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Obvious advantage of vaginal natural orifice transluminal endoscopic surgery hysterectomy against total laparoscopic hysterectomy in small uterus patients and the future prospects at a regional core institution: A retrospective study

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ABSTRACT

Objective: Owing to the combination of benefits, including permanent visual guidance and no abdominal skin incision, vaginal natural orifice transluminal endoscopic surgery hysterectomy (vNOTES-H) is currently widely used. However, the introduction of vNOTES-H has been delayed in many Japanese regional core hospitals because of its specific device and skill requirements. Therefore, the characteristics and advantages should be explained for the widespread use of this technique.

Study design: We reviewed the medical records of 17 patients with vNOTES-H and 94 patients with total laparoscopic hysterectomy (TLH) from January 1, 2015 to December 31, 2022. In this analysis, to compare the results of vNOTES-H to TLH, we excluded certain patients with a relatively heavy uterus (>255 g) and the presence of abdominal adhesions. In this report, first, the characteristics of the vNOTES-H procedures using a transvaginal access platform are explained by referring to one representative patient. Second, the patient characteristics of the vNOTES-H and TLH groups, including operation time and blood loss amount, were compared. Then, to detect the influence of vNOTES-H on the difficulty of operation among all 111 patients, we performed a multivariate logistic regression analysis to assess the influence of each of 9 factors, including "vNOTES-H", "Advanced age", "High BMI", "3 parity", "Gynaecological operation history", "Adenomyoma", "Large leiomyoma", "Heavy uterus" and "Large uterus", on the two indexes, including "Short time operation" and "Massive blood loss".

Results: In the simple comparison between the groups with vNOTES-H and TLH, the operation time in the former group was significantly shorter than in the latter group, although other factors did not show significant differences, including blood loss amount. Moreover, in the multivariate logistic regression analysis of all 111 patients, the "vNOTES-H" factor showed a significantly high possibility of "short time operation", although no factor, including "vNOTES-H", showed a significant influence on "massive blood loss".

Conclusions: vNOTES-H showed advantages in terms of operation time without increasing blood loss for patients with a relatively small uterus. However, to expand the selection for vNOTES-H, we should accumulate further patients and perform more analyses.

1. Introduction

Since minimally invasive surgery has become increasingly important in the field of gynaecological surgeries, hysterectomy has also been widely performed with laparoscopes, such as total laparoscopic hysterectomy (TLH) and robotic-assisted laparoscopic hysterectomy (RALH) [1–5]. These operation methods can be performed under permanent visual guidance by laparoscopy with 3–5 trocars, which can be set using 5–10 mm skin incisions. Regarding the merits and demerits of these operation methods, including cost, skill, and abdominal skin

Abbreviations: BMI, Body mass index; CI, Confidence interval; MRI, Magnetic resonance imaging; NA, Not available; OR, Odds ratio; TLH, Total laparoscopic hysterectomy; TVUS, Transvaginal ultrasound; VTH, vaginal total hysterectomy; vNOTES-H, Vaginal natural orifice transluminal endoscopic surgery hysterectomy.

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scarring, many studies have been performed [5–8]' and we also concluded that the disadvantages of RALH, namely, the number of abdominal skin incisions and the cost of the device, cannot be ignored [9]. On the other hand, vaginal total hysterectomy (VTH) has also been frequently performed for benign gynaecological diseases with the advantages of cosmetic effect and faster recovery because it is performed without an abdominal incision by using a natural orifice, namely, the vagina [4]. Therefore, to combine the various advantages of both TLH and VTH techniques, recently, the number of vaginal natural orifice transluminal endoscopic surgery hysterectomies (vNOTES-H) has gradually increased with ensuring safety to some extent [8,10,11]. Consistent with this recent trend, even in our hospital, which is one of the regional core hospitals, the number of patients treated with vNOTES-H by using the transvaginal access platform has gradually increased, although the application of this operation method is limited to patients with leiomyoma/adenomyoma. However, the introduction of vNOTES-H has been delayed in many Japanese regional core hospitals because of the particular laparoscopic surgical skill requirements, as well as the cost of specific devices. Therefore, for spreading this technique widely, this report will aim to describe the characteristics and advantages by comparing the results of TLH.

2. Methods

2.1. Data collection

This study was reviewed and approved by the Human Ethical Committee of the University of Teikyo Hospital (trial registration number: 20–094). The deidentified medical records of 20 multiparous female patients who underwent vNOTES-H for the treatment of leiomyoma/adenomyoma from November 1, 2021 to March 31, 2023, were reviewed retrospectively. These patients had undergone bilateral salpingectomy or bilateral salpingo-oophorectomy during the operation. Since the weight of the resected uterus was over 255 g (namely, 338 g) in only one patient, this patient was excluded. Additionally, we excluded one nulliparous patient and another patient who experienced only caesarean section delivery. Finally, 17 patients with vNOTES-H were included for this research.

As a control group, we also collected the deidentified medical records of 360 multiparous female patients who underwent TLH for the treatment of leiomyoma/adenomyoma from January 1, 2015 to March 31, 2023. From the viewpoint of collecting all patients in which their situations showed the potential of being selected for vNOTES-H and for matching with the aforementioned 17 patients with vNOTES-H, we excluded patients for the following reasons, in the sequential order: 1) the presence of abdominal adhesion (150 patients) and 2) the weight of the resected uterus being over 255 g (176 patients). In 69 patients, these two factors overlapped. Among these remaining 103 patients, we excluded 9 patients, who were all multiparous patients who experienced only caesarean section delivery, and in total, 94 patients were listed.

To evaluate the level of difficulty of vNOTES-H or TLH, we classified 111 patients into the following categories according to their outcomes, including the average and standard deviation: 1) “short time operation” defined as an operation time < 2 h (10 vs. 6 patients) and 2) “massive blood loss”, defined as blood loss ≥ 200 ml (2 vs. 8 patients). When compared to other hospitals, the results regarding the operation time and blood loss amount might be relatively poor in our hospital; however, these 2 indexes were confirmed to fall within the ranges of other past reports [10,12–14]. Other surgical complications, such as bowel injury, ureteral injury and postoperative infection, were not detected in all patients, probably because the targets were limited to relatively easy cases involving only multiparous patients with a relatively small uterus and no abdominal adhesion.

2.2. Analysis methods

First, to compare the characteristics of vNOTES-H and TLH, we classified the patients into two groups according to the operation procedure (17 vs. 94 patients). In this analysis, we compared the following indexes: 1) patient age; 2) patient body mass index (BMI); 3) operation time; 4) blood loss amount; 5) resected uterine weight measured immediately after the operation; 6) whole uterine size measured with transvaginal ultrasound (TVUS) one day before the operation, defined as the average length of the uterus measured in two or three directions; 7) leiomyoma size measured with magnetic resonance imaging (MRI) before the operation; 8) the number of patients in which the indication of operations were adenomyoma; and 9) the number of deliveries.

Second, to verify the safety and potential advantage of vNOTES-H, we tried to provide two categories, including “massive blood loss” and “short time operation”. To control for confounding factors, we divided the patients into two groups according to the presence or absence of each factor and performed multivariate logistic regression analysis. From the viewpoint of the selection of surgical methods among patients with similar situations, we included the vNOTES-H or TLH procedure itself. Therefore, in this analysis, we assessed the influence of the following 9 factors: 1) vNOTES-H, defined as patients who underwent vNOTES-H; 2) advanced age, defined as an age ≥ 50 years; 3) high BMI, defined as a BMI ≥ 25 (kg/m^2) [15]; 4) 3 parity, defined as patients with three deliveries; 5) gynaecological operation history, defined as patients with a gynaecological operation history; 6) adenomyoma, defined as patients whose indication for surgery was adenomyoma; 7) large leiomyoma, defined as a dominant leiomyoma ≥ 8 cm by MRI; 8) heavy uterus, defined as a resected uterine weight ≥ 210 g; and 9) large uterus, defined as the whole uterus ≥ 8 cm by TVUS. Since we could only perform vNOTES-H in our hospital for patients with resected uterine weights less than approximately 250 g, we adopted this cut-off value, namely, 210 g, as a heavy uterus in this study by referring to the average and standard deviation of the uterine weight of all 111 patients. The criteria for “Advanced age”, “High BMI” and “Large leiomyoma” were determined based on past reports [16–19]. A “High BMI” was defined according to the definition of obesity of the Japan Society for the Study of Obesity. An “Advanced age”, which assumed menopause, was defined according to the definition of the Japan Society of Obstetrics and Gynaecology.

Statistical analyses were performed using Microsoft Excel (Microsoft Corporation, Redmond, WA) and JMP version 12 for Windows (SAS Institute, Inc., Tokyo, Japan) to determine the correlations between the aforementioned 9 factors and 2 categories. The odds ratios (ORs) and 95% confidence intervals (CIs) were estimated to determine the strengths of the correlations. $P < 0.05$ was considered statistically significant.

2.3. Surgical procedures

The representative characteristics of the procedures are as follows. 1) In our hospital, as described in the previous report [20], in addition to intravenous 1 g cefazolin administered immediately before starting the operation, we added metronidazole vaginal tablets before and after the operation. As bowel preparation, all patients received two tablets of sennoside (24 mg) one day before operation, though vaginal culture examination were not performed before operation. These preoperative and postoperative procedures were also performed in 94 cases with TLH. 2) After performing general anaesthesia, using the hysteroscopy drape kit to cover anal region (Fig. 1-c, f), to open the Douglas fossa and bladder uterine fossa in the transvaginal operation, the vaginal mucosa was circumferentially incised at the junction of the vagina and cervix (Fig. 1-a), and the uterosacral ligaments were cut by LigaSure™ (Medtronic, Minneapolis, MN, US) (Fig. 1-b). 3) A transvaginal access platform, namely, GelPOINT V-Path (Applied Medical Resources Corporation, Rancho Santa Margarita, CA, US), which included a

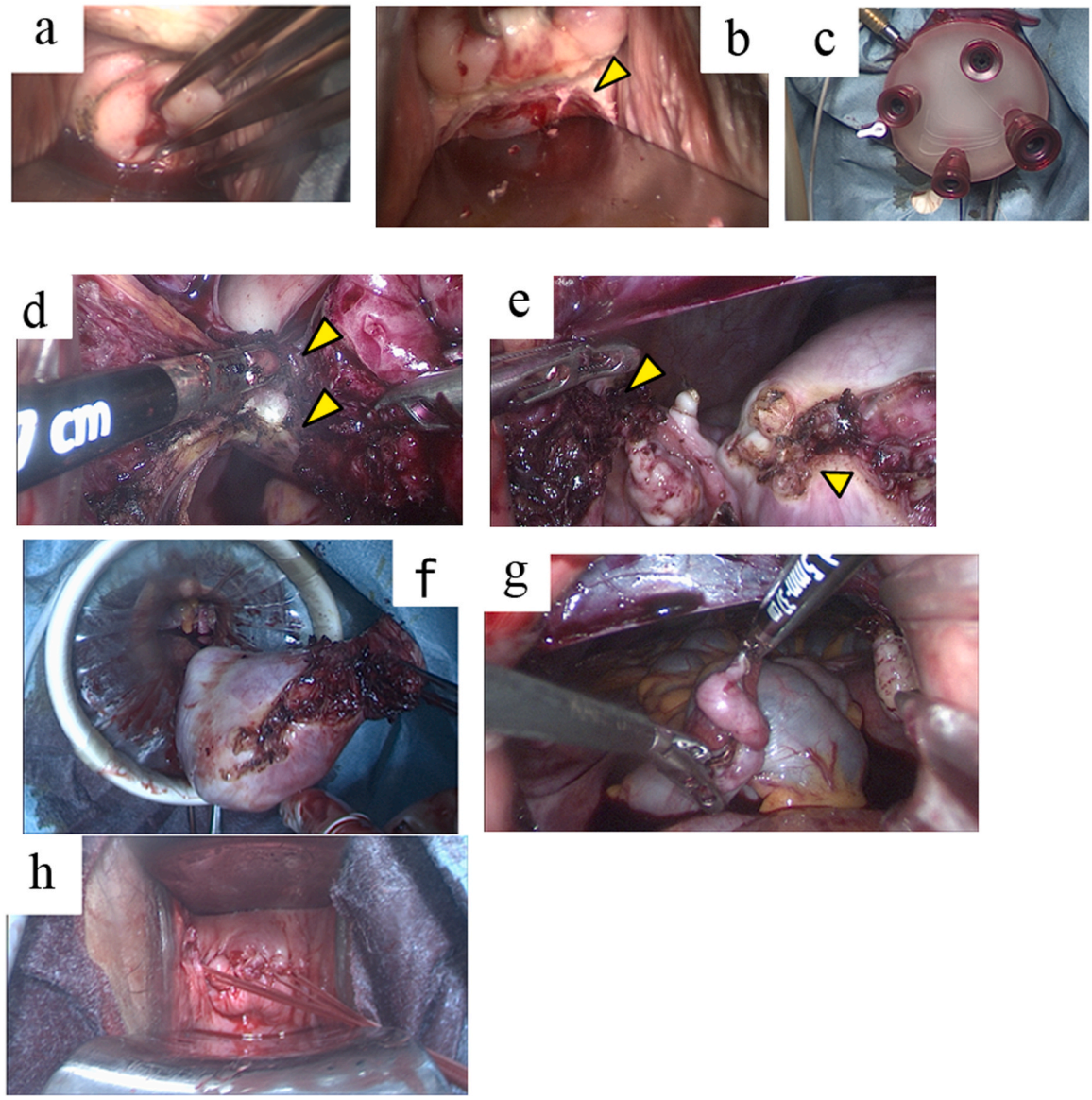

Fig. 1. : Surgical procedure. This patient with vNOTES-H and bilateral salpingectomy was a 43-year-old woman with multiple uterine leiomyomas. The largest leiomyoma was 4.0 cm in diameter, as detected by MRI on outpatient inspection, and the size of the whole uterus was 58 × 56 mm, as detected by TVUS. She was administered an oral gonadotrophin-releasing hormone receptor antagonist, namely, relugolix. She had a history of 2 gravidity and 2 parity, and her BMI was 19.7 kg/m^2. The operation time was 106 min, and the blood loss was 22 ml. The weight of the uterus was 144 g. (a) The vaginal mucosa was circumferentially incised at the junction of the vagina and cervix. (b) The opened Douglas fossa (Arrow). (c) Transvaginal access platform, namely, GelPOINT V-Path with one 10 mm and three 5 mm sleeves. (d) Right cardinal ligament (Arrow). (e) Right utero-ovarian ligament (arrows). (f) The resected uterus was removed from the vaginal wound. (g) After removing the uterus, bilateral salpingectomy was performed. (h) The vaginal wound was sutured.

GelSeal® cap, the Alexis retractor, and one 10 mm and three 5 mm sleeves, was placed inside the vaginal wound (Fig. 1-c). The patients were placed in a 20-degree Trendelenburg position under a pneumoperitoneum of 8–10 mmHg with abdominal carbon dioxide (CO_2). 4) LigaSure™ was used to cut the cardinal ligaments and round ligaments (Fig. 1-d). 5) Utero-ovarian ligaments were cut by pulling the uterine adnexa (Fig. 1-e), and the resected uterus was removed transvaginally (Fig. 1-f). 6) The bilateral fallopian tubes were resected (Fig. 1-g). 7) After confirming no abnormal bleeding, the vaginal wound was sutured (Fig. 1-h). In this procedure, we could use four trocars, similar to those established in abdominal skin for performing TLH in our hospital.

3. Results

3.1. Simple comparison of the patient characteristics between the vNOTES-H and TLH group

The average age, BMI, parity, operation time, blood loss amount, resected uterine weight, uterine size measured by TVUS, size of dominant leiomyoma measured by MRI and parity were 46.6 ± 4.2 (36−58) years, 22.7 ± 3.4 (18.2–36.0) kg/m^2, 157.2 ± 38.5 (93−324) min, 67.0 ± 84.5 (0−550) ml, 162.5 ± 49.7 (59−254) g, 6.1 ± 1.1 (3.5–8.9) cm, 4.5 ± 1.7 (0.5–8.2) cm and 1.9 ± 0.7 (1−3), respectively (Table 1). In 17 out of 110 patients, the main indication for surgery was adenomyoma, but in 5 out of these 17 patients, the sizes of the dominant leiomyoma were also measured by MRI.

When comparing the results simply between vNOTES-H and TLH, as

Table 1
Patient characteristics.

Index	Total	vNOTES-H	TLH	P value
Age (years old)	46.6 ± 4.2 (36–58)	47.0 ± 4.7 (36–54)	46.5 ± 4.1 (38–58)	0.67
BMI (kg/m^2)	22.7 ± 3.4 (18.2–36.0)	22.9 ± 3.4 (18.2–29.4)	22.6 ± 3.4 (18.3–36.0)	0.78
Operation time (minutes)	157.2 ± 38.5 (93–324)	113.8 ± 15.1 (93–141)	165.1 ± 36.1 (101–324)	< 0.01
Blood loss amount (ml)	67.0 ± 84.5 (0–550)	76.2 ± 85.3 (0–309)	65.3 ± 84.7 (0–550)	0.63
Resected uterine weight (g)	162.5 ± 49.7 (59–254)	170.2 ± 54.8 (86–252)	161.1 ± 48.9 (59–254)	0.49
Uterine size (TVUS) (cm)	6.1 ± 1.1 (3.5–8.9)	6.2 ± 1.1 (4.6–8.4)	6.1 ± 1.1 (3.5–8.9)	0.79
Leiomyoma size (MRI) (cm)	4.5 ± 1.7 (0.5–8.2)	4.3 ± 1.8 (0.5–8.0)	4.5 ± 1.6 (1.1–8.2)	0.62
Parity	1.9 ± 0.7 (1–3)	2.1 ± 0.7 (1–3)	1.8 ± 0.6 (1–3)	0.18
Adenomyoma	n = 17/111	n = 2/17	n = 15/94	0.66

After dividing the 111 patients into two groups according to performing vNOTES-H or TLH, we compared 9 indexes. In this analysis, only the factor of operation time showed significant differences.
Abbreviations BMI: Body mass index, MRI: Magnetic resonance imaging, TLH: Total laparoscopic hysterectomy, TVUS: Transvaginal ultrasound, vNOTES-H: Vaginal natural orifice transluminal endoscopic surgery hysterectomy.

shown in Table 1, vNOTES-H seemed to be superior to TLH, since the average operation time was significantly shorter (113.8 ± 15.1 (93−141) min vs. 165.1 ± 36.1 (101−324) min, P < 0.01) without a significant increase in blood loss amount (76.2 ± 85.3 (0−309) ml vs. 65.3 ± 84.7 (0−550) ml, P = 0.63). Moreover, the average resected uterine weight in vNOTES-H was nearly equal to that in TLH (170.4 ± 54.6 (86−252) g vs. 161.1 ± 48.9 (59−254) g, P = 0.48), since the TLH group was matched by the weight of the resected uterus, which had to be under 255 g, in advance. Other factors were also similar between the 2 groups (Table 1).

3.2. Confirmation of safety and potential advantage of vNOTES-H by multivariate analysis

Next, to confirm the safety and potential advantage of vNOTES-H compared with TLH, we evaluated the significant factors affecting the possibility of "massive blood loss" and "short time operation" by a multivariate analysis of 9 factors. By incorporating the procedure of vNOTES-H itself into these factors, we tried to investigate the effectiveness of vNOTES-H without confounding factors.

In the analysis of "massive blood loss", all 9 factors, including "vNOTES-H" (OR = 1.4, P = 0.61), did not indicate a significant difference (Table 2). These results could indicate to some extent that there was no significant difference in safety between vNOTES-H and TLH.

On the other hand, the analysis of "short time operation" revealed that there was a significant advantage in operation time in patients with "vNOTES-H" (OR = 21.0, P < 0.01), although other factors did not show a significant difference (Table 2). These results showed the possibility that the vNOTES-H procedure had the potential to supersede TLH when matching some conditions, including multiparous patients, a relatively small uterus and no abdominal adhesion.

4. Discussion

Similar to other institutions [10,11,21], in our hospital, vNOTES-H has received attention as an alternative surgical method to TLH to reduce abdominal skin incisions. By using this transvaginal access platform provided in the vaginal wall, we could use 3 laparoscopic forceps under laparoscopic view, similar to TLH. This platform, namely, GelPOINT V-Path, is relatively low cost compared with RALH, and

Table 2
Influential factors of operational results for vNOTES-H or TLH.

	Massive blood loss		Short time operation	
Factors	OR (95%CI, Number)	P value	OR (95%CI, Number)	P value
vNOTES-H	1.4 (0.3–7.4, n = 2/17)	0.66	21.0 (5.9–74.7, n = 10/17)	< 0.01
Advanced age	1.5 (0.3–6.1, n = 3/26)	0.58	1.1 (0.3–3.8, n = 4/26)	0.93
High BMI	1.2 (0.2–5.9, n = 2/20)	0.79	0.6 (0.1–2.9, n = 2/20)	0.42
3 Parity	1.4 (0.3–7.4, n = 2/17)	0.86	3.1 (0.9–10.6, n = 5/17)	0.22
Gynaecological operation history	NA (NA - NA, n = 0/15)	0.22	0.9 (0.2–4.4, n = 2/15)	0.63
Adenomyoma	0.6 (0.1–5.0, n = 1/17)	0.68	1.3 (0.3–5.3, n = 3/17)	0.58
Large leiomyoma	3.6 (0.3–38.6, n = 1/4)	0.32	2.0 (0.2–21.0, n = 1/4)	0.56
Heavy uterus	0.3 (0.0–2.8, n = 1/26)	0.29	0.4 (0.1–2.0, n = 2/26)	0.11
Large uterus	1.8 (0.2–16.3, n = 1/7)	0.68	1.0 (0.1–8.8, n = 1/7)	0.80

Multivariate analyses of the 111 patients were performed to examine the influence of the 9 factors, including vNOTES-H, on 2 indexes of the difficulty of operation. The number of patients with each factor, the ORs and 95% CIs for the occurrence of these indexes and the P values are shown in this table. Only vNOTES-H showed a significant difference in the possibility of a short time operation.
Abbreviations BMI: Body mass index, CI: Confidence interval, MRI: Magnetic resonance imaging, NA: Not available, OR: Odds ratio, TLH: Total laparoscopic hysterectomy, TVUS: Transvaginal ultrasound, vNOTES-H: Vaginal natural orifice transluminal endoscopic surgery hysterectomy.

additionally, the attaching procedure is similar to our original procedure for removing a resected uterus from a vaginal wound [16]. These conditions have been advantageous for introducing vNOTES-H, and this surgical method may be expected to become more prevalent for younger generations of gynaecologists who are familiar with laparoscopic techniques [10]. However, in Japan, the spread of vNOTES-H may not have been sufficient in regional hospitals. Therefore, this study was performed to investigate the advantages and disadvantages against TLH, although there were some limitations. Concretely speaking, we performed vNOTES-H only for multiparous patients with a relatively small uterus, in which the weight of the resected uterus was less than 255 g, and no abdominal adhesions predicted before surgery. We could not yet introduce it for treating patients with a large uterus and other adhesive diseases, such as ovarian endometrial cyst and severe adenomyoma. However, apart from past reports [11,12,21,22], in which researchers simply compared the groups with vNOTES-H and other surgical methods, we tried to improve the analysis method for clearly detecting the influence of vNOTES-H itself. Namely, considering "vNOTES-H" as one factor, multivariate analysis was performed on all 111 patients. Due to the aforementioned limitation, the factor of "heavy uterus" was relatively light, but even when expanding the adaptation of vNOTES-H to patients with a large uterus in the future, this analysis method might be applied for detecting the influence of uterus size by changing the criteria for uterine weight.

As expected, similar to past reports [12,13], this analysis indicated the advantage of vNOTES-H regarding operation time without a significant increase in blood loss. This advantage may be derived from the characteristics of this surgical procedure in which uterine arteries are cut together with cutting cardinal ligaments by using LigaSure™ without exposure and ligation of uterine arteries, such as with VTH with vessel-sealing devices [23,24]. The suture method, in which the vaginal wall was sutured from the outside of the vagina, might also contribute to the short time operation. This result may show the potential that vNOTES-H can become an alternative surgical method to TLH, at least

when multiparous patients have a relatively small uterus and no abdominal adhesion. In particular, the latter factor seems to be important for selecting this surgical method because the locations of uterine arteries and ureters are difficult to visualize. To create an adequate surgical field, nulliparous patients may be inappropriate because of a narrow vagina. However, we may note the potential that patients with a large uterus can be selected for vNOTES-H in the future, since in this study, "heavy uterus" did not show significant differences in operation time or blood loss amount. Therefore, to create the criteria for adequate patients and expand the selection for vNOTES-H, we should collect more patients and perform further analyses, since past reports have indicated the possibility of performing vNOTES-H safely for treating patients with a large uterus to some extent [22,25].

5. Conclusions

Not only can vNOTES-H with a transvaginal access platform provide similar procedures as TLH without abdominal skin incisions, but it may also show sufficient advantages over TLH in terms of operation time without increasing the amount of blood loss, at least when the surgical indication is limited to patients with a relatively small uterus and no abdominal adhesion. Therefore, vNOTES-H can become an alternative method of TLH. On the other hand, to expand the selection for vNOTES-H, more patients and further analyses should be accumulated.

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Prior presentation

None.

Consent for publication

Written informed consent was obtained from all patients for the publication of the data.

Precis

vNOTES-H has sufficient advantages over TLH in terms of operation time, at least for patients with a relatively small uterus.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

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