UNIVERSITÉ DE LILLE

FACULTÉ DE MÉDECINE HENRI WAREMBOURG

Année : 2024

THÈSE POUR LE DIPLÔME D'ÉTAT

DE DOCTEUR EN MÉDECINE

Succès de l'hystérectomie en ambulatoire : V-NOTES vs Voie vaginale

Présentée et soutenue publiquement le 11/10/2024 à 14h00
au Pôle Formation
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Abstract

Study objective: Vaginal hysterectomy (VH) is the approach of choice of hysterectomy for benign uterine conditions and is suitable for an outpatient procedure. Many studies suggest that the vaginal natural orifice transluminal endoscopic surgery (V-NOTES) technique is reliable and safe for outpatient surgery, but the literature only includes pilot studies with small cohorts. The aim of this study is to assess the V-NOTES technique compared to VH in outpatient settings with a larger cohort.

Design: Retrospective cohort study.

Setting: French teaching hospital

Patients: The study included all patients who underwent hysterectomy planned as outpatient procedure, using either the V-NOTES or VH approach, between 2016 and 2022.

Interventions: Baseline characteristics and surgical outcomes were compared. The primary outcome assessed was the success of outpatient surgery. Secondary endpoints were intraoperative and postoperative complication rates, as well as the incidence of factors that could limit the feasibility of outpatient procedure.

Measurements and main results: 373 patients were included, with 204 in the V-NOTES group and 169 in the VH group. In the V-NOTES group there were more nulliparous women (27.9% vs 14.8%, $p < 0.002$), more women with a large uterus (>280g) (30.8% vs 12.9%, $p < 0.001$) and more salpingectomy performed during the procedure (98% vs 79.9%, $p < 0.001$), compared with the VH group. The outpatient success rate did not differ significantly between the two groups (83.3% vs 79.9%, $p = 0.39$, adjusted $p = 0.50$). There were no differences between the two techniques regarding intraoperative and postoperative complications, as well as the occurrence of other factors that could limit the feasibility of outpatient procedure.

Conclusion: V-NOTES hysterectomy is a safe outpatient procedure showing no significant differences compared to VH, even if the patients had a larger uterus and were more often nulliparous. Moreover, the V-NOTES approach appears promising for hysterectomies in women who are nulliparous or have large uteri.

Introduction

Hysterectomy is the most common gynecological procedure, with 60,000 performed in France in 2019, including 85% for benign conditions (1). According to the latest scientific opinions from the International Society for Gynecologic Endoscopy (ISGE) and Cochrane, vaginal hysterectomy (VH) is the recommended approach for benign conditions (2), due to better surgical outcomes and lower postoperative complication rates compared to other approaches (3,4). Outpatient procedures are increasingly promoted to improve cost and bed management in France and can enhance patient satisfaction (5,6). VH is recognized in literature as reliable and safe for daycare surgery in selected patients (7,8). However, standard vaginal approach can be challenging with large or non-prolapsed uteri, difficult vessel control, and narrow access, especially in nulliparous patients. These issues lead operators to prefer laparoscopic approaches over the recommended vaginal approach.

Recently, new enthusiasm for the vaginal Natural Transluminal Endoscopic Surgery (V-NOTES) technique has gained interest. Unlike the standard vaginal approach, the V-NOTES technique allows total surgical exploration of the abdominal cavity, continuous visual control of adjacent organs, better access to the adnexa and better control of hemostasis (9). Moreover, a V-NOTES hysterectomy permits a reduction of post-surgery analgesic use and avoids visual scarring compared to abdominal laparoscopy, which are important patient considerations (10). These benefits may support outpatient management (6).

Nevertheless, studies comparing V-NOTES with standard approaches in outpatient contexts rely pilot studies with small cohorts (9).

The main objective was to assess the success of outpatient vaginal procedures by comparing V-NOTES hysterectomies and VH in a larger cohort.

Materials and methods

1. Ethics

The study protocol was approved by the national ethics committee (CEROG 2023-GYN-0607) and conformed to French ethical standards and the 2008 Declaration of Helsinki.

2. Study design and population

This was a retrospective cohort of patients that underwent a hysterectomy for benign conditions (such as menorrhagia, symptomatic fibroids, essure removal…) with the V-NOTES or VH technique at Lille University Hospital (France) between 2016 and 2022. All these procedures were planned as daycare surgery. The surgical approach and the hospitalization length were left up to the surgeon's discretion, depending on their usual practices and the patients comorbidities, with the patient's agreement.

The exclusion criteria were surgery planned with at least one overnight stay or carcinological conditions (except for grade 1 endometrioid adenocarcinoma) or when hysterectomy was performed by abdominal laparotomy or abdominal laparoscopic approaches. Operators were skilled in vaginal surgery and were senior physicians, assistants and supervised residents. Before surgery, patients had a medical consultation in which the surgical procedure was explained and also the possibility of changing the surgical approach during the procedure if needed. They had a medical examination and imaging if required. The type of anesthesia was determined by the anesthesiologist with regards to the patient's comorbidities, both general or spinal aesthesia being suitable for the V-NOTES or VH technique.

We determined two groups depending on the surgical route used for hysterectomy : V-NOTES and the standard vaginal approach. For each group we gathered information about the patients such as age, body mass index (BMI) and medical history and information about surgical characteristics such as operative indication, salpingectomy or other operation at the same

surgical time, operative time, blood loss and uterine weight. Operative indications include benign conditions such as menorrhagia, symptomatic fibroids and Essure removal or for endometrial intraepithelial neoplasia and grade 1 endometrioid adenocarcinoma. As a preventive measure, bilateral salpingectomy was planned for every patient in the V-NOTES group (11). In the VH group, some surgeons planned salpingectomy pre operatively while some operators did not propose it systematically because of potential technical difficulties. The weight of 280g was chosen to characterize a large uterus (11). We collected information about post operative events including per and post operative complications, hospitalization length and other indications of surveillance that could lengthen the hospital stay.

3. Primary outcome

The primary endpoint was to assess and compare the success of outpatient management between the two techniques, which was defined as a hospital discharge the same day of the surgery.

4. Secondary outcome

The second endpoints were to compare these two approaches in terms of per and post operative complications as well as other indications of surveillance that can restrict the outpatient procedure. Postoperative complications were categorized into five groups according to the Clavien-Dindo classification (12).

5. Surgical procedure

VH was performed under general anesthesia, in lithotomy position. A prophylactic intravenous cephalosporin injection was done before the surgical procedure. A Foley catheter and a speculum were introduced to empty the bladder and expose the cervix. At the beginning of the procedure, we performed a paracervical injection of adrenaline xylocaine diluted to 50% to prepare the dissection planes and to reduce bleeding. In both groups, the surgeon had the choice

of using a bipolar vessel sealing system device or a conventional suture ligature, at their own discretion.

For the V-NOTES technique, similar steps took place at the beginning of the procedure except a gel point patch device (Applied) was inserted after the opening of the anterior and posterior colpotomy. An insufflation at 8 mmHg through the gel point patch was initiated to insert a 10 mm rigid laparoscopy and two standard rigid laparoscopic 5-mm graspers. This setup enabled us to explore the peritoneal cavity and the transection of the uterine vessels with the bipolar device, followed by the transection of the broad and round ligaments. The utero ovarian ligament, the mesosalpinx and the round ligament were coagulated and sectioned. If an salpingectomy was planned, the infundibulo pelvic ligaments were also coagulated and sectioned. After controlling hemostasis, the gel point patch device was removed and the vagina was sutured with stitches of Vicryl n°1 (13).

6. Statistics

Categorical variables were described by frequencies and percentages. Quantitative variables were expressed as mean and standard deviations in the case of Gaussian distribution, or as median (25th and 75th percentile) otherwise. Normality of distribution was checked graphically and using the Shapiro-Wilk test.

Patient and surgical characteristics were compared between the two surgical approaches by using Chi-square or Fisher exact test in the case of categorical variables; by using Student t test for Gaussian distribution, or Mann-Whitney U test otherwise, for quantitative variables.

The impact of the surgical technique on the success of outpatient management and other surgical outcomes was studied using logistic regression models. Only the success of outpatient management could have been adjusted for the clinical and surgical characteristics significantly different between to the group in univariate analyses. The number of events of other surgical

outcomes was too small to be adjusted. The odds ratios (OR) and their 95% confidence intervals were calculated as effect sizes.

Statistical analyses were performed using SAS software (SAS Institute version 9.4). Statistical testing was done at the two-tailed α level of 0.05.

Results

1. Study population

373 patients underwent an outpatient hysterectomy between 2016 and 2022, among them 204 with the V-NOTES technique (54.7%) and 169 with the VH technique (46.3%) (Figure 1).

There were no differences between the two groups concerning most of the baseline characteristics (Table 1). However, there were significantly more nulliparous women in the V-NOTES group compared to VH with a rate of 27.9% versus 14.8% (p <0.002), and the distribution of operative indications was significantly different between the two groups with more fibroid uterus in the V-NOTES group (36.3% vs 25.4%, p = 0.009) (See Table 1).

2. Surgical characteristics

There were no differences between the two groups for the rate of other associated gestures in the same surgical procedure and for the intraoperative bleedings. In contrast, there were significantly more salpingectomies in the V-NOTES group (200 patients of 204, 98%) than in the VH group (135 patients of 169, 79.9%) (p <0). There were also more large uteri ≥ 280g in the V-NOTES group (61 patients of 204, 30.8%) than in the VH group (20 patients of 169, 12.9%) (p < 0.001). The operative time was also longer in the V-NOTES group (72 minutes [54 ; 100] vs 63 minutes [51 ; 83], p = 0.016). Surgical characteristics are shown in Table 2.

3. Surgical outcomes

The success of outpatient management didn’t differ significantly between the two groups (83.3% in the V-NOTES group vs 79.9% in the VH group, OR [95%CI] : 1.26 [0.74 to 2.13], p = 0.39),

even after adjustment on nulliparity, operative indication, salpingectomy and uterus weight ≥ 280g (adjusted OR [95%CI] : 1.24 [0.66 to 2.34], adjusted p=0.50) (Table 3). In the V-NOTES group, 14.2% of patients stayed one day in hospital and 2.5% stayed two days or more, and in the VH group, 16.0% of patients stayed one day in hospital and 4.1% stayed two days or more.

The intraoperative complication rate (4.4% in the V-NOTES group vs 3.6% in the VH group, P= 0.67) and the postoperative complication rates (4.9% in the V-NOTES group vs 4.7% in the VH group, P=0.93) did not differ between the two groups (Table 3). Major intraoperative complications were laparoscopic conversions due to bleeding for both group or due to failure to open the Douglas pouch in the V-NOTES group. Postoperative complications were mainly cases requiring diuresis monitoring after Foley catheter removal and in the V-NOTES group, 4 cases of bleeding from the vaginal suture. All the complications depending on the surgical approach are listed in supplemental data 1.

Conversion to conventional hospitalization for surveillance (6.9% vs 4.1%, P=0.93), and other postoperative complications unrelated to the surgery (2% vs 3%, P=0.53) were not significantly different between the two groups. Those indications for surveillance and complications are also listed in supplemental data 1.

Discussion

The success of outpatient hysterectomy does not significantly differ between the V-NOTES technique and the standard vaginal approach. Similarly, there were no differences between the two groups for surgical outcomes or other factors that can restrict outpatient management. However, the V-NOTES technique enables us to perform hysterectomies in more nulliparous women and women with larger uteri, as well as to perform more salpingectomies during the same surgical procedure compared with VH.

These results reveal that the V-NOTES technique is not less efficient than the standard vaginal approach for outpatient management, with a slightly advantage for V-NOTES even if it was not significant (83% in the V-NOTES group vs 79% in the VH group) unless the uterine weight was significantly higher. These results confirm the findings of our pilot study with 50 patients, with outpatient management success greater than 75% (10). Currently, the most popular approach to hysterectomy in France is still the laparoscopic approach and it represented 30% of overall hysterectomies vs 15% for V-NOTES hysterectomy in 2019 (1). However, in the Baekelandt et al. study, the V-NOTES technique allowed more women to be treated in a day-care setting (77% in the V-NOTES group vs 43% in the laparoscopic group) because of its shorter length of hospital stay compared with laparoscopic hysterectomy (10). In the same study, several factors contributing to the successful management of outpatient care were highlighted for the V-NOTES approach, such as a reduction in operative time and decreased use of postoperative analgesics compared to the laparoscopic approach.

Insufflation of the abdomen is known to be less tolerated by patients with poor heart or lung function and could lead to post operative shoulder pain. Studies on laparoscopic cholecystectomy reported decreasing frequency and intensity of post operative shoulder tip pain, decreasing demand for postoperative analgesics and a lower hospital stay, with a 8mmHg pneumoperitoneum compared to a 14mmHg pneumoperitoneum (14). The V-NOTES technique

allows lower insufflation pressure than standard laparoscopic procedure (8mmHg for V-NOTES vs 12mmHg for laparoscopic procedure). This could be an argument for the outpatient management of the V-NOTES hysterectomy.

The V-NOTES technique can even be used for nulliparous or virginal women in many studies without increasing the operative time, the rate of conversion or the rate of complications (17,18). At the present time, fertility rates are declining in France and the rate of nulliparous women is increasing. The V-NOTES technique should be evaluated in comparison to other surgical approaches for this growing category of patients and appears to be highly promising in this context (19).

Having a large uterus leads to more technical challenges, and these large uteri were more prevalent in the V-NOTES group. Despite that difficulty, we obtained the same success rate in this group as in the VH group. Moreover, in cases of large uteri, the vaginal access provided by the V-NOTES technique allows direct access at the beginning of the procedure to coagulate the vessels, unlike in laparoscopy. This could result in a reduction of intraoperative bleeding. In the Kheirbek et al. study, in comparison to the laparoscopic hysterectomy for large uteri, the V-NOTES technique reduces the operative time, the length of hospital stay (0.5 day vs two day in the laparoscopic group, $p < 0.001$) and improves outpatient management (50% vs 3.7%, $p < 0.001$) without any differences in blood loss or conversion rate (20).

The operative time was slightly longer in the V-NOTES group than in the VH group by 8.5 minutes. This result corresponds to others studies such as the one from Drahonovsky et al. where the mean operative time for V-NOTES is 85 minutes compared to 66 minutes for the VH group (15). This difference could have many reasons. First of all, V-NOTES is a recent technique that needs to be learnt and practiced. The Mereu et al. study reported a fast learning curve in their operator’s team, with five cases required to reach competence and 25 to reach proficiency in a V-NOTES hysterectomy (16). Among the operators in our study, more and more new operators

have been performing V-NOTES hysterectomies over the years, such as assistants and residents (Supplemental data 2). We can assume that these new operators are still learning this technique and it could be a reason for the longer operative time in the V-NOTES group than in the VH group. Also, a V-NOTES hysterectomy includes an incompressible operative step that is the insertion of the gel point patch device. Nevertheless, this technique allows for more salpingectomies and the removal of larger uteri compared to VH, which could also explain the longer operative time. Finally, the operative time difference between the two groups is only about 8.5 minutes, that duration does not lead to any major clinical outcomes. This operative duration is still suitable for outpatient management and is still shorter than the standard laparoscopic operative time (111 minutes in the Drahonovsky et al. study (15)).

Major strengths of this study were its large cohort and the absence of special criteria for the selection of the patient that could benefit from outpatient management or the different approach for hysterectomy, which differentiates our series from other studies which promote hard selection for outpatient hospitalization (21)(22). The limitation was the retrospective nature of the study, with inherent confusion and selection bias. First of all, there is a selection bias in the allocation of patients to the groups. Indeed, the choice of surgical technique was left to the surgeon's discretion, and patient characteristics such as a large uterus or nulliparity may have influenced the surgeon's decision, particularly in favor of the V-NOTES group. The same bias exists for the performance of salpingectomy. We do not know if salpingectomy was planned in all procedures regardless of the hysterectomy technique. It is therefore impossible to assess the actual failure of this additional procedure based on the surgical approach.

Conclusion

Vaginal hysterectomy remains the gold standard technique for benign uterine conditions. However, the V-NOTES technique allows us to improve the management of nulliparous women, large uteri by performing more salpingectomies. This new technique allows us to overcome the limitations of the vaginal approach while retaining the advantages of the laparoscopic approach, and adds value to the management of a hysterectomy, especially with outpatient management.

At present, the laparoscopic approach is still the most frequently used technique for hysterectomy in France. Other studies comparing the laparoscopic and the V-NOTES approach with larger cohorts should be performed to assess which approach is the most effective, especially for specific patients such as nulliparous women or women with large uteri.

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Table 1. Patient characteristics

	V-NOTES Hysterectomy (n=204)	**Vaginal Hysterectomy (n=169)**	**P**
Age (years)	46.5 ± 7.4	46.5 ± 6.4	0.95
BMI, kg.m-2	26.4 ± 5.7	25.6 ± 5.2	0.16
Vaginal delivery			**<0.002**
0	57 (27.9)	25 (14.8)	
≥1	147 (72.1)	144 (85.2)	
Operative indication			**0.009**
Menorrhagia	69 (33.8)	74 (43.8)	
Symptomatic fibroids	74 (36.3)	43 (25.4)	
Essure removal	30 (14.7)	37 (21.9)	
Other	31 (15.2)	15 (8.9)	
History of C-section (1 or more)	24 (11.8)	21 (12.4)	0.85
History of conisation	13 (6.4)	19 (11.2)	0.095
History of pelvic surgery	28 (13.7)	27 (16)	0.54
History of vaginal prolapse correction	0 (0)	2 (1.2)	NA

BMI = Body Mass Index, NA=Not applicable
Values are expressed as mean ± standard deviation, or numbers (percentage)

Table 2. Surgery characteristics

	V-NOTES Hysterectomy (n=204)	**Vaginal Hysterectomy (n=169)**	**P**
Salpingectomy	200 (98)	135 (79.9)	**<0.001**
Uterus weight ≥ 280g	61 (30.8)	20 (12.9)	**<0.001**
Associated surgical gesture	21 (10.3)	13(7.7)	0.38
Operating time (min)	71.5 [53.5 ; 99.5]	63 [51.0 ; 82.5]	**0.016**
Bleeding rates (mL)	20.0 [20.0 ; 20.0]	20.0 [20.0 ; 20.0]	0.95

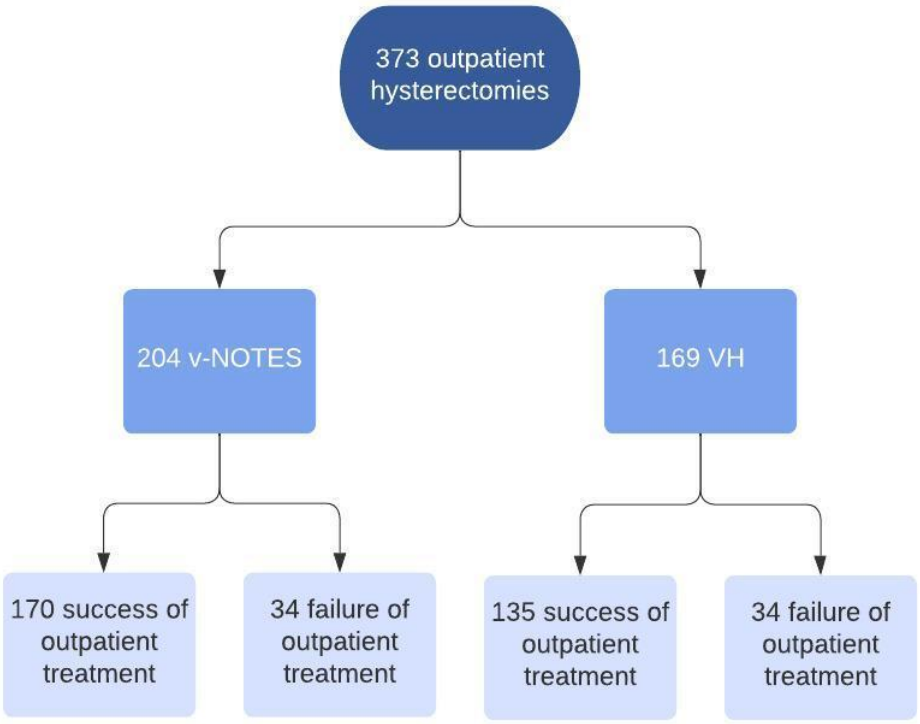
Values are expressed as median [range] or numbers (percentage)

Table 3. Surgery outcomes

	V-NOTES Hysterectomy (n=204)	Vaginal Hysterectomy (n=169)	OR [95%CI]	P	Adjusted OR [95%CI]	Adj. p
Outpatient surgery success	170 (83.3)	135 (79.9)	1.26 [0.74 to 2.13]	0.39	1.24 [0.66 to 2.34]	0.50
Peroperative complications	9 (4.4)	6 (3.6)	1.25 [0.44 to 3.60]	0.67	NA	NA
Postoperative complication	10 (4.9)	8 (4.7)	1.04 [0.40 to 2.69]	0.93	NA	NA
Indication for surveillance	14 (6.9)	7 (4.1)	1.71 [0.67 to 4.33]	0.26	NA	NA
Postoperative complication independent from the surgery	4 (2)	5 (3)	0.66 [0.17 to 2.48]	0.53	NA	NA

OR[95%CI] :Odds Ratio [95% Confidence Interval], Adj. p: p-value adjusted for nulliparity, operative indication, salpingectomy and uterus weight ≥ 280g; NA: Not Applicable
Values are expressed as numbers (percentage)

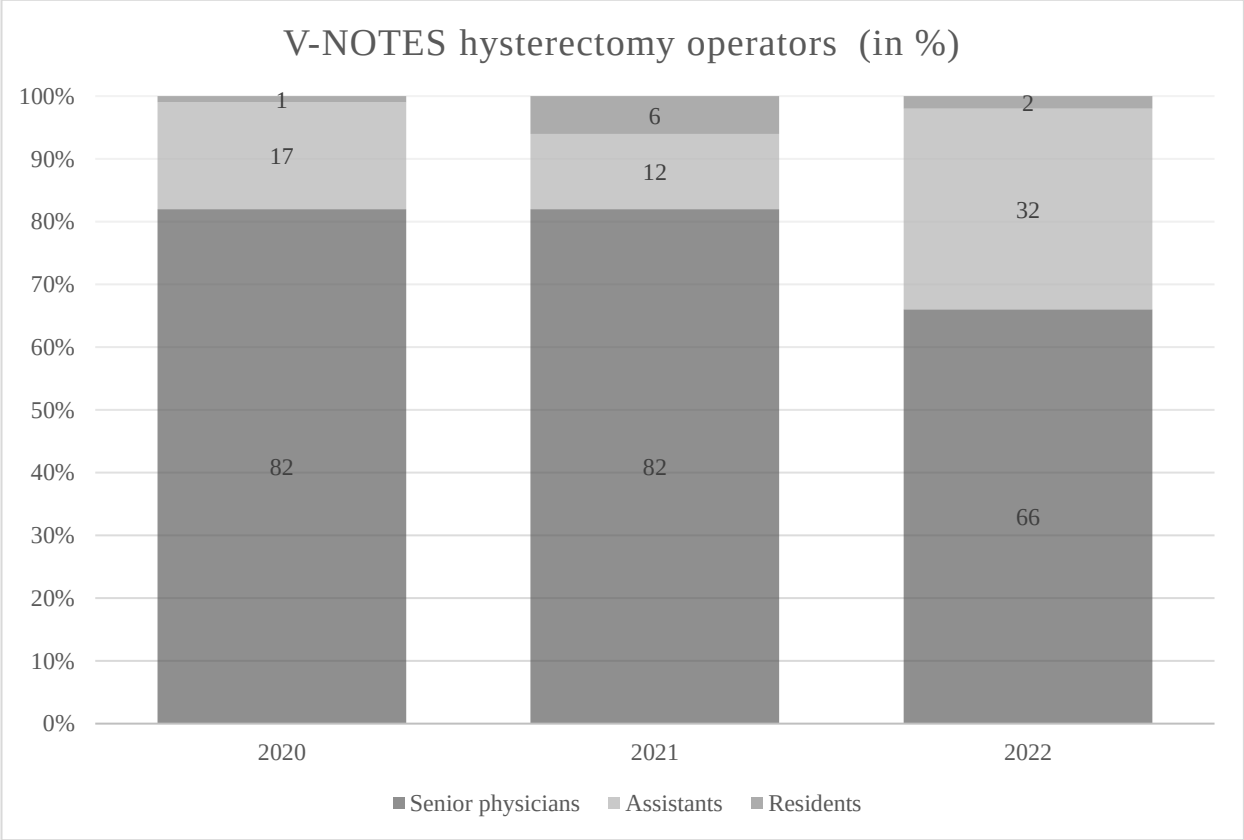
Figure 1. Flow Chart



Supplemental data 1. Details of complications

		V-NOTES Hysterectomy (n=204)	**Vaginal Hysterectomy (n=169)**
Intraoperative complications		- 6 laparoscopic conversions • 4 due to bleeding • 2 due to failure to open the Douglas pouch - 1 laparoconversion due to excessive abdominal adhesions - 2 organ injuries • 1 bladder injury • 1 rectal serosa injury	- 5 laparoscopic conversions • 4 due to bleeding • 1 due to suspicion of ovarian malignancy - 1 bladder injury
Postoperative complication according to the Clavien-Dindo classification	**Grade I**	- 3 cases requiring diuresis monitoring after Foley catheter removal	- 4 cases requiring diuresis monitoring after Foley catheter removal
	Grade II	- 1 pyelonephritis - 1 blood transfusion	- 1 urinary tract infection
	Grade III	- 4 cases of bleeding from the vaginal suture - 1 pelvic abscess	- 2 pelvic abscesses - 1 case of renal failure requiring a double J catheter placement
Indication for surveillance and Postoperative complication independent from the surgery		- 7 cases of postoperative pain - 5 cases requiring monitoring after major bleeding - 2 cases of discomfort with no medical cause found - 1 decompensated ketoacidosis in a diabetic patient - 1 oxygen therapy related to medical comorbidities - 1 drug reaction - 1 major anxiety	- 4 cases of postoperative pain - 2 cases requiring monitoring after major bleeding - 3 cases of discomfort with no medical etiology found - 1 stroke suspicion - 1 meningeal syndrome following spinal anesthesia - 1 hyperthermia with no medical etiology found

Supplemental data 2. Evolution of V-NOTES hysterectomy operators



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Date de soutenance : 11/10/2024

Titre de la thèse : Succès de l'hystérectomie en ambulatoire : V-NOTES vs Voie vaginale

Thèse - Médecine - Lille 2024

Cadre de classement : *Gynécologie chirurgicale*

DES + FST/option : *Gynécologie obstétrique*

Mots-clés : chirurgie endoscopique transluminal par orifice naturel transvaginal (V-NOTES) ; hystérectomie vaginale ; chirurgie ambulatoire ; résultats chirurgicaux

Résumé :

Introduction : La voie vaginale représente la voie d'abord de référence pour la réalisation d'une hystérectomie pour pathologie bénigne, de par ses meilleures suites opératoires et son faible taux de complications. Elle permet une prise en charge en ambulatoire, ce qui est un atout budgétaire majeur pour les hôpitaux avec une amélioration de la satisfaction des patientes. Cependant, elle présente certaines limites, notamment en cas d'utérus polyfibromateux et/ou non prolabés, avec un contrôle parfois délicat des artères utérines et des pédicules annexiels. La technique V-NOTES, qui est actuellement de plus en plus utilisée, permet de s'affranchir de ses limites tout conservant les avantages de la voie vaginale. Plusieurs études ont montré l'efficacité et la faisabilité de cette technique en ambulatoire. Cependant, la littérature rapporte uniquement des études pilotes de faible effectif concernant sa faisabilité en ambulatoire en comparaison au gold standard qu'est la voie vaginale classique.

Objectif : L'objectif principal était d'évaluer le succès d'une prise en charge en ambulatoire après une hystérectomie par voie V-NOTES, en comparaison à la voie vaginale.

Les objectifs secondaires concernaient le taux de complications per et post opératoire ainsi que les facteurs ayant limité une prise en charge en ambulatoire (douleurs, sensation de malaise, anxiété…), en fonction de la voie d'abord chirurgicale.

Matériel et méthode : Il s'agit d'une étude de cohorte rétrospective de patientes qui ont bénéficié d'une hystérectomie V-NOTES ou d'une hystérectomie par voie vaginale au CHU de Lille entre 2016 et 2022 pour pathologies bénignes. Toutes les patientes avaient une chirurgie initialement programmée en ambulatoire.

Résultats : Nous avons inclus 373 patientes dont 204 dans le groupe V-NOTES et 169 dans le groupe voie vaginale classique. Le taux de succès de l'ambulatoire n'était pas différent entre les 2 groupes : 83.3% pour le groupe V-NOTES et 79.9% pour le groupe hystérectomie vaginale classique ($p = 0.39$). Il n'y avait pas de différence en termes de taux de complications per et post opératoires et de facteurs limitants la prise en charge ambulatoire entre les deux groupes. Il a été retrouvé plus de patientes nullipares ($p < 0.002$), d'utérus volumineux défini par un poids supérieur à 280g ($p < 0.001$) et d'annexectomie dans le même temps opératoire ($p < 0.001$) dans le groupe V-NOTES en comparaison au groupe voie vaginale classique.

Conclusion : L'hystérectomie par voie V-NOTES apparaît comme une technique innovante dans le domaine de la chirurgie mini-invasive. Elle peut être réalisée en ambulatoire de manière sûre, sans différence avec la voie d'abord de référence. Elle permet par ailleurs de s'affranchir des limites de la voie vaginale classique avec un meilleur accès aux annexes. De plus, elle apparaît prometteuse chez les patientes nullipares ainsi que dans le cas d'utérus volumineux.

<u>Composition du Jury</u> :

Président : Monsieur le Professeur Michel COSSON

Assesseurs :
Madame le Docteur Sophie Delplanque
Monsieur le Docteur David Vandendriessche
Monsieur le Docteur François Kraus

Directeur de thèse : Madame le Docteur Geraldine GIRAUDET