Safety and Efficacy of Transvaginal Natural Orifice Specimen Extraction for Large Organ Specimen: a Prospective Pilot Study

Woo Yeon Hwang
Seoul National University Bundang Hospital
Dong Hoon Suh (sdhwcj@naver.com)
Seoul National University College of Medicine
Sangchul Lee
Seoul National University Bundang Hospital

Research Article

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Abstract

Background: This study aimed to evaluate the safety and efficacy of transvaginal natural orifice specimen extraction (NOSE) in patients who underwent laparoscopic or robotic surgery for the treatment of benign or malignant diseases of solid organs, including the kidney, liver, stomach, adrenal gland, and bladder.

Methods: This prospective study was conducted at a tertiary hospital between March 2015 and May 2020. The main outcome was cosmetic outcomes of scars assessed using the Patient and Observer Scar Assessment Scale (POSAS) 1 and 8 weeks after surgery. The secondary outcomes were postoperative pain, operating time, and complications. Sexual function was assessed using the Female Sexual Function Index (FSFI) questionnaire 6 months after surgery in 17 patients who were sexually active at the time of surgery.

Results: A total of 38 transvaginal NOSE procedures were performed for the extraction of 33 kidneys, 2 livers, 1 stomach, 1 adrenal gland, and 1 bladder. Observers rated pigmentation and relief scores as most deviant from normal skin (2.9 ± 1.7, 3.0 ± 2.1 at postoperative 1 week; 3.6 ± 1.9, 3.5 ± 2.2 at postoperative 8 weeks, respectively), but the overall scores of each item were low. The patients' overall satisfaction with postoperative scars was high, and the mean scores for pain and itching were low, with significant improvement from the first week to the eighth week (P=0.014 and P=0.006, respectively). Patients also reported low scores on vaginal assessment items, indicating better symptoms, and bleeding improved significantly between the two time points (P=0.001). The mean FSFI total score was 21.2 ± 8.7 (cutoff score for dysfunction is 21), with higher scores indicating better sexual functioning. Postoperative pain was reduced from moderate during the first 24 h after surgery to mild after 24 h. The mean operative time of the transvaginal NOSE procedure was 28.3 ± 13.3 min. No postoperative complications were associated with the procedure.

Conclusions: Transvaginal NOSE may be a safe and feasible procedure with promising cosmetic benefits for patients who undergo minimally invasive surgery for large organs including the kidney, liver, stomach, adrenal gland, and bladder. A prospective randomized clinical trial is needed to provide solid evidence to support transvaginal NOSE.

Trial registration: This trial is registered at ClinicalTrials.gov (NCT05113134).

Background

Minimally invasive surgeries have been performed for benign and malignant diseases to minimize complications, shorten recovery times, and decrease scars after surgery (1). When performing multiport laparoscopic surgery for large organs such as the stomach, colon, kidney, liver, and spleen, the extraction of surgical specimens requires an additional or enlarged abdominal wall incision to remove the resected organ or tissue. Enlargement of the incision may cause abdominal pain, infection, and incisional hernia

during the postoperative period (2). Natural orifice specimen extraction (NOSE) has been suggested to reduce incision-related morbidity and maximize the advantages of laparoscopic surgery (1).

Among various developed NOSE techniques, gynecologists have most widely selected the transvaginal access route through a posterior colpotomy incision (2, 3). The posterior vaginal fornix is a large recess behind the cervix, a relatively accessible part of the vagina, and has good healing ability due to adequate vascular supply (4). Although previous studies have demonstrated the safety and feasibility of transvaginal NOSE, concerns remain regarding sexual dysfunction and postoperative complications associated with colpotomy incision.

This study aimed to evaluate the postoperative complications, cosmetic outcomes, and effects on sexual function of transvaginal NOSE in patients who underwent multiport laparoscopic surgery for resection of large organs, including the kidney, liver, stomach, adrenal gland, and bladder.

Methods

Study aim

The aim of the study was to evaluate the postoperative complications, cosmetic outcomes, and effects on sexual function of transvaginal NOSE in patients who underwent multiport laparoscopic surgery for resection of large organs, including the kidney, liver, stomach, adrenal gland, and bladder.

Study design and setting

This prospective study was conducted at Seoul National University Bundang Hospital, a tertiary hospital in Korea, between March 2015 and May 2020. The study was approved by the Institutional Review Board of Seoul National University Bundang Hospital (No. B-1411-276-005) and was performed in accordance with the principles of the Declaration of Helsinki. All patients were adequately informed of the benefits and risks of the procedure and written consent was obtained prior to the surgical procedure.

Study population

The inclusion criteria were as follows: patients over 20 years of age; patients who were accessible with a vaginal approach; patients scheduled for laparoscopic resection of the stomach, liver, adrenal gland, bladder, colon, kidney, and spleen for benign or malignant diseases; and patients with normal cervical cancer screening tests (except inflammatory findings) within the last 3 years. The exclusion criteria were as follows: patients without sexual intercourse; patients with a narrow introitus noted on gynecological examination which would prevent removal of the specimen through the vagina; patients who were expected to have severe adhesions due to deep infiltrative endometriosis or previous pelvic surgery history; patients with abnormal cervical cancer screening tests; and patients scheduled to undergo concomitant hysterectomy.

Operative technique

Under general anesthesia, multiport (robot-assisted) laparoscopic surgery is performed and the resected specimen is placed in an endopouch by specialized surgeons. Following the resection procedure, transvaginal NOSE is performed by gynecologic team. For the NOSE procedure, patients are placed in the Trendelenburg and lithotomy position. An approximately 1–2 cm incision is made at the posterior vaginal fornix through vaginal approach (posterior colpotomy), and laparoscopic forcep is introduced into the abdominal cavity through the colpotomy site. The thread of endopouch in the abdominal cavity is grasped by the laparoscopic forcep and taken down out of the body cavity through vagina. While pulling the thread down, the initial incision at the posterior vaginal fornix is laterally extended using finger enough for the specimen extraction. The specimen inside the endopouch is removed through the vagina exactly like the normal vaginal delivery of baby. Colpotomy closure is achieved transvaginally with a 2/0 absorbable suture. For this study, all procedures were performed by a single gynecologic surgeon.

Data collection

We collected clinicopathological data from the patients' medical records, such as age, body mass index (BMI), surgical history, history of keloid scars, perioperative outcomes including estimated blood loss, requirement of transfusion and hemoglobin level, pathologic reports, and treatment outcomes.

The primary endpoint was cosmetic outcomes of scars assessed using the Patient and Observer Scar Assessment Scale (POSAS) 1 and 8 weeks after surgery. POSAS is an internationally validated scar assessment questionnaire that measures the quality of a scar from the perspective of both patients and observers (5). The POSAS consists of two distinct scales: OSAS (Observer Scar Assessment Scale) and PSAS (Patient Scar Assessment Scale). The OSAS includes five variables: vascularity, pigmentation, thickness, relief, and pliability. The PSAS includes six variables: scar-related pain, itching, color, stiffness, thickness, and irregularity. Each scar characteristic has a 10-point scoring system ranging from the lowest score of 1, representing normal skin, to the highest score of 10, representing the largest difference from normal skin. The total score of both scales is calculated by summing the items, ranging from 5 to 50 for the OSAS and 6 to 60 for the PSAS. In addition, patients ranked their overall opinion of the scars ranging from 1 to 10, with 1 representing the best scar imaginable and 10 the worst scar imaginable. These were not included in the total score. For vaginal wound evaluation, we created a questionnaire consisting of three items: vaginal bleeding, discharge, and pain. Each item was graded on a 3-point scale ranging from 1 (minimal symptoms) to 3 (maximum symptoms). The total score represented the addition of scores for all items ranging from three to nine.

The secondary outcomes were total duration of operating time, operating time for transvaginal NOSE, postoperative pain, postoperative complications, and analgesic needs 2, 6, 24, and 48 h after surgery. Six months after surgery, sexual function was assessed using the Female Sexual Function Index (FSFI) questionnaire. The FSFI consists of 19 items that measure female sexual function in six domains: desire, arousal, lubrication, orgasm, satisfaction, and pain (6). The total score is the sum of six domains, with a maximum score of 36. The lower scores represent worse sexual function. A total score of 21 has been validated as the cutoff score for the diagnosis of female sexual dysfunction (6).

Statistical analysis

The normality of the distribution was determined using the Kolmogorov-Smirnov test. Student's *t*-test and Mann-Whitney *U* test were used to compare continuous parametric and non-parametric variables, respectively. Pearson's chi-square test or Fisher's exact test was used to compare categorical variables. All analyses were performed using the SPSS software for Windows (version 25.0; SPSS Inc., Chicago, IL, USA). Statistical significance was set at $p < 0.05$.

Results

Sixty patients were assessed for eligibility, and 9 patients were excluded due to withdrawal of consent and cancellation of the operation (Fig. 1). Among 51 patients, 8 (15.7%) patients failed to undergo the transvaginal NOSE procedure in unexpected circumstances such as difficulty in the vaginal approach due to vaginal stenosis, the presence of a bulky specimen, and severe adhesion. Of the 43 enrolled patients, five withdrew from the study because of loss to follow-up or prolonged postoperative intensive care unit stay. Finally, 38 patients completed the 6-months follow up.

Baseline demographics and characteristics are shown in Table 1. The mean age and body mass index (BMI) were 57.6 (14.1) and 23.5 (2.7). Thirteen (34.2%) and 1 (2.6%) patients had a history of abdominal surgery and keloids, respectively. The transvaginal NOSE procedure was performed to extract 33 kidneys, 2 livers, 1 stomach, 1 adrenal gland, and 1 bladder tissue. Histopathology was identified as benign in 8 (21.1%) and malignant in 30 (78.9%) patients. Of the 30 patients with malignant disease, 3 (10.0%) experienced recurrence other than at the vaginal site during a median length of observation of 32.3 months (range, 7.2–73.1 months).

Table 1
Characteristics of overall patients (n = 38)

Characteristics	Value
Age, years	57.6 ± 14.1
BMI, kg/m^2	23.5 ± 2.7
Previous abdominal surgery	13 (34.2)
Previous keloid history	1 (2.6)
Extracted specimen	
Kidney	33 (86.8)
Liver	2 (5.3)
Stomach	1 (2.6)
Adrenal gland	1 (2.6)
Bladder	1 (2.6)
Histopathology	
Benign	8 (21.1)
Malignant	30 (78.9)
Recurrence in Malignant disease	
Yes	3 (10.0)
No	27 (10.0)
BMI, body mass index	
Values are presented as mean ± standard deviation or n (%) unless otherwise indicated.	

The surgical outcomes are described in Table 2. The mean (± standard deviation [SD]) total operation duration and operative time for the transvaginal NOSE procedure were 233.8 ± 78.2 minutes and 28.3 ± 13.3 minutes, respectively. The mean (± SD) estimated blood loss was 163.7 ± 162.0 mL, and blood transfusions were required in 4 (10.5%) and 8 (21.1%) patients intraoperatively and postoperatively, respectively. The mean drop of hemoglobin was 1.1 ± 1.4 g/dL before and 24 h after operation. The median number of trocar ports was 5 (range, 2–5) with a mean (± SD) incision length of 1.4 ± 0.3 cm. Analgesic consumption was similar until 48 h, but the Visual Analog Scale (VAS) score gradually improved from moderate to mild pain. No intraoperative complications occurred; however, 2 patients had early postoperative complications and 1 patient had late postoperative complications which were not

associated with the transvaginal NOSE procedure. The mean (± SD) gas passing and hospital stay days were 2.2 ± 1.0 days and 6.7 ± 1.7 days, respectively.

Table 2
Surgical outcomes (n = 38)

Variable	Value
Operating time, min	233.8 ± 78.2
Transvaginal NOSE time, min	28.3 ± 13.3
Estimated blood loss, mL	163.7 ± 162.0
Transfusion	
Intraoperative	4 (10.5)
Postoperative	8 (21.1)
Hemoglobin level, g/dL	
Preoperative	12.1 ± 1.6
Postoperative	10.9 ± 1.3
Preoperative-postoperative	1.1 ± 1.4
Scar	
Port number, median (range)	5 (2–5)
Incision length, cm	1.4 ± 0.3
2hour postoperative period	
VAS	5.3 ± 2.1
PCA amount, mL	6.9 ± 6.7
Painkiller consumption	9 (23.7)
6hour postoperative period	
VAS	4.9 ± 1.8
PCA amount, mL	11.5 ± 4.3
Painkiller consumption	8 (21.1)
24hour postoperative period	
VAS	3.5 ± 1.8
PCA amount, mL	29.4 ± 12.1
Painkiller consumption	12 (31.6)
NOSE, natural orifice specimen extraction; VAS, visual analog scale; PCA, patient-controlled analgesia	
Values are presented as mean ± standard deviation or n (%) unless otherwise indicated.	

Variable	Value
48hour postoperative period	
VAS	2.5 ± 1.5
PCA amount, mL	52.3 ± 19.3
Painkiller consumption	9 (23.7)
Postoperative complication	3 (7.9)
Acute kidney injury	1 (2.6)
Delirium	1 (2.6)
Epidermal cyst	1 (2.6)
Postoperative recovery	
Gas passing day	2.2 ± 1.0
Hospital stay, day	6.7 ± 1.7
NOSE, natural orifice specimen extraction; VAS, visual analog scale; PCA, patient-controlled analgesia	
Values are presented as mean ± standard deviation or n (%) unless otherwise indicated.	

Observers rated the scores of pigmentation and relief as most deviant from normal skin (2.9 ± 1.7, 3.0 ± 2.1 at postoperative 1 week; 3.6 ± 1.9, 3.5 ± 2.2 at postoperative 8 weeks, respectively), but the overall scores of each items were low (Table 3, Fig. 2A). The patients' overall satisfaction regarding postoperative scars was high (3.4 ± 2.5 at postoperative 1 week; 3.2 ± 2.2 at postoperative 8 weeks) and the mean scores of pain and itching were low with improvement between 1 week and 8 weeks (P = 0.014, P = 0.006, respectively) (Table 3, Fig. 2B). Patients also reported low scores for vaginal assessment items, and bleeding improved significantly between the two time points (P = 0.001) (Table 3, Fig. 2C). Seventeen patients who underwent vaginal NOSE were sexually active at the time of the surgery. The mean FSFI total score was 21.2 ± 8.7, above the cutoff for sexual dysfunction (defined as 21) (Table 4).

Table 3
Postoperative scar assessments

Variables	Postoperative 1 week	Postoperative 8 weeks	*P* value
OSAS*			
Vascularity	1.8 ± 1.2	1.4 ± 0.9	0.082[b]
Pigmentation	2.9 ± 1.7	3.6 ± 1.9	0.048[b]
Thickness	2.8 ± 1.6	3.2 ± 2.1	0.635[b]
Relief	3.0 ± 2.1	3.5 ± 2.2	0.251[b]
Pliability	2.6 ± 1.9	2.5 ± 1.6	0.558[b]
Total score	13.0 ± 7.1	14.1 ± 7.4	0.825[b]
PSAS*			
Pain	2.2 ± 1.6	1.5 ± 1.3	0.014[b]
Itching	2.6 ± 1.6	1.6 ± 1.1	0.006[b]
Color difference	3.7 ± 2.3	3.5 ± 2.3	0.767[a]
Stiffness	3.7 ± 2.2	3.3 ± 2.0	0.525[a]
Thickness	3.2 ± 2.1	3.0 ± 2.0	0.766[a]
Irregularity	3.5 ± 2.3	2.8 ± 1.8	0.057[a]
Total score	18.9 ± 9.3	15.7 ± 8.2	0.053[a]
Overall opinion	3.4 ± 2.5	3.0 ± 2.2	0.314[a]
Vaginal complications†			
Bleeding	1.4 ± 0.5	1.1 ± 0.2	0.001[b]
Discharge	1.3 ± 0.5	1.3 ± 0.5	> 0.999 [b]
Pain	1.2 ± 0.4	1.0 ± 0.2	0.096 [b]
Total score	3.9 ± 1.1	3.4 ± 0.6	0.006[b]
OSAS, observer scar assessment scale; VAS, visual analog scale; PSAS, patient scar assessment scale; PVSAS, patient vaginal scar assessment scale			
Values are presented as mean ± standard deviation.			

Variables	Postoperative 1 week	Postoperative 8 weeks	*P* value
[a] P values were calculated by paired t-test			
[b] P values were calculated by Wilcoxon signed rank test			
* Each scar characteristics of scar assessment scale has a 10-point scoring system ranges from lowest score 1 representing the situation of normal skin to highest score 10 representing largest difference from normal skin.			
† Each items graded on a 3-point scale ranging from 1 indicating minimal symptoms to 3 indicating maximum symptoms.			

Table 4
Postoperative sexual function assessments (n = 38)

Variables (score range)	Value
Sexually active women	17 (44.7)
FSFI*	
Desire (1.2-6)	2.6 ± 0.9
Arousal (0–6)	4.1 ± 1.7
Lubrication (0–6)	3.4 ± 1.8
Orgasm (0–6)	3.6 ± 1.9
Satisfaction (0.8-6)	4.5 ± 1.8
Pain (0–6)	3.0 ± 1.8
Total score (2–36)	21.2 ± 8.7
FSFI, female sexual function index	
Values are presented as mean ± standard deviation or n (%) unless otherwise indicated.	
* FSFI consist of 19 items that measures female sexual function in 6 domains. The total score is a maximum score of 36 with lower scores representing poor sexual function.	

Discussion

Our study showed that transvaginal NOSE is a feasible and safe procedure for extracting large-organ specimens for both benign and malignant diseases in patients undergoing multiport laparoscopic surgery. Compared to open surgery, the laparoscopic approach generally results in less postoperative pain, shorter recovery time, and improved cosmetic outcomes (7). However, multiport laparoscopic surgery often requires an additional or enlarged abdominal wall incision for specimen extraction.

Enlargement of the abdominal wall incision can lead to postoperative complications, including postoperative pain, surgical site infections, incisional hernias, and cosmetic problems (2, 3). NOSE can address these problems when surgeons incorporate it into existing minimally invasive surgical procedures.

Previous studies have shown that NOSE results in faster recovery, shorter hospital stay, better postoperative pain control, fewer incisional complications, and improved cosmesis (4). In addition, NOSE can resolve the difficulty in transabdominal specimen removal in patients with deep abdominal walls (8). Although the feasibility of NOSE has been demonstrated, some potential concerns remain.

One of the main concerns when extracting malignant disease specimens via transvaginal NOSE is the fear of implantation of tumor cells within the vaginal extraction site. Consistent with our results, other studies have reported that NOSE is safe for malignant diseases. A systematic review concluded that there was no significant difference in oncologic outcomes between NOSE and abdominal incision groups (9). One study reported similar overall survival and disease-free survival between the two approaches, and another study reported no tumor implantation problems during the follow-up period after the NOSE procedure (10, 11). The use of a protective bag before specimen extraction would reduce the risk of cancer cell implantation.

Another major concern of transvaginal NOSE is the possibility of postoperative sexual dysfunction. Previous studies evaluating transvaginal NOSE in laparoscopic nephrectomy and nephroureterectomy reported there were no significant changes in sexual function (12, 13). Our study showed low FSFI scores, however, still higher than the cutoff of 21 for sexual dysfunction. We did not measure the preoperative FSFI score; therefore, it is difficult to determine whether the procedure lowered the score from baseline. In a study conducted on patients who underwent transvaginal NOSE in laparoscopic partial or radical nephrectomy, the mean preoperative and postoperative FSFI scores were 21.6 and 21.8 respectively, which were similar to the scores in our study (11). As innervation in the posterior vaginal fornix is sparse, transvaginal NOSE may not affect sexual impulses or cause dyspareunia.

In addition, consistent with our results, most previous studies have reported that postoperative infections were not related to posterior colpotomy and transvaginal extraction (14–16). Conversely, the complication of vaginal abscess has been reported after transvaginal NOSE procedure following laparoscopic myomectomy (17, 18). However, the authors explained that the abscess could be attributed to the adhesion barrier used during surgery. Theoretically, increased exposure time of the abdominal cavity to vaginal cavity during NOSE procedure might cause possible contamination by vaginal microorganisms. However, this concern could be dismissed because the positive intraabdominal pressure generated by pneumoperitoneum may prevent peritoneal bacterial contamination (2).

Our study has some limitations. First, transvaginal NOSE was performed by a single surgeon with advanced experience in vaginal surgery. Therefore, it may not be applicable to surgeons who are not urogynecological surgeons. Second, to minimize dropouts due to the burden of completing the questionnaires, we did not perform a preoperative FSFI questionnaire, which limited the evaluation of

sexual function. Finally, the specimen size, which we did not measure, may be a restriction in applying the transvaginal NOSE procedure. However, in other studies, specimen mass size was not an important determinant of the success of NOSE (19, 20).

Conclusions

Due to the widespread advancement of laparoscopic and robotic surgery in recent years, most surgeons have experience in minimally invasive surgery, which has led to the development of NOSE procedures. In performing transvaginal NOSE, we found that the procedure is safe, feasible, and resulted in good cosmetic results and other outcomes, even in cases with malignant diseases, when combined with (robot-assisted) laparoscopic surgery that required extraction of bulky specimens.

Abbreviations

NOSE, natural orifice specimen extraction

POSAS, Patient and Observer Scar Assessment Scale

OSAS, Observer Scar Assessment Scale

PSAS, Patient Scar Assessment Scale

FSFI, Female Sexual Function Index

BMI, body mass index

VAS, visual analog scale

SD, standard deviation

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of Seoul National University Bundang Hospital (No. B-1411-276-005) and was performed in accordance with the principles of the Declaration of Helsinki. All patients were adequately informed of the benefits and risks of the procedure and written consent was obtained prior to the surgical procedure. This trial was registered at ClinicalTrials.gov (NCT05113134) at 09/11/2021.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Conceptualization: SDH, LS; Methodology: HWY, SDH, LS; Formal analysis and investigation: HWY, SDH; Writing-original draft preparation: HWY; Writing-review and editing: HWY, SDH, LS; Funding acquisition: SDH; Supervision: SDH, LS

All authors read and approved the final manuscript.

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Not applicable

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Figures

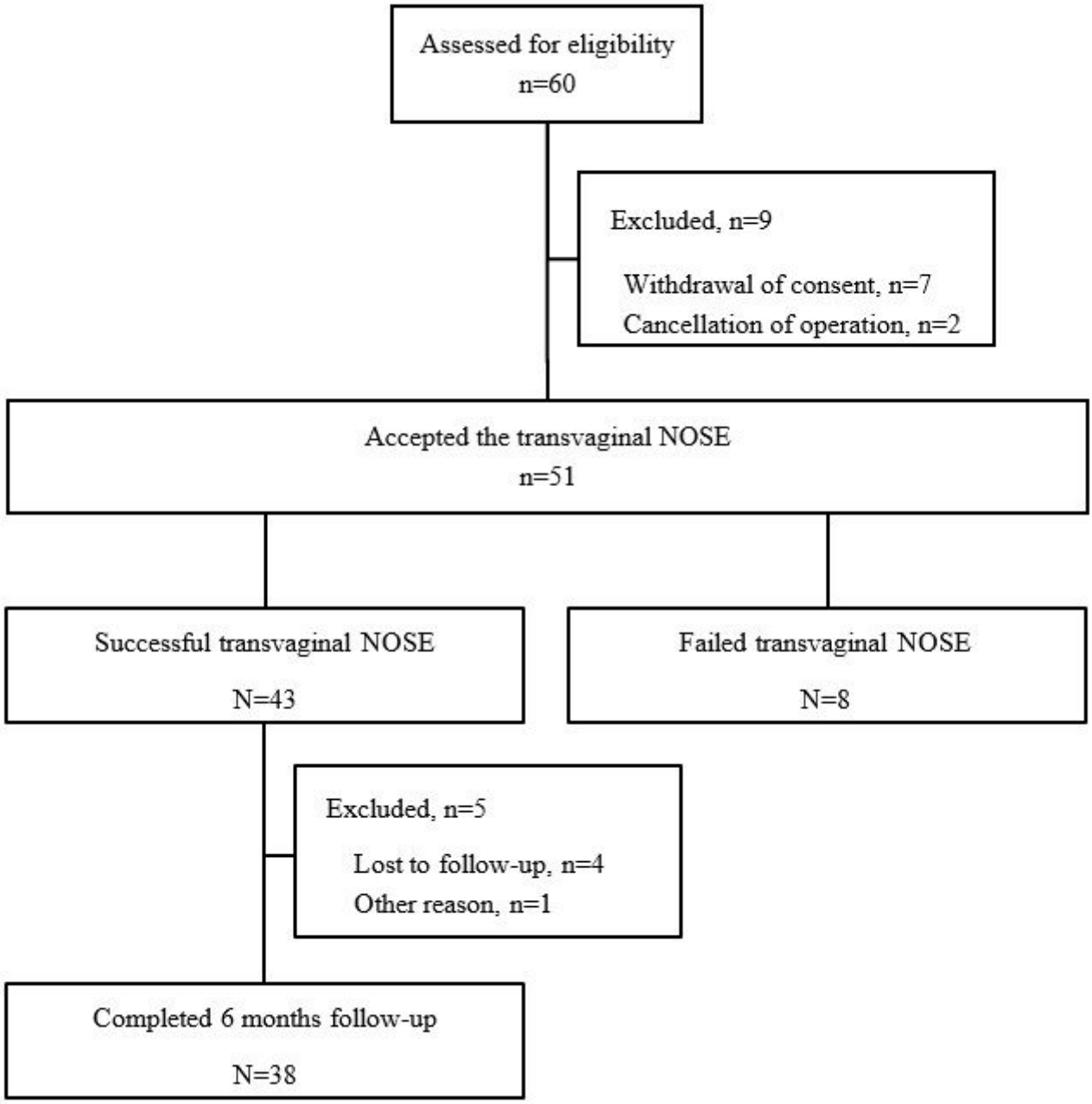

Figure 1

Study flow chart

NOSE, natural orifice specimen extraction

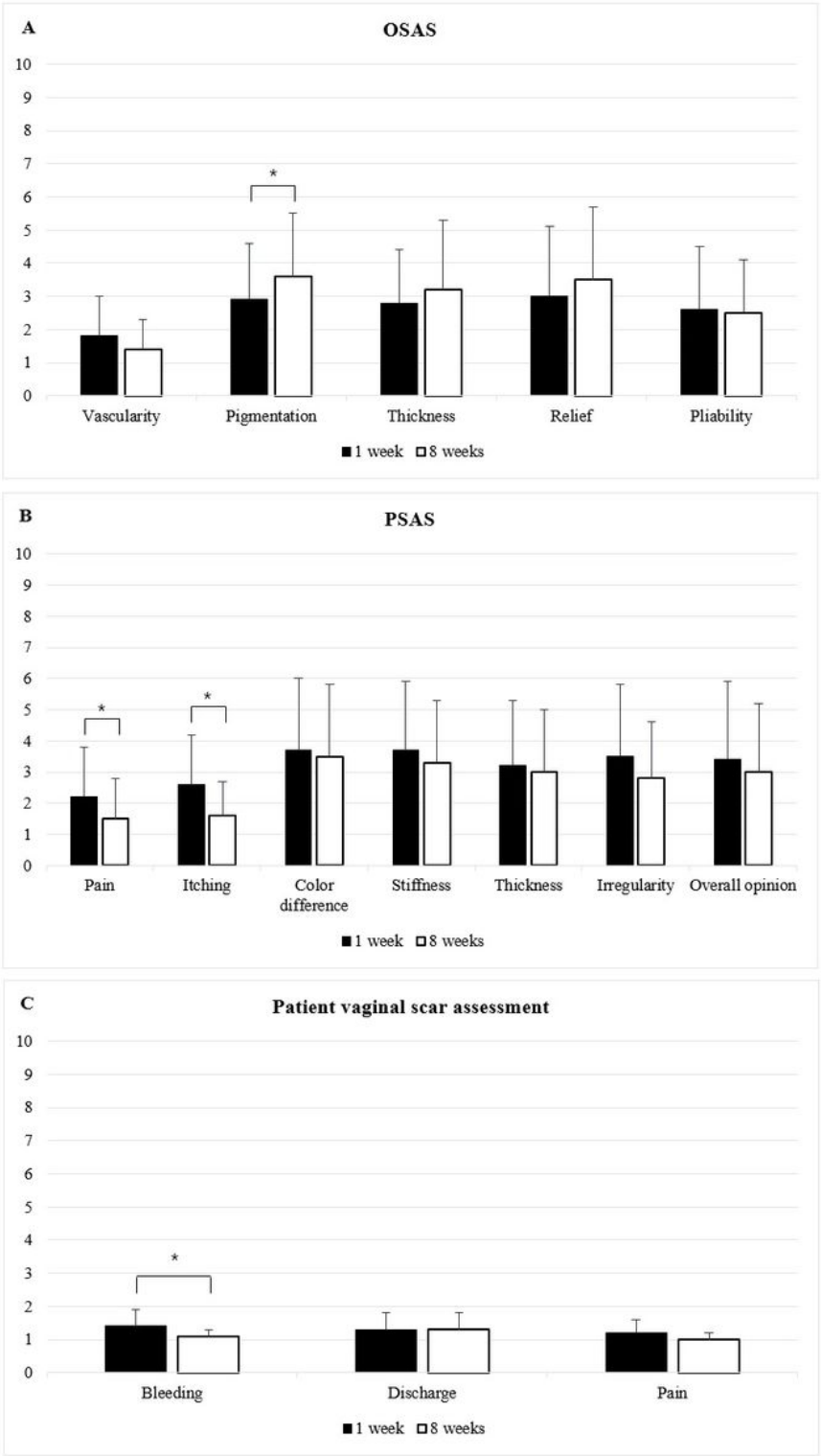

Figure 2

Scar assessments

(A) Observer scar assessment scale at 1 week and 8 weeks after surgery (mean ± standard deviation). (B) Patient scar assessment scale at 1 week and 8 weeks after surgery (mean ± standard deviation). (C)

Patient vaginal scar assessment at 1 week and 8 weeks after surgery (mean ± standard deviation). OSAS, Observer Scar Assessment Scale; PSAS, Patient Scar Assessment Scale