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Original article

Surgical Outcomes of Transvaginal Neobladder-Vaginal Fistula Repair after Radical Cystectomy with Ileal Orthotopic Neobladder

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ABSTRACT

Background*:** To present surgical methods and outcomes of neobladder-vaginal fistula (NVF) repair after radical cystectomy (RC) with ileal orthotopic neobladder (IONB). ***Methods: We retrospectively reviewed 136 women who underwent RC with IONB for bladder cancer between January 2010 and December 2018. The NVF was confirmed by cystoscopy and/or voiding cystography. NVF repair was performed using a transvaginal approach, which included circumferential incision of the fistula tract, creation of a plane between the neobladder serosa and the vaginal epithelium, and multi-layered transvaginal closure. ***Results:*** During a median follow-up of 47.9 months, NVF was identified in 12 (8.8%) women. Eight fistulas were located in the proximal anterior vaginal wall and four in the vaginal apex. Median time from RC to NVF repair was 3.4 months. Median NVF size and duration of urethral Foley catheter indwelling was 6.0 mm and 24.0 days, respectively. Initial repair of NVF was successful in ten (83.3%) patients. Two (16.7%) patients who relapsed retained IONB through the subsequent operation. Two (16.7%) patients developed urinary incontinence after NVF repair, requiring anti-incontinence surgery. ***Conclusions:*** The transvaginal approach for NVF repair is feasible, yielding successful surgical outcomes. However, women should be counseled about the risks of relapse and urinary incontinence.

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1. INTRODUCTION

Radical cystectomy (RC) is the standard surgical treatment for muscle infiltrating or recurrent, high risk, non-muscle invasive bladder cancer (BCa) [1,2]. Ileal orthotopic neobladder (IONB) results in a better quality of life [3] than other methods of urinary diversion, with 60–70% of women being candidates for IONB at the time of RC [4]. Some of these patients, however, may experience surgical complications, such as uretero-intestinal anastomotic stricture, urine leakage, calculus formation and neobladder-vaginal fistula (NVF) [5].

NVF is a relatively unusual complication, occurring in 2.7–6.0% of women following IONB formation [6-9]. Risk factors for NVF include damage to and poor tissue vascularity within the anterior vaginal wall (AVW), an adjacent suture line between the urethral-neobladder anastomosis and the AVW, and local tumor recurrence [5,9]. Several surgical modifications have been introduced to reduce the risks of NVF, such as AVW preservation [10], avoidance of overlapping suture lines, and covering the vaginal stump with the omentum [11]. These modifications, however, did not protect all patients from these surgical complications.

The treatment of NVF is a surgical challenge, with no consensus regarding the optimal approach and surgical technique for NVF repair. The present study therefore describes the experience of our center in surgical technique and outcomes in patients requiring the correction of NVF after RC with IONB.

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2. MATERIALS AND METHODS

2.1. Study population

This retrospective, descriptive study was approved by the Institutional Review Board of our institution (IRB No. 2019-10-032), which waived the requirement for informed consent because of the retrospective design of this study. A prospectively collected cystectomy-oncology database of 558 patients who underwent RC for BCa between January 2010 and December 2018 by a single urologic oncology surgeon was retrospectively reviewed. Of the 163 women included in the study cohort, 27 were excluded, 24 who underwent ileal conduit urinary diversion and three who underwent ureterocutaneostomy. Ultimately, this study analyzed 136 women who underwent Studer IONB following RC. None of these patients had a history of radiation therapy preoperatively.

2.2. Data collection

The medical records of all patients, recorded at the time of surgery, were reviewed, and their clinical and pathological characteristics were determined, including age at surgery, body mass index (BMI), comorbidities such as diabetes mellitus, pathologic tumor stage, neoadjuvant and/or adjuvant chemotherapy, postoperative complications, and management. The details of the modified surgical technique used at our institution have been described, with all ileal reservoirs constructed as Studer pouches [12]. All RCs were performed as open procedures and included anterior exentration with excision of the upper third of the vagina, as well as standard bilateral pelvic lymphadenectomy.

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2.3. Follow-up

In general, patients were followed-up 1 month after surgery, every 3 months for the first 2 years, every 6 months for the next 3 years, and annually thereafter. All follow-up visits included physical examination with laboratory tests, urine analysis with cytology, chest radiography, and radiologic evaluation including computed tomography (CT) or magnetic resonance imaging (MRI) of the chest, abdomen, and pelvis. Cystoscopy was performed when urine cytology showed abnormal findings and/or patients experienced urinary symptoms, such as hematuria or irritative voiding. A bone scintigraphy scan was performed when clinically indicated.

Suspicion of NVF was based on history taking and physical examination, with the diagnosis confirmed by cystoscopy and/or voiding radiography. Cystoscopy included determination of the number, locations, and sizes of the NVFs.

2.4. Surgical technique and postoperative management

The surgical technique for NVF repair was similar to that used in repair of vesico-vaginal fistula (VVF) with an intact bladder [13], and included a multi-layer transvaginal closure. NVF repair was performed using a transvaginal approach with the patient under general anesthesia. The patient was placed in an extended lithotomy position, and the suprapubic and perineal areas and vagina were sterilized with iodine-containing wash.

After insertion of the cystoscope through the urethra, the neobladder was filled with normal saline to identify the features of the fistula. The vaginal canal was exposed using a weighted speculum and a US army retractor (Fig. 1A). A solution of lidocaine with

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epinephrine was allowed to infiltrate the AVW for hydrodissection. A sharp, circumferential incision was made around the fistula opening, and the fistula was dissected to create a plane between the serosa of the neobladder and the epithelium of the vagina (Fig. 1B). The neobladder was closed with continuous sutures using poliglecaprone 3-0 (Monocryl®; J and J Medical, Somerville, NJ, USA; Fig. 1C), and the AVW was repaired with continuous sutures of Polyglactin 2-0 (Vicryl®, J and J Medical; Fig. 1D).

A 24Fr urethral Foley catheter was inserted into the neobladder, and 200 ml saline was infused to test for possible leakage. The vagina was packed for 24 hours postoperatively with gauze soaked in povidone iodine. The urethral Foley catheter was maintained for at least 3 weeks, depending on the size of the NVF and the quality of the vaginal tissue. Cystography was performed prior to removal of the urethral Foley catheter for final confirmation

2.5. Statistical analysis

The clinical and pathological characteristics of the patients were compared by descriptive statistical analyses. Quantitative variables were reported as median (range) and compared by independent *t*-tests; and qualitative variables were reported as number (percentage) and compared by Pearson's chi-square test or Fisher`s exact test. All statistical analyses were performed using IBM SPSS statistics for Windows, version 23.0 (IBM Corp. Armonk, NY, USA). Two-sided *P*-values < 0.05 were considered statistically significant.

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3. RESULTS

The baseline clinicopathologic characteristics of the 136 women who underwent RC with IONB for BCa are summarized in Table 1. Their median age at surgery was 65.0 years (range, 31.0–81.0 years), and their median BMI was 23.8 kg/m^2 (range, 15.0–32.8 kg/m^2). Sixteen (11.8%) women had diabetes mellitus, and 46 (33.8%) showed locally advanced tumor stage (≥ pT3) at the time of RC. Neoadjuvant chemotherapy was administered to 27 (19.9%) patients and adjuvant chemotherapy to 55 (40.4%). During a median follow-up of 47.9 months, 12 (8.8%) women were diagnosed with NVF. The clinicopathologic characteristics of these 12 women did not differ significantly from those of the 124 women without NVF (all $P > 0.05$, respectively). None of these patients had evidence of local recurrence.

Median time from RC to NVF repair was 3.4 months (range, 2.1–5.6 months). The characteristics of the 12 patients with NVF and the details of NVF repair are summarized in Table 2. Median operation time was 47.5 min (range, 25.0–100.0 min), and median estimated blood loss was 27.5 ml (range, 10.0–75.0 ml). Eight (66.7%) fistulas were located in the proximal AVW and four (33.3%) in the vaginal apex. Median NVF size was 6.0 mm (range, 4.0–22.0 mm), and median duration of urethral Foley catheter indwelling was 24.0 days (range, 15.0–43.0 days).

Following NVF repair, the 12 patients were followed-up for a median 43.1 months (range, 12.9–69.7 months). Initial transvaginal repair of NVF was successful in ten (83.3%) patients. However, two patients, #7 and #11, developed recurrent NVF 3.2 and 14.8 months, respectively, after initial NVF repair. Both underwent secondary NVF repair using the same

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procedure. The operation was successful in Patient #11, whereas Patient #7 developed a recurrent NVF 6.5 months after secondary repair. The third operation was successful. The overall surgical outcomes of NVF repair are depicted in Figure 2.

Of the 12 patients, two, #2 and #4, required intermittent self-catheterization. Two others, #1 and #7, experienced severe urinary incontinence, requiring anti-incontinence surgery with a synthetic transobturator mid-urethral sling. Although surgical results were satisfactory, both of the latter patients required the use of 1–2 pads per day. Ultimately, all patients retained their IONBs.

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4. DISCUSSION

The present study showed that, of the 136 women who underwent RC with IONB for BCa, 12 (8.8%) developed NVF. Initial transvaginal repair of NVF was successful in ten (83.3%) of these 12 women, with the other two patients experiencing NVF recurrence, although both retained their IONB through subsequent operations. Even after successful NVF repair, it is necessary to counsel patients about the risk of urinary incontinence. To our knowledge, this is one of the largest case series to evaluate the surgical outcomes of transvaginal NVF repair.

Treatment of NVF after RC in women is challenging. These fistulas do not heal spontaneously. Although the surgical technique used for NVF repair is similar to that used for VVF repair in patients with an intact bladder, several factors mitigate against successful NVF repair. First, the neobladder wall is much thinner and less vascular than the walls of the intact bladder [5]. Second, atrophic vaginitis is more frequent in patients undergoing NVF repair, as their vaginas were hypovascular and scarred after anterior exentration. Furthermore, it is difficult to assess the extent of incontinence in patients with NVF, and repair of NVF could aggravate the incontinence itself [14].

Table 3 compares our results with those of recently published studies of NVF repair [6-8,15]. These case series included 6–14 patients with NVF, with an incidence of NVF ranging from 2.7% to 6.0%. Recurrent fistulas were identified in 0–50% of patients who underwent NVF repair, with IONB retained by 38.5–100% of patients. Compared with these earlier studies, we observed a higher overall incidence (8.8%) of NVF and a higher success rate of initial NVF repair (83.3%) with IONB retained by 100% of patients.

The main surgical difference between our study and these previous studies was in our

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ability to preserve the distal two-thirds of the AVW during anterior exentration. The distal AVW is the most common site of injury during urethral dissection. In addition, we found that the most common site of NVF was the proximal ends of the AVW, followed by the vaginal apex. These results emphasize the need for tight closure of the vaginal cuff after hysterectomy [11]. Moreover, rates of successful repair were higher for fistulas located in the AVW than in the urethra-neobladder anastomosis (UNA) (100% vs. 44%), suggesting that outcomes are better in patients with NVF more proximal to the UNA [8].

Our experience suggests that the transvaginal approach is feasible and should be considered as an initial approach in patients with NVF. Both sides of the proximal AVW and the vaginal apex are easily accessible through the transvaginal approach. Moreover, this approach avoids the potential risk of neobladder or bowel injury that could occur using an abdominal approach. In addition, outcomes using the transvaginal approach were successful in one patient with a 22 mm sized NVF and two patients with recurrent NVF. Thus, NVF size and history of previous treatment failure should not be a limiting factor for the transvaginal approach [15].

In general, a synthetic mid-urethral sling is not recommended for treatment of incontinence after NVF repair due to the increased risks of NVF erosion in atrophic vaginas, as well as injuries to the bowel and neobladder. However, two patients in our study (#2 and #12) lacked vaginal atrophy and had good tissue quality, enabling an urologist specializing in female reconstruction surgery to perform anti-incontinence surgery with a transobturator mid-urethral sling without complications. Injection of bulking agents is the preferred surgical option [8,15] as it can compensate for the loss of urethral coaptation due to intrinsic sphicteric deficiency [8]. However, *de novo* NVF has been reported following injection of

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bulking agent [7,16]. In addition, patients should be fully counseled that restoration of continence may not persist, and that they may require repeated injections.

Tissue interposition has been reported to be effective for NVF repair [14]. An omental flap is preferred, as it is robust and does not require additional incision [8]. If an omental flap is unavailable, a Martius labial fat flap can be used because it offers extra-vascularization and a better epithelization surface. If both flaps do not reach the NVF site, gracilis muscle flaps can be considered. However, none of the patients in the current study required tissue interposition, as most of the NVFs were < 2 cm in size, and the tissue used for repair was well-vascularized and of sufficient strength. Despite the lack of tissue interposition, the success rate of NVF repair was comparable to success rates in studies that used tissue interposition [6,8,15].

The usefulness of tissue sealant at anastomosis sites is unclear [17-20]. Polyglycolic acid (PGA) sheets (Neoveil®; Gunze Co., Tokyo, Japan) are a new type of hemostasis reinforcement material, which promotes tissue sealing and prevents leakage. PGA sheets have been reported to reduce the rates of pancreatic fistula [18] and cervical anastomotic fistula in patients with esophageal cancer [20]. Few studies in urologic surgery have tested the efficacy of PGA sheets for hemostasis after partial nephrectomy [19]. Further studies are needed to determine the role of bio-absorbable material in reducing fistula formation in patients undergoing urologic surgery.

This study has several strengths. First, it is the largest case series to date of patients undergoing transvaginal NVF repair with a detailed description of NVF characteristics. In addition, the median follow-up was relatively long, 43.1 months, enabling assessment of the clinical course and outcomes following subsequent surgical intervention.

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However, this study also had several limitations. First, it was retrospective in design and included patients treated at a single tertiary referral center by a single surgeon, raising concerns about selection bias. Second, despite this being the largest case series to date, the number of patients was quite low because this condition is uncommon. Third, it was difficult to determine the impact of perioperative chemotherapy on NVF. Large, prospective, multicenter studies are therefore warranted.

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5. CONCLUSION

NVF is a distressing complication for women following IONB, and NVF repair is a surgical challenge. This study suggests that a transvaginal approach is feasible and can result in successful surgical outcomes. However, women should be counseled about the risks of relapse and urinary incontinence.

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Conceptualization, W.S.and D.H.L.

Methodology, W.S.and D.H.L.

Formal analysis, W.S.and D.H.L.

Funding acquisition, W.S.

Investigation, W.S.and D.H.L.

Resources, W.S.and D.H.L.

Data curation, W.S.and D.H.L.

Writing—original draft preparation, W.S.

Writing—review and editing, W.S.and D.H.L.

Supervision, W.S.

All authors have read and agreed to the published version of the manuscript.

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FIGURE LEGENDS

Figure 1. Transvaginal neobladder-vaginal fistula repair technique. (A) Exposure of the vaginal canal using a weighted speculum and a US army retractor. (B) Making of a sharp, circumferential incision around the fistula tract, followed by dissection of the serosa of the neobladder and the vaginal epithelium. (C) Closure of the neobladder with continuous poliglecaprone 3-0 sutures. (D) Repair of the anterior vaginal wall with continuous Polyglactin 2-0 sutures.

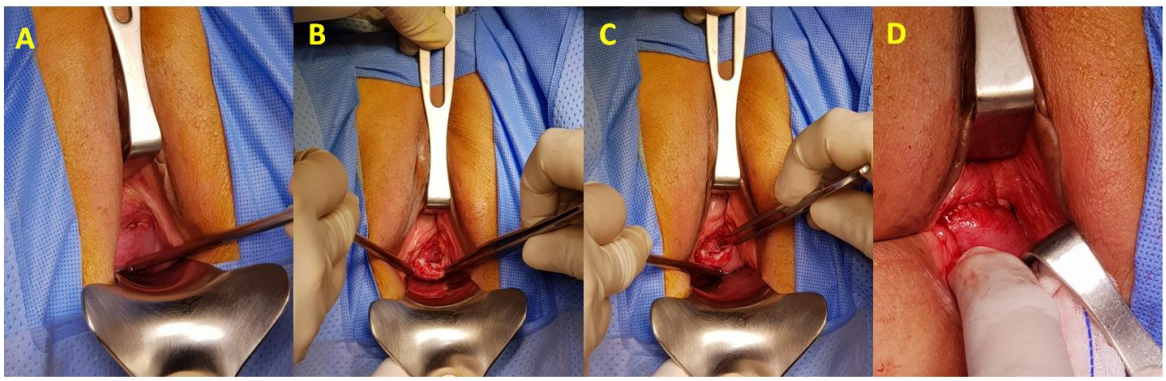

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Figure 2. Outcome of patients following neobladder-vaginal fistula repair.

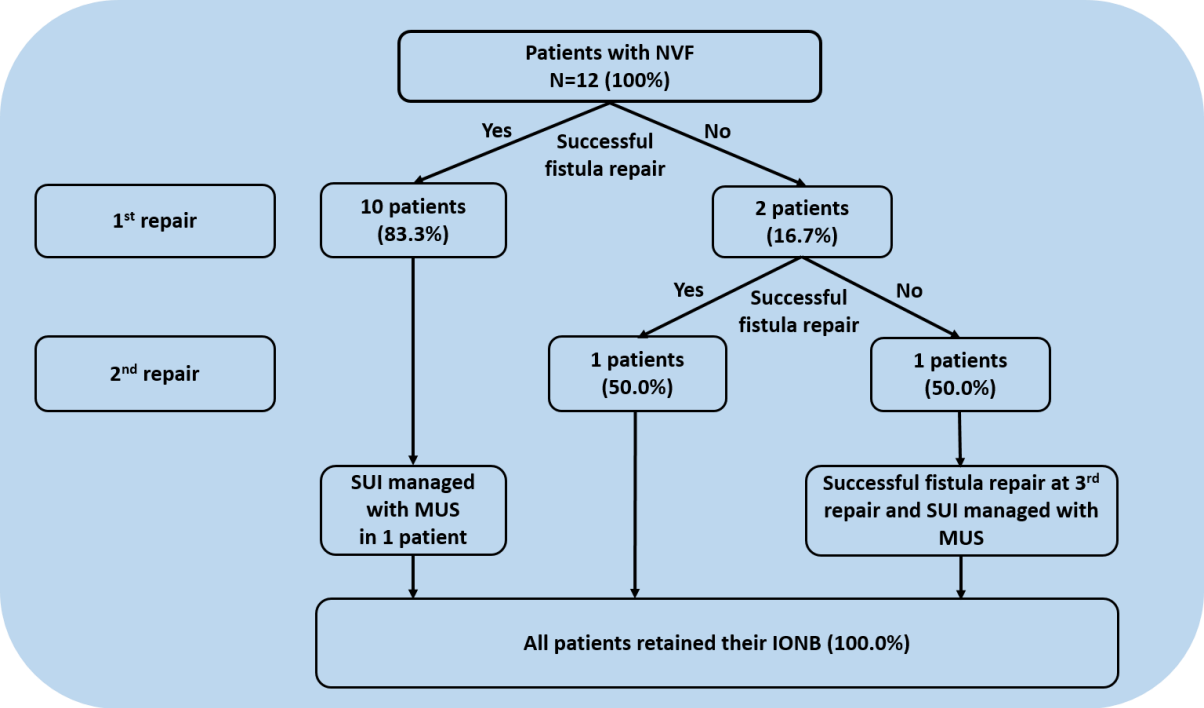

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Table 1. Baseline demographic and clinical characteristics of all patients who underwent radical cystectomy with ileal orthotopic neobladder

Parameters	Total	Neobladder-vaginal fistula		*P*
		No	Yes	
No. of patients	136 (100.0)	124 (91.8)	12 (8.8)	
Age at surgery, years				0.995
Median (range)	65.0 (31.0–81.0)	65.5 (31.0–81.0)	62.5 (53.0–71.0)	
Body mass index, kg/m^2				0.309
Median (range)	23.8 (15.0–32.8)	24.6 (17.2–32.8)	22.5 (15.0–31.5)	
Diabetes mellitus, n (%)				0.634
Yes	16 (11.8)	14 (11.3)	2 (16.7)	
No	120 (88.2)	110 (88.7)	10 (83.3)	
Neoadjuvant chemotherapy, n (%)				0.705
Yes	27 (19.9)	24 (19.4)	3 (25.0)	
No	109 (80.1)	100 (80.6)	9 (75.0)	
Pathologic T stage, n (%)				0.539
≤ pT2 (organ confined)	90 (66.2)	83 (66.9)	7 (58.3)	
≥ pT3 (locally advanced)	46 (33.8)	41 (33.1)	5 (41.7)	
Adjuvant chemotherapy, n (%)				0.480
Yes	55 (40.4)	49 (39.5)	6 (50.0)	
No	81 (59.6)	75 (60.5)	6 (50.0)	
Follow-up, months				0.331
Median (range)	47.9 (15.0–82.5)	48.7 (18.0–82.5)	46.5 (15.0–73.5)	

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Table 2. Surgical outcomes of neobladder-vaginal fistula repair

Patients	Age at surgery (years)	BMI (kg/m^2)	Location of fistula	Size (mm)	Duration of catheter indwelling (days)	Overall follow-up (months)	Outcomes
1	71	25.1	Proximal right anterior vaginal wall	22	29	69.7	No recurrence SUI managed with MUS
2	57	17.3	Vaginal apex	5	23	43.9	No recurrence CIC
3	71	27.6	Proximal left anterior vaginal wall	6	31	52.1	No recurrence
4	64	23.3	Vaginal apex	4	16	40.9	No recurrence CIC
5	66	30.0	Proximal right anterior vaginal wall	13	24	39.7	No recurrence
6	70	18.2	Proximal left anterior vaginal wall	5	24	42.3	No recurrence
7	59	15.0	Vaginal apex	18	20	49.2	Recurrent NVF SUI managed with MUS
8	56	19.9	Proximal left anterior vaginal wall	6	15	47.2	No recurrence
9	61	31.5	Proximal left anterior vaginal wall	15	43	35.3	No recurrence
10	69	22.2	Vaginal apex	4	30	44.4	No recurrence
11	59	22.9	Proximal right anterior vaginal wall	12	28	26.4	Recurrent NVF
12	53	21.2	Proximal right anterior vaginal wall	5	15	12.9	No recurrence

Abbreviations: BMI, body mass index; SUI, stress urinary incontinence; MUS, mid urethral sling; CIC, clean intermittent catheterization;

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NVF, neobladder-vaginal fistula.

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Table 3. Comparison of the present results with results from studies evaluating the outcomes of neobladder-vaginal fistula repair

Parameters	Carmel *et al*.[15]	Rosenberg *et al*.[8]	Ali-El-Dein *et al*.[6]	Bailey *et al*.[7]	Present study
Location	USA	USA	Egypt	USA	Korea
Year of publication	2016	2018	2013	2016	
No. of patients	NR	249	298	100	136
No. of NVF	8	14	8	6	12
Incidence of NVF, %	NR	5.6	2.7	6.0	8.8
Median age, years	57.0	67.0	52.0	NR	62.5
Median duration of urethral catheter, days	24.0	NR	NR	NR	24.0
Concomitant flap, %	75.0	84.6	25.0	0	0
Median follow-up, months	33.0	35.2	146.0	22.9	43.1
NVF recurrence, %	0	38.5	NR	50.0	16.7
SUI requiring surgical intervention, %	62.5	58.3	0	33.3	16.7
Retained neobladder, %	100	38.5	100	66.7	100

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Abbreviations: NVF, neobladder-vaginal fistula; SUI, stress urinary incontinence.