outcomes. Pearson's Chi square ( $\chi^2$ ) was used to compare proportions of treatment outcomes for selected variables with a level of significance set at  $P = 0.05$  and a 95% confidence intervals.

## Ethics

Ethics approval was obtained from the Guinean National Ethics Committee for Health Research, the MSF Ethics Review Board (Geneva, Switzerland) and the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France.

## Results

### Sociodemographic and clinical characteristics

Overall 2116 women underwent surgical repair for female genital fistula at the three repair hospitals. The demographic and clinical characteristics of these women are presented in Table 1. The median age at presentation was 32 years (interquartile range (IQR) 25-40). The majority of women (n=2045, 97%) had vesico vaginal fistula and 3% had rectovaginal fistula or a combination of both. Half of the women were married before the age of 17 years and 29% developed the fistula at their first pregnancy and 1978 women (93%) had stillbirths for the referent pregnancy. Almost one of five women had the fistula for 5 years or more at the time they came to the hospital for repair.

### Treatment outcomes

Figure 1 shows patient flow and treatment outcomes after surgery, at discharge and three months after follow-up. Of the 2116 women who underwent surgical repair, 1748 (83%) had a closed fistula and were dry immediately after surgery. At discharge, 1795 (85%) of all the repaired women had a closed fistula. 1680 of these (79%) were closed and dry of urine and/or faeces while 115 (5%) had residual incontinence despite fistula closure. Of the 1663 (79%) who completed three months of follow-up, 1405 (84.5%) had a closed fistula and 80% were continent (dry). Overall 453 women (21%) were lost to follow-up.

Over the seven-year duration of the project, fistula closure rate at discharge increased from 85% in 2007 to 89% in 2013, and the continence rate rose from 78% in 2007 to 88% in 2013 (Figure 2). At three months of follow-up, fistula closure rate increased from 88% in 2007 to 95% in 2013, and the continence rate from 85% in 2007 to 94% in 2013 (Figure 2).

At hospital discharge, all women with a recto-vaginal fistula (RVF) had a closed fistula and remained dry (Table 2). Of those with vesico-vaginal fistula, 80% had a closed fistula and were dry, while 5% had a closed fistula with residual incontinence. Of those with both a VVF and an RVF 56% were closed and dry and 2% were closed but had residual incontinence. Compared to women with a previous history of repair attempts, women with no previous history of repair attempts had statistically signifi-

cantly better surgical outcomes ( $p=0.001$ ). Women who had their fistula fewer than five years had a better outcome than women with five years or more duration ( $p=0.003$ ). Also surgical outcomes were better in women with recto-vaginal fistula than those with vesico-vaginal fistula or both types ( $p<0.001$ ).

## Discussion

This is the first retrospective study of data from Guinea reporting on cumulative outcomes at three-month follow-up among women who underwent surgical repair for female genital fistula over a period of seven years. Overall, the study showed high rates of fistula closure and continence at discharge and at three months follow-up. The rate of loss to follow-up at three months in this setting is low compared to 40% reported by *Bishinga et al* (15) from Burundi.

We observed a high closure rate at discharge (85%) and at 3 months of follow-up (84.5%), similar to what was reported in other studies in African settings (11;25-28). The continence rate was 79% at discharge and 80% at 3 months of follow-up, which falls within the range reported by Arrowsmith et al (13) and higher than what was reported by Bishinga et al (67%) (15) in Burundi. Even though rates of closure and continence depend on the severity of the fistula, making comparison of different settings difficult, one explanation could be the fact that our program built on experience in surgical repair of fistula over time, with closure and continence rates increasing over time, while the one in Burundi was in its first year of implementation. In addition, fistula management requires specialized training for not only surgeons but also medical staff involved in the hospital management of patients to ensure good and sustainable results. Our results showed an improvement in the continence rate over time suggesting an improvement in the quality of care due to continuous training and supervision throughout the project life cycle. It has been reported that fistula that are repaired sooner after occurrence, as well as simple fistula provide better results (12;20) and our results could suggest the unusual situation of an established program seeing progressively 'earlier' and 'simpler' cases. Introducing physiotherapy in the package of fistula care at the repair hospitals could also contribute in improving outcomes and reducing residual incontinence (24).

Our lost to follow-up rate at three months (21%) was lower than that reported from a routine program setting (41%) in Burundi by Bishinga et al (15) and by Browning et al (16) at six months (39.5%). However, some of the women in our study (17%) were part of either a prospective cohort study or a randomized controlled trial conducted at one of the sites, which used specific proactive strategies to reduce loss to follow-up (14;25), thus potentially causing an artificial inflation of our follow-up rate.

Our loss to follow-up rate was however higher than the 8% reported by Maulet et al (26) from a 18 months prospective follow-up of a 120 fistula patients' cohort conducted in Mali and Niger, and the 14% reported by Nielsen et al (27) in Western Ethiopia after a 14-28 months community-based follow-up. In both studies, active search of women was conducted and could explain the low rate of loss to follow-up observed.

We observed a high rate of stillbirths with the referent delivery, better repair outcomes in women with no history of previous repair attempt, women with shorter duration of fistula, and women having recto-vaginal fistula, consistent with the findings reported by other studies from Africa (12;20).

Finally, prevention of fistula occurrence is the definite answer towards a fistula free generation. This must include education about community awareness to reduce socio-cultural factors that increase risk of obstetric fistula, promotion of deliveries in health facilities, improvement of contraceptive methods use (28), and advocacy for compliance with country laws aimed to reduce pregnancies in teenagers.

As the government in Guinea is planning to launch a new fistula project, we concur with Bishinga et al (15) that fistula programs might benefit from a model of cohort monitoring such as that used routinely with chronic diseases such as tuberculosis, where patients are closely followed up for longer periods with various strategies (phones, home visits, community health workers, etc.) to evaluate programs success.

For instance a study in Ethiopia (16) reported 22 women who came back leaking at six months of follow-up among 141 women initially cured at discharge. This confirms the risk of late breakdown after successful repair and warrants more research into the causes and associations of late fistula.

The main limitation of this study was that the reasons for loss to follow-up could not be determined, as patients lost to follow-up were not routinely followed up using home visits or phone calls. A strength of our study is the large number of patients with different types of fistula, making this the largest reported national cohort of fistula patients. Because some data were routinely collected during the course of the Fistula Care project at the three repair hospitals, capacity building in the area of data recording and review, with regular monitoring and supervision were routinely carried out, thus the data are likely to be accurate and representative of what was actually going on at the sites. Finally, we report our results using the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (29).



## Conclusion

In conclusion, routine repair services for female genital fistula in low resources settings are feasible and can yield good outcomes. However, for clinical services to be successful, they must be couched in a “holistic program” that encompasses supportive policies, active community engagement and partnership, psychosocial support in addition to an effective and functioning supply of services. Further work is needed to trace women who are lost to follow-up, and to maintain excellent repair services throughout Guinea and other countries where obstetric fistulas are common.

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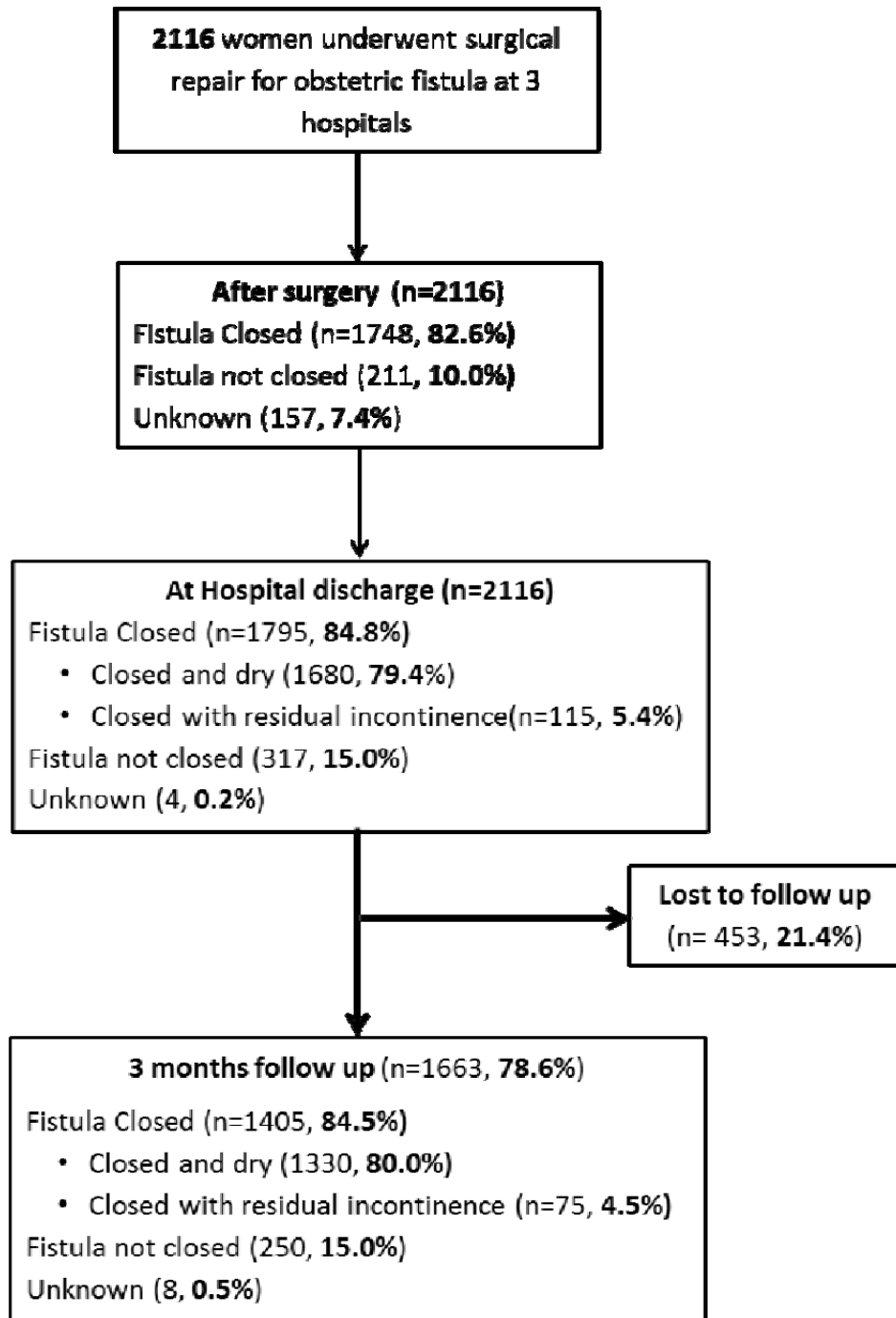
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**TABLE 1:** Demographic and clinical characteristics of women who underwent fistula repair in hospitals supported by Fistula Care in Guinea, 2007 to 2013

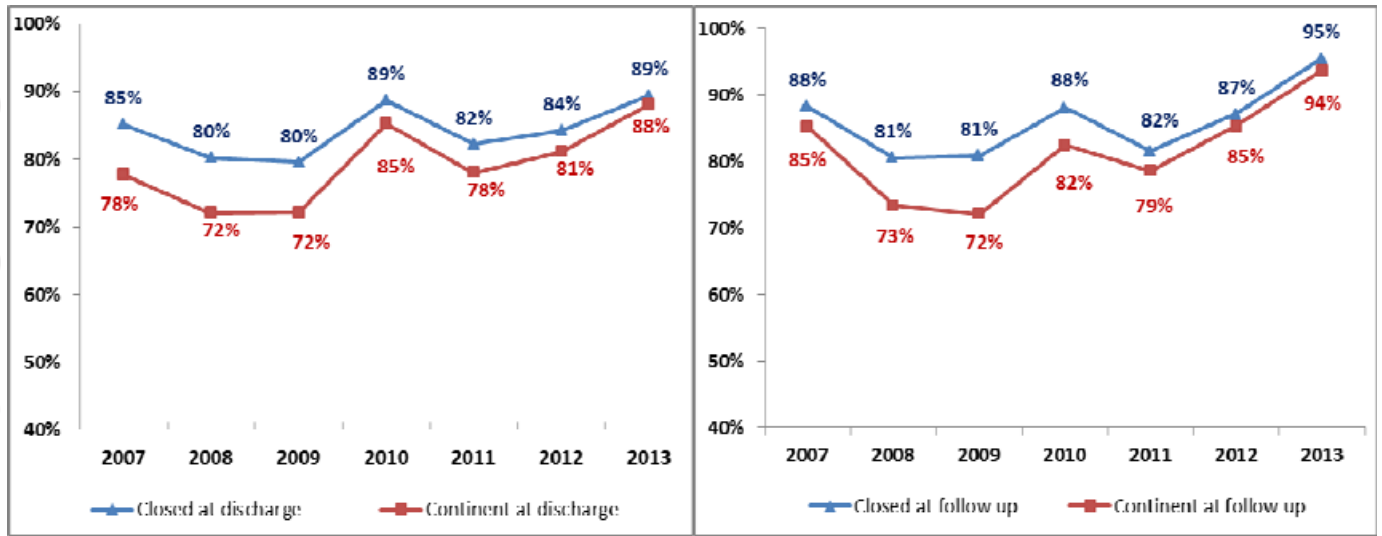
Variables	Number (%)
<b>Total</b>	<b>2116</b>
<b>Age at presentation to repair center (in years)</b>	
< 17	63(3.0)
17 – 24	402(19.0)
25 – 49	1293(61.1)
≥ 50	326(15.4)
Unknown	32(1.5)
<b>Marital status</b>	
Single	82(3.9)
Married/Union	1442(68.1)
Separated	378(17.9)
Widow	189(8.9)
Unknown	25(1.2)
<b>Age at marriage (in years)</b>	
< 17 <sup>1</sup>	1212(57.3)
≥ 17	279(13.2)
Unknown	625(29.5)
<b>Occupation</b>	
Housewife	2026(95.7)
Worker	65(03.1)
Unknown	25(1.2)
<b>Education</b>	
None	1896(89.6)
Primary	99(4.7)
Secondary & higher	22(1.0)
Unknown	99(4.7)
<b>Residence</b>	
Rural	1912(90.4)

<sup>1</sup> In Guinea, the legal age of marriage for women is 17 years

Urban	195(09.2)
Unknown	9(0.4)
<b>Parity</b>	
1 birth	625(29.5)
2 – 5 births	950(44.9)
≥ 6 birth	510(24.1)
Unknown	31(1.5)
<b>Previous repairs attempts</b>	
0	1219(57.6)
1	514(24.3)
2	236(11.1)
≥ 3	107(5.1)
Unknown	40(1.9)
<b>Duration of fistula (in years)</b>	
≤ 1	405(19.1)
2 to 4	448(21.2)
≥ 5	1017(48.1)
Unknown	246(11.6)
<b>Mode of causal delivery</b>	
Vaginal	1377(65.1)
Caesarean section	698(33.0)
Unknown	41(1.9)
<b>Neonatal outcome</b>	
Alive	102(4.8)
Stillborn	1978(93.5)
Unknown	36(1.7)
<b>Type of fistula</b>	
Vesicovaginal fistula (VVF)	2045(96.6)
Rectovaginal fistula (RVF)	23(1.1)
VVF + RVF	48(2.3)



**Figure 1** Patient flow and follow-up at three fistula repair hospitals supported by the Fistula Care Project in Guinea, 2007 to 2013.



**Figure 2:** Annual trend in treatment outcomes at hospital discharge and at 3 months of follow-up for women undergoing surgical repair for fistula in Guinea, 2007 to 2013.

**Table 2:** Fistula closure and continence status by type, number of previous repair attempts and duration of fistula for women undergoing surgical repair for obstetric fistula at hospital discharge in Guinea, 2007 to 2013.

Selected variables	Surgical outcome				P*
	Fistula closed		Fistula not closed	Fistula status unknown	
	Dry	Residual in-continence			
<b>Type of fistula (n=2116)</b>					
VVF	1630(79.7)	114(5.6)	297(14.5)	4(0.2)	< 0.001
RVF	23(100.0)	0(0.0)	0(0.0)	0(0.0)	
VVF & RVF	27(56.3)	1(2.0)	20(41.7)	0(0.0)	
<b>Previous repair attempts (n=2076)</b>					
No previous repair attempt	1019(83.6)	48(3.8)	153(12.5)	1(0.1)	0.001
≥1 previous repair attempt	634(74.0)	67(7.8)	153(17.9)	3(0.3)	
<b>Duration of fistula (1870)</b>					
≤ 1 year	350(86.4)	13 (3.2)	41 (10.1)	1 (0.2)	0.003
2 to 4 years	371(82.8)	23 (5.1)	54 (12.1)	0 (0.0)	
≥ 5 years	777(76.4)	72 (7.1)	167 (16.4)	1 (0.1)	

\* Comparing proportions of closed fistula