

Transvaginal Natural Orifice Transluminal Endoscopic Surgery for Uterosacral Ligament Suspension: a Pilot Study of 35 Cases with Severe Pelvic Organ Prolapse

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Abstract

Background To describe the short-term outcomes of transvaginal natural orifice transluminal endoscopic surgery (vNOTES) for uterosacral ligament suspension (USLS) in patients with severe prolapse.

Methods This is a retrospective study conducted for patients with severe prolapsed (\geq stage 3) who underwent vNOTES USLS between May 2019 and July 2020. The Pelvic Organ Prolapse Quantification (POP-Q) score, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form (PISQ-12) and Pelvic Floor Inventory-20 (PFDI-20) were used to evaluate physical prolapse and quality of life before and after vNOTES USLS.

Results A total of 35 patients were included. The mean operative time was 111.7 ± 39.4 minutes. The mean blood loss was 67.9 ± 35.8 ml. Statistically significant differences were observed before and after vNOTES USLS in regard to Aa ($+0.6 \pm 1.7$ versus -2.9 ± 0.2), Ba ($+1.9 \pm 2.2$ versus -2.9 ± 0.3), C ($+1.5 \pm 2.2$ versus -6.9 ± 0.9), Ap (-1.4 ± 1.0 versus -3.0 ± 0.1) and Bp (-1.1 ± 1.4 versus -2.9 ± 0.1) ($P < 0.05$ for all). The mean pre- and post-operative PFDI-20 score was 19.9 ± 6.7 versus 3.2 ± 5.4 , and the PISQ-12 score was 24.8 ± 2.3 versus 38.3 ± 4.1 ($P < 0.05$ for both). During 1–13 months of follow-up, no severe complications or recurrence.

Conclusions vNOTES USLS may be a feasible technique to manage severe prolapse, with promising short-term efficacy and safety data. However, a study with a larger number of patients and a longer follow-up period should be conducted.

Background

Pelvic organ prolapse (POP) is a common benign condition with a high occurrence risk of 40–60% in elderly women [1] and a reported lifetime risk for surgical intervention of 10–20% [2]. The gold-standard surgical treatment for POP is resuspension of the pelvic anatomy by native tissue repair or mesh repair. The placement of mesh might result in high rates of surgical complications and postoperative adverse events [3]. On 16 April 2019, the transvaginal repair products were withdrawn from the market by the FDA [4]. Native tissue repair has received increasing attention in reconstructive pelvic surgery. Uterosacral ligament suspension (USLS) is a commonly performed procedure to support the vaginal apex [5].

However, the traditional vaginal approach (vaginal USLS) or an abdominal approach via laparoscopy makes USLS more effective in patients with stage II prolapse, while it is not optimal for patients with more severe prolapse [6]. This may be attributed to 1) the poor visibility in vaginal USLS, limiting the operative precision of the surgeon [7, 8]; and 2) the fact that the abdominal approach via laparoscopy cannot confirm the tensile strength of the uterosacral ligaments. Surgeons have long been looking for a better approach with a pronounced effect and low complication rates.

The advent of transvaginal natural orifice transluminal endoscopic surgery (vNOTES) perfectly meets the criterion of minimally invasive surgery and overcomes the dilemma of the traditional vaginal approach or

abdominal approach via laparoscopy. In this study, we performed USLS for POP using the vNOTES approach. Our objective was to describe the short-term outcomes of vNOTES USLS in patients with severe apical and anterior prolapse.

Methods

Patients

We retrospectively collected data on all cases of vNOTES USLS at the Obstetrics and Gynecology Hospital of Fudan University between May 2019 and July 2020. The inclusion criteria were as follows: 1) patients aged 25–79 years old, 2) severe apical and anterior prolapse (\geq stage 3), 3) patients desiring preserved coital function, 4) first surgical treatment for POP, and 5) patients refusing mesh implantation. The exclusion criteria were as follows: 1) patients who could not tolerate surgery, 2) coagulation dysfunction, 3) severe vaginal ulcers, 4) a history of severe adhesions, a fixed uterus or strong pelvic adhesions noted upon pelvic examination, 5) patients who could not tolerate the Trendelenburg position, 6) relapsed patients who underwent previous POP repair surgery, and 7) suspicion of gynaecologic malignancy. This retrospective study was approved by our institutional review board before any data collection (no. 2019–32).

We extracted the following information from medical records: patient demographics (age, body mass index, parity, and history of prior hysterectomy or prolapse repair) and perioperative outcomes. Perioperative data included the operative time, blood loss, intraoperative complications (transfusion and injury), postoperative complications (infection, urinary retention, persistent pain, haematoma, constipation, dyspareunia, de novo stress urinary incontinence and deep vein thrombosis), postoperative hospital stay, and hospitalization costs. We also assessed the change in physical prolapse with Pelvic Organ Prolapse Quantification (POP-Q). Two validated questionnaires, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form (PISQ-12) and Pelvic Floor Inventory-20 (PFDI-20), were completed before and after (at least 3 months postoperatively) vNOTES USLS to assess the impact on quality of life. Postoperative follow-up visits were scheduled at 1 months, 3 months, 6 months, 1 year and 2 years after surgery. Any POP-Q scores more than or equal to -1 cm were defined as recurrence [9].

Surgical procedures

All participants received general anesthesia and underwent standard operative care. Patients with hysterectomy received 1.5 g cefuroxime preoperatively (dosed by weight). A single-port device with four trocars (HTKD-Med, China) was inserted through the vagina. Laparoscopic instruments were then inserted through the port: a 30° 10-mm laparoscope, 5-mm for traumatic or atraumatic graspers, ultrasound knife (Harmonic), a 5-mm Ligasure vessel-sealing system (Covidien, Valleylab), needle holder, and so on. Non-absorbable sutures (2 – 0, Ethicon LLC, America) were used.

Hysterectomy with USLS

This surgical procedure was originally described by Lowenstein et al in 2019 [10]. Bilateral salpingo-oophorectomy (BSO) was performed for patients in whom it was indicated.

Fertility-preserving USLS

The single-port platform was placed from the vaginal orifice to the pelvic cavity through the posterior fornix. In these cases, apical support was attained by suturing the uterosacral ligaments, shortening the ligaments and reinforcing their attachment to the cervix.

Uterine-preserving USLS

For patients who desire preservation of the uterus without fertility requirements, part of the cervix can be cut off according to the degree of cervical extension, and finally, the cervix can be reconstructed. The other procedures are the same as those of fertility-preserving USLS.

Anterior and posterior colporrhaphies were performed at the discretion of the operating surgeon such that points Aa, Ba, Ap and Bp were less than or equal to -1 cm (i.e., anterior and posterior vaginal points located at least 1 cm above the hymen) at the end of the procedure. Colporrhaphies, when performed, were performed with 2 – 0 or 0 delayed absorbable sutures. The placement of a tension-free mid-urethral sling was allowed according to the presence of preoperative stress urinary incontinence (SUI).

After surgery, routine postoperative care was provided. Cefuroxime was repeated once postoperatively in patients with hysterectomy. the longest duration of follow-up to date is 13 months.

Statistical analysis

Data collection and statistical analyses were performed using IBM SPSS Statistics 24.0 software (IBM Corp., Armonk, New York, USA). All the variables were presented as the mean and standard deviation (SD), or n and percentage (%). Continuous variables were compared using parametric Student's t test. A P value < .05 was considered statistically significant.

Results

In total, 35 patients underwent vNOTES USLS; in one patient, vNOTES sacrocolpopexy was planned, but the patient was converted to vNOTES USLS because of a suspected malignant lesion on the surface of the colon. The patient characteristics are shown in Table 1. One patient underwent previous POP surgery, where only total hysterectomy was performed, without any repair. Thirty-three patients (94.3%) had stage III prolapse, and the other two patients (5.7%) had stage IV prolapse.

Table 1
Patient characteristics.

Variable	Values
Number	35
Age (years)	53.7 ± 11.4
BMI (kg/m ²)	24.0 ± 3.3
Parity	1.6 ± 0.8
Diabetes mellitus	1 (2.9)
Smoker	0
Prior hysterectomy	1 (2.9)
Prior prolapse repair	1 (2.9)
Prolapse stage	
Anterior	2.5 ± 0.7
Apical	2.6 ± 0.7
Posterior	1.4 ± 0.6
Baseline POP-Q stage	
III	33 (94.3)
IV	2 (5.7)
Values are mean ± standard deviation or n (%).	
BMI: body mass index; POP-Q: Pelvic Organ Prolapse Quantification.	

Table 2 shows the perioperative outcomes and complications. Twenty patients (57.1%) underwent hysterectomy, 10 of whom underwent simultaneous BSO as indicated. Two patients (5.7%) preserved fertility, and 12 patients (34.3%) preserved uterus. Three patients had concomitant TVT-A. The mean operative time was 111.7 ± 39.4 min. The mean blood loss was 67.9 ± 35.8 ml. The mean duration of postoperative hospital stay was 3.7 ± 1.1 days. The mean hospitalization cost was 3408.9 ± 592.6 dollars.

Table 2
 Perioperative and short-term outcomes (n = 35).

Variable	Values
Intraoperative hysterectomy	20 (57.1)
Preserve fertility	2 (5.7)
Preserve uterus	12 (34.3)
Operative time (min)	111.7 ± 39.4
Blood loss (ml)	67.9 ± 35.8
Postoperative hospital stay (days)	3.7 ± 1.1
Hospitalization costs (USD)	3408.9 ± 592.6
Overall complications	3
Patients occurred complications	3(8.6)
Intraoperative complications	
Transfusion	0
Injury	0
Postoperative complications	
Infection	1 (2.9)
Urinary retention	1 (2.9)
Persistent pain	0
Hematoma	0
Constipation	1 (2.9)
Dyspareunia	0
De novo SUI	2 (5.7)
Deep vein thrombosis	0
Follow-up time (months)	3.9 ± 3.8(1–13)
Recurrence	0
Values are mean ± standard deviation (range) or n (%).	

There were no intraoperative complications of blood transfusion or injury (Table 2). In total, 3 postoperative complications occurred among 3 patients (8.6%). One patient (2.9%) developed urinary tract infection, was positive for *Escherichia coli*, and was cured after anti-infection treatment. One patient

(2.9%) developed postoperative urinary retention, so she underwent urine catheterization. She was cured after acupuncture treatment for 3 days. One patient (2.9%) suffered from constipation, which was relieved with glycerine enema. There were no postoperative complications of de novo SUI, deep vein thrombosis, persistent pain, haematoma or dyspareunia. The mean follow-up time was 3.9 ± 3.8 (1–13) months. No patients had obvious recurrence.

Table 3–5 show the changes in POP-Q, PFDI-20 and PISQ-12 scores respectively, which were the latest follow-up examination results of each patient. All variables except total vaginal length (TVL) in Table 3 showed significant improvement in physical prolapse after surgery. Seventeen patients (48.6%) were followed for more than 3 months and completed the PFDI-20 (Table 4). The POPDI-6, CRADI8, UDI-6 and total PFDI-20 scores were significantly decreased after surgery, indicating notable symptom alleviation (relating to pelvic, urinary and colorectal symptoms). Nine patients (25.7%) had recovered their sexual life and completed the PISQ-12 (Table 5). The PISQ-12 score was significantly increased after surgery, indicating notable improvements in quality of sexual life.

Table 3
Change in POP-Q score (n = 35).

Variable	Preoperative	Postoperative	P
Aa	+ 0.6 ± 1.7	-2.9 ± 0.2	0.000*
Ba	+ 1.9 ± 2.2	-2.9 ± 0.3	0.000*
C	+ 1.5 ± 2.2	-6.9 ± 0.9	0.000*
Ap	-1.4 ± 1.0	-3.0 ± 0.1	0.000*
Bp	-1.1 ± 1.4	-2.9 ± 0.1	0.000*
TVL	+ 7.4 ± 0.5	+ 7.2 ± 0.4	0.058
Values are mean ± standard deviation. *P < 0.05 was statistically significant.			
POP-Q: Pelvic Organ Prolapse Quantification. TVL: total vaginal length.			

Table 4
Change in PFDI-20 score (n = 17).

Variable	Preoperative	Postoperative	P
Quality of life			
POPDI-6	9.9 ± 3.5	0.9 ± 1.9	0.000*
CRADI-8	2.5 ± 3.0	0.7 ± 2.1	0.047*
UDI-6	7.5 ± 4.4	1.6 ± 2.8	0.000*
Total PFDI-20	19.9 ± 6.7	3.2 ± 5.4	0.000*
Values are mean ± standard deviation. *P < 0.05 was statistically significant.			
POPDI-6: Pelvic Organ Prolapse Distress Inventory 6.			
CRADI-8: Colorectal Anal Distress Inventory 8.			
UDI-6: Urinary Distress Inventory 6.			
PFDI-20: Pelvic Floor Distress Inventory 20.			

Table 5
Change in PISQ-12 score (n = 9).

Variable	Preoperative	Postoperative	P
PISQ-12	24.8 ± 2.3	38.3 ± 4.1	0.000*
Values are mean ± standard deviation. *P < 0.05 was statistically significant.			
PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form.			

Discussion

In the present study, vNOTES USLS showed marked improvement in both anatomic prolapse and quality of life without conversion or serious peri- or postoperative complications. These information suggest that vNOTES USLS may be a feasible technique for treating severe POP.

USLS is a classic surgical method for the treatment of middle compartment POP. Lavelle et al described uterosacral ligament suspension performed vaginally or traditionally via laparoscopy, resulting in a higher prolapse recurrence rate than sacrocolpopexy for stage III prolapse [6]. vNOTES provides direct visualization of the uterosacral ligaments and important organs, such as the ureter and rectum, which results in operative precision by the surgeon. Precise surgery often leads to satisfactory results. Additionally, this approach provides a chance to pull down the sutured uterosacral ligament to further confirm the tensile strength of the suspension. This may be the key step for this procedure to be suitable

for patients with severe prolapse. vNOTES USLS in this study presents good short-term efficacy in both anatomic prolapse and quality of life, without serious complications.

vNOTES decreases the risk of abdominal wound infection because of the absence of incisions on the abdomen [10, 11]. However, infection remains the most concerning complication after transvaginal laparoscopic surgery [12]. In this study, we took the following measures to avoid infection. First, prophylactic antibiotics were administered: cefuroxime half an hour before the operation until the day of the operation. Second, the repeated demolition and construction of a vaginal single hole platform were reduced. Third, the pelvic cavity was washed with normal saline after the pelvic operation to reduce the bacterial load. In this study, there were no serious infections except a urinary tract infection, which was cured after anti-infection treatment. Our preventive measures could be effective. This is in accordance with the opinion of Linke, indicating a low risk of peritoneal contamination caused by transvaginal access [12].

Postoperative urinary retention is a common complication after POP surgery [13]. Houlihan et al reported that the rate was 31% in vaginal USLS and 15% in laparoscopic USLS [14]. In this study, the rate was 2.9%. Good visualization under vNOTES played a big role. The patient was cured after 3 days of acupuncture and moxibustion. De novo SUI is another common complication of prolapse surgery [15]. Occult SUI may be originally covered by prolapsed organs. De novo SUI appeared after the anatomic deconstruction was restored. Fortunately, there were no de novo SUIs in this study. Studies with a longer follow-up period should be conducted. Another patient had difficulty defecating, which may be related to the limited postoperative activity.

Sexual activity was suggested to be restored 3 months after surgery in this study. However, only nine of the 17 patients recovered their sexual life. The main reasons were as follows. 1) The patients were older with less of a need for sex. This is different from that in western countries. The sexual needs of Chinese women decrease rapidly with age, especially after the age of 50 [16]. 2) Patients fear that sex will cause prolapse recurrence. Compared with sacrocolpopexy in our hospital [17], with this approach, the postoperative hospital stay was shorter, and the hospitalization cost was lower, which significantly reduces the national medical insurance cost. The main reasons were as follows: 1) fewer complications; and 2) no price for the mesh.

This study has several limitations. First, the follow-up time was relatively short, and the sample size was limited. Second, most of our patients were perimenopausal or postmenopausal women, and only 8 (< 45 y) of 35 participants (22%) were sexually active before surgery, limiting the ability to evaluate postoperative sexual function and dyspareunia. Moreover, it is difficult for Chinese people to talk about their sex lives, so the patients had poor cooperation in the investigation of sexual quality of life.

Conclusions

vNOTES USLS, with promising short-term efficacy and safety data, may be a feasible technique for severe prolapse. Hence, additional studies with a larger number of patients and a longer follow-up period should

be conducted.

Abbreviations

vNOTES

transvaginal natural orifice transluminal endoscopic surgery

USLS

uterosacral ligament suspension

POP-Q

Pelvic Organ Prolapse Quantification.

PISQ-12

Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form

PFDI-20

Pelvic Floor Inventory-20

TVL

total vaginal length.

POP

pelvic organ prolapse

SUI

stress urinary incontinence

BSO

bilateral salpingo-oophorectomy

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Obstetrics and Gynecology Hospital of Fudan University (no. 2019–32).

Consent for publication

Consent for publication have been obtained.

Competing interests

None

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None

Authors' contributions

All authors have read and approved the manuscript.

ZYL: patient recruitment, data collection and analysis, manuscript writing.

YSC: data collection and analysis, statistical analysis, and manuscript writing.

XJW: patient recruitment, data collection.

JWL: patient recruitment, data collection.

KQH: study design, patient recruitment, data collection.

CDH: study design, patient recruitment, responsible surgeon.

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