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Management of Vesicovaginal Fistulae: A Multicenter Analysis From the Fellows' Pelvic Research Network

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Abstract

Objectives—Vesicovaginal fistulae (VVF) are the most commonly acquired fistulae of the urinary tract, but we lack a standardized algorithm for their management. The purpose of this multicenter study was to describe practice patterns and treatment outcomes of VVF in the United States.

Methods—This institutional review board–approved multicenter review included 12 academic centers. Cases were identified using *International Classification of Diseases* codes for VVF from July 2006 through June 2011. Data collected included demographics, VVF type (simple or complex), location and size, management, and postoperative outcomes. χ^2 , Fisher exact, and Student *t* tests, and odds ratios were used to compare VVF management strategies and treatment outcomes.

Results—Two hundred twenty-six subjects were included. The mean age was 50 (14) years; mean body mass index was 29 (8) kg/m². Most were postmenopausal (53.0%), nonsmokers (59.5%), and white (71.4%). Benign gynecologic surgery was the cause for most VVF (76.2%). Most of VVF identified were simple (77.0%). Sixty (26.5%) VVF were initially managed conservatively with catheter drainage, of which 11.7% (7/60) resolved. Of the 166 VVF initially managed surgically, 77.5% resolved. In all, 219 subjects underwent surgical treatment and 83.1% of these were cured.

Conclusions—Most of VVF in this series was managed initially with surgery, with a 77.5% success rate. Of those treated conservatively, only 11.7% resolved. Surgery should be considered as the preferred approach to treat primary VVF.

Keywords

catheterization; genitourinary fistulae; Latzko; surgical repair; vesicovaginal fistulae

Vesicovaginal fistulae (VVF) are the most commonly acquired fistulae of the urinary tract. In the developing world, the etiology is often obstetric trauma; although in the United States, pelvic surgery is more frequently the cause.^{1–3} Predisposing risk factors for the development of fistulae include hysterectomy, prior pelvic surgery, endometriosis, diabetes, hypertension, cancer, and history of pelvic irradiation.^{2–6} Regardless of etiology, the effects of VVF may be profound. Symptoms include urinary incontinence, vaginal discharge, chronic pelvic pain, and malodor, resulting in physical and emotional trauma to the patient.^{7,8}

Despite its significant impact, there is no consensus on the optimal approach to treat VVF. Choice of therapy is based largely on expert opinion and surgeon experience. Classic teaching is to initially proceed with conservative management and catheter drainage to allow for spontaneous resolution.^{9–12} However, many surgeons believe that early surgical intervention is effective and minimizes patient suffering. It is unclear which approach is of greater benefit. Further lacking is a surgical treatment algorithm based on characteristics of the fistulae.¹³ The purpose of this multicenter study was to describe practice patterns and

outcomes of VVF treatment in the United States, to aid practitioners in selecting appropriate therapy for their patients.

MATERIALS AND METHODS

This multicenter retrospective study incorporated data from 12 academic sites affiliated with Female Pelvic Medicine and Reconstructive Surgery fellowship programs within the United States after receiving approval from all participating institutional review boards. Cases of VVF were identified using *International Classification of Diseases, Ninth Revision (ICD-9)* codes of female genital urinary fistula during July 2006 through June 2011. The following *ICD-9* codes: 596.1 (intestinovesical fistula), 596.2 (vesical fistula, not elsewhere classified), 619.0 (urinary-genital tract fistula, female), 619.2 (genital tract-skin fistula, female), 619.8 (other specified fistulae involving female genital tract), and 619.9 (unspecified fistula involving female genital tract), were used for an outpatient query at each site to produce several charts for further examination and confirmation of correct diagnosis.¹⁴ This method permitted the inclusion of charts initially coded incorrectly that would otherwise be excluded due to restricted use of more specific *Current Procedural Terminology* codes. All charts were screened for accuracy of coding by the primary investigator at each site and finally by the principal investigator. Those charts with missing data for diagnosis or management were excluded (Fig. 1).

Information manually extracted from the electronic medical record chart review included patient age, body mass index (BMI), demographics, medical and surgical history, and risk factors for fistulae (tobacco use and hormonal status). For each case, fistula-specific information was recorded regarding presenting complaint, method of diagnosis, and fistulae characteristics. A simple VVF was defined as less than 2 cm, in setting of normal vaginal length (> 7 cm), without history of radiation, or vaginal or cervical malignancy. A complex VVF was defined as greater than or equal to 2 cm, shortened vaginal length (<7 cm), or a history of pelvic malignancy, with or without radiation therapy.^{2,15-17}

Information was also recorded regarding therapeutic management of fistulae. Details about treatment included type and duration of catheter placement in cases of conservative management, intraoperative details regarding surgical management, and postoperative management course including duration of postoperative catheterization, antibiotic or anticholinergic use, success and reoperation rates, and postoperative sequelae. Cases were divided into 2 groups based on initial management, namely, conservative versus surgical. Placement of either a suprapubic or transurethral catheter with or without follow-up imaging was categorized as initial conservative management. Initial surgical interventions included cystoscopic electrocoagulation, fibrin glue sealant, vaginal repair with excision or closure of fistulous tract, with or without concomitant Martius flap, and abdominal repair with or without concomitant omental flap.

Those cases initially managed conservatively were compared with those initially managed surgically using Student *t* tests for continuous variables and χ^2 test or Fisher exact test, when appropriate, for categorical variables. Similar analyses were performed to compare success rates for initial surgical management versus success rates for surgical management

after failed conservative management. Lastly, comparative analyses, including odds ratios (ORs), were performed to identify factors associated with resolution of fistula after surgical management. Statistical analyses were performed using SPSS Version 19 (IBM Company, Chicago, Ill) and $P < 0.05$ was considered significant. As this was a descriptive study at time of study design, a query of *ICD-9* codes pertaining to VVF at the primary site was performed. This search yielded 66 cases over 5 years. A conservative estimate of the availability of 25 cases over 5 years at 8 to 10 other institutions was made. Thus, a minimum of 10 sites contributing 10 cases each was deemed adequate for analysis.

RESULTS

A total of 457 charts were reviewed, of which 226 (49%) subjects met inclusion criteria (Fig. 1). The mean age of included cases was 50 (14) years and mean BMI was 29 (8) kg/m². Most were white (71.4%), nonsmokers (59.5%), postmenopausal (52.8%), and had undergone prior hysterectomy (82.3%) (Table 1). Median gravidity was 2 (range, 0–12); parity was 2 (range, 0–10). Twenty-six and a half percent (60/226) were initially managed conservatively with catheter drainage, whereas 73.5% (166/226) were initially managed surgically. Included subjects ($n = 226$) were further divided into 4 main geographic regions with 4 sites per region as follows: Northeast, Southeast, Midwest, and West. Further analysis of these subgroups for all variables revealed no significant differences (data not shown).

Sample characteristics stratified by initial management strategy (catheterization vs surgery) are reported in Table 1. Women initially managed conservatively were younger (43.6 [10.2] vs 51.6 [14.7] years, $P < 0.001$), more likely to be married (74.6% vs 61.3%, $P = 0.04$), premenopausal (54.2% vs 32.7%, $P = 0.002$), and current smokers (33.9% vs 23.7%, $P = 0.043$) than those initially managed surgically. Women initially managed surgically were more likely to have a history of malignancy (24.1% vs 11.7%, $P = 0.043$) and pelvic irradiation (13.3% vs 1.7%, $P = 0.011$) than women managed conservatively. There were no statistically significant differences in mode of prior hysterectomy between women undergoing initial conservative versus surgical management (88.3% vs 80.1%, $P = 0.172$). Among the 186 women who had undergone prior hysterectomy, indications included fibroids (33.0%), menorrhagia (23.1%), pelvic pain (12.4%), prolapse (3.2%), and malignancy (2.2%). Complications of hysterectomy included cystostomy (22.6%), ureteral injury (4.0%), blood transfusion (2.0%), and bowel injury (0.5%). There were no statistically significant differences in indications for or complications of prior hysterectomy between women undergoing initial conservative versus surgical management (Table 1).

Characteristics of VVF stratified by initial management strategy are outlined in Table 2. The most common presenting symptom was urinary leakage, reported by 95.6% (216/226), and most were diagnosed with both physical examination (with or without dye instillation) and imaging (215/226). Most of VVF were simple (77.0%; 171/222), small (52.6%; 110/209), and located in the trigone (37.7%; 80/212) or bladder dome (23.6%; 50/212). Complex VVF were more likely to be initially managed surgically ($P = 0.001$); otherwise, there were no statistically significant differences in VVF cause, method of diagnosis, size, or location between those initially managed conservatively versus surgically.

Among the 60 VVF initially managed conservatively, the median duration of catheterization was 35 days (range, 1–120; interquartile range [IQR], 16.8–60.0). Seven (11.7%) of these resolved with conservative management and 53 required subsequent surgical repair. The 7 patients whose VVF resolved with initial conservative management did not differ from those who went on to require surgical management in terms of demographics, medical history, fistulae characteristics, or duration of catheter drainage (data not shown).

Among the 166 subjects initially managed surgically, 41.3% underwent vaginal repair (73.4% simple excision; 56.3% Latzko; not mutually exclusive), 15.5% had an abdominal repair (70.8% with omental flap; 29.2% without), 2.6% received electrocautery, and 5.2% received fibrin glue sealant. Among the 129 cases with complete postoperative data, 77.5% resolved after surgery. Of those that persisted after surgery, 17.2% opted for catheter insertion and 82.8% underwent a second surgery. The median duration for surgical management, from initial presenting complaint until final office visit postoperatively, was 159 (IQR, 97.8–289.3) (data not shown).

Most of initial conservative management cases (53/60, 88.3%) went on to surgery, including vaginal approach (52.3%) with simple excision (60.9%) and/or Latzko technique (30.4%), abdominal approach (34.1%) with omental flap (53.3%) or without (46.7%), and electrocautery (2.3%). Among these 53 cases, 91.2% (31/34; data missing for 19 cases) resolved after surgery. Of the 8.8% that persisted after surgery, 100% (3/3) underwent second surgery (data not shown).

Surgical data were available for a total of 219 cases (53 cases that underwent surgery after failed conservative management and 166 cases initially managed surgically). Further analysis of those VVF undergoing primary surgery ($n = 219$) revealed 2 groups: VVF resolving with primary surgery ($n = 182$) and VVF persistent after primary surgery ($n = 37$). Although nonsignificant, premenopausal women were 1.7 times more likely to have resolution of their VVF with surgery (confidence interval [CI], 0.7–3.9). However, there were no significant differences noted between these 2 groups regarding demographics, medical history, cause of VVF, or type of VVF. Interestingly, those subjects with an abdominal repair at the time of primary surgery were 3.3 times more likely to have a successful repair (CI, 1.0–11.6), although the addition of an omental flap increased the success another 3.2 times (Table 3). Overall, most of surgeons evaluated ureteral patency intraoperatively with cystoscopy (79.7%), and used a catheter (100%), oral antibiotics (80.3%), or anticholinergics (43.7%) postoperatively. The median duration for a postoperative catheter was 21 days (suprapubic; IQR, 14–29) and 14 days (transurethral; IQR, 14–21).

Overall, 83.1% of the 219 surgeries performed in this series resulted in cure, defined as patient declining further treatment. The success rate for initial surgical management was 77.5%; the success rate for surgery after failed conservative management was 91.2% ($P = 0.091$). Among the cases not cured with first surgery, 86.5% ($n = 32$) went on to undergo a second surgery, whereas 13.5% ($n = 5$) opted for reinsertion of catheter. There were no statistically significant differences between women whose VVF resolved after surgery and

those whose did not in terms of age, BMI, menopausal status, tobacco use, or medical comorbidities, although history of pelvic irradiation approached significance.

Among the 32 women who underwent second surgical repair of their VVF, 17/32 (53.1%) underwent abdominal surgery, 13/32 (40.6%) underwent vaginal surgery, and 2/32 (6.3%) underwent an alternative approach (Table 4). The success rate for second surgery overall was 56.3% with a nonsignificant increased odds of success via abdominal approach (OR, 1.25; CI, 0.3–5.1).

DISCUSSION

In this multicenter study, almost three quarters of VVF were managed surgically, and 83% resolved without a second surgery. Patients initially treated conservatively often required subsequent surgery for treatment of their VVF, suggesting that immediate surgical intervention of VVF may be of benefit to the patient.

The overall success rate after primary surgery for VVF in this series was 83%, and did not differ between those who underwent initial surgical management (78%) and those who had surgery after failed conservative management (91%). A recent study by Cromwell and Hilton¹⁸ demonstrated a surgical failure rate of merely 12% in their retrospective review of more than 900 charts; however, their study period was more than 10 years and included other types of genitourinary fistulae. Regarding surgical success, our study did not find a significant difference between vaginal and abdominal approaches. In the literature, evidence for a repair through a transvaginal approach for fistulae is convincing given the high success, minimal morbidity, and quicker recovery as described by Latzko.^{19,20} In addition, Lee et al.²¹ reported vaginal success rates of 98%, whereas Tancer²² purported 100% success. Nonetheless, our rates for vaginal and abdominal approaches are virtually unchanged from the initial report of Lee et al.²¹ Indications for an abdominal route are generally those of previous surgical failures, need for ureteral reimplantation, poor accessibility vaginally, irradiated pelvis, or plans for omental flap interposition.²³ In our series, many women underwent primary surgical repair via abdominal approach without these indications. Ultimately, the only factor significantly associated with surgical success was the use of omental flap at the time of secondary abdominal repair. Additional literature has shown that use of flaps at the time of vaginal repair is the most effective; however, those studies were performed in developing countries and often after failed initial surgical management without flaps.^{24,25} It is important to optimize chances for success with primary surgical repair, because the overall success rate after second surgery for VVF is lower, both in this series (56%) and in other studies in the literature (50% successful on second attempts; 33% successful on third attempts).²⁶ We therefore conclude that any surgical approach is reasonable for primary VVF repair, and that an omental flap should be placed when using an abdominal approach.

The resolution rate with initial catheterization in this series of 11.7% is comparable to those rates reported in the literature for posthysterectomy (1%–8%)^{10,27,28} and postobstetric (15%) VVF.²⁸ Despite the fact that women selected for initial conservative management in this series were younger and less likely to have a history of cancer or pelvic malignancy,

almost 90% of them went on to require subsequent surgery. We did not identify any factors associated with a higher likelihood of success with conservative management. It is possible that the higher prevalence of current tobacco use among women managed conservatively contributed to their low rate of spontaneous resolution, because tobacco use may compromise capacity for wound-healing.²⁹

A controversial point among fistulae literature is the timing of the repair. Traditional teaching suggests conservative management to decrease inflammation and enable tissue healing until surgery can be performed. Our study reports a median catheterization time of greater than 1 month. Although most of VVF still required subsequent surgical management, the success rate of these surgeries was higher (91%) than it was among those cases managed initially with surgery (78%), although this difference did not meet statistical significance. In our sample, there was also a higher rate of simple fistulae treated initially with catheterization, whereas more complex fistulae were more likely to be treated with primary surgery; thus, the noted higher success rate in this group could be impacted by their simple nature. Although some studies suggest that time allocated toward tissue healing during the initial catheterization phase leads to improved success rates, this benefit should be weighed against the discomfort, anxiety, and distress many women with VVF experience.^{9–12} Prompt intervention may bear the advantage of minimizing unnecessary suffering.^{2,8}

This study was inherently limited by its retrospective nature and the constraints regarding classification that all studies of VVF face. The diagnosis of fistulae is as varied as the factors influencing their development and can be based on size, type, or location (ie, the surgical grading system which describes the VVF in relation to the urethra).^{13,16,17,30–32} For the purposes of this review, we divided VVF into simple or complex.^{2,15–17} Although this system takes into account the location and size of the VVF in addition to a history of prior pelvic malignancy or irradiation, the specificity of these definitions does exclude some data from being fully analyzed. We were further limited by missing data that prevented complete analysis of all variables of interest. The strengths of this study include its multicenter nature, incorporating data from 12 academic centers with diverse geographic representation, as well as the large number of cases in the series.

In conclusion, most VVF in this series were initially managed surgically, and most resolved with primary surgery, regardless of approach. The use of an omental flap may improve success rates with abdominal approach to primary VVF surgery. There is a role for conservative management with prolonged catheterization for women who opt for this strategy, but they should be counseled that the likelihood of resolution with catheterization alone is low (12%). It does not seem that catheterization before surgical management compromises success, and may in fact improve postsurgical success rates. Further prospective investigation is warranted to confirm this information and delineate other factors that predict successful treatment.

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FIGURE 1.
Flow chart of study participants.

TABLE 1

Sample Characteristics Stratified by Initial Management Strategy

	Total Sample, n = 226	Initial Catheter, n = 60	Initial Surgery, n = 166	P
Age, mean (SD), y	49.5 (14.1)	43.6 (10.2)	51.6 (14.7)	<0.001
BMI, mean (SD), kg/m ²	28.6 (7.7)	28.2 (6.7)	28.8 (8.1)	0.623
Ethnicity, n (%)				0.701
White	157 (71.4)	40 (70.2)	117 (71.8)	
Black or African American	21 (9.5)	8 (14.0)	13 (8.0)	
Hispanic	30 (13.6)	6 (10.5)	24 (14.7)	
Asian	8 (3.6)	2 (3.5)	6 (3.7)	
Other	4 (1.8)	1 (1.8)	3 (1.8)	
Relationship status, n (%)				0.04
Married	144 (64.9)	44 (74.6)	100 (61.3)	
Divorced	19 (8.6)	6 (10.2)	13 (8.0)	
Widowed	16 (7.2)	0 (0)	16 (9.8)	
Single	43 (19.4)	9 (15.3)	34 (20.9)	
Tobacco use, n (%)				0.043
Current	57 (26.5)	20 (33.9)	37 (23.7)	
Past	30 (14.0)	3 (5.1)	27 (17.3)	
Never	128 (59.5)	36 (61.0)	92 (59.0)	
Hormone status, n (%)				0.002
Premenopausal	84 (38.5)	32 (54.2)	52 (32.7)	
Perimenopausal	19 (8.7)	8 (13.6)	11 (6.9)	
Postmenopausal (hormone therapy)	20 (9.2)	5 (8.5)	15 (9.4)	
Postmenopausal (no hormone therapy)	95 (43.6)	14 (23.7)	81 (50.9)	
Medical comorbidities, * n (%)				
Asthma	25 (11.1)	6 (10.0)	19 (11.4)	1.000
COPD	5 (2.2)	3 (5.0)	2 (1.2)	0.118
Diabetes	22 (9.7)	3 (5.0)	19 (11.4)	0.205
Endometriosis	21 (9.3)	9 (15.0)	12 (7.2)	0.116
Hypertension	64 (28.3)	18 (30.0)	46 (27.7)	0.740
Pelvic irradiation	23 (10.2)	1 (1.7)	22 (13.3)	0.011
Cancer	47 (20.8)	7 (11.7)	40 (24.1)	0.043
Prior hysterectomy (n = 186), n (%)	186	53	133	0.172
Abdominal	121 (65.1)	32 (60.4)	89 (66.9)	0.123
Vaginal	19 (10.2)	4 (7.5)	15 (11.3)	0.123
Laparoscopic	31 (16.6)	8 (15.1)	23 (17.3)	0.123
Robotic	14 (7.5)	9 (17)	5 (3.9)	0.123
Hysterectomy indication * (n = 186), n (%)				
Fibroids	61 (33)	20 (37.7)	41 (31)	0.466
Menorrhagia	43 (23.1)	15 (28.3)	28 (21.1)	0.326
Prolapse	6 (3.2)	3 (1.9)	3 (2.3)	0.357

	Total Sample, n = 226	Initial Catheter, n = 60	Initial Surgery, n = 166	P
Pelvic pain	23 (12.4)	10 (18.9)	13 (10)	0.133
Cancer	4 (2.2)	4 (7.5)	21 (15.8)	0.150
Hysterectomy complications* (n = 186), n (%)				
Cystostomy	42 (22.6)	12 (22.6)	30 (12)	1.000
Ureteral injury	7 (4)	0 (0)	7 (5.3)	0.096
Blood transfusion	3 (2)	0 (0)	3 (2.3)	0.550

* Comorbidities, indications, and complications reported in less than 1% of cases are not listed here.

TABLE 2

VVF Characteristics Stratified by Initial Management Strategy

	Initial Catheter, n (%)	Initial Surgery, n (%)	P
Presenting complaints [*]	n = 60	n = 166	
Leaking urine	59 (98.3)	157 (94.6)	0.297
Pelvic pain/dyspareunia	2 (3.3)	5 (3.0)	1.000
Skin complaints	1 (1.7)	6 (3.6)	0.678
Other	5 (8.3)	15 (9.0)	1.000
Attributable cause [†]	n = 60	n = 163	
Obstetric	2 (3.3)	6 (3.7)	1.000
Gynecologic	51 (85.0)	119 (73.0)	0.076
Cancer	3 (5.0)	15 (9.2)	0.412
Irradiation	2 (3.3)	18 (11.0)	0.110
Method of diagnosis	n = 58	n = 157	0.370
Pelvic examination alone	11 (19.0)	41 (26.1)	
Imaging (cystoscopy, CT scan, MRI, ultrasound)	47 (81.0)	116 (73.9)	
VVF type	n = 59	n = 163	0.001
Simple	54 (91.5)	117 (71.8)	
Complex	2 (3.4)	42 (25.8)	
Other	3 (5.1)	4 (2.5)	
VVF location	n = 55	n = 157	0.689
Bladder dome	14 (25.5)	36 (22.9)	
Trigone	20 (36.4)	60 (38.2)	
Bladder neck	2 (3.6)	4 (2.5)	
Ureteral orifice	9 (16.4)	17 (10.8)	
Other	10 (18.2)	40 (25.5)	
VVF size, cm	n = 55	n = 154	0.299
Tiny (<0.5)	15 (27.3)	34 (22.1)	
Small (0.5–1.5)	32 (58.2)	78 (50.6)	
Medium (1.6–3.0)	6 (10.9)	30 (19.5)	
Large (>3.0)	2 (3.6)	12 (7.8)	

^{*} Presenting complaints are not mutually exclusive.

[†] Causes reported in less than 1% of cases are not listed here.

CT indicates computed tomography; MRI, magnetic resonance imaging.

TABLE 3

Resolution After Primary Surgery (n = 219) for VVF

	Resolution With Primary Surgery, n = 182, n (%)	Persistent VVF After Primary Surgery, n = 37, n (%)	<i>P</i>	OR (95% CI)
Type of surgical management *				
Cystoscopic electrocoagulation	2 (1.5)	2 (6.1)	0.120	0.2 (0.0–1.7)
Fibrin glue sealant	7 (5.1)	1 (3.0)	0.607	1.7 (0.2–14.5)
Vaginal repair	58 (42.6)	19 (57.6)	0.122	0.5 (0.2–1.2)
Excision type	32 (55.2)	7 (36.8)	—	2.1 (0.7–6.1)
Latzko	24 (41.4)	9 (47.4)	—	0.8 (0.3–2.2)
Abdominal repair	34 (25.0)	3 (9.1)	0.047	3.3 (1.0–11.6)
With omental flap	21 (61.8)	1 (33.3)	—	3.2 (0.3–39.3)
No omental flap	8 (23.5)	1 (33.3)	—	0.6 (0.0–7.7)

* Surgical management types reported in less than 1% of cases are not listed here.

TABLE 4

Characteristics of and Outcomes After Second Surgery for VVF, n = 32

	n (%)	OR (95% CI)
Vaginal repair	13	
Vaginal repair successful	7 (63.6)	0.8 (0.2–3.5)
Abdominal repair	17	
Abdominal repair successful	10 (76.9)	1.25 (0.3–5.1)
Other repair	2	
Other repair successful	1 (50)	0.8 (0.0–13.4)