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CLINICAL ARTICLE

Gynecology

Learning curve analysis of transvaginal natural orifice transluminal endoscopic hysterectomy combined under the standard operating procedure

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Abstract

Objective: To investigate the learning curve of transvaginal natural orifice transluminal endoscopic hysterectomy (tVNOTEH) when using a standard operating procedure (SOP).

Methods: Seventy-nine patients were treated with tVNOTEH by a single surgeon. The SOP for tVNOTEH was created after the first eight cases. Patients' perioperative data were retrospectively reviewed. Operative time (OT) was regarded as a replaceable marker for surgical competency. The learning curve was drawn using the cumulative sum method.

Results: All patients completed surgeries without switching to other surgical paths. The overall mean OT was 90.23 ± 29.85 min. Four unique phases of the learning curve were identified: phase I (the exploring stage over eight cases), phase II (after adopting the SOP, acquirement of competence over 20 cases), phase III (post-learning of 19 cases, in which more difficult cases were introduced), phase IV (more adept at tVNOTEH), with OT 113.75 ± 43.07 min, 82.50 ± 25.88 min, 101.05 ± 27.83 min, 82.75 ± 25.53 min, respectively. No significant differences were found apart from OT, uterine size, and disease types.

Conclusion: Our data demonstrated four distinct phases of the learning curve of tVNOTEH. For an experienced surgeon, surgical competence in tVNOTEH can be grasped after eight cases. With SOP, surgical competence could be rapidly acquired.

KEYWORDS

cumulative sum method, standard operating procedure, transvaginal natural orifice transluminal endoscopic hysterectomy

Zheng'ai Xiong and Yonghong Lin contributed equally.

1 | INTRODUCTION

Hysterectomy is the first-choice surgery in the treatment of diverse benign gynecologic diseases, such as uterine myoma, adenomyosis, and high-grade squamous intraepithelial lesion. Hysterectomy is the basal surgical procedure for malignant gynecologic diseases. Therefore, mastery of hysterectomy is very important for gynecologists. Until now, the surgical approaches for hysterectomy have included abdominal hysterectomy, multiport laparoscopic hysterectomy, transumbilical laparoendoscopic single-site surgery (TU-LESS), vaginal hysterectomy, laparoscopy-assisted vaginal hysterectomy, and transvaginal natural orifice transluminal endoscopic hysterectomy (tVNOTEH).[1]

First performed in 2010,[2,3] tVNOTEH, which uses the vagina as the surgical channel for endoscopy, has numerous advantages, including scarless surgery and rapid postoperative recovery. Due to the visualization of the pelvic cavity, tVNOTEH combines the advantages of TU-LESS and vaginal hysterectomy. As such, tVNOTEH has rapidly been adopted around the world. As a novel surgery path, how to promote the technology and shorten the time of mastering this technique are very important. To the best of our knowledge, no importance has yet been put on the standard operating procedure (SOP) of tVNOTEH. SOP indicates that surgical procedures are broken up into several parts and emphasizes the key points and difficulties and details in order to quickly master the technique.[4]

In the present study, we attempted to evaluate the learning curve of tVNOTEH with double salpingectomy combined with SOP based on 79 consecutive cases handled by a single surgeon at a single hospital.

2 | MATERIALS AND METHODS

The present study was performed under the remit of the Chengdu Longitudinal Cohort Study on vNOTES (LovNOTES), an ongoing gynecology cohort study conducted in Chengdu that aims to implement a long-term and detailed follow up for vNOTES and TU-LESS to identify the incidence and risk factors of incisional hernia, and the potential impact of vNOTES impact on patients' sexual function, pregnancy and vaginal delivery. This sub-cohort study was conducted at the Chengdu Women's and Children's Central Hospital, and 79 women receiving tVNOTEH were recruited through our hospital from March 2018 to February 2022 The LovNOTES study, which was established in January 2021 (Chinese Clinical Trial Registration Number: 2100053483), was approved by the Ethics Committee of the Chengdu Women's and Children's Central Hospital (No. 202162). All patients were informed of the risks and benefits before operation including risks of intraoperative bleeding, bladder, ureteral and intestinal injury, and the possibility to switch to transumbilical laparoscopy or laparotomy procedures. Written informed consent was obtained from all participants.

The inclusion criteria were as follows: (1) patients' vital signs were stable without contraindications for anesthesia or surgery; (2) indications and desire for hysterectomy; and (3) preoperative examination showed that uterine lesions were benign. Benign uterine lesions include uterine myoma, adenomyosis, high-grade squamous intraepithelial lesion, and endometrial complex hyperplasia with atypia. Thin-prep cytology test and diagnostic curettage were necessary before hysterectomy to exclude malignant uterine lesions. The exclusion criteria were as follows: (1) history of rectal and bladder surgery, suspicion of rectovaginal septum and urinary endometriosis, tumors, or severe pelvic adhesions; (2) virginity; (3) pregnancy; and (4) uterine prolapse.[2]

tVNOTEH could only be performed if the preoperative hemoglobin level was more than 8 mg/L. If not, suspended red blood cells should be transfused to meet the surgical standard. Intravenous cefmetazole was administered during the perioperative period.

2.1 | tVNOTEH technique

For preoperative preparation, the patients were given sodium phosphate oral solution for bowel preparation and underwent iodophor scrubbing of the cervix, uterus, and vagina twice the day before operation. In addition, 1 g cefmetazole was intravenously infused half an hour before operation to prevent infection.

For the operation process, patients were placed in the lithotomy position with their legs bandaged and supported in the stirrups with hips suspended 2–3 cm out of the bed. After skin disinfection, draping and general anesthesia with endotracheal intubation, a Foley catheter was inserted. tVNOTEH was then performed with the following steps.

2.1.1 | Incision of the vesicocervical space and posterior fornix

The anterior fornix was exposed using a Breisky-Navratil retractor; a vaginal anterior fornix incision of about 2 cm was made 0.5 cm away from the vesicocervical junction, close to the cephalic side (Figure 1a). Subsequently, the vesicocervical space was opened by blunt dissection with the index finger. The connective tissue between the bladder and cervix was cut with tissue scissors. The distance from the incision to the peritoneal reflection between the bladder and the uterus is about 3.5–4 cm. The peritoneal reflection between the bladder and the uterus was opened slowly to avoid bladder injury. Exposure of the posterior fornix was performed with the Breisky-Navratil retractor and a vaginal posterior fornix incision about 2 cm in length was made 0.5 cm away from the cervicovaginal junction, close to the caudal head, and the pouch of Douglas was opened (Figure 1b).

2.1.2 | Incision of the bilateral cardinal ligaments, uterosacral ligaments, and uterine arteries

After exposure of the unilateral cardinal ligament and uterosacral ligament, the surgeon used the left hand to identify the cardinal ligament and the uterosacral ligament complexes and to move adjacent organs away, while using the right hand to hold the great vessel closure device (Beijing Aerospace Kadi Technology Development Institute, Beijing, China; HK-TH-60.4TY) to clamp them from back to front, maintaining a 45-degree angle between the tip of the forceps

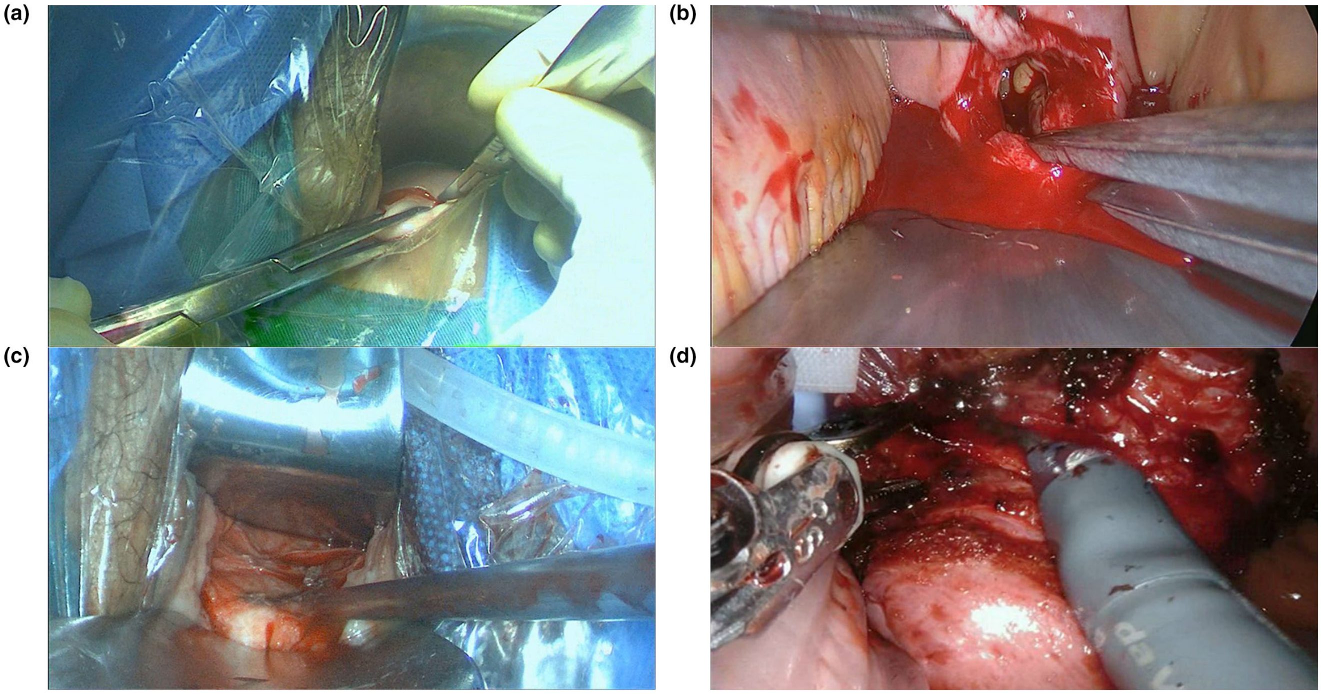

FIGURE 1 (a) Incision of the anterior fornix. (b) Incision of the posterior fornix. (c) Incision of the peritoneum between the bladder and the uterus. (d) Exploring the pelvic and the abdominal cavity in transvaginal natural orifice transluminal endoscopic hysterectomy.

and the cervix uteri. After cauterizing the ligament complexes, they were cut with the ultrasound-guided needle-knife (Beijing Anhegalier Technology Co. Ltd; AH-600) and the stump of the ligaments was sutured. Then, identifying, isolating, clamping, cauterizing, cutting, and suturing of the uterine vessels was performed using the great-vessel closure device and ultrasound-guided needle-knife. The contralateral ligaments and vessels were treated in the same manner. The peritoneal reflection between the bladder and the uterus was then opened with tissue scissors (Figure 1c).

2.1.3 | Establishing the vaginal channels for endoscopic surgery and exploring the pelvic and abdominal cavity

The disposable multiple-instrument access port was inserted through the incision around the cervix uteri into the pelvic cavity. A pneumoperitoneum was created with 14 mm Hg of CO_2 insufflation. Patients were then placed in the Trendelenburg position to retract the bowel. A 10-mm, 30-degree endoscope was inserted to explore the pelvic and abdominal cavity (Figure 1d).

2.1.4 | Endoscopic incision of the upper portion of the uterus

The remaining board and round ligaments were clamped, cauterized, and cut step-by-step using the great-vessel closure device and ultrasound-guided needle-knife. For preserving the bilateral ovary, the mesosalpinx and utero-ovarian ligament were cut. After clearing all of the pedicles, the uterus was removed through the vagina. Finally, the vaginal cuff was sutured using 2–0 Vicryl suture.

2.2 | Data collection

The general characteristics and perioperative data of patients were collected. The age, height, weight, gravidity, parity, delivery mode, previous operation history, and uterine size were estimated by general and gynecologic examination. The SOP gynecologic ultrasound, date of surgery, operation method, whether a switch to transumbilical laparoscopy or laparotomy procedures was needed and the reason, operating time (OT), estimated blood loss, blood transfusion or not, postoperative visual analog scale (VAS) scores in 24 h, time of flatus after surgery, postoperative body temperature, preoperative and postoperative 72-h hemoglobin, postoperative stay, pathologic diagnosis, and intraoperative and postoperative complications within 1 month were recorded.

The VAS score was used to evaluate postoperative pain, with pain ranked on a scale of 1–10. The higher the score, the more serious the pain; 0 was painless and 10 was the most painful.

We counted the pathologic diseases of the four phases and counted OT among the four phases stratified by pathologic disease to see whether pathologic diseases would affect the OT, or affect the learning curve.

2.3 | Statistical analysis

Statistical analysis was performed using SPSS 20.0 (IBM). Kruskal-Wallis test was used to compare continuous variables, while χ^2 or

Fisher exact tests were used to compare categorical data. All probability values were checked bilaterally, with $P < 0.05$ considered statistically significant.

In the study of learning curve of tVNOTEH, OT was regarded as a replaceable marker of surgical competency. The average OT was 90.23 ± 29.85 min. The learning curve was described as follows: setting operation number in order of operation date as the abscissa, and setting the Cumulative sum (CUSUM) of OT ($CUSUM_{OT}$) as the ordinate. The $CUSUM_{OT}$ was defined as the sum of all the differences of OT in order of operation date minus the average OT.[5] For example, the first y value was the first patient's OT minus the average OT, the second y value was the second patient's OT minus the average OT plus the first y value, the 79th y value was the 79th patient's OT minus the average OT plus the 78th y value. The calculation was repeated until the last $CUSUM_{OT}$ reached zero.

3 | RESULTS

All 79 patients completed tVNOTEH with double salpingectomy without switching to transumbilical laparoscopy or laparotomy procedures. There were no complications of Grade II to V in Clavien-Dindo classification. Two patients had complications of a moderate fever (a rise in body temperature greater than 38.5°C and less than 39°C 48 h after operation), three patients required blood transfusion because of intraoperative hemorrhage.

Figure 2a shows the relationship between the operation time and chronologic number of cases; the average OT was 90.23 min. In the first to eighth cases, the OT was above the average level. From the ninth surgery, after establishing the SOP of tVNOTEH, the OT dropped rapidly and stabilized below the average OT. From the 29th surgery, as the surgeon performed more difficult operations, the OT again surpassed the average. From the 48th surgery, after becoming more adept at tVNOTEH, the OT was greatly shortened again.

The total surgeries were divided into four phases according to the learning curve (Figure 2b). The first phase (cases 1–8) was termed the exploration stage with the OT 113.75 ± 43.07 min. The surgeon attempted to cure diseases such as uterine myoma, adenomyosis, high-grade squamous intraepithelial lesion, among which the uterine size ranged from normal size to the size of a 2-month pregnant uterus. The second phase (cases 9–28) was acquirement of competence with the OT 82.50 ± 25.88 min. After establishing and constantly improving the standard operating procedure of tVNOTEH, which standardized the preparation of surgical instruments, the implementation of every surgical step and the coordination of surgeon, assistant, and instrument nurse, the surgeon quickly grasped the tVNOTEH technique, and the OT of the second phase was significantly shorter. The third phase (cases 29–47) involved challenging the surgeon with more difficult surgeries with the OT 101.05 ± 27.83 min. With increasing uterine size, the OT went up again. In the fourth phase (cases 48–79), the surgeon was more adept at tVNOTEH, and the OT (82.75 ± 25.53 min) was again greatly shortened.

Table 1 shows the general demographic information and perioperative data of the patient. The uterine size and OT in the four phases showed significant differences. With increasing stage, although the uterine sizes in the four phases were not statistically significantly different, the average uterus size in phase III and phase IV was larger than that in phase I and phase II (higher statistical difference in the proportion of uteruses of 2-month and 3-month size: phase III versus phase I ($P = 0.03$); phase III versus phase II ($P = 0.015$); phase IV versus phase I ($P = 0.027$); phase IV versus phase II ($P = 0.01$); and phase IV versus phase III ($P = 0.909$).

The other data, including age, body mass index (calculated as weight in kilograms divided by the square of height in meters), parity, previous operation history, estimated blood loss, hemoglobin decrease at postoperative 72 h, postoperative VAS scores in 24 h, time of flatus after surgery, and postoperative stay, showed no significant differences between stages.

Table 2 describes the pathologic type of all 79 surgeries. Pathologic type among the three phases showed a significant difference.

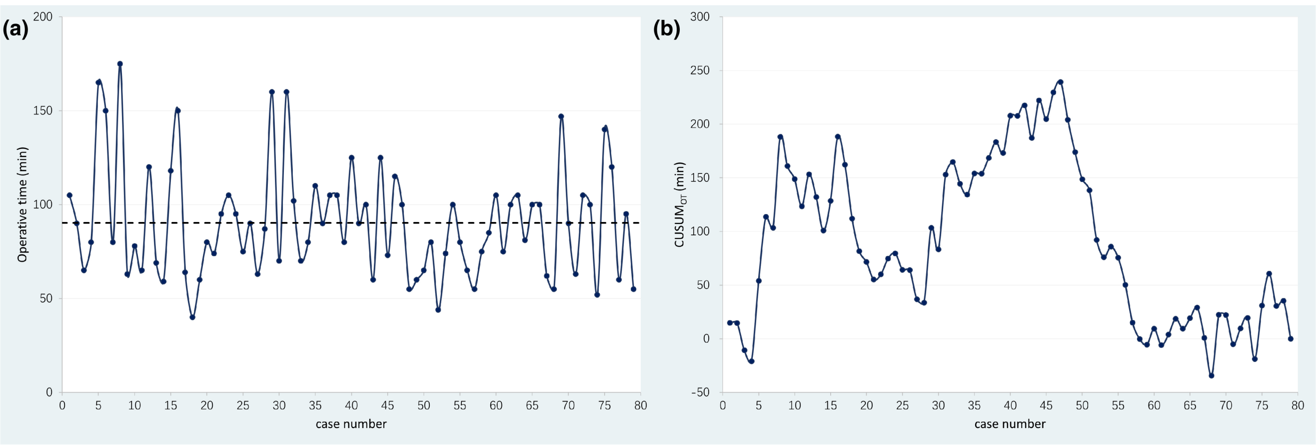

FIGURE 2 (a) Relationship between the operative time and chronologic number of cases (79 consecutive cases). (b) Relationship between the cumulative sum (CUSUM) of operative time and chronologic number of cases (79 consecutive cases).

TABLE 1 Characteristics and perioperative data of four phases[a]

	Phase I	Phase II	Phase III	Phase IV	P
N	8	20	19	32	
Age, years	51.13±7.99	52.80±7.35	51.37±8.63	49.28±9.17	0.478
Body mass index[b]	24.65±3.31	22.99±2.88	24.68±5.92	23.91±3.31	0.530
Child-bearing history					0.360
Yes	8	18	19	31	
No	0	2	0	1	
Operation history	0	4	6	10	0.261
Uterine size (gynecologic check-up)					0.119
Normal	5	12	4	8	
1 month	2	4	4	6	
2 months	1	3	6	10	
3 months	0	1	5	8	
Operation time, min	113.75±43.07	82.50±25.88	101.05±27.83	82.75±25.53	0.023
Estimated blood loss, ml	133.75±190.78	61.50±47.16	60.00±26.25	60.31±61.77	0.209
Hb decrease at postoperative 72 h, g/L	23.13±10.16	16.05±10.58	15.53±12.68	20.16±10.69	0.204
VAS at 24 h after operation	2.88±0.35	2.95±0.22	3.16±0.69	3.00±0.00	0.132
Time of flatus after surgery, h	31.83±15.25	32.13±19.04	33.25±10.56	28.06±10.31	0.413
Postoperative stay, days	4.88±0.83	4.80±1.88	4.63±2.22	4.09±1.42	0.114

Abbreviations: Hb, hemoglobin; VAS, visual analog scale.

[a]Data are presented as mean ± standard deviation or as number.

[b]Body mass index is calculated as weight in kilograms divided by the square of height in meters.

TABLE 2 Pathologic type of four phases[a]

Phases	N	Adenomyosis	High-grade squamous intraepithelial lesion	Uterine myoma	Endometrial complex hyperplasia with atypia
Phase I	8	1 (12.5%)	1 (12.5%)	6 (75.0%)	0 (0.0%)
Phase II	20	3 (15.0%)	11 (55.0%)	4 (20.0%)	2 (10.0%)
Phase III	19	1 (5.3%)	2 (10.5%)	14 (73.7%)	2 (10.5%)
Phase IV	32	6 (18.8%)	9 (28.1%)	11 (34.4%)	6 (18.8%)
P		0.017			

[a]Data are presented as number (percentage).

TABLE 3 Operation time (in minutes) among the four phases stratified by pathologic disease[a]

	Phase I (n = 8)	Phase II (n = 20)	Phase III (n = 19)	Phase IV (n = 32)	P
Adenomyosis (n = 11)	80.00±0.00	74.67 ±15.50	100.00 ±0.00	94.17 ±27.10	0.395
High-grade squamous intraepithelial lesion (n = 23)	105.00±0.00	73.27 ±18.16	97.50 ±10.61	74.22 ±22.13	0.208
Uterine myoma (n = 35)	120.83±47.90	109.25 ±32.57	102.14 ±31.80	85.82 ±31.82	0.291
Endometrial complex hyperplasia with atypia (n = 10)	–	91.50 ±40.31	97.50 ±24.75	78.50 ±12.94	0.576
P	0.677	0.243	1.000	0.605	

[a]Data are presented as mean ± standard deviation.

We further explored whether there was a significant difference between operative time for the same pathology in every phase, the results showed no significance among the phases stratified by pathologic disease, and no significance among pathologic diseases in every phase (Table 3).

4 | DISCUSSION

In our hospital, a total of 1236 VNOTES were carried out between March 2018 and February 2022, among which 79 were performed using the tVNOTEH technique by a single surgeon. We analyzed the effects of uterine size and pathologic disease on the learning curve and found no significance of OT among the four phases stratified by pathologic disease, which excluded the effect of pathologic disease on the learning curve. The uterine size indeed affected the learning curve, which caused a prolonged OT in phase III. But when the surgeon became more adept at tVNOTEH, we could conquer the adverse effect of increasing uterus size.

Wang et al.[6] reported on 240 patients who underwent tVNOTEH in a retrospective study, which divided the total surgeries into four phases: the initial stage, the stage of acquisition of competence, the stage of proficiency and plateau, and post-learning, in which more challenging cases were managed. As the number of cases requiring hysterectomy in our hospital was fairly small, the surgeon had a steep learning curve. In the initial learning phase of eight cases, the surgeon attempted to treat various diseases with the uterine size ranging from normal to a size matching that of a 2-month pregnant uterus to explore the approach of tVNOTEH. Subsequently, our team created an SOP for tVNOTEH and constantly improved it during phase II. SOP comprise written documents that indicate how to perform a routine or repetitive activity to ensure the consistency and high quality of the results.[7] SOP is mainly applied to veterinary clinics' surgery and practice management; to communicate government regulations regarding health and safety, and for best practices for achieving a high standard of patient care; and in clinic laboratories and bioanalytical laboratories for the validity of the generated data.[8,9] In the present study, the SOP was used in surgery of tVNOTEH to optimize surgical procedures, thus decreasing the OT and the rate of complications. A complete SOP includes the objective, scope of application, preoperative preparation, introduction of special surgical instruments, patient position, the order of disinfection, position of the surgeon and assistants, surgical procedures, the coordination of the surgeon and assistant, the postoperative follow up, the flow chart of surgical procedures, indications and contraindications, and the records, reports and references. In the second phase, after adopting the SOP, the OT was reduced significantly. In the third phase, as the surgeon challenged some more difficult surgeries involving increased uterine size, the OT was prolonged again. In the fourth stage, as the surgeon became more adept at tVNOTEH, the OT was shortened. No plateau stage was observed in the learning curve.

Successfully opening of the anterior and posterior fornix provides half of the success of tVNOTEH. Familiarity with the anatomical structure of the vaginal fornix is an important basis for choosing the location of the anterior and posterior fornix incisions. Weyl et al.[10] reported that the mean distance between the ureter and the ipsilateral angle of the posterior fornix incision was 3.7–3.8 cm (range 2.3–5 cm), while the mean distance between the middle of the posterior fornix incision and the anterior surface of the rectum was 3.8 cm (range 2–7 cm). Further, the average thickness of the anterior vaginal fornix and posterior fornix were 4.5 mm and 2.5 mm, respectively. Based on our observations, vaginal fornix incisions about 2 cm in length, made 0.5 cm away from the vesicocervical junction and cervicovaginal junction away from the cervix side were proper and safe. According to our data, the distance from the anterior fornix incision to the peritoneal reflection between the bladder and the uterus was about 3.5–4 cm, which helped surgeons to perceive the longitudinal distance of the opening of the anterior fornix. It is important not to make this incision too distally, as this will increase the length of dissection required to access the reflection of the peritoneum. Conversely, it also cannot be made too proximally, given the risk of cystotomy. Similarly, regarding depth, the incision should reach into the connective tissue, but not so deep as to direct the dissection into the cervix.[11]

Huang et al.[12] reported that VNOTES was advantageous over TU-LESS in terms of less postoperative pain, and a shorter postoperative stay and time to flatus in ovarian cystectomy. Chen et al.[13] reported similar results in tVNOTEH. In the present study, although no comparison between VNOTES and TU-LESS in hysterectomy was made, the observation that VNOTES was superior in terms of earlier recovery, less pain, and better cosmetic effects was clinically observed. In the study by Wang et al.,[6] the repetition of a similar learning curve placed high demands on the qualifications of the surgeon, hospital set-ups and instruments. However, in our team, the repetition of a similar learning curve could be gained if the surgeon strictly adhered to the SOP, which ensures the repeatability and safety of surgery.

The present study has several limitations. Firstly, our work was limited by its retrospective design with potential errors. Secondly, as the present study included cases with double salpingectomy, the learning curve obtained here was not purely based on hysterectomy. Finally, the sample size was small. Studies with a larger sample size and long-term observations are required to confirm our conclusions.

AUTHOR CONTRIBUTIONS

Lu Huang, Liqiong Huang, Yonghong Lin, and Zheng'ai Xiong were responsible for the conception and design of the study; Li He and Xiaoqin Gan contributed to data collection. Yonghong Lin contributed to data analysis and interpretation and statistical analysis. Li He was the responsible surgeon or imager and contributed to patient recruitment. Liqiong Huang, Li He, Yonghong Lin, and Zheng'ai Xiong contributed to manuscript preparation.

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CONFLICT OF INTEREST

The authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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