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Feasibility and safety of transvaginal natural orifice transluminal endoscopic surgery (V-NOTES) panhysterectomy: a polycentric retrospective study

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Abstract

Objectives To investigate the feasibility and safety of Transvaginal Natural Orifice Transluminal Endoscopic Surgery (V-NOTES) panhysterectomy.

Methods A retrospective analysis was conducted on the data of 75 patients who underwent panhysterectomy for hysteromyoma in the Department of Obstetrics and Gynecology of Tongxiang Maternal and Child Health Hospital; Department of Gynecology, The Affiliated Changzhou Second People's Hospital of Nanjing Medical University and Department of Gynecology, The First Affiliated Hospital of USTC from June 2019 to June 2020. According to the operation mode, the patients were divided into two groups: the traditional multi-port laparoscopic surgery (MPLS) group (n = 45) and the Transvaginal Natural Orifice Transluminal Endoscopic Surgery (V-NOTES) group (n = 30). The operation duration, intraoperative blood loss, postoperative exsufflation time, postoperative activity time, hospital stay, treatment cost, 6 h activities of daily living (ADL) score after the operation, cosmetic score, visual analog score, and complications were observed in the two groups.

Results Perioperative period related indicators: Compared with the MPLS group, the total treatment cost and cosmetic score of the V-NOTES group were significantly better than those of the MPLS group, but the operation duration was longer, and the HB decreased more significantly (P < 0.05). However, there was no significant difference in intraoperative blood loss, postoperative exsufflation time, postoperative activity time, 6 h ADL score after the operation, and hospital stay between the two groups (P > 0.05). Postoperative pain: The VAS score 1 h, 6 h, 12 h, and 24 h after the operation was lower in the V-NOTES group than in the MPLS group (P < 0.05). Postoperative complications: The complication rate of the V-NOTES group was significantly lower than that of the MPLS group (P < 0.05).

Conclusions In treating panhysterectomy patients, both V-NOTES and MPLS can achieve satisfactory efficacy and prognosis, and both have advantages and disadvantages. Specifically, the V-NOTES surgery has significant

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advantages such as a lower treatment cost, lower incidence of postoperative complications, less pain, and more beautiful wounds.

Keywords Panhysterectomy, Transvaginal natural orifice transluminal endoscopic surgery (V-NOTES), Multi-port laparoscopic surgery (MPLS)

Transvaginal natural orifice transluminal endoscopic surgery (V-NOTES), a novel surgical method, has been praised by the public for its minimally invasive and excellent cosmetic effect. Compared with the traditional multi-port laparoscopic surgery (MPLS), V-NOTES is called the "third-generation surgical operation" [1]. NOTES refers to using endoscopic equipment through a natural body cavity such as the oral cavity, esophagus, stomach, nodal (straight) intestine, vagina, and bladder into the pelvic cavity or chest cavity for surgical operations. Compared with other body cavities, endoscopic operation through the vagina has less possible damage to normal organs and is more widely used in gynecology. Moreover, gynecologists are more familiar with the anatomy of the vagina and female pelvic cavity and have rich experience in Yin surgery. With this unique advantage, V-NOTES surgery in gynecology will certainly have a broader prospect of application [1, 2]. Currently, the transvaginal perforation technique has been used in the operation of common gynecological benign diseases with properly controlled indications, such as uterinerelated surgery, adnexal surgery, pelvic organ prolapse and staged surgical treatment of endometrial carcinoma [3-10] and systematic and repeatable experience and skills have been summarized. In addition, surgical safety is relatively reliable, which lays a solid foundation for the study of surgical techniques and large-scale clinical trials in the future.

With the progress and development of medical technology, laparoscopic technology has been widely used in clinical practices. However, laparoscopic technology has high equipment requirements, great operation difficulty, and a small scope of adaptation, which limits its clinical promotion and use to a certain extent [11]. However, with the surgical concept innovation in recent years, V-NOTES surgery has gradually gained popularity in the surgical field with its wide adaptability, fewer complications, high safety, and quick recovery, among other advantages. The study conducted by Ozceltik et al. demonstrated that: Implementing vNOTES and integrating it into traditional VH can increase the utilization of the vaginal route for hysterectomy [12]. This study retrospectively analyzed the clinical medical records of patients to compare the clinical feasibility and safety of Transvaginal Natural Orifice Transluminal Endoscopic Surgery panhysterectomy and traditional multi-port laparoscopic surgery panhysterectomy.

Data and methodologies Data

Research objects

This study included relevant data from 75 patients who underwent panhysterectomy for uterine fibroids admitted to Department of Obstetrics and Gynecology of Tongxiang Maternal and Child Health Hospital; Department of Gynecology, The Affiliated Changzhou Second People's Hospital of Nanjing Medical University and Department of Gynecology, The First Affiliated Hospital of USTC from June 2019 to June 2020. The patients were divided into two groups according to the surgical methods, among whom 30 were treated by V-NOTES, and 45 were treated with MPLS.

Inclusion and exclusion criteria

Inclusion criteria: (1) All patients were diagnosed by ultrasound, hysteroscopy, and pathology; (2) They had indications of panhysterectomy; (3) The diameter of uterine leiomyoma was less than 8 cm; (4) They had no need for fertility and their drug treatment effect was not good; (5) The patients were informed of the method and purpose of this study and voluntarily signed the consent form.

Exclusion criteria: (1) Malignant lesions of hysteromyoma; (2) Patients with severe cardiac, liver, and renal dysfunction; (3) Patients with severe abnormal coagulation function; (4) Patients with a history of multiple pelvic surgeries; (5) Incomplete clinical data.

Method of operation

MPLS group

The patient took the bladder lithotomy position and received general anesthesia, with the bladder emptied and the uterine cup placed. The navel was chosen as an incision of about 10 mm in length. After the puncture with a pneumoperitoneum needle, the CO_2 pneumoperitoneum was established, and the pressure was maintained at 13–15 mmHg. A 5 mm incision was, respectively, made at the anti-McDonnell point, the umbilical 5 cm point, and the McDonnell point in the vascularized area of the lower abdominal wall, and the cannula was inserted into the laparoscopic system. With the help of laparoscopy to

fully evaluate the situation in the abdominal and pelvic cavity, bipolar electrocoagulation was used after contraindications were excluded to cut off the bilateral round ligament of the uterus completely and proper ligament of the ovary, separate the uterine artery retrogradely to the branch origin of the internal iliac artery and then cut it. Then cut off the bilateral uterine main ligament and sacral ligament, use a unipolar hook to open the uterus and bladder peritoneum, and then push the bladder down. Next, the assistant pushed the fornix cup up and lifted the anterior dome to let the surgeon cut off the vaginal wall along its top. The whole uterus was removed from the vagina, the vaginal stump was sutured, and the pelvis was washed. After a hemostasis check and instrument removal, the operation was completed [13].

Surgical method of V-NOTES group

The patient took the bladder lithotomy position, with the labia minora sutured on both sides and fixed on the lateral skin to fully expose the cervix. Then clamp the cervix with an Allis clamp. First, inject diluted epinephrine or normal saline to form a water cushion (Fig. 1a), cut open the anterior wall of the vagina on the left and right sides at 1.5 cm on top of the cervicovaginal junction, push up the bladder to unfold the bladder peritoneum and facilitate entry into the abdominal cavity (Fig. 1b). Next, make an incision on the left and right sides of the posterior wall of the vagina at 1.5 cm on top of the cervicovaginal junction, separate the cervix and vaginal mucosa upward along the posterior wall of the cervix and unfold the uterus-rectum reflex peritoneum to facilitate entry into the abdominal cavity (Fig. 1c). Next, use an S-shaped retractor to fully expose the visual field for operation, use a clamp close to the cervix to cut off the bilateral uterine-sacral ligament and the main ligament (Fig. 2a), and double suture the incision with the No. 7 line to the level of bilateral uterine arteries and veins. Laparoscopic operation was performed after the insertion of Port (in this study, glovport was used, which was made of surgical aseptic gloves. The cuffs of the gloves were connected to the outside of the protective ring and fixed by silk thread. Cut off the 3 fingertips of the glove, insert the Trocar, and fix it with silk thread again) (Fig. 2b). Cut off the fallopian tube, ovarian ligament, broad uterine ligament, and the round ligament (Figs. 2c, 3a, b), and remove the uterus via the transvaginal port (Fig. 3c). Examine the



Fig. 1 a Inject diluted epinephrine to form a water cushion b cut open the anterior wall of the vagina and unfold the bladder peritoneum c cut open the posterior wall of the vagina and unfold the uterus–rectum reflex perineum



Fig. 2 a Cut off the bilateral uterine-sacral ligament and the main ligament b inserted the port c cut off the fallopian tube



Fig. 3 a Cut off the ovarian ligament b cut off the broad uterine ligament and the round ligament c remove the uterus

Table 1 Baseline data comparison

Baseline data	MPLS group	V-NOTES group	P Value
Age	51.180±5.001	40.470±12.540	0.000
BMI	23.820 ± 2.670	22.700 ± 3.440	0.060
Pregnancies	3.090 ± 1.240	2.730 ± 1.310	0.620
Deliveries	1.360 ± 0.530	1.570 ± 0.820	0.000
Uterine weight	319.770±31.290	321.180 ± 30.450	0.602

MPLS: multi-port laparoscopic surgery; V-NOTES: transvaginal natural orifice transluminal endoscopic surgery; BMI: body mass index

Bold values indicate statistical significance (P<0.05)

peritoneum and vaginal wall to eliminate uterine residue and bleeding, and then suture them to complete the operation [14].

Observation and evaluation indicators **Baseline** information

The numbers of pregnancies and deliveries, BMI, and age in the baseline information were queried and collected from the intelligent medical record system of the hospital. The uterine weight was measured and recorded by designated personnel after the specimens were taken out (see Table 1 for details).

Perioperative indicators

The perioperative indicators, such as operation duration, hemoglobin (Hb) decline, intraoperative blood loss, postoperative exsufflation time, postoperative activity time, hospital stay, and treatment cost, were queried from the hospital medical record system and the registration forms of related departments or calculated. Specifically, the operation duration is calculated based on the time of anesthesia completion to the end of the operation. The hemoglobin decline is the difference between the patient's hemoglobin before surgery and the first day after surgery. The treatment cost is the original cost not covered by medical insurance (see Table 2 for details).

Related scores

Visual Analogue Score (VAS) at 1 h, 6 h, 12 h, and 24 h after surgery [15] of patients was calculated and registered by designated personnel at the corresponding time after surgery. VAS score is clinically used to evaluate patients' pain and follows a scale from 0 to 10. The lower the score, the less pain the patient feels [16, 17]. CS was followed up on and registered by designated personnel at 4-6 weeks after surgery and assessed via 6-8 questions on the Body Image Questionnaire (BIQ), with a score ranging from 3 to 24. The higher the score, the more satisfied the patient is regarding the aesthetic effect of their

Table 2	Comparison of	perioperative indicators between the two groups ($\overline{x} \pm s$)

Indicator	MPLS group	V-NOTES group	<i>P</i> Value
Operation duration	103.240±22.860	122.800±46.990	0.000
Intraoperative blood loss	44.110±43.270	33.500 ± 36.440	0.810
HB decline	6.250 ± 4.190	13.900±8.310	0.001
Hospital stay	9.870 ± 3.990	6.370 ± 3.860	0.490
Exsufflation time	27.180 ± 10.120	16.830±13.110	0.360
Treatment cost	14,053.970±2367.690	10,822.830±3627.200	0.001

MPLS: multi-port laparoscopic surgery; V-NOTES: transvaginal natural orifice transluminal endoscopic surgery; HB: hemoglobin Bold values indicate statistical significance (P<0.05)

Table 3 Comparison of postoperative scores between the two groups ($\overline{x} \pm s$)

Indicator	MPLS group	V-NOTES group	P Value
1H VAS score	5.63±1.42	3.59±0.71	0.010
6H VAS score	4.58 ± 0.61	2.33 ± 0.45	0.013
12H VAS score	2.74 ± 0.55	1.09±0.26	0.011
24H VAS score	1.33 ± 0.29	0.24 ± 0.08	0.007
CS score	17.62 ± 0.58	20.7 ± 0.92	0.001
ADL score after 6H	48.22 ± 9.95	53.67 ± 9.19	0.730

Bold values indicate statistical significance (P<0.05)

Table 4Comparison of postoperative complications betweenthe two groups

Complication	MPLS group	V-NOTES group	P value
Fever	3 (6.66)	0 (0)	-
Vaginal wall hematoma	2 (4.44)	1 (3.33)	-
Vaginal stump hemorrhage	1 (2.22)	1 (3.33)	-
Bladder injury	1 (2.22)	1 (3.33)	-
Ureteral injury	1 (2.22)	0 (0)	-
Subcutaneous emphysema	1 (2.22)	0 (0)	-
Total incidence rate (%)	9 (20)	3 (10)	0.002

MPLS: multi-port laparoscopic surgery; V-NOTES: transvaginal natural orifice transluminal endoscopic surgery

Bold values indicate statistical significance (P<0.05)

wound [18, 19]. The activities of daily living (ADL) score 6 h after surgery is clinically used to evaluate the postoperative ability of patients in daily life, including eating, dressing, washing, walking, and defecating. The internationally modified BARTHEL score is adopted, following a 0–100 scale. The higher the score, the less impact on daily life [20, 21] (see Table 3 for details).

Operative complications

Patients with fever, hematoma of the vaginal wall, bleeding of the vaginal stump, bladder injury, ureter injury, subcutaneous emphysema, and other related complications after the operation shall be registered by designated personnel (see Table 4 for details).

Statistical analysis

Data in this study were analyzed and processed with the *SPSS 26.0* software. The baseline data, perioperative indicators, related scores, and other measurement data were represented by " $\bar{x} \pm s$ ", and an independent sample *T* test was used. *P*<0.05 means that the difference is statistically significant Usebold notation in the table. "%" represents the statistical data of complications, and the χ^2 test was used. *P*<0.05 means that the difference was statistically significant.

Technology roadmap

See Fig. 4. [14]

Results

Baseline data of the two patient groups

A total of 75 patients who underwent panhysterectomy due to uterine fibroids were included in this study, including 45 patients in the MPLS group and 30 in the V-NOTES group. The baseline data of the two groups were statistically analyzed, and there were no statistically significant differences in mean uterine weight (g), pregnancies, and BMI (kg/m₂) (P>0.05). The difference between age and number of deliveries was statistically significant (P<0.05), but the two indicators did not significantly impact the relevant data discussed in this study. Therefore, it was considered that the two groups of data were still comparable. See Table 1 for details.

Perioperative related indicators of the two patient groups

There were no significant differences in the two groups' intraoperative blood loss, exsufflation time, postoperative activity time, and hospital stay (P > 0.05). The operation duration in the V-NOTES group was significantly longer than that in the MPLS group, and the former's HB decline was significantly greater than that in the MPLS group. However, the former's treatment cost was significantly lower than that in the MPLS group, with statistically significant differences (P < 0.05), as shown in Table 2.

Relevant scores of the two patient groups

The VAS scores of the V-NOTES group at 1 h, 6 h, 12 h, and 24 h after the operation were significantly lower than those in the MPLS group, and the CS scores of the V-NOTES group were higher than those in the MPLS group, with statistically significant differences (P < 0.05). However, there was no significant difference in ADL scores at 6 h after the operation between the two groups (P > 0.05), as shown in Table 3.

MPLS, multi-port laparoscopic surgery; V-NOTES, transvaginal natural orifice transluminal endoscopic surgery; VAS, visual analog score; CS, cosmetic score; ADL, activities of daily living; H, hour;

Postoperative complications of the two patient groups

The incidence of postoperative complications in the V-NOTES group (6.66%) was significantly lower than that in the MPLS group (20%), and the difference was statistically significant (P < 0.05). In the V-NOTES group, there was 1 case of postoperative hematoma of the vaginal wall, vaginal stump hemorrhage, and bladder injury, respectively. In the MPLS group, there were



Fig. 4 The specific experimental procedures of this study

3 cases of fever, 2 cases of vaginal wall hematoma, and 1 case of vaginal stump hemorrhage, bladder injury, ureteral injury, and subcutaneous emphysema, respectively, as shown in Table 4.

Discussion

Patients who underwent panhysterectomy due to hysteromyoma were selected for the study. As hysteromyoma is a common clinical disease, its prevalence rate is on the rise and tends to be found among younger patients [22, 23], making it easier for clinical data collection. The existing hysteromyoma treatment options include drug therapy and surgical therapy, and surgery is the most effective and direct mode of treatment. If the patient has no fertility requirements, panhysterectomy can be adopted to avoid recurrence and effectively achieve radical treatment [24]. Panhysterectomy includes laparotomy, transvaginal panhysterectomy, traditional laparoscopic panhysterectomy, and transvaginal single-port laparoscopic panhysterectomy. Currently, traditional laparotomy is gradually being replaced by more advanced minimally invasive surgical techniques due to the former's disadvantages of large trauma, slow recovery, and many complications [25]. This article discusses the feasibility and safety of transvaginal natural orifice transluminal endoscopic surgery panhysterectomy through a comparative analysis of patients' clinical data.

Our team's study showed that, in the treatment of panhysterectomy patients, both groups achieved satisfactory efficacy and prognosis, with advantages and disadvantages. Specifically, the V-NOTES group had significant advantages of a lower treatment cost, less pain, and more beautiful wound. In addition, its postoperative pain score was lower than that of laparoscopic surgery in various periods, with a lower incidence rate of complications as well. Especially in the VAS score of each time period after operation, it is consistent with the research results of Kaya [26, 27]. The existing research of foreign scholars also shows that laparoscopic surgery can cause damage to nerves, blood vessels, ligaments, and other tissues to varying degrees, which may lead to abnormal secretion of postoperative hormones, and ultimately adversely affect libido and sexual life quality. V-NOTES, however, has smaller damage to the body and plays a certain comforting role in pain reduction, wound beauty, and other aspects of patients, to improve patients' subjective feelings, avoid mood disorders, and ultimately improve the sexual life quality. It can also effectively reduce the risk of postoperative complications [28, 29]. In this study, the incidence of postoperative bladder injury, vaginal wall hematoma, vaginal stump bleeding, and other related complications in the observation group was significantly lower than that in the control group, with statistically significant differences, which was in good agreement with the research results of scholars such as Rakotomahenina [29].

But our results also showed that the operation time of V-NOTES group was significantly longer than that of MPLS group, and the decrease of HB was significantly higher than that of MPLS group. The results of this study were contrary to the results of Kaya et al. [26, 27, 30]. The results of their team showed that V-NOTES time was shorter, and there was no significant difference in HB decrease between the two groups. However, when this study was conducted, V-NOTES surgery was initially carried out in our hospital, and the surgery was greatly affected by subjective factors such as the proficiency of the surgeon, which made the data corresponding to these two indicators biased, so the results obtained by different studies were also very different. The main consideration was that V-NOTES, contrary to the traditional field of view of MPLS, adopts a bottom-up perspective of the uterus and the two appendages, increasing the difficulty of operation. Although the vagina had good ductility, it was relatively narrow, making it difficult to place V-NOTES dedicated port, especially for physicians who are not that experienced in this operating procedure. Therefore, it may take longer to establish the pelvic approach and suture the incision on the vaginal wall after the operation. Besides, intraoperative suture and hemostatic operations are relatively slow, increasing the total operation duration. Especially for doctors who are new to this procedure. Therefore, surgeons need more time to get familiar with and adapt to V-NOTES, which is one of the reasons for the relatively slow promotion of V-Notes [31].

Combined with the results of this study and existing domestic and foreign literature reports, the author summarized the advantages of V-NOTES in clinical application as follows: (1) The vaginal incision has relatively good expansibility, without a need to crush the specimens with a morcellator, which is more conducive to the removal of large specimens such as the uterus, and V-NOTES makes the operation directly visible, allowing a clear view of the entire pelvic cavity, expanding its application [8, 32]. (2) V-NOTES achieves "no scar" on the body surface in the real sense, which meets the pursuit of beauty by female patients in the new era [33]. (3) The vaginal fornix is innervated by visceral nerves, so the incision pain is less [34], and the complications of abdominal wall incision infection and hernia can be avoided, compared with traditional laparoscopy. (4) V-NOTES has less effect on the gastrointestinal tract and can effectively promote better and faster recovery of gastrointestinal motility, shortening the exsufflation time and facilitating rapid postoperative recovery. (5) The anesthesia depth required for this procedure is shallow, which reduces the anesthesia risk. Combined with the advantages of V-NOTES in less pain, patients can get out of bed earlier, indirectly reducing the incidence of postoperative pulmonary atelectasis and lung infection and shortening the postoperative hospital stay and recovery time [35].

With the continuous innovation and progress of medical device research and development in China, the minimally invasive concept can be popularized among gynecologists. However, its development is also restricted by many factors, such as equipment, instruments, and technology. For example, the glov port adopted in this study is made of sterile surgical gloves. Although the thermal cost is lower than that of the special port, there is a risk of air leakage during use, and it is inconvenient for frequent specimen removal. In addition, soft gloves or inappropriate length of gloves will affect surgical operation. Therefore, it is also the common responsibility of domestic enterprises and gynecological endoscopists to improve the existing laparoscopic equipment and instruments to better serve most female patients. Developing and promoting a new technology cannot go without stepped training. V-NOTES training also requires a series of procedures such as a pelvic simulator, animal model, surgical observation, and tutor guidance. This new technology can only be applied after it completes a learning curve with more practice of various operations under the microscope, with the mastery of instruments and knowledge about female pelvic anatomy [8].

The retrospective nature and sample size is the main limitations of this study. Limited by time and other factors, this study only conducted a single-center, smallsample retrospective analysis, and failed to conduct long-term follow-up of patients and evaluate the longterm effects of postoperative sexual life and vaginal delivery. Therefore, it is expected to increase the sample size in future studies, extend the follow-up time of patients, and carry out more comprehensive and indepth evidence-based studies.

The development of V-NOTES, like other emerging technologies, necessitates an initial phase of exploration and gradual refinement. However, we firmly believe that with advancements in instrumentation, technological enhancements, and the accumulation of experience, V-NOTES will undoubtedly bring greater benefits to a larger number of patients in the future.

Author contributions

Panlian Qian wrote the manuscript; Weimin Chen, Bin Su is in charge of collecting data and drawing graphs; Yao Chen, Wulin Shan, Huimin Tang and Weiwei Wei assisted in revising, polishing and collecting related images; Huihui Wang provided critical input to the study and was responsible for the final review of the manuscript; Bairong Xia and Jiming Chen provided key technical support for this study and the revision of the article. All authors reviewed the manuscript.

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Availability of data and materials

This study used data to ensure authenticity, provided by the obstetrics and Gynecology department of Tongxiang Maternal and Child Health Hospital.

Declarations

Ethics approval and consent to participate

This study has passed the review of the Ethics Committee of Changzhou Second People's Hospital and agreed to participate and agree to publish.

Competing interests

The authors declare no competing interests.

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