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How to cite

BAEKELANDT, Jan et al. vNOTES retroperitoneal sentinel lymph node dissection for endometrial cancer staging : First multicenter, prospective case series. In: Acta obstetricia et gynecologica Scandinavica, 2024, vol. 103, n° 7, p. 1311–1317. doi: 10.1111/aogs.14843

This publication URL: https://archive-ouverte.unige.ch/unige:181878

Publication DOI: 10.1111/aogs.14843

Received: 25 November 2023 | Revised: 11 March 2024 | Accepted: 19 March 2024

DOI: 10.1111/aogs.14843

ORIGINAL RESEARCH ARTICLE

vNOTES retroperitoneal sentinel lymph node dissection for endometrial cancer staging: First multicenter, prospective case series

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Abstract

Introduction: The current standard treatment for endometrial cancer is a laparoscopic hysterectomy with adnexectomies and bilateral sentinel node resection. A retroperitoneal vNOTES sentinel node resection has several theoretical potential advantages. These include being less invasive, leaving no visible scars, operating without Trendelenburg, and therefore offering the anesthetic advantage of easier ventilation in obese patients and following the natural lymph node trajectory from caudally to cranially and therefore a lower risk of missing the sentinel node. The aim of this study is to determine the feasibility of a retroperitoneal vNOTES approach to sentinel lymph node dissection for staging of endometrial cancer.

Material and methods: A prospective multicenter case series was performed in four hospitals. A total of 64 women with early-stage endometrial carcinoma suitable for surgical staging with sentinel lymph node removal were operated via a transvaginal retroperitoneal vNOTES approach. The paravesical space was entered through a vaginal incision after injecting the cervix with indocyanine green. A vNOTES port was placed into this space and insufflation of the retroperitoneum was performed. Sentinel lymph nodes were identified bilaterally using near-infrared light followed by endoscopic removal of these nodes.

Results: A total of 64 women with early-stage endometrial cancer underwent sentinel lymph node removal by retroperitoneal vNOTES technique. All patients also underwent subsequent vNOTES hysterectomy and bilateral salpingo-oophorectomy. The median age was 69.5 years, median total operative time was 126 min and the median estimated blood loss was 80 mL. In 97% of the cases bilateral sentinel nodes could be identified. A total of 60 patients had negative sentinel nodes, three had isolated tumor cells and one had macroscopically positive sentinel nodes. No complications with sequel occurred.

Abbreviations: VD, vaginal delivery; vNOTES, vaginal natural orifice transluminal endoscopic surgery.

Conclusions: This prospective multicenter case series demonstrates the feasibility of the vNOTES approach for identifying and removing sentinel lymph nodes in women with endometrial carcinoma successfully and safely. vNOTES allows sole transvaginal access with exposure of the entire retroperitoneal space, following the natural lymph trajectory caudally to cranially, and without the need for a Trendelenburg position.

KEYWORDS
endometrial cancer, lymph nodes, retroperitoneal dissection, sentinel, staging, vNOTES

1 | INTRODUCTION

Endometrial carcinoma is the most frequently diagnosed gynecologic cancer in high income countries with a life-time risk of 3% and a rising incidence worldwide, mainly due to obesity.[1]

Systematic surgical staging is of the utmost importance for endometrial carcinoma, providing essential information guiding clinical decisions about adjuvant radiation and chemotherapy. Sentinel lymph node analysis provides a highly accurate and sensitive way to detect metastasis. This technique has proven to be a viable alternative to complete pelvic and para-aortic lymphadenectomy, thereby avoiding complications such as lymphoedema and lymphocyst formation and is now standard practice in the staging of endometrial cancer.[2] Ultrastaging of the sentinel node allows the detection of micrometastases and isolated tumor cells that are not always detectable via conventional pathological examination. This allows for a higher identification of patients with nodal disease via sentinel node mapping than via lymphadenectomy.[3] Standard laparoscopic sentinel node dissection, however, can be technically challenging, especially in an obese population, which affects a significant share of patients with endometrial cancer.[1]

Hysterectomy by natural orifice transluminal endoscopic surgery (vNOTES) is a minimally invasive technique using vaginal surgical access eliminating the need for abdominal incisions. The first vNOTES hysterectomy on humans was performed in 2012, and in 2019 the first RCT was published showing noninferiority of vNOTES hysterectomy compared to total laparoscopic hysterectomy for benign indications.[4,5] Since then, consensus was reached on the safe implementation of vNOTES in the gynecologic practice. Several studies including recent systematic reviews and meta-analysis showed the advantages for benign gynecologic indications, including shorter operation time, less postoperative pain, and shorter length of hospital stay with similar outcomes concerning intra- and postoperative complications.[6,7] Given the vaginal access, vNOTES offers an additional benefit in the obese population where standard laparoscopic access can be technically challenging.[8] For the treatment of gynecologic malignancies, currently only IDEAL stage 1 studies have been conducted.[9,10]

The initial experience with a transperitoneal approach to sentinel node dissection via vNOTES showed a good visualization of the cranial pelvic retroperitoneum; however, optimal visualization of the caudal part could not be achieved. Therefore, a new retroperitoneal vNOTES approach was developed to provide better exposure of the entire pelvic area including the caudal part of the obturator space, the iliac arteries, and the sacral plexus.[11]

Key message

In the hands of experienced surgeons, it is feasible to stage endometrial cancer via vNOTES using a transvaginal retroperitoneal sentinel node dissection with high detection sensitivity. The lymphatic system is explored along its natural distribution from caudally to cranially.

This case series was designed to determine the feasibility of the vNOTES retroperitoneal approach to sentinel lymph node dissection in women with endometrial carcinoma. This is the first publication of the results and summarizes patient characteristics and short-term surgical outcomes.

2 | MATERIAL AND METHODS

2.1 | Patients

Data from 64 women with histologically proven endometrial cancer who underwent a vNOTES hysterectomy with bilateral salpingo-oophorectomy and retroperitoneal sentinel lymph node dissection from March 2016 until May 2023 were prospectively collected in four hospitals in Switzerland (Sion Hospital), the USA (Winthrop P Rockefeller Cancer Institute, University of Arkansas), Brazil (AC Camargo Cancer Center) and Belgium (Imelda Hospital Bonheiden). The surgery was performed by four surgeons in the international NOTES societies gynecologic oncology special interest group.

2.2 | Surgical technique

All women underwent surgical staging via vNOTES including total hysterectomy with bilateral salpingo-oophorectomy and retroperitoneal sentinel lymph node dissection.

The patient was placed in dorsal lithotomy. Draping allows conversion to standard laparoscopy if needed. Prophylactic antibiotics (second generation cephalosporin and metronidazole) were administered intravenously. After disinfection, a Foley catheter was placed to empty the bladder and Indocyanine green was injected into the cervix.

To the surgeon's preference the incision in the vaginal mucosa can be made in two different places: bilateral incision in the lateral vaginal fornix[11] or via single anterior midline incision.[12]

The obturator fossa was accessed paravesically via blunt and sharp dissection laterally towards the internal obturator muscle and the vNOTES port (Gelpoint vPath mini or small) was inserted to create a sealed retroperitoneal space and to insufflate CO_2.[12]

All optic and standard endoscopic instruments were inserted transvaginally through the Gelport. The obturator space was entered and the ureter, iliac bifurcation, internal and external iliac artery and vein and the obturator nerve were identified.

The retroperitoneal space was further developed, and the sentinel node was identified by using fluorescence imaging. As endoscopic instruments, 5 mm bipolar graspers, 5 mm disposable scissors and sealing devices were used. The afferent and efferent lymph vessels to the sentinel node were identified and the sentinel lymph node was identified and isolated from the surrounding tissues by careful dissection. The sentinel node was resected and removed transvaginally.[11] The same procedure was performed on the contralateral side. The procedure was performed entirely transvaginally without the need for abdominal incisions.

After removal of the sentinel nodes bilaterally, a vaginally assisted notes hysterectomy (VANH) with bilateral salpingo-oophorectomy was performed on all patients. When performing a VANH vaginal hysterectomy the pouch of Douglas and the vesicouterine pouch are entered under direct vision, as in a conventional vaginal hysterectomy, whereas the rest of the hysterectomy is performed endoscopically.[13] All patients underwent clinical follow-up of at least 6 weeks.

3 | RESULTS

3.1 | Patient characteristics

A total of 64 patients underwent surgical staging for histologically proven early-stage endometrial carcinoma or complex atypical hyperplasia. The baseline patient characteristics are summarized in Table 1. The mean age of the patients was 69.5 years, The median BMI was 26 kg/m^2, with 18 women being obese (BMI ≥30 kg/m^2) and four patients were morbidly obese (BMI >40 kg/m^2).

3.2 | Surgical outcomes

The surgical outcomes are summarized in Table 2. The median total surgical time was 126 min, and the median estimated blood loss during surgery was 80 mL. In 32 cases (50%) bilateral incisions in the lateral vaginal fornix were used to access the obturator fossa, in the other 32 cases the anterior approach via a single anterior midline incision was used. The location of these incisions was made to the surgeon's preference. Both techniques showed a similar success rate and number of identified nodes. There was no difference in the number of complications between both techniques as summarized in Table 3.

On average, three nodes were resected. In 62 (97%) of the cases bilateral sentinel nodes were identified and in two cases the sentinel node was only identified unilaterally. A peritoneal defect with leakage of CO_2 to the intraperitoneal space on the right side prevented identification of the nodes in one of the cases. The analyzed node was negative, and the patient underwent adjuvant radiotherapy. In

TABLE 1 Patient characteristics.

Patient characteristics	Total (*N* = 64)
Age in years Median (range)	69.5 (45–89)
BMI in kg/m^2 Median (range)	26 (16–48)
BMI >30 kg/m^2 *n* (%)	18 (28)
BMI >40 kg/m^2 *n* (%)	4 (6)
Nulliparity *n* (%)	10 (16)
Previous vaginal delivery *n* (%)	51 (80)
Previous cesarean section *n* (%)	4 (6)
Previous abdominal surgery *n* (%)	24 (38)

Abbreviation: BMI, body mass index.

TABLE 2 Surgical outcome.

Surgical outcomes	Total *N* = 64
Duration of surgery, min, median, (range)	126 (63–211)
Outpatient, *n* (%)	19 (30)
Estimated blood loss, mL, median (range)	80 (30–400)
Bilateral sentinel nodes defined, *n* (%)	62 (97)
Number of sentinel nodes, *n*, median, (range)	3 (0–9)
Positive sentinel nodes, *n*, (%)	4 (6) • 3 (5) isolated tumor cells • 1 (1.5) macrometastasis
Conversion to laparoscopy, *n* (%)	1 (1.5)
Conversion to laparotomy, *n* (%)	0
Postoperative surgical reintervention, *n* (%)	1 (1.5)
VAS scores, *n*, median, (range)	1 (1–2)

Abbreviation: VAS, visual analog scale.

TABLE 3 Anterior vs lateral approach.

	Lateral approach	Anterior approach
Number of cases	32	32
Bilateral sentinel nodes identified, *n*, (%)	31 (97)	31 (97)
Median number of sentinels, *n*, median, (range)	2 (2–9)	3 (2–9)
Duration of surgery, min, median, (range)	137.5 (87–180)	111.5 (62–211)
Complications, *n*	5	5

TABLE 4 Cases with complication or conversion.

Complication	Surgical reintervention	Management	BMI	Obstetric history	Previous abdominal surgery
Cystotomy	No	Conservative, Foley catheter for 10 days	31	Nulliparous	None
Cystotomy during blunt dissection	No	Sutured with Vicryl, Foley catheter 10 days, RX cystography ok	25	VD	None
Cystotomy	No	Foley catheter for 14 days	22	VD	Appendectomy, laparoscopic CCE
Adductor paresis	No	No treatment needed	31	Nulliparous	None
Left obturator vein cut	No	Conservative, no sequelae	40	VD	Umbilical hernia repair
Peritoneal defect	No	No treatment necessary	48	VD	None
Atrial fibrillation during surgery	No	Medically treated	26	Nulliparous	None
Postoperative bleeding infundibulopelvic ligament	Yes	Laparoscopic revision, coagulation	33	VD	None
Left obturator space bleeding	No	Conversion to laparoscopy, coagulation	22	VD	None
Vaginal vault hematoma on anticoagulants for femoral DVT	No	Conservative, completely resorbed after 6 months	68	VD	None

Abbreviations: BMI, body mass index; CCE, cholecystectomy; DVT, deep vein thrombosis; VD, vaginal delivery.

the other case only a right sided sentinel node could be identified. No lymphadenectomy was performed due to age and early stage of the endometrial carcinoma. Sentinel nodes were negative in 60 (94%) of the cases.

Four patients had positive sentinel nodes, three of which showed isolated tumor cells, and one with macrometastasis without capsular rupture. A total of 13 (20%) patients underwent adjuvant treatment according to hospital guidelines. A total of 19 patients (30%) were discharged from the hospital the same day of surgery. For the other patients the median hospital stay was 2 days. Median visual analog scale (VAS) pain scores of the hospitalized patients were 1 out of 10 24 h postoperatively.

There were 10 perioperative or short-term postoperative complications, as summarized in Table 4. Bladder injury was reported in three cases (incidence 5% or 3/64). Two did not require surgical repair and were managed conservatively with a Foley catheter for 1–2 weeks. In the third case the cystotomy was repaired with vicryl 3/0 and a Foley catheter remained in place for 10 days after which a cystography was performed, showing no signs of leakage. In all three cases, a postoperative examination after 6 weeks showed complete recovery with normal micturition and no sequelae.

Surgical reintervention was needed in one case because of bleeding 48 h post-surgery. The surgery was uncomplicated, and the patient had left the hospital after one night. The patient was readmitted postoperative day 2 with signs of anemia and abdominal pain. Laparoscopy showed bleeding around the infundibulopelvic ligament which was coagulated. There was no need for a blood transfusion.

In one case, paresis of the adductor muscles of the hip was observed, presumably due to neuropraxy of the obturator nerve. The patient recovered spontaneously without any residual symptoms after 6 weeks.

In one case the obturator vein was lacerated and repaired during surgery. There were no sequelae.

In one case 3 weeks after surgery a femoral deep vein thrombosis developed for which anticoagulant therapy was started. This patient developed a 5-cm vaginal vault hematoma that was diagnosed at the 6 weeks follow-up appointment. It was managed conservatively, and

TABLE 5 Histology.

Category	Total patients
Preoperative histology	
Endometrioid	53
Complex atypical hyperplasia	5
Clear cell	3
Mixed	1
Endometrial intraepithelial hyperplasia	1
Serous	1
Preoperative grading	
No grading (EIN, hyperplasia)	8
Grade 1	38
Grade 2	9
Grade 3	9
Preoperative staging (FIGO 2023)	
No staging (EIN, atypical hyperplasia)	6
cIA	37
cIB	20
cIIA	1
Postoperative histology (FIGO 2023)	
Atypical hyperplasia, EIN	4
pIA	32
pIB	12
pIC	2
pIIA	2
pIIB	3
pIIC	3
pIIIB1	1
pIIIC1	4
pIVB	1

Abbreviations: EIN, endometrial intraepithelial neoplasia; FIGO, International Federation of Gynecology and Obstetrics.

complete resorption was confirmed with an ultrasound scan after 6 months.

There were no conversions to laparotomy and one conversion to laparoscopy, due to bleeding in the left obturator space during the sentinel procedure which could not be adequately managed via vNOTES. There were no complications that postponed adjuvant therapy.

All specimens were sent off for histology, and the results are summarized in Table 5.

4 | DISCUSSION

This study demonstrates that vNOTES retroperitoneal sentinel node resection with hysterectomy may be a feasible alternative for early-stage endometrial cancer, with a success rate of 97% for bilateral and 3% for unilateral lymph node identification. Although our dataset is not comparable in size to larger laparosopic or robotic studies, these data are an initial indication that the retroperitoneal vNOTES sentinel detection is at least as efficacious as the 92.5% indocyanine green sentinel detection sensitivity via the current standard approach described in the last Cochrane review.[14]

The benefits of vNOTES hysterectomy described in the HALON trial for benign indications can largely be extrapolated to patients with endometrial carcinoma, with shorter hospitalization period, less postoperative pain, and no trocar related complications. On the other hand, a vaginal entrance to the abdomen is associated with other access related complications, such as bladder injury.

This transvaginal retroperitoneal approach to sentinel node dissection has other potential benefits over other techniques. Compared to the standard laparoscopic or robotic sentinel node resection, the retroperitoneal approach has an advantage, especially in the obese population, as the entire sentinel dissection is performed without Trendelenburg position. As the lymph nodes are dissected caudally to cranially, this new technique follows the typical trajectory of lymph flow from the uterus upwards. It reduces the risk of inadvertently removing a secondary green node instead of the primary sentinel node. The lymph pathway can be fully mapped from caudal to cranial in the same manner as a laparoscopic procedure but in the opposite direction. In the vaginal approach the distance to the sentinel nodes is shorter than it would be compared to operating laparoscopically making abdominal adiposity less disturbing.

vNOTES retroperitoneal lymph node dissection is a relatively new technique requiring a surgeon with expertise in vaginal, as well as laparoscopic surgery. Considering the recency of this procedure there is still a significant learning curve that impacts the results. The first patient was included in 2016 and this is the first publication of the results. In this case series there were three cystotomies (5%). In comparison incidence of cystotomies in laparoscopic hysterectomies overall is 1% and urinary tract injuries in the first 7 years of performing laparoscopic and robotic hysterectomies was 2.3%.[15,16]

This difference can be explained by the developmental phase of the technique.

Perioperative complications and surgical time are expected to decline over time as the surgeons gain more experience in this technique.

In this case series, in 97% of the cases bilateral sentinel nodes could be identified which is equivalent to trials assessing laparoscopic sentinel node resection.[2,17]

Only low-grade endometrial cancers were included in this study. The evidence is sparse regarding the risks of spilling of cancerous endometrial cells while operating vaginally. Evidence suggests no increased risk of peritoneal positive cytology after diagnostic hysteroscopy for early-stage endometrial carcinoma.[18,19] It seems therefore reasonable to assume vNOTES hysterectomy would not create a more significant risk than

hysteroscopy. In addition, a safety measure was performed to prevent potential spilling by suturing the cervix closed before the surgery.

A strength of this study was that it was a prospective multicenter trial and procedures were performed by four different surgeons in different countries improving the generalizability of the findings.

A weakness of this study was that data consisted of a small and early cohort and there was no comparison with the current gold standard techniques.

Further large-scale investigations are required to allow both accurate comparison with existing large laparoscopic and robotic cohort studies and determination of long-term safety.

5 | CONCLUSION

This is the first publication of prospective data on vNOTES retroperitoneal lymph node resection, performed according to the idea, development, exploration, assessment, and long-term (IDEAL) study criteria.[9,10] In this stage 2A trial, prospective multicenter data was collected to determine the feasibility of the retroperitoneal sentinel lymph node dissection for endometrial cancer staging.

Bilateral sentinel nodes were identified via retroperitoneal access in 97% of the cases, with similar complication rates as laparoscopic procedure.

Based on these data, vNOTES staging of endometrial carcinoma, when performed by experienced surgeons, may be a safe, reproducible, and less invasive alternative to the standard laparoscopic staging. Potential benefits include a less invasive hysterectomy approach, as demonstrated for benign hysterectomy[7]; eliminating the need for Trendelenburg position during the sentinel node dissection, facilitating anesthesia in an obese population; and an anatomical following of the lymph distribution from caudally to cranially. Larger studies are necessary to determine the long-term safety of vNOTES hysterectomy for endometrial cancer and for vNOTES retroperitoneal sentinel node dissection.

AUTHOR CONTRIBUTIONS

Data was processed and article was written by Astrid Jespers, Jan Baekelandt and Andrea Stuart. All authors contributed to the gathering of the data and revision and writing of the article.

CONFLICT OF INTEREST STATEMENT

Jan Baekelandt and Andrea Stuart disclose consultancy for Applied Medical.

ETHICS STATEMENT

The study was approved on January 18, 2022 by Commission cantonale d'éthique de la recherche sur l'être humain, Lausanne (IRB number: CER-VD 2021-02346). This study is in line with the Idea, Development, Exploration, Assessment, and Long-term Study recommendations on the development of new surgical techniques (stage 2A, development).[9,10]

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How to cite this article: Baekelandt J, Jespers A, Huber D, et al. vNOTES retroperitoneal sentinel lymph node dissection for endometrial cancer staging: First multicenter, prospective case series. *Acta Obstet Gynecol Scand*. 2024;103:1311-1317. doi:10.1111/aogs.14843