

# Comparison of the Outcome of Vesicovaginal Fistula Repair with Omental Transposition and Peri-vesical Fat Emplacement in Terms of Recurrence

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## ABSTRACT

**Background:** Persistence of urinary incontinence after an attempted vesicovaginal fistula (VVF) repair leads to frustration for the patient as well as for the surgeon. Optimal approach for the surgery, stage and use of additional measures to strengthen VVF repair is controversial. However, it has been found that interposition of some sort of tissue has provided more promising results. **Objective:** To compare the outcome of Vesicovaginal fistula repair by omental transposition and peri-vesical fat emplacement in terms of recurrence and maximum bladder capacity. **Study Design:** Randomized control trial. **Settings:** Urology department of Lahore General Hospital, Lahore Pakistan. **Duration:** Study period was 1 year. **Methodology:** Overall 40 patients with VVF were added in the research, split into two identical groups, each consisting of 20. In group 1, omental transposition and in group 2, peri-vesical fat emplacement was done. After 6, 12 and 24 weeks, all the patients were assessed for recurrence. The complications like wound infections, urgency, urge incontinence and paralytic ileus were also noted. The data was collected in a specially designed proforma. **Results:** In this study 40 patients fulfilling the inclusion criteria were included, 20 patients in each group. The success rate was 19/20 (95%) in Group-1, only one case had recurrence. While in group 2 all the cases were successful. **Conclusion:** It is concluded that both the techniques of Vesicovaginal fistula repair, either with omental transposition or peri-vesical fat emplacement are equally good in terms of recurrence and maximum bladder capacity.

**Keywords:** Vesico-vaginal fistula, Recurrence, Bladder capacity.

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## INTRODUCTION

Vesicovaginal fistula (VVF) is a disastrous situation for women. Large VVF after an obstetrical trauma has been described since 2050-BC.<sup>1</sup> It is an unusual connection between urinary bladder and vagina, causing continuous leakage of urine in the vagina.<sup>2</sup> Vesicovaginal fistulae are usually due to bladder wall ischemia followed by necrosis during obstructed labor. Etiology of the obstetric fistula is absolutely distinct from surgical fistula. Vesicovaginal fistula may also result as a complication of pelvic surgery, i.e. injury due to inaccurate clamp employment in hysterectomy. These fistulae are generally supra-trigonal and have healthy tissue around. In comparison obstetric fistula is a huge injury, with dead tissue around. They mostly involve the trigone, bladder neck and urethra.<sup>3</sup>

Most of the patients with VVF require conventional surgical treatment but in smaller VVF's i.e. lower than 8mm numerous less invasive accesses are also helpful. Patterson repaired a small VVF by fibrin in 1979 (Patterson S). To protect fibrin plug, per urethra catheter was left and tranexamic acid was given to block fibrinolysis, for 8 weeks. Mortia and Tokue described an endoscopic repair of 5mm Vesicovaginal fistula by using fibrin paste and bovine collagen. It requires electro fulguration of the fistulous tract. Stovsky analyzed 15 patients with small VVF; treated with electrocoagulation.<sup>4</sup>

Fulguration alone was found rewarding treatment for 9 from 12 patients (75%). Dogra and Nabi fulgurate the fistulous tract by using laser (Nd-YAG) through bladder approach.<sup>5</sup> Fistulae always require surgical interference. Surgery can be done through abdominal or vaginal approach. Preference of approach in a particular patient depends at the location of fistula, existence or absenteeism of vaginal stenosis and expertise of the surgeon. To provide support, increase vascularization and better lymphatic drainage, tissue/ graft interposition between urinary bladder and vaginal wall is done. In case of vaginal repair of VVF, Martius fat graft and for abdominal approach omental transposition is the gold standard. But free bladder mucosa autograft, peritoneum, rectus sheath, ileal graft and even duramater have been used.<sup>6</sup>

Singh O *et al*<sup>7</sup> successfully attempted VVF repair by using peri-vesical fat interposition. The superiority of one surgical approach over the other is difficult to prove, due to the different etiology of fistula, site and surgeon's competency. Every fistula is different so surgeon has to modify his access and technique of surgery.<sup>8</sup>

Evans DH *et al*<sup>9</sup> conducted a retrospective study on 29 patients with VVF, flap interposition was made in 10 patients, with all 10 successful (100%). Rest of 19 were repaired without flap, only 12(63%) were successful. Of the 8 patients with large VVF's, 2 patients were repaired by using interposition flap and both

were successful (100%). In the rest of 6 large VVF's, flap was not used during the repair and only 4 were found successful with this method (67%). According to this study, there is higher success of VVF repairs with tissue interposition as compared to the repair without tissue transpositions (100% success). Wein AJ found that omental transposition is very useful adjunct for various genitourinary reconstructive procedures.<sup>10</sup>

RB Singh *et al* studied the technique of harvesting pelvic fat as an interposition flap for the treatment of high Vesicovaginal fistula. They concluded that peri-vesical fat proved an effective interposition flap in the repair of VVFs. In our study we have compared repair of Vesicovaginal fistula by Omental Transposition versus Peri-vesical fat Emplacement. Parameters of our study were recurrence and bladder capacity.<sup>11</sup>

The objective of the study was, to compare of the outcome of Vesicovaginal fistula repair with omental transposition and peri-vesical fat emplacement in terms of recurrence.

## METHODOLOGY

**Study Design:** This was a randomized control trial

**Settings:** Urology Department of Lahore General Hospital, Lahore Pakistan.

**Duration:** Study period was 1 year.

**Sample Technique:** Non probability, purposive sampling was used to select the patients and then the patients underwent surgical procedure randomly. Randomization was done by lottery method.

**Sample Size:** Total 40 patients were included in this study based on predefined inclusion and exclusion criteria.

Sample size was calculated by taking magnitudes of outcome variables from previous study.

(Sample Size calculation by Shien-Chung Chow *et al*)

P1 is the assumed proportions of Group A= 2.5% (Mehmood A *et al*)

P2 is the assumed proportions of Group B = 0.0% (RB Singh *et al*)

$p_1 - p_2$  is the disparity among the proportions = 2.5%

$Z_{1 - \beta}$  is the desired power of study = 80%

**Inclusion Criteria:** Adult female patients with Vesicovaginal fistula, resulting from obstetrical and as a complication of surgery. This was confirmed by physical examination, IVU, pelvic computerized tomography scan with contrast, retrograde urethrocystogram, ultrasound KUB and cystoscopy.

**Exclusion Criteria:** Patients with systemic illness like diabetes mellitus, chronic renal failure and chronic, liver disease etc., patients on immunosuppressant therapy like: steroids intake, patients undergone irradiation of the pelvis due to any malignant disease.

**Ethical Issues:** Helsinki declaration of human rights was followed during the study conduction. Study approval was taken from the Ethical Committee of Post Graduate Medical Institute (PGMI), Lahore and data was collected only after obtaining fully informed, explained and voluntary consent of the patient. All observations and related data were collected by the researcher himself.

**Data Collection:** After recording of all demographic information, complete physical examination and investigations of the

patients were performed to confirm the diagnosis. All the routine investigations i.e. complete blood count with bleeding profile, random blood Sugar levels, renal and liver function tests and Hepatitis B, C were done. Demographics like age, parity and etiological factor (prolonged labor, lower caesarean section, instrumental delivery and total abdominal hysterectomy) were noted. Both of the procedures were fully explained to the patients and consent was obtained. Consent was taken on a prescribed proforma. During surgery, the size of fistula was noted. All the procedures were performed by the surgeon who has a surgical experience of at least 5 years for urological surgery. After aseptic measures lower midline or Pfannenstiel incision was made in the abdomen. The posterior surface of the bladder was approached by opening the peritoneum. Abdominal sponges were placed to pack the gut gently and stay sutures applied using 2/0 chromic catgut at the posterior surface of the urinary bladder. Incision was made at the dome and anterior bladder wall until it reached at the upper end of fistula. At this stage, closeness of the ureteric orifices to the fistula was observed and a 5-6 Fr feeding tube passed into the ureteric orifices, where fistulous opening is near to ureteric orifices. The cystostomy was extended to encircle the fistula. In this manner, bladder was separated from the anterior wall of vagina. The plane between the bladder and vaginal wall was dissected. Continuous interlocking, closely positioned stitches were applied to close the vaginal wall in single layer by using polyglycolic acid (vicryl 2/0) in a transverse line. In group I patients, an intact omental pedicle graft was mobilized for covering the stitched vaginal wall and anchored with the fistulous margins of the bladder with polyglycolic acid (vicryl 2/0), this way the flap was interposed between vagina and the urinary bladder. In group II peri-vesical fat, with pedicle intact was mobilized and emplaced between the suture lines of vagina and anchored with the dissected fistulous margins of the bladder. Urinary bladder is then closed in two layers with vicryl 3/0, drain placed in the peri-vesical area and wound was closed in layers, in both the groups. The urethral catheter was passed at the end of the procedure and was kept for two weeks. The patient was advised to avoid sexual intercourse for at least three months. After 6, 12 and 24 weeks, all the patients were assessed for recurrence. The complications like wound infections, urgency, urge incontinence and paralytic ileus were also noted. The data collection was done in a especially designed proforma.

**Data Analysis:** All collected information was entered in SPSS version 20 and evaluated through it. Quantitative data like age was presented in the form of Mean  $\pm$ SD. Whereas qualitative data, like recurrence was presented as frequency and percentages. Comparison of the success / failure rates and their levels were compared between the two procedures by using Chi-square. P-value  $\leq 0.05$  was considered significant.

## RESULTS

Mean age of patients in this study was  $35.95 \pm 10.58$  years. Mean bladder capacity of patients was  $275.15 \pm 36.60$ . The most frequent etiology among patients was hysterectomy (57.50%)

followed by C-section (15%), and obstructive labor (7.50%). Recurrence rate did not show statistically significant difference between the two groups and in Group-1 only 1(2%) patient had recurrence while in Group-2 none of the patients had recurrence. i.e. p-value=0.468

**Table 1: Age and Bladder Capacity of patients in Treatment Groups**

n	40
Age	35.95±10.58
Bladder Capacity	276.15±36.60
Etiology	
Hysterectomy	23(57.50%)
C-Section	6(15%)
C-Section + Hysterectomy	6(15%)
Obstructive Labor	3(7.50%)
DNC	1(2.50%)
RTA	1(2.50%)

**Table 2: Outcome in Treatment Groups**

Outcome	Group 1	Group 2	Total	p-value
Successful	19(98%)	20(100%)	39	0.468
Recurrence	1(2%)	0(0%)	1	
Total	20	20	40	

## DISCUSSION

This study was a randomized control trial and carried out in the Urology department of Lahore General Hospital, Lahore. The sample consisted of 40 patients of VVF, divided into two equal groups, each consisting of 20 patients. In this study two techniques of repair of Vesicovaginal fistula were compared in terms of recurrences. Multiple studies are available in the literature on this important subject on various aspects. There are varieties of surgical techniques for the treatment of VVFs. However, it was found that inter-positioning of some healthy tissue in between the bladder and vaginal mucosa lead to success rate reaching almost 100%. Multiple studies are found in which interpositioning of healthy tissue has been employed for the treatment of VVFs with convincing results.

Omental graft is highly suitable adjunct in complicated vesicovaginal, rectovaginal and prostorectal fistulae because of its immense vascular and lymphatic supply and its extreme potential to promote healing, even in the coexisting infection. Singh O *et al*<sup>7</sup> found that interposition of peritoneal flap is also a useful and effective treatment for VVF repair. They compared peritoneal flap versus Martius flap interposition through transabdominal and transvaginal approaches respectively.<sup>7</sup> RB Singh et al. studied the technique of harvesting pelvic fat as an

interposition flap for the treatment of high Vesicovaginal fistula. They concluded that peri-vesical fat proved an effective interposition flap in the repair of VVFs.<sup>11</sup>

Follow up for all the patients was done for 1 year. They concluded that as the VVF repair through vaginal approach is a less invasive procedure, high cure rates and low cost, so new approaches for repair of VVF must be evaluated carefully before suggesting as an alternative. Angioli et al. found that comparable results were achieved through the vaginal approach when compared to other approaches. It has an advantage of minimal operative and post-operative complications. Therefore, they recommend the vaginal approach for repair of VVF. Moreover, they feel that the second repair can be performed through vaginal route if the first vaginal repair is failed. Abdominal approach is mostly preferred when there is suspicion of ureteric involvement, which may than require re-implantation.

Though traditional surgical approaches are required to close VVF in majority of patients, but promising results are obtained by several non-surgical therapies for the closure of fistulae smaller than 8mm. Successful results for the closure of VVFs smaller than 8mm are reported by many less invasive techniques. Peterson and his colleagues were the first to report VVF occlusion by fibrin in 1979. (Peterson S). Patient was advised tranexamic acid for 8 weeks to block fibrinolysis and catheter per urethra was also kept for few weeks.

A case report is given by Morita and Tokue in which it is described that a 5-mm VVF produced due to radiations is closed with fibrin paste and bovine collagen.<sup>12</sup> Electro fulguration of the fistulous tract was needed in this procedure. Electrocoagulation was used in treating 15 patients having very small VVF's by the Stovsky and associates.<sup>4</sup> Out of 12 patients 9(75%) were found successfully treated by fulguration as a sole treatment modality. Dogra used laser (Nd-YAG) to fulgurate the fistula tract.<sup>5</sup>

Success rate was found 100% in all the patients having fistula repair of 3 mm or less by fulguration, though fulguration was failed in 2 patients with 6mm fistulas. Tissue bio glues such as cyan acrylic and fibrin glue is a new addition to the therapies available for repair of small VVF. These glues may be applied percutaneously,

per vaginally or endoscopically. Interestingly, a typical screw passed through the fistulous opening in the vagina up to the bladder, to disrobe the fistulous tract epithelium and promote healing. 7 patients were treated successfully by this way. In our study omental pedicle transposition versus peri-vesical fat emplacement in the transabdominal VVF repair, were compared in terms of recurrence and bladder capacity. After 6, 12 and 24 weeks, all the patients were assessed for recurrence and maximum bladder capacity. The complications like wound infections, urgency, urge incontinence and paralytic ileus were also noted. Data was collected and entered in a specially designed proforma. 40 patients who accomplish all the inclusion paradigms were included in our study and further divided into 2 groups with 20 patients in each group (Group 1 & 2). The age ranged between 18 to 60 years, mean age was found to be 35 years. Mean age in group 1 was 37.55 ± 11.48 and in group 2 it

was 34.35 ± 9.62 years. So far etiology is concerned the predominant cause was hysterectomy (55 to 60 %) followed by c section (10 to 15 %).

The success rate was 95 % (19 /20) in group 1, only one case had recurrence. While in group 2 the success rate was 100 % Bladder capacity in group 1 was 282.11±34.04 ml and in group 2 it was 270.50+ 38.89 ml.

## CONCLUSION

It is concluded that both the Vesicovaginal fistula repair techniques either with omental transposition or peri-vesical fat emplacement are equally effective in terms of recurrence and bladder capacity.

## LIMITATIONS

This study was conducted at one center but incidence of this disease is very high and it is a social calamity. Hence, we recommend further extension of this study to multiple centers and more researchers may be involved to formulate guidelines regarding usefulness of this technique.

## SUGGESTIONS / RECOMMENDATIONS

As many cases found resulted in iatrogenic bladder injury, Government should have check on malpractice and should also start health education and awareness for females.

## CONFLICT OF INTEREST / DISCLOSURE

The authors have no conflict of interest in this study.

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