

Original Article

# Hysterectomy via transvaginal natural orifice transluminal endoscopic surgery (NOTES): Feasibility of an innovative approach

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## Abstract

**Objective:** To evaluate the feasibility and safety of performing a hysterectomy using the transvaginal natural orifice transluminal endoscopic surgery (NOTES).

**Materials and Methods:** From May through December 2010, 16 patients with benign uterine diseases who were eligible for laparoscopic hysterectomy were recruited to undergo transvaginal NOTES at a tertiary referral medical center. Intraoperative and postoperative surgical outcomes were measured.

**Results:** All of the included hysterectomies were completed via transvaginal NOTES without conversion to conventional laparoscopy. The mean ( $\pm$  standard error of mean (SEM)) uterine weight was  $538.8 \pm 102.9$  g, the mean operative time was  $122.7 \pm 17.6$  minutes, and the mean blood loss was  $379.4 \pm 95.4$  mL. The mean postoperative hospital stay was  $2.8 \pm 0.2$  days. No intraoperative or postoperative complications were noted in this series.

**Conclusion:** Hysterectomy for the treatment of benign diseases can be feasibly carried out via transvaginal NOTES. However, prospective studies are needed to determine its full clinical applications.

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**Keywords:** hysterectomy; innovation surgery; natural orifice transluminal endoscopic surgery; NOTES

## Introduction

The concept of natural orifice transluminal endoscopic surgery (NOTES), which uses the natural orifices of the body as the surgical channels for endoscopy, is a new development in the field of minimally invasive surgery and it can be used to avoid injuring the abdominal wall. Recently, we performed the transvaginal NOTES by applying the techniques of laparoendoscopic single-site surgery (LESS) surgery via the

vaginal route, and we found that it can be used to carry out adnexal procedures in select patients [1].

Vaginal hysterectomy has been a convention in gynecology for hundreds of years and our daily practice [2]; however, its application is restricted by the poor visualization and limited space for manipulation, and that are especially notable uteri that present without descensus or with adhesions. Though it is still recommended as the route of choice [3], the use of vaginal hysterectomy declined after the rise of abdominal laparoscopic hysterectomy in the 1990s [4,5].

According to the findings in our previous report [1], we believe that our innovative approach of transvaginal NOTES can be feasibly applied to hysterectomy. The objective of this study was to evaluate its feasibility and safety and to determine if there are any additional advantages of NOTES over the conventional approach.

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## Materials and methods

### Patients

From May through December 2010, hysterectomies were performed using transvaginal NOTES in Chang Gung Memorial Hospital. Patients with benign uterine diseases who were eligible for laparoscopic hysterectomy were included. Exclusion criteria included virginity, international continence society (ICS) classification Stage III or IV uterine prolapse, uterus > 20 weeks of gestation,  $\geq 2$  previous cesarean deliveries, suspected severe endometriosis, and complete obliteration of the cul-de-sac noted at pelvic examination. On the contrary, obesity (body mass index  $\geq 30$  kg/m<sup>2</sup>) and no previous with vaginal deliveries were not considered as contraindications.

This study was reviewed and approved by the human investigational review board of Chang Gung Memorial Hospital. All patients who underwent surgery gave their informed written consent. All surgeries were performed by experienced gynecologic endoscopists.

### Surgical techniques

Under general anesthesia with endotracheal intubation, each patient was placed in the Trendelenburg position with their legs bandaged and supported in the stirrups. A 12-French Foley catheter was indwelled. Then, the hysterectomy was carried using the following steps.

- 1) *Circumcision of the uterine cervix and posterior colpotomy.* With tractions placed on the uterine cervix using two teneculums, each operation began with the circumcision of the vaginal mucosa around the cervix followed by a 3-cm posterior colpotomy, as is the case for conventional vaginal surgery. The anterior portion was carried out by pushing up the vaginal mucosa along with the uterine-cervical fascia at the anterior fornix. Unless the peritoneum between the bladder and the uterus could be identified and cut confidently, anterior colpotomy was not completed at this stage and was performed during the later laparoscopic phase. By exposing the extraperitoneal space along with the bilateral broad ligaments, the transverse cervical and the uterosacral ligament complexes were well exposed and then clamped and divided using a bipolar vessel sealer (Liga Sure Impact system; Covidien, Boulder, CO, USA).
- 2) *Establishing the vaginal channels for endoscopic surgery.* We used our established method as previously reported to create the vaginal ports for endoscopy [1]. In brief, a small-size Alexis wound retractor (Applied Medical Resources Corp., Rancho Santa Margarita, CA, USA) was inserted into vagina, and the outer rim was draped with a surgical glove into which one 10-mm and two 5-mm cannulas were inserted through the fingers of the glove. The endoscope we used was a 5-mm, 30-degree endoscope (KARL STORZ GmbH & Co. KG, Tuttlingen Germany),

and the energy source was a 5-mm bipolar Liga Sure system (Covidien) designed for laparoscopy.

- 3) *Endoscopic management of the uterine arteries and completion of the anterior colpotomy.* After adequate creation of pneumoperitoneum, the endoscope was inserted to explore the pelvis. The bilateral broad ligaments of the uterine vessels were identified by grasping the cervix and pushing toward the contralateral site with an endoscopic single-tooth tenaculum. Then, the uterine vessels were secured and divided using a bipolar vessel sealer (Fig. 1). Following the stump of the uterine arteries and the anterior margin of uterus, we were able to trace and identify the uterovesical junction from both the caudal and cephalic point of view. After dissecting the junction with laparoscopic scissors, the anterior colpotomy was completed under laparoscopic guidance (Fig. 2).
- 4) *Endoscopic management of the upper portion of the hysterectomy.* The remaining broad and round ligaments were secured and divided step-by-step using the Liga Sure bipolar forceps. If the adnexa were preserved, the tubo-ovarian pedicles were divided (Fig. 3). If the adnexa were removed, the bilateral infundibulopelvic ligaments are clamped, secured, and divided. After clearing all of the pedicles, the uterus was removed through the vagina (Fig. 4).

Finally, the vaginal cuff was closed using 2-0 Vicryl sutures and the operation was concluded after a routine diagnostic cystoscopy.

### Treatment protocol

Prophylactic antibiotics were administered along with preoperative cefazolin, and postoperative cefazolin and gentamicin were administered for 1 day. No additional oral antibiotics were prescribed without evidence of infection. Nonsteroidal anti-inflammatory drugs were routinely prescribed after the operation, and 30 mg nalbuphine was

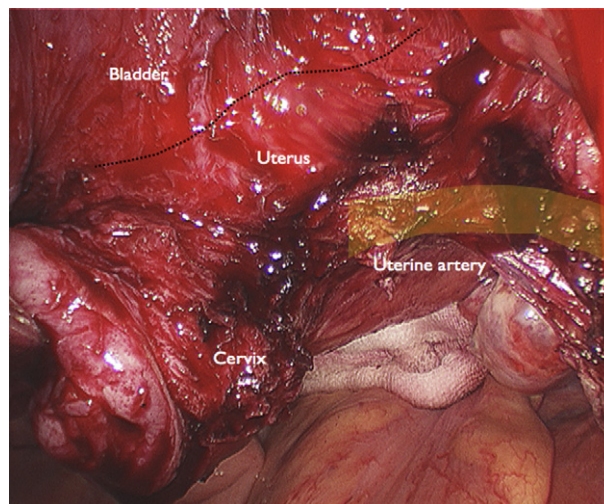


Fig. 1. Exploring the left parametrial space and dividing the uterine artery.

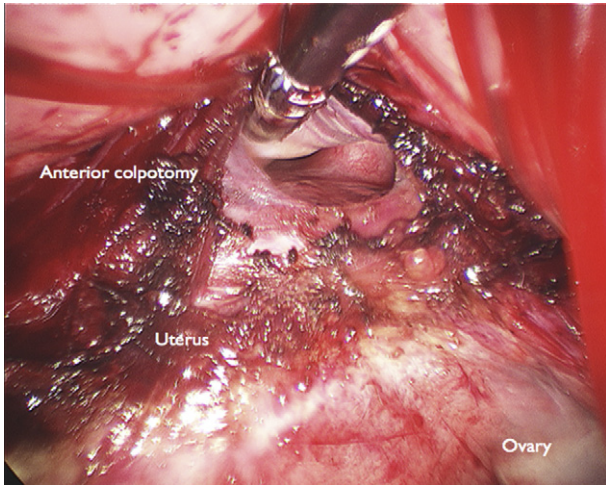


Fig. 2. Identifying the uterovesical junction by tracing along the vessels stumps and anterior uterine wall, then dividing the junction in order to perform the anterior colpotomy.

intramuscularly administered if necessary. The Foley catheter was maintained overnight after the operation. The patients were discharged, according to national regulations, if they were afebrile for at least 24 hours and demonstrated no evidence of surgical complications, good wound healing, and full recovery of gastrointestinal function with satisfactory oral intake. Patients were asked to abstain from sex for at least 6 weeks after the operation and to return to the clinic 1 week and 2 months after the surgery for follow-up examinations. Three months later, patients were evaluated for sexual function, including dyspareunia, postcoital bleeding, and satisfaction.

#### Data analysis

The patient demographics, intraoperative findings, postoperative outcomes, and pathological reports were recorded. Surgical outcomes, including operation times, estimated blood loss, decrease in hemoglobin, uterine weight, length of

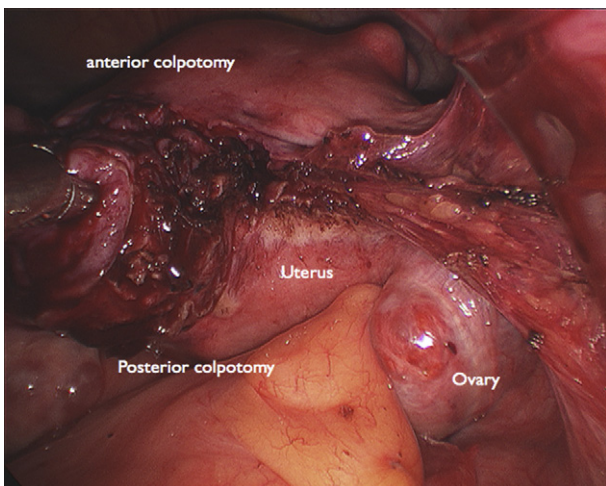


Fig. 3. Exploring and dividing the left adnexal pedicles during the left-side procedures.

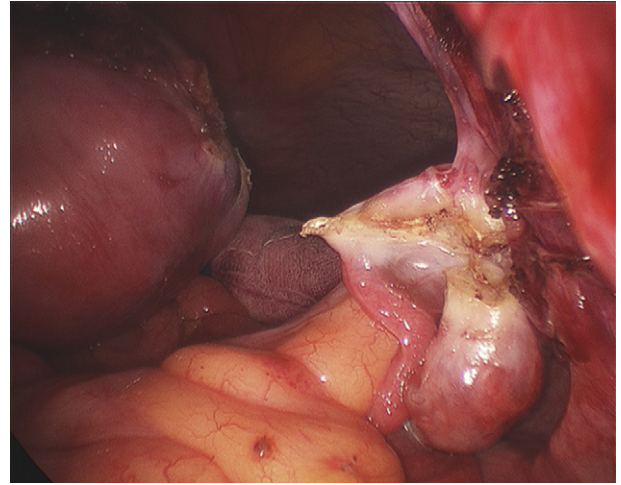


Fig. 4. Completely dividing the left adnexal pedicles during the left-side procedures.

hospital stay, and complications, were all recorded. Age, body mass index (BMI), and uterine weight were considered continuous variables and are presented as the means  $\pm$  standard error of mean (SEM), whereas parity was considered a discrete variable and is presented as the median value and range. Descriptive statistics were calculated using SPSS for Windows (release 17.0.0/2008; IBM-SPSS, Inc., Chicago, IL, USA).

#### Results

From May through December 2010, 16 patients underwent purely transvaginal NOTES and were enrolled in this study. The detailed patient characteristics and surgery-related measurements are presented in Table 1. The mean age of the study patients was  $47.8 \pm 1.2$  years, the median of parity was 2, and the mean BMI was  $24.1 \text{ kg/m}^2$ . Two patients were nulliparous and one was multiparous who had no experiences with vaginal delivery. Six patients had undergone previous abdominal surgeries, including cesarean deliveries, laparotomies, and laparoscopies. Indication for hysterectomies included 11 (68.7%) cases of leiomyoma, four (25%) cases of adenomyosis, and one (6.3%) case of stage III cervical intraepithelial neoplasm.

Transvaginal NOTES was completed in each patient without an ancillary port in the abdomen or conversion to conventional laparoscopy or even laparotomy. The mean operation time was  $122.7 \pm 17.6$  minutes, mean blood loss was  $379.4 \pm 95.4 \text{ mL}$ , mean decrease in hemoglobin between preoperation and the first day of postoperation was  $-1.35 \text{ g/dL}$ , four patients required an intraoperative blood transfusion, mean uterine weight was  $538.8 \pm 102.9 \text{ g}$ , and the mean postoperative hospital stay was  $2.8 \pm 0.2$  days.

On follow-up examinations performed 1 week after discharge and 2 and 6 months after the operation, all patients demonstrated good healing of the vaginal cuff, no complaints regarding intercourse, and none complained of dyspareunia or post-coital bleeding.

Table 1  
Patient characteristics and surgical outcomes.

Case No.	Age	Parity	C/S	BMI (kg/m <sup>2</sup> )	Other abdominal surgery	Operation indication	Operation time (min)	Blood loss (mL)	Hb Change (g/dL)	BT	Uterine weight (g)	Length of stay (d)
1	59	3	0	23.78		CIN 3	153	150	-2.6		178	3
2	49	1	0	26.70		Myoma	323	800	-1.0	+	1214	3
3	42	0	0	27.78		Myoma	380	1300	-1.3	+	1630	3
4	40	2	2	38.39		Myoma	178	800	-2.2	+	711	4
5	44	2	0	29.61	+	Myoma	234	250	-1.3		454	1
6	53	3	0	23.80		Adenomyosis	133	400	-1.3		284	3
7	45	2	0	25.86	+	Adenomyosis	196	1100	1.1	+	605	3
8	46	2	0	20.82	+	Myoma	110	250	-6.8		387	3
9	45	0	0	24.41	+	Adenomyosis	60	20	-1.7		205	3
10	43	2	0	28.20		Adenomyosis	82	150	-1.4		263	3
11	43	3	0	22.28	+	Myoma	84	400	-0.7		500	3
12	54	2	0	22.08		Myoma	105	600	-0.5		960	3
13	47	2	0	20.44		Myoma	55	50	0.2		300	2
14	50	2	0	19.15		Myoma	85	100	-2.7		115	3
15	48	2	0	20.31		Myoma	75	150	-1.9		601	2
16	48	2	0	25.00		Myoma	84	150	-2.2		611	4

C/S, cesarean section; BMI, body mass index; Hb, hemoglobin; BT, blood transfusion; CIN, cervical intraepithelial neoplasia.

## Discussion

The present method of performing hysterectomy using transvaginal NOTES is more than a vaginal hysterectomy assisted by culdoscopy. It combines conventional vaginal surgery and the newly offered LESS surgery as an innovative surgical concept, which not only widens the feasibility of vaginal surgery but also results in a scarless abdomen.

To the best of our knowledge, the present study is the first report on the use of transvaginal NOTES for performing hysterectomy that has appeared in the literature. Although hysterectomy is preferential performed using the vaginal approach [6] and a large uterus (> 300 g) is not a contraindication [7–10], transvaginal NOTES is still rarely used to perform hysterectomy due to several disadvantages, including the restriction and poor visualization of the surgical field and technical difficulties in patients with a narrow vagina, large uterus, or pelvic adhesions. The laparoscopic approach could provide better visualization than the vaginal approach even for large uteri [11], but it still needs to create several incisions through the abdomen. In comparison with laparoscopic hysterectomy, transvaginal NOTES for hysterectomy avoids the disruption of the muscles and fascia in the abdomen and prevents possible complications from trocar insertion, such as wound infection, bleeding, and hernia. The most superior part of transvaginal NOTES for hysterectomy is the easier approach to the uterine vessels at the level of the isthmus, especially if the uterus is large. When a large uterus occupies the pelvis, it is challenging to seal the feeding vessels of the uterus through the laparoscopic approach in such a limited space. Moreover, any manipulation before occlusion of the feeding vessels results in more blood loss, which blurs the operative field and increases morbidity. On the contrary, a large uterus usually has a relatively small cervix, so ligating the uterine vessels from the vagina first in order to decrease blood loss is easy and feasible. Therefore, the superiority of

transvaginal NOTES for hysterectomy is significantly demonstrated for large uteri.

As for the concern of increased risk of postoperative wound infection when using a nonsterile entry, we did not observe any pelvic abscess or pelvic inflammatory disease in this preliminary study. This issue should be further investigated before drawing a conclusion because of the limited number of cases included in this initial report. Another disadvantage found in our initial experiences is the blind angle of performing transvaginal NOTES when using a 5-mm 30-degree endoscope, especially the areas of the broad ligaments and anterior cul-de-sac. Subsequently, lesions at the peritoneal endometriosis at the base of the bladder, uterine myomas at the anterior wall, or lesions in the broad ligaments could possibly be missed and the patient's diagnosis might be compromised. The same problem was encountered even when a semirigid endoscope was used [12]. Hopefully, a flexible endoscope may overcome this main limitation. Before the development of new endoscopes that enabled the clear visualization of the whole abdomen and pelvis, conversion to conventional laparoscopy was essential when there was a discrepancy between the preoperative imaging studies and the operative findings.

In conclusion, hysterectomy can be feasibly performed using transvaginal NOTES, which not only overcomes limitations but broadens the indications for vaginal hysterectomy. Although this study is only preliminary and reports a small number of patients, it makes the concept of NOTES a reality. A larger case series, or even prospectively randomized controlled trials, should proceed in order to evaluate its significance and applications in clinical practice.

## Financial disclosure

None of the authors have any conflicts of interest to declare.

### Author disclosures

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Drs. H. Su, C.-L. Lee, K.-Y. Wu, C.-M. Han, and C.-F. Yen have no conflicts of interest or financial ties to disclose.

### Author contributions

H.S., C.-F. Y., K.-Y. W., and C.-L. L. conceived and designed the study; H.S., K.-Y.W., and C.-M. H. acquired the data; H.S. and C.-F. Y. analyzed and interpreted the data; H.S. and K.-Y. W. drafted the manuscript; C.-L. L. and C.-F. Y. reviewed the data and critically revised the manuscript for scientific and intellectual content. All authors approved the final version for submission.

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