

# Transvaginal natural orifice endoscopic surgery (vNOTES) for elderly patients

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## ABSTRACT

**Objectives:** To evaluate the feasibility and safety of transvaginal natural orifice transluminal endoscopic surgery (vNOTES) in patients 70 years and over.

**Material and methods:** The study consisted of eleven patients aged 70 and over who underwent vNOTES for a variety of gynaecological indications at a tertiary referral hospital. The medical and surgical data were noted: age, parity, history of comorbidity, number and type of previous surgeries, body mass index (BMI), operating time, the requirement of intraoperative conversion, the presence of intra- or postoperative complication, estimated blood loss, pre- and postoperative hemoglobin levels, visual analog scale (VAS) pain scores at 6<sup>th</sup>, 12<sup>th</sup> and 24<sup>th</sup> hours, length of hospital stay, and the final pathology results.

**Results:** vNOTES surgery was performed safely and successfully in eleven patients. There were no intra- and postoperative complications or instances of conversions to conventional laparoscopy or laparotomy. The mean age of patients was 75.91 ± 6.47 (range 70–93), and the mean BMI was 42.49 ± 8.77 kg/m<sup>2</sup> (range 30.2–56). Seven cases of endometrioid adenocarcinoma, two cases of uterine leiomyoma, one case of complex atypical hyperplasia, and one case of postmenopausal uterine bleeding due to atrophic endometrium were diagnosed. All endometrial carcinomas were early stage; no adjuvant therapy was needed.

**Conclusions:** vNOTES seems to be a safe and feasible approach for the treatment of gynecologic pathologies in elderly patients. This study suggests that vNOTES become a viable treatment option for existing minimally invasive procedures since it offers better surgical outcomes in various gynecologic surgeries.

**Keywords:** elderly; hysterectomy; natural orifice surgery; transvaginal NOTES

Ginekologia Polska 2024; 95, 3: 175–180

## INTRODUCTION

Improvements in social, economic, public health, and medicine have reduced premature deaths and remarkably increased average life expectancy and the ageing of the population over the past century. According to the United Nations (UN), the elderly population is defined as people aged 65 and over. In 2020, there were 727 million people aged 65 and over worldwide, and women constitute the majority of the population, especially at advanced ages [1].

Advanced age is one of the most important risk factors for postoperative morbidity and mortality [2, 3]. For this reason, it is important to evaluate the elderly in terms of cognitive function, nutritional status, cardiac and pulmonary condition, endocrinological diseases, musculoskeletal problems, mobility status, pain, and analgesia before and after surgery [4]. Minimally invasive methods seem to be a promising surgical option for elderly patients that offers shorter operation time, less postoperative pain, earlier

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Received: 6.06.2023 Accepted: 28.08.2023 Early publication date: 23.10.2023

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ambulation, shorter hospital stay, and faster return to routine activities in this age group [5–7]. Natural orifice transluminal endoscopic surgery (NOTES) is a novel technique in the field of minimally invasive surgery [8]. Transvaginal natural orifice transluminal endoscopic surgery (vNOTES) is a combination of endoscopic and vaginal surgery and has gained popularity in gynecology practice over the last ten years [9, 10]. vNOTES can be performed safely and feasibly in malign and benign gynecologic procedures. However, there is still a lack of cumulative data regarding the feasibility of vNOTES procedures in patients over 70 years and over.

Therefore, in this study, we aimed to assess the feasibility and efficacy of the vNOTES technique for elderly patients who underwent vNOTES for benign and malignant gynecological diseases.

## MATERIAL AND METHODS

The study comprised 11 patients over 70 years old who underwent vNOTES at the Kartal Dr.Lütfi Kırdar City Hospital, between June 2021 and December 2021 for a variety of gynecological indications, such as uterine leiomyoma, endometrioid cancer, complex atypical endometrial hyperplasia, and postmenopausal uterine bleeding.

The study protocol was in line with the tenets of the Declaration of 1964 Helsinki and approved by the ethics committee of Kartal Dr.Lütfi Kırdar City Hospital (Approval number: 2021/514/202/19). Verbal and written informed consent forms were obtained from all study participants prior to the study.

The following data were retrieved from the hospital's electronic medical records system: age, parity, history of comorbidity, number and type of previous surgeries, body mass index (BMI), operating time, the requirement of intra-operative conversion, the presence of intra- or postoperative complication, estimated blood loss, pre- and postoperative hemoglobin levels, visual analog scale (VAS) pain scores at 6<sup>th</sup>, 12<sup>th</sup> and 24<sup>th</sup> hours, length of hospital stay, and the final pathology results. All patients were preoperatively staged according to the International Federation of Gynecology and Obstetrics (FIGO) system. Pain scores were evaluated using a Likert-type VAS (0 = no pain, 10 = worst pain imaginable) during the postoperative periods. The operation time was calculated from the first incision of the posterior vaginal wall to the end of vaginal closure. Intra- and postoperative complications were defined as intraoperative blood loss exceeding 300 mL, excessive postoperative bleeding requiring transfusion or reoperation, vaginal vault hematoma or abscess, conversion to another technique, and injuries to the bladder, ureter, bowel, and/or major vessels. Hemoglobin change was defined as the difference between the hemoglobin level recorded one day before surgery and the first postoperative day.

## Patients

All patients were evaluated preoperatively by past medical and surgical histories, gynecologic examination, blood tests (complete blood count, tumor markers, and inflammatory markers), cervicovaginal smear, radiologic imaging (transvaginal ultrasonography and magnetic resonance imaging), endocervical curettage, and endometrial biopsy.

Exclusion criteria were as follows; any contraindication for pneumoperitoneum, the dorsal lithotomy position, general anesthesia, sepsis, severe renal failure, severe cardiopulmonary disease, history of colorectal surgery, suspicion of uterine sarcoma, blood coagulation disorders, history of pelvic radiotherapy, tubo-ovarian abscesses, and an obliteration of the pouch of Douglas (uterine immobility in pelvic examination, endometriosis, and pelvic inflammatory disease).

All surgeries were performed by a single surgeon with extensive experience in minimally invasive surgery.

## Surgical technique

Patients were positioned in the 15° Trendelenburg position under general anesthesia. The anterior lip of the cervix was grasped with a tenaculum. A circumferential cervical incision was made via an 11-mm scalpel and/or cautery. Then, the cervical fascia was dissected by blunt and sharp dissections, and anterior and posterior colpotomy was performed. A GelPoint vPath (Applied Medical Resources Corp., Rancho Santa Margarita, CA, USA) was inserted into the vaginal opening.

After pneumoperitoneum with 12–15 mm Hg CO<sub>2</sub> insufflation, a 10-mm 30° telescope (Karl Storz, Tuttlingen, Germany) was introduced for optimal imaging. Conventional laparoscopic devices such as graspers, a suction-irrigation device, scissors, bipolar forceps, and tissue sealing devices (LigaSure, 5-mm diameter, blunt tip; Covidien) were used where needed. Sacro-uterine ligaments, uterine arteries, and adnexal roots were sealed and cut caudally to cranially. The uterus and adnexa were extracted through the vaginal opening. The vaginal opening was closed with a Vicryl 1–0 suture (Ethicon, Piscataway, NJ, USA).

## RESULTS

We reviewed 11 elderly patients who underwent hysterectomy and bilateral salpingo-oophorectomy via the vNOTES approach for benign or malign indications between June 2021 and December 2021. There were no intra- and postoperative complications or instances of conversions to conventional laparoscopy or laparotomy. The mean age of patients was  $75.91 \pm 6.47$  (range 70–93), and the mean BMI was  $42.49 \pm 8.77$  kg/m<sup>2</sup> (range 30.2–56). All patients were multiparous (mean = 3.91; range, 2–8) and no one had delivered by cesarean sections. Only two patients had no

Patient no	Age [years]	BMI [kg/m <sup>2</sup> ]	Parity	History of C/S	Previous surgeries	Systemic Diseases	Indication for surgery
1	75	51.1	3	0	Nephrectomy	DM, HT and Chronic renal failure	Endometrioid adenocarcinoma Grade 1
2	73	46.7	4	0	Cholecystectomy	DM and HT	Leiomyoma uteri + dysfunctional uterine bleeding
3	76	45	5	0	Nil	HT and Thrombocytosis	Endometrioid adenocarcinoma Grade 1
4	72	40	5	0	Heart surgery	HT, chronic heart failure and atrial fibrillation	Endometrioid adenocarcinoma. Grade 1
5	81	30.2	3	0	Cholecystectomy	HT	Endometrioid adenocarcinoma Grade 1
6	71	38	4	0	Appendectomy	DM and HT	Leiomyoma uteri + dysfunctional uterine bleeding
7	72	46	5	0	Thyroidectomy	Hypothyroidism	Endometrioid adenocarcinoma Grade 1
8	75	50.7	4	0	Nil	DM and HT	Complex atypical hyperplasia
9	77	56	5	0	Heart surgery	DM, chronic heart failure and atrial fibrillation	Endometrioid adenocarcinoma Grade 1
10	70	33.3	2	0	Nil	HT	Endometrioid adenocarcinoma Grade 1
11	93	30.4	3	0	Bilateral hip replacement	Chronic heart failure	Postmenopausal uterine bleeding — atrophic endometrium

C/S — cesarean section; BMI — body mass index; DM — diabetes mellitus; HT — hypertensive disorder; BMI is calculated by the formula of kg/m<sup>2</sup> where kg is a person's weight in kilograms and m<sup>2</sup> is their height in metres squared

systemic disease, while nine patients had one or more systemic diseases such as diabetes mellitus, hypertension, chronic renal failure, thrombocytosis, hypothyroidism, chronic heart failure or atrial fibrillation. Of patients, two had a history of prior heart surgery, one had nephrectomy, two patients had cholecystectomy, one patient had appendectomy, one patient had thyroidectomy, one patient had bilateral hip replacement. Seven cases of endometrioid adenocarcinoma, two cases of uterine leiomyoma, one case of complex atypical hyperplasia, and one case of postmenopausal uterine bleeding due to atrophic endometrium were diagnosed. All endometrial carcinomas were early stage; no adjuvant therapy was required. The TNM stage was T1aN0M0, and the histological type endometrioid carcinoma (type 1) for these patients. The demographics and clinical data are presented in Table 1.

The mean operation time was 66.18 ± 25.69 min (range, 40–136). The mean estimated blood loss was 43.64 ± 14.50 mL (range, 30–80). Mean hemoglobin change was 1.463 g/dL. The mean duration of postoperative hospital stay was 2.55 ± 1.21 days (range, 2–6). The mean postoperative VAS pain scores at 6, 12 and 24 h were 2.9, 2.0, and 0.8 respectively (Tab. 2). The surgical outcomes are shown in Table 3.

## DISCUSSION

To the best of our knowledge, this is the first report of vNOTES to treat elderly patients with benign or malign gy-

Variables	Mean ± SD	Median (Min.–Max.)
Age [y]	75.91 ± 6.47	75 (70–93)
BMI [kg/m <sup>2</sup> ]	42.49 ± 8.77	45 (30.2–56)
Parity	3.91 ± 1.04	4 (2–5)
Operation time [min]	66.18 ± 25.69	60 (40–136)
Estimated blood loss [mL]	43.64 ± 14.50	40 (30–80)
Hb change [g/dL]	1.463 ± 0.23	1.4 (1.2–2)
Postoperative hospital stay [d]	2.55 ± 1.21	2 (2–6)
<b>Postoperative pain score (VAS)</b>		
6 h	2.91 ± 0.70	3 (2–4)
12 h	2.00 ± 0.63	2 (1–3)
24 h	0.82 ± 0.75	1 (0–2)

y — year; BMI — body mass index; min — minute; d — day; h — hour; VAS — visual analog scale; SD — standard deviation; Hb — hemoglobin levels; BMI is calculated by the formula of kg/m<sup>2</sup> where kg is a person's weight in kilograms and m<sup>2</sup> is their height in metres squared

necologic diseases. To date, data on the feasibility of vNOTES for gynecologic surgeries in the elderly group remain scarce. This could be attributed to the lack of visualization and surgeons experience with vaginal surgeries in the era of minimally invasive surgery.

With the improvement of the treatment of acute or chronic diseases, perioperative care, the development of advanced surgical techniques and equipment, and the

**Table 3. The surgical characteristics and postoperative treatment**

Patient	Operation	Operation time [minute]	Estimated blood lose [mL]	Hb change [g/dL]	Postoperative hospital stay [day]	Postoperative pain score VAS VAS VAS (6h) (12h) (24h)
1	vNOTES hysterectomy + BSO	40	30	-1.4	2	3 2 0
2	vNOTES hysterectomy + BSO	55	40	-1.3	2	3 1 0
3	vNOTES hysterectomy + BSO	50	40	-1.5	2	3 2 0
4	vNOTES hysterectomy + BSO	60	60	-1.6	3	4 2 1
5	vNOTES hysterectomy + BSO	70	40	-1.5	2	3 2 1
6	vNOTES hysterectomy + BSO	60	40	-1.2	2	3 2 1
7	vNOTES hysterectomy + BSO	65	30	-1.4	2	2 1 0
8	vNOTES hysterectomy + BSO	65	35	-1.2	2	2 2 1
9	vNOTES hysterectomy + BSO	80	45	-1.7	3	3 3 2
10	vNOTES hysterectomy + BSO	47	40	-1.3	2	2 2 1
11	vNOTES hysterectomy + BSO	136	80	-2	6	4 3 2

BSO — bilateral salpingo-oophorectomy; Hb — hemoglobin levels; VAS — visual analog scale

increment in the longevity of the population, the elderly has become an increasing proportion of the world's population. It can be concluded that more surgical procedures will then be necessary as the elderly population increases. It is now well established from a variety of studies that traditional laparoscopic surgery (LS) and Robotic surgery (RS) are safe, feasible treatment options for the elderly population [11, 12]. In a comprehensive study that compares the elderly with younger patients undergoing robotic-assisted gynecologic surgery, it was concluded that RS is safe in the elderly population. Similarly, several studies have reported that LS had some advantages, such as less postoperative pain, quicker recovery, and less blood loss, and reported that LS is a feasible, safe, and efficient surgical choice in the elderly group for benign gynecological disease [11, 13, 14].

Recently, researchers have shown an increased interest in vNOTES, a combination of laparoscopic techniques and vaginal surgery. It has been proposed as a promising approach over both LS and RS in the gynecology practice due to its advantages such as shorter operating time, less postoperative pain, less estimated blood loss, early hospital discharge, improved intraoperative visualization of the surgical field, lower rate of wound site infection, and better cosmetic outcomes [15–20]. In addition, vNOTES has been shown to be a feasible technique for gynecological emergencies, obese, benign gynecological surgeries and apical pelvic organ prolapse [21–24]. The RS has some disadvantages compared with vNOTES. That is, high operational cost, the absence of haptic tactile feedback, restricted positioning the operating table after docking the robot, limited patient access, and an interprofessional team is required in terms of emergency undocking [25–27].

Our technique has some innovative features over our previously described technique [13]. A colpotomy was performed via an 11-mm scalpel and/or cautery instead of ultrasonic scalpel. This allowed us to reduce operating time. In the 15° Trendelenburg position, we placed Gel-Point vPath (Applied Medical, Rancho Santo Margarita, CA) instead of a self-construct glove port, which helped us to reduce the operative time. Subsequently, we performed a total hysterectomy and salpingo-oophorectomy without first detaching the uterus. These steps facilitated adequate exposure to the surgical field, shortened operative time, as well as maintained adequate pneumoperitoneum.

Controversies still exist regarding the appropriate Trendelenburg angle. Although previous research has established that at least a 30–35° Trendelenburg angle is required in the minimally invasive gynecological robotic and laparoscopic procedures, we used a 15° Trendelenburg positioning to avoid hemodynamic and cardiac consequences for the elderly [11, 28]. A recent systematic literature review concluded that vNOTES had significantly lower values for the duration of surgery and length of hospital stay compared to laparoscopy, whereas no difference was found in the VAS scores and hemoglobin change between pre- and postoperative 24 h [20]. In the present study, the VAS pain scores were consistently decreased at the postoperative 6<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hours. We believe this to be attributed to the technique of removing the uterus with both ovaries and fallopian tubes without pulling the uterine ligaments and the lack of an abdominal wall incision [8]. This combination of findings provides some support for the conceptual premise that the vNOTES procedure is feasible and safe in the elderly groups.

The strength of our work lies in providing the first comprehensive assessment of vNOTES in elderly patients who

underwent gynecologic surgeries. The fact that all the surgeries were performed by an experienced gynecologic surgeon may be interpreted as both a strength and a limitation, as it may contribute to the production of more consistent data, but it may not be representative of all physicians who perform minimally invasive surgery. Another point worth mentioning is that the present study focused on elderly patients, as these patients are vulnerable to postoperative morbidities and complications. This is due to their prolonged steep Trendelenburg positioning during surgeries and reduced function of several organs. In our study, we have described the application of vNOTES techniques, such as the utilization of a commercial vNOTES glove port system, the insufflation pressure, the degree of tilt, and removing ovaries with the uterus, which all were effective and provides significant advantages to the elderly group.

We are aware that the present study has several limitations to be acknowledged. One limitation was its small sample size and a single-center experience, as our data came from eleven patients. Notwithstanding the relatively limited sample, this work has gone some way towards enhancing our understanding of vNOTES techniques in the elderly group. Further large prospective multi-center randomized trials need to be carried out in order to determine the efficacy, safety, and feasibility of vNOTES for gynecologic surgeries in elderly patients. Research questions that could be asked include women's health and comparative financial cost.

## CONCLUSIONS

The present study has demonstrated, for the first time, that vNOTES could be a safe and feasible approach for the treatment of gynecologic pathologies in elderly patients. By advancing both surgeons' expertise and instruments, vNOTES seem to be the next frontier in the gynecology practice. We might speculate that vNOTES become a viable treatment option for existing minimally invasive procedures since it offers favorable surgical outcomes in various gynecologic surgeries.

### Article information and declarations

#### Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

#### Ethics statement

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Research Ethics Committee of the Kartal Dr. Lütfi

Kirdar City Hospital (Date: 26.05.2021, No: 2022/514/222/7). Informed consent was obtained from all individual participants included in the study.

#### Author contributions

All authors attest they meet the International Committee for Medical Journal Editors (ICMJE) criteria for authorship. Emre Mat: conceptualization, study design and organization, supervision, investigation and writing-original draft. Pınar Yıldız: investigation and writing-reviewing and editing Rezzan Berna Temoçin: investigation, data acquisition and manuscript writing-reviewing, editing and revisions. Özgür Kartal: conceptualization, methodology, investigation and writing-reviewing and editing. Esra Keles: manuscript writing-reviewing, editing, critically revised the work for important intellectual content. All authors approved the final submitted version. and agree to be accountable for all aspects of the work.

#### Funding

The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

#### Acknowledgments

None.

#### Conflict of interest

The authors declare no competing interests.

#### Supplementary material

None.

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