Original Article

# Natural Orifice Transluminal Endoscopic Surgery-assisted Vaginal Hysterectomy versus Total Laparoscopic Hysterectomy: A Single-center Retrospective Study Using Propensity Score Analysis

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## Abstract

**Objectives:** The aim of this study is to evaluate the safety and efficacy of natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy (NOTES-AVH) compared with total laparoscopic hysterectomy (TLH).

**Materials and Methods:** The population was a cohort of women who underwent NOTES-AVH and TLH for a nonprolapsed uterus and benign gynecological disease between October 2015 and December 2017 at Rajavithi Hospital, Thailand. Study outcomes included operative time, the requirement of blood transfusion, perioperative complications, and postoperative pain. Factors applied for propensity score matching included age, body mass index, parity, underlying disease, previous abdominal surgery, preoperative diagnosis, presence of endometriosis, and uterine weight. Mean difference (MD) and risk ratio with 95% confidence interval (CI) were calculated to represent relative measures of the comparison.

**Results:** Among the 50 pairs, there were no differences in operative time (MD 15.9 min; 95% CI − 9.3–41.1), intraoperative complications (relative risk [RR] 0.33; 95% CI 0.04–3.10) or requirement of blood transfusion (RR 1.50; 95% CI 0.26–8.60) between the NOTES-AVH and TLH groups. NOTES-AVH was associated with lower intensity of postoperative pain (MD − 1.5 at 6-h; 95% CI − 0.8–2.2 and MD − 1.0 at 24-h; 95% CI − 0.4–−1.6) and shorter length of stay (MD − 0.3 day; 95% CI − 0.1–0.7 day).

**Conclusion:** NOTES-AVH was safe and feasible for an alternative approach for hysterectomy. This technique was superior to TLH in that no abdominal incision was required, and postoperative pain was less intense.

**Keywords:** Hysterectomy, laparoscopy, natural orifice transluminal endoscopic surgery, vaginal surgery

## Introduction

Natural orifice transluminal endoscopic surgery (NOTES) is the latest promising innovation in the field of minimally invasive surgery.[1] Currently, NOTES represents diagnostic or therapeutic procedures conducted through existing orifices of the human body (mouth, anus, urethra, and vagina). Nowadays, this advanced surgical technique has gained popularity among gynecologists, urologists, and gastroenterologists.[1-4]

Vaginal NOTES (vNOTES) is an operation in which the surgeon accesses the pelvic cavity through the vagina to perform surgery.[5] The fundamental benefit of vNOTES over conventional laparoscopic surgery is the potentially scar-free surgery that avoids skin incision-related adverse events and avoiding trocar-related complications. Other potential

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benefits of vNOTES are decreased postoperative pain, less need for postoperative analgesia, and faster postoperative recovery.[5] In addition, vNOTES may be more feasible for morbidly obese patients as it offers easy alternative access to the peritoneal cavity compared with conventional laparoscopic access, which can be difficult because of abdominal wall thickness.[5]

Hysterectomy using vNOTES was first used on humans by Su *et al*. in 2012.[6] Although several previous studies have consistently noted that NOTES-assisted vaginal hysterectomy (NOTES-AVH) is feasible for hysterectomy,[7-10] the safety and efficacy of this technology must be studied with scrutiny. Accordingly, this study was undertaken to evaluate the safety and efficacy of NOTES-AVH compared with total laparoscopic hysterectomy (TLH).

## Materials and Methods

This retrospective cohort study was conducted by reviewing the medical records of women undergoing hysterectomy for a nonprolapsed uterus and benign gynecological disease between October 2015 and December 2017 in the Department of Obstetrics and Gynecology, Rajavithi Hospital, Bangkok, Thailand.

The population of interest was a cohort of women who had undergone NOTES-AVH and TLH. The individual surgeon decided on the surgical approach for hysterectomy based on their own preference. The study protocol was approved by our Institutional Review Board (IRB number 028/2561). Since it was a retrospective study, and the data were analyzed anonymously, the need for informed consent was waived by the Research Ethics Committee. In our institution, a wound retractor with its port cap was used as the vaginal port.

Outcomes of interest included operation time, estimated blood loss (EBL), perioperative complications, and postoperative pain. The intensity of postoperative pain was evaluated using a visual analog scale. The pain score was determined as overall pain assessed at 6-h and 24-h after the surgery. Postoperative fever was defined as body temperature ≥38°C excluding the first 24 h, taken by mount following a standard measurement technique at least four times daily. The amount of blood loss was clinically estimated by the anesthesiologist.

Baseline characteristics of women undergoing TLH and NOTES-AVH groups were compared using Fisher's exact test for categorical variables and the independent sample *t*-test or Mann–Whitney U-test for continuous variables. We applied a propensity score matching analysis to minimize the effect of treatment selection bias and other potential confounding effects when comparing the outcomes between the two comparison groups. Factors applied for matching included patients' age, body mass index (BMI), parity status, comorbidity, previous abdominal surgery, preoperative diagnosis, presence of endometriosis, and uterine weight. Matching was conducted in a 1:1 ratio. Mean difference (MD) and risk ratio with their associated 95% confidence interval (CI) were calculated to assess the relative comparison measures. All statistical tests were two-sided, and a $P < 0.05$ was considered statistically significant. Statistical analysis was performed using SPSS (IBM-SPSS, Inc, Chicago, IL USA).

## Results

This study included 228 patients who underwent NOTES-AVH (50 women) and TLH (178 women) during the study period. Table 1 shows the baseline characteristics of the entire cohort. Women undergoing TLH were more likely to be diagnosed with endometriosis and to have a larger uterus than those who underwent NOTES-AVH [Table 1]. There was no difference in terms of age, BMI, parity, underlying disease, and prior history of previous abdominal surgery across the two comparison groups [Table 1]. Table 2 displays the baseline characteristics of women after propensity score 1:1 matching, which was similar across the two comparison groups.

Perioperative outcomes are shown in Table 3. There was no significant difference in operative time (MD 15.9 min; 95% CI − 9.3–41.1), intraoperative complications (relative risk [RR] 0.33; 95% CI 0.04–3.10) or postoperative fever (RR 0.69; 95% CI 0.33–1.47) between the groups. Although there was a significantly higher amount of EBL among women undergoing NOTES-AVH, the requirement of packed red cell transfusion did not differ between the two groups (RR

**Table 1: Baseline characteristics of patients of the entire cohort**

| Characteristics | NOTES-H (*n*=50) | TLH (*n*=178) | *P* |
|---|---|---|---|
| Age (years) | 47.3±6.7 | 45.3±5.5 | 0.034 |
| Body mass index (kg/m$^2$) | 24.7±4.4 | 24.6±4.1 | 0.849 |
| Nulliparity | | | |
| Parity | 17 (34.0) | 73 (41.0) | 0.370 |
| Currently sexually active | 41 (82.0) | 136 (76.4) | 0.674 |
| Presence of underlying disease | 12 (24.0) | 48 (27.0) | 0.647 |
| Previous abdominal surgery | 18 (36.0) | 66 (37.1) | 0.135 |
| Preoperative diagnosis | | | |
| Myoma uteri | 24 (48.0) | 80 (44.9) | 0.178 |
| Adenomyosis | 19 (38.0) | 86 (48.3) | |
| Others | 7 (14.0) | 12 (6.8) | |
| Presence of endometriosis | 1 (2.0) | 43 (24.2) | <0.001 |
| Uterine weight (g), median (IQR) | 159.0 (138) | 231.5 (240.2) | 0.009 |

Data are present as number (percentage) or mean±SD unless stated otherwise. NOTES-AVH: Natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy, TLH: Total laparoscopic hysterectomy, IQR: Interquartile range, SD: Standard deviation

1.50; 95% CI 0.26–8.60). NOTES-AVH was significantly associated with lower postoperative pain intensity and slightly shorter length of hospital stay compared with TLH [Table 3].

TLH was converted to laparotomy in one case. There were no conversions to conventional laparoscopy or laparotomy in women undergoing NOTES-AVH.

## Discussion

Although numerous studies have consistently reported that hysterectomy performed using the vNOTES technique is feasible, most of the data were gathered from noncomparative studies. Therefore, there is a need for information comparing perioperative outcomes of vNOTES hysterectomy with the conventional laparoscopic approach to ascertain the clinical application of this relatively new surgical approach.[11] This study showed that NOTES-AVH was technically feasible in all cases. There were no conversions to conventional laparoscopy or laparotomy in all women who underwent NOTES-AVH, which reaffirms the feasibility of this surgical technique. The odds of perioperative complications (such as adjacent organ injury, massive blood loss, or postoperative fever) and blood component transfusion among women undergoing NOTES-AVH were similar to those who underwent TLH. In addition, NOTES-AVH was superior to TLH in that no abdominal incision was required, and postoperative pain was less intense.

Safety is the central issue when considering the clinical application of NOTES hysterectomy. In a retrospective cohort study by Wang *et al*.,[12] which was conducted among 512 women to compare NOTES-AVH and laparoscopic-assisted vaginal hysterectomy (LAVH), the rate of perioperative complication after applying propensity score 1:1 matched comparison among women undergoing NOTES-AVH was 2.7% compared with 4.8% of women undergoing LAVH. In a case-matched study by Yang *et al*.,[13] no perioperative complication occurred in NOTES-AVH or single-port LAVH. Recently, a randomized controlled trial conducted to compare surgical outcomes between NOTES-AVH and TLH noted similar risks of intraoperative complications (3.0% vs. 0%) and postoperative infection (3% vs. 6%) of these two surgical approaches. However, the postoperative complication was more common among women undergoing TLH (37% vs. 9% for TLH and NOTES-AVH, respectively).[14] The rate of readmission within 6 weeks after operation was also higher among women undergoing TLH (3% vs. 17%). In this study, the risks of intraoperative complications (RR 0.33; 95% CI 0.04–3.10) and postoperative fever (RR 0.69; 95% CI 0.33–1.47) among women undergoing NOTES-AVH were comparable to those who underwent TLH. These findings, therefore, indicate that NOTES-AVH appears to be a safe procedure compared with LAVH or TLH.

NOTES-AVH appears to be feasible when performed by an experienced surgeon. In this study, NOTES-AVH could

**Table 2: Characteristics of patients after a propensity score matching**

| Characteristics | NOTES-H (*n*=50) | TLH (*n*=50) | *P* |
|---|---|---|---|
| Age (years) | 47.3±6.7 | 48.2±5.8 | 0.455 |
| Body mass index (kg/m$^2$) | 24.7±4.4 | 24.5±4.2 | 0.754 |
| Nulliparity | 17 (34.0) | 20 (40.0) | 0.534 |
| Currently sexually active | 41 (82.0) | 40 (80.0) | 0.799 |
| Presence of underlying disease | 12 (24.0) | 12 (24.0) | 1.000 |
| Previous abdominal surgery | 18 (36.0) | 20 (40.0) | 0.916 |
| Preoperative diagnosis‡ | | | |
| Myomauteri | 24 (48.0) | 23 (46.0) | 0.977 |
| Adenomyosis | 19 (38.0) | 20 (40.0) | |
| Others | 7 (14.0) | 7 (14.0) | |
| Presence of endometriosis§ | 1 (2.0) | 1 (2.0) | 1.000 |

Data are present as number (percentage) or mean±SD.
NOTES-AVH: Natural orifice transluminal endoscopic surgery- assisted vaginal hysterectomy, TLH: Total laparoscopic hysterectomy, SD: Standard deviation

**Table 3: Perioperative outcomes cross-tabulated by the type of surgical approach after a propensity score matching**

| Outcomes | NOTES-AVH (*n*=50) | TLH (*n*=50) | Relative measures (95% CI) |
|---|---|---|---|
| Operative time (min) | 146.0±57.9 | 161.9±68.8 | MD: 15.9 (−9.3-41.1) |
| EBL (mL), median (IQR) | 300 (450) | 100 (212.5) | NA |
| Packed red cell transfusion | 3 (6.0) | 2 (4.0) | RR: 1.50 (0.26-8.60) |
| Intraoperative complications | 1 (2.0)* | 3 (6.0)** | RR: 0.33 (0.04-3.10) |
| VAS of pain at 6-h after operation | 3.4±1.8 | 4.9±1.8 | MD: 1.5 (0.8-2.2) |
| VAS of pain at 24-h after operation | 1.7±1.5 | 2.7±1.5 | MD: 1.0 (0.4-1.6) |
| Morphine consumption (mg), median (IQR) | 0.0 (3.0) | 0.0 (3.0) | NA |
| Postoperative fever | 9 (18.0) | 13. (26.0) | RR: 0.69 (0.33-1.47) |
| Length of hospital stay (days) | 2.5±0.8 | 2.8±0.8 | MD: 0.3 (0.1-0.7) |

*Massive blood loss, **Including conversion to laparotomy (1); bowel injury (1); and urologic injury (1). Data are present as number (percentage) or mean±SD unless stated otherwise. NOTES-AVH: Natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy, TLH: Total laparoscopic hysterectomy, MD: Mean difference, RR: Risk ratio, CI: Confidence interval, EBL: Estimated blood loss, NA: Not assessed, IQR: Interquartile range, VAS: Visual analog scale, SD: Standard deviation

be successfully performed in all cases without switching to laparoscopy or laparotomy. This finding is in line with previous retrospective cohort studies and randomized controlled trials, which also reported that no conversion was required for women who underwent NOTES-AVH.[12-14]

The benefit of NOTES in reducing the length of hospital stay has been consistently noted in the existing literature.[13,14] In a propensity score-matched cohort study, the median length of hospital stay among women undergoing NOTES-AVH was 3.5 days (range 3–5 days), which was significantly shorter the 4 days (3–6 days) reported for those undergoing LAVH ($P < 0.001$).[13] In a recent published randomized study, length of hospital stay among women undergoing NOTES-AVH was significantly shorter than that for women undergoing TLH (MD −0.5 days; 95% CI −0.98– −0.02 days).[14] The study confirmed the advantage of NOTES-AVH in shortening the length of hospital stay. Women undergoing NOTES-AVH carried a small, but statistically significant association with shorter length of hospital stay compared with those who underwent TLH (MD −0.3 day; 95% CI −0.1– −0.7 days).

Recently, the results of a paired sample cross-sectional study comparing NOTES-AVH and TLH noted a shorter operative time in the NOTES-AVH group (79.56 ± 32.54 min) and length of hospital stay (44 ± 16.47 h) compared to the TLH group (120.67 ± 38.35 min and 57.86 ± 21.31 h, respectively).[15]

In this study, NOTES-AVH was superior to TLH in that postoperative pain was less intense. Compared with TLH, women undergoing NOTES-AVH experienced significantly less pain intensity assessed at 6 h (MD − 1.5; 95% CI −0.8–−2.2) and 24 h (MD −1.0; 95% CI −0.4– −1.6) following the operation. This advantage might be secondary to the avoidance of abdominal incision using this surgical approach.

Some limitations of the present study must be noted. First, this study contained a relatively small sample size, which might preclude the ability to assess differences between comparison groups, particularly the potential perioperative complication, which is a considerably infrequent occurrence. Second, this study did not determine long-term outcomes (such as sexual function or quality of life) and cost-effectiveness, which are also important issues when considering the benefits and risks of NOTES. The strength of this study is its application of a propensity score matching approach to balance observed baseline covariates when analyzing the study outcomes. It mimics some of the characteristics of a randomized controlled trial and increases the internal validity of this study.

## Conclusion

In summary, NOTES was a feasible alternative approach for hysterectomy when performed by an experienced surgeon. The odds of perioperative complications of NOTES-AVH were similar to those of TLH. Moreover, NOTES-AVH was superior to TLH in that no abdominal incision was required, and postoperative pain was less intense.

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### Conflicts of interest

There are no conflicts of interest.

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