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Prevention of neovesico-vaginal fistula in female ileal orthotopic neobladder surgery: Autologous peritoneal graft interposition

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Abstract

Objectives

To identify predictive factors for neovesico-vaginal fistula (nVVF) in female patients with ileal orthotopic neobladder (IONB) and introduce autologous peritoneal graft (APG) interposition as a potential preventive technique.

Materials and Methods

Female bladder cancer patients who underwent radical cystectomy and IONB between January 2010 and December 2022 were reviewed. The surgical methods were practically uniform; initial extraperitoneal approach for pelvic lymph-node dissection and ureter ligation, and peritoneum was later opened for further procedures. In cases of APG interposition, the peritoneum was harvested large enough to cover the vaginal cuff just before bowel manipulation. The incidence, characteristics, and predictive factors for nVVF were analyzed.

Results

A total of 175 patients (control; n = 118, APG; n = 57; mean age: 63.9 ± 10.1 years) were included. More patients in the APG group received neoadjuvant chemotherapy (40.4% vs. 20.3%, *p* = 0.005), but the incidence of nVVF was lower (20.3% vs. 3.5%, *p* = 0.002) than control. On multivariate analysis, old age (odds ratio (OR) 1.050; 95% confidence interval (CI): 1.001–1.101, *p* = 0.045) and neoadjuvant chemotherapy (OR 4.031; 95% CI: 1.448–11.219, *p* = 0.008) were risk factors for nVVF, whereas peritoneal graft interposition (OR 0.094; 95% CI: 0.020–0.439, *p* = 0.003) was a preventive factor.

Conclusions

APG interposition between the vaginal stump and neobladder is a promising technique to prevent nVVF in female IONB surgery. Old age and neoadjuvant chemotherapy might have negative effects on the healing process of female IONB.

INTRODUCTION

Radical cystectomy (RC) with urinary diversion is a standard surgical treatment option for muscle invasive bladder cancer or recurrent, high-risk nonmuscle invasive bladder cancer.(1, 2) Compared with an ileal conduit, an ileal orthotopic neobladder (IONB) following RC is advantageous as it preserves body image. IONB after RC requires discrete anatomical and functional reconstruction of the lower urinary tract system to enable adequate voiding.(3) Historically, IONB was unsuitable for female bladder cancer patients because traditional RC included removal of the female urethra. It was not until 2001 that IONB

was reported also to be effective for selected female patients(4, 5) but sex-specific functional outcomes and health-related quality of life remain controversial.(6)

Postoperative complications differ between female and male IONB patients; females are more vulnerable to voiding dysfunction, such as urinary retention requiring intermittent catheterization, urinary incontinence, and possible neovesico-vaginal fistula (nVVF).(7, 8) The incidence rate of nVVF reportedly ranges from 0% to 33% in the literature(9–11) and is estimated to range from 3% to 6% in high-volume centers. Most studies have focused on successfully repairing nVVF without recurrence. However, it would be much more efficient to select suitable candidates for IONB in advance and investigate surgical techniques to prevent nVVF.

Various attempts with conventional techniques, such as avoidance of overlapping suture lines and rigorous closure of vaginal cuff, and vascular flap (especially omentum) interposition, to prevent nVVF have not been sufficient to eliminate the incidence of nVVF.(11, 12) This study aimed to analyze the factors predictive of nVVF in female patients with IONB and introduce autologous peritoneal graft interposition between the neobladder and vaginal stump as a potentially preventive method for nVVF. We also determined if there were any differences in the characteristics of nVVF between peritoneal graft interposition and conventional surgical techniques.

MATERIALS AND METHODS

Ethics statement

This study was approved by the Institutional Review Board of our center (2022-04-003). Informed consent from the participants was waived due to the retrospective study design.

Study design

Female patients who underwent RC and IONB diversion between January 2010 and December 2022 were included. Oncological demographics and use of peritoneal graft to prevent nVVF were reviewed. Patients with insufficient medical records or development of nVVF due to cancer recurrence in the pelvic cavity were excluded from the analysis. Baseline oncological demographics and the incidence of nVVF were compared between the peritoneal graft group and control group.

Surgical technique

I. Overall surgical process

The surgical procedures for RC and IONB were practically uniform in all patients; Initially, bilateral pelvic lymph-node dissection and ureter ligation were performed via an extraperitoneal approach. Next, the peritoneum was opened to dissect posterior and bilateral pedicles of the urinary bladder and uterus.

Finally, RC with or without hysterectomy (depending on surgical history) was performed, then a Studer-type IONB was then created.

II. Peritoneal graft *interposition*

In cases of autologous peritoneal graft interposition, the peritoneum was harvested in a rectangular shape when it was opened (Fig. 1a). The harvested peritoneal graft (Fig. 1b) was approximately 5 cm x 5 cm, which is large enough to cover the vaginal cuff, and it was preserved in 0.9% normal saline during RC. After meticulous bleeding control, the graft was anchored on the surrounding tissue of the vaginal cuff (Fig. 1c) with 3–0 Monocryl® (polyglactin; J and J Medical) just before bowel manipulation for neobladder creation The vaginal cuff was successfully covered with a peritoneal graft (Fig. 1d).

Figure 1. Peritoneal graft interposition **during female radical cystectomy with ileal orthotopic neobladder.**

(a) Peritoneum harvest of rectangularly-shaped tissue for a graft, (b) harvested graft, and (c) vaginal cuff after radical hysterectomy. The exposed V-shape suture lines (marked with white arrow) are inevitably overlapped with an ileal orthotopic neobladder. (d) Peritoneal graft anchored on surrounding tissue of the vaginal cuff to cover the suture materials.

Postoperative care

Daily manual irrigation was not routinely performed. Manual irrigation was avoided if possible and was performed only once on postoperative day 6 unless there was a sign that the nephrostomy catheter was obstructed. Healing of the neobladder was evaluated on postoperative day 14 by performing dye-filling bladder computed tomography (CT). Normal saline mixed with contrast agent was naturally instilled into the bladder under gravity (approx. 30 cc). If contrast leakage was observed, flexible cystoscopy was performed to identify the leakage point and remove the mucous plugs. The nephrostomy catheter was changed under fluoroscopic guidance and remained indwelled until neobladder healing.

Follow-up protocol and management of neovesico-vaginal fistula

The follow-up schedule for patients was 1 month postoperatively, every 3 months for the first 2 years, every 6 months for the next 3 years, and annually thereafter. Each visit included thorough history taking with laboratory tests, urinalysis with voided urine cytology, and radiological evaluation, including CT or magnetic resonance imaging. Outpatient cystoscopy was recommended in cases of abnormal urine cytology, changes in lower urinary symptoms, or the presence of gross hematuria. If nVVF was suspected, cystoscopy and cystography were performed to identify the location, size, and number of fistulas. Confirmed nVVF was repaired via the transvaginal approach at least 3 months after IONB creation, as previously described.

Statistical analysis

IBM SPSS software version 23.0 (IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY) was used for all statistical analyses. Differences were considered significant for values of $p < 0.05$. To evaluate the significance of differences between groups, Student's *t*-test for numeric parameters and the Chi-square test or Fisher's exact test for non-numeric parameters were performed. Binary logistic regression analysis was performed to identify significant risk factors for nVVF and presented with the odds ratio (OR) and 95% CI.

RESULTS

Baseline and oncological demographics of patients

A total of 175 female patients (control; n = 118, peritoneal graft; n = 57) with IONB were included. The mean age of the included patients was 63.9 ± 10.1 years, with a median follow-up of 31.3 (0.7–131.2) months. Forty-seven (26.9%) patients received neoadjuvant chemotherapy. Pathological T0 (no residual tumor) was identified in 18 (10.3%) patients, 103 (58.8%) patients had localized (≤ pT2) cancer, and 54 (30.8%) patients had locally advanced (≥ pT3) cancer. More patients in the peritoneal graft group received neoadjuvant chemotherapy prior to RC ($p = 0.005$) than in the control group (Table 1).

Table 1
Baseline and oncological demographics of patients

Age at operation (years)	**Control (n = 118)**	**Peritoneal graft (n = 57)**	***p* value**
	63.5 ± 10.6	**64.9 ± 9.1**	**0.371**
Diabetes mellitus	12 (10.2)	5 (8.8)	0.770
BMI (kg/m^2)	24.0 ± 3.7	23.6 ± 3.1	0.482
Pelvic operation history	13 (11.0)	11 (19.3)	0.136
Pelvic radiation history	2 (1.7)	1 (1.8)	1.000
Pathological T-stage			0.962
pT0	11 (9.3)	7 (12.3)	
pTis, Ta, T1	43 (36.4)	22 (38.6)	
pT2	26 (22.0)	12 (21.1)	
pT3	31 (26.3)	13 (22.8)	
pT4	7 (5.9)	3 (5.3)	
Neoadjuvant chemotherapy	24 (20.3)	23 (40.4)	0.005
Adjuvant chemotherapy	47 (39.8)	19 (33.3)	0.406
Fistula occurrence	24 (20.3)	2 (3.5)	0.003
Time gap for fistula (months)	3.5 ± 2.0	1.0 ± 1.0	0.092
BMI: body mass index			

Incidence, characteristics, and predictive factors for neovesico-vaginal fistula

The overall incidence of nVVF was 14.9% and fistula was identified at a median of 2.9 (0.3–8.4) months. Additionally, nVVFs were observed in 24 (20.3%) patients in the control group with conventional surgical technique and in two (3.5%) patients in the peritoneal graft group ($p = 0.003$). Successful repair of nVVF was performed transvaginally in all patients except for one in the peritoneal graft group who recently had undergone IONB diversion and preferred prolonged indwelling of a Foley catheter because of adjuvant chemotherapy. In multivariate analysis, the risk factors for nVVF were old age (OR 1.050; 95% CI: 1.001–1.101, $p = 0.045$) and neoadjuvant chemotherapy (OR 4.031; 95% CI: 1.448–11.219, $p = 0.008$), and a preventive factor for nVVF was peritoneal graft interposition (OR 0.094; 95% CI: 0.020–0.439, $p = 0.003$) (Table 2).

Table 2
Predictive factors for neovesico-vaginal fistula

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	***p* value**	**OR (95% CI)**	***p* value**
Age (years)	1.028 (0.983–1.076)	0.220	1.050 (1.001–1.101)	0.045
BMI (kg/m^2)	1.060(0.943–1.191)	0.328		
Diabetes				
No	Reference			
Yes	0.744 (0.160–3.466)	0.707		
Previous pelvic operation				
No	Reference			
Yes	1.173 (0.366–3.759)	0.789		
Neoadjuvant chemotherapy				
No	Reference		Reference	
Yes	1.892 (0.790–4.530)	0.152	4.031 (1.448–11.219)	0.008
Adjuvant chemotherapy				
No	Reference			
Yes	1.038 (0.441–2.445)	0.932		
Urine leakage				
No	Reference			
Yes	0.908 (0.257–3.202)	0.908		
Peritoneal graft				
No	Reference		Reference	
Yes	0.142 (0.032–0.626)	0.010	0.094 (0.020–0.439)	0.003

BMI: body mass index

Characteristics of fistula in the peritoneal graft group

Two nVVFs were identified in the peritoneal graft group. Both patients had received neoadjuvant chemotherapy, but their final pathology differed (Table 3).

Table 3
Baseline characterization of nVVF patients in peritoneal graft group

Patient no.	Age (years)	BMI (kg/m^2)	Diabetes mellitus	Previous hysterectomy	Neoadjuvant chemotherapy	Final pathology
1	59	23.8	No	No	Yes	yT3
2	73	20.5	No	Yes	Yes	yT1

BMI: body mass index; nVVF: neovesico-vaginal fistula

Patient 1 needed adjuvant chemotherapy, so transvaginal nVVF repair was performed only in patient 2. The clinical course and features of nVVFs in the two patients differed from those in the conventional group. Only two n-VVF patients in the conventional group (2 out of 24, 8.3%) experienced transient urine leakage from the ileal neobladder during postoperative care; however, all nVVF patients in peritoneal graft group suffered from transient urine leakage requiring prolonged indwelling of nephrostomy catheter. On pre-fistula repair cystoscopy and vaginoscopy, the peritoneal graft was not identified (Fig. 2). The graft was identified at the upper margin (12 o'clock) of the vaginal vault during the dissection of the neobladder serosa and vaginal epithelium. The graft was very fibrotic, resulting in severe adhesion between the neobladder and vagina but without any fistulous tract. Part of the peritoneal graft was resected to close the vaginal fistula, which was performed with 2 – 0 Vicryl, and the neobladder defect was sutured with 3–0 Monocryl. The resected tissue was sent to the pathology department, where analysis revealed inflamed granulation tissue with fibrosis.

DISCUSSION

This study introduced autologous peritoneal graft interposition by reviewing the incidence of nVVF in female bladder cancer patients with IONB and identified its predictive factors. The incidence of nVVF was significantly reduced by autologous peritoneal graft interposition relative to that after conventional omental flap interposition, and old age and neoadjuvant chemotherapy were risk factors. Occurrence of nVVF in the peritoneal graft group was only observed in the patients who had undergone neoadjuvant chemotherapy, and the characteristics of nVVF were different from those in the conventional group.

Although the peritoneal graft group showed a significantly higher tate of neoadjuvant chemotherapy compared to the control group (40.4% vs. 20.3%, p = 0.005), the incidence of nVVF was remarkably lower (3.5% vs. 20.3%). Given that NAC is recognized for its negative impact on tissue healing, the observed reduction in nVVF suggests that autologous peritoneal graft interposition may effectively mitigate the elevated fistula risk associated with systemic chemotherapy in female IONB patients.

All patients with nVVF in peritoneal graft group received neoadjuvant chemotherapy and transient urine leakage from neobladder was observed. In addition, the fistulous tract was not observed where peritoneal graft was interposed. Notably, the clinical characteristics of these cases differed from those of the conventional group; these patients experienced urine leakage and chronic inflammation,

suggesting that the fistulous tract formed away from the site of the graft. This indicates that severe tissue compromise resulting from systemic chemotherapy, rather than a technical failure of the graft itself.

The types of urinary diversion after RC include ileal conduit or orthotopic neobladder using intestinal substitutes. The optimal urinary diversion following RC is controversial because all types of diversion could tremendously affect overall body image, renal function, voiding function, sexual activity, and quality of life. Female IONB was considered tricky because maintenance of adequate continence is difficult, and vaginal complications (fistula, prolapse, dyspareunia, and short-vaginal length) should also be taken into account.(13, 14) Some patients are reported to have received re-diversion of IONB to the ileal conduit due to the aforementioned problems.(11) However, with the development and modifications in surgical techniques, female IONB became feasible for women without urethral or bladder neck tumors.

The overall incidence of nVVF in the current study was 14.9%, which is higher than in our previous report (8.8%)(15) and the literature.(9–12, 16) According to a recent systematic review and meta-analysis, the incidence of nVVF ranged from 3% to 6% in a high-volume center.(7) We assume that this discrepancy was because of the increased use of neoadjuvant chemotherapy in patients with bladder cancer. The benefit of neoadjuvant chemotherapy has been reported in multiple randomized trials, and the recommendation for neoadjuvant chemotherapy has been strengthened to category 1 for muscle invasive bladder cancer patients in National Comprehensive Cancer Network guideline since the mid to late 2010s.(1, 17, 18) Most publications that have been used for analysis included patients who underwent RC before 2016 when neoadjuvant chemotherapy was not robustly applied. The proportion of patients who received neoadjuvant chemotherapy in our study population increased sharply from 13% in 2017 to 47.8% in 2022.

In the present study, nVVF occurred more frequently in the patients who underwent neoadjuvant chemotherapy (21.3%; 10/47) than in those who were naïve to neoadjuvant chemotherapy (12.5%; 16/128), but the difference was not statistically significant ($p = 0.148$). The incidence of nVVF was also proportional to the rate of neoadjuvant chemotherapy. Specifically, nVVF occurred in 8.3% of women between 2010 and 2017, and 46.2% in 2018, with neoadjuvant chemotherapy rates of 18.1% and 30.8%, respectively. This abrupt increase in nVVF in 2018 motivated the development of alternative surgical techniques to reduce these complications. Consequently, we replaced the conventional omental flap with an autologous peritoneal graft interposition between the neobladder and vaginal cuff.

Chemotherapeutic agents affect the function and synthesis of neoplastic cells by interfering with nucleic acids (DNA and RNA), proteins, or metabolite synthesis that are mandatory for cellular survival.(19) This cytotoxic effect is systematic; normal tissue is also affected, and common side effects of chemotherapy result from suppressed cellular differentiation, decreased vascularity, and delayed healing. Among various risk factors for nVVFl overlapping suture lines between the vaginal stump and neobladder, previous radiation therapy to the pelvic cavity, local cancer recurrence, and intraoperative injury or poor vascularity of the anterior vaginal wall(11), the decreased vascularity of the ileum and vaginal wall

resulting from neoadjuvant chemotherapy could have hindered normal healing of the IONB. Although neoadjuvant chemotherapy reportedly eradicated micrometastasis before major operations and improved cancer survival, it could lead to delayed recovery in the neobladder. Therefore, the increased risk for urine leakage and fistula should be explained to patients preoperatively.

Interposition of flaps has been widely accepted as effectively preventing fistula recurrence at the time of vesicovaginal fistula repair. Various autologous tissues can be used; for example, labial fat pad (Martius flap), gracilis muscle, or omental fat. Fibrin sealant patches, such as the TachoSil or polyglycolic acid sheets, can also be considered (bio-absorbable material in reducing fistula formation).(20, 21) Omental flaps and mesentery are each easy to apply and have favorable surgical outcomes during transperitoneal surgeries. In one study, the incidence of nVVF was reported to be 0% in one group but was 5.8% in the other group.(11) However, complications of the omental flap include postoperative ileus, infection, abscess formation, intestinal obstruction, and total necrosis of the omental flap.(22, 23) In addition, omental flaps cannot be applied in all cases involving RCs with IONB, especially when the omental flap is too short to be lengthened enough to reach the pelvic cavity.

The peritoneum is a serosal membrane that originates from mesenchymal stem cells and has a single layer of mesothelial cells supported by a basement membrane.(24) The advantages of an autologous peritoneal graft is that the peritoneum is a simple structure with plenty of tissue available in the abdominal cavity. Peritoneal graft s can be applied in all cases except for patients with inflammatory or malignant peritoneal diseases. Although ossification of transplanted autologous peritoneum to urothelium in a preclinical model has been reported, no abnormal calcification was observed in follow-up CT scans of our study population.(25, 26) To prevent any unexpected histological changes, we placed the slippery surface of the peritoneum toward the abdominal cavity not the ileal neobladders. The use of a peritoneal graft has been reported in a wide range of surgeries, including those involving the inferior vena cava, vaginal reconstruction, and prevention of lymphocele after robot-assisted radical prostatectomy with bilateral extended pelvic lymph-node dissection.(27) Considering that there is no single effective surgical technique to prevent nVVF, autologous peritoneal grafts could be a promising option for female IONB patients.

Formation of nVVF occurs because of the connection between the simple columnar epithelium of the ileum and squamous epithelium of the vagina during the healing process, which includes inflammation, fibroblast proliferation, neovascularization, and tissue remodeling with progressive granulation tissue, re-epithelialization, and collagen deposition.(28) The peritoneal graft prevents this abnormal re-epithelialization between two surfaces by directly covering the overlapping suture lines between the ileal neobladder and vagina. However, the mechanism of nVVF formation in the peritoneal graft group might be different from that of conventional groups. Continuous urine leakage from the neobladder defect despite prolonged Foley catheterization and bilateral percutaneous nephrostomy indwelling resulted in chronic inflammation, which hindered normal healing of both the neobladder and vaginal wall. Consequently, a fistulous tract was observed away from the peritoneal graft.

Alongside neoadjuvant chemotherapy and peritoneal graft interposition, age was also associated with an increased risk of nVVF formation. The negative effect of aging has been previously discussed in other operations as well. Hohenberger et al. reported that surgical complications, including bleeding, infection, and delayed wound healing, are associated with age in elective lumbar surgery.(29) Similarly, Sun et al. reported that age was an independent risk factor for postoperative complications in emergency abdominal surgery.(30) Given that old age is also associated with increased anesthesia risks, a bladder preservation strategy with maximal transurethral resection of a bladder tumor with concurrent chemotherapy and radiation therapy should be actively considered for patients at higher risk of surgical complications.

This study has several limitations, including its retrospective design and the lack of randomized group assignment. A notable factor is the potential impact of temporal variations in the surgical team; a transition in the primary team occurred in 2019, followed by the addition of a new member in September 2021. While the incidence of nVVF observed from 2018 might be partially attributed to the learning curves associated with these team adjustments, our multivariate analysis confirmed that neoadjuvant chemotherapy remained an independent predictor of nVVF even after adjusting for these temporal shifts. Despite these limitations, this study represents one of the largest single-center cohorts addressing nVVF prevention in female IONB patients. By documenting our clinical experience - particularly our adaptation to the increasing use of NAC and team transitions - we provide a practical, evidence-based surgical strategy. These findings offer a robust and scalable solution for surgeons managing high-risk female patients undergoing radical cystectomy and IONB diversion, demonstrating that the autologous peritoneal graft technique remains effective even as the surgical team evolves.

CONCLUSIONS

Autologous peritoneal graft interposition between the vaginal stump and neobladder is a promising technique for preventing nVVF in female IONB surgery. Old age and neoadjuvant chemotherapy were found to have negative effects on the healing process of female IONB. Certain patients, especially older female patients with bladder cancer who have undergone neoadjuvant chemotherapy, should be counseled about their increased risk of nVVF. For such patients, autologous peritoneal graft interposition between the vaginal stump and neobladder could be a promising option to reduce nVVF formation in female IONB surgery.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki. The protocol for this study was reviewed and approved by the Institutional Review Board (IRB) of Ewha Womans University Mokdong Hospital (IRB No. 2022-04-003). The requirement for informed consent was waived by the Institutional Review Board of Ewha Womans University Mokdong Hospital due to the retrospective nature of the

study, as it involved the analysis of existing medical records and posed no more than minimal risk to the participants.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to institutional policy regarding patient privacy and confidentiality. Access to these data may be granted upon reasonable request to the corresponding author, subject to approval by the Data Review Board of Ewha Womans University Mokdong Hospital.

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Author Contributions

JHS: Designed the study, collected the data, performed the statistical analysis, and drafted the initial manuscript.

HR: Contributed to data collection and performed clinical evaluations.

MSK: Provided critical insight into the study design and assisted in the interpretation of the data.

DHL: Conceptualized the study, supervised the overall research process, reviewed and edited the manuscript, and acts as the corresponding author.

All authors have read and approved the final manuscript.

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Figures

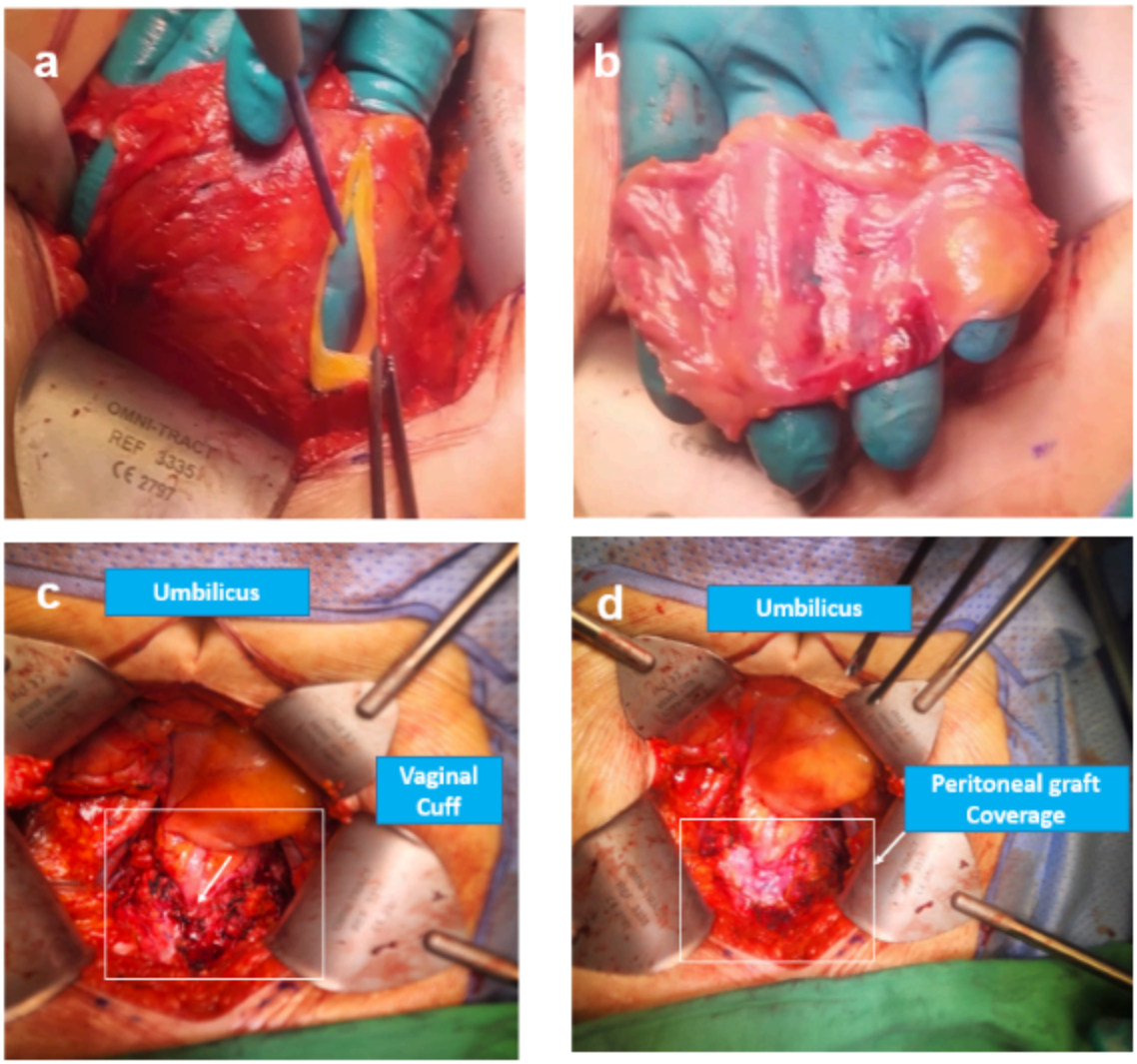


Figure 1

Peritoneal graft interposition **during female radical cystectomy with ileal orthotopic neobladder.**

(a) Peritoneum harvest of rectangularly-shaped tissue for a graft, (b) harvested graft, and (c) vaginal cuff after radical hysterectomy. The exposed V-shape suture lines (marked with white arrow) are inevitably overlapped with an ileal orthotopic neobladder. (d) Peritoneal graft anchored on surrounding tissue of the vaginal cuff to cover the suture materials.

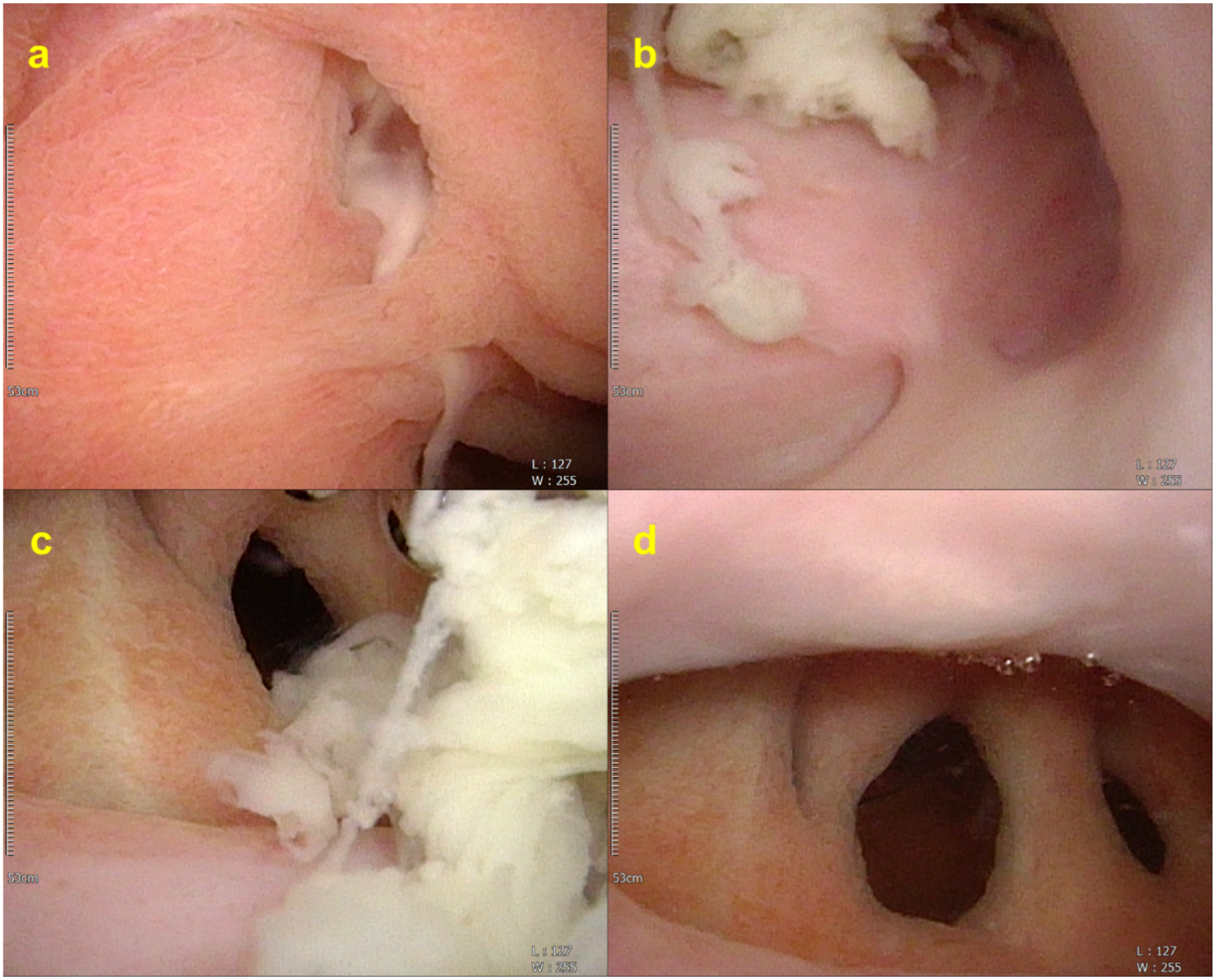


Figure 2

Representative cystoscopy and vaginoscopy image of neovesico-vaginal fistula in the peritoneal graft **group.**

(a) Fistula tract identified from a neobladder, (b) mucous plugs in the vagina, (c) fistulous tract consisting of a single defect in the vaginal vault but multiple defects in the neobladder, and (d) visualization of neobladder defect after removal of mucous plug. Multiple neobladder defects are in accordance with the suture lines to create the neobladder. Images from anOlympus flexible cystoscope used to perform a cystoscopy and vaginoscopy.