# Clinical effects of transvaginal vesicovaginal fistula repair surgery mediated by the Foley catheter (64 cases)

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#### Summary

Objective: To investigate the clinical effects and superiority of transvaginal vesicovaginal fistula (VVF) repair surgery mediated by the Foley catheter. *Patients and Methods*: We retrospectively reviewed the case notes of 129 patients with vesicovaginal fistulas who received surgery in our hospital; 68 patients received VVF repair surgery mediated by the Foley catheter (modified group), and 61 patients received traditional transvaginal VVF repair surgery (traditional group). *Results*: The success rate of the primary operation, mean operation time, mean intraoperative blood loss, mean postoperative hospitalization time, and rate of patients with postoperative urine leakage were significantly different between the modified group and traditional group. However, the mean bladder capacity, postoperative recovery time of self-miction, and postoperative wound infection rate were not significantly different between the groups. *Conclusions*: Transvaginal VVF repair surgery mediated by the Foley catheter had a higher success rate, shorter operation time, less blood loss and sooner recovery time postoperatively. Therefore, it should be applied in clinics generally.

Key words: Vesicovaginal; Urinary fistula; Foley catheter.

#### Introduction

Vesicovaginal fistula (VVF) is the most common urogenital fistula; once one is diagnosed almost all patients must undergo surgery. Despite the advances in medical care, VVF continues to be a distressful problem, particularly in some poor and undeveloped countries that do not have adequate obstetric assistance. Nonetheless, urogenital fistula is a worldwide problem even in wealthy countries where it is mainly related to hysterectomy [1]. With the development of urogenital fistula repair surgery, the success rate has been improved, but the failture rate remains as high as 15% or more [2]. The high failure rate is the main problem in treating urogenital fistula, therefore improving the success rate of surgery is critical. We have been carrying out VVF repair surgery mediated by the Foley catheter based on the traditional transvaginal VVF repair surgery in our hospital since 2002. The Foley catheter is used so masterly that it expands the operative view and improves the success rate of surgery. Therefore, it should be applied in clinics generally.

#### Patients and Methods

Clinical data

We retrospectively evaluated cases and follow-up data of 129 patients with VVF in our hospital between January 2002 and November 2009. Out of the 129 patients, 68 patients were treated by VVF repair surgery mediated by the Foley catheter (modified group). The mean age of the patients with urogenital fistulae was  $41 \pm 12$  (range 25 to 70 years). The etiology of cases was as follows: 22 cases were secondary to uterine cervix cancer radical correction, ten cases received ovarian cancer

cytoreductive surgery, 16 cases had total abdominal hysterectomy, eight cases underwent vaginal hysterectomy, eight cases had cesarean section, three cases were due to dystocia, and one case had an abortion; the diameter of the fistula was less than 3 cm. In 11 cases the diameter of the fistulae was more than 2 cm while duration of the fistula varied from three months to 35 months (median 24 months). Out of the 129 patients, 61 patients were treated by traditional transvaginal VVF repair surgery (traditional group). The mean age of the patients with urogenital fistulae was  $42 \pm 12$  (range 26 to 72 years). Twenty cases were secondary to uterine cervix cancer radical correction, six cases underwent ovarian cancer cytoreductive surgery, 16 cases had total abdominal hysterectomy, eight cases had vaginal hysterectomy, eight cases had cesarean section, two cases were due to dystocia, and one case was because of trauma; the diameter of the fistula was less than 3 cm, the number of fistulae was > 2 in 11 cases, and the duration of the fistulae varied from three months to 31 years (median 21 months). None of the patients were suffering from diabetes, hypertension or other chronic diseases that may have influenced wound healing, and all of them underwent surgery for the first time.

Self-miction, urine leakage and bladder capacity of the patients were followed-up in the outpatient department or inpatient department at one month, three months and 12 months after surgery. Although four cases in the modified group could not be followed-up, the follow-up rate was 94.12% (64/68); three patients in the traditional group could not be followed-up, thus the follow-up rate was 95.08% (58/61).

The diagnosis and exclusion standard of VVF: all patients were evaluated by medical history, the time and clinical situation of leaking urine, gynecological examination and physical examination (including bladder filling with methylene blue to demonstrate the fistula tract). If the patient had the typical clinical situation of leakage or the fistula could be found by vaginal examination, it could be diagnosed. If it was difficult to be diagnosed, the following auxiliary examinations were done: urinallysis, ureteral examination, voiding cystouretrography, intravenous urography (IVU), cystoscopy and nephrogram.

Success outcomes of surgery included healing of the postoperative fistulae negative methylene blue test after removal of the

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bladder catheter and disappearance of urine leakage. Bladder storage, voiding function and urodynamic examination were in the normal range after follow-up of three to six months.

#### Operation method

#### The vaginal fistula repair surgery mediated by Foley catheter

The patient was operated in the dorsal lithotomic position after epidural anesthesia. Diluted methylene blue solution (250-300 ml) was injected via a catheter. A Foley catheter was inserted into the bladder through the vaginal fistula (if the fistula was too small to be inserted with the Foley catheter, blood vessel forceps were used to enlarge the fistula under the guidance of methylene blue stain and exploring needle). Gas (2) ml) was inserted so that the erocyst could be filled in the bladder, dragging the Foley catheter slightly outward to press and expose the fistula more clearly, which also could support the bladder wall near the fistula to implement the next procedure. A cystoscope was used to observe the bladder shape, fistula size, location and number, to judge whether there were vesical calculus, surrounding tissue scar formation and the neighboring anatomical relationship, especially the ureteral orifice situation. The vaginal wall surrounding the edge of the fistula was cut (about 0.2-0.3 cm) with a small sickle knife dissociating the vaginal wall outside about 0.3-0.5 cm, removing the old fistula scar tissue (including the bladder and vaginal tissue and even previous sutures). Continuous half purse-string sutures for the bladder fascia and muscle above and under the fistula with 0/3 absorbable catgut were done. After deflation the Foley catheter was dragged outside and a knot was tied between the over and under thread.

# Traditional transvaginal vesicovaginal fistula repair surgery [3]

The method was the same as the above method, except for using a Foley catheter.

#### Statistical analysis

SPSS 13.0 software was used for statistical analysis. Data were analyzed by the chi-square test and Fisher's exact tests, and measurement data were were compared using t tests. Non-normal distribution data were compared using the nonparametric tests; p < 0.05 was considered to indicate statistical significance.

# Results

# Comparison between the two groups of patients

We did t-testing for age and fistula size of the two groups, and found that there were no significant differences (Table 1). Chi-square tests for fistula number of the two patients groups showed that there were also no significant differences between the two groups, as shown in Table 1. We also did two samples of the rank sum test for the two groups duration; Wilcoxon W statistic was 3724.000 – there was no significant difference between the two groups duration (p = 0.253).

# Etiolgical factors for the VVF

The etiolgical factors for the VVF in this study are shown in Table 2. The factors of gynecological surgery

Table 1. — Patient characteristics in the two groups (n = 129).

General health state	Modified group	Traditional group	t value / χ² value	p value
Age	41 ± 12	42 ± 12	0.551	0.582
Fistula size	$1.68 \pm 0.82$	$1.61 \pm 0.80$	0.431	0.667
Single fistula	57	52	0.049	0.824
Mutiple fistulae	11	9	0.047	0.024

Table 2. — Etiology of vesicovaginal in the two different groups.

Etiology	No. of cases	Ratio (%)	
Radical correction			
of uterine cervix cancer	42	32.56%	
Radical correction			
of ovarian cancer	16	12.41%	
Complete hysterectomy	32	24.80%	
Vaginal hysterectomy	16	12.41%	
Cesarean section	16	12.41%	
Dystocia	5	3.87%	
Artificial abortion	1	0.77%	
Trauma	1	0.77%	
Total	129	100.00%	

Table 3. — Comparion of the two different operations (n = 122).

Modified group	Traditional group	T value	p value
$85 \pm 8.1$	$116 \pm 19.5$	12.51	0.001
$109 \pm 23.4$	$175 \pm 60.2$	8.10	0.001
	85 ± 8.1	85 ± 8.1 116 ± 19.5	85 ± 8.1 116 ± 19.5 12.51

(87%) were prominent for most patients, of which radical correction of the uterine cervix cancer was responsible for 32.56%, radical correction of ovarian cancer was responsible for 12.41%, complete hysterectomy was responsible for 24.80%, and vaginal hysterectomy was responsible for 12.41%. The factors for obstetrical surgery (17.05%) were insignificant, of which cesarean section was responsible for 12.41%, dystocia for 3.87%, artificial abortion for 0.77%, and trauma was responsible for 0.77%.

#### Comparion of therapeutic effect

The mean operation time was  $85 \pm 8.1$  min, ranging from 70 to 100 min. Mean intraoperative blood loss was  $109 \pm 23.4$  ml, ranging from 80 to 150 min in the modified group, but the mean operation time was  $116 \pm 19.5$  min (ranging from 90 to 150 min), and mean intraoperative blood loss was  $175 \pm 60.2$  ml (ranging from 100 to 300 min). There was a significant difference between the two groups (p < 0.001) (Table 3).

Comparion of hospitalization and recovery are shown in Table 4. Mean self-miction recovery time of the patients in the modified group was  $10 \pm 1.8$  days, ranging from 7 to 14 days. Mean postoperative hospitalization time was  $13 \pm 1.8$  days, ranging from 10 to 17 days.

Table 4. — Comparion of patient hospitalization and recovery time  $(\bar{x} \pm s, n = 122)$ .

	Modified group	Traditional group	t value / χ² value	<i>p</i> value
Mean self-urination				
recovery time (d)	$10 \pm 1.8$	$17 \pm 2.08$	21.30	0.000
Mean postoperative				
hospitalization time (d)	$13 \pm 1.8$	$20 \pm 2.1$	19.03	0.000
Rate of urine leakage	3.13%	15.52%	4.873	0.027
_	(2/64)	(9/58)		
Rate of incision infection	1.56%	8.62%	1.908	0.167
	(1/64)	(4/58)		

Table 5. — The comparion of the postoperative further situation ( $\bar{x} \pm s$ , n = 122).

	Modified group	Traditional group	χ² value	p value
Mean bladder capacity (ml)	378 ± 52.6	389 ± 54.4	1.165	0.246
Success rate	96.88%	84.48%	5.696	0.017
of primary operation	(62/64)	(49/58)		

However the mean self-miction recovery time of the patients in the traditional surgical group was  $17 \pm 2.1$  days, ranging from 14 to 21 days. Mean postoperative hospitalization time was  $20 \pm 2.1$  days, ranging from 17 to 24 days. There were significant differences between the two groups (p < 0.001). Two cases could not be operated successfully in the modified group and urine leaking occurred postoperatively; the rate was 3.13% (2/64). However, nine cases could not be operated successfully in the traditional group and had urine leaking postoperatively; the rate was 15.52% (9/64), and there was a significant difference (p < 0.05). The rate of incision infection was 1.56% (1/64) in the modified group, and the rate of incision infection was 8.62% (4/58), but there was no significant difference.

Comparion of the postoperative period is shown in Table 5. Mean bladder capacity in the modified group was  $378 \pm 52.6$  ml, but it was  $389 \pm 54.4$  ml in the traditional group, and there were no significant differences. The success rate of primary surgery in the modified group was 96.88% (62/64) and it was 84.48% (49/58) in the traditional group, and there was a significant difference (p < 0.05).

#### Discussion

# Surgery for VVF

If the fistula of the patient is very small without infection, and the surrounding tissue is healthy without ureteral involvement or radiotherapy, it can be treated by an indwelling catheter or fulguration of the fistulous orifice, and the patients should receive antibiotics [4, 5]. However only 2% patients with VVF can be cured [6] with continuous urethral catheterization; four weeks later if the fistula has not closed, it would be impossible to close it [7]; which could improve the life quality of the patients and prepare them for further surgery.

Most patients should receive surgery that is performed

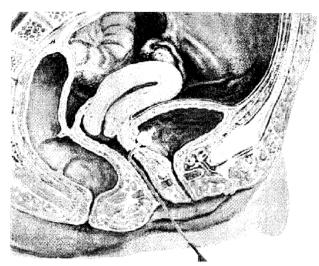


Figure 1. — Illustration of transvaginal vesicovaginal fistula repair surgery mediated by a Foley catheter.

by abdominal, vaginal, or a combined approach. Raashid *et al.* [8] found that whether transabdominal or transvaginal, the success rate of VVF repair surgery was only 87%. Many factors influence the surgery repair – it can be achieved by the vaginal or abdominal approach and depends on the surgeon's experience as well as local factors like size, location, and previous radiotherapy.

In recent years, several reports have been designed supporting new procedures for vesico-vaginal fistula repair [9, 10]. With the development of laparoscopic minimally invasive surgery, we can repair an urogenital fistula using laparoscopy. Melamud *et al.* reported that they had done the first VVF repair by robot-assisted laparoscopy in 2005 [12]. Subsequently, Nabi and Hemal reported they had completed the first case of vesico-vaginal fistula repair successfully for the first time by laparoscopy [13].

Laparoscopy not only has the same benefits as traditional transabdominal surgery, but also own the benefit of less trauma and fewer postoperative complications. However it was considered so difficult that it could not be applied clinically in general [13-15].

Most VVF is in the medium or lower position fistula, and can be repaired by the vaginal approach. The vaginal approach is minimally invasive with short-term hospitalization, lower costs, more esthetic, fewer complications, less blood loss and better results [16]. The vaginal approach also allows a high cure rate, short recovery, and does not require any sophisticated material. The vaginal approach could also be avoided through the previous surgical field, and even if it fails, it can be repaired repeatedly. It is welcomed by the women popularly. Thus the vaginal approach is the first choice for all patients with VVF.

# Unique innovations of the operation

The difficulty of traditional transvaginal VVF repair surgery is to accurately label and successfully repair the fistula. However there is a small operative view, poor exposure and unclear patch level by the vaginal approach. It also has the disadvantage that the fistula can not be dragged down if it is difficult to find the fistula. In addition, inflammation of the tissuse surrounding the fistula makes the tissue adhere and scar. Thus it is difficult to distinguish the stump hole and fistula. These would make urogenital fistula repair more difficult and these are the keys to failure of traditional urogenital fistula repair surgery.

This innovational operation with insertion of a Foley catheter directly into the bladder via the vaginal approach, filling gas into the aerocyst to support the fistula in the bladder, can broaden the operation view, clearly explore the fistula under the direction of a Foley catheter and exactly and quickly distinguish the fistula and stump hole. After the aerocyst supports the fistula, it makes the surrounding tissue maintain a certain tension, and fully separates the bladder or vaginal tissue surrounding the fistula. It would allow the organizational structured layers of the bladder/vagina to be clearer and could be beneficial by cutting the scar tissue of the bladder or vagina surrounding the fistula hole. It could also ensure the fistula surrounding tissue blood supply and promote fistula healing. The scar is the key factor to influence the effect of surgery.

The first surgery is the best time to repair the fistula and it should be carefully planned and performed to reach the highest cure rate. This study found that the primary success rate of traditional transvaginal VVF repair was only 84.48% (49/58), which is similar to the literature [1]. The primary success rate (96.88% vs 84.48%, p < 0.05), mean operation time (85 ± 8.1 min vs 116 ± 19.5 min, p < 0.001), mean intraoperative blood loss (109 ± 23.4 ml vs 175 ± 60.2 ml, p < 0.001), mean postoperative hospitalization (13 ± 1.8d vs 20 ± 2.1d, p < 0.001), rate of postoperative urine leakage postoperatively (3.13% (2/64) vs 15.52% (9/58), p < 0.05) differed for the modified and traditional group and these differences were significant.

However, the mean bladder capacity (378  $\pm$  52.6 ml vs 389  $\pm$  54.4 ml), postoperative self-miction recovery time (10  $\pm$  1.8d vs 17  $\pm$  2.1d), and rate of postoperative wound infection (1.56% (1/64) vs 8.62% (4/58) between the modified group and traditional group were not significantly different.

Therefore, the VVF repair surgery mediated by the Foley catheter has a higher success rate, shorter operation time, less blood loss and quicker postoperative recovery. Thus the VVF repair method is superior and should be

applied in clinics generally. In addition, we successfully repaired one case of rectovaginal fistula mediated by the Foley catheter but whether it could be applied to repair rectovaginal fistulas needs further study.

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