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Original Article

The outcomes of transvaginal NOTES hysterectomy in various uterine sizes

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ABSTRACT

Objectives: Natural orifice transluminal endoscopic surgery (NOTES) is an emerging technique in the area of minimally invasive procedures. Preliminary reports have confirmed transvaginal NOTES to be a safe and feasible method for performing hysterectomy and adnexal procedures. However, there are limitations regarding the feasibility of performing transvaginal NOTES hysterectomy in various uterine sizes. **Materials and methods:** Two hundred and seventy-five women who had undergone transvaginal NOTES hysterectomy for benign pelvic lesions were recruited from May 2012 to May 2016. Their medical records were retrospectively reviewed. All patients were placed into one of three groups depending on weight of the surgical specimen in order to assess surgical outcomes.

Results: One hundred ninety-one patients (69.46%) had a uterine weight of <500 g (group 1), 67 (24.36%) had a uterine weight of 500–999 g. (group 2), and 17 (6.18%) had a uterine weight of ≥1000 g. (group 3). The mean age ± SD of group 1, group 2, and group 3 were 48.68 ± 6.63, 47.22 ± 3.81, and 46.53 ± 2.96 years, respectively (*p* value = 0.110). There was no statistical differences in terms of parity, body mass index (BMI), or history of abdominal surgery among the three groups. With regard to surgical outcomes, the mean operative times (Standard error: SE) were 76.70 (0.68), 99.99 (1.14), and 152.88 (3.37) minutes in Group 1, Group 2, and Group 3, respectively. The mean amounts of blood loss (SE) was 180.85 (4.61), 342.57 (6.98), and 532.35 (11.85) ml in Group 1, 2, and 3, respectively. There were statistically significant differences in terms of operative time and blood loss among the three groups (*p* = 0.0001 and 0.0001, respectively).

Conclusions: Although the size of uterus has a significant effect on operative time and blood loss, NOTES hysterectomy can be successfully performed without any increase in complication rates. Natural orifice transluminal endoscopic surgery hysterectomy is a safe and feasible procedure even in large uteri.

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Introduction

Natural orifice transluminal endoscopic surgery (NOTES) is an emerging technique in the area of minimally invasive procedures. The surgery is performed directly, using the natural orifices as entry points for approaching the peritoneal cavity without abdominal wall incisions [1]. The transvaginal route is the most common approach among NOTES procedures [2]. The first hybrid NOTES

hysterectomy was accomplished by entering through the posterior colpotomy [3].

Natural orifice transluminal endoscopic surgery carries the potential advantage of allowing for endoscopic guidance in the detection of extrauterine pathologies. In addition, the procedure can be completed using conventional laparoscopic instruments (thus, avoiding traditional vaginal surgery) even in cases of a narrow vagina or large pelvic lesions [2]. However, NOTES is associated with some rare complications, such as rectal perforation, bleeding from the vaginal puncture site, omental prolapse [4], pelvic abscesses [5], and broad ligament hematoma with emphysema [6], which are all similar to those associated with traditional vaginal procedures [2,7].

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Preliminary reports from previous studies have confirmed transvaginal NOTES to be a safe and feasible method for performing hysterectomy and adnexal procedures [2,3]. However, there are limitations regarding the feasibility of performing transvaginal NOTES hysterectomy in various uterine sizes. Large uterine size and fixed masses can undoubtedly increase the technical difficulty and should raise concerns during preoperative evaluation. Large uterine size poses a technical challenge when performing NOTES, as the uterine vessels at the level of the isthmus are easier to access and manage during traditional vaginal or transvaginal NOTES procedures, resulting in a reduction of intraoperative blood loss [8].

Objective

To ascertain the outcomes of the transvaginal NOTES hysterectomy procedure in different uterine sizes.

Materials and methods

This was a retrospective study of women who underwent transvaginal NOTES hysterectomy from May 2012 to May 2016 at Linkou Chang Gung Memorial Hospital in Taoyuan, Taiwan. The inclusion criteria were the presence of benign pelvic organ lesions of the uterus, cervix, or ovaries that required surgical intervention. Women were excluded if they had no history of sexual intercourse, history of tubo-ovarian abscess, severe endometriosis, suspected severe pelvic adhesion from previous abdominal surgeries, or on whom NOTES hysterectomy had been initiated but was abandoned in favor of conventional laparoscopy procedures. Medical records were reviewed after approval from the institutional review board (IRB No.201701116B0). The baseline demographic data were collected including age, parity, body mass index (BMI), and history of abdominal surgery. The details regarding surgical outcomes, such as the amount of blood loss, uterine weight, changes in hemoglobin levels after surgery, the rate of blood transfusion, concomitant surgery, and complications were also recorded. All women were divided into three groups depending on the weight of the surgical specimen in order to assess surgical outcomes: Group 1 - uterine weight less than 500 gm, Group 2 - uterine weight of 500–999 gm, and Group 3 - uterine weight of 1000 gm or more.

Descriptive statistics were expressed in terms of quantitative value as mean \pm standard deviation (SD) or median and interquartile range (IQR) and percentage. Data analysis was conducted using logistic equation for categorical data and analysis of covariance (ANCOVA) for continuous data to compare the differentiation among three groups regarding uterine weight. The data were analyzed using the STATA version 10 (Stata Corp., Texas, USA). A *p* value of less than 0.05 was considered statistically significant.

Results

Two hundred and seventy-seven women had undergone transvaginal NOTES hysterectomy for benign lesions of the pelvic organs such as leiomyoma, adenomyosis, and cervical intraepithelial lesions (CIN). Two cases (0.72%) were excluded in which NOTES hysterectomy could not be performed successfully due to severe dense adhesion at the anterior part of the uterus, thus necessitating conventional laparoscopy. The baseline data was grouped by uterine weight. One hundred ninety-one patients (69.46%) had a uterine weight of <500 g (group 1), 67 (24.36%) had a uterine weight of 500–999 g. (group 2), and 17 (6.18%) had a uterine weight of \geq 1000 g. (group 3). The mean age \pm SD of group 1, group 2 and group 3 were 48.68 ± 6.63 , 47.22 ± 3.81 , and 46.53 ± 2.96 years, respectively (*p* value = 0.110). There were no

statistical differences in terms of parity, BMI, history of abdominal surgery, or experience with vaginal birth as shown in Table 1.

The surgical outcomes were evaluated after adjustment from baseline (Table 2). The mean operative times (SE) in Group 1, Group 2, and Group 3 were 76.70 (0.68) minutes, 99.99 (1.14) minutes, and 152.88 (3.37) minutes, respectively. The mean blood loss (SE) was 180.85 (4.61), 342.57 (6.98), and 532.35 (11.85) ml in Group 1, 2 and 3, respectively. The operative times and estimated blood loss differed significantly among the three groups (*p* value 0.0001 and 0.0001, respectively). However, there were no differences in concomitant surgery rates, blood transfusion rates, changes in hemoglobin levels, length of hospital stay, or complication rates found among the three groups. In all cases, the specimens were removed vaginally, with the exception of six (35.29%) patients in Group 3 with high BMI (Median BMI (IQR) was 30.55 (24.50, 36.75) kg/m²), in which they were removed via transumbilical incision.

Discussion

We found the operative time and the amount of blood loss differed significantly among the three groups (*p* value < 0.0001 and < 0.0001, respectively). This suggests that larger uterine mass caused prolonged operative time and increased the amount of blood loss.

NOTES is a novel procedure that combines the use of conventional laparoscopic instruments and the natural orifice to perform a surgical procedure without abdominal scarring. The transvaginal NOTES procedure was originally developed as a technique for performing adnexal surgery [9,10]. In 2012, Lee et al. successfully performed transvaginal NOTES hysterectomies in cases of gynecologic disease [3,9]. Moreover, according to preliminary reports, transvaginal NOTES surgery can be used in cases of myomectomy with isolated posterior leiomyoma [11] and as a surgical staging technique in cases of endometrial cancer [12].

Conducting a preoperative assessment of uterine size is important in order to decrease complication rates [13]. Larger uteri cause difficulty with regard to manipulation and limit the space in which the procedure can be conducted. This study found that uterine weight significantly affected the operative time and intraoperative blood loss, as did a study by Wang et al., which noted that there was a significant linear correlation between uterine size and operative time [13]. However, there was no difference in the rate of blood transfusion among the three groups in this study. Thus, we have determined that NOTES hysterectomy can be successfully performed even in cases of large uterine size (\geq 1000 gm) as long as it is conducted using precise surgical skills and technique, although it requires a longer operative time.

In cases of large uteri, vaginal hysterectomy was considered preferable to laparoscopic and laparoscopic assistance, as it significantly reduces operative time hospital cost [14]. Natural orifice transluminal endoscopic surgery hysterectomy is a modified vaginal hysterectomy that uses laparoscopic instruments, and thus involves the devascularization of uterine vessels under visualization to reduce uterine perfusion before performing the hysterectomy in order to decrease intraoperative blood loss [8]. There was no statistically significant difference in the complication rates among the three groups. In six patients in Group 3 (uterine weight greater than or equal to 1000 g), the uterus could not be removed vaginally even when the hysterectomy was ultimately successful. However, this may be related to BMI, which was higher in these patients (the median BMI was 30.55 kg/m²). It is possible that the vaginal space in obese patients was limited due to redundant vaginal tissue and prominent buttocks [15]. In addition, the shape of large uteri might be grossly disproportionate to the pelvis, thus necessitating significantly more time for retrieval. In these cases,

Table 1
Patient characteristics by uterine weight (N = 275).

	Uterine weight <500 g (Group 1) (N = 191)	Uterine weight 500–999 g (Group 2) (N = 67)	Uterine weight ≥1000 g (Group 3) (N = 17)	p-value
Patient characteristics				
Age (years) (Mean ± SD)	48.68 ± 6.63	47.22 ± 3.81	46.53 ± 2.96	0.110
Parity (Median [IQR])	2 (2, 3)	2 (2, 3)	2 (2, 2)	0.295
Body mass index (kg/m ²) (Median [IQR])	23.5 (21.10, 26.40)	24.60 (22.80, 27.00)	23.10 (22.10, 28.50)	0.056
History of abdominal surgery N(Percent)	69 (36.13%)	20 (29.85%)	6 (35.29%)	0.648
No. experience of vaginal birth n(Percent)	165 (86.39%)	61 (91.04%)	13 (76.47%)	0.262

SD is standard deviation.

IQR is interquartile range.

Table 2
Multivariate analysis of surgical outcomes by uterine weight (N = 275).

	Uterine weight < 500 g (Group 1) (N = 191)	Uterine weight 500–999 g (Group 2) (N = 67)	Uterine weight ≥1000 g (Group 3) (N = 17)	p-value
Surgical outcomes				
Operative time (minutes) (Mean [SE])	76.70 (0.68)	99.99 (1.14)	152.88 (3.37)	<0.0001*
Concomitant surgeries (Percent [Adjusted OR; 95%CI])	20.94% (1)	28.36% (1.84; 0.92,3.67)	23.53% (1.23; 0.35, 4.37)	0.227
Estimated blood loss (ml) (Mean [SE])	180.85 (4.61)	342.57 (6.98)	532.35 (11.85)	<0.0001*
Change of hemoglobin level (g/dL) (Mean [SE])	−0.83 (0.01)	−0.99 (0.01)	−1.26 (0.03)	0.075
Blood transfusion (Percent [Adjusted OR; 95%CI])	3.14% (1)	4.48% (1.19; 0.27,5.23)	11.76% (4.58; 0.76, 27.48)	0.242
Hospital stay (day, Mean [SE])	1.34 (0.01)	1.42 (0.01)	1.47 (0.02)	0.392
Complications (n (Percent) [Adjusted OR; 95%CI])	8 (4.19%) (1)	1 (1.49%) (0.60; 0.10, 3.48)	0 (NA)	0.571
- Postoperative bleeding n (Percent)	4 (2.09%)	0	0	
- Pelvic infection n (Percent)	2 (1.05%)	1 (1.49%)	0	
- Bladder injury n (Percent)	2 (1.05%)	0	0	

Differences are considered significant at the level of 0.05.

SE is standard error.

Adjusted OR is adjusted odd ratio.

* Indicates statistically significant values.

specimens were, therefore, retrieved through umbilical incision by manual morcellation. The transvaginal use of power morcellators with an endobag is another method for retrieving large specimens. However, power morcellators should be used with caution. In 2014, the FDA issued a public warning that their use may cause unrecognized cancerous cells (uterine sarcoma) to be inadvertently disseminated into the abdomen, resulting in poor prognosis. Patients should, thus, be given information regarding the risks and benefits of power morcellation before undergoing the procedure [16,17]. Moreover, performing morcellation in a bag seems to reduce the risk of tissue dissemination, although there is no robust scientific evidence to support this [14,17–19].

In this study, we performed NOTES hysterectomy only in cases of benign pelvic organ tumors. This procedure can be performed even in cases of non-prolapsed uteri [20]. There are also many advantages to the NOTES procedure in cases that involve prolapse with extra-uterine disease, such as ovarian masses or undescended ovaries, that would present challenges for traditional vaginal hysterectomy. Even in patients with previous history of abdominal surgery, there are 34.55% in this study, NOTES hysterectomy can be successfully completed without having to resort to conventional laparoscopy or laparotomy. However, there are limitations to NOTES hysterectomy in that severe adhesion (especially from dense endometriosis occupying the pouch of Douglas or severe infection such as pelvic inflammatory disease) is a major hurdle during colpotomy.

The average operative time of the NOTES hysterectomy procedure in our study was 87.08 min. A systematic review published in 2016 found the operative time of the NOTES hysterectomy procedure to be significantly shorter than that of LAVH [20]. The average operative time of NOTES was 70.6–76.6 min, whereas that of the LAVH procedure was 93.2–98.4 min [13,21]. A possible reason might be that switching from conventional laparoscopy to a vaginal procedure requires more time, in addition to the time required for skin closure.

Through this retrospective study, we were able to ascertain the surgical outcomes of NOTES hysterectomy in various uterine sizes. It was limited in that it was a retrospective study with small sample size. Thus, further prospective studies with larger sample sizes are needed. This study reports a significant difference in terms of operative time and intraoperative blood loss among patients with different uterine sizes, so considerable caution must be exercised when dealing with particularly large uteri (uterine weight ≥1000 gm).

In conclusion, NOTES hysterectomy is a safe and feasible novel procedure, even in cases of large uterine size. Although the size of the uterus has a significant effect on operative time and blood loss, NOTES hysterectomy can be successfully performed without increased risk of complications, assuming meticulous surgical technique is employed.

Conflicts of interest

Teerayut Temtanakitpaisan, Kai-Yun Wu, Chen-Ying Huang, Amruta Jaiswal, Chih-Feng Yen and Chyi-Long Lee have no conflicts of interest or financial ties to disclose.

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