The Necessity of Incorporating an Interposition Flap During Vesicovaginal Fistula Repair: Can Modifying the Method of Vaginal Repair Serve as a Substitute? A Randomized Clinical Trial

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Purpose: Traditionally, an omental flap is employed to reduce the risk of recurrence of vesicovaginal fistula (VVF) repair. In this study, we employed a modified surgical technique wherein the vaginal defect was closed using Connell sutures, without incorporation of an omental flap, aiming to mitigate potential complications.

Material and method: Between 2010 to 2018, the current randomized clinical trial was conducted on 52 women who were candidates for open fistula repair. The patients were randomly allocated into two groups. In one group, the conventional method of fistula repair was performed involving an omental flap, while in the other group, we used a modified approach with a variation in the vaginal wall closure technique. In-hospital variables, including the length of surgery, hospital stay, and occurrences of ileus, were recorded. Patient follow-up extended for one year, with assessments conducted one, six, and twelve months postoperatively. These evaluations encompassed pad test to ascertain success rates and identify any potential complications.

Results: The final analysis comprised 49 patients, with an average age of 46.5 years. Baseline characteristics were comparable between the two groups (*P*-values > 0.05). The modified technique was associated with significantly reduced surgical duration ($P = < 0.001$), and shorter hospital stays ($P < 0.001$). Ileus occurrence was reduced, but it was not significant($P = 0.856$). However, the success rate showed no significant difference between the groups, with a success rate of 100% for the modified technique compared to 91.6% for the classic O'Conner method ($P = 0.288$).

Conclusion: Based on the findings of this study, vaginal wall closure using Connell sutures during VVF repair demonstrates a success rate equivalent to the classic approach involving an omental flap. Moreover, this technique presents a reduced incidence of adverse effects, along with decreased surgical duration, hospital stay, and postoperative ileus.

Keywords: Vesicovaginal fistula, Treatment outcome, Postoperative complication, Length of stay

INTRODUCTION

Vesicovaginal fistula (VVF) can arise from various underlying causes including prolonged labor, post-hysterectomy complication, radiation therapy, malignant diseases, infection, and the presence of foreign bodies [1,2]. Surgical intervention becomes necessary when either the VFF is sizable (> 5 mm) or fails to respond to conservative treatments[3,4].

Different surgical approaches have been employed for VVF repair, encompassing transvaginal, transabdominal, the combination of transabdominal/transvaginal, and laparoscopic approaches. The incorporation of an interposition graft might be considered in all strategies [5]. The existing body of literature comprises retrospective cohort series and limited comparative analyses. However, there is currently no substantiated proof that the utilization of a Martius graft or any other interposition graft significantly enhances the outcomes in primary fistula repair. Furthermore, there is no conclusive evidence indicating the opposite.

The transabdominal route is the most commonly applied method as it provides a better access to fistulas[6, 7], particularly those located high in the bladder, often resulting from hysterectomy or obstetric events. The O'Connor technique, recognized as the classic transabdominal method, has exhibited success rates of up to 97%. This technique involves bivalving the bladder followed by the interposition of an omental flap between the vaginal and bladder walls[8]. Nonetheless, this procedure entails the manipulation of omental tissue and bowel, potentially contributing to the formation of adhesions at the surgical site[9].

In this study, we employed a modified surgical technique wherein the vaginal defect was closed using Connell sutures, without incorporating an omental flap, to minimize potential complications. Consequently, the primary objective of this study is to introduce a new transabdominal surgical approach, followed by a comparative analysis of its outcomes in comparison to the classic technique.

METHODS

Study Design

This study employed a parallel-group randomized clin-

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Table 1. Baseline characteristics of the studied population

Variables		Classic O-Conner (n=24)	Modified treatment method (n=25)	*P*-value
Demographic characteristics				
Age (years), mean±stanard deviation		45.9 ± 4.6	47.1±8.3	0.531
Body mass index (kg/m^2), mean±stanard deviation		26.3 ± 3.0	26.9 ± 1.8	0.431
Medical and clinical characteristics, n (%)				
Diabetes mellitus		6 (23.1)	7 (27)	1.002
Etiology of vesicovaginal fistula	Hysterectomy	19 (73.1)	16 (61.5)	0.762
	Cesarean section	7 (27)	8 (31)	
History of vesicovaginal fistula surgery		16 (61.5)	12 (46.1)	0.262
History of cearean section		22 (84.6)	22 (84.6)	1.002
Current UTI		9 (34.62)	4 (15.38)	0.202
Menopausal state		14 (54)	13 (50)	0.782
Ileus 2		0	0.856	
1Independent t-test				
2 Fischer's exact test or Chi-square test				

ical trial design to compare the outcomes of our modified technique and the classical O'Connor surgery for VVF repair. Women diagnosed with VVF, who were admitted to Alzahra Hospital, affiliated with Isfahan University of Medical Sciences, between January 2010 and March 2018, were assessed for eligibility.

The study proposal, adhering to the criteria of the Helsinki Declaration, received approval from the Ethics Committee of Isfahan University of Medical Sciences under code number IR.MUI.MED.REC.1398.411. This clinical trial has been registered and accepted with the code number "TCTR20230111001" in "thaiclinicaltrials.org". All patients were provided with a comprehensive explanation of the study protocol, including details of both surgical techniques employed in the groups, and were informed of their random allocation into the groups.

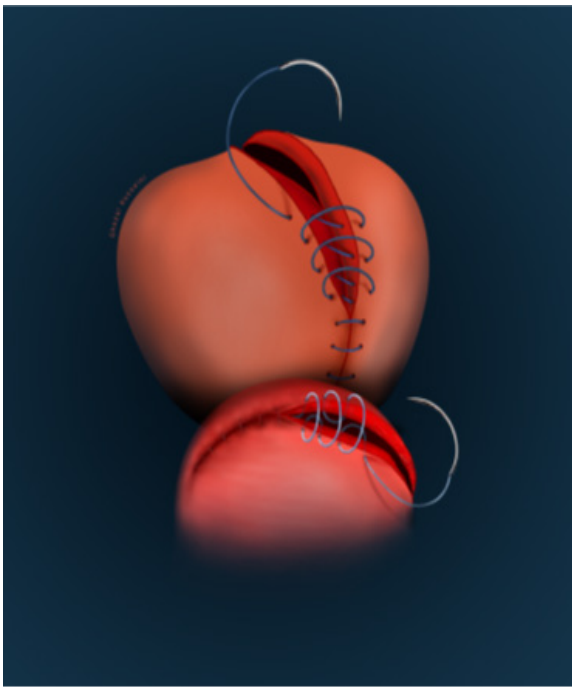

Figure 1. Modified method; The edges of the vaginal defect are transversally brought together using inverting Connell's sutures , serosa to mucosa and "outside in-inside out utilizing 2-0 polyglactin suture perpendicular to the axis of bladder vertical closure. For bladder closure, continuous suturing is performed vertically, encompassing the full thickness of the bladder. The second layer is further strengthened through the application of continuous Lambert sutures.

Study population

Women aged 18 and above, presenting with documented VVF and requiring surgical intervention, were eligible for inclusion. Exclusion criteria encompassed a medical history of pelvic malignancy, having urogenital fistulas other than VVF (e.g., ureterovaginal fistula), history of radiation therapy, and cystoplasty.

Initially, the eligibility of 61 patients for study participation was assessed, resulting in 52 individuals meeting the study criteria, while 9 were not included (6 for not meeting the criteria and 3 declining participation). These included subjects were then allocated to either the classical treatment group (n = 26) or the modified treatment group (n = 26). During the follow-up, 2 patients in the classical treatment group and one patient in the modified treatment group did not attend subsequent visits. Ultimately, data from 49 patients were included in the final analysis.

Clinical and paraclinical diagnostic criteria for vesicovaginal fistula

The patients' age, weight, and height were documented in the study checklist. Additional collected data encompassed the etiology of VVF (hysterectomy/cesarean), comorbidities like diabetes mellitus, history of previous VVF surgery, history of cesarean section, presence of urinary tract infection (UTI) at the time of surgery, hormonal status, and the duration between the onset of urinary leakage and VVF diagnosis.

Patients presenting with persistent urinary leakage from the vagina following gynecological or cesarean surgeries were subjected to assessment using the pad test. In the event of a positive pad test, a vaginal examination was conducted, involving a meticulous inspection of the vaginal canal using a speculum to identify the presence urinary leakage. Additionally, patients were asked to cough to facilitate the visualization of stress urinary leakage. Subsequently, a double dye test was administered to confirm the existence of a vesicovaginal fistula (VVF) while excluding the possibility of a ureterovaginal fistula (UVF). Ultimately, voiding cystourethrography (VCUG) was performed to further validate the presence of the fistula[9].

For patients with confirmed VVF, a cystoscopy was carried out prior to surgery to delineate the precise location, dimensions, and number of fistulas. To urinary diversion and prophylaxis of ureteral trauma bilateral insertion of ureteral catheters was undertaken.

Table 2. Perioperative assessments

Variables	Classic O'Conner (n=24) mean ± SD	Classic O'Conner (n=24) median (range)	Modified method (n=25) mean ± SD	Modified method (n=25) median (range)	*P*-value (crud)*	β (CI=95%)	*P* value**
The length of surgical procedure (minutes)	218	210(150-260)	82	66 (60-180)	< 0.001	0.97 (0.81-1.12)	< 0.001
The length of hospital stay (days)	6.2 ± 1.2	6 (4-8)	4.0 ± 0.9	4 (3-8)	< 0.001	0.45 (0.32-0.57)	< 0.001

*Mann-Whitney test
**Adjusted for Generalized Linear Model, distribution of GAMMA, and link of age, comorbidity and et.

Randomization

The allocation of patients to either the classic or modified treatment groups was carried out through computer-generated random sequences. We used Randomized block in block size of 2:2. Every two persons with inclusion criteria that come to hospital, are sorted based on the national code and according to random number tables, if the number obtained is 0-4, intervention A and then intervention B will be done. If the number obtained is 5-9, intervention B and then intervention A will be done. This process should continue until 26 random blocks are completed.

A designated physician assessed the eligibility of women, while another physician assigned them to their respective groups using sequentially numbered, opaque, sealed envelopes (SNOSE). Regrettably, blinding the surgeon was not feasible. Nevertheless, the individual responsible for data analysis and the participants themselves were kept blinded.

Intervention

To minimize potential operator-related bias, all procedures were performed by a designated urology team. In the "classic treatment group," patients underwent the classic bivalve O'Connor surgery. Following cystoscopy and ureteral and fistula catheterization, patients were positioned supine and administered general anesthesia. According to classic technique abdominal lower-midline incision was made to access the Retzius space. The bladder was bivalved down to the level of the VVF. A watertight continuous suture technique was employed to repair the vaginal defect and bladder wall in two layers. Additionally, the greater omentum, functioning as a posterior bladder wall flap, was mobilized and placed between the vagina and bladder. A Jackson-Pratt drain was placed within the Retzius space and 22 Fr foley catheter inserted and saved for up to 3 weeks.

The modified technique

The modified technique was implemented for the second group, where the initial incision steps were carried out similarly to the classic O'Connor approach. In this group, the edges of the vaginal wall defect were brought together using inverting Connell sutures, utilizing 2-0 polyglactin suture. In the Connell suture technique, the suture passes through the lumen and suture passage is made in the direction of the incision. Then a passage is made from the other side of the incision parallel to the first pass and in the same direction. When the suture is pulled, the tissue becomes inverted. The suture runs from both sides of the incision, parallel to each other. For closing the bladder, continuous watertight repair with 2-0 polyglactin suture was applied in a transverse manner, incorporating the full thickness of the bladder, from serosa to mucosa. Continuous Lambert sutures were used in the second layer for reinforcement. The bladder wall was closed similar to the first group.(**Figure 1**)

For adequate bladder drainage, a 20F Foley catheter was introduced via cystostomy. Moreover, a 22F Foley catheter was inserted in the urethra for both groups. The later catheter remained in place until three days after the operation.

In both groups, patients were not discharged until their postoperative ileus had resolved. The cystostomies were removed during the follow-up visit within three weeks after the operation.

Outcome assessment

The clinical assessments were categorized into three groups of intraoperative, and immediate and late postoperative variables. The length of the surgical procedure was defined as the interval between the skin incision initiation to the end of the surgery, while the skin was sutured. The mean hospital stay and the incidence of ileus were the other in-hospital assessments. Successful VVF closure was defined as no complaint of leakage in the pad test done in the follow-up visits performed within one, 6 and 12 months postoperatively.

Statistical analyses

Data were entered into the Statistical Package for the Social Sciences (SPSS) software version 23.0 (IBM Corp. USA). The normality of data distribution was assessed using the Kolmogorov-Smirnov test . For normally distributed data, the Independent t-test was employed for comparisons; otherwise Mann-Whitney *U* test was utilized. Categorical variables were compared using Fisher's Exact test or the Chi-square test. If more than 20% of cells in table have expected count less than 5, we should use Fisher's exact tests otherwise chi-square test. A significance level of less than 0.05 was considered statistically significant.

RESULTS

Preoperative assessments

In the current study, a total of 52 patients with VVF were enrolled, with 26 (50%) undergoing the classical O'Connor procedure and 26 (50%) undergoing a modified technique(figure 2). The two studied groups exhibited similar characteristics in terms of age and body mass index (*p*-values > 0.05). Baseline variables, including the history of previous VVF surgery, past cesarean section, etiology of VVF, presence of UTI at the time of surgery, menstrual status, diabetes mellitus, and the interval between urinary leakage and VVF diagnosis, demonstrated no significant differences between the groups (*p*-values > 0.05). tabk, in Age and BMI, equal variance assumed. Detailed information is presented in **Table 1**. The surgical procedure was performed for an average interval of 6.2 months after the onset of urinary incontinence, with a range of 1 to 13 months.

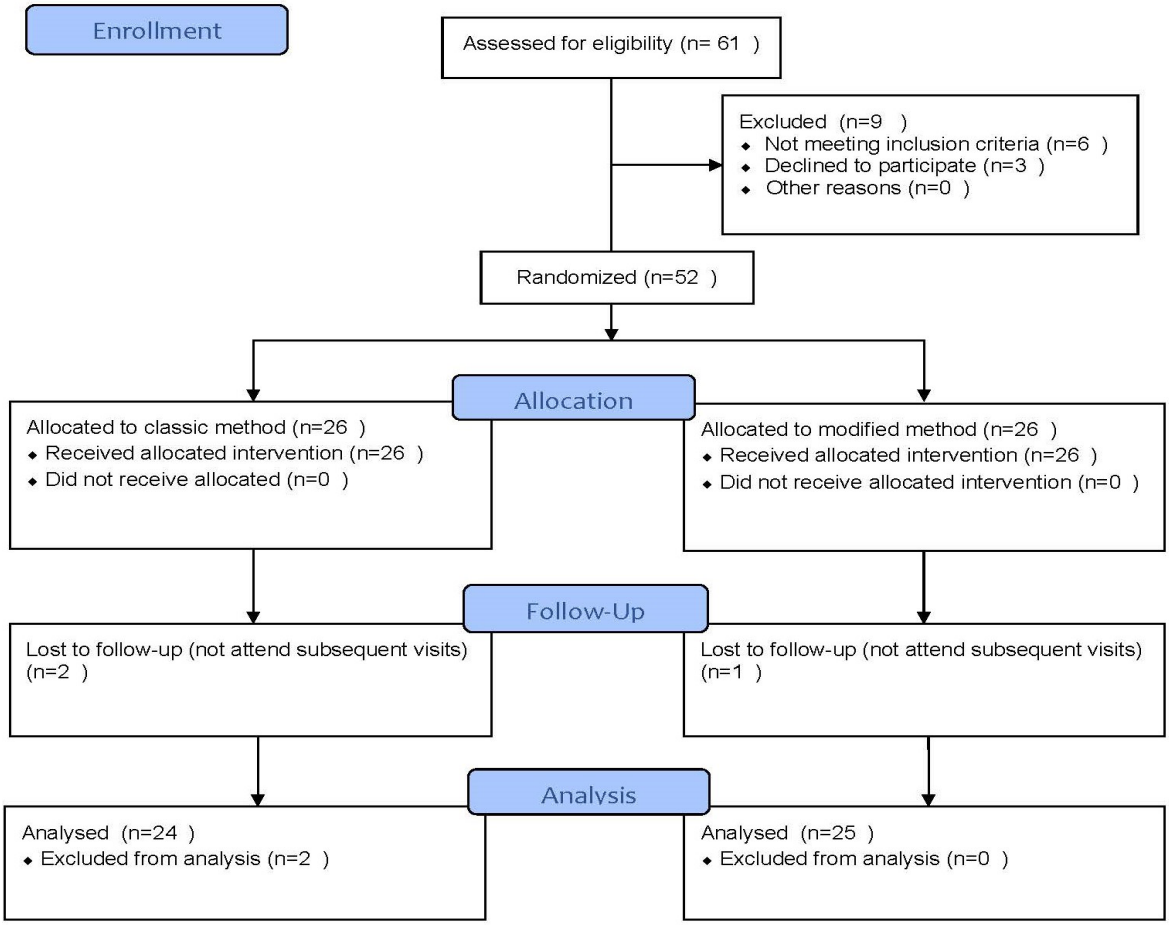

Figure 2: Consort flow diagram

Perioperative assessments

The surgical duration was measured as 218 minutes in the classic treatment group and 82 minutes in the modified treatment group ($P = < 0.001$, $\beta = 0.97$ (CI=95%)). Moreover, the length of hospital stay exhibited a statistically significant reduction in the modified group ($P < 0.001$, $\beta = 0.45$(CI=95%)) (**Table 2**). Ileus occurrence was reduced, but it was not significant ($P = 0.856$) (**Table 1**).

Complications and failures

Upon one-year follow-up, the closure of VVF was successfully achieved in 22 out of 24 patients (91.6%) within the classic treatment group and in all patients (100%) within the modified treatment group ($P = 0.288$). Importantly, none of the patients experiencing relapse presented with complex fistulas.

Within the classic treatment group, a case of failure occurred in a patient with morbid obesity, necessitating subsequent procedures for the removal of adhesion bands during the classical O'Conner surgery. Although her initial postoperative visit revealed a negative pad test, she reported leakage before her second-month visit, and this was confirmed by a positive dye test.

In a separate case within the classic treatment group, a patient experienced failure due to obstruction of the suprapubic catheter caused by encrustation. However, removing encrustation led to the bladder suture dehiscence in the second post-operative week. This patient underwent a re-operation during the eighth week following the initial procedure. Two patients within the classic group discontinued their participation in the study due to their failure to attend follow-up visits.

No failure was observed in the modified treatment group. One patients within the modified group withdrew from the study due to their unavailability for follow-up visits.

Two patients who underwent the classic method of treatment reported abdominal pain during the third postoperative month. Subsequently, a computed tomography scan was conducted, revealing an inclusion cyst located at the site of the omentum. For one of the cysts, percutaneous drainage was performed, while the other was managed conservatively. Conservative management involved the use of oral acetaminophen as an analgesic and dicyclomine as an antispasmodic agent. Both patients were closely monitored for a period of two weeks until their symptoms were relieved.

DISCUSSION

Our study findings indicate that if the repair of the damaged tissues of the vagina and bladder is done with precision and delicacy, placing on omental flap will not effect the results of the operation ,while without a fine and careful repair, the omental flap will not help. there was no significant difference in the success rates between the two surgical methods. However, our mod-

ified approach exhibited several advantages. Notably, it was associated with a shorter duration of surgery, reduced hospital stays, and a decreased incidence of ileus. Our research suggests that the modified technique holds superiority over the classic method due to its ability to achieve optimal closure while minimizing suture line contact by inverting Connell sutures, resulting in watertight and more effective incision healing. Furthermore, owing to the decreased manipulation of the bowel tract, the incidence of ileus reduced, leading to a significantly shorter hospital stay duration for these patients.

The choice of surgical approach is heavily influenced by the underlying etiology determining the location of the fistula. The transabdominal procedure offers a clear visual field and enhanced access for the surgeon, particularly beneficial for addressing high vault fistulas [10-12].

Since its proposal by Turner Warwick in 1967[13], the application of omental flap interposition has become widespread. This is largely attributed to its robust vascularization, which promotes the healing process and establishes an anatomical barrier between the suture lines of the bladder and vagina[14]. Another theoretical rationale for employing interposing flaps is their role in lymphatic drainage, aiding wound healing by absorbing exudates released at the surgical site, and potentially reducing the risk of infection[15]. Consequently, the classic O'Connor surgical method has prominently utilized the omental flap interposition to enhance surgical outcomes.

However, the utilization of interposition flaps in healthy tissues, particularly in cases devoid of a history of radiotherapy and concurrent fistulas, has undergone a notable decline[16,17]. In fact, Singh et al. reported a higher morbidity rate among those undergoing repairs with interposition grafts compared to those without tissue interposition. It's important to note that they excluded patients with complex fistulas from their study[18].

In addition, bowel manipulation and tissue interposition might potentially lead to the complications such as hematoma, blood loss and pain. This alignment with our findings is particularly evident in the presentation of postoperative pain observed in two cases. Upon evaluation, it was discovered that inclusion cysts had formed at the site of flap transposition[19].

Although earlier studies emphasized the pivotal role of interposition flaps in complex fistula repairs[20], our study challenged this notion. Specifically, we successfully managed 11 cases with complex fistulas using the modified method, devoid of flap interposition . This approach yielded effective and watertight fistula closure without any notable postoperative complications. Conversely, the classic method, which incorporated omental flap interpositioning, was applied to another 10 cases with complex fistulas, leading to similarly favorable outcomes.

As previously mentioned, the omission of omental flap interposition significantly reduces the operation duration by approximately 136 minutes, constituting around 60% of the total time spent. Moreover, a noteworthy reduction of up to 30% in hospital stay was observed in patients undergoing the modified technique.

Warner et al. reported an average duration of 223 minutes for the transabdominal route with omental flap interposition, although their study primarily focused on simple cases rather than complex fistulas[21]. Nonetheless, our modified approach stands as a rapid and highly responsive technique for VVF repair, especially among patients with complex fistulas.

The optimal timing for surgical management of vesicovaginal fistula (VVF) has been a longstanding question. Traditionally, it was suggested to initiate surgical approaches within 3-6 months after the onset of symptoms, once inflammation and infection had subsided[22]. Furthermore, reports of spontaneous closure in uncomplicated fistulas following prolonged labor have sparked interest in conservative management[23]; however, the major body of evidence have represented surgical treatment as the gold standard[24]. HongWook Kim et al. reported a laparoscopic extraperitoneal transvesicoscopic approach to repair of VVF could become treatment of choice[25].

In line with these considerations, our study adopted a mean postponement of 6 months for the operation, spanning from 1 to 13 months. Notably, this delay wasn't aimed at evaluating responses to conservative management; rather, it was due to the interval between symptom onset and diagnosis. In confirmation, it appears that earlier surgical intervention could enhance the patients' quality of life. This notion is reinforced by our findings, as this duration of delay did not result in spontaneous fistula closure among any of the patients examined in this study.

Despite the considerable strengths of the present study in introducing a novel surgical approach for correcting VVF, its primary limitation lies in the small sample size. Furthermore, the exclusion of patients with a history of radiation, obstetric fistulas, or prior failed repairs poses a constraint on the generalizability of the findings to a broader patient population.

Considering these limitations, it is prudent to advocate for further investigations conducted on larger cohorts. Additionally, assessing the utility of the modified technique for managing complex fistulas is highly recommended. This broader scope of research would provide more comprehensive insights and contribute to a more robust understanding of the technique's effectiveness. Considering the rapid shift of operative technologies towards laparoscopic techniques, confirming this fact that the use of omental flap does not have a noticeable effect on the results of the operation, will open a new way for less invasive surgeries by simplifying the technique and reducing the operation time.

CONCLUSIONS

Based on our findings, the modified technique of vaginal defect closure using Connell sutures exhibits advantages in terms of surgical duration, hospital stay length, and postoperative ileus compared to the classic O'Conner method using omental flap interposition. Importantly, both methods demonstrated comparable success rates. This study underscores the potential benefits of the modified approach in optimizing surgical outcomes and patient care.

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