Robotic repair of vesicovaginal fistulas using fibrin sealant

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Introduction: *Although infrequent, when encountered vesicovaginal fistulas (VVF) are a difficult condition for both patients and physicians alike. After the first robotic repair was described in 2005, this has been an increasingly common treatment modality. At our institution between 2009 and 2014, eleven of these patients were evaluated and treated with robotic repair. However, fibrin sealant was used in place of the traditional tissue flap. Included are six patients who had previously undergone operative repair.*
Materials and methods: *After IRB approval was obtained, a retrospective study was undertaken to identify patients with VVF. Inclusion criteria were operative repair utilizing a da Vinci robotic system; there were no exclusion criteria. A total of eleven patients were identified, and in each case, a robot assisted laparoscopic approach was utilized and Tisseel fibrin sealant was used in lieu of tissue interposition*
Results: *All patients underwent successful repair of their VVF without evidence of recurrence at a mean follow up of 15.6 months.*
Conclusions: *Robotic vesicovaginal fistula repair with fibrin sealant seems to be a safe and viable alternative to the traditional repair utilizing a tissue flap.*

Key Words: robotic surgery, vesicovaginal fistulas, fibrin sealant

Introduction

Vesicovaginal fistulas (VVFs) have long been a challenging condition for surgeons. In developed countries, the most common etiology remains iatrogenic during pelvic surgery, specifically hysterectomies.[1] The estimated incidence of fistula after hysterectomy is 0.1%-0.3%,[2] and these are most commonly identified 1-6 weeks after surgery. Recurrent VVFs usually occur within the first 3 months after attempted repair.[3]

Although several surgical options exist, a technique becoming increasingly utilized is reconstruction using the da Vinci robotic system. The first robotic repair was described in 2005 by Melamud et al.[4] Since that time, several case series have reported a 100% success rate.[5-7] These case reports described utilization of a flap or tissue transfer to separate the suture lines of the vagina and bladder. For the past several years at our institution, VVFs have been repaired using fibrin sealant in lieu of tissue transposition. Our experience with this technique is described below.

Materials and methods

After IRB approval was obtained, a retrospective chart review was performed on patients who had a VVF repaired at our institution by a single robotic specialist between 2009 and 2014. Inclusion criteria were operative repair utilizing the da Vinci robotic system. There were no exclusion criteria. Charts were reviewed and patient demographic data, operative time, complications, and follow up information were analyzed. In each patient, a robot-assisted laparoscopic

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approach was utilized, and Tisseel fibrin sealant (Baxter Healthcare Corporation, Westlake Village, CA, USA) was used in lieu of tissue interposition.

Operative technique

The patients were placed in a low-lithotomy position. Cystoscopy was performed to identify the defect. A 5 Fr open-ended catheter was placed into each ureter. The fistula tract was cannulated cystoscopically with a guidewire, and a 6 Fr open-ended catheter was advanced over the wire through the fistula tract to exit the vagina. A foley catheter was placed into the bladder and a gauze sponge stick was placed in the vagina to allow manipulation of the vaginal tissues.

The patients were then positioned in steep Trendelenburg. Insufflation was achieved with the use of a Veress needle through a 1 cm infra umbilical incision. A 10 mm trocar was inserted at this location, and the abdomen was carefully examined. Three 8 mm ports were placed under direct vision in the left lower quadrant, left paramedian, and right paramedian locations. A fifth 10 mm-12 mm trocar was placed in the right lower quadrant and used as an assistant port. See Figure 1 for illustration of port placement.

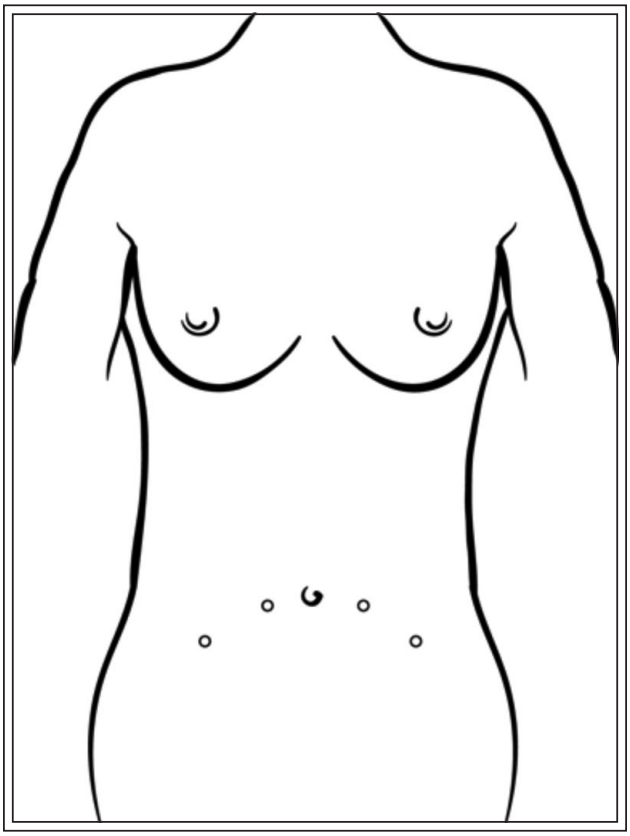

Figure 1. Illustration of port placement.

The da Vinci system was then docked in the standard fashion, with the 0-degree telescope in the camera arm, monopolar curved shears in the right arm, bipolar Maryland forceps in the left arm, and ProGrasp instrument in the fourth arm.

The bladder was backfilled via the Foley catheter. A transverse incision was made in the peritoneum between the vaginal cuff and posterior wall of the bladder, and dissection was continued inferiorly between the posterior bladder wall and anterior vaginal wall to the level of the fistula. A midline cystotomy was made in the posterior bladder wall and the catheterized fistula was identified. Cystotomy was then extended to the fistula and the open-ended catheter was removed. The edges of the fistula were mobilized to ensure a tension free closure. The bladder was closed in two layers, 4-0 Monocryl was used for the mucosa and 2-0 Vicryl was used for the seromuscular layer. Once complete, the bladder was backfilled to confirm a watertight closure and to evaluate for incidental cystotomies. The bladder was drained and the ureteral catheters were removed. The vaginal defect was closed with a running 2-0 Vicryl and Tisseel fibrin, approximately 5 mL, was then placed over the repairs. The abdomen was inspected to ensure hemostasis before undocking the robot, removing the ports, and closing the abdominal incisions.

Results

See Table 1 for a summary of the results. A total of eleven patients aged 31 to 50 years were diagnosed with a VVF between 2009 and 2014. Nine of the patients developed a fistula following hysterectomy, one occurred after a nephroureterectomy, and one after a caesarean section. Six of the patients had previously undergone at least one operative attempt to repair the fistula, three through an open abdominal approach, two transvaginally, and two through cystoscopy and fulguration of the fistula. In each patient, the decision to proceed with robotic repair was based on either a history of previously attempted repair and/or location of fistula.

The mean operative time for repair was 223.9 minutes. Average estimated blood loss was 28.1 cc. Hospital stay was 1.4 days on average, and mean duration of urethral catheterization was 10.9 days. One individual did have a prolonged catheterization of 29 days due to a small amount of apparent contrast extravasation on cystogram. After the imaging finding persisted 2 weeks later, the bladder was examined via cystoscopy, and the lesion ultimately appeared to be a pseudo-diverticulum, and the foley was removed. A cystogram was performed on every patient prior to foley removal without evidence of

TABLE 1. **Summary of patient data**

Patient	Age	History of radiation	s/p hysterectomy	Prior fistula repair	OR time (min)	EBL (mL)	LOS (days)	Complications	Length of catherization (days)	Length of follow up (months)
1	48	no	Y	Y	223	100	2	none	7	80
2	39	no	Y	Y	164	25	1	UTI	8	52
3	31	no	N	N	268	100	1	UTI, septic pelvic thrombophlebitis	29	37
4	36	no	N	N	363	50	1	none	7	2
5	41	no	Y	Y	190	5	1	UTI	8	1
6	50	no	Y	Y	198	10	3	none	11	42
7	46	no	Y	Y	255	15	1	none	8	42
8	49	no	Y	N	130	25	2	none	8	3
9	39	no	Y	N	306	50	1	none	10	19
10	37	no	Y	N	168	20	1	none	21	15
11	39	no	Y	Y	181	50	1	none	14	1
Mean (SD)	42.1 (5.5)				223.9 (78.1)	28.1 (19.1)	1.4 (0.7)		10.9 (4.7)	15.6 (17.9)

urinary extravasation or persistent fistula. The most common complication was urinary tract infection, which occurred in three patients. One patient also developed septic pelvic thrombophlebitis in the postoperative period; she initially presented febrile to the emergency department on POD 8, and a CT scan identified bilateral ovarian vein thrombosis. She was admitted, started on anticoagulation, and was able to be discharged home several days later.

Mean duration of follow up with the operating surgeon was 45 days. After this time, the patients were referred back to their gynecologist or primary care provider. Three patients were lost to follow up, however upon review of records the remaining individuals had no evidence of recurrence or other complications at a minimum of 8 months (mean 32.4). One patient did endorse some stress incontinence several months postoperatively requiring the use of 1 pad per day. However, this was not demonstrable on physical exam in clinic, and the issue seemed to resolve on subsequent visits.

Discussion

Robotic repair of VVF was initially developed to remedy the limitations of other surgical approaches. Transvaginal repair is typically the preferred initial operation by most gynecological surgeons given that it is minimally invasive with low morbidity and high success rates. In some instances, this approach may not provide adequate exposure, in particular with large (> 3 cm) and/or supratrigonal or peri-ureteral VVF, necessitating a transabdominal approach. This repair may be indicated if the patient has previously failed a transvaginal operation as well.[8] While good success rates were achieved with an open operation, the morbidity was considerable; thus laparoscopic techniques were developed. However, the widespread use of pure laparoscopy in VVF repair is hampered by the technical difficulty of the operation.[9] In our series, the indications for robotic repair included previous failed operations and the location of the fistula. The fistulas in ten of the patients were supratrigonal; in the remaining individual it was just lateral to one of the ureteral orifices. Additionally, one patient was felt to have a narrow vaginal introitus in which adequate exposure likely could not be achieved transvaginally.

To date only several small case series exist describing outcomes of robotic-assisted repair of VVF. In a recent review article by Miklos et al,[10] they found 33 cases of robotic-assisted VVF repair described in the literature. Additionally, only one case report exists in which fibrin glue is used in the robotic-assisted VVF repair, making ours the largest series in which tissue interposition was not used.[4]

The use of fibrin sealant for vesicovaginal fistula repair seems to have first been described in 1985. At that time it was found to have a 0% recurrence rate when used in reconstruction of rabbit VVFs.[11] Melamud et al in the first case report of robotic-assisted repair of VVFs described using fibrin glue to separate the bladder and vagina.[4] As mentioned, several other case series exist describing robotic-assisted repair of these defects; however, interposition of either omentum, epiploic appendages of the sigmoid colon, or peritoneal flaps was used to separate the suture lines of the vagina and bladder. As steep Trendelenburg is typically required for the operation, bringing down these tissue flaps can present a technical challenge.[6] Additionally, fibrin is biodegradable, does not cause tissue inflammation, and may promote local tissue repair.[12] In our series, use of fibrin sealant obviated the need for tissue transfer or use of a flap and appears to be safe and feasible, as evidenced by our 100% success rate. The result proved durable in patients who had undergone multiple previous attempts at surgical repair of their fistulas.

One drawback to using the Tisseel fibrin sealant is the cost. A 10 mL aliquot of the substance totals $556.63. However, given the efficacy of the sealant and the increased ease of using Tisseel as opposed to a tissue flap, the increased cost was felt to be justified.

Furthermore, recent studies have called into question the benefit of a tissue flap. For example, Miklos and Moore recently published a case series which included 11 laparoscopic repairs of recurrent VVFs without the use of a flap and had a 100% success rate.[13] Although further studies are necessary to evaluate, these results in combination with our experience do support the idea that a flap may be unnecessary in minimally invasive cases.

One obvious limitation of this study is the lack of a comparison arm, specifically one in which neither fibrin sealant or tissue interposition were used. As indicated previously, while technically simple, the cost of the Tisseel is not insignificant and could be avoided if a comparison were to reveal equivalent results. Further weaknesses include the retrospective nature and small sample size. Additionally, our follow up was highly variable. Four of the patients were discharged to their PCP after 1-2 months of follow up at outside facilities. If these patients are excluded from the data analysis, the average follow up is 41 months. Lastly, given that none of the patients in our series had a history of pelvic malignancy or radiation, the results may not be generalizable to this more challenging population.

Conclusion

A robotic-assisted approach to VVF repair is a reasonable option for patients who require an abdominal approach for repair of a vesicovaginal fistula. Based on our small series, fibrin sealant is a safe and feasible way to separate the suture lines, obviating the need for additional tissue mobilization. □

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