

Comparison of Outcome among patients undergoing Vesicovaginal Fistula Repair through Transabdominal approach with and without Interposition Omental Flap

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ABSTRACT:

Background: Vesicovaginal fistula (VVF) is an abnormal connection between the bladder and vagina, causing urinary incontinence. It often results from surgical injury or malignancy. Interposition flaps, including the omentum flap in trans-abdominal repairs, help close the defect and improve outcomes.

Objective: To compare the outcome among patients undergoing vesicovaginal fistula repair through transabdominal approach with and without interposition omental flap.

Patients and Methods: A randomized controlled trial was conducted from July 2021 to January 2022 at the Urology Department, Sir Ganga Ram Hospital, involving 44 patients with supratrigonal vesicovaginal fistulas (VVF) ≤ 2 cm and ≤ 2 openings. Patients with malignancy, radiotherapy, recurrent or infratrigonal VVF, ureterovaginal fistula, or localized infection were excluded. The experimental group underwent VVF repair with an interposition omental flap, while the control group underwent repair without the flap. SPSS version 24 was used for data analysis. The comparison between groups for proportions of fistulous openings, peri-operative complications and treatment success by chi-square test. P-value of ≤ 0.05 was considered as significant

Results: The experimental group (mean age 36.5 ± 7.4 years) and control group (mean age 39.1 ± 10.1 years) showed similar peri-operative wound infection rates (9.1%). Complications in the experimental group included bleeding (9.1%), bowel perforation (4.5%), and higher fistula recurrence (22.7% vs. 18.2%). Treatment success at 2 weeks was 81.8% with the graft and 90.9% without it.

Conclusion: In conclusion, using an interposition graft in VVF repair did not significantly improve success rates or reduce morbidity compared to repairs without a graft.

Keywords:

vesicovaginal fistula; Omental Flap, Urology; trans-abdominal approach

INTRODUCTION

Vesicovaginal fistula (VVF) is an abnormal connection between the urinary bladder and the vagina that results in urinary incontinence. It is the most common acquired fistula of the urinary tract.¹ Its recognized causes include iatrogenic injury during obstetric, gynecological surgery; and local invasion as a result of radiotherapy or pelvic malignancy.² It has a significantly devastating impact on patient's quality of life such as social isolation leading to divorce and involves costly and chronic medicinal and surgical treatments.³

According to the World Health Organization (WHO), Globally 50,000-100,000 women are affected by obstetric fistula every year and about 2.0 million young women live with untreated fistula in Asia and sub-Saharan Africa.⁴

A number of surgical approaches are used for VVF repair but there is no consensus on the optimal approach. The choice of approach usually depends on characteristics of VVF and experience of surgeon.⁶ The interposition flaps are used during repair to fill dead-space, improve vasculogenesis and reinforce the repair.⁷

It always remains a challenge to achieve 100% success rate in VVF repair. The early diagnosis and timely repair are essential for successful management;⁵ and the first attempt of VVF repair has higher chances of success.^{8,9}

Several studies have evaluated the outcomes of transabdominal approach with and/or without interposition flap. Tariq et al. reported a success rate of 96% for VVF repair with an omental flap and 84% without. They recommended the abdominal approach with an omental flap for larger VVFs in the trigonal or supratrigonal region.¹⁰ In a descriptive case series study, the role of the transabdominal approach with an omental graft in improving the outcomes of

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vesicovaginal fistula (VVF) repair was evaluated.¹¹ Hassan et al. reported a higher success rate for VVF repair with an omental patch (76%) compared to without (57%), highlighting the role of omental grafts in reducing recurrence and improving.¹² In a recent review study, Breen M and Ingber M have reported that the use of interposition flap is useful; but also recommended a trial on the use of interposition flaps.¹³

The review of literature shows that the data available on the outcomes of VVF repair greatly varies between studies. Most of the studies on the topic are either retrospective or observational; therefore, the quality of evidence suggests for well-designed prospective experimental studies. Moreover, the debate that use of interposition flap is necessary or not is still ongoing. Therefore, our study was done to compare the successful outcome among patients undergoing vesicovaginal fistula repair through transabdominal approach with and without interposition omental flap.

METHODS

Randomized controlled trial conducted from July 2021 till January 2022 in the department of Urology Sir Ganga Ram Hospital after taking the ethical approval from Fatima Jinnah Medical University/Sir Ganga Ram Hospital Lahore. The inclusion criteria for the study were patients with a vesicovaginal fistula (VVF) that had two or fewer openings located supratrigonal, and with a fistula size of 2 cm or less. Additionally, only patients aged 18 years or older were included in the study. Exclusion criteria included patients with VVF resulting from malignancy or radiotherapy, recurrent VVF, concomitant ureterovaginal fistula, infratrigonal VVF, or those with a localized infection at the surgical site. Sample size of 22 in each group was calculated by using expected rate of treatment success 100.0% in VVF repair with interposition flap group versus 63.0% in VVF repair without interposition flap group.¹⁴

After taking the written informed consent from the patients, they were randomly allocated into treatment groups by opaque sequentially sealed envelopes having card showing allocated group written on it. The envelope was opened just before the surgery. The patients in Experimental group (EG group) underwent VVF repair by transabdominal approach with interposition omental flap; while the patients in Control (CG) group underwent VVF repair by transabdominal approach without interposition omental flap.

To ensure standardized skill, a single surgical team performed all the VVF repair procedures. This

approach minimized variability in technique and skill level, ensuring consistency across all surgeries. Under general anesthesia, patients were placed in the lithotomy position for cystoscopy to assess the VVF's location, size, and number of openings. They were then positioned supine, a 16Fr Foley catheter was inserted, and a Pfannestiel or infraumbilical incision was made to access the bladder. After opening the bladder transversally and localizing the fistula, the Foley catheter was placed and inflated. The fistulous tract was encircled with a 2 cm margin, and the vaginal opening was closed with polydioxanone sutures. In the experimental group, an omental flap was interposed over the vaginal suture line. The bladder was closed in two layers, and a suprapubic catheter was inserted. The bladder was tested for watertight closure, a drain was placed, and the abdomen was closed with dressing. Pyodine-soaked gauze was packed in the vagina and removed on the first postoperative day.

Intraoperative variables include size, number of VVF and operating time. VVF repair by transabdominal approach was performed. Intra-operative and post-operative variables noted using a predesigned proforma. Patients were routinely discharged after 3-7 days with postoperative advice regarding the intake of anticholinergics (Tolterodine 2 mg, twice a day), antibiotics, stool softeners and to avoid sexual intercourse for 3 months. Continuous urinary drainage maintained for three weeks with per urethral catheter in situ and suprapubic catheter for 2 week. Treatment success was assessed by wound examination at one week post-VVF repair and confirmation of VVF closure, evidenced by the absence of urinary leakage on a cystogram at two weeks post-surgery.

Stitch removal after two weeks of VVF repair; and for per-urethral Foley removal after three weeks of VVF repair was done. The patients with treatment success were followed-up for continuity of treatment success at three months. The patients with treatment failure were called for repeat VVF repair.

Statistical Package for Social Sciences (SPSS) version 24 was used for data entry and analysis. Numerical variables such as age, size of VVF and operating time reported as mean \pm SD; and categorical variables such as etiology, number of VVF and treatment success will be reported as n(%). The comparison between groups for proportions of fistulous openings, peri-operative complications and treatment success by chi-square test. The data was stratified for age, VVF size and number. P-value of ≤ 0.05 was considered as significant.

Table 1: Distribution of Fistulous Openings Between Groups with and without Interposition Graft

Group	Single fistulous opening	Double fistulous opening	P-value
With Interposition Graft	18 (81.8%)	4 (18.1%)	0.03
Without Interposition Graft	21 (95.5%)	1 (4.5%)	

Table 2: Frequency of peri-operative complications among Groups

Complications	With Interposition Graft N=?	Without Interposition Graft N=?
Intra-operative bleeding	2 (9.1%)	0 (0.0%)
Bowel perforation	1 (4.5%)	0 (0.0%)
Vaginal perforation	0 (0.0%)	0 (0.0%)
Wound infection	2 (9.1%)	2 (9.1%)
Fistula recurrence	5 (22.7%)	4 (18.2%)

Table 3: Frequency of treatment success in each group

Treatment success*	2 week follow up		3 rd month follow up	
	With Interposition Graft	Without Interposition Graft	With Interposition Graft	Without Interposition Graft
Yes	18 (81.8%)	20 (90.9%)	17 (77.27%)	18 (81.8%)
No	4 (18.1%)	2 (9.09)	5 (22.7%)	4 (18.1%)
P-value*	0.38		0.70	

P-values≤0.05 taken as significant *Treatment success was assessed by wound examination at one week post-VVF repair and confirmation of VVF closure, evidenced by the absence of urinary leakage on a cystogram at two weeks post-surgery.

RESULTS

The study included 22 patients in each group: the experimental group with an interposition graft and the control group without it. The experimental group had a mean age of 36.50 years (S.D. 7.38), while the control group had a mean age of 39.14 years (S.D. 10.14). Cystoscopy prior to surgery documented the number, size, and location of fistulas. The experimental group had a mean number of 1.18 fistulas (S.D. 0.39), compared to 1.05 (S.D. 0.21) in the control group. The number of fistulas ranged from 1 to 2 in both groups. The mean operating time in the experimental group was 124.9 S.D 29.25 minutes and in the control group was 121.5 S.D 15.03 minutes.

At the 2-week follow-up, 81.8% of patients who received the interposition graft experienced treatment success, compared to 90.9% in the group without the graft. The p-value of 0.38 suggests that this difference is not statistically significant. By the 3-month follow-up, 77.27% of the graft group had successful outcomes, while 81.8% of the non-graft group did. The p-value of 0.70 indicates no significant difference between the groups in long-term success. Overall, the use of an interposition graft did not significantly effect treatment success rates at either follow-up point.(Table 2)

In the experimental group, peri-operative complications included intra-operative bleeding in 9.1% of patients (n=2) and bowel perforation in 4.5% (n=1). There were no cases of vaginal perforation. Wound infection occurred in 9.1% of patients (n=2), and fistula recurrence was observed in 22.7% of patients (n=5). In the control group, peri-operative

complications were as follows: no cases of intra-operative bleeding, bowel perforation, or vaginal perforation were reported. Wound infection occurred in 9.1% of patients (n=2), and fistula recurrence was observed in 18.2% of patients (n=4).

DISCUSSION

VVF repair depends on fistula size, location, complexity, and surgeon experience. Skilled surgeons should be versatile in both abdominal and vaginal approaches. In our study, all cases used the transabdominal approach with or without interposition omental flap.¹⁵ In this study the author had a very large difference between the success of repair with and without graft. This was not the case seen in our cohort of patients study where in the graft group 5(%) patients had a recurrence and with no graft 4 patients had a recurrence. The gap in our patient population was much smaller than this study.

A center reviewed VVF repair success rates with and without interposition flaps, finding a 100% success rate with grafts for benign etiology, compared to 63% without grafts. They used grafts only when tissue appeared less healthy or vascularized. ¹⁴

In a similar local study, patients with benign VVFs less than 3 cm in diameter were compared based on whether they received an omentum graft or not. Wound infection occurred in 3 cases without the graft and 2 cases with the graft, which mirrors our findings of 2 wound infections in each group. Their study reported 2 failures in the no-graft group and 1 in the graft group. In contrast, our study found 5 failures in the omentum

graft group and 4 in the no-graft group. Overall, the local study concluded that there was no statistically significant difference in success rates between patients with or without an omentum graft for simple VVF.¹⁶ This aligns with our findings, which also showed no difference in success rates. However, we identified a statistically significant higher risk of gut perforation in the graft group, attributed to the additional surgical manipulation required for graft mobilization.

In a retrospective study, Ghosh and colleagues compared the outcomes of laparoscopic versus open abdominal approach for VVF repair.¹² The comparison between groups showed that mean blood loss (58.69 ml vs. 147.30 ml; p-value <0.001), mean hospital stay (4 vs. 13 days; p-value <0.001) and analgesic requirement (261.53 mg vs. 617.30 mg; p-value <0.001) were significantly different.¹⁶ However, VVF repair was successful in all patients of both groups. In another retrospective study, Ojewola and colleagues reported that VVF repair by transabdominal approach achieved an excellent result in women who had previously failed VVF repair; and suggested that transabdominal approach may be considered as the first option in such cases.¹⁷

A study done in Iraq compared the use of an omentum graft with no graft via the transabdominal repair of a VVF. For the group with the omentum interposition, 94.4% were successfully repaired whereas in the other group 86.6% were successfully repaired. Though their reported success rates were higher than ours, the success rate for patients without a graft was similar to our 81.8% success rate. It is interesting to note that in the literature the success of a repair is considerably higher with the usage of a interposition graft whereas in our study this was reversed.¹⁸ The study found no statistically significant difference in outcomes with or without an omental graft, similar to our results.

A tertiary care hospital in Karachi, Pakistan published their audit data on VVFs. They had 193 patients. All patients repaired by a transabdominal approach were successfully repaired, regardless of omentum graft usage or not.¹⁹ The success of the transabdominal approach with or without graft usage, emphasizing the impact of surgical expertise, multidisciplinary care, and center volume on patient outcomes.²⁰ Similarly, a study at Koochi Goth Fistula Hospital reported an 86% success rate for transabdominal repairs and a 92% success rate for repairs using interposition grafts.²¹

Our study has a small sample size and our center deals with a small volume of annual fistula cases. High volume centers may reflect the best results of repair success and the utility of an interposition graft. Multi-center audits with pooled data from hospitals across Pakistan may in effect generate the most representative results of the success rate of VVF repairs in Pakistan, with and without transposition grafts and the different access routes.

CONCLUSION

In conclusion, the study revealed that using an interposition graft in VVF repair did not significantly enhance overall success rates or reduce morbidity compared to repairs without a graft. The experimental group had a higher incidence of complications, including intra-operative bleeding and bowel perforation, and a slightly lower success rate at the 2-week follow-up compared to the control group. These results indicate that an interposition graft may not be essential in all cases. Larger sample studies need to be conducted in Pakistan to reflect the success rates in the local population using an interposition graft in VVF repair.

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