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Original Research

Comparison of Hysterectomy and Bilateral Adnexectomy Performed via Laparoscopy or vNOTES: A Retrospective Cohort Study of 390 Patients

Li Chen[1], Bingli Zhang[1], Shan He[1], Ping Zhou[1], Qijun Zhong[1], Tao Hou[1,*], Wen He[1,2,*]

[1]Department of Gynecology, Meizhou People's Hospital, 514031 Meizhou, Guangdong, China
[2]Department of Reproductive Medicine, Meizhou People's Hospital, 514031 Meizhou, Guangdong, China
*Correspondence: GDhoutao@126.com (Tao Hou); doctorhoman@163.com (Wen He)

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Abstract

Background: This research aims to evaluate the clinical outcomes of vaginal natural orifice transluminal endoscopic surgery hysterectomy (vNOTESH) compared with conventional laparoscopic hysterectomy (cLH) on non-prolapsed uteri for presumed benign gynecologic disorders. **Methods**: We retrospectively analyzed the data of all patients receiving vNOTESH or cLH in Meizhou People's Hospital, Meizhou, China from January 2018 and December 2020. Relevant patient characteristics and clinical outcomes data were collected after written informed consent. **Results**: There were no significant differences between cLH and vNOTESH groups regarding age, body mass index (BMI), number of pregnancy, history of abdominal operation, type of surgery, blood loss, changes in hemoglobin levels, postoperative fever, complications, 12th-hour, and 48th-hour Visual Analog Scale (VAS) scores. The vNOTESH group had significantly shorter operative time (67.37 $\pm$ 25.90 *vs.* 89.71 $\pm$ 36.43 min, $p < 0.001$) and postoperative hospitalization (5.25 $\pm$ 1.67 *vs.* 5.82 $\pm$ 2.88 d, $p = 0.007$) than the cLH group. Besides, the 24th-hour VAS scores were noticeably lower (1.50 $\pm$ 0.75 *vs.* 1.78 $\pm$ 0.77, $p = 0.001$) in the vNOTESH group. Furthermore, the subgroup analysis showed similar trend in operative time (83.56 $\pm$ 33.37 *vs.* 95.84 $\pm$ 33.83 min, $p = 0.017$) and 24th-hour VAS scores (1.38 $\pm$ 0.59 *vs.* 1.79 $\pm$ 0.75 min, $p = 0.001$) between the two enlarged uterine subgroups. **Conclusions**: The vNOTESH can offer a safe and effective alternative to laparoscopy for women with non-prolapsed benign uteri. Even in case with a large uterus, the vNOTESH can be a feasible treatment with promising short-term efficacy and safety as compared with cLH.

Keywords: hysterectomy; adnexectomy; bilateral salpingectomy; transvaginal natural orifice transluminal endoscopic surgery

1. Introduction

Hysterectomy and bilateral adnexectomy (or bilateral salpingectomy) is one of the most common gynecological operations worldwide, which is majorly performed for benign gynecologic diseases, such as leiomyoma, adenomyosis, severe dysmenorrhea and uterine prolapse [1]. Nowadays, there are four main approaches to perform hysterectomy: abdominal hysterectomy, vaginal hysterectomy (VH), conventional laparoscopic hysterectomy (cLH), and the emerging vaginally assisted natural orifice transluminal endoscopic surgery hysterectomy (vNOTESH) [2]. Increasing evidence has demonstrated that cLH and VH can provide shorter recovery period, less postoperative pain, and fewer complications than conventional abdominal hysterectomy [3]. Furthermore, vNOTESH, which derived from the combination of endoscopic techniques and vaginal procedures, has clear advantages over cLH or VH including outstanding scar-free cosmetic outcomes and no trocar-related complications [4,5].

It has been a decade since Su *et al.* [6] firstly described that hysterectomy via vaginal natural orifice transluminal endoscopic surgery (vNOTES) can be performed in human. To date, increasing data highlighted the feasibility of vNOTESH for benign gynecological indications [7]. However, the current reports on the vNOTESH are small sample reports [8–10]. Up to date, there is only one published randomized control trial demonstrating that vNOTESH was non-inferior to cLH with small numbers of included patients [11]. Whilst still a relatively new gynecological surgery concept, the evidence pertaining to vNOTESH in benign gynecology is in its infancy due to the insufficient relevant data. Thus, the aim of this study is to compare the clinical outcomes between vNOTESH and cLH on non-prolapsed uteri for benign gynecologic indications in a large reported cohort of patients.

2. Materials and Methods

2.1 Patients

This was a retrospective cohort study comparing the clinical outcomes between vNOTESH and cLH in women with non-prolapsed benign uteri. The study was conducted in the Department of Gynecology, Meizhou People's Hospital in China. The patients included underwent treatment between January 2018 and December 2020. The study was

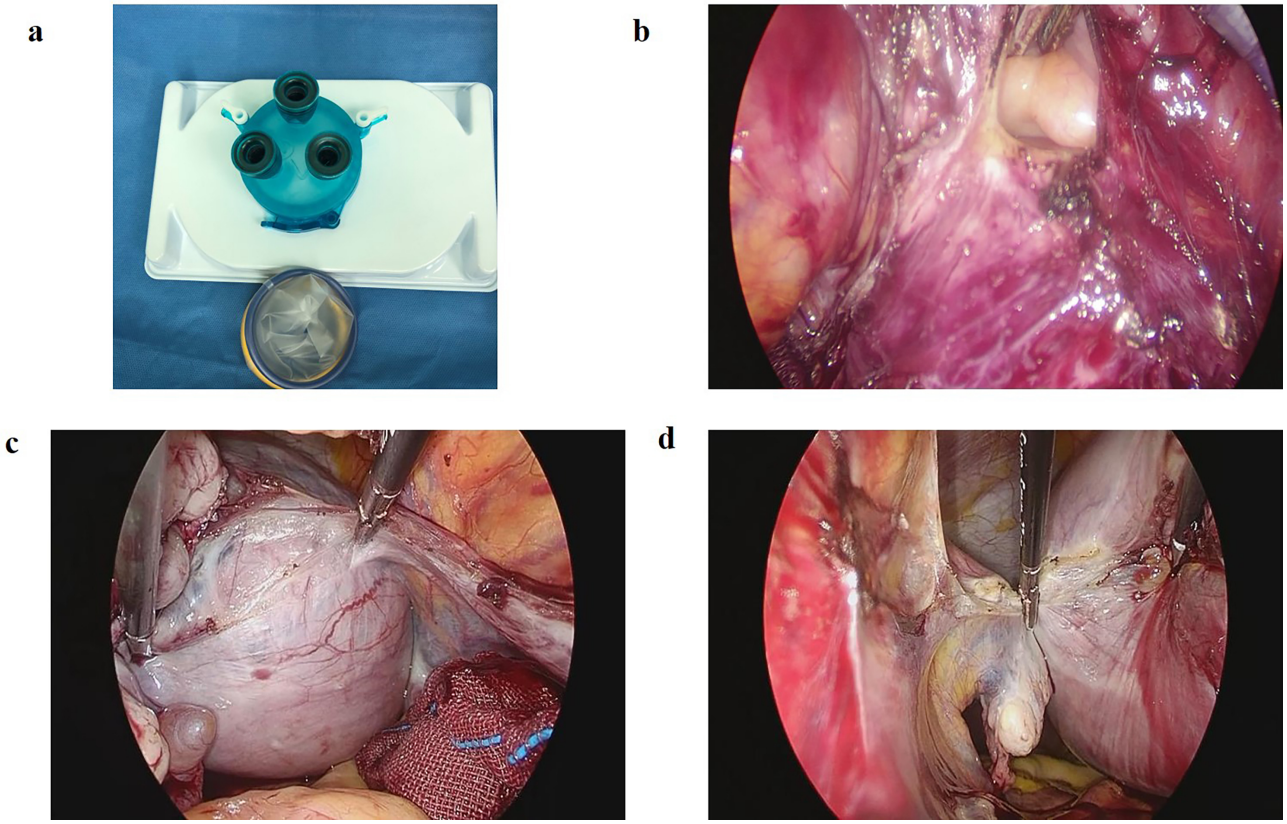

Fig. 1. The vNOTES single-ports device and hysterectomy procedure via vNOTES. (a) The vNOTES single-ports device. (b) A 2–3 cm incision was made in anterior peritoneum identified by the "Bubbling sign". (c) Appearance of pelvic cavity in vNOTES. (d) It was shown that the right ovaria propria ligaments were sealed.

approved by the Research Ethics Committee of the Meizhou People's Hospital.

The women between 31–72 years of age undergoing hysterectomy and bilateral adnexectomy (or bilateral salpingectomy) for benign disease (fibroids, adenomyosis, dysfunctional uterine bleeding, endometrial hyperplasia, and high-grade cervical intraepithelial lesion) were eligible for the study. To minimize the potential confounding factors, exclusion criteria of subjects were as follows: (1) women with no history of vaginal sex life, or (2) women with suspected complete obliteration of the cul-de-sac associated with severe endometriosis at pelvic examination, or (3) women with suspected malignancy, or (4) women with vaginal stenosis, or (5) women with a prolapsed uterus. Obesity (body mass index (BMI) $\geq$30 kg/m^2) or history of cesarean section were not considered as surgical contraindications. In this study, the selections for the surgery approaches were based on the patients' preference after preoperative education about the benefit and risks of laparoscopic and vNOTESH.

2.2 Surgical Treatment

Antibiotics were given routinely 0.5 hours before operation. Patients were performed general anesthesia and placed in Trendelenburg lithotomy position lithotomy. A foley catheter or metal catheter was inserted to empty the bladder.

2.3 vNOTESH Surgical Process

After injection of a 10 mL 0.9% Nacl cushion around the cervix, a circumferential cervical incision was performed with a scalpel. The vaginal mucosa was pushed by blunt/sharp dissections along with the cervical fascia to achieve appropriate anterior and posterior colpotomy. We clamped and then cut off the posterior and lateral ligaments to block the blood supply of the uterus. Then the anterior and posterior cul-de-sac was incised, followed with the insertion of the single-ports device (AQ-Z-B-60/70-60/-100, Nantong Angel Medical Instruments Co., Ltd, Nantong, Jiangsu, China). The pneumoperitoneum was established with 10 mmHg pressure. Notably, "Bubbling sign" may appear in the peritoneum after pneumoperitoneum, which can help us identify the anterior peritoneum (**Supplementary Video 1**). It was prior to establish the vNOTES to explore the pelvic abdominal cavity especially when the anterior colpotomy was not completed due to adhesion or the bladder peritoneum moved upward. The hysterectomy and the bilateral infundibulopelvic ligaments/ligamentum ovarii propriums excision procedure was proceeded by Ligasure vessel sealer device (Fig. 1). The uterus and bilateral

Table 1. Baseline characteristics of the included patients between vNOTESH and cLH groups.

Characteristics	vNOTESH (n = 200)	cLH (n = 190)	*p*-value
Age (year)	49.24 ± 5.71	49.18 ± 1.53	0.929
Body mass index (kg/m^2)	24.42 ± 3.24	24.26 ± 3.38	0.641
Number of pregnancy	3.28 ± 1.56	3.49 ± 1.76	0.214
Parity (through vaginal delivery)			
0	8 (4.0%)	18 (9.5%)	0.030*
1	30 (15.0%)	35 (18.4%)	0.365
2	103 (51.5%)	66 (34.7%)	0.001**
≥3	59 (29.5%)	71 (37.4%)	0.099
History of abdominal surgery			
1	12 (6.0%)	21 (11.1%)	0.073
≥2	2 (1.0%)	2 (1.1%)	>0.999
Histopathological diagnosis			
Uterine myoma	84 (42.0%)	93 (48.9%)	0.168
Adenomyosis	35 (17.5%)	49 (25.8%)	0.047*
Both Adenomyosis and hysteromyoma	8 (4.0%)	7 (3.7%)	0.871
Endometrial hyperplasia	22 (11.0%)	5 (2.6%)	0.001*
High-grade cervical intraepithelial lesion	51 (25.5%)	36 (18.9%)	0.120
Type of surgery			0.368
Hysterectomy + Salpingo-oopherectomy	65 (32.5%)	70 (36.8%)	
Hysterectomy + Salpingectomy	135 (67.5%)	120 (63.2%)	
Uterine size			< 0.001***
<10-week pregnant uterus	145 (77.0%)	72 (37.9%)	
≥10-week pregnant uterus	55 (23.0%)	118 (62.1%)	

Notes: The values are presented as mean ± standard or number (percentage) (*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$). vNOTESH, vaginally assisted natural orifice transluminal endoscopic surgery hysterectomy; cLH, conventional laparoscopic hysterectomy.

adnexal were removed through the single-ports device. Finally, the peritoneum and vaginal vault were closed using the 1-0 absorbable suture.

For the specimen removement, we gained a better surgery field than the simple vaginal hysterectomy and a larger operation space than the cLH with the single-port in the vaginal vault. We used the vulsellum forceps to hold the cervix and provide the traction. Briefly, we incised the uterus at 12 o'clock position while keeping the traction of the cervix downwards and slightly to the left. The incision continued in an upward circular manner clockwise to 6 o'clock position. Then, we could gradually move it downward. Another vulsellum forceps were used to grasp the upper uterus and the incision was repeated until we could remove the uterus in one piece (**Supplementary Video 2**).

2.4 cLH Surgical Process

After the establishment of the pneumoperitoneum, four trocars were used to entry into the abdominal cavity (one 10 mm main trocar in the supraumbilical area, three 5 mm trocars in the avascular area of abdominal wall). Bipolar and ultrasonic scalpel were used to seal and cut off the round ligaments, uterine arteries, and cardinal ligaments. The uterus and bilateral adnexal were withdrawn through the vaginal stump. Finally, the peritoneum and vaginal vault were closed using the 1-0 absorbable suture.

2.5 Outcome Measures

Demographic information was extracted from both cohorts, including age, body mass index (BMI), gravida, parity, history of abdominal surgery, histopathology, concomitant surgeries, and uterine size. Perioperative date including the operative time, blood loss during the operation, a decrease in hemoglobin level after operation, postoperative Visual Analog Scale (VAS) scores at 12 h, 24 h, 48 h after surgery, perioperative or postoperative complications (such as fever, urinary system injury, pelvic infection, poor healing of vaginal stump), conversion to open operation and length of hospital stay were also extracted.

Patients were subdivided into two subgroups: normal uterine and large uterine subgroups. The normal uterus was defined as the uterus size was smaller than 10-week pregnant uterus, which was measured by gynecological examination (two experienced chief/deputy chief physicians). Otherwise, the uterus which was larger than 10-week pregnant uterus was considered as enlarged uterus.

2.6 Statistical Analysis

The continuous variables were presented as mean ± standard deviation (SD) and were tested by unpaired Stu-

Table 2. Comparison of perioperative outcomes between vNOTESH and cLH groups.

Characteristics	vNOTESH (n = 200)	cLH (n = 190)	*p*-value
Operative time (min)	67.37 ± 25.90	89.71 ± 36.43	<0.001***
Blood loss (mL)	37.15 ± 22.42	43.58 ± 43.79	0.071
Changes in Hemoglobin levels (g/L)	–10.81 ± 14.32	–9.68 ± 10.95	0.385
Postoperative fever	3 (1.5%)	12 (6.3%)	0.017*
Postoperative hospitalization	5.25 ± 1.66	5.82 ± 2.88	0.007
Post-operative complications			>0.999
Urinary system injury	3 (1.5%)	1 (0.5%)	
Vaginal infection/bleeding	2 (1.0%)	1 (0.5%)	
Pelvic hematoma	2 (1.0%)	0	
Conversions	1 (0.5%)	0	
Post-operative pain (VAS)			
12 h	2.48 ± 1.06	2.40 ± 0.88	0.446
24 h	1.5 ± 0.75	1.78 ± 0.77	0.001**
48 h	1.06 ± 0.57	1.11 ± 0.57	0.436

Notes: The values are presented as mean ± standard or number (percentage) (*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$). vNOTESH, vaginally assisted natural orifice transluminal endoscopic surgery hysterectomy; cLH, conventional laparoscopic hysterectomy; VAS, visual analog scale.

dent's *t* test. Dichotomous data were shown as percentages. Differences between categorical variables were tested using Pearson's Chi-square test or Fisher's exact test. Two-sided *p* value less than 0.05 was considered as statistically significant. Statistical analyses were conducted using SPSS version 26.0 (SPSS Inc., Chicago, IL, USA).

3. Results

A total of 390 patients were enrolled in this research from January 2018 to December 2020. 190 women were treated with cLH and the other 200 cases were treated with vNOTESH. The baseline characteristics were shown in Table 1. There were no significant differences between vNOTESH and cLH groups regarding age, BMI, number of pregnancy, history of abdominal surgery, and the type of surgery. However, women with two prior vaginal deliveries in the vNOTESH group were more than that in the cLH group (103 *vs.* 66, $p = 0.001$).

Furthermore, 145 patients (77.0%) had a uterus size <10-week pregnant uterus in vNOTESH group, whereas 72 patients (37.9%) undergoing cLH ($p < 0.001$). The most common histopathological diagnosis was uterine myoma in both groups. The proportion of adenomyosis (17.5% *vs.* 25.8%, $p = 0.047$) and endometrial hyperplasia (11.0% *vs.* 2.6%, $p = 0.001$) were observed significantly different between the two groups.

The perioperative outcomes were demonstrated in Table 2. The operative time (67.37 ± 25.90 *vs.* 89.71 ± 36.43 min, $p < 0.001$), postoperative hospitalization (5.25 ± 1.66 *vs.* 5.82 ± 2.88 d, $p = 0.007$) and 24th-hour post-operative VAS scores (1.5 ± 0.75 *vs.* 1.78 ± 0.77, $p = 0.001$) were significantly lower in vNOTESH group than those in cLH group. However, there were no obviously differences regarding blood loss, changes in hemoglobin levels, postoperative fever, complications, or 12th-hour and 48th-hour post-operative VAS scores between vNOTESH and cLH groups. Only one patient in vNOTESH group was converted into conventional laparoscopy due to deep pelvic endometriosis. There were 3 urinary system injury cases in vNOTESH group and 1 case in cLH group ($p > 0.999$). One of the 3 urinary system injury cases in vNOTESH group happened during opening the anterior peritoneal reflection in a patient with a large uterus. Therefore, it was necessary to open the anterior peritoneal reflection under the "Bubbling sign" for vNOTESH for large uterus.

In order to further illustrate the feasibility of vNOTESH, we sub-analyzed the data according to different sizes of uterus (Table 3). About 2/3 of the enlarged uterine patients were in the cLH group. Women with smaller uteri were apt to undergo vNOTESH. Regardless of the size of the uterus, there were no statistical differences in terms of age, BMI, changes in hemoglobin levels, postoperative fever and 12th-hour and 48th-hour post-operative VAS scores between the two groups. However, in the large uterine subgroup, the 24th-hour post-operative VAS scores (1.38 ± 0.59 *vs.* 1.79 ± 0.75, $p = 0.001$) and operative time (83.56 ± 33.37 *vs.* 95.84 ± 33.83 min, $p = 0.017$) were significantly lower in the vNOTESH group than that in the cLH group. Furthermore, in the normal uterine subgroup, postoperative hospital stays (5.28 ± 1.66 *vs.* 5.83 ± 1.87 d, $p = 0.026$) and operative time (61.61 ± 19.44 *vs.* 79.65 ± 38.50 min, $p < 0.001$) were significantly lower in vNOTESH group than that in cLH group.

4. Discussion

The present research revealed that vNOTESH and cLH had comparable clinical outcomes for women with non-prolapsed benign uteri regardless of the size of the

Table 3. Sub-analysis of clinical outcomes between vNOTESH and cLH groups according to the size of uterine.

Characteristics	vNOTESH	cLH	*p*-value
Uterine size ≥10-week pregnant uterus			
	n = 55	n = 118	
Age (year)	47.29 ± 4.19	48.43 ± 4.81	0.132
Body mass index (kg/m^2)	24.48 ± 3.46	24.52 ± 3.49	0.590
Operative time (min)	83.56 ± 33.37	95.84 ± 33.83	0.017*
Blood loss (mL)	46.00 ± 4.42	48.81 ± 52.92	0.717
Changes in Hemoglobin levels (g/L)	–10.44 ± 16.25	–9.63 ± 10.76	0.698
Postoperative fever	1 (1.8%)	10 (8.4%)	0.177
Postoperative hospitalization	5.18 ± 1.67	5.81 ± 2.50	0.900
Post-operative pain (VAS)			
12 h	2.51 ± 1.13	2.46 ± 0.96	0.757
24 h	1.38 ± 0.59	1.79 ± 0.75	0.001**
48 h	0.96 ± 0.51	1.11 ± 0.58	0.110
Uterine size <10-week pregnant uterus			
	n = 145	n = 72	
Age (year)	49.97 ± 6.04	50.42 ± 6.40	0.617
Body mass index (kg/m^2)	24.39 ± 3.17	23.83 ± 3.17	0.224
Operative time (min)	61.61 ± 19.44	79.65 ± 38.50	<0.001***
Blood loss (mL)	33.79 ± 15.81	35.00 ± 19.28	0.624
Changes in Hemoglobin levels (g/L)	–10.95 ± 13.58	–9.78 ± 11.33	0.528
Postoperative fever	2 (1.4%)	2 (2.8%)	0.601
Postoperative hospitalization	5.28 ± 1.66	5.83 ± 1.87	0.026*
Post-operative pain (VAS)			
12 h	2.46 ± 1.03	2.31 ± 0.74	0.251
24 h	1.54 ± 0.79	1.76 ± 0.79	0.058
48 h	1.10 ± 0.59	1.10 ± 0.56	0.994

Notes: The values are presented as mean ± standard or number (percentage) (*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$). vNOTESH, vaginally assisted natural orifice transluminal endoscopic surgery hysterectomy; cLH, conventional laparoscopic hysterectomy; VAS, visual analog scale.

uterus. Furthermore, it was also found that vNOTESH offered significantly less post-operative pain, shorter duration of surgery and hospitalization than cLH. Currently, the largest series of hysterectomy performed via vNOTES has been reported by Wang *et al*. [12]. However, only few researches exist which access the feasibility and clinical outcomes between vNOTESH and cLH for benign gynecologic conditions [10,13]. To the best of our knowledge, this is the largest retrospective study of natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy combining the advanced devices being successfully performed on patients with cLH as control.

Along with the development of devices, we have used the single ports and 30-degree lens for vNOTESH procedure. Compared with the gloves [12], the single ports can not only prevent the carbon dioxide leakage, but also facilitate the entry and exit of instruments and specimens [13]. Furthermore, the easy-to-attach/detach single-ports device can reduce the "chopstick effect" between the instruments as compared with the gloves. As results, the mean duration of surgery for the normal uterine vNOTESH subgroup was 61.61 ± 19.44 min, much less than the previous results [5,9,12–15]. All of which, combined with no extra incision and closure of the abdominal wall and no need for the uterine manipulator, further shortens the duration of surgery in vNOTESH as compared with cLH. Regarding the feasibility of vNOTESH for the management of enlarged uterine, our results revealed that the mean duration of surgery decreased significantly vNOTESH group comparing with cLH. Unlike traditional VH or cLH, the distention of vagina by the single port allowed the surgeon to remove the specimen solely. Consistent with a recent report by Kaya *et al*. [16], the present data confirmed that vNOTESH is an effective technique even for women with undescended enlarged uterine.

VH had been generally considered as the most minimally invasive approach to hysterectomy, which ended up with the least postoperative pain and lowest incidence of postoperative complications [17,18]. However, a recent clinical practice suggests that VH was less likely accompanied by a concomitant adnexal surgery due to a narrow surgery field and so on [19]. In the vNOTESH group, we could easily approach to the uterine vessels and block the blood supply effectively and safely, like the procedure

of VH [20]. Furthermore, vNOTESH can offer a clear and wide visual field of operation on the concomitant adnexal surgery under direct vision with the 30° laparoscope [12]. With the vaginally assisted procedure, we could seal the round, broad and infundibulopelvic ligament sunder an endoscopic view, which improved the surgery safety and processed the operating time. Gynecologists can inspect for hemostasis on the pelvic side walls before removing the port, which is difficult to be viewed through simple VH. Therefore, the vNOTESH group achieved comparable blood loss, changes in hemoglobin levels, and postoperative complications to cLH group.

As for the postoperative pain, theoretically, the postoperative pain of cLH is composed mainly of abdominal wall nerves damage and the vaginal distension-derived vaginal vault nerves compression. However, as vNOTESH can be performed without abdominal incisions, we speculated that the vNOTESH would cause less postoperative pain. Unsurprisingly, the results suggested that the 24th-hour post-operative VAS score was significantly lower in the vNOTESH group than in the cLH group. In line with the previous studies, the duration of postoperative hospitalization in vNOTESH was shorter than in cLH, largely because no abdominal incision related pain and complications in vNOTESH group [13]. Last but not the least, vNOTESH offers an excellent cosmetic effect with a scar-free abdomen.

The major limitation of this study is inherent in its retrospective nature. Although most the two group's uterine baseline characteristics were similar, the parity and histopathological diagnosis were significantly different between the two groups. We considered the slightly different histopathological diagnosis may not affect the main conclusions of the present study. However, the difference of parity between might influence the choice of hysterectomy route. We favored the cLH in case of the women with enlarged uterine. Additionally, a subgroup analysis based on the size of uterine was carried out and the results did not change considering the major clinical outcomes. Further multicenter randomized controlled trials comparing hysterectomy and bilateral adnexectomy (or bilateral salpingectomy) between vNOTES and laparoscope are needed.

5. Conclusions

In conclusion, our study confirmed that hysterectomy and bilateral adnexectomy (or bilateral salpingectomy) via vNOTES is a feasible alternative to laparoscope, even in patients with enlarged uterine. Furthermore, vNOTESH shows favorable postoperative outcomes compared to cLH in terms of shorter duration of surgery, less VAS scores, and shorter postoperative hospitalization.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

LC wrote the main manuscript text. LC, BZ, and SH made substantial contributions to the data collection and analysis. PZ and QZ prepared the figure and video. TH and WH served as the lead investigators, who determined the method and purpose of the research and constructed the overall framework of the research. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

All patients have given their written informed consent for the anonymous processing of personal data for research purposes. The study protocol was approved by the Research Ethics Committee of the Meizhou People's Hospital (No. 2021-C-112).

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Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/j.ceog5006135.

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