

Prospective Study on Clinical Outcomes of Laparoscopic Repair of Vesicovaginal Fistula with V-Loc 90 Suture

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1. Abstract

1.1. Objective

To study feasibility, efficacy and postoperative outcomes of laparoscopic vesicovaginal repair with barbed, resorbable 3-0 V-Loc 90 sutures.

1.2. Methods

Patients presented with vesicovaginal fistula and failed with more than 3 weeks of bladder drainage using a foley catheter are selected for study. The cases where the fistula can be approached via vaginal route adequately without episiotomy or moderate to heavy traction, recurrent cases, complex fistulas, post radiation and malignant fistula are excluded from this study.

1.3. Results

In our study from March 2019 to November 2021, total 15 patients were enlisted for laparoscopic VVF repair using V-Loc suture. The main objective of laparoscopic repair of VVF is rapid cessation of urinary leakage with early return of normal and complete urinary and genital function. The most common cause of VVF in our studies was hysterectomy 12 (80%), caesarean section 3 cases (20%). In our study in all cases laparoscopic transperitoneal transvesical mini-O'Conor approach with an interposition of omental graft or appendices epiploicae were adopted. In our study all fistulas were supratriangular with average size of 1.8 cm (range 0.8 to 3.4 cm). Mean age of patients undergoing VVF repair was 39.9 years (range 26 to 48 years). Estimated blood loss was 63 ml (range 30

ml to 160 ml), and mean operative time 130 minutes (range 100 to 190 minutes). There was no serious intraoperative or postoperative complications including: conversion to open procedure, denying operative procedure, vascular, bowel or ureteric injury, blood transfusion, blood clots, pulmonary embolism, cardiac events or strokes. Length of hospital stay was mean 5.2 days (range 3 to 8 days). Patients were instructed to return our outpatient department 14 to 21 days after surgery for cystogram, cystoscopic and vaginal inspection to confirm successful VVF repair and subsequent suprapubic catheter removal. At a mean of 14.7 months (range 6 to 37 months) no recurrence of VVF occurred with success rate is 100% (15 out of 15 patients).

1.4. Conclusions

In the era of minimally invasive surgery, it is difficult to deny its role in the management of VVF. It can be performed safely and effectively with shorter operative time. It seems to offer patients a shorter hospital stay, less morbidity, quicker convalescence, better cosmesis and equal efficacy. Technically, laparoscopy provides better visualization through magnification, but is more difficult to learn, as is intracorporeal suturing. Use of resorbable continuous barbed sutures (V-Loc) simplify the technique and reduce the time of surgery while avoiding implementation of knots. Successful treatment using a laparoscopic approach in VVF is highly dependent on the surgeon's experience, tissue conditions around fistulae, tension-free watertight closure, and adequate postoperative urinary drainage.

2. Introduction

Genitourinary fistulae are considered one of the most devastating complications in the urogynaecology practice, with the vesicovaginal fistula (VVF) being the most common type of these fistulae. Other common types being ureterovaginal and urethrovaginal. In the developed countries >90% cases are caused by inadvertent injury to bladder during surgery [1]. Obstetric VVF related to prolonged labour remains a major medical problem in many underdeveloped countries with low standard of obstetric care [2]. VVF is a debilitating condition that leads to persistent foul odour with urinary leakage leading to excoriation of vulva and vagina. This causes a lot of social taboos leading to social isolation, physical and emotional distress of the patients. In 1852, Sims reported a successful repair of VVF in female slaves [3], since then, many surgical techniques have developed to correct this abnormality, including transabdominal, transvaginal and endoscopic approaches [4-9]. The success of VVF repairs depends on various factors, including fistulae size, location, timing from the antecedent event, severity, quality of surrounding tissue, clinical experience, and surgical skill [10]. The approach to VVF repair is often dictated by surgeon's preference and the location or complexity of the VVF. The majority of low-lying vesicovaginal fistulae can be repaired through transvaginal route. The abdominal route is indicated for large fistula, multiple fistulas, supratrigonal fistulas, associated ureterovaginal fistulas, fistula locating near ureteric orifice requiring reimplantation, small capacity bladder which requires augmentation, multiple failed transvaginal repairs, deep narrow vagina and inability to lithotomy position of the patients. A surgeon's preference is usually based on his or her training and experience [11]. Laparoscopic repair is now a well-established modality in the management of VVF, with a number of studies demonstrating its safety, feasibility and efficacy with a good success rate and less morbidity compared with those of open surgery [10-12]. In our study laparoscopic VVF repair bladder and vaginal wall defects are closed in two layers with two separated continuous barbed, reabsorbable 3-0 sutures V-Loc 90.

3. Materials and Methods

After receiving Institutional Ethical committee clearance, we conduct a prospective study on VVF patient presented urology out patient department or referred from gynaecology ward from our institution who under went VVF repair in our department from March 2019 to November 2021. Data analysis of 15 patients who underwent laparoscopic fistula repair in this period was done. The most common cause of VVF in our studies was hysterectomy 12 (80%), lower segment caesarean section 3 cases (20%). Patients were referred to our institute between 5 to 24 weeks following the operative procedures which caused the VVF. Prior to surgical intervention all patients reported their through history and underwent a physical examination and pelvic examination and also per speculum examination of vagina. Cystourethroscopy and vaginoscopy

were performed to characterize the site, size, number of fistula and feasibility of transvaginal repair if possible (Figure 1). Intravenous urogram (IVU) or a computed tomography scan with contrast medium were done to exclude ureteric involvement (Figure 2) . It was observed that up to 12% of post surgical VVF had an associated ureteral injury or ureterovaginal fistula (Goodwin and Scardino, 1980). All cases performed by same surgeon with similar surgical procedures. Under general anaesthesia with endotracheal intubation, patient was first positioned in lithotomy position. Cystoscopy was done, and double J stent were placed bilaterally (Figure 3). Ureteric catheters with guidewire were placed in the fistulous tract from the bladder into the vagina for easy identification of fistula after cystotomy. 16 F Foley's catheter was inserted and soaked vaginal pack was given to prevent leakage during bladder filling and escape of carbon-dioxide gas after cystotomy with resultant loss of pneumoperitoneum. The patient was then placed in supine position with 15^o-30^o Trendelenburg position. First 10-mm trocar was placed midline infraumbilical position by open Hasson technique. Two working ports, 10 mm at right iliac fossa and 5 mm at left iliac fossa over the spino-umbilical line were placed under laparoscopic vision after establishing pneumo-peritoneum. Another 5 mm accessory port was placed in the lower abdomen according the requirement. After adhesiolysis, the bladder was filled with about 300 ml of saline to appreciate the bladder outline. A small vertical cystotomy of about 2 cm was performed just above the vaginal vault. The above technique helped in limiting the cystotomy size from the classical description given by O'Connor. The fistula was then identified by ureteric catheter and cystotomy was then extended up to the fistula. One patient had a double fistula, which were incised and joined to form a single opening and repaired as a single fistula. A plane was created between bladder and vagina for about 1-1.5 cm all round the fistulous opening. Edges of the fistula were not excised. Vaginal opening was repaired with 3-0 V-Loc 90 suture in a single-layer continuous manner placing the suture line horizontally. We always used interposition flap of omentum or appendices epiploicae of sigmoid colon between the vaginal and bladder repair. In all cases suprapubic cystostomy drain was placed before closure of cystotomy for better bladder drainage. Cystotomy was closed with 3-0 V-Loc 90 suture in a single layer continuous manner in vertical orientation to get a non -overlapping suture line with respect to vaginal suture line (Figure 4). The bladder was filled with about 200-250 ml of saline mixed with methylene blue to assess a watertight closure. Additional sutures may required when a leak was identified. A 16 F urethral Foley catheter was left in place. An 20 F abdominal drain tube was kept in the dependent part of the pelvis as a drain. Only 10 mm ports were closed with port closure sutures. Patients were encouraged to take food after 6 hours and betadine soaked vaginal pack is removed after 12 hours. Patients were given anticholinergic agents to prevent bladder spasm till removal of all catheters and double J stents. The drain was removed once the output was below 50 ml per day. All

the patients were discharged after removal of drain. Per urethral catheter was removed on the 10 th post operative day following cystogram, if there was no suspicion of leakage. Suprapubic catheters and double J stents were removed on the 14 th post operative days. Complications were recorded according to Clavien-Dindo grading system. All cases were advised to abstain from sexual intercourse for 3 months following surgery. We will record patient's age, reason for fistula, operative time, estimated blood loss, hospital stay and operative complications. Post operatively, patients were followed up at 3 months , 6 months and yearly. They are also encouraged to call if surgical failure were suspected.



Figure 1: cystoscopy showing double fistula.



Figure 2: IVU showing cup-in-saucer appearance.



Figure 3: Supratrigonal VVF identified and catheterized with 6 F ureteric catheter for easy identification of fistula during laparoscopic repair.

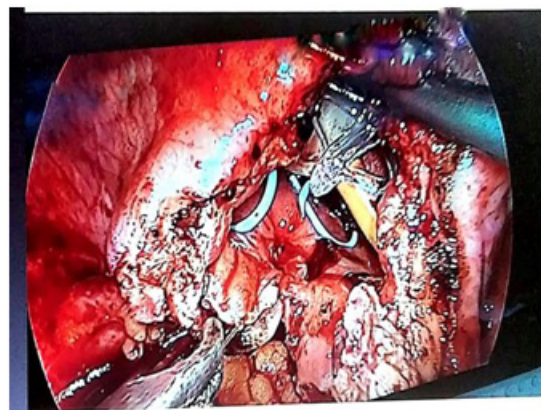


Figure 4: Laparoscopic VVF repair showing bilateral double J stents, malecot type suprapubic catheter, perurethral foleys catheter and V-Loc suture repairing bladder wall.



Figure 5: We used 3-0 V-Loc 90 suture in laparoscopic VVF repair.

Table 1: Results.

Variables	Number of patients
Age, years, mean (range)	39.9 (26-48)
BMI (Kg/ m2)	26.8 (22.1-31.7)
Etiology of fistula Hysterectomy	12 (80%)
Caesarean section	3 (20%)
Number of fistula	Single 14 (93%) , double 1 (7%)
Location of fistula	Supratrigonal (100%)
Type of fistula Primary	15 (100%)
Operative time (min)	130 (100-190)
Estimated blood loss (ml)	63 (30-160)
Flap interposition Omental	9 (60%)
Appendices epiploicae	6 (40%)
Ureteric stents	15 (100%)
Supra pubic catheter	15 (100%)
Time to oral intake (hr)	8 (6-16)
Time to ambulation (hr)	10 (8-24)
Hospital stays (days)	5.2 (3-8)
Pain in VAS (visual analog scale)	3.9 (3-5)
Foleys catheter duration	12 (10-16)
Supra pubic catheter duration	16 (14-21)
Follow up (months)	14.7 (6-37)

Table 2: Reported series of laparoscopic transabdominal transvaginal VVF Repair (≥10 cases).

Author	No of patients	Causes of VVF	Mean operative time(min) (range)	Mean estimated blood loss (ml) (range)	Mean hospital stay (day) (range)	Mean catheter duration(day)	Open conversion (number)	Success	Mean
								rate(%)	(range)
									Follow up
									(months)
Zhang et al 2013 (23)	18	Abd. Hysterectomy (16) Obstetric trauma (2)	135	95	5	15	none	100	22.7(3-45)
Nezhat et al 1996 (24)	19	NA	NA	NA	NA	14-Jul	None	95	Jun-48
Sotelo et al 2005 (16)	15	Hysterectomy (14) Obstetric trauma (1)	170	NA	3	10	None	93.3	26-2
Shah et al 2005 (26)	25	Hysterectomy (16) Obstetric trauma (3) Caesarean (3) Post-abortion (1) Uterine rupture (1)	145	180-200	4.5	NA	3	86	NA
Nagraj et al 2007 (22)	13	Abd.Hysterectomy (13)	130	NA	4.5	15	1	91.6	21
Mohapatra et al 2007 (25)	11	Abd. Hysterectomy (6) Obstetric trauma (4) Caesarian(1)	166	125	5.5	14	None	91.7	Mar-36
Singh et al 2013 (27)	28	NA	160	70	6	28	2	100	24
Sharma et al 2014 (28)	22	NA	140	75	5	14	None	100	Jun-60
Ghosh et al 2016 (29)	13	Lap. Hysterectomy (6) Open bd. Hysterectomy (4) Caesarean (2) Uterine rupture (1)	157	73.8	4.6	11	None	100	15.6(4-27)
This study	15	Abd. Hysterectomy (12) Caesarean (3)	130 (100-190)	63 (30-160)	5.2 (3-8)	14	None	100	14.7(6-37)

4. Results

In our study from March 2019 to November 2021., total 15 patients were enrolled for laparoscopic VVF repair using V-Loc 90 suture. The main objective of laparoscopic repair of VVF is rapid cessation of urinary leakage with early return of normal and complete urinary and genital function. The most common cause of VVF in our studies was hysterectomy 12 (80%), caesarean section 3 cases (20%) . In our study all cases laparoscopic transperitoneal mini-O' Connor approach with an interposition omental or appendices epiploicae graft. In our study all fistulas were supratrigonal with average size of 1.8 cm. Mean age of patients undergoing VVF repair was 39.9 years (range 26 to 48years). Estimated blood loss was 63 ml (range 30 ml to 160 ml) , and mean operative time 130 minutes (range 100 to 190 minutes). There was no serious intra-operative or postoperative complications including: conversion to open procedure, denying operative procedure, vascular, bowel or ureteric injury, blood transfusion, blood clots, pulmonary embolism, cardiac events or strokes. Length of hospital stay was mean 5.2 days (range 3 to 8 days). Patient's were instructed to return our outpatient department 14 to 21 days after surgery for cystogram, cystoscopic and vaginal inspection to confirm successful VVF repair and subsequent suprapubic catheter and double J stent removal. At a mean of 14.7 months (range 6 to 37 months) no recurrence of VVF occurred with success rate is 100% (15 out of 15 patients).

5. Discussion

Vesicovaginal fistulae (VVF) are the most common acquired fistula of the urinary tract. The etiology of VVF differs in the various parts of the world. In the developed countries, most common cause (75%- 90%) of VVF is the injury to the bladder at the time of gynaecologic, urological, or other pelvic surgery. Abdominal hysterectomy is the most common surgical cause of VVF. The incidence of fistula after hysterectomy is estimated approximately 0.1% to 0.2%. In the developing countries, most common cause of VVF is prolonged obstructed labour due to cephalopelvic disproportion, with resulting pressure necrosis to anterior vaginal wall, bladder, bladder neck, and proximal urethra from the baby. Surgical treatment is the mainstay in the management of VVF. Surgical repair of VVF is commonly done by vaginal route. Potential advantages of the transvaginal approach include short operative time, less morbidity, quick recovery, short hospital stay. But transabdominal approach is preferred in case of large fistula, supratrigonal fistula, location high in a deep narrow vagina, repair requiring addition procedure like bladder augmentation, ureteric reimplantation and preservation of sexual function without shortening of vaginal length. However, the approach chosen should be one the surgeon is most comfortable with. Most urologist are familiar with VVF repair via abdominal route; with the use of laparoscopy, the morbidity is reduced significantly along with better cosmetic outcome. The O' Connor transvesical technique was performed via laparomy for more than 30 years before the first laparoscopic transvesical

case was published in 1994 [4]. In our study, we achieved 100% success rate by using the transabdominal transvesical approach with limited cystostomy repaired with V-Loc 90 suture. In 1998 von Theobold described the first laparoscopic extravesical VVF repair [13]. A few months later, Miklos et al. described a laparoscopic extravesical technique utilizing a three-layer closure, a double – layer bladder and single layer vagina closure, with an intervening omental flap for a patient with recurrent fistula despite two latzko procedure [6]. High success rate depends on meticulous dissection as well as a triple-layer closure, which included a double –layered bladder closure as supported by Sokol et al [14]. Proponents of transabdominal extravesical approach of VVF repair claim the benefit of avoiding cystostomy with reduced operative time, post-operative bladder spasm and voiding dysfunction. But there is more chance of injury to ureteric orifices. Some authors suggest guidance by cystoscopy or vaginoscopy to aid in the dissection of correct vesicovaginal plane during extravesical approach [15,16]. In classical O'Connor technique, liberal cystostomy helps in easy identification of ureteric orifices and fistula, thus avoiding injuries to ureteric orifices. Laparoscopic VVF repair using smaller cystostomy (Mini O'Commor technique) was first described by Rizvi et al, with the intent of decreased suturing time and decreased voiding dysfunction. In our cases used smaller cystostomy of about 2 cm in size, but there was no difficulties in identification of the fistula. This avoids extensive peritoneal mobilization from bladder and mobilization of adherent bowel at vaginal vault. It reduces the operative time and risk of bowel injury. The literature documents excellent success rates for the treatment of VVF if the following general principles are followed : (a) careful evaluation of the type of fistulae , (b) Careful dissection and/or anatomic separation of the involved organ cavities (c) watertight bladder closure without tension, (d) multiple-layer closure (e) tension-free, nonoverlapping suture lines (e) suture on healthy tissue with good blood supply and without the presence of infection, (f) maintenance of hemostasis and (h) adequate postoperative drainage [16,17]. Several studies have published that there is no difference between surgical outcome and complication rates between open and laparoscopic approaches [18,19]. In one study compared the surgical procedure between laparoscopic- open abdominal-transvaginal in patients with VVF . Their data found that laparoscopic approach had a better outcome and lower morbidity than transabdominal and vaginal approaches [9]. One retrospective chart review by Javali et al. with a total of 22 patients on whom a laparoscopic approach to VVF repair was performed produced excellent results with minimal morbidity [20]. All patients were continent after catheter removal at postoperative day 14 and remained symptom free in follow-up period, which ranged from 2 to 45 months. They also reported no open conversions and no intraoperative complications with minimal estimated blood loss. Repair of fistula with resorbable continuous barbed sutures (V-Loc) simplify the technique and reduce the time of surgery while avoiding implementation of knots. One of

the major problems when suturing the layers of the repaired VVF are the lines of suture of the vagina and the bladder and perhaps, the inflammation produced by the knots when tying the suture, is one of the most important factors in the relapse of the defect [21]. The suture employed in our patients does not have any knot, as it is integrated in the tissue ; therefore , this could reduce the inflammation of the tissues. There is controversy about the right time of repairing of VVF following injury. Surgical repair of VVF is traditionally deferred for 3-6 months following the injury to subside inflammation of the tissues. Early repair of the VVF has the advantage of shortening period of discomfort for the patient. Delay can have a devastating impact on quality of life and ability to function. Considering all these factors we repair the fistula as early as possible after subsidence of inflammation.

6. Conclusion

With the advancement of laparoscopic surgery, most ablative and reconstructive surgery in urology can be accomplished with laparoscopy. Laparoscopic repair of VVF is also not exception of this rule. Laparoscopic transabdominal transvesical VVF repair with limited cystotomy (mini O' Connor) reduces operative time and use of resorbable continuous barbed suture (V-loc), further reduces operative time. This repair with omental or sigmoid appendices epiploica flap interposition can be performed safely with short operative time, shorter hospital stay, quicker convalescence, better cosmesis, equal efficacy and less complications. Technically, laparoscopy provides better visualization through magnification, but is more difficult to learn, as is intracorporeal suturing. Use of resorbable continuous barbed sutures (V-Loc) simplify the technique and reduce the time of surgery while avoiding implementation of knots. Successful treatment using a laparoscopic approach in VVF is highly dependent on the surgeon's experience, tissue conditions around fistulae, tension-free watertight closure, and adequate postoperative urinary drainage.

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