FISTULA CAMPAIGNS—ARE THEY OF ANY BENEFIT?

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SUMMARY

Objective: Evaluation of the problems encountered during a voluntarily fistula campaign in a regional hospital of Niger (Africa).

Materials and Methods: Women underwent basic gynecological examination, methylene blue testing, and/or direct cystoscopy as necessary. According to their clinical condition, women were informed and surgical options offered as appropriate. Operations were performed under spinal or epidural anesthesia. Immediate postoperative outcomes were followed during the stay of the surgical team in the country.

Results: A total of 62 women were examined and 11 had causes of incontinence other than obstetric fistula. In 9.8% of the women, severe local infection precluding any surgical intervention was evident. In 58.8% of patients, the trigonal region and/or urethra were irreversibly damaged. A proportion of patients (9.8%) with large lesions and intact urethra that were offered vaginal layered closure refused the intervention. Of the women that were operated on (21.6%), six underwent vaginal layered closure with Martius fat flap and five women underwent a combined abdomino-vaginal approach.

Conclusion: It is extremely difficult to meet the needs of this global problem with short term programs and volunteers. Directing these efforts to specialist fistula centers and creating reliable scientific evidence should be the main goal. [Taiwan J Obstet Gynecol 2010;49(3):291-296]

Key Words: ethical problems, fistula campaign, obstetric fistula

Introduction

ELSEVIER

It is well known that vesicovaginal fistulas from obstructed labor, obstetric fistulas (OFs), require specialized surgical skills and management [1]. Unfortunately, such injuries are very prevalent in impoverished countries of sub-Saharan Africa where adequate medical conditions are lacking. As the problem of OFs has received more publicity in recent years, the number of surgical volunteers traveling to these countries to perform OF repairs has increased [2]. To date, these efforts have been carried out largely at district general hospitals by well-intentioned individuals acting alone [3]. Therefore, it is not surprising that a standardized

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has to be taken into account in planning repair operations in these countries. Victims are often malnourished and infected, and conditions of district general hospitals are not designed for the specific management of OFs and even actions taken with the best of intentions can produce unethical results [2]. Our intent was to report the problems encountered by volunteers trying to carry

out OF repair in a regional hospital in Niger (Africa).

clinical database among all the centers worldwide that are engaged in treating women with this condition does

not exist. Each author reports their case series individ-

ually and somewhat subjectively [4]. The current data

regarding OFs are not reliable [5]. It has been reported that as high as 90% of all fistulas are correctable by

simple vaginal surgery [6-8], but this percentage is

thought to be an overestimation [4] and may frustrate

volunteers due to the unexpected extent of OFs and

the complexity of OFs is not the only problem which

Despite the controversies reported in the literature,

associated complexities [9].

Material and Methods

After local radio programs announcing an option of foreign doctors aiming to help women with OFs, women presumably suffering from urinary incontinence due to vesicovaginal fistula were voluntarily gathered for examination in Maradi Regional Hospital, Niger.

All patients underwent basic gynecological examination. Pregnant women and patients with malignant causes of incontinence were excluded. In women in whom the fistula tract could not be directly visualized upon gynecologic examination, methylene blue testing was performed. Women with a positive methylene blue test result and no directly visible fistula tract underwent direct cystoscopy. After establishing their clinical condition, women were informed and surgical options such as layered closure together with Martius fat or Gracilis flaps, or abdominal transvesical repair with omental flap were offered as appropriate. Operations were only performed after obtaining the verbal consent of patients and of the local hospital medical director. The surgical team consisted of two urogynecologists, one urologist, one anesthesiologist, and two residents of an urogynecology clinic from a teaching hospital. Operations were performed under spinal or epidural anesthesia. Immediate postoperative outcomes were followed during the stay of the surgical team in the country.

GraphPad Instat 3.06 (Windows) was used for the statistical analysis. During the evaluation of the study data, along with the descriptive statistical methods, unpaired t tests with Welch correction for different standard deviations and Fischer's exact test were used. Results were given with a 95% confidence interval and considered statistically significant when the p value was less than 0.05.

Results

A total of 62 women were eligible for examination. One woman with suspected advanced stage cervical cancer and two pregnant patients were excluded. In seven patients, the extra-urethral leakage of the dye under resting conditions could not be demonstrated and in four of these women the reasons for their incontinence was revealed to be due to detrusor overactivity and stress incontinence. In one patient who had undergone a previous fistula repair operation, the cause of her incontinence was found to be due to a short urethra with a very weak sphincter function without any fistula.

In total 51 women were diagnosed as having OFs. Five (9.8%) patients had severe local infection precluding any surgical intervention. In 30 (58.8%) patients,

the trigonal region and/or urethra were irreversibly damaged with or without scarring. Five (9.8%) patients with intact urethra were offered vaginal layered closure and Gracilis flap because of the extent of their lesions. In another six (11.8%) patients with intact continence mechanisms, the surgical option was vaginal layered closure with Martius fat flap. In five (9.8%) women with intact urethrovesical area, a combined abdominovaginal route was chosen because of the immobility and fixation of the bladder and urethrovesical junction against the pubic bone with extensive scarring stenosing the vagina. Women with irreversibly damaged continence mechanisms were not operated upon and the option of closure with Gracilis flap were refused by patients. Among 11 (21.6%) women operated upon, six were subjected to vaginal layered closure with Martius fat flap and five by the combined abdomino-vaginal approach. None of the women were diagnosed as having rectovaginal fistula. A comparison of demographic and social/sexual data of women that were and were not operated upon can be seen in Tables 1 and 2.

Discussion

There is no reliable data in the literature about OF. This lack of evidence may harm attempts to combat the situation, particularly impoverished countries with a high OF prevalence, where facilities typically have very limited services and resources. Although some specialized fistula centers exist in these regions, it is estimated that the unmet need for the treatment of OFs could be as high as 99%.

As a result, OF has surfaced as an issue of international public health concern with public health communities and initiatives sponsored by international institutions like the United Nations Population Fund, the World Health Organization, and the International Federation of Gynecology and Obstetrics [3].

The problem of obstetric fistula was eliminated long ago in the west but the international medical community has slowly become aware of its persistence in Africa and Asia when Reginald and Catherine Hamlin first wrote about this catastrophic condition in 1966. Since then, proposals for its solution have been put forth with increasing frequency [10]. Although fistula repair has been performed in several countries, there are few hospitals, such as the Hamlin Addis Ababa Fistula Hospital, that are dedicated only to fistula repair. Similar sites in Ethiopia, Kenya, Malawi, Mali, Mozambique, Niger, and Nigeria are reported to have inadequate training and limited supplies, resulting in restricted availability of treatment [11]. Two decades ago, some have suggested

Table 1. Demographic data for women who were and were not operated upon

	Operated $(n=11)$	Not operated $(n=40)$	Þ
Age (yr)	28.2±10.4 (17-42)	32.6±14.5 (18-65)	>0.05
Gravidity (n)	6.0 ± 3.2 (2-12)	$4.6 \pm 2.8 (1-10)$	> 0.05
Parity (n)	$1.5 \pm 0.5 (1-2)$	$1.6 \pm 0.9 (1-6)$	> 0.05
Duration of fistula (mo)	$16.3 \pm 9.6 (12-36)$	$46.1 \pm 90.7 (2-370)$	< 0.05
Multiple attempts	5 (45)	29 (72)	> 0.05
Death of the baby	7 (64)	24 (60)	> 0.05
Operative delivery	3 (27)	15 (38)	> 0.05
Ceserean section	3 (27)	11 (28)	>0.05

^{*}Data are presented as mean \pm standard deviation (range) or n (%).

Table 2. Social and sexual data of women who were and were not operated upon

	Operated $(n=11)$	Not operated (n=40)	p
Age at marriage (yr)	15.3 ± 1.1 (14–16)	14.7±0.4 (14-15)	> 0.05
Monthly income (US\$)	$27.9 \pm 10.6 (20.0 - 37.5)$	$29.4 \pm 6.6 (20.0 - 37.5)$	> 0.05
Absent sexual relation	10 (91)	36 (90)	> 0.05
Divorced	5 (45)	19 (48)	> 0.05
Abandoned by husband	5 (45)	17 (43)	> 0.05
Socially isolated	2 (18)	15 (38)	> 0.05

^{*}Data are presented as mean \pm standard deviation (range) or n (%).

that mass surgical campaigns may be a suitable approach to the fistula problem in parts of the world where large numbers of women with unrepaired vesicovaginal fistulas reside [12]. This led to the problem of OF receiving more publicity in recent years. In a database search on PubMed using "obstetric fistula" as the keyword, 540 articles were displayed and only the articles dealing with OF in developing countries were considered. It was noted that 76.4% of such articles were published in the last two decades over a period of more than five decades, and as many as 58.6% were published in the last decade. Obviously, the number of surgical volunteers involved in campaigns for the treatment of OF in developing countries has increased [13]. These programs, policies, and campaigns are mainly developed by organizations or by the actions of wellmeaning individuals. Some international aid agencies and non-governmental organizations generally work together using international reproductive health funds to organize and/or support anti-fistula activities. On the other hand, some organizations function almost entirely through the donation of time and supplies of its administrative and physician members [5].

Some campaigns maintain the idea of being a short but intensive organization in which hundreds of women undergo surgical operations over a short period of time, such as 2 weeks [12]. Other approaches are longer in duration and involve training local surgeons to deal with these complex cases and to increase foreign interest and financial involvement through publishing their

experiences [5]. Global, rather than local campaigns like the first Global Campaign to End Fistula led by the United Nations Population Fund, has the goal of eventually making fistula as rare in Africa and Asia as it is in the developed world. The campaign currently covers more than 30 countries in sub-Saharan Africa, South Asia, and some Arab states [14].

As the problem of OF has received more publicity, the number of surgical volunteers has increased [8]. These good intentioned attempts may have cured some victims but also contributed to a lack of data. In various cases reported, the systems used to stage the fistulas were highly individualized by the authors. Some of these systems were subjectively descriptive, with terms such as "simple" and "complex"; other investigators based their systems on location and/or size of the fistula. Follow-up data was often lacking, and success and failure definitions are mostly made with the status of the fistula at discharge from the hospital but data regarding the procedure's outcome on quality of life, continence, and societal integration are not reported [9].

Additionally, all case series in the literature report the conditions and/or results of women who underwent surgical interventions. It should be obvious that not all the victims of OF can be surgically managed especially when little is known about the poor local conditions and the true clinical status of these women desperately waiting for help from "fistula campaigns" carried out by surgical volunteers. In this report, we present for the

first time data about a cohort of women operated and not operated on by volunteers and discuss the problems encountered.

Fistula campaigns are generally planned within a limited time frame and the reported numbers of women surgically managed are less than the extent of the public burden of the disease. The number of women operated on is not more than 100 per year or approximately two operations per week [5,15]. In contrast, specially designed fistula centers seem to work more efficiently. One report from such a center reveals approximately six times more surgically intervened patients per year compared with the numbers of patients in published fistula campaigns [16]. This reflects the inefficiency of isolated actions. These actions are generally announced with public services [15] with apparently little effect on rural regions because they have no electricity. It is possible that many women are still unaware of the availability of treatment and it is estimated that 80% of women with fistulas never seek treatment. The main reason for this is a lack of knowledge that anything can be done for their condition [17]. It is noteworthy that in a report of such a campaign, more than half of the patients presenting for treatment had a history of at least one previous repair. The authors speculate that this might be a reflection of the self-selection of women who were already aware of fistula surgery missions [15]. In our series, only 62 women came together 11 months following public announcements, with 82% of them diagnosed as suffering from OF and likewise more than half of these patients (66%) had a history of previous attempts for repair.

Not all the women seeking a cure for their incontinence suffered from OF. In a cohort of women not previously examined in any way, diagnosis was a challenge, especially with the limited resources of a regional hospital where the campaigns were generally carried out. It is surprising that most reports in the literature about OFs are lacking in their diagnostic methods. Although a significant portion of OFs is large enough to diagnose with simple inspection, dyes and cystoscopic intervention are inevitable, particularly for smaller, multiple, and previously repaired fistulas. In a significant number of women we examined waiting to be freed from the burden of their fistulas, the extraurethral leakage of the dye in resting conditions could not be demonstrated; detrusor overactivity and stress incontinence were the possible diagnoses. Although very difficult in fistula patients, urodynamic investigations should be an essential part of the pre- and postoperative assessment of these women because of the high incidence of abnormal lower urinary tract function in patients with urogenital fistulae [18]. These cystometric data are lacking even in papers that

report about creating a neourethra in fistula patients [15,19]. Simple office cystometric techniques are proposed elsewhere but they are not indicated in such complicated cases of incontinence [20]. Urodynamic investigations were impossible in our study because of the limited conditions of the hospital with diagnoses like stress incontinence and detrusor overactivity made using supine stress test and patient history.

One of the most confusing aspects in the literature is the classification of the lesions. Unfortunately, a standardized classification system for OF does not exist. There are more than 20 classification systems proposed for genitourinary fistulas. Various authors have focused on different characteristics of fistulas and emphasized elements like the type, location, number, and size (length and width of the fistula); involvement of other organs; degree of vaginal scarring; attachment of the fistula to the pelvic wall; condition of the urethral sphincter and permeability of the internal orifice of the urethra; location of ureteral orifices and their relation to the edges of the fistula; and presence of complications such as a recto-vaginal fistula and inflammatory lesions of the pelvis, vagina, vulva, or peritoneum as important factors for their classification systems [21]. A more clinical approach is to describe the OF as simple or complex. Complexity of a fistula is defined with relation to the bladder neck and ureteral orifices, its size influencing the residual bladder and urethra, and its degree of scarring affecting accessibility and mobility as well as the vagina's residual capacity, function, and its interference with the integrity of the sphincteric mechanism. A fistula is considered complex when it is greater than 4 cm and involves the continence mechanism (whether the urethra is partially absent, the bladder capacity is reduced, or both), is associated with moderately severe scarring of the trigone and urethro-vesical junction, and/or has multiple openings. It should also be noted that a simple fistula may become complex when repair fails [9]. The majority of OFs are reported as complex [9]. Owing to the controversies about the classification of OF, we neither used any proposed system nor reported our patients as simple or complex because we agree with Genadry's opinion that "In the absence of a universally accepted classification, the degree of complexity reported for a vesicovaginal fistula is inversely related to the surgeon's experience and remains subjective" [9]. It should be noted that in our cohort of women, 80.4% had fistulas greater than 4cm and/ or trigonal-urethral involvement and/or severe scarring reducing vaginal or bladder capacity. Some 66% of patients had experienced previously failed repairs. Only 19.6% of fistulas were primary, less than 4 cm, and not involving any adjacent structure.

A compliant bladder of adequate capacity; adequate bladder outlet resistance; adequate bladder emptying; and maintenance of a sterile, non-obstructed, nonrefluxing upper urinary tract are the four criteria to be fulfilled in urinary tract reconstructive operations [9]. Given the fact that the majority of OFs are located at the trigonal and/or urethral region [10], the repair of OF is not a simple skill. Reported success rates should be critically interpreted and a definition of success is required. Incontinence rates due to stress incontinence, mixed incontinence, detrusor overactivity, and/or impaired bladder compliance after successful closures are not uncommon [4]. One half of the patients after successful fistula operations may show evidence of voiding dysfunction [15]. Management of these complications is nearly impossible in local hospitals where the campaigns were generally carried out, especially when the volunteers returned home, leaving some women with the burden of another lower urinary tract dysfunction. The condition is graver when the continence mechanism is irreversibly damaged or bladder capacity is significantly reduced due to extensive scarring. It has been reported that increasing numbers of these women are being subjected to urinary diversion. Under the rudimentary circumstances of a fistula campaign, the morbidity and mortality from these operations is high and several deaths have now been documented [2]. It is unjustifiable that inexperienced volunteers perform such operations. Even skilled surgeons who are familiar with these operations should keep in mind that his/her patient will not get the proper follow-up which may have fatal consequences. We did not perform any operation in 30 patients with reduced bladder capacity due to fibrosis and/or irreversible destruction of the urethrovesical junction and/or absent urethra. Only in one patient with urethral defect was direct reanastomosis of the remaining distal urethra to the urethrovesical junction with a combined abdomino-vaginal approach carried out.

Fistula victims waiting for volunteers for months in a regional hospital with extremely poor facilities may suffer from malnutrition and anemia. A significant number of them are either divorced or socially abandoned and they rely only on the food provided by the hospital, which is far lower than the needs of such a patient. The poor general health conditions of approximately 10% of our patients precluded their surgical intervention.

Obtaining informed consent is an essential part of medical practice in developed countries but this issue may become an ethical dilemma in fistula campaigns dealing largely with uninformed women from impoverished rural backgrounds. These women may place too much faith in their caregivers and give consent to undergo operations that they do not really understand.

Additionally, a desperate woman without other alternatives may regard the proposed management of her condition from a "foreign doctor" as a command rather than advice owing to her cultural presuppositions [2]. This makes them extremely vulnerable to manipulation, and institutional safeguards and policies governing organizational ethics are often lacking in African medical institutions. It is questionable whether these campaigns ensure adequate patient safeguards. All of our patients were illiterate and this added to the problem of how truly informed consent could be obtained. Help from family members was limited because 90% of them were either divorced or abandoned by their husbands and one third were socially isolated. We obtained verbal informed consent from all patients with the help of a local surgeon who spoke the local language and was familiar with the proposed procedures. As a result, all five patients that were offered vaginal closure with Gracilis flap did not give their consent to the operations because they were fearful of becoming more "crippled" and of worsening their physical conditions, which they would have to face alone because of their social isolation.

Fistula patients often face the loss of their babies, and any obstetrical help like operative delivery or cesarean section is often performed after the major hazard of obstructed labor has already occurred for both the mother and fetus [15]. In our study, more than half of the patients underwent obstetrical intervention but fetal loss was as high as 63% reflecting the inadequate conditions for prompt access to obstetric care in these countries. The only statistical difference in the demographic data between both groups was the duration of the fistula. In women who could not be operated on, the duration of the fistula was significantly longer. The main reason for this difference may be the complexity of their fistulas precluding surgical treatment in these circumstances. A simple fistula may become complex when repair fails. The number of previous repair attempts is reported to be an important factor for a successful surgical closure and the first repair affords the best success rate [22]. Although not statistically significant, the number of multiple attempts for surgical repair was higher in women with longer duration of their fistulas. Besides the health problems, the existence of permanent leakage of urine constitutes a major violation of a woman's right to social life. In both groups, the vast majority of women were either divorced or abandoned by their husbands. Sexual relationships were practically non-existent in these women aggravating their personal and social status by losing their femininity, which was also exacerbated by childlessness. The offensive odor of a fistula victim does not only lead them to

be ostracized by their husbands and families, but the community also discriminates against and isolates these women. Families may not want fistula survivors preparing food or participating in family events [17]. The prevalence of socially isolated women was higher in those who could not be treated surgically. This statistically insignificant difference may also due to the higher duration of the fistula.

Follow-up is a major concern in fistula campaigns, especially in the developing world, because caregivers leave the scene after campaign is over. Local medical organizations are unable to track patients, especially those coming from rural areas, and sometimes help from charitable organizations may be needed to locate women [15]. Although all of our patients were continent in the first week after their operations, we were not able to provide any follow-up data for our patients.

Fistula campaigns are generally organized by public health communities and if they deal with system operational issues rather than adopting a surgical perspective, their programs may conflict with the clinical behavior of surgeons. Public health professionals may tend to treat surgeons merely as "technicians" who can be used to provide "surgical services" [2]. Surgeons should not be affected by these policies and should be held strictly to surgical and ethical principles even though the number of adequately treated women would fall behind the expected levels.

In conclusion, although the need is great, the benefit from fistula campaigns organized in regional hospitals of impoverished countries obviously lies far below expectations. It seems to be impossible to combat OF with short-term programs and short term volunteers. Fistula campaigns using the non-supportive environments of regional hospitals should be abandoned. Funding organizations should work in concert globally and be encouraged to use their resources to create specialist fistula centers where appropriate. A common standardized clinical database among all these special centers should be used and with the interpretation of this information, reliable data about the classification and prognostic factors for surgical outcomes established.

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