Total Vaginal NOTES Hysterectomy (TVNH): A new approach to hysterectomy via Natural Orifice Transluminal Endoscopic Surgery

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Total Vaginal NOTES Hysterectomy (TVNH):

A new approach to hysterectomy via Natural Orifice Transluminal Endoscopic Surgery

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Transvaginal - NOTES - hysterectomy - frugal innovation - standard reusable instruments - low cost single port device - TVNH - VANH - VAMIS - vNOTES
Abstract

The aim of this study was to demonstrate the feasibility of a total hysterectomy performed entirely by transvaginal natural orifice transluminal endoscopic surgery (vNOTES). Conventional, reusable laparoscopic instruments were used, inserted through an inexpensive, self-constructed single port device.

Ten Total Vaginal NOTES Hysterectomies (TVNH) were performed by a single surgeon (BJ). The self-constructed single port device was made by assembling a surgical glove, a wound protector or modified laryngeal mask airway, one reusable 10 mm trocar, and four reusable 5 mm trocars. This gloveport was inserted into the vagina to create a pneumovagina. The conventional steps of a vaginal hysterectomy were followed, but performed endoscopically with standard reusable endoscopic instruments. Patient and perioperative data were analysed.

No conversion to standard laparoscopy or laparotomy was necessary in any of the ten patients who underwent a TVNH. Mean operation time was 97 min (60-120 min); mean drop in haemoglobin level was 1.5 g/dl (0.5-2.4 g/dl). There were no operative complications, and post-operative pain scores were very low.

This first report on a small number of patients demonstrates that TVNH is possible. Incorporating the advantages of endoscopic surgery it broadens the indications for vaginal hysterectomy and helps overcome its limitations. Simultaneously the NOTES approach avoids abdominal wall wounds and trocar related complications. TVNH is feasible, even when performed with reusable, conventional laparoscopic instruments. This frugally innovative technique also enables surgeons to perform hysterectomies by vNOTES in low resource settings.

Introduction

Aiming to reduce surgical morbidity, the evolution from laparotomy to laparoscopy has now broadened to include even less invasive techniques, such as single incision laparoscopic surgery (SILS), and natural orifice transluminal endoscopy (NOTES). Minimally invasive surgery not only improves cosmetic outcome, but also reduces surgical injury. This in turn decreases the inflammatory and neuroendocrine response resulting in less post-operative pain and quicker recovery (1, 2).
NOTES reaches the abdominal cavity by scar-free means, i.e. numerous surgical procedures are performed via a natural body orifice. This technique has gained popularity amongst general surgeons, gynaecologists, urologists and gastroenterologists over the past few years and its feasibility and safety have been approved (3).

NOTES can be performed via a variety of approaches including stomach, oesophagus, bladder, and rectum, but the majority of NOTES procedures have been performed transvaginally (4). The vagina can be easily decontaminated and provides direct access. Culdotomy has been used widely for several surgical procedures (not only by gynaecologists but also by general surgeons for extraction of large specimens) and it has been approved as safe and easy to close (5).

In hybrid NOTES the surgical procedure is performed through a natural body orifice with transabdominal assistance. The term pure NOTES refers to procedures that involve only transluminal access.

Given its potential benefits, including scarless intervention, fewer port-related complications, and less painful and faster post-operative recovery, transvaginal pure NOTES (vNOTES) for benign adnexal masses was introduced into our surgical practice in November 2013. After one year experience with vNOTES for adnexal surgery, the feasibility of performing a total hysterectomy entirely via vNOTES was assessed. Hysterectomy via NOTES, after performing an anterior and posterior colpotomy and transecting the sacro-uterine ligaments via classical open vaginal surgery, has been described (6,7). We refer to this technique as vaginally assisted NOTES hysterectomy (VANH) as the first part of this procedure is performed by conventional vaginal surgery. Despite experience in vaginal surgery (BJ is gynaecological oncological surgeon, experienced in Schauta surgery (8,9)), it is suggested that, for most gynaecological surgeons, it can be challenging to perform an anterior and posterior colpotomy, and transect the sacro-uterine ligaments (as required for VANH) in patients without any uterine prolapse or in patients with a narrow vagina (7). In addition, the complication rate for vaginal hysterectomy is higher in nulliparous women than in parous women (10). We therefore wanted to evaluate the feasibility of performing a total vaginal NOTES hysterectomy (TVNH), where the entire procedure is performed via vNOTES using endoscopic instruments. Our initial clinical experience with TVNH is described here. A full Poor Man’s NOTES approach was used (11). The feasibility and surgical outcome of TVNH when performed with only conventional, reusable laparoscopic instruments, and an inexpensive, self-constructed single port device that can be quickly and easily assembled, was evaluated. We aimed to demonstrate the possibility of performing a TVNH and that it is not necessary to use expensive, commercially available disposable SILS-ports, other disposable instruments, or sealing devices, to perform a total hysterectomy completely by vNOTES.
Materials and methods

Patients

A single surgeon (BJ) performed 10 TVNH’s to evaluate the feasibility of the technique. To assess if a pneumovagina could be maintained in parous and nulliparous women, 5 patients who had not delivered vaginally and 5 patients who had delivered vaginally were selected. All patients were selected for hysterectomy due to benign gynaecological disease. Patients were selected based on the following criteria: no contraindication for general anaesthesia, pneumoperitoneum or Trendelenburg position; no fixed uterus, strong pelvic adhesions or nodularity in the Pouch of Douglas on clinical examination; no history of pelvic inflammatory disease; no suspicion for malignancy. Obesity (BMI > 30) was not considered to be an exclusion criteria.

The following patient and perioperative data were collected and retrospectively analysed: patient age, body mass index (BMI), parity, history of vaginal delivery, previous pelvic surgery, type of surgery, total operating time, serum hemoglobin (Hb) drop (change between the preoperative Hb and postoperative Hb one day after surgery), peri-operative complications, and postoperative pain score.

The duration of surgery was defined as the time from the placement of the Foley catheter to the end of vaginal closure. Bowel, bladder, ureteral or vascular injuries, as well as blood loss > 300 ml were considered as intraoperative complications. Short-term postoperative complications were identified to be urinary tract infection, postoperative ileus, vaginal vault bleeding or infection, or hematuria.

Postoperative pain was assessed using the visual analogue pain scale (VAS) (scoring from 0 = no pain, to 10 = worst imaginable pain). The VAS score was evaluated at 6 and 24 hours postoperatively. All patients received the same intraoperative analgesia: intravenous paracetamol 1000 mg and ketorolac trometamol 20 mg.

Postoperative pain was managed by paracetamol 1000 mg and ketorolac trometamol was administered on patient’s demand.

Prophylactic intravenous antibiotic therapy, cefazoline 2 g and metronidazol 500 mg, was administrated during surgery.

No vaginal intercourse was allowed for 6 weeks after the procedure. Each patient was re-assessed at the post-operative consultation 6 weeks after surgery.

Surgical technique

The patient was placed in lithotomy position under general anaesthesia. A rectovaginal examination was performed to exclude pelvic adhesions or obliteration of the Pouch of Douglas.
Construction of the low cost NOTES port:

For the five patients who had not delivered vaginally, an Alexis Wound Protector/Retractor (Applied Medical, Rancho Santa Margarita, CA, USA) attached to a size 8 surgical glove was used. One finger of the surgical glove was incised to place a 10 mm reusable trocar for CO2 insufflation and laparoscope insertion. Four 5 mm reusable trocars were placed through the remaining fingers for insertion of the reusable laparoscopic instruments (Figure 1). In nulliparous women the ring of the wound protector holds the gloveport in the vagina during the procedure. CO2 insufflation at 15mmHg does not dislodge the port.

For the five patients who had delivered vaginally, the same glove construction was used, but it was attached to an opened size 5 laryngeal mask airway (LMA) instead of a wound protector. The central part of the LMA was excised, leaving only the outer rim and inflatable cushion. The wrist side of the glove (with trocars in the fingers) was passed through the opening of the LMA and folded around the cushion part of the LMA (Figure 2). After inserting the LMA into the vagina, the cushion part was inflated and an orthostatic wound protector was placed in the LMA to hold it in place in the vagina. Tightening the orthostatic wound protector fixes the LMA in the caudal part of the vagina and prevents the CO2 insufflation from pushing the vaginal port out of the vagina.

Endoscopic equipment:

We used a standard rigid zero-degree 10 mm laparoscope. Only reusable conventional laparoscopic instruments were used: a bipolar forceps, a pair of cold scissors, a grasping forceps (Manhes), a monopolar hook, and a suction-irrigation cannula. No disposable instruments or sealing devices were used.

Procedure description (Video 1)

The operation field was disinfected and draped. A Foley catheter was placed and the self-constructed NOTES port was placed into the vagina. CO2 was insufflated at 15 mmHg to maintain an adequate pneumovagina.

With traction placed on the uterine cervix using the Manhes forceps the cervix was circumcised using the monopolar hook. At the anterior fornix the vaginal mucosa and the bladder were pushed up along the uterine-cervical fascia using a small swab in the atraumatic grasper, while maintaining traction on the cervix using the Manhes forceps. Once the peritoneum between the bladder and the uterus could be identified, it was opened using cold scissors. The same technique was used in the posterior fornix until the peritoneum of the Pouch of Douglas could be visualised and opened.
Once the anterior and posterior peritoneum were opened, both sacro-uterine ligaments were coagulated using the bipolar forceps and subsequently transected using the cold scissors. After identification of both ureters, this procedure was repeated, caudally to cranially, for the remainder of the parametrium, the uterine arteries and the ovarian ligament, and Fallopian tube. In patients where a bilateral adnexectomy was performed, the infundibulopelvic ligament was transected instead of the ovarian ligament and Fallopian tube. One patient had an 8 cm ovarian cyst. In this case the infundibulopelvic ligament was transected after having first transected the ovarian ligament and Fallopian tube to place the free uterus in the upper abdomen, thus allowing space to perform the adnexectomy.

In patients with a small uterus, the entire procedure was performed with the NOTES port in the vaginal introitus. In patients with a larger uterus, the NOTES port was moved up from the introitus into the Pouch of Douglas after transecting the sacro-uterine ligaments. This significantly improved visualisation.

After haemostasis and rinsing of the peritoneal cavity, the pneumoperitoneum was deflated and the port device was removed. The uterus (and adnexae) were extracted and the colpotomy was closed using a Vicryl-1 (Ethicon, Piscataway, NJ, USA) suture.

**Results**

Ten TVNH’s were successfully performed by Poor Man’s tNOTES using conventional, reusable laparoscopic instruments. No conversion to standard multi incision laparoscopy or laparotomy was necessary. In four patients one or both adnexae were also removed; one of them had an 8 cm mucinous cystadenoma.

Table 1 presents an overview of patient and perioperative data. Individual patient details are presented in Table 2. Mean operation time was 97 minutes. Five patients had had previous pelvic surgery. There were no intraoperative complications. One patient had a postoperative cystitis for which oral antibiotic therapy was administered; and one patient had a small vault haematoma that was managed conservatively under antibiotic cover. The mean drop in hemoglobin level was 1.5 g/dl. Most patients scored a low postoperative pain score (range 1-2) 24 hours after surgery. All uteri were benign upon pathological examination (specimen weight 51-353g).

As these were the first 10 patients to be operated by a new surgical technique, we requested all patients to remain hospitalised for 72 hours for comprehensive follow up. Each patient was examined six weeks after surgery. There was no vaginal wound infection nor dehiscence, and none of the patients complained of pain during pelvic examination. All patients were in good health and were back at work.
Discussion

In this feasibility study, TVNH for benign uteri was successfully performed in ten patients, using only conventional, reusable laparoscopic instruments and a self-constructed NOTES port. The procedures were completed within a reasonable operation time and without major complications, no conversion to laparotomy or standard laparoscopy was necessary. We demonstrated that this technique can be used in parous and nulliparous women, provided that a different port is constructed to maintain a pneumovagina.

To the best of our knowledge this is the first report of TVNH being successfully performed on patients. A PubMed search revealed that a cadaveric model for hysterectomy by Vaginal Access Minimally Invasive Surgery (VAMIS) has recently been presented (12). The major difference between TVNH and a VANH lies in the opening of the anterior and posterior peritoneum and the transsection of the sacro-uterine ligaments. This is performed entirely endoscopically in the TVNH, whereas it is performed by classical vaginal surgery in a VANH (Table 3). The TVNH technique can therefore also be used in nulliparous patients, patients without uterine prolapse, and patients with a narrow vagina where classical vaginal surgery can be more challenging (7,10).

An inexpensive, self-constructed single port device, that can be quickly and easily made, was used. By combining this self-constructed port device with easily available, conventional, and reusable laparoscopic instruments, this study shows that the TVNH technique is feasible without increasing the cost of laparoscopic surgery. This frugally innovative technique can thus potentially be performed in a low resource setting. Poor Man’s vNOTES has previously been described as an approach for adhaesiolysis (11).

A self-constructed port using a surgical glove has advantages when compared to commercial ports. It is less costly, it has flexible material that enables greater manipulation of instruments, and a greater number and size of instruments can be passed through the incision. Multiple instruments can therefore be left in place in the trocars limiting the number of instrument changes and port transfers. In our experience constructing a Poor Man’s NOTES port takes approximately 3 minutes for a gloveport with wound protector and approximately 5 minutes for a gloveport with LMA. It is constructed by the first assistant while the surgeon disinfects and drapes the patient and therefore does not add to the total operation room time.

Conventional transvaginal surgery has the advantage of the absence of abdominal scarring and is the preferential approach to hysterectomy (13). By performing vNOTES, the technical drawbacks of transvaginal surgery,
including limited visualisation to attempt good hemostasis and difficulty in performing adnexectomy in case of adhesions between the adnexa and the uterus, can be overcome. Additionally, vNOTES eliminates the risk of trocar related complications and induces less post-operative pain (14). It has been demonstrated that very large uteri can be removed via VANH, and that ligating the uterine vessels transvaginally before dissecting the rest of the uterus, results in less blood loss compared to a transabdominal laparoscopic approach where there is more manipulation before occlusion of the feeding vessels (6,7). This still needs to be demonstrated in further studies for TVNH but as the second part of the procedure is identical to VANH, the same advantage can be expected. TVNH also enables the removal of uteri when the cervix is less accessible for classical vaginal surgery or VANH.

To perform vNOTES various technical difficulties, comparable to those for transumbilical SILS, need to be overcome. The surgeon has to deal with problems due to instrument collision, limited triangulation, and reduced traction of tissue (15, 16). Due to the vagina providing a more flexible entry point compared to the infraumbilical fascia opening, these difficulties were found to be less restricting when compared with SILS. Further advances in optics, instruments and robotic surgery will help overcome these technical challenges, enabling more surgeons to perform more hysterectomies via transvaginal access.

One could argue the possibility of pelvic infection after vaginal surgery, however none of our patients presented with this complication after the TVNH procedure. Previous studies have also shown that post-operative pelvic infection is unlikely to happen particularly when prophylactic antibiotics are administered (7, 17). As the vaginal vault is closed in the same way as in a classical vaginal hysterectomy, no differences in incidence of dyspareunia are to be expected. As was the case for our study protocol, sexual abstinence should be recommended for six to eight weeks, as is the recommendation for conventional transvaginal surgery (7).

The same contra-indications should be considered before performing TVNH as before performing vNOTES. In patients with a massive hemoperitoneum the endoscopic view will get disturbed (18). If Pouch of Douglas adhesions can be expected, a thorough pelvic examination should be performed prior to surgery, and in case of unexpected Pouch of Douglas obliteration, conversion to transabdominal laparoscopy should be considered. Virginity is another contra-indication for vNOTES. Nulliparity or absence of history of vaginal delivery are not contra-indications to perform vNOTES.
As previously mentioned by Lee et al (19), the major limitation of vNOTES is the inability to overview the pelvic area, in particular the vesico-uterine pouch, and thus lesions such as bladder endometriosis or anterior uterine wall myomas can be missed. Innovation of endoscopes is desirable to overcome this limitation and have the ability to explore the entire abdominal cavity.

Further concern is the possibility of performing TVNH after a previous vNOTES procedure. To date, only one group of surgeons has reported on repeated vNOTES, performed in two patients 6 and 8 months after previous vNOTES (19).

Conclusion

In this study, TVNH for benign uteri was successfully and safely completed in appropriately selected parous and nulliparous patients. We showed this frugally innovative technique to be feasible with only standard reusable laparoscopic instruments and a low cost, self-constructed single port device. This technique may potentially be applied in a low resource setting. Although this is only a feasibility study on a small number of patients, it is the first report to demonstrate that TVNH is possible.

According to the Cochrane Database the preferred technique to perform a hysterectomy is via conventional vaginal surgery. When a vaginal hysterectomy is not possible, a laparoscopic hysterectomy may avoid the need for an abdominal hysterectomy (13). Vaginal hysterectomy can be safely performed for large uteri (20) and in nulliparous women (10). The risk of complications however is higher in nulliparous women (10). The accessibility of the vaginal passage, disease confined to the uterus, and the surgeons experience are the major determining factors for the choice of route of hysterectomies (21). Over the last years, the incidence of robotic hysterectomy and laparoscopic hysterectomy has increased and the incidence of vaginal and abdominal hysterectomy has decreased (22). Conventional vaginal hysterectomy can be challenging in cases of enlarged uterus, undescensens, or because of restricted vaginal space in women who have never delivered (7). Making use of the advantages of endoscopic surgery TVNH broadens the indications for vaginal hysterectomy and helps overcome its limitations, while the NOTES approach avoids abdominal wall wounds and trocar related complications.

When compared to classical vaginal hysterectomy, NOTES hysterectomy offers good endoscopic visibility to operate and perform haemostasis. Using the enlarged endoscopic view, the surgeon can operate accurately using endoscopic instruments, whereas in some conditions in conventional vaginal hysterectomy, certain steps can
only be achieved by palpation (7). In addition, adnexal procedures in conventional vaginal surgery can be
difficult due to limited accessibility in the restricted space (7). Salpingectomy, oophorectomy, ovarian
cystectomy or adhaesiolysis can be performed via the same NOTES approach after a TVNH (11,18). Due to the
pneumovagina, TVNH is not more difficult in nulliparous than in parous women, whereas a narrow vaginal
access can make a classical vaginal hysterectomy more challenging (7,10,21).

When compared to laparoscopic hysterectomy, TVNH offers the advantage of no visible scars. In addition, in
patients with previous abdominal surgery (e.g. patient 8), there is no need to perform adhaesiolysis to gain access
to the pelvis in order to perform the hysterectomy via TVNH approach, contrary to a laparoscopic approach.

NOTES hysterectomy (TVNH and VANH) can provide surgeons the comfort of operating under good
endoscopic vision but via vaginal access without increasing the invasiveness of the procedure by making
abdominal incisions.

When compared to robotic hysterectomy, TVNH offers the same advantages as mentioned in the comparison
with laparoscopic hysterectomy. In addition, the cost of a robotic hysterectomy is higher than a Poor Man’s
NOTES TVNH. Further developments in robotic equipment in the future could be helpful to improve the
ergonomics of NOTES surgery.

Failure of VANH is almost always due to impedance of the transvaginal colpotomy (7). When compared to
VANH, TVNH enables the surgeon to perform the colpotomy endoscopically instead of via classical vaginal
surgery. This provides better visualisation and, as in laparoscopic surgery, the CO2 pressure helps identify and
dissect the surgical planes. This enabled us to easily perform the anterior and posterior colpotomy in patients
who had not delivered vaginally and in patients with previous caesarean sections.

Less post-operative pain and a quicker recovery are also potential advantages of vNOTES. The major limitation
of vNOTES with the currently available instruments and endoscopes appears to be the inability to explore the
vesico-uterine pouch. Innovations in instruments and endoscopes will help overcome this limitation.

A surgeon who wants to perform TVNH should be confident in both classical vaginal hysterectomy and total
laparoscopic hysterectomy (TLH). Being experienced in single incision laparoscopic surgery TLH and vNOTES
for adnexal surgery certainly helps to keep the learning curve short. In our experience introduction of NOTES
into the hysterectomy armamentarium did not influence the percentage of hysterectomies performed by classical
vaginal hysterectomy, but reduced the percentage of TLH in favour of the less invasive NOTES approach.

TVNH is a novel approach that requires further validation.
Acknowledgment

None.

Conflict of interest

Jan Baekelandt declares that he has no conflict of interest.

Contributions

Jan Baekelandt recruited and operated all the patients. He collected the data, performed the literature review, wrote and submitted the article, and made the video.
References


Figure legends

Figure 1 Low cost self-constructed single port device for TVNH, used in nulliparous women.

Figure 2 Low cost self-constructed single port device for TVNH, used in parous women.
Table 1 Overview of patient and perioperative characteristics

<table>
<thead>
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<th>Data</th>
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<th>Range</th>
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<td>19.7 – 33.3</td>
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<td>Total operating time (min)</td>
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<td>60 - 120</td>
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<tr>
<td>Serum hemoglobin drop (g/dl)</td>
<td>1.5</td>
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<tr>
<td>Postoperative pain score</td>
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<td></td>
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<td>6h</td>
<td>2.5</td>
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<td>24h</td>
<td>1.7</td>
<td>1 – 2</td>
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Table 2 Patient and perioperative data

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<th>Patient no.</th>
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<th>Serum hemo-globine drop (g/dl)</th>
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<td>9</td>
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AE = appendectomy; EUG = laparoscopic salpingectomy for ectopic pregnancy; CS = caesarean section; LLETZ = large loop excision of transformation zone; LS = laparoscopic sterilisation; endometriosis = laparoscopy for pelvic endometriosis; adhesiolysis = laparoscopy for adhesiolysis; USO = unilateral salpingo-oophorectomy; TVNH= total vaginal NOTES hysterectomy; BSO= bilateral salpingo-oophorectomy; LMA= self-constructed NOTES port using laryngeal mask airway; PMB = persistent postmenopausal bleeding
**Table 3 Types of Hysterectomy**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Name</th>
<th>Description</th>
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<tr>
<td>VH</td>
<td>Vaginal Hysterectomy</td>
<td>Total hysterectomy performed entirely through vaginal access under direct vision using conventional surgical instruments</td>
</tr>
<tr>
<td>LAVH</td>
<td>Laparoscopic Assisted Vaginal Hysterectomy</td>
<td>Total hysterectomy where first the cranial part of the uterus is dissected via transabdominal laparoscopy and afterwards the caudal part of the uterus is dissected under direct vision using conventional instruments.</td>
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<tr>
<td>TLH</td>
<td>Total Laparoscopic Hysterectomy</td>
<td>Total hysterectomy where the entire uterus is dissected via transabdominal laparoscopy</td>
</tr>
<tr>
<td>VANH</td>
<td>Vaginally Assisted NOTES Hysterectomy</td>
<td>Total hysterectomy where first the caudal part of the uterus is dissected vaginally under direct vision and afterwards the rest of the hysterectomy is performed via transvaginal NOTES using an endoscopic camera and endoscopic instruments</td>
</tr>
<tr>
<td>TVNH</td>
<td>Total Vaginal NOTES Hysterectomy</td>
<td>Total hysterectomy where the entire uterus is dissected via transvaginal NOTES using an endoscopic camera and endoscopic instruments</td>
</tr>
</tbody>
</table>
This feasibility study reports on the first 10 cases of Total Vaginal NOTES Hysterectomy.