

## LITERATURE REVIEW

# Is the scar-less hysterectomy with Natural Orifice Transluminal Endoscopic Surgery (NOTES) the future of benign gynecological surgery? A Review of the literature.

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### Abstract

As the tide advances towards minimally invasive surgical approaches which are favourable over open methods in terms of patient analgesia requirements and recovery time, Natural Orifice Transluminal Endoscopic Surgery (NOTES) has emerged as a technique within gynaecology which uses laparoscopic instruments and methods without the need for abdominal incisions. NOTES surgery has been conducted within gynecology via a vaginal colpotomy to perform procedures such as adnexectomy, hysterectomy, myomectomy and urogynecological procedures. This review summarises the available literature data on NOTES surgery with preliminary results showing reduced postoperative pain, improved cosmesis, and the potential for faster patient recovery and hospital discharge as compared to traditional methods. Larger studies and more robust data is needed to truly compare the efficacy of gynecological NOTES over traditional methods, however initial literature suggests this may be a promising innovation emerging in the field of Gynecology.

**Key Words:** Natural Orifice Transluminal Endoscopic Surgery, VNOTES, NOTES, hysterectomy, benign gynecology

## **1. Introduction**

The shift towards minimally invasive techniques within surgery has emerged in the last decade with a drive to reduce postoperative pain, decrease recovery time and hospital stay and provide improved esthetic results for patients<sup>1</sup>.

There have been many minimally invasive approaches described in the literature including Single Incision Laparoscopic Surgery (SILS) which uses one umbilical port and Low Impact Laparoscopic Surgery (LILS) which uses low insufflation pressures and 3mm instruments<sup>2</sup>. Natural Orifice Transluminal Endoscopic Surgery (NOTES) uses an incision in an orifice such as the stomach, vagina or colon to gain entrance to the peritoneal cavity and therefore avoids abdominal wall incisions. Transvaginal NOTES (vNOTES) has become most popular due to the ease of removing large specimens, the ease of decontamination and vault closure, and proximity to the peritoneal cavity<sup>2</sup>.

Advocates of NOTES suggest it is associated with reduced postoperative pain, improved cosmesis, reduced physiological and immunological reactions to surgery and faster patient recovery and hospital discharge. Where dense adhesions or morbid obesity hinder access with traditional approaches, vNOTES may also allow safer access and visualisation<sup>3</sup>.

The first NOTES surgery was first performed on humans in 2008 where the gallbladder was removed via the vaginal vault<sup>4</sup>. Since this time, the technique has been expanded to perform a wide variety of

gynecological procedures. This review will look at the safety and feasibility of vNOTES procedures within gynecology and explore the possible benefits of such an approach over traditional methods.

## **2 NOTES Technique**

All vNOTES procedures start with patient is positioned in lithotomy but prepared to allow conversion to a laparoscopic or open alternative. Access to the pouch of Douglas and/or uterovesical fold is created and a vNOTES device such as the Gelpoint™ is then inserted through the colpotomy. Pneumoperitoneum is created by insufflation of carbon dioxide. Standard endoscopic instruments are passed through ports in the vNOTES device. A moderate trendelenburg tilt is used. Ureters are then identified to reduce the risk of complication. At the end of the procedure, specimens are removed through the Gelpoint™ and colpotomy is closed after reduction of the pneumoperitoneum with a resorbable suture<sup>5</sup>.

### **2.1 Adnexectomy**

The first gynecological vNOTES was adenectomy for benign pathology<sup>6</sup>. In this case-series of ten there were three tubal sterilizations, three salpingectomies for ectopic pregnancy and three cystectomies for ovarian teratoma, the largest of which was 6cm x 4.5cm. Although there was one conversion to laparoscopy as the mass was not of ovarian origin, the study demonstrated the feasibility of vNOTES

with no intra-operative or post-operative complications.

Wang et al., later undertook a case-matched study comparing NOTES Assisted Ovarian Cystectomy (NAOC) versus Laparoscopic Ovarian Cystectomy (LOC). In the NAOC group there were no conversions. Blood loss was equivocal with a mean loss of 50mls. However, length of operating time and length of stay were significantly greater in the LOC group. They demonstrated a linear correlation between size of ovarian mass and operative time with the LOC group but not in the NAOC group. No patients reported new onset dyspareunia or problems with sexual intercourse at follow-up allowing authors to conclude that NAOC can be safely performed in moderate to large benign ovarian masses and may even be less technically challenging for larger ovarian cysts as compared to LOC<sup>7</sup>.

One particular strength of the vNOTES is the ability to remove large specimens through the vaginal vault without cyst rupture, the need for morcellation, or mini-laparotomy. With laparoscopy, the risk of leakage of cyst fluid is a serious consideration and one that often means laparotomy will be performed for cysts >10cm (8). Spillage of cyst contents can be associated with complications such as chemical peritonitis, upstaging of a malignant tumour, pelvic adhesions, abscess formation and fistulation as well as impacting fertility. The use of endoscopic bags and removal via colpotomy is commonplace in laparoscopic surgery as a means of avoidance of spillage of cyst contents and removal of large specimens<sup>8</sup>. It

therefore seems reasonable that vNOTES is worth consideration as a primary method of approach.

Furthermore, as a large proportion of patients undergoing adnexectomy for indications such as ectopic pregnancy are young, the option to offer scarless surgery may be attractive. The vNOTES technique may also reduce the number of post-operative adhesions associated with abdominal trocar insertion which over the lifecourse of a patient may reduce the risk of future complications.

## **2.2 Hysterectomy**

Hysterectomy remains the most common gynecological operation worldwide<sup>9</sup>. The development of pharmacological treatments and ablation techniques mean surgeons are duty bound to offer these before definitive surgery<sup>10</sup>. Thirty years have passed since Laparoscopic hysterectomy (LH) was developed by Harry Reich and the substantial developments in this area have shifted trends away from abdominal hysterectomy (AH). Cochrane reviews largely assert laparoscopic techniques are superior to AH in terms of patient recovery time, postoperative pain, blood loss, and wound related complications<sup>11,12</sup>.

Looking to vNOTES hysterectomy, there are multiple published case series in the literature<sup>13-15</sup>. In 2015 Baekelandt's team published a case-series of ten patients having had vNOTES hysterectomy<sup>16</sup>. There were no conversions, no adverse patient outcomes and they suggested there were low post-operative pain scores and fast recovery

times. By 2018, the same team were performing day-case vNOTES and conducted a randomised single-centre blinded trial, designed as a non-inferiority study randomizing 35 patients to LH and 35 to vNOTES<sup>5,17</sup>. They stratified patients according to size and volume of uteri and blinded patients by performing sham incisions on the abdomen of vNOTES patients. This study successfully demonstrated non-inferiority showing average length of stay after vNOTES was shorter (0.8 days vs 1.3 days,  $P=0.004$ ). They also demonstrated significantly lower postoperative analgesic requirements and concluded that vNOTES hysterectomy may allow more women to be operated on in a day-case setting.

Importantly, the study notes that vNOTES procedures were only performed in patients who weren't eligible for VH. They state that where VH can be done it should be as its associated with shortest operating time and lower overall costs<sup>11</sup>. Whilst this may be the case in patients eligible for either operation, certain factors make VH technically challenging.

As compared to VH, vNOTES allows better visualisation, even in cases without prolapse. Ureters are easy to visualise, and adnexa can be removed with easier access and visibility<sup>13</sup>. This is pertinent as clinicians move to routinely offering prophylactic salpingectomy for prevention of epithelial ovarian cancers<sup>18</sup>. Although still performed by experienced operators, performing VH and concurrent adnexectomy is becoming less common

which may be due to the technical expertise required<sup>19</sup>.

As compared to LH, vNOTES is scarless and avoids port related complications. Previous abdomino-pelvic surgery (midline laparotomy or mesh hernia repairs) causing dense adhesions make laparoscopy more challenging and thus in these patients vNOTES is optimal allowing good access and exposure<sup>13</sup>.

NOTES surgery does however have limitations and patient selection is key. Previous surgery to the rectum or vaginal, endometriosis obliterating the POD or multiple cesareans may make access to the POD and uterovesical fold harder increasing the possibility of urinary tract injury<sup>16</sup>.

### **2.3 Myomectomy**

Uterine fibroids have a lifetime prevalence of approximately 30% in women of reproductive years and are even more common amongst Afro-Caribbean women, and those with high BMI. Symptoms experienced by fibroids are most commonly experienced as pelvic fullness and heavy menstrual bleeding and as many as 25% of women will be symptomatic. Where pharmacological methods are unsuitable or have failed, surgical options must be based on fibroid position as well as the wishes of the patient<sup>20</sup>.

Two large reviews comparing laparoscopic versus open myomectomy have concluded that there is less postoperative pain, lower rates of postoperative pyrexia and shorter hospital inpatient stay in those patients receiving laparoscopic myomectomy<sup>21,22</sup>.

However, fibroid morcellation remains controversial due to the risks of seeding leiomyosarcoma which has made laparoscopic surgery less popular amongst some surgeons.

Removing large specimens through a colpotomy remains possible, however, there have been very few reports of myomectomy performed vaginally<sup>23</sup>. This is largely owing to difficulty with access and visualisation. However, vNOTES myomectomy has report successful outcomes. Baeklandt et al., presents a series of eight patients with pedunculated, subserosal and intramural fibroids in whom successful vNOTES myomectomy was performed<sup>24</sup>. They resected anteriorly sited fibroids through anterior colpotomy and posterior fibroids through posterior colpotomy. Fibroid size ranged from 30mm-70mm. Closure was performed using two-layer endoscopic closure. Specimens were removed in a bag through the colpotomy incision. There were no post-operative complications. The median operating time was 50 minutes and median blood loss was 1.6 g/dl. The authors concluded that this was a feasible alternative technique providing scarless surgery and ease of removal of the specimen.

At present numbers of myomectomies performed by the vNOTES technique are small. Often women undergoing myomectomy are women in whom medical methods have failed. It is commonplace for myomectomy to therefore be on women with large fibroids<sup>20</sup>. vNOTES myomectomy has not been performed on fibroids >80mm. As new guidance has been published on fibroids and morcellation, the

addition of morcellation may well help vNOTES develop as a legitimate alternative<sup>25</sup>.

#### **2.4 NOTES in urogynecology**

Colposuspension procedures have long been used as a treatment for stress urinary incontinence and have undergone a resurgence since discontinuation of transvaginal tape procedures in the UK. Open colposuspension is successful with good long-term outcome data, however, as with open procedures recovery times are longer. The long-term outcome data of laparoscopic colposuspension remains uncertain and larger trials are needed to assert their safety and efficacy over open colposuspension<sup>26</sup>. Only 29 patients have undergone vNOTES colposuspension procedures in the literature to date. All authors suggested it was feasible and provided good visualisation of deep structures including the ureters, sacral promontory and middle sacral artery<sup>27,28</sup>. One author also suggests it reduces the risk of mesh complications as well as port site complications<sup>28</sup>.

Furthermore, urogynecologists are likely to be comfortable operating in this orientation and thus whilst still too novel an approach, this may gain popularity as urogynecology advances to more minimal access methods.

#### **3. Discussion**

The vNOTES approach is emerging as a feasible alternative approach to a number of gynaecological operations. This is

particularly the case with vNOTES hysterectomy.

Hysterectomy remains the most commonly performed gynaecological procedure undertaken worldwide<sup>9</sup>. However, debate still exists between superiority of the differing routes of access. A 2015 Cochrane review suggested that VH has shorter operating time, lower overall costs and better patient satisfaction when compared with laparoscopically assisted vaginal hysterectomy (LAVH)<sup>11</sup>. No difference was found to exist between VH and LH when looking at return to normal activity or operative complications such as urinary tract damage<sup>11</sup>.

The authors conclude that VH should be the first line approach to hysterectomy for women with benign gynecological conditions. However, VH operative rates are declining annually and LH rates are rising<sup>11,29</sup>. The reasons for this is multifactorial but gynecologists cite factors such as nulliparity, narrow introitus, lack of uterine descent, need for adnexectomy, previous pelvic surgery, or large uteri as reasons why vaginal surgery is not the preferred method<sup>19</sup>.

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<sup>18</sup>. 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. NOTES surgery may therefore bridge this gap offering the advantages of vaginal surgery with the benefit of better visualisation and the use of vessel sealing devices as used in laparoscopic surgery.

As compared to traditional minimal access surgery, 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.

vNOTES also typically only needs one assistant who is seated next to the primary surgeon whilst the patient is in lithotomy. This is ergonomically beneficial over LH and AH for both operators as well as economically advantageous over LH which requires a second assistant for uterine manipulation.

In Western practice, operating on women of raised BMI is commonplace. Whilst pharmacological methods are first line measures for the treatment of these conditions, surgeons are increasingly citing the difficulties of laparoscopic surgery in obese patients<sup>30</sup>. These difficulties include

anesthetic factors such as patient intolerance of deep Trendelenburg or higher operating pressures. Port site injuries such as incisional hernias, bowel injury and vascular injury are also more common in obese patients often secondary to displacement of the umbilicus secondary to pannus<sup>30</sup>. vNOTES surgery carries no possibility of port site injuries and can be beneficial for those who are deemed higher risk anesthetically as it requires low pressures and minimal Trendelenburg. Colpotomy has the potential to cause injury to the urinary tract but this has not been documented widely in the literature.

Results from the authors and from the existing literature looking at VNOTES show that there is a procedural learning curve encountered when adopting this approach. Time taken for operation and estimated blood loss both decreased with increasing number of procedures performed<sup>13</sup>. Encouragingly, operating times do not increase particularly in patients of higher BMI, nor does the surgery appear to be particularly more challenging with bowel easier to retract in a shallow Trendelenburg than in laparoscopy.

In the authors experience and commonplace amongst the literature vNOTES does appear to have some limitations. The first, most crucial step in the procedure is access to the pelvic cavity without damage to the surrounding viscera. Just as in vaginal surgery, this can be complicated in cases of previous recto-vaginal surgery, recto-vaginal endometriosis or in patients that

have had multiple caesareans<sup>13</sup>. Such cases may be complicated by dense scar tissue or adhesions making access to the pouch of Douglas and uterovesical fold difficult with an increased risk of bladder injury. Thorough pre-operative workup and patient imaging will highlight the majority of patients in whom access may be difficult. Adhesions from midline laparotomy or previous laparoscopy do not limit the use of vNOTES.

Another potentially limiting factor for the surgeon looking to add this approach to their surgical armoury is the acquisition of new equipment to facilitate vNOTES. The authors have experience of the Gelpoint™ device which was purchased equitably for use within the setting of an NHS hospital. Multiple other devices have been used to achieve the same effect. Using the Gelpoint™ device in a systematic review comparing LH and NOTES hysterectomy Baeklandt demonstrated that the hospital charges for treatment by NOTES were higher compared to LAVH with a mean difference of 137.00 € (95% CI 88.95–185.05 €; 294 women; 1 study)<sup>17</sup>. For low resource settings a NOTES approach has also been demonstrated with the use of a self-constructed single-port device. This was made assembling a surgical glove, a wound protector or modified laryngeal mask airway, 1 reusable 10-mm trocar, and 4 reusable 5-mm trocars to create a pneumovagina following the same steps of a vaginal hysterectomy with standard reusable endoscopic instruments<sup>31</sup>. The authors demonstrated feasibility of

vNOTES procedures even in low resource settings.

#### **4. Conclusions**

NOTES surgery is a highly promising area of emerging technology within gynecological surgery. The number of gynecological NOTES operations documented in the literature is still under 1000 patients and when compared to traditional methods which have large scale grade 1 evidence, it is difficult to make a case for the superiority of NOTES. Further randomized trials, larger patient series and long-term outcome data will be required to

truly compare the efficacy of gynaecological NOTES.

However, early studies demonstrate that once a surgeon becomes familiar with vNOTES as an approach, it has great utility for a wide range of procedures and may be considered as an alternative option particularly in obese women or those who are likely to need to the removal of a large specimen. Whilst surgeons will inevitably find ways to adapt common practices to the more technically challenging patient, vNOTES may offer a feasible and efficient approach particularly with regards to hysterectomy and concurrent adenectomy.



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