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ORIGINAL ARTICLE

Vesicovaginal Fistula Repair by Transvaginal Route: Comparison of Resource Utilisation and Outcome with Literature Reported Population Matched Cohort of Patients Operated by Minimally Invasive Route

Naveen Kumar[1] · Sanjoy Kumar Sureka[1] · Uday Pratap Singh[1] · Rohit Kapoor[2] · Sanchit Rustagi[1] · Priyank Yadav[1] · Aneesh Srivastava[1] · Rakesh Kapoor[3]

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Abstract

Introduction and Objectives VVF is conventionally repaired by open transvaginal or transabdominal routes. In last few decades, minimally invasive techniques (laparoscopic/robotic) for VVF repair have gained popularity. We have reported our experience of transvaginal vesicovaginal fistula (VVF) repair and compared it with the literature reported population matched cohort of VVF repair done by laparoscopic or robot-assisted techniques.

Material and Methods Intraoperative and post-operative parameters including aetiology of fistula, location, operative time, blood loss, major complications, hospital stay and success rate of 202 patients with simple VVF undergoing transvaginal repair at a tertiary care hospital from 1999 to 2019 were recorded. We also compared our transvaginal repair cohort ($n=202$) with the literature reported cohort of 260 patients undergoing VVF repair by minimally invasive (laparoscopic and robot assisted) techniques in the systematic review by Miklos et al.

Results Most common aetiology of VVF in our series was post hysterectomy in 122 (60.39%) cases followed by trauma during emergency caesareans section in 80 (39.60%) cases. Transvaginal route had higher success rate than minimally invasive approach (99.50 vs. 96.50%, respectively). Mean operative time was lesser in transvaginal group than the minimally invasive group (63 ± 16 min vs. 161.56 ± 41.02 min, $p<0.01$) with shorter mean hospital stay in transvaginal group (3 ± 1 days vs. 3.5 ± 1.16 days, respectively, $p<0.01$). Mean estimated blood loss was significantly lesser in transvaginal repair ($p<0.01$). 62% patients were sexually active at last follow-up. The cost of transvaginal VVF repair is significantly lower compared to repair by minimally invasive approach.

Conclusion Transvaginal VVF repair is comparable to minimally invasive approach in terms of post-operative outcomes and morbidity; however, transvaginal repair performs better in terms of cost and resource utilization.

Keywords Transvaginal · Vesicovaginal · Fistula · Outcome · Minimally invasive

Introduction

Urogenital fistulae, most commonly vesicovaginal fistula (VVF) is a global health issue, more prevalent in resource-limited countries. It leads to physical and psychological distress and social stigma for the afflicted females due to continuous leakage of urine with resultant genital excoriation and emanating foul odour. VVFs in developed world most commonly occur due to iatrogenic injuries, with more than 60% following hysterectomy whereas in developing world, majority of VVFs have been attributed to prolonged obstructed labour [1]. However, owing to improved obstetric

Dr. Naveen Kumar works as a consultant urologist and kidney transplant surgeon in Patna.

✉ Rakesh Kapoor
rakesh.kapoor@medanta.org

[1] Department of Urology and Renal Transplant, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India

[2] Department of Urology, DY Patil Medical College, Pune, India

[3] Department of Urology and Renal Transplant, Medanta Hospital, Lucknow, India

care in Indian subcontinent, incidence of gynaecological VVFs is rising with concurrent decrease in incidence of fistula associated with obstructed labour injury complex [2, 3].

The approach to repair depends most significantly on surgical expertise, but also on the fistula size, location in the bladder and involvement of other structures, duration of fistula and previous repairs. Couvelaire in 1953 gave the key to successful VVF repair in the form of classic principles of good visualization, good dissection, good approximation of the margins and good urine drainage, which are to be fulfilled while operating upon VVFs by any technique [4]. Surgical approaches include transvaginal and open or minimally invasive transabdominal, with/without tissue interposition. Most repairs in developed countries are performed by transabdominal route as the iatrogenic fistulae are mostly high in the bladder wall with large defects and involving ureters or uterus which may be difficult to reach through vaginal route while transvaginal approach is mainly practiced in low lying fistula with advantages of early recovery, no peritoneal violation, lesser cost and better cosmesis. However, currently there is no strong evidence to prefer one approach over other.

Further reducing morbidity, minimally invasive repairs including laparoscopic and robotic are also gaining popularity due to perceived benefit of decreased pain, early ambulation and better post-operative recovery with improved cosmesis over open transabdominal approach [5]. They mandate general anaesthesia, experience in minimally invasive approaches and specialised equipments, leading to high cost. There is no robust evidence at present to suggest their superiority over the conventional approaches.

At present there are no guidelines regarding approach to repair as no clinical trials have been conducted and contemporary knowledge is based on expert opinion and case series without standardised techniques, outcomes or follow-up.

We share our experience of patients with VVF who underwent transvaginal repair and compare the outcomes of our series of transvaginal VVF repair with the literature reported population matched cohort of VVF repair done by laparoscopic or robot-assisted techniques [5].

Materials and Methods

We performed a retrospective observational study in patients diagnosed with vesicovaginal fistula by history, physical examination and cystoscopy and who underwent transvaginal VVF repair between January 1999 and December 2019 at our tertiary care centre. Data of 202 patients were reviewed for the statistical analysis. Demographic and clinical records were noted including age, aetiology, details of any previous repair. All laboratory and imaging investigation results were recorded. Preoperative findings regarding cystoscopy, per vaginal and per speculum examination were noted.

Obstetric fistulae developing after obstructed labour with vaginal delivery, fistulae requiring ureteric reimplantation/augmentation cystoplasty, fistula with large bladder stone or fistula with scarred and noncapacious vagina and post-radiotherapy fistula were considered complex fistulae while the rest as simple fistula. Simple fistulae were managed with transvaginal route while complex fistula with transabdominal ± transvaginal route [6]. Size of the fistula was not considered a criterion for surgical approach. Exclusion criteria were complex fistulae and follow-up duration less than 6 months.

Technique of transvaginal repair [6]: Under spinal anaesthesia, patients were placed in dorsal lithotomy position and cystoscopy was done followed by double-J stenting/ureteric catheter insertion in cases where the ureteric orifice was close to the fistula. In small VVFs, a Terumo 0.035″ guidewire was placed under cystoscopic guidance through the fistula to exit through the vaginal introitus. A 12–16 Fr Foley's catheter was placed into the bladder from vagina through the fistula over guidewire (in small VVFs) or directly (in large VVFs) and balloon was inflated to 30–50 cc. Traction was provided on the catheter to bring the fistula closer to the operating surgeon. A 16 Fr Foley's catheter was placed per urethra to drain the bladder. Retractors were applied from the sides of vagina and Auvard weighted vaginal speculum was inserted for adequate exposure by making a triangle with fistula in the centre with patient in slight Trendelenberg position. Saline was infiltrated in vaginal mucosa surrounding the fistula and a circular incision was given in the vaginal mucosa just outside the fistula. Plane between bladder and vagina was dissected circumferentially 1–2 cm beyond the fistula or till the bladder falls in after closure, using Metzenbaum scissors to raise bladder and vaginal flaps. Fistula was not excised; rather the bladder walls of the fistula were approximated as first layer using 2–0 polyglactin. Perivesical fascia was approximated as second layer of closure. Preperitoneal fat or peritoneum of cul-de-sac or Martius flap was used as interposition flap to perform third layer closure in most patients in whom any of them was easily available. Vaginal flaps were then closed with avoidance of overlapping suture lines. (Fig. 1) Vagina was packed with sterile povidone-iodine soaked gauze and the pack was removed after 24 h.

Post-operative parenteral antibiotic was continued for 24 h followed by oral antibiotics and anticholinergics till catheter was in situ. Antibiotic vaginal pessary was placed daily for 1 week. Per urethral catheter was kept for 14 days in all patients to prevent bladder distension and suture line tension. Patients were counselled regarding abstinence of vaginal intercourse for 3 months.

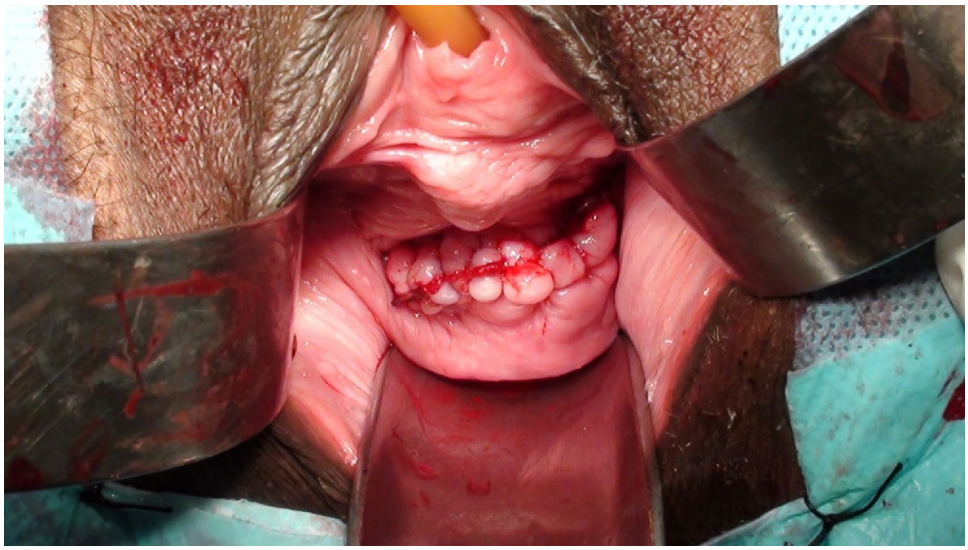

Fig. 1 Final appearance after transvaginal VVF repair

Patients were followed up postoperatively at two weeks, at three months and six months and then as needed based on patients' complaints.

Operative parameters noted were operative time, estimated blood loss and concomitant procedures done. Intraoperative and post-operative complications were recorded including bleeding/haematoma and infection, urethral, ureteric or bladder injury, injury to the small bowel and rectum, vaginal shortening/stenosis, dyspareunia and chronic pelvic pain and incidence of partial or total urinary incontinence. Sexual activity was also noted postoperatively; however, no questionnaire was used to assess sexual function. Success was defined as the absence of total incontinence in the follow-up period after catheter removal.

Statistical Analysis: Continuous variables were considered normally distributed when Z score of skewness was within ± 3.29. The continuous variables were presented as mean ± standard deviation, whereas the categorical variables were presented as frequency (%). We also compared outcomes of our transvaginal repair cohort with the literature reported cohort of patients undergoing VVF repair by minimally invasive techniques [5]. In case, the standard deviation of the mean was not given, it was estimated assuming equal coefficient of our study. We computed the mean parameters from the data given in this review and the standard deviation was assumed to be in the same proportion to the mean, as it was in our series. To compare the means between two groups, independent sample t-test was used whereas for comparing proportions, Z-test for two proportions was used. p values < 0.05 were taken as statistically significant. Statistical analysis was done using SPSS-26 (IBM, Chicago, USA).

Results

Data of 202 patients who underwent transvaginal VVF repair at our institute during the study period were analysed (Table 1).

Mean age of the patients was 32 ± 7 years. Most common aetiology of fistula was post hysterectomy in 122 (60.39%) cases followed by trauma during emergency caesarean section in 80 (39.60%) cases. Recurrent VVF was present in

Table 1 VVF Characteristics

Mean age (years)	32 ± 7
Aetiology	
Post hysterectomy	122 (60.39%)
Trauma during caesarean section	80 (39.60%)
Location	
Trigonal	92 (45.54%)
Supratrigonal	81 (40.09%)
Mixed	29 (14.35%)
Presentation	
Primary	143 (70.79%)
Recurrent	59 (29.2%)
Number of fistulae	
Single	178 (88.11%)
Multiple	24 (11.88%)
Ureteric catheterisation/Double-J stent	
Yes	3 (1.48%)
No	199 (98.52%)
Interposition tissue	
None	19 (9.40%)
Preperitoneal fat or Peritoneum	158 (78.21%)
Martius flap	25 (12.37%)

59 (29.2%) patients. Solitary fistula was present in majority of cases with multiple fistulae in 24 (11.88%) patients. The location of the fistulae was supratrigonal in 81 (40.09%), trigonal in 92 (45.54%) and mixed supratrigonal and trigonal in 29 (14.35%) cases.

Double-J stent or ureteric catheter was placed before undertaking transvaginal repair in 3 (1.48%) cases. Preperitoneal fat in cul-de-sac or peritoneum was placed as interposition flap in 158 (78.21%) cases and Martius flap in 25 (12.37%) patients. In 19 (9.40%) cases, no interposition flap was placed.

Mean operative time was 63 ± 16 min (30–100). Mean estimated blood loss was 48 ± 14 (10–150) ml. None of the patients required blood transfusion. There were no instances of urethral, ureteric or bowel injury intraoperatively. Mean hospital stay was 3 ± 1 days.

Median follow-up period was 15 months (6–112). At the end of follow-up, there was one patient with total incontinence, who had multiple large fistulae preoperatively and postoperatively a small fistula was seen which was again closed transvaginally with success. 62% patients were sexually active at last follow-up with 22 (10.89%) patients complaining of mild to moderate dyspareunia.

Parameters of our transvaginal repair cohort were compared with the literature reported minimally invasive cohort (Table 2).

Discussion

Genitourinary fistulae are a socially and physically debilitating problem, more common in the developing countries in women of low socioeconomic strata [7].

In our series, most common aetiology was post hysterectomy followed by trauma during caesarean section indicating that as affluence, awareness and health care facilities increase in developing countries, maternal complications reduce and aetiology shifts from obstructed labour to post-surgical causes [8, 9]. We had excluded obstetric VVF developing after vaginal delivery as these fistulae were very rare in our practice and invariably involved bladder neck and/or urethra leading to obstructed labour injury complex.

There is a lack of consensus in the literature regarding catheter drainage after initial trauma and the optimal interval after inciting event and repair of VVF. Initial catheter drainage alone may result in spontaneous closure of fistula in 10–28% of cases [10–12]. However in our experience, if the fistula is well formed, long-term catheter drainage beyond 2–6 weeks is not effective, rather it leads to persistent inflammation of bladder mucosa and thus, we let the urine drain through the vagina.

In the present series, fistula repair was undertaken after a minimum interval of 8–12 weeks from initial gynaecological surgery to allow inflammation to subside and for old sutures absorption. All primary surgeries were performed for benign conditions at other hospitals.

Various surgical approaches have been described in the literature including transvaginal, transabdominal and combined abdominovaginal. Minimally invasive transabdominal repair by laparoscopic or robotic route is also performed at many centres, however none has a proven superiority. The choice of surgical procedure depends on the surgeon's experience, location and size of the fistula, and patients' preferences [13]. In a systematic review by Hillary et al., [1] the most common route of repair has been transvaginal in both low- and well-resourced countries. Hilton in 2012 described primary closure rate for transabdominal approach to be 83.3%, and for transvaginal repair 96.1% ($p < 0.001$) [14].

In our series, supratrigonal and mixed supra- and subtrigonal VVF were present in 40.09% and 14.35% cases, respectively. In carefully selected cases with no other complexities, transvaginal repair can be performed in supratrigonal VVF also by applying unique principles like no trimming of bladder edges and traction applied to inflated balloon of Foley's catheter enabling the operating surgeon to pull it closer to the introitus [15, 16], although Cetin et al. [17] had recommended abdominal approach for VVF situated above interureteric ridge. Trimming of bladder edge of the fistula was not performed in any case in our series, as has been demonstrated by Shaker et al. [18] that it does not make any statistically significant difference. We did not excise the fistula tract so as not to compromise the vaginal capacity and to avoid injury to ureteric orifices. Ureteric catheter was placed in 3 patients in the initial duration of our series,

Table 2 Comparison of transvaginal VVF repair with the literature reported minimally invasive VVF repair

Parameters	Transvaginal Repair (*n*-202)	Minimally invasive repair [8] (*n*-260)	*p* value
Operative time (min)	63 ± 16	161.56 ± 41.02 (238/260)	< 0.01
Estimated blood loss (cc)	48 ± 14	103.64 ± 30.23 (174/260)	< 0.01
Post-operative Hospital stay (days)	3 ± 1	3.5 ± 1.16 (232/260)	< 0.01
Follow-up period (months)	6–112	1–20	
Success rate (%)	99.50% (201/202)	96.50% (248/257)	

in whom the ureteric orifice was close to the fistula. Later we did not place ureteric catheter even in such cases as we closed the bladder flap from outside not taking the mucosa, thus minimising chances of ureteric injury.

Mean operative time in our series was 63 ± 16 min, which was lesser than the mean operative time of 98 min in transvaginal repair in previous series from our centre. [6] Warner et al. [19] have experienced longer mean operative time of 197 min in transvaginal VVF repair in their recent series. However, they have included positioning for preliminary cystoscopy up to removal of drapes after completion of repair in their definition of operative time. Also, they repaired complex fistula transvaginally leading to increase in operative time. Operative time has been reported for 238 patients in the systematic review of minimally invasive VVF repair by Miklos et al. [5] and the computed mean was 161.56 ± 41.02 which is significantly higher compared to our series ($p < 0.01$). The likely cause for less operative time in our data is that all cases were operated by a single surgeon with progressive expertise in transvaginal repair. Also, port insertion, creation of pneumoperitoneum, port closure, etc. are some of the vital steps of minimally invasive repair which lead to increase in operative time.

Mean blood loss was 48 ± 14 ml and none of the patients required blood transfusion. On computing mean blood loss mentioned for 174 patients in the systematic review of minimally invasive VVF repair by Miklos et al [5], it was 103.64 ± 30.23 ml which is significantly higher compared to our series ($p < 0.01$). In the recent Indian series of 30 patients by Bora et al. who underwent robotic VVF repair, the mean surgical duration (excluding port placement and docking) was 133 ± 48 min and the median estimated blood loss was 50 ml [20].

Patients were ambulated on first post-operative day. They were mostly discharged on the third post-operative day with post-operative hospital stay 3 ± 1 days, shorter than the hospital stay reported in the minimally invasive group (3.5 ± 1.16 days, $p < 0.01$) [5]. The post-operative per urethral catheter indwelling time was 2 weeks equivalent to or shorter than robotic VVF repair [20, 21], thus minimising discomfort to the patient. Our success rate in this series was 99.50% (201/202), which is higher than the median overall closure rate of 87.0% in patients undergoing surgical repair in developing countries [1]. The success rate for VVF repair by laparoscopic or robotic approach has been reported to be 96.50% [5]. Even for previously failed repairs, transvaginal VVF repair can be attempted for simple fistula regardless of location with respect to trigone, as shown in our series. Sexual activity after VVF repair was reported in 62% patients at 6 months with 10.89% patients complaining of dyspareunia. Most of the patients with abstinence of sexual activity had lack of partner or reluctance of partner as the main reason. Flynn et al. [22] had reported on 40 patients of post hysterectomy fistula, of which 86% were sexually active at 3 months of transvaginal repair with 6% patients experiencing dyspareunia, implying that transvaginal VVF repair has minimal impact on sexual function.

Benefits of transvaginal VVF repair are requirement of regional anaesthesia, high success rate with minimal blood loss and post-operative complications, no visible external scars with better cosmetic outcomes and significantly lesser cost along with short hospital stay. Previous abdominal surgeries and adhesions do not preclude this approach. It also does not require expensive equipments or specially trained staff.

Transabdominal approach in these patients would lead to peritoneal violation and bowel handling and its inherent complications [23]. Although these issues have been partially addressed by laparoscopic and robotic routes, their main drawback is high cost in a low resource setting along with steep learning curve and need of specialised expensive equipments. Even for open transabdominal VVF repairs, the cost effectiveness is less than the transvaginal VVF repair [19]. Most VVF patients in low resource countries are from poor background in rural locations, and distressed due to resources already spent in the primary gynaecological surgery, so cost optimisation is a major factor for them. Also, recurrence after open or minimally invasive transabdominal VVF repair may be difficult to repair due to encountering adhesions during subsequent surgeries.

The limitations of our study are its retrospective nature with inherent biases and single institutional experience, which may not be generalised in terms of success rate and operative costs. Also, we performed comparative analysis with minimally invasive VVF repair cohort from a systematic review which was a heterogeneous population in which various surgeons with different expertise have operated in the included studies. These results need further validation by prospective studies before applying in general population.

Conclusion

The excellent outcome along with minimal morbidity after transvaginal VVF repair makes it comparable to the literature reported outcomes by minimally invasive approaches in simple VVF. However transvaginal approach performs better in terms of resource utilization, particularly in low resource settings.

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Declarations

Conflicts of interest The authors declare that they have no conflict of interest.

Ethical Approval This study was approved by institutional ethics committee.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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About the Author

Dr. Naveen Kumar works as a consultant urologist and kidney transplant surgeon in Patna. He has completed his MBBS from Armed Forces Medical College, Pune and MS from Command Hospital, Kolkata. He completed MCh urology from Sanjay Gandhi postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow where he was also adjudged best senior resident (MCh student) in 2019. He has multiple national and international publications to his credit and he has presented various papers and posters in national and international conferences including SIU 2019 at Athens Greece. His field of interest includes urooncology and female and functional urology.