Repeat Vaginal Natural Orifice Transluminal Endoscopic Surgery: A First Feasibility Study

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Keywords

Repeat vaginal natural orifice transluminal endoscopic surgery · Colpotomy · Benign gynaecologic surgery · Hysterectomy · Vaginally assisted natural orifice transluminal endoscopic surgery hysterectomy

Abstract

Objectives: Vaginal natural orifice transluminal endoscopic surgery (vNOTES) is an emerging minimally invasive technique in benign gynaecologic surgery whereby surgical access to the peritoneal cavity is achieved through natural orifices, namely through a vaginal colpotomy. Experience in repeat vNOTES cases is limited and so far, repeat vNOTES cases have not been described in the literature. The purpose of this study was to demonstrate the feasibility of vNOTES hysterectomy in women with a history of previous vNOTES adnexal surgery. **Design:** We performed a retrospective cohort study of the first 11 repeat vNOTES cases in our centre. All vNOTES procedures, primary adnexal surgery as well as repeat vNOTES hysterectomy, were performed by one surgeon (J.B.). **Materials, Setting, Methods:** Between March 2016 and May 2020, 11 patients underwent a vNOTES hysterectomy after prior vNOTES adnexectomy or cystectomy in Imelda Hospital, Bonheiden, Belgium. Relevant patient characteristics and outcome data were collected after written informed consent. **Results:** Median age was 49 years (range

44–65) at the moment of the first vNOTES procedure. Two patients had one or more caesarean sections in history, and 2 women were nulliparous. Median interval between primary and repeat vNOTES procedure was 15 months (range 0.8–37 months). All patients underwent a vaginally assisted NOTES hysterectomy (VANH) as repeat vNOTES procedure. Performing a colpotomy and entering the peritoneal cavity after prior vNOTES was technically feasible in all cases. All VANHs were successfully performed. There were 3 minor complications after repeat vNOTES, of which one was anaesthesia-related. The 2 complications associated with the surgical procedure were both cystitis. In one of these 2 patients, there were high post-void residues, which were easily managed by bladder training. There were no conversions to laparoscopy or laparotomy, neither serious nor life-threatening complications. No ureteric, bladder, or intestinal injuries have occurred. **Limitations:** The retrospective design and small sample size are the main limitations of this study. Moreover, the follow-up period of the most recently operated patients was too short to draw conclusions on long-term outcomes, including sexual function. **Conclusions:** In all patients in this case series, vNOTES hysterectomy after prior vNOTES adnexal surgery was successfully performed. Large-scale prospective trials with long-term follow-up are needed to evaluate the safety and feasibility of multiple consecutive vNOTES procedures in 1 patient.

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Introduction

The surgical approach for benign gynaecologic indications has changed markedly in the last decades with an increase in minimally invasive techniques and a concurrent decrease in associated morbidity [1, 2]. Laparoscopy has become a standard technique to perform a hysterectomy, with recent attempts to further minimize invasiveness [3]. Natural orifice transluminal endoscopic surgery (NOTES) is one of the newest evolutions in minimally invasive surgery whereby natural orifices are used to gain access to the abdominal cavity without visible scars [4]. NOTES has been adopted by general surgeons, urologists, gynaecologists, and gastro-enterologists and has shown to be a feasible and safe technique [5]. In benign gynaecology, the vaginal NOTES (vNOTES) technique has gained popularity over the past few years. The first randomized controlled trial comparing vNOTES to laparoscopic hysterectomy showed non-inferiority in successfully performing a hysterectomy without conversion. Moreover, there was a shorter hospital stay with more patients leaving the hospital within 12 h after surgery and less postoperative pain after vNOTES compared to laparoscopy [6]. A vaginally assisted NOTES hysterectomy (VANH) starts as a conventional vaginal hysterectomy. After anterior and posterior colpotomy and transection of both uterosacral ligaments, hysterectomy (with or without adnexectomy) is continued endoscopically through a vNOTES port [7]. In vNOTES adnexal surgery (adnexectomy, cystectomy, or salpingectomy), a colpotomy in the posterior vaginal fornix is used to directly access the pelvis through the pouch of Douglas. A small vNOTES port is then placed through the posterior fornix to enter endoscopic instruments into the peritoneal cavity [8]. The technique of colpotomy has been studied in the context of transvaginal specimen removal and seems to be safe and feasible with a minimal complication risk [9, 10]. Moreover, previous studies did not show a negative effect on sexual function in women, neither an increased risk for adhesions [9]. However, whether vNOTES is technically feasible after previous surgery using colpotomy has not been described. To our knowledge, repeat vNOTES cases have never been reported in literature. This series of repeat vNOTES cases is in line with the IDEAL recommendations on the development of new surgical techniques (stage 1, innovation).

Table 1. Patient characteristics

Case no.	Age, years	BMI, kg/m ²	Parity	VD, <i>n</i>	CS, <i>n</i>
1	47	17.5	1	1	0
2	48	26.6	2	1	1
3	45	20.2	2	2	0
4	49	23.0	2	2	0
5	65	23.0	2	2	0
6	48	25.2	0	0	0
7	54	29.8	2	0	2
8	56	24.7	2	2	0
9	52	31.6	2	2	0
10	50	22.5	2	2	0
11	44	23.4	0	0	0

VD, vaginal delivery; CS, caesarean section.

Materials and Methods

Patients

Between March 2016 and May 2020, 11 vNOTES hysterectomies were performed in patients with a history of vNOTES adnexectomy or vNOTES cystectomy in Imelda Hospital in Bonheiden, Belgium. Data from all women undergoing a vNOTES procedure are collected after written informed consent. Retrospectively, we analysed the following data from the 11 repeat vNOTES cases: age, BMI, gravidity, parity, number of vaginal deliveries, type of adnexal surgery (surgery no. 1), indication for adnexal surgery, indication for hysterectomy (surgery no. 2), interval between primary and repeat surgery, total operating time surgery no. 1 and 2, complications, postoperative visual analogue scale (VAS) pain scores, size of the adnexal mass (surgery no. 1), uterine weight (surgery no. 2), hospital stay, and the presence of adhesions. As this is a retrospective study, ethics approval was not required.

Surgical Technique

The surgical techniques have also been described in detail in the HALON [7] and NOTABLE [8] study protocol. In both vNOTES adnexal surgery and vNOTES hysterectomy, the patient is placed in lithotomy position after induction of general anaesthesia (GA). By rectovaginal examination, obliteration of the pouch of Douglas is excluded both in primary and repeat vNOTES procedures. The abdomen, pelvic area, and vagina are disinfected and draped. The bladder is emptied using a Foley catheter. At the end of each vNOTES procedure, after closure of the colpotomy or vaginal cuff, a plug is inserted in the vagina for haemostatic compression. The Foley catheter and the vaginal plug are both removed 3 h after the end of surgery [7, 8].

Vaginal Natural Orifice Transluminal Endoscopic Surgery Adnexectomy

For a vNOTES adnexectomy, the procedure starts with a 2.5 cm posterior colpotomy using a cold knife whereby the pouch of Douglas is opened using cold scissors [8]. The vNOTES port (Gelpoint vPath, Applied Medical, Rancho Santa Margarita, CA, USA) is inserted into the pouch of Douglas. After CO₂ insufflation until a max-

Table 2. Characteristics of primary adnexal surgery

Case no.	Type of surgery no. 1	Indication	Total operating time, min	Largest diameter of adnexal mass, mm	Perioperative complications	VAS pain score after 6/24 h	Hospital stay, days
1	USO R + hysteroscopy + D&C	Ovarian cyst R, haemato-metrium	35	50	–	2/2	2
2	USO R + LLETZ	Ovarian cyst R + abnormal cervical smear	40	45	–	2/–	1
3	USO L + TOT	Ovarian cyst L stress incontinence	45	50	–	2/2	3
4	USO L + endometrial ablation	Ovarian cyst L, menorrhagia	60	40	PONV	1/3	2
5	USO R	Ovarian cyst R	30	55	–	1/1	2
6	USO R	Ovarian cyst R	45	90	Anaemia (Hb 8.7 g/dL)	2/2	2
7	USO L + LLETZ + hysteroscopy + D&C	Ovarian cyst L, abnormal cervical smear	40	55	–	2/1	2
8	BSO + hysteroscopy + D&C	Ovarian cyst R + endometrial polyp	60	R: 20 L: 18	–	0/–	1
9	BSO	Persisting ovarian cyst L, postmenopausal	50	R: 25 L: 40	–	2/0	2
10	Cystectomy R	Ovarian cyst R	60	35	–	2/–	2
11	USO L	Ovarian cyst L	42	140	–	1/1	2

VAS, visual analogue scale; h, hours; min, minutes; USO, unilateral salpingo-oophorectomy; BSO, bilateral salpingo-oophorectomy; R, right; L, left; LLETZ, large loop excision of transformation zone; TOT, transobturator tape; Hb, haemoglobin; PONV, postoperative nausea and vomiting; D&C, dilation and curettage.

imal intraperitoneal pressure of 10 mm Hg, a 10 mm rigid 30° endoscope is inserted into the peritoneal cavity. The operating table is tilted in Trendelenburg position, the small intestine is lifted out of the pelvis, and the ureters are identified. The proximal end of the Fallopian tube is coagulated and transected. The ovarian and infundibulopelvic ligament are coagulated and cut to perform a unilateral salpingo-oophorectomy. Depending on the indication, the procedure can be repeated on the contralateral side for a bilateral salpingo-oophorectomy. When a cystectomy is performed, the cyst is dissected from the ovarian cortex and the ovary stays in place. Haemostasis is confirmed and the peritoneal cavity is rinsed. Small benign-looking adnexae can be removed directly through the wound protector part of the vNOTES port. Large adnexae or adnexae with uncertain biologic behaviour are removed in an endobag after aspiration of cyst fluid without intraperitoneal spilling. By using 3 interrupted figure-of-eight Vicryl 2/0, the colpotomy is sutured.

Vaginal Natural Orifice Transluminal Endoscopic Surgery Hysterectomy

All patients in this series underwent a VANH. The surgical procedure in these repeat vNOTES cases was identical to classic primary VANH. Pozzi tenaculum forceps are placed on the anterior and posterior cervical lip to provide caudal traction. Cold-knife circumcision of the cervix is performed after submucosal infiltration of an adrenalin-ropivacaine solution (for hydrodissection and local anaesthesia). The vaginal mucosa is sheared off by

a gauze compress. Then, the vesico-uterine peritoneum and the pouch of Douglas are opened with cold scissors by anterior and posterior colpotomy, respectively. Subsequently, the uterosacral ligaments are cut, as done in conventional vaginal hysterectomy. The vNOTES port is inserted into the peritoneal cavity to establish a pneumoperitoneum. This device enables several trocars to be inserted through a single port. Again, a 10 mm rigid 30° laparoscope is used. Anatomic structures of the female pelvis, including the ureters, can be identified. The hysterectomy is performed by dissecting caudally to cranially using endoscopic instruments with bipolar coagulation. The Fallopian tubes are removed in all women after counselling; the ovaries only when indicated. At the end of the hysterectomy, the surgeon removes the vNOTES port and the uterus through the vagina. When the uterus is too large to extract vaginally, transvaginal cold-knife morcellation is performed. The vaginal cuff is closed as in a conventional vaginal surgery.

Anaesthesia and Pain Management Protocol

Standard induction of GA was performed by using intravenous (IV) propofol 2.5 mg/kg, sufentanil 0.15 µg/kg, rocuronium 0.6 mg/kg, and dexamethasone 0.1 mg/kg (max 5 mg). Desflurane was used for maintenance of GA at a minimal alveolar concentration of 1. During surgery, alfentanil 5 µg/kg was administered when indicated. Thirty minutes before the end of the procedure, all patients received IV paracetamol 1 g and ketoro-

Table 3. Characteristics of the repeat vNOTES procedure

Case no.	Type of surgery	Indication	Total operating time, min	Uterine weight, g	Intraoperative diagnosis of adhesions	Perioperative complications	Postoperative complications	VAS pain score after 6/24 h	Hospital stay, d	Interval between surgery 1 and 2, months
1	VANH + USO L	Post-coital blood loss, dyspareunia, persisting abnormal cervical smear	40	60	Mild adhesions between caecum and pelvic wall	-	Cystitis	2/2	2	25.7
2	VANH + USO L	Cervical occlusion with hydrometra	35	44	-	-	-	3/1	2	21.8
3	VANH	Menorrhagia and dysmenorrhea	31	87	Scar tissue posterior vaginal wall	-	-	3/1	3	15.0
4	VANH	Menorrhagia	42	63	-	-	-	2/1	1	14.7
5	VANH + OE	Borderline tumour ovary	100	45	Sigmoid	-	-	1/1	2	2.1
6	VANH	Menorrhagia	40	320	-	-	-	2/-	1	37
7	VANH + USO R	Ovarian cyst R 5 cm	45	69	-	-	-	3/2	2	15.6
8	VANH	Endometrial polyp with focal complex hyperplasia	35	54	Mild adhesions caecum	-	-	1/-	1	3.9
9	VANH + OE	Borderline tumour ovary	90	92	-	-	Cystitis and high post-void residue	2/1	4	1.4
10	VANH + BSO	Recurrent cysts	50	102	Pronounced adhesions in upper abdomen, colon completely adhered	-	PONV	4/2	2	31.1
11	VANH + USO R + OE + AE	Borderline tumour ovary	60	160	-	-	-	2/2	4	0.8

VAS, visual analogue scale; VANH, vaginally assisted NOTES hysterectomy; BSO, bilateral salpingo-oophorectomy; USO, unilateral salpingo-oophorectomy; R, right; L, left; PONV, postoperative nausea and vomiting; AE, appendectomy; OE, omentectomy; vNOTE, vaginal natural orifice transluminal endoscopic surgery.

lac 0.5 mg/kg (max 30 mg) with a maximum of 30 mg. When the patient reported a VAS pain score >4 on the recovery, 2.5 mg piritramide IV was used. Postoperative pain is routinely assessed after 6 and 24 h by the nurse on the ward. Paracetamol 1 g IV and ketorolac 30 mg IV are the first-line analgesics for patients reporting a VAS score >4. Tramadol (300 mg in 24 h) is used in second line.

Results

Patient characteristics are shown in Table 1. The median age was 49 years (range 44–65). The median BMI was 23.4 kg/m² (range 17.5–31.6). Two patients were nulliparous. One woman had had 2 caesarean sections and no vaginal deliveries. One patient had a normal vaginal delivery and a caesarean section. Characteristics of the primary adnexal surgery of the consecutive patients are summarized in Table 2.

Table 3 shows the surgical outcomes of the repeat vNOTES procedures (i.e., VANH) and the interval between primary and repeat vNOTES. The median interval between the 2 surgeries was 15 months (range 0.8–37 months). The mean operating time was 51 min. Mean uterine weight was 99 g. Median VAS pain score 6 h after surgery was 2 (range 1–6) and 24 h after surgery 1.5 (range 1–2). Postoperatively, 2 patients had complications related to surgery. Cystitis was diagnosed in case number 1 and managed with antibiotics *lege artis*. In case 9 in Table 3, there was a problem of incomplete bladder emptying with increased post-void residues due to cystitis, which resolved after bladder training and antibiotics. Moreover, one patient had postoperative nausea and vomiting, which was treated with IV anti-emetics.

Discussion

vNOTES is a relatively novel technique in the field of minimally invasive surgery that gained popularity in the past few years. In experienced hands, it is a safe and scarless alternative to vaginal, laparoscopic, and open surgery. Besides non-inferiority in successfully performing a hysterectomy, possible advantages of vNOTES hysterectomy over laparoscopy are shorter hospital stay and less postoperative pain [6]. Especially when nulliparity, obesity [11], or large uterine volume is present, all factors that may complicate the feasibility of a vaginal hysterectomy, vNOTES offers the advantages of endoscopic surgery with better visualization of pelvic anatomy. Moreover, the endoscopic access facilitates removal of the Fallopian

tubes or ovaries during vNOTES compared to classic vaginal hysterectomy. In adnexal surgery via vNOTES (i.e., unilateral salpingo-oophorectomy, bilateral salpingo-oophorectomy, salpingectomy, or cystectomy), a colpotomy is made in the posterior vaginal fornix to enter the peritoneal cavity. This also means that vNOTES uses a vaginal incision into the pouch of Douglas that is not made via the conventional abdominal access (laparoscopy or laparotomy). Relative contraindications for vNOTES are severe pelvic adhesions (frozen pelvis), obliteration of the pouch of Douglas, and rectovaginal endometriosis [12, 13]. Whether a previous colpotomy may complicate future surgery due to adhesions or scar tissue has not yet been studied in the light of vNOTES. However, there is plenty of experience in the use of a colpotomy for specimen extraction, and it has shown to be a safe and feasible technique with a very low complication rate [9, 10, 14]. Moreover, a colpotomy does not seem to increase the risk for later sexual dysfunction or postoperative adhesions although more research is needed.

In this case series, we describe the patient characteristics and surgical outcome of 11 women who underwent a vNOTES hysterectomy after prior vNOTES adnexectomy (in 10 cases) or cystectomy (1 case). To the best of our knowledge, repeat vNOTES cases have never been reported in the literature.

In this small case series, only 2 minor perioperative surgical complications were seen: 2 patients presented with postoperative cystitis. There were no conversions to laparoscopy or laparotomy. Exactly the same surgical steps were followed in these repeat vNOTES cases as in VANH cases without prior vNOTES surgery. During the repeat vNOTES procedure (VANH), the posterior colpotomy and the opening of the pouch of Douglas went smoothly in all cases. Intra-abdominal adhesions were present in varying degree, and mild fibrotic scar tissue at the colpotomy site was noticed in one case. However, there were no problems in accessing the peritoneal cavity due to the absence of relevant adhesions at the colpotomy site that interfered with safely performing a repeat colpotomy. vNOTES allowed easy adhesiolysis.

Postoperative VAS pain scores were low, both after primary and repeat vNOTES. This is in line with the findings of the first randomized controlled trial comparing VANH with laparoscopic hysterectomy, wherein vNOTES was associated with significantly lower pain scores [6]. The study design of a retrospective case series is an important limitation in the assessment of the safety and feasibility of repeat vNOTES. Moreover, all procedures were performed by one surgeon (J.B.) in a single

centre, which is possibly less generalizable. Follow-up was limited due to the retrospective design, whereby long-term effects on sexual function, dyspareunia, pelvic, or vaginal pain cannot properly be assessed. Large, prospective studies are needed to further evaluate the immediate and long-term outcome of repeating vNOTES procedures in the same patient.

Conclusion

In this case series, vNOTES hysterectomy was safely and successfully completed in patients with a history of vNOTES adnexal surgery. Only 2 minor surgical complications (postoperative cystitis in patients) were reported. There were no conversions to laparoscopy or laparotomy. Neither were their significant adhesions after prior vNOTES that complicated the feasibility of entering the peritoneal cavity. This IDEAL stage 1 study is the first report on repeat vNOTES surgery and is only a first small step in the scientific evaluation process needed to validate repeat vNOTES. Large-scale prospective clinical trials are needed to further evaluate the safety and feasibility of repeat vNOTES procedures, as well as the long-term impact on sexual function in women.

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Statement of Ethics

All patients have given their written informed consent for the anonymous processing of baseline characteristics and surgical outcome data for research purposes. Seen the retrospective design of this study, ethical approval was not required.

Conflict of Interest Statement

Dr. Jan Baekelandt discloses consultancy for Applied Medical. Dr. Katrien Nulens has no conflicts of interest to declare. Ilse Van Genechten has no conflicts of interest to declare.

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Author Contributions

Dr. Jan Baekelandt was the gynaecologist performing all surgical procedures and was involved in the writing of the manuscript. Dr. Katrien Nulens was involved in the writing of the manuscript as first author. Ilse Van Genechten was involved in the writing of the manuscript.