Complex vesicovaginal fistula: Analysis of patient characteristics & functional outcome of surgical reconstruction

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Abstract

Complex vesicovaginal fistulas present a unique challenge to surgeons, and surgical reconstruction outcomes may be suboptimal. The aim is to evaluate the patient's characteristics as well as the factors influencing the functional outcome of complex vesicovaginal fistula surgical reconstruction. From 2016 to 2020, the medical records of 28 patients with complex fistulas were analyzed retrospectively. Means, ranges, and standard deviations were used in descriptive analysis. For categorical data, the Fisher exact probability test was used. The mean (standard deviation) age at presentation was 44.4 (10.04) years, while 85.7% (24) of patients were below 50 years of age. Hysterectomy was the most common aetiology in 21 (75%) patients, followed by radiotherapy in 3 (10.7%). Surgical repair success was seen in 24 (85.7%) patients. Four (14.2%) patients had an unsuccessful repair, one vaginal and three abdominal approach. All the failed abdominal repairs were radiation-induced fistula (p=0.001). Other factors that significantly influenced repair failure include vaginal mucosal atrophy (3 failures out of 8 patients, p=0.013), severe fibrosis around the fistula (4 failures out of 12 patients, p=0.024), non-placement of suprapubic catheter (2 failures out of 3 patients, p=0.006), and non-placement of interposition tissue flap (p=0.005). Hysterectomy and radiotherapy are the common causes of complex vesicovaginal fistula. The outcome of the repair is hampered by vaginal mucosal atrophy and severe scarring. The use of a suprapubic catheter and an interposition tissue flap improves the outcome. Post-irradiation fistula has a significant impact on repair outcome and necessitates special consideration for a comprehensive management strategy.

Introduction

Vesicovaginal Fistula (VVF) is an abnormal communication between the vagina and the bladder. It is a devastating condition that affects women physically, socially, and psychologically leading to poor quality of life. The true incidence of VVF is challenging to estimate as the affected women often suffer silently due to the social stigma. At least 3 million women worldwide, most of them in Africa and southern Asia, have an untreated VVF.[1] Aetiology varies between developed and developing countries.[2] The most common aetiology in developed nations is pelvic and gynecologic surgeries, less common causes being advanced pelvic malignancies and radiation injuries.[2] The most prevalent aetiology in developing nations is associated with childbirth, accounting for more than 90% of cases. Low socioeconomic level and early marriage traditions also contribute to aetiology.[2]

At least 25 systems of classification exist for obstetrics and gynaecological fistulas, although the reliability and validity of most have not been empirically tested.[3] The two important classification systems used for Obstetric fistula are Goh and Waaldijk.[2,4–6] For iatrogenic fistula the classification is highly variable as most centres use their own classification. In general, VVF is classified as a simple or complex fistula. Simple fistulas are small in size (≤0.5cm) and are present as single non radiated fistulas. Complex fistulas include previously failed fistula repairs or large-sized (≥2.5 cm) fistulas, more often a result of chronic diseases or radiotherapy. Many authors consider intermediate-sized fistulas (between 0.5 and 2.5 cm) as complex.[4,7–9] VVF repair can be achieved through both vaginal and abdominal route, and is often dictated by the expertise of the individual treating surgeon, as a standardized treatment algorithm is lacking.[2] The success rate of surgical reconstruction is >90%, but it may be far poorer in a complex fistula.[1] Laparoscopic and Robotic repair of fistula in recent times has shown promising results but limited to very few centres due to steep learning curve, high cost, and need for expertise in the field of reconstruction. Despite numerous publications on this subject, the management of VVF remains a source of debate. Complex VVF is an agonisingly morbid condition and is a unique challenge to surgeons. Here in the study, we have evaluated the patient's characteristics and factors affecting the functional outcome of surgical reconstruction of complex fistula.

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Materials and Methods

Medical records of patients treated for complex vesicovaginal fistulas from January 1st, 2016 to December 31st, 2020 were retrospectively analysed. The study was conducted at the department of urology

at Kasturba Hospital in Manipal, a university tertiary care hospital in southern India that serves as the leading health care referral centre for a large geographical region. Institutional ethical committee approval was obtained before the retrieval of the patient's files [Institutional Ethical Committee (ECR/146/1nst/KA/2013/RR-19) number: IEC 494/2020]. All the patients were managed by three urology professors with vast experience in urogenital fistula care. Solitary fistula of small size (<2.5cm), non-recurrent fistula, and fistula not associated with malignancy or radiation were considered as simple fistulas and were excluded. Large (≥2.5cm) and multiple fistulae on cystoscopy, recurrent (previous failed repair), the involvement of ureters, post-radiation-induced, or malignancy-associated fistulas are termed as complex fistulas and were included. Patients who were operated on before 2016 in our institute or operated elsewhere but were on follow-up during the study period were omitted due to disparities in the availability of full record information.

To ensure accuracy, two separate researchers retrieved the patient's data from the patient's files and converted it to electronic form. Patient information such as socio-demographics, obstetric history, past repair history, fistula details, imaging data, pan-endoscopy findings, and operation details were gathered. Follow-up information, such as time of follow-up, complications, and details on subsequent management of patients with failed repairs, were collected.

Means, ranges, and standard deviations were used in descriptive analysis. To evaluate for categorical differences in repair results across all socio-demographic and clinical factors, the Fisher exact probability test was applied. The variable impact was considered significant at $p<0.05$.

Results

In the study period, 63 patients with VVF underwent treatment, of which 28 patients with complex fistula were included in the study. The mean (Standard Deviation-SD) age at presentation was 44.4 (10.04) years, ranging between 27 to 68 years. 46.4% of patients are between 41 to 50 years of age. Most of them were hailing from rural areas 22 (78.5%). Most patients (42.9%) were in the overweight group (BMI 24.9-29.9 kg/m^2), and 25% of patients were obese (Tables 1 and 2).

In the study, 21 (75%) patients had a hysterectomy as the aetiology of urine leak, 3 (10.7%) patients received radiotherapy for carcinoma cervix, 2 (7.1%) patients had a history of obstructed labour, 1 (3.5%) patients had caesarean (C-section) delivery and 1 (3.5%) patient underwent other pelvic surgery. One of the two obstructed labour patients was required to undergo a C-section for delivery. Past history of failed fistula repair was present in 12 (42.9%) patients. 6 of them had a history of failed vaginal repair, 4 patients with failed abdominal repair, and 2 patients had multiple failures (both vaginal and abdominal repair). Patient records on the use of interposition tissue flap were available in 8 of 12 recurrent fistulas. History of omental flap use in 3 abdominal repairs, a martius flap in 4 of 5 vaginal repairs.

On local examination, the vagina was unhealthy and atrophied in 8 (28.5%) patients, and in 3 (10.7%) patients, labia were atrophied. In 12 (42.8%) patients, severe scarring/induration was seen around the fistula, and in 4 (14.2%) patients, the fistula was not seen clearly on per-speculum examination because of scarring. In the study, 7 patients had Goh's type 1 fistula (>3.5cm distance from urethral meatus), 12 patients had type 2 fistula (2.5 to 3.5cm distance), and 9 patients had type 3 (1.5-2.5cm distance).

On pan-cystoscopy, 3 patients showed >1 fistula, and the fistula was >2.5cm diameter in 15 (53.6%) patients. The fistula was supra-trigone location in 15 (53.6%) patients and involved trigone partially or completely in 13 (46.4%) patients. The ureteric orifice was involved in 11 (39.3%) patients, and among them, one patient had bilateral orifice involved.

Table 1. Patient and procedure characteristics of complex VVF.

Variable		N (%)
Age (years)		44.4 (±10.04) Mean (SD)
Residence	Rural	22 (78.5)
	Urban	6 (21.4)
BMI (kg/m^2)	<24.9	9 (32.1)
	25-29.9	12 (42.8)
	>29.9	7 (25)
Onset of urine leak after the Incident(days)	<14 days	22 (78.5)
	>14days	6 (21.4)
Aetiology	C-section	1 (3.5)
	Hysterectomy	21 (75)
	Obstructed Labour	2 (7.1)
	Pelvic surgery	1 (3.5)
	Radiotherapy	3 (10.7)
History of recurrence (previous repair)	No	16 (57.1)
	Single recurrence	10 (35.7)
	Multiple recurrences	2 (7.1)
Vaginal health	Atrophied	8 (28.5)
	Roomy	20 (71.4)
Scarring / Induration around the fistula	Absent	16 (57.1)
	Present	12 (42.8)
Cystoscopy- Fistula Number	1	25 (89.2)
	2	3 (10.7)
Cystoscopy- Fistula size(cm)	<2.5cm	13 (46.4)
	>2.5cm	15 (53.5)
Cystoscopy- Fistula location	Supra-trigone	15 (53.5)
	Trigone (Partial/complete)	13 (46.4)
Associated Ureterovaginal fistula (UVF)	No	18 (64.2)
	Yes	10 (35.7)
Approach to surgical repair	Abdominal	26 (92.8)
	Vaginal	2 (7.1)
Tissue Flap Interposition	Not placed	1 (3.5)
	Placed	27 (96.4)
Ureteric stent	Not placed	16 (57.1)
	Placed	12 (42.8)
Suprapubic catheter	Not placed	3 (10.7)
	Placed	25 (89.2)
Surgical repair	Failed	4 (14.2)
	Success	24 (85.7)

Imaging showed unilateral Hydroureteronephrosis (HUN) in 10 patients and bilateral HUN in 1 patient. 4 patients underwent percutaneous nephrostomy tube placement on presentation. Imaging studies confirmed the presence of associated Ureterovaginal Fistula (UVF) in 10 (35.7%) patients. In the study, 26 (92.8%) patients underwent an open abdominal VVF repair and a vaginal was done in 2 (7.1%) patients. In 25 of the 26 abdominal approaches, a tissue interposition flap was used. Omentum was the choice of flap except in two cases where the peritoneal flap was used due to the unavailability of good omental tissue. In both vaginal approaches, the martius flap was used as an interposition layer. Ureteric reimplantation was done in all 10 UVF patients. Double J stent was placed in 12 patients; among them, 3 patients had a bilateral stent placed. The suprapubic catheter was placed in the abdominal approach before bladder closure in 25 out of 26 (96.1%) patients, and none in the vaginal approach.

In the study, surgical repair was successful in 24 out of 28 (85.7%) patients. Anatomical repair failed in 4 (14.2%) patients with 1 vaginal approach and 3 abdominal approaches. All three patients with irradiation fistula developed urine leak postoperatively, and one patient with a history of hysterectomy developed urine leak.

Discussion

The first attempt in VVF repair is always the best attempt.[10] VVF is termed as complex when it is large size (≥2.5cm), multiple, recurrent (previous failed repair), involvement the urethra/continence mechanism, severe induration/scarring around fistula, post-radiation, or malignancy-associated fistulas are termed as complex fistulas.[3,4,7,11] However, there is no clear definition of complicated fistula in the literature, and no study that clearly describes the exact size of a complex fistula. Complex VVF presents a challenge to treating surgeons, since it has a higher failure rate and may necessitate more than one attempt.[12–14]

Table 2. Factors influencing the surgical outcome in complex VVF repair patients.

Variable		Repair Failure (N=4)	Repair Success (N=24)	P-value (Fisher's exact test)
Age (years)	<40	1	10	0.002*
	40-50	0	13	
	>50	3	1	
Onset of urine leak after the Incident(days)	<14 days	1	21	0.005*
	>14days	3	3	
Aetiology	Radiotherapy	3	0	0.001*
	Others	1	24	
History of recurrence (previous repair)	No Recurrence	3	13	0.436
	Recurrence	1	11	
Vaginal health	Atrophied	3	5	0.026
	Roomy	1	19	
Scarring / Induration around the fistula	Absent	0	16	0.024
	Present	4	8	
Cystoscopy- Fistula Number	Single	3	22	0.318
	Multiple	1	2	
Cystoscopy- Fistula size(cm)	<2.5cm	2	11	0.877
	>2.5cm	2	13	
Cystoscopy- Fistula location	Supra-trigone	1	14	0.216
	Trigone (Partial/complete)	3	10	
Associated Ureterovaginal fistula (UVF)	Absent	2	16	0.520
	Present	2	8	
Approach to surgical repair	Abdominal	3	23	0.134
	Vaginal	1	1	
Tissue Flap Interposition	Not placed	1	0	0.005*
	Placed	3	24	
Ureteric stent	Not placed	1	17	0.161
	Placed	3	7	
Suprapubic catheter	Not placed	2	1	0.006*
	Placed	2	23	

*Indicates statistically significant value.

Table 3. characteristics of complex VVF based on the size of the fistula.

Complex fistula size	Scarring around istula	Recurrence history	Trigone involvement (partial or complete)	Ureteric involvement	Repair failure
<2.5cm (n=13)	7 (36.8)	11 (91.7)	5 (38.5)	2 (20)	2 (50)
>2.5cm (n=15)	12 (63.2)	1 (8.3)	8 (61.5)	8 (80)	2 (50)
Total	19	12	13	10	4

Different studies classify various fistula diameters as complex fistulas, with sizes ranging from >2cm,[2] >2.5cm,[4,7] >3cm,[15] and even 4cm. Here in the study intermediate-size (0.5 to 2.5cm) is not included as complex fistula, but many authors consider them as part of complex fistula.[7] According to a meta-analysis, the fistula type was documented in just 47% of studies, and only 36% of them reported on complex VVF.[16] It demonstrates the gaps in the available literature on complicated fistula.

Vesicovaginal fistula is a severely morbid illness that primarily affects women in their prime reproductive years.[4] The study's mean (SD) age of presentation was 44.4 (10.04) years, and 85.7 percent of patients were under 50, showing that the majority of these women in their prime productive age have to endure severe physical and psychological suffering. In the current study, 75% of failed repairs were seen in patients over the age of 50 (p=0.002), implying that complex fistula repairs in advanced age are associated with increased failure rates.

According to Hillary *et al.* systematic review, 95.2% of cases of VVF in low-resourced countries had an obstetrics aetiology.[17] The aetiology trend has shifted due to improved prenatal health care in developing countries, particularly rural areas. In contrast to earlier studies, hysterectomy was the primary reason for fistula incidence in 75% of complex fistula patients in our study, followed by radiotherapy in 10.7 percent of patients.[1] It implies that the rate of iatrogenic gynecologic VVF has comparatively increased in developing nations.

Patients with a history of recurrence will have a higher rate of further surgical failure.[10,13,18] In our analysis, only one of twelve patients (p=0.436) with a history of recurrence developed failure; however, this patient had multiple recurrences. The findings, with the exception of one study by Ockrim *et al.*, contradict earlier studies.[14] This could be owing to the fact that there were more failures in irradiation fistulae in the current study.

In general, severe scar and atrophic tissue around the fistula tract by principle have poor vascularity and pliability for good tissue closure and wound healing. It is attributed to cautery induced tissue ischaemia, previous failed fistula repair, or radiation-induced tissue changes. There is, however, no clear consensus on the classification, documentation, or grading of radiation-induced vaginal damage and surgical vaginal scars. In the study, four patients had failed current repair, three had vaginal mucosal atrophy (p=0.013), and all four had extensive scarring around the fistula site (p=0.024). It suggests that good vaginal mucosal integrity and minimal scarring/induration plays a vital role in successful repair.

VVF with large size fistula and multiple fistulae have a poor surgical outcome, due to the need for extensive tissue dissection. However, in contrast to prior studies, the number (p=0.318) and size (p=0.877) of the fistula are not statistically significant in the current complex fistula study (Table 3).[14,19]

There is no single best approach for all VVF patients. There are no randomised studies available that directly compare the outcomes of transabdominal versus transvaginal approaches; nevertheless, in non-randomised studies the overall success rates were 90.8% in vaginal repairs and 83.9% in abdominal repairs.[17] There was no statistical difference in surgical success between the abdominal and vaginal approaches in the current study (p=0.134).

In the present study, due to the history of fistula recurrence, associated UVF, and complex nature of fistulas, all abdominal repairs were attempted via open technique. "Open progressive VVF repair" procedure, in which the initial transvesical approach of Gilvernet for fistula tract excision is attempted, and if this is not possible, the entire bivalve technique of classical O'Conor is used. In all VVF cases, this method avoids the need for a total bivalve of the bladder. Laparoscopic VVF repair is a realistic and effective method with encouraging results in a number of patients. However, there are technical limitations, especially in the pelvis. Due to these technical difficulties, laparoscopy has not gained widespread popularity and has been limited to a handful of centres.[20] Success rates for the laparoscopic approach vary from 75% to 98%, but failure rates are higher for recurrent complex fistulas.[8] Ultimately, the surgical approach to VVF repair is determined by the patient's and fistula's characteristics, as well as the surgeon's preference and expertise, as most gynaecologists prefer a vaginal approach to repair.[8,16]

Although there is no high-quality data to support the routine use of tissue interposition, it is indicated in situations with complex fistula, such as recurring, radiation-induced, or long-standing VVFs.[1,14] Evans *et al.*, reported a higher success rate in a small series of radiation-induced VVFs when interposition grafts were used 100% of time, compared to 67% when no grafts were used.[21] Interposition tissue was employed in all patients except one in our study. Failure occurred in one patient with a high BMI with no tissue interposition (p=0.005).

The success of VVF repair depends on good postoperative urine drainage. It can be a per-urethral catheter alone, suprapubic catheter alone, or a combination of the two.[22] In a survey among high volume centres in Asia and Africa, urine catheters were retained for 14-29 days.[23] Despite the fact that Nardos et al suggested that a short duration of urine drainage of 10 days was not inferior to 14 days,[24] catheters were kept in place for 3-4 weeks in all patients in our study due to the complex nature of the fistula. Two out of three patients who did not have a suprapubic catheter developed repair failure (p=0.006), indicating the importance of clear urine drainage with an additional suprapubic catheter in complex fistula, particularly in the first 10 postoperative days. Suprapubic catheter drainage, on the other hand, is not routine in vaginal repair cases, and consideration of this point in predominantly vaginal repair approach centres is dubious.

The definition of surgical success varies among different authors. In the study, surgical success was defined as anatomical closure of the fistula, and success timing as no urine leak at the first follow-up visit at 3-4 weeks for catheter removal. Surgical repair was successful in 85.7% of patients. Four (14.2%) patients had failed repairs, with one vaginal and three abdominal methods (p=0.134). One patient's urine leaked on the first postoperative day, and three patients' urine leaked within ten days. All the failed abdominal repairs (3 patients) are radiation-induced fistula (p 0.001).

While the current study focuses on difficult fistulas, its limitations include the fact that it is a retrospective study with a small number of patients and no information on quality of life or sexual function. In addition, the small number of patients is a significant limitation for conducting multi-factor analysis in the study.

Conclusions

Complex vesicovaginal fistula is a highly morbid condition that affects women in their fourth to fifth decades and poses a significant challenge to treating surgeons. The more common causal factors for complex fistula are hysterectomy and radiotherapy. Good vaginal mucosal integrity and minimal scarring/induration play a vital role in success. Placing a suprapubic catheter and interposition tissue flap helps in complex fistula repair success. There is no substantial difference between the abdominal and vaginal approach to complex fistula repair, but this requires larger studies as most patients in our study had associated ureterovaginal fistula requiring an abdominal approach. Post-irradiation fistula greatly

impacts repair outcome, and this select category of complex fistula requires utmost attention for a comprehensive management strategy.

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