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# Gynecological natural orifice transluminal endoscopic surgeries from an anesthesiologist's perspective: A retrospective cohort study

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All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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## Abstract

**Background/Aim:** Natural orifice transluminal endoscopic surgical (NOTES) approach allows either transgastric or transvaginal access to the targeted organs by endoscopes without a skin incision. This study aimed to evaluate the intraoperative and postoperative outcomes of patients who underwent vaginally assisted NOTES (VaNOTES) for gynecological surgery.

**Methods:** One hundred ten patients who underwent hysterectomy and/or bilateral salpingo-oophorectomy (BSO) under general anesthesia either with conventional laparoscopy (CL) or VaNOTES methods were examined. The data of the patients were obtained from the medical records retrospectively. Demographic data, perioperative hemodynamic data, Visual Analogue Scale (VAS) scores, and analgesic consumption at the 1st, 6th, and 24th postoperative hours were assessed.

**Results**: Among all patients, the median duration of anesthesia, median operation time, and hospital stay were lower in the VaNOTES group compared to those in CL ($P$<0.001). The change in perioperative hemodynamic findings was similar in both patient groups. While the median VAS scores were lower in the VaNOTES group at the 6th and 24th postoperative hours in patients with BSO ($P$=0.024 and $P$=0.021), those of patients who underwent hysterectomy were lower at the 1st postoperative hour ($P$=0.002). However, the change in VAS scores was similar in both patient groups. In addition, no postoperative complications or mortality were observed in any of the groups.

**Conclusion:** Application of NOTES technique in gynecological operations may contribute to the reduction of invasive procedures, shorten the duration of surgery and anesthesia, lower pain severity, and improve hospital stay postoperatively.

**Keywords:** Gynecologic surgery, Natural orifice transluminal endoscopic surgery, Pain assessment

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## Introduction

The natural orifice transluminal endoscopic surgical (NOTES) approach allows either transgastric or transvaginal access to the targeted organs by endoscopes without any skin incision [1, 2]. NOTES is associated with minimal surgical trauma, early patient mobilization, less postoperative pain, and better cosmetic results in cholecystectomy, appendectomy, hysterectomy, and salpingo-oophorectomy procedures [2].

NOTES requires $CO_2$ insufflation and steep Trendelenburg position, both of which are necessary to adequately visualize the abdominal and thoracic cavity, as is also the case in the conventional laparoscopic approach [3]. From the viewpoint of anesthesiologists, this new technique provides benefit to respiratory functions perioperatively due to less intraabdominal pressure requirement, shortening of the operation time, decreased need of perioperative analgesia, and a lower angular Trendelenburg angle. In a randomized controlled trial, the results of the NOTES technique in patients undergoing hysterectomy were strong enough to be compared with total laparoscopic hysterectomy [4]. However, there is still limited information about the feasibility, intraoperative complication, postoperative pain scores, and duration of surgery of the VaNOTES procedure in gynecologic practice.

This study evaluated whether the gynecological VaNOTES procedure contributes to an improvement in intraoperative hemodynamic data, postoperative pain scores, operation time, and hospital stay.

## Materials and methods

Bakirkoy Dr. Sadi Konuk Training and Research Hospital Ethics committee approved (approval date: 20/05/2019-approval number:2019/237) the protocol of this study, which was conducted per the declaration of Helsinki. Assuming an alpha of 0.05, a power of 0.80, and a minimum 20% difference in terms of outcomes, the required sample size was at least 50 patients in each group. The charts of 110 patients who underwent hysterectomy and/or bilateral salpingo-oophorectomy (BSO) under general anesthesia either with conventional laparoscopy or VaNOTES method in a training and research hospital between March 2018 and April 2019 were reviewed retrospectively. Consent was obtained from the patients who were operated on in our clinic for the use of their medical data for clinical research purposes. Patients with an ASA 1-3 risk group who underwent hysterectomy and/or BSO surgery, without contraindications for pneumoperitoneum or the Trendelenburg position, were included in this study.

To avoid any selection bias, patients with previous endometriosis surgery, history of tubo-ovarian abscess, suspicion of pelvic inflammatory disease (PID), and intrauterine pregnancy were excluded from the study.

The patients received intravenous (IV) midazolam (0.02 mg/kg) for premedication. Induction of anesthesia was carried out with IV propofol (2-3 mg/kg), fentanyl (1-2 µg/kg) and rocuronium bromide (0.6 mg/kg). Anesthesia was maintained with an IV remifentanil infusion (0.05-0.1µg/kg) and sevoflurane at 0.7-1 minimum alveolar concentration (MAC). For postoperative analgesia, 1 gram of paracetamol and 1 mg/kg tramadol hydrochloride were administered intravenously at the end of the operation and 2x20 mg tenoxicam were given during hospitalization in the ward. The data of the patients were obtained from the hospital's electronic medical records.

Demographic data, perioperative hemodynamic data, Visual Analogue Scale (VAS) scores, and analgesic consumption at the 1st, 6th, and 24th postoperative hours were collected. Postoperative pain scores were evaluated with a Likert-type VAS (scoring from 0 = no pain to 10 = worst pain ever) after the 1st, 6th, and 24th hours postoperatively.

**Statistical analysis**

The parameters were analyzed by SPSS for Windows version 23.0. The Kolmogorov Smirnov test and histogram were used to clarify whether the data were normally distributed. The continuous variables were non-normally distributed in each group; therefore, non-parametric tests were used. The continuous variables were expressed as mean (standard deviation) or median (interquartile range (IQR) 25-75), while the categorical variables were expressed as n (%). The difference between the continuous variables of the two groups was calculated by the Student's T-test or the Mann-Whitney-U test. The Chi-square test was used in the analysis of categorical parameters. The changes in the perioperative findings between groups were evaluated with the mixed model for repeated measurements. $P<0.05$ was considered statistically significant.

In the post-hoc analysis where the duration of hospitalization was used as the data in hysterectomy cases, an 86% power was calculated for 69 patients who were screened retrospectively.

## Results

The study population consisted of 110 patients who underwent hysterectomy (n: 69) and/or BSO (n: 41) under general anesthesia either with CL or the VaNOTES methods. The demographic and clinical findings of both groups are shown in Table 1. In both groups of patients who underwent hysterectomy or BSO operation, the median duration of anesthesia, median operation time, and hospital stay were lower in the VaNOTES group compared to the CL group (Table 1). The distributions of ASA scores did not differ significantly between the two groups.

Table 1: Distribution of demographic and clinical findings in BSO and hysterectomy cases

| Variables | BSO | | *P*-value | Hysterectomy | | *P*-value |
|---|---|---|---|---|---|---|
| | CL | VaNOTES | | CL | VaNOTES | |
| Preoperative period | | | | | | |
| Age, years | 42.2(12.4) | 41.1(10.8) | 0.759 | 49.4(7.9) | 51.9(9.2) | 0.246 |
| Weight, kg | 70.5(8.0) | 74(12.5) | 0.296 | 79.1(11.5) | 78.7(15) | 0.900 |
| BMI, kg/m$^2$ | 26.5(3.6) | 28(5.8) | 0.317 | 30.2(4.9) | 30.3(6.5) | 0.941 |
| ASA score | | | | | | |
| ASA 1 | 5(26.3) | 10(45.5) | 0.33 | 3(9.7) | 7(18.4) | 0.257 |
| ASA 2 | 14(73.7) | 12(54.5) | | 27(87.1) | 27(71.1) | |
| ASA 3 | - | - | | 1(3.2) | 4(10.5) | |
| Hemoglobin, mg/dL | 11.9(2.0) | 11.4(1.7) | 0.411 | 11.2(1.9) | 12.0(1.5) | 0.092 |
| Perioperative period | | | | | | |
| Anesthesia time, minutes | 127(90-150) | 50(40-60) | <0.001* | 175(138-220) | 104(64-127) | <0.001* |
| Operation time, minutes | 110(74-125) | 35(25-45) | <0.001* | 150(120-200) | 90(45-110) | <0.001* |
| Removed uterine weight, gr | - | - | - | 400(0-780) | 250(0-815) | 0.133 |
| Postoperative period | | | | | | |
| Hemoglobin, mg/dL | 10.8(1.5) | 9.9(1.6) | 0.067 | 10.2(1.4) | 10.7(1.4) | 0.153 |
| Verbal pain score | | | | | | |
| 1st hours | 5(4-6) | 4(3-5) | 0.136 | 5(4-6) | 4(3-5) | 0.002* |
| 6th hours | 6(4-7) | 4(4-5) | 0.024* | 5(5-6) | 4(4-6) | 0.136 |
| 24th hours | 3(2-3) | 2(2-3) | 0.021* | 2(2-4) | 2(2-3) | 0.728 |
| CRP, mg/L | 11(5-45) | 10(5-19) | 0.511 | 15(6-36) | 10.5(5-22) | 0.216 |
| Hospital stay time, hours | 69(47-72) | 47(44-65) | 0.009* | 67(51-80) | 54.5(42-63) | 0.001* |

Numerical variables are shown as mean (standard deviation) or median (IQR 25-75). Categorical variables are shown as numbers (%). * $P<0.05$ shows statistical significance. CRP: C-Reactive Protein, VaNOTES: Vaginally Assisted Natural Orifice Transluminal Endoscopic Surgery, CL: Conventional Laparoscopy, BSO: Bilateral Salpingoopherectomy

In patients who underwent a BSO, the median VAS scores at the postoperative 1st hour did not differ significantly in the VaNotes group compared to the CL group, but the median VAS scores were lower at the 6th and 24th hours. In patients who underwent a hysterectomy, the median VAS scores at the postoperative 1st hour were significantly lower in the VaNotes group compared to the CL group but were similar at the 6th and 24th hours (Table 1).

There was no difference between the groups in terms of perioperative heart rate, SpO2, and MAP and there was no hemodynamic instability requiring inotropes or vasopressors (Table 2).

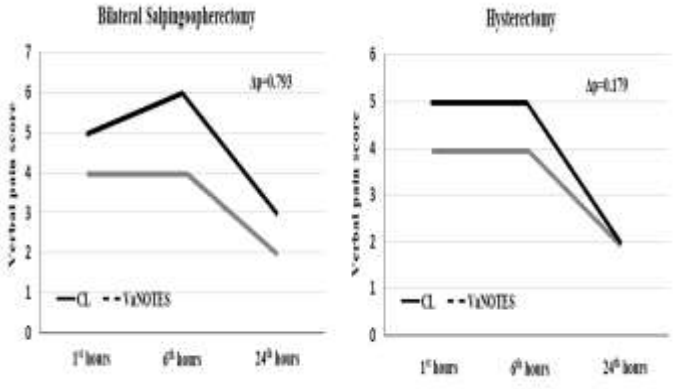
Table 2: Distribution of perioperative hemodynamic findings in BSO and hysterectomy cases

| Variables | BSO | | *P*-value | Hysterectomy | | *P*-value |
|---|---|---|---|---|---|---|
| | CL | VaNOTES | | CL | VaNOTES | |
| MAP, mmHg | | | | | | |
| 1 min | 80.4(8.1) | 81.8(10.9) | 0.658 | 81.0(10.1) | 82.6(8.9) | 0.494 |
| 10 min | 70.3(7.7) | 73.6(6.7) | 0.153 | 68.6(10.9 | 69.8(7.7) | 0.621 |
| 20 min | 69.5(7.8) | 73.4(6.8) | 0.097 | 71.5(7.7) | 73.7(8.1) | 0.263 |
| 30 min | 73.9(9.7) | 71.0(8.7) | 0.319 | 69.4(9.0) | 68.4(8.2) | 0.662 |
| 40 min | 78.3(9.8) | 81.8(10.9) | 0.295 | 73.7(7.5) | 73.6(8.0) | 0.934 |
| 50 min | 73.3(7.1) | 75.0(8.0) | 0.458 | 68.4(5.9) | 66.9(6.0) | 0.332 |
| 60 min | 69.5(8.0) | 73.4(6.8) | 0.100 | 71.5(7.7) | 72.2(7.3) | 0.728 |
| *P*t | <0.001* | <0.001* | | <0.001* | <0.001* | |
| Δ*P* | 0.372 | | | 0.775 | | |
| Heart rate, beats/min | | | | | | |
| 1 min | 85.1(16.8) | 79.9(13.2) | 0.280 | 82.2(16.0) | 85.8(12.5) | 0.288 |
| 10 min | 72.8(12.4) | 68.8(11.0) | 0.272 | 70.8(12.9) | 69.2(10.5) | 0.568 |
| 20 min | 70.6(11.1) | 70.6(11.6) | 0.997 | 70.4(10.0) | 69.3(11.2) | 0.681 |
| 30 min | 68.7(11.3) | 66.8(6.3) | 0.101 | 70.1(9.7) | 68.5(10.9) | 0.533 |
| 40 min | 65.4(8.7) | 63.8(6.8) | 0.345 | 63.1(7.5) | 64.3(8.1) | 0.520 |
| 50 min | 63.3(7.0) | 62.2(10.9) | 0.108 | 71.3(11.0) | 71.5(11.8) | 0.932 |
| 60 min | 69.1(9.8) | 70.1(10.7) | 0.739 | 71.3(11.0) | 71.5(11.8) | 0.932 |
| *P*t | <0.001* | <0.001* | | <0.001* | <0.001* | |
| Δ*P* | 0.113 | | | 0.659 | | |
| SPO2 | | | | | | |
| 1 min | 100(100-100) | 100(100-100) | 0.999 | 100(100-100) | 100(100-100) | 0.999 |
| 10 min | 100(100-100) | 100(100-100) | 0.999 | 100(100-100) | 100(100-100) | 0.999 |
| 20 min | 100(100-100) | 100(100-100) | 0.999 | 100(100-100) | 100(100-100) | 0.999 |
| 30 min | 100(100-100) | 100(100-100) | 0.999 | 100(100-100) | 100(100-100) | 0.999 |
| 40 min | 100(100-100) | 100(100-100) | 0.999 | 99(99-100) | 99(99-100) | 0.999 |
| 50 min | 100(100-100) | 100(100-100) | 0.999 | 99(99-100) | 99(99-100) | 0.999 |
| 60 min | 100(100-100) | 100(100-100) | 0.999 | 99(99-100) | 99(99-100) | 0.999 |
| *P*t | 0.999 | 0.999 | | 0.999 | 0.999 | |
| Δ*P* | 0.999 | | | 0.999 | | |

Numerical variables with normal distribution are shown as mean (standard deviation) or median (IQR 25-75). * $P<0.05$ shows statistical significance. *P*t: Statistical difference of changes in laboratory findings in the group, Δ*P*: Statistical difference of changes in laboratory findings between groups, VaNOTES: Vaginally Assisted Natural Orifice Transluminal Endoscopic Surgery, CL: Conventional Laparoscopy, BSO: Bilateral Salpingoopherectomy

In patients who underwent BSO and hysterectomy, the postoperative changes in VAS scores were similar between the VaNotes and CL groups (Δ*P*=0.793, and Δ*P*=0.179, respectively) (Figure 1).

Figure 1: Changes in VAS scores




Δp: Statistical difference of changes in laboratory findings between groups, VaNOTES: Vaginally Assisted Natural Orifice Transluminal Endoscopic Surgery, CL: Conventional Laparoscopy, BSO: Bilateral Salpingoopherectomy

Nausea and vomiting due to opioid use in the postoperative period, pulmonary or mortal complications, or mortality were not observed among the two patient groups who underwent BSO, while the hysterectomy group was free of postoperative complications and mortality only.

## Discussion

Since VaNOTES is a new surgical technique, data on anesthesia and postoperative pain management are limited. Considering the limited data in VaNOTES studies, our study has several important results. First, we found that the VaNOTES technique provides shorter anesthesia and operation time in hysterectomy compared to traditional laparoscopy. Second, VAS scores were low in the postoperative period in both the BSO and hysterectomy groups. Finally, VaNOTES was associated with early discharge in both patient groups. The VaNOTES technique suggests that the "Enhanced Recovery After Surgery (ERAS)" protocol is a suitable method, as it is less invasive and offers shorter anesthesia time, surgery time, and hospital stay compared to the traditional method.

In rare studies evaluating the feasibility of VaNOTES in hysterectomy procedures, the average uterine weight varies between 206-538 g, and it has been reported that NOTES reduces the duration of surgery, blood loss, and postoperative hospital stay [5-7]. Among these studies, the first randomized controlled study by Baekelandt et al. [5] presented and compared patients who underwent conventional total laparoscopic hysterectomy and VaNOTES hysterectomy. The uterine weight did not differ between the groups, and an approximately 1.5-fold reduction in operative time, total analgesic use, and hospital stay was reported with the VaNOTES procedure [5]. The largest hysterectomy series treated with VaNOTES in the literature was reported by Lee et al. In this study, the average operative time was 88 minutes, and the mean hospital stay was 2.8 days [6]. In the study of Kaya et al. [4] comparing the patients who underwent hysterectomy/BSO and adnexectomy with VaNOTES, the mean uterine weight, operation time, and hospital stay were 298 g, 85 minutes, and 2 days, respectively. To the best of our knowledge, our study is the second largest series in the literature, and similar findings were found in the VaNOTES protocol among hysterectomy patients. However, we determined that the VaNOTES technique is associated with a shorter operation time and hospital stay compared to CL. In addition, VaNOTES can reduce the length of hospital stay by providing significant advantages in wound infection and postoperative inflammatory response [8].

The ease of pneumovaginal tissue dissection and the surgeon's ability to enlarge the image with endoscopic imaging may play a role in the reduction of the operative time in the VaNOTES protocol. Difficulty accessing ligaments and uterine vessels in the large uterus and manipulation may prolong the operation time. An important advantage of VaNOTES in hysterectomy is the easy access to uterine vessels in the presence of a large uterus. It is difficult to close the feeding vessels in a limited area in the pelvis occupied by the large uterus with the laparoscopic approach [7]. We believe that the less manipulation requirement in VaNOTES eliminates this disadvantage and shortens the duration of surgery and anesthesia. The positive correlation we found between uterine weight and duration of anesthesia supports our idea. Wang et al. [9] compared the surgical results between VaNOTES hysterectomy and laparoscopic-assisted vaginal hysterectomy (LAVH). Operation time, amount of blood loss and postoperative hospital stay were lower in the VaNOTES group. They found more complications

in the LAVH group when uterine weight exceeded 500 grams. As a result, LAVH and VaNOTES groups were matched 1:1 with propensity score matching. Despite this matching, they found that there was a significant linear correlation between operative time and uterine weight in both groups, and similar results were obtained in terms of estimated blood loss. They concluded that VaNOTES can be safely performed on a large and prolonged uterus and that the operative efficiency of VaNOTES increases with the uterine weight [9]. On the other hand, in both case groups (BSO and hysterectomy), the duration of anesthesia was shorter in the VaNOTES technique. The short duration of anesthesia reduces the need for opioid and muscle relaxant use. Baekelandt et al. [5] also made a similar point.

VaNOTES procedures are reported to cause less pain [10, 11]. However, VAS scores may not differ compared to conventional methods [5]. In our study, the postoperative VAS values were significantly lower at the 6$^{th}$ and 24$^{th}$ hours in the BSO group who underwent VaNOTES and at the 1$^{st}$ hour in the hysterectomy group. However, VAS changes did not differ between the 1$^{st}$-24$^{th}$ hours. Yang et al. [12] compared the patient who underwent VaNOTES hysterectomies and LAVH. In their study, demographic characteristics such as age, BMI, and uterine weights were similar in both groups. The VAS scores at the 12$^{th}$ and 24$^{th}$ hours did not differ between groups, but the operation time and hospital stay were lower in the VaNOTES group [12]. The change in VAS scores in our study is similar to that reported by Kaya et al [4]. Santos et al. [13] reported that only the closure of the vaginal cuff in VaNOTES caused this difference in VAS scores compared to the closure of 3-4 trocar accesses in the abdomen in conventional laparoscopy. The absence of transabdominal incision due to transvaginal access in the VaNOTES method reduces the need for postoperative analgesia by protecting the muscle groups in this area, which makes patients feel less parietal pain [1]. Visceral pain is more common in the VaNOTES technique. On the other hand, somatic pain is most prominent in conventional laparoscopic or open surgery techniques because of the skin incisions. Less postoperative pain leads to a reduction in postoperative narcotic analgesic use. This helps to avoid side effects such as nausea/vomiting, respiratory depression, constipation, and ileus and reduces hospital stay. In addition, it decreases wound infection rates and improves cosmesis [14]. The absence of an abdominal wall incision may prevent long-term wound healing and eliminate the risk of incisional hernia formation [15]. The innervation of the vaginal wall spreads to several spinal segments through the pelvic and hypogastric nerves (L2-S2). Therefore, regional anesthesia (spinal or epidural) techniques that provide sensory blockade on several spinal segments can be applied in VaNOTES surgery. Regional anesthesia may be preferred especially in patients with COPD and respiratory failure and the risk of postoperative respiratory complications may be reduced.

The main limitations of our study are its retrospective design and lack of randomization. Due to these limitations, the need or consumption of analgesic agents and opioid consumption could not be evaluated between the groups. Another limitation is that we could not reach patient data regarding perioperative intraabdominal pressure values and shoulder pain. Therefore, the effect of intra-abdominal pressures on perioperative respiratory and hemodynamic parameters, postoperative analgesic consumption, and possible shoulder pain could not be determined. Our results can only be generalized to the hospital where the study was conducted.

In our clinic, the preferred intra-abdominal pressure for VaNOTES cases is 10-12 mmHg, which is a lower pressure compared to the traditional method. The degree of the negative effect of $CO_2$ on the patient depends on both the intra-abdominal pressure and the exposure time. Even a difference of approximately 5 mmHg in intra-abdominal pressure can cause serious changes in respiratory physiology and mechanical ventilation strategies during the operation. Navarrove et al. [16] showed that the intra-abdominal pressure of the VaNOTES group in pigs was lower than that in the conventional group and reported its positive effects on hemodynamic and respiratory parameters. Low intraabdominal pressure may also reduce the incidence and severity of postoperative shoulder pain, which is common in laparoscopic surgery. Hua et al. [17] compared intraabdominal low and standard pressures for laparoscopic cholecystectomy. The incidence of shoulder pain and analgesic consumption were lower in the low-pressure group [17].

**Conclusion**

The use of the VaNOTES technique in gynecologic operations is less invasive, decreases surgical and anesthesia time, as well as pain intensity postoperatively, and improves the duration of the hospital stay. In the light of the obtained results, this new technique can provide clinical advantages for anesthesiologists as well as surgeons. Further prospective and randomized controlled studies are needed to evaluate VaNOTES in gynecologic surgery.

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