

# Comparison of hysterectomy cases performed by transvaginal natural orifice transluminal endoscopic surgery

## A paired sample cross-sectional study

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### Abstract

This study aimed to investigate the feasibility, indications, and benefits of transvaginal natural orifice transluminal endoscopic surgery (v-NOTES) hysterectomy for nonmalignant gynecological diseases. The clinical data, including the baseline information and surgical conditions of 81 patients who underwent v-NOTES hysterectomy for nonmalignant gynecological diseases in a tertiary university hospital from October 2018 to August 2022, were retrospectively analyzed and compared with the total laparoscopic hysterectomy group (200 cases) and the transumbilical laparoendoscopic Single Site Surgery group (150 cases). In comparison with the other 2 groups, the highest proportion of patients in the v-NOTES group had cervical intraepithelial neoplasia. Accordingly, mean preoperative uterine volume measured by sonography was significantly smaller in the v-notes group. In the v-NOTES group, the mean number of vaginal deliveries and age were significantly higher, while the mean number of previous abdominal surgeries was lower compared to the other 2 groups. The V-NOTES group had a shorter operation time, shorter postoperative urinary catheter insertion time, earlier intestinal recovery days, shorter hospital stay, and lower visual analogue scale scores after surgery, and the differences were statistically significant. When indicated appropriately, v-NOTES hysterectomy can be a feasible and advantageous surgical modality. In particular, in comparison to the laparoendoscopic Single Site Surgery and total laparoscopic hysterectomy groups, the v-NOTES group had advantages in postoperative recovery and had more aesthetic surgical results.

**Abbreviations:** LESS = laparoendoscopic Single Site Surgery, OT = operating time, TLH = the total laparoscopic hysterectomy, v-NOTES = transvaginal natural orifice transluminal endoscopic surgery.

**Keywords:** hysterectomy, laparoscopic, LESS, nonmalignant, v-NOTES

### 1. Introduction

Hysterectomy is a common surgical method for the treatment of uterine diseases in gynecology. Approximately 30% of women by the age of 60 in the USA and about 2.8 million cases in China of total hysterectomy are performed every year.<sup>[1]</sup> At present, the available surgical options include transabdominal hysterectomy (TAH), total laparoscopic hysterectomy (TLH), transumbilical laparoendoscopic single-site surgery (LESS) hysterectomy, vaginal hysterectomy (TVH), transvaginal natural orifice transluminal endoscopic surgery (v-NOTES) hysterectomy, and robotic-assisted laparoscopy.

Due to the unique anatomy of women and the increasing demand for minimally invasive procedures, vaginal surgery has become a more favorable option for patients as it offers

smaller incisions and better cosmetic outcomes. The v-NOTES surgery combines the advantages of traditional vaginal surgery, which leaves no visible scars, with the improved visualization of laparoscopic surgery. In 2012, Su et al reported the first case of v-NOTES hysterectomy,<sup>[2]</sup> and since then, the v-NOTES hysterectomy has gradually become a preferred minimally invasive technique in gynecology. However, large-scale comparative analyses on the safety, feasibility, and postoperative recovery of different surgical approaches for hysterectomy are still lacking.

In this study, we aim to compare the clinical data of v-NOTES hysterectomy with TLH and LESS techniques through a retrospective analysis, evaluating the safety, feasibility, and advantages of v-NOTES surgery. This will provide valuable data for clinical diagnosis and treatment.

The authors have no funding and conflicts of interest to disclose.

The study was approved by the Ethics Committee of West China Second University Hospital, Sichuan University.

The data that support the findings of this study are available from a third party, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are available from the authors upon reasonable request and with permission of the third party.

This work is not being submitted to any other journal for consideration for publication and has not been previously presented in any form.

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## 2. Materials and methods

This cross-sectional study included patients who underwent v-NOTES, TLH, and LESS hysterectomy for gynecological non-malignant diseases, such as uterine fibroids, adenomyosis, atypical endometrial hyperplasia, cervical intraepithelial neoplasia, and uterine fibroids combined with adenomyosis, at a tertiary university hospital from October 2018 to August 2022. Patients were divided into the v-NOTES group, TLH group, and LESS group. Exclusion criteria included patients with a pathological diagnosis of malignant tumors, uterine prolapse, and incomplete medical records. A total of 81 patients in the v-NOTES group, 150 patients in the LESS group, and 200 patients in the TLH group included.

Clinical indicators in this cross-sectional study included the preoperative basic characteristics, perioperative outcomes, and postoperative outcomes. The preoperative basic characteristics included age, body mass index (BMI), number of previous abdominal surgery, gravidity, parity, number of vaginal deliveries, preoperative uterine volume (ultrasound/cm<sup>3</sup>), indication for surgery and preoperative blood transfusion. Perioperative outcomes included operative time, blood loss, preoperative/postoperative hemoglobin level and decrease in Hb, intraoperative complications, and additional surgical procedures such as bilateral salpingo-oophorectomy (BSO) and unilateral salpingo-oophorectomy (USO). Postoperative indicators included postoperative hospital stay, postoperative intestinal recovery days, postoperative urinary catheter insertion days, postoperative complications (classified according to the Clavien-Dindo classification system), readmission, and visual analog scale pain scores at 6, 24, and 48 hours after surgery.

Preoperative uterine volume (ultrasound/cm<sup>3</sup>) was calculated using the following formula:  $L \times W \times AP \times 0.542$ , where L represents the longitudinal diameter from the uterine fundus to the internal cervical os, W represents the width between both uterine angles, and AP represents the anteroposterior diameter from the endpoint of the transverse diameter of the anterior uterine wall.<sup>[3]</sup> The indications for surgery included uterine myoma, adenomyosis, atypical endometrial hyperplasia, cervical intraepithelial neoplasia, and uterine fibroids with adenomyosis. The operative time was documented as the duration from the start to the end of the surgery according to the anesthesia record. Intraoperative complications included vascular, intestinal, and urinary system injuries (bladder and ureter), as well as the need for blood transfusion. Postoperative intestinal recovery days was defined as the time from the end of the surgery to the first passage of flatus by the patient. Postoperative complications included fever, bleeding, blood transfusion, and poor incision healing, assessed using the Clavien-Dindo classification system. Postoperative fever was defined as a postoperative body temperature higher than 37.3°C (measured with an infrared forehead thermometer). The hospital stay was defined as the time from the end of the surgery to the patient's discharge.

### 2.1. Surgical technique

**2.1.1. TLH.** Step 1. Insert an abdominal puncture needle above the umbilicus, establish artificial pneumoperitoneum and insert 4 auxiliary trocars at 2 horizontal fingers above the umbilicus and both lower abdomens.

Step 2. Release pelvic and abdominal adhesions, excise bilateral ligaments and bilateral fallopian tubes or adnexa, open the broad ligament and bladder peritoneum fold, push the bladder to the cervix, cut off the uterine arteries, cut off the bilateral cardinal ligaments, incise the vagina horizontally along the vault, and completely remove the uterus.

Step 3. Retrieve the uterus through the vagina, use absorbable suture SXP1B401 (Johnson & Johnson, USA) to suture the cut ends and peritoneum under laparoscopy, close the puncture holes.

**2.1.2. LESS.** The surgical steps of laparoendoscopic single-site surgery (LESS) hysterectomy are consistent with those of traditional multi-port laparoscopy surgery. No pneumoperitoneum is required before entering into the abdomen. Instead, the tissue of the umbilicus is cut layer by layer, and a single-port access device (disposable trocar, single-port type, Kangji Hangzhou, China) is installed through the umbilicus. After surgery, an umbilical plastic surgery is performed.

**2.1.3. v-NOTES.** Step 1. Expose the cervix, incise the vaginal mucosa, separate the bladder-cervix gap, open the bladder-peritoneal fold and enter the pouch of Douglas.

Step 2. Incise the posterior fornix of the vagina, open the rectouterine peritoneal fold, and enter the cul-de-sac.

Step 3. Cut off the bilateral cardinal and uterosacral ligaments.

Step 4. Install a vaginal access device (disposable trocar, single-port type, Kangji, Hangzhou), establish an artificial pneumoperitoneum, and enter the instrument.

Step 5. Separate pelvic and abdominal adhesions, cut off bilateral broad ligaments, ovarian ligaments, and round ligaments, excise bilateral fallopian tubes or adnexa, retrieve the surgical specimen through the vagina and suture the vaginal fracture ends and anterior and posterior peritoneum.

### 2.2. Statistical analysis

Statistical analysis of the data was performed using SPSS 26.0 software. Categorical data were presented percentages and compared using chi-square tests. Continuous data were presented as mean  $\pm$  standard deviation and compared using *t* tests. A *P* value of less than .05 was considered statistically significant.

## 3. Result

During the review period, 81 patients who underwent v-NOTES total hysterectomies were screened (Table 1). There were no statistically significant differences in BMI ( $23.47 \pm 2.97$  kg/m<sup>2</sup>) and parity ( $3.02 \pm 1.86$ ) between the v-NOTES group and the other 2 groups (*P* > .05). The age range of the v-NOTES group was 34 to 79 years, with an average  $51.36 \pm 7.18$  years. The number of previous vaginal deliveries ranged from 0 to 5, with an average of  $1.25 \pm 0.91$ , and the number of previous abdominal surgeries ranged from 0 to 2, with an average  $0.38 \pm 0.58$ . The preoperative uterine volume (measured by ultrasound) ranged from 5.92 to 444.99 cm<sup>3</sup>, with an average of  $92 \pm 86.32$  cm<sup>3</sup>. The v-NOTES group had statistically significant differences compared the TLH and LESS groups, showing older age, more vaginal deliveries, fewer previous abdominal surgeries, and smaller preoperative uterine size (*P* < .05). In terms of the indications for surgery, the v-NOTES group had the highest proportion of patients with cervical intraepithelial neoplasia (50 cases, 61.7%), followed by uterine myoma (16 cases, 19.8%). In the TLH and LESS groups, the highest proportion of patients had uterine myoma, with 95 cases (47.5%) and 87 cases (58.0%), respectively. These differences were statistically significant (*P* < .05).

In terms of the operative time, the v-NOTES group ( $144.07 \pm 51.46$  minutes) had a shorter duration compared to the LESS group ( $167.62 \pm 51.57$  minutes), with statistically significant differences (Tables 2 and 3). However, there was no statistically significant difference between the v-NOTES group and the TLH group ( $142.03 \pm 54.57$  minutes). The v-NOTES group

**Table 1****A comparison of the preoperative basic characteristics.**

Group	v-NOTES (n = 81) Mean ± SD/n (%)	LESS (n = 150) Mean ± SD/n (%)	TLH (n = 200) Mean ± SD/n (%)	P
Age (yr)	51.36 ± 7.18	49.01 ± 4.83*	48.36 ± 5.37*	.004
BMI (kg/m <sup>2</sup> )	23.47 ± 2.97	23.58 ± 2.81	23.71 ± 3.05	.804
Number of vaginal deliveries	1.25 ± 0.91	0.8 ± 0.71*	0.95 ± 0.82*	.001
Number of previous abdominal surgery	0.38 ± 0.58	0.69 ± 0.83*	0.77 ± 0.86*	.001
Preoperative uterine volume(ultrasound/cm <sup>3</sup> )	80.92 ± 86.32	161.97 ± 119.87*	175.7 ± 132.60*	.001
Indication for surgery				
Uterine myoma	16 (19.8)	87 (58.0)*	95 (47.5)*	.001
Adenomyosis	5 (6.2)	20 (13.3)	35 (17.5)*	.044
Uterine fibroid with adenomyosis	6 (7.4)	14 (9.3)	42 (21.0)*†	.001
Atypical endometrial hyperplasia	5 (6.2)	6 (4.0)	9 (4.5)	.0749
Cervical intraepithelial neoplasia	50 (61.7)	23 (15.3)*	23 (11.5)*	.000
Preoperative blood transfusion	3 (3.7)	2 (1.3)	18 (9.0)†	.005

BMI = body mass index, LESS = transumbilical Laparoendoscopic Single Site Surgery hysterectomy, TLH = total laparoscopic hysterectomy, v-NOTES = transvaginal natural orifice transluminal endoscopic surgery hysterectomy.

\*A statistically significant difference between the v-NOTES group and the LESS or TLH groups.

†A statistically significant difference between the TLH group and the LESS group.

**Table 2****A comparison of perioperative outcomes.**

Group	v-NOTES (n = 81) Mean ± SD/n (%)	LESS (n = 150) Mean ± SD/n (%)	TLH (n = 200) Mean ± SD/n (%)	P
Operative time (min)	144.07 ± 51.46	167.62 ± 51.57*	142.03 ± 54.57†	.000
Blood loss (mL)	67.16 ± 90.57	102.93 ± 134.08	104.23 ± 154.04*	.017
Preoperative Hb	124.89 ± 18.91	117.68 ± 20.30*	118.24 ± 21.10*	.016
Postoperative Hb	108.36 ± 15.83	102.57 ± 18.21*	104.92 ± 18.59	.045
Decrease in Hb	17.55 ± 7.45	15.11 ± 9.45	13.33 ± 9.21*	.000
Bilateral salpingo-oophorectomy (BSO)	43 (53.1%)	45 (30%)*	46 (23%)*	.000
Unilateral salpingo-oophorectomy (USO)	3 (3.7%)	5 (3.3%)	33 (16.5%)*†	.000

Hb = hemoglobin, LESS = transumbilical Laparoendoscopic Single Site Surgery hysterectomy, TLH = total laparoscopic hysterectomy, v-NOTES = transvaginal natural orifice transluminal endoscopic surgery hysterectomy

\*A statistically significant difference between the v-NOTES group and the LESS or TLH groups.

†A statistically significant difference between the TLH group and the LESS group.

**Table 3****A comparison of postoperative outcomes.**

Group	v-NOTES (n = 81) Mean ± SD/n (%)	LESS (n = 150) Mean ± SD/n (%)	TLH (n = 200) Mean ± SD/n (%)	P
Postoperative intestinal recovery days (d)	1.67 ± 0.61	2.15 ± 0.77*	2.18 ± 0.59*	.000
Postoperative urinary catheter insertion days (d)	1.96 ± 0.93	2.42 ± 1.61*	2.72 ± 0.87*†	.000
Hospital stay (d)	3.48 ± 1.05	4.53 ± 1.86*	4.21 ± 1.18*†	.000
VAS score at 6th hour	2.67 ± 1.31	3.06 ± 1.60	3 ± 1.41	.100
VAS score at 24th hour	1.63 ± 0.70	1.87 ± 0.81*	2.11 ± 0.90*†	.000
VAS score at 48th hour	0.84 ± 0.77	1.1 ± 0.69*	1.25 ± 0.7*	.000
Fever after operation	5 (6.2)	12 (8)	22 (11)*	.024
Postoperative blood transfusion	1 (1.2)	4 (2.7)	6 (3.0)	.079

LESS = transumbilical Laparoendoscopic Single Site Surgery hysterectomy, TLH = total laparoscopic hysterectomy, VAS = visual analogue scale, v-NOTES = transvaginal natural orifice transluminal endoscopic surgery hysterectomy.

\*A statistically significant difference between the v-NOTES group and the LESS or TLH groups.

†A statistically significant difference between the TLH group and the LESS group.

also had significantly less blood loss (67.16 ± 90.57 mL) compared to the LESS group (102.93 ± 134.08 mL) and the TLH group (104.23 ± 154.04 mL).

In terms of postoperative recovery outcomes, the v-NOTES group had faster time to bowel recovery (1–3 days, average 1.67 ± 0.61 days), shorter duration of urinary catheterization (0–6 days, average 1.96 ± 0.93 days), shorter postoperative hospital stay (1–7 days, average 3.48 ± 1.05 days), and lower pain scores at 24 and 48 hours postoperatively (0–3, average 1.63 ± 0.70 and 0.84 ± 0.77, respectively) compared to the

LESS and TLH groups. These differences were statistically significant ( $P < .05$ ).

In terms of intraoperative complications, there were no complications in the v-NOTES group. In the TLH group, one patient required bladder repair due to thin bladder wall. In the LESS group, one patient required bladder repair due to bladder perforation, and one patient had severe adhesions leading to bladder and colon repair. One patient in the LESS group also experienced intraoperative bleeding requiring transfusion of packed red blood cells.

In terms of postoperative complications, one patient in the v-NOTES group experienced vaginal cuff dehiscence and required emergency vaginal cuff repair and blood transfusion. This patient had stage III cervical intraepithelial neoplasia and adenomyosis, with a preoperative estimated uterine size of approximately 45.70 cm<sup>3</sup>. The Clavien-Dindo classification for this case was grade IV. In the TLH group, one patient was readmitted 1 month postoperatively due to vaginal stump bleeding and was treated with vaginal packing. The patient improved and was discharged with a Clavien-Dindo classification of grade IIIa. The remaining postoperative complications in all groups were classified as grade II or below according to the Clavien-Dindo classification system.

#### 4. Discussion

The v-NOTES is a perfect combination of traditional vaginal surgery and laparoscopic surgery which can overcome the limitations of poor visualization and manipulation related to vaginal surgery with the help of endoscopic equipment. Although the security and feasibility of vNOTES have been proved, there is still some debate regarding the v-NOTES advantages compared to other techniques like LESS and TLH.

In our study, the highest proportion of patients in the v-NOTES group had cervical intraepithelial neoplasia. Accordingly, mean preoperative uterine volume measured by sonography was significantly smaller in the v-notes group. In the V-Notes group, the mean number of vaginal deliveries and age were higher, while the mean number of previous abdominal surgeries was lower compared to the other 2 groups. These results may be due to the fact that v- NOTES is preferred in patients with a small uterus, a lower likelihood of pelvic adhesions, as it has only recently been discovered and the extent, limitations, and feasibility of the procedure are still being explored.

In the first report on the use of v-NOTES in hysterectomy,<sup>[2]</sup> Su et al suggested that although a large uterus (>300g) is not a contraindications, the feasibility of v-NOTES was limited in patients with vaginal stenosis, large uterus, or pelvic adhesions. The first vaginal step of v-NOTES surgery was described as the most challenging step,<sup>[4]</sup> as it involves visualizing and dissecting the posterior vaginal fornix, opening the pouch of Douglas, dissecting the space between the uterus and rectum and opening the peritoneum. Consequently, in case of severe pelvic adhesions or the pouch of Douglas cannot be entered, there is an increased risk of bladder and rectal injuries.

in Italian initial experience,<sup>[5]</sup> Interdonato et al reported a case that converted to transabdominal laparoscopy due to a severe pouch of Douglas obliteration. Also, Lee et al<sup>[6]</sup> reported a conversion secondary to cul-de-sac obliteration. Additionally, These confirms our finding that v-NOTES may be contraindicated for patients with severe pelvic adhesions and closure of the pouch of Douglas, such as rectovaginal endometriosis.

However, recent studies have demonstrated that v-NOTES, by utilizing laparoscopy, can significantly compensate for the disadvantages of conventional vaginal hysterectomy or laparoscopic hysterectomy in cases of large uterus (>12 weeks).<sup>[6–12]</sup> A retrospective cohort study,<sup>[7]</sup> including 114 patients who underwent v-NOTES hysterectomy, reported only one case requiring conversion to transabdominal hysterectomy for specimen extraction. This suggests that v-NOTES can serve as a safe and effective alternative to laparoscopic or abdominal surgery for cases involving large uterus. Kheirbek et al<sup>[10]</sup> proposed that compared to laparoscopic methods, v-NOTES hysterectomy for large uteri (>280g) is associated with reduced operating time, shorter hospital stay. Additionally, Wang et al<sup>[13]</sup> indicated that for patients with uterine weights exceeding 500 grams, the v-NOTES group had reduced hospital stays and fewer complications.

Therefore, our experience highlights the importance of careful patient selection when using v-NOTES. including thorough preoperative manual rectal examination to assess uterine size and the possibility of pelvic adhesions.

A series of studies have shown a statistically significant reduction of operative time and estimated blood loss compared to TLH, LAVH and LESS. This is consistent with the findings of our study.<sup>[14–17]</sup>

However, it is worth noting that our operating time (OT) is similar to the reported times by Su et al<sup>[2]</sup>(OT = 122.7 minutes) and Yang et al (OT = 129 minutes),<sup>[18]</sup> but higher than the majority of reported findings (70–80 minutes),<sup>[13,19–21]</sup> significant differences between groups (60–331 minutes). The possible reasons for this discrepancy might be that v-NOTES surgery was introduced relatively late and is still in the initial learning phase,<sup>[22]</sup> with data collected from multiple surgeons. Mereu et al<sup>[23]</sup> retrospectively studied the learning curve process for v-NOTES Hysterectomy, finding that 5 cases are required to rich competence and 25 cases to rich proficiency in vNOTES hysterectomy, with even more complex cases requiring 30 procedures. Furthermore, in our study, additional cone biopsy of the cervix and adnexal surgery were included.

In our study, we observed that v-NOTES for hysterectomy exhibited a quicker gas passage by the anus, shorter ureteral retention time, shorter hospital stays, and lower pain scores compared to LESS and TLH. This suggests that v-NOTES for hysterectomy leads to faster patient recovery and less postoperative pain. Similar results have been reported by Baekelandt et al<sup>[24]</sup>, Yang et al<sup>[25]</sup>, and Kaya et al.<sup>[26]</sup> However, a study by Yang et al<sup>[27]</sup> showed no significant difference in hospital stay. Furthermore, in a study by Park et al<sup>[28]</sup>, it was reported that women who underwent v-NOTES hysterectomy experienced significantly higher postoperative vaginal pain compared to those who underwent multi-port laparoscopic hysterectomy.

Yang et al conducted a meta-analysis<sup>[27]</sup> including 1340 patients from clinical trials and found no statistically significant differences in intraoperative risks and postoperative complications between v-NOTES and traditional laparoscopy. It is worth noting that in our study, we observed one severe complication classified as Clavien-Dindo grade IV in the v-NOTES group. Baekelandt et al described in their randomized controlled trial<sup>[4]</sup> that women treated with v-NOTES hysterectomy had fewer postoperative complications compared to TLH group (9.0% vs 37%), with no severe complications classified as Clavien-Dindo grade IV. In 2021, Baekelandt et al reported 28 postoperative complications in a study involving 750 v-NOTES hysterectomy cases,<sup>[19]</sup> including 11 complications classified as Clavien-Dindo grade III but no one classified as Clavien-Dindo grade IV. The complication rate in this study (1.4% intraoperatively, 3.8% postoperatively) was relatively higher than that in vaginal hysterectomy studies but lower than the results of several laparoscopic hysterectomy studies (6.6–15%).

Unfortunately, our study had some limitations. Firstly, there was a lack of data on the final postoperative uterine weight of the patients, and there may have been discrepancies between the actual size of the uterus and the data provided by preoperative ultrasound, but this could not be confirmed. Secondly, additional adnexal surgery were included in this study. Thirdly, since v-NOTES surgery was introduced relatively late, our study included data from multiple surgeons with varying levels of skill and experience. Fourthly, there may have been selection bias in patient selection, as during the initial learning phase, patients with smaller uteri and less pelvic adhesions were more frequently selected, and more future attempts should focus on larger uterine resections.

Additionally, v-NOTES has been shown to be a safe and suitable procedure for obese women and adnexal surgery. Mat et al observed that v-NOTES can not only be used for the diagnosis and treatment of benign obese cases,<sup>[29]</sup> but also provides greater benefits for patients with early endometrial cancer and severe obesity

(mean body mass index of 51.4 kg/m<sup>2</sup>)<sup>[30]</sup> or unexplained ascites.<sup>[31]</sup> In recent years, a study has shown that the success of v-NOTES in adnexectomy has significantly increased the utilization rate of v-NOTES for hysterectomy (94.3%) and the accompanying BSO rate (6.8% vs 75%).<sup>[32]</sup> This also allows us to use it in challenging cases, such as transgender men and patients with ovarian cysts or ectopic pregnancy.<sup>[33,34]</sup> Furthermore, further research will also be conducted on the application of v-NOTES in malignant tumors.

In conclusion, when indicated appropriately, v-NOTES hysterectomy is a feasible surgical modality that facilitates post-operative recovery. Further randomized controlled trials with larger sample sizes should be conducted to establish the location of v-NOTES in hysterectomy surgeries.

## Author contributions

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