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Hysterectomy and Adenextomy via transvaginal natural orifice transluminal endoscopic surgery (vNOTES): A UK perspective with a case series of 33 patients

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ABSTRACT

Objective: : To evaluate operative outcomes of hysterectomy +/- adnexectomy by Trans-vaginal Natural Orifice Endoscopic Surgery (vNOTES) in a case series of 33 patients.
Study Design: : It was a prospective case series study carried out in Darent Valley and Benenden Hospital, to our knowledge, the first units in the United Kingdom to have undertaken VNOTE Hysterectomy.
We collected data on a private shared drive noting patient demographics, indications for surgery, operation outcomes and patient follow-up details.
Results and Conclusions: : Between January and December 2018, 33 patients underwent surgery between two units. Indications for surgery included dysfunctional uterine bleeding, endometrial hyperplasia, pelvic pain, post-menopausal bleeding, prophylactic surgery in BRCA positive patients and one grade 1 stage 1 endometrial cancer in whom laparoscopic hysterectomy was technically difficult and complicated by previous midline laparotomy. Ages ranged from 35 to 75 and BMI from 20-53.
Mean operation time was 68.5 min and mean blood loss intraoperatively was 269mls. 15.2% (n = 5) had a blood loss equal or more than 500 mls. There were no intraoperative complications and no conversions to open surgery.
The median visual analogue pain score at 6 h post operatively and at discharge was 0. All patients received regular Paracetamol and Ibuprofen and opiate based analgesics were only used on an as required basis. Postoperative complication which included failed trial without catheter, urinary tract infection and urinary dysfunction were reported by four women (12.4%).
Only 2 patients re-presented to hospital over a 30-day period and neither required inpatient management.
Hysterectomy by vNOTES has advantages over traditional laparoscopic and vaginal hysterectomy that include reduced requirement for intra-abdominal insufflation and head down, absence of trocar related injuries and easier operative access in patients with morbid obesity, or previous abdominal surgery such as midline laparotomy or mesh hernia repair. In addition, both tubes and ovaries can be removed easily due to easier access and visibility and there is no requirement for vaginal descent in order to do so.
Plans for a comparative study between laparoscopic hysterectomy and vNOTES hysterectomy are underway.

Introduction

Natural Orifice Transluminal Endoscopic Surgery (NOTES) refers to an emerging field of surgery that allows the surgeon to access the peritoneal cavity through internal transvisceral incisions rather than abdominal incisions [1].

Supporters of NOTES surgery suggest that as compared to laparoscopic surgery it has reduced postoperative pain, improved cosmesis, reduced physiological and immunological responses to surgery and the potential for quicker recovery and discharge from hospital. It may also offer better access to organs in patients where factors such as dense adhesions or morbid obesity hinder access with a traditional approach [1].

The NOTES technique was first demonstrated in the late 1990s in animal studies with procedures such as exploration of the peritoneal cavity and resections of the pancreas, spleen and kidney.

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The first published surgery on human participants was a transvaginal endoscopic cholecystectomy in 2007 [2].

NOTES surgery has been performed via the rectum, oesophagus, bladder and stomach, however the transvaginal approach is still the most commonly used owing to its ease of access to the peritoneal cavity, the ability to remove large specimens and the safety and ease of closure. [3]

Whilst transvaginal access requires the general surgeons to familiarize themselves with culdotomy, this has long been a method of access for the gynaecologist. Conrad Langenbeck performed the first hysterectomy vaginally in 1813 and this technique still remains in practice today. [4]

NOTES surgery was first used in gynaecology in 2012 with the removal of adenexa for benign pathology via a trans-vaginal NOTES (vNOTE) approach [2]. Ovarian cystectomy, salpingectomy for ectopic pregnancy and tubal sterilization procedures were undertaken on an initial series of ten patients [2]. Since then, a few centers have published small case series aiming to demonstrate the safety and feasibility of vNOTES surgery [5–9].

A randomized controlled trial of vNOTES hysterectomy has also been conducted in Europe comparing vNOTE and laparoscopic Hysterectomy) for removal of non-prolapsed uteri (HALON study)[10]. Results from this are unpublished.

There have been no published accounts of vNOTE procedures from the UK. We set out to determine if vNOTE hysterectomy is a safe and viable alternative to the existing forms of hysterectomy. Our primary outcome measure was successful completion of a vNOTE hysterectomy with or without adnexectomy. Secondary outcome measures were the time taken for procedure, patient length of stay and operative complications including estimated blood loss.

Methods

Both senior authors (EK, AG) sought approval from the new procedure committee at one NHS hospital (Dartford & Gravesham NHS trust) and one private hospital (Benenden Hospital). Patient information leaflets were created. Consent was obtained for information sharing and research purposes. All procedures were carried out by one of the two senior authors.

Inclusion criteria were all women with benign uterine pathology or grade one stage one endometrial cancer suitable for hysterectomy at a local unit. For women in whom endometrial cancer was identified on tissue biopsy, confirmation was required that hysterectomy was appropriate at our local district general hospital by pre-staging MRI and discussion at the local gynaecology-oncology multidisciplinary meeting. Where LH is the operation offered for such endometrial cancers, vNOTE Hysterectomy was offered in one instance due to the patient's morbid obesity and anaesthetic concern over ventilation in trendelenburg.

Patients were excluded if they had a history of surgery to the rectovaginal pouch, rectovaginal endometriosis, or two or more previous caesareans. Women with uterine prolapse were also excluded, as traditional VH was deemed more appropriate.

Patients were informed of the research surrounding prophylactic salpingectomy and prevention of epithelial ovarian cancer and were therefore offered concurrent salpingectomy [11].

Technique

Patients were placed in lithotomy position but prepared and draped to allow conversion to laparoscopy if needed. A circular incision was made around the cervix with a cold knife. Access to the pouch of douglas and utero-vesical fold was created. The uterosacral ligaments were transected and ligated using 1-0 vicryl. A GelPoint device (Applied Medical, Fig. 1) was set up and inserted

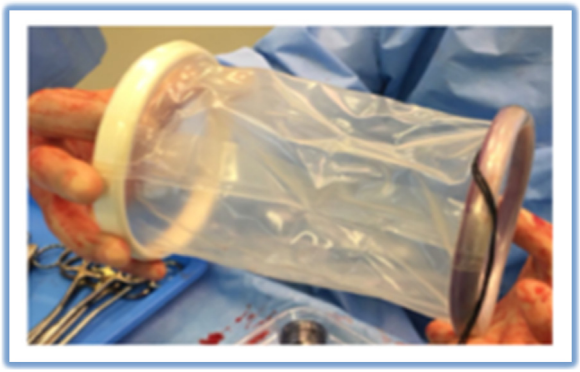

Fig. 1. Alexis Retractor.

into the pouch of douglas and peritoneal space between the bladder and uterus. A pneumoperitoneum (8–10 mmHg) was created. Standard laparoscopic instruments were passed through ports placed in the GelPoint device (Figs. 2, 3). The patients were then placed in a moderate trendelenburg and bowel was moved away from the pelvis. Trendelenburg could later be corrected by the placement of large swab between the bowels and pelvic organs.

The ureters are identified but not dissected to reduce risk of complication.

Hysterectomy and in some cases, adenextomy was then performed using a bipolar vessel sealing device. Haemostasis was ensured. At the end of the procedure the Gelpoint device was removed with pelvic organs removed through the retractor. Colpotomy was then closed after deflation of pneumoperitonem with a resorbable suture.

A standardized post-operative protocol was then followed with involvement of anaesthetics. All patients were prescribed simple analgesia (paracetamol and ibuprofen) as regular analgesia postoperatively. Stronger opiate analgesia was given on an 'as required' basis if requested.

Patients were discharged once they had passed urine and were back to baseline mobility.

Patient demographics, intra-operative times, blood loss and complications were recorded contemporaneously and on to a secured anonymised shared drive by the operating surgeon. Operating time was recorded by theatre staff as time from knife to skin to operation end. Follow-up data at 3 months was also recorded.

Fig. 2. Port insertion into device.

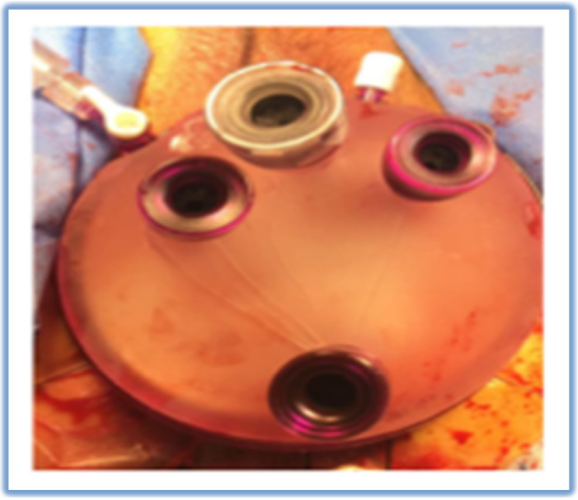

Fig. 3. Final port insertion.

Table 1
Patients' characteristics and outcome data of vNOTE surgery.

Patients' Characteristics	Results (N = 33)
Age, yrs mean (range)	50.0 (35.0–75.0)
BMI, kg/m^2 mean (range)	30.0 (20.0–53.0)
ASA mean (range)	2 (1–3)
Number of vaginal births n mean (range)	4 (0–4)
Previous surgery, n (%)	23 (69.0)(23)
Previous Caesarean section, n (%)	6 (18.2)
Indication for surgery	
Treatment resistant Dysfuntional Uterine Bleeding n (%)	14 (42.4)
Atypical Endometrial Hyperplasia n (%)	5 (15.2)
BRCA Positive Breast Cancer n (%)	2 (6.1)
Pelvic Pain n (%)	7 (21.2)
Post-Menopausal Bleeding n (%)	4 (12.1)
Endometrial Cancer Stage 1 n (%)	1 (3.0)
Outcome data	
Conversions n (%)	0 (0)
Operation time, minutes mean (range)	68.5 (43.0–110.0)
Estimated Blood loss, milliliters mean (range)	269 (50.0–1200.0)
Length of hospital stay, nights mean (range)	1.4 (1.0–2.0)

Results

Results of the study are summarized in Table 1.

33 patients underwent vNOTES hysterectomy between January and December 2018. 32 patients had a planned and successful adnexectomy. Mean age was 50 (range 35–75). Mean BMI was 30 (range 20–53). Mean ASA grade was 2.

69% had previous abdominal surgery and 18% had a previous caesarean section,

Indications for surgery included treatment resistant dysfunctional uterine bleeding, atypical endometrial hyperplasia, pelvic pain, post-menopausal bleeding and BRCA positive patients undergoing prophylactic surgery.

Mean operating time was 68.5 min Mean estimated blood loss was 269 milliliters. 15% had an estimated blood loss equal to or more than 500 ml. The average length of stay was 1.4 nights. All patients had the primary operation intended with no conversions to open or laparoscopic hysterectomy.

There were no major postoperative complications and no post-operative returns to theatre. No patients required blood transfusion. The median VAS pain score at 6 h post op and at discharge was 0.

2 Patients required readmission and both were treated conservatively

All patients received regular paracetamol and Ibuprofen (unless contraindicated) and opiate based analgesics such as codeine or oropmorph were only used on a PRN basis

Discussion

Hysterectomy still remains the most commonly performed gynecological operation performed worldwide [12]. In the UK over the last three decades there has been a decline in numbers performed [13]. This is likely attributable to the development of levonorgestrel intra-uterine systems and endometrial ablation techniques. In those whom hysterectomy is still required, there has been a drive towards the most minimally invasive approach for women. Two decades have now passed since Reich developed the laparoscopic hysterectomy (LH) and these advances have shifted trends away from abdominal hysterectomy(AH) [4]. Large multicentre systematic reviews have widely asserted the benefits of minimally invasive techniques over open abdominal hysterectomy (AH) in terms of patient recovery time, postoperative pain, blood loss, and wound related complications [4,14].

Debate still exists between gynaecologists when comparing LH over VH. A 2015 Cochrane review suggests that VH has shorter operating time, lower overall costs and better patient satisfaction when compared with laparoscopically assisted vaginal hysterectomy (LAVH)[4]. No difference has been found to exist between VH and LH when looking at return to normal activity or operative complications such as urinary tract damage [4].

Whilst these large multicentre systematic reviews support the use of VH as a preferred method of hysterectomy in women with benign gynaecological disease, the observed trends in hysterectomy in the UK and USA do not reflect this as VH operative rates are declining [4,13,15]. Many gynaecologists will cite factors such as nulliparity, minimal uterine descent, need for adnexectomy, previous pelvic surgery, or enlarged uteri as reasons why alternative methods are preferable.

Several studies have demonstrated the feasibility of hysterectomy and adnexectomy in women with complicating factors such as large uteri or minimal descent, however, an experienced operator is required in order to do so [16–18].

Results from our preliminary case series of 32 patients suggest vNOTE surgery is a promising new field within gynaecology that appears to combine the advantages of both vaginal and laparoscopic surgery.

As compared to VH, vNOTE hysterectomy allows better access and is not technically limited by non-descent. All pelvic structures including ureters can be seen and both tubes and ovaries easily removed with better access and visibility over VH. This is especially relevant as clinicians start to routinely offer prophylactic salpingectomy for prevention of epithelial ovarian cancers [11]. Whilst still performed in some units worldwide it has become less common practice to perform VH and concurrent adnexectomy, this is in part due to the technical expertise required.

As compared to traditional LH, vNOTE surgery appears scarless per abdomen and has the absence of trocar related injuries. Where traditional laparoscopy may be challenging due to patient factors such as previous abdominal surgery (midline laparotomy or mesh hernia repairs) where dense adhesions are expected, the transvaginal route is optimal as the surgeon has good access and exposure to the pelvic organs without encountering abdominal adhesions.

Our case series of 32 women included 26 who were overweight or obese by classification (BMI > 24.9). vNOTE hysterectomy operation times were comparable in patients of varying BMI. This is advantageous to the UK surgeon where the obesity epidemic is a complicating factor in laparoscopic surgery. Furthermore, we observed that intra-operative pressures ranged from 8 to 10 mmHg

with the need for patients in only moderate trendelenburg position rather than overt as with traditional laparoscopy. These were particularly positive findings and suggest that vNOTE hysterectomy may have particular application amongst those patients who have higher BMI.

Both in the private and NHS sector, there is often difficulty with the acquisition of second assistant. We observed no need for a second assistant with vNOTES hysterectomy as the surgeon and only one assistant are positioned seated between the patient in lithotomy position. This is both ergonomically and economically advantageous over laparoscopic hysterectomy.

Previous recto-vaginal surgery, recto-vaginal endometriosis or multiple caesareans may make access to the pouch of douglas and uterovesical fold difficult with an increased risk of bladder injury.

A procedural learning curve was encountered by both surgeons. Time taken for operation and estimated blood loss both decreased with increasing number of procedures performed.

Conclusions

From our preliminary case series of 32 patients, vNOTE hysterectomy appears to be as a safe and feasible approach. Successful operative outcomes were achieved in all patients with no intra-operative or post-operative complications. Secondary outcomes also suggest good patient satisfaction, minimal postoperative pain and quicker discharge from hospital than anticipated. Unexpected preliminary findings suggest this may be a particularly helpful approach in patients with obesity, or previous abdominopelvic surgery where laparoscopic surgery can be complicated.

Whilst VH may be superior where uterine decent is concurrent, vNOTE offers better access and views of the pelvic organs in cases of non-decent. For this reason it might therefore be of interest to clinicians as an alternative technique for patients requiring hysterectomy and adnextomy.

Plans for a prospective comparative study are underway to compare outcomes such as post-operative pain, quality of life and patients satisfaction between LH and vNOTE hysterectomy. Whilst our unit does not perform vaginal hysterectomy and concurrent adnexectomy comparative study to assess superiority would also be of interest.

Moreover there is also scope to make vNOTE hysterectomy a day case procedure in our unit which we anticipate to be favorable for patients as well as economically beneficial.

Declaration of Competing Interest

None.

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