

UNIVERSITÉ DE LILLE
FACULTÉ DE MÉDECINE HENRI WAREMBOURG
Année : 2021

THÈSE POUR LE DIPLÔME D'ÉTAT
DE DOCTEUR EN MÉDECINE

« IS V-NOTES HYSTERECTOMY AS SAFE AND FEASIBLE IN DAY CARE
SURGERY AS VAGINAL HYSTERECTOMY ? »

Présentée et soutenue publiquement le 15/10/2021 à 18h
au Pôle Formation
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TABLES OF CONTENTS

<i>ABSTRACT</i>	4
<i>INTRODUCTION</i>	6
<i>MATERIAL ET METHODS</i>	8
<i>RESULTS</i>	12
<i>DISCUSSION</i>	15
<i>CONCLUSION</i>	18
<i>REFERENCES</i>	19
<i>TABLES</i>	21

ABSTRACT

STUDY OBJECTIVE: The vaginal approach is the reference surgical route to perform hysterectomy for benign pathologies. Hysterectomy via transvaginal natural orifice transluminal endoscopic surgery (V-NOTES) is a new technique that would overcome the limitations of vaginal surgery by allowing a complete exploration of the peritoneal cavity and a constant visual control of the adjacent structures. The aim of this study is to assess the V-NOTES technique compared to vaginal hysterectomy (VH).

DESIGN: A retrospective cohort study.

SETTING : French teaching hospital

PATIENTS : The first 50 V-NOTES hysterectomies were included successively and compared to the last 50 VH performed from March 2019 to November 2020. The study concerned all patients requiring hysterectomy unless it was for endometriosis or cancer (except for grade 1 endometrioid adenocarcinoma).

INTERVENTIONS : The baseline characteristics and the surgical outcomes were compared. The main outcome assessed was the performing of outpatient surgery. Secondary endpoints were uterine weight, intraoperative and postoperative complications.

MEASUREMENTS AND MAIN RESULTS: The rate of outpatient surgery did not differ between the two surgical techniques ($p=0.23$). The success rate of outpatient management was 77% in the V-NOTES group versus 75% in the VH group ($p=0.85$). There was no difference in surgical outcomes between the two groups except for the rate of salpingectomies or adnexectomies which was significantly higher in the V-NOTES group, with 100% of patients undergoing one of these procedures compared

to 60% of patients in the vaginal route group ($p < 0.001$). There were two cases of re-admission in the month following the intervention in the vaginal group and 0 cases in the V-NOTES group.

CONCLUSION: Hysterectomy by V-NOTES can be performed as a safe and adequate alternative to VH. This surgical route is a good candidate for outpatient management. However, more studies need to be conducted to confirm these findings.

KEYWORDS: Outpatient surgery ; Surgical outcomes ; Transvaginal natural orifice transluminal endoscopic surgery (V-NOTES), Vaginal Hysterectomy

INTRODUCTION

Hysterectomy is a very common surgical procedure in gynecological surgery ⁽¹⁾. Aarts et al ⁽²⁾, in the Cochrane Database published in 2015, classifies the approaches into two groups: laparotomy and minimally invasive surgery (MIS), which includes the vaginal route, laparoscopy, robot-assisted laparoscopy and laparoscopically assisted vaginal hysterectomy. The vaginal approach, due to its better post-operative outcomes and lower complication rate, is the recommended reference surgical route in the management of benign pathologies ^(2,3). Moreover, vaginal hysterectomy (VH) can easily be performed on an outpatient basis, allowing patient satisfaction ^(1,4-6) while reducing institutional costs ^(7,8). However, the evolution of practices tends to increase the number of total laparoscopic hysterectomies (TLH) at the expense of VH ⁽²⁾. This can be explained by the possibility to operate under permanent visual guidance, with a better accessibility to adnexa.

Transluminal endoscopic surgery through natural orifice is a new evolution of MIS, also known as NOTES. It consists of using a natural orifice, such as the vagina, as a way to access the peritoneal cavity. Initially described in 2007 for cholecystectomies ⁽⁹⁾, Su et al ⁽¹⁰⁾ reported in 2012 the first series of hysterectomies V-NOTES in Taiwan. Since then, several studies have demonstrated the feasibility and safety of this technique ⁽¹¹⁻¹⁹⁾. Patients who benefited from it have a scar-free abdomen and a reduction in postoperative pain, which could facilitate outpatient management ⁽²⁰⁾.

The V-NOTES technique is a way to overcome the limitations of VH, while keeping the benefits, as well the advantages of laparoscopic sight. To the best of our knowledge, there is no study that compares VH, the reference approach to perform hysterectomy for benign pathologies, to V-NOTES hysterectomy. The aim of this study

is to assess the surgical outcomes of hysterectomies performed with V-NOTES technique in comparison to VH.

MATERIAL & METHODS

Study population

This study was a single-center, retrospective, chart review study conducted in a Regional University Hospital in France. From February 2019 to November 2020, a total of 100 women were scheduled to undergo hysterectomy by V-NOTES or VH. The first 50 V-NOTES hysterectomies carried out in our unit, corresponding at our learning curve, were included successively from February 2020 to November 2020. They were compared to the last 50 VH performed from March 2019 to August 2020. The vaginal route was chosen for all patients requiring hysterectomy unless it was for endometriosis or oncological indications (except for grade 1 endometrioid adenocarcinoma). The choice to use the new technique rather than the traditional vaginal approach was at the surgeon's discretion. There were five surgeons who decided to train in this new technique, including two surgeons with experience in vaginal surgery and three young hospital practitioners. Patients treated as outpatients came in on the morning of the operation and left in the afternoon. Outpatient care depended on the surgeon's habits and the patients' comorbidities.

The indications for surgery included menometrorrhagia, uterine myomas, persistent symptoms following sterilization with the Essure device (like abdominal or muscular pain, asthenia, headache...), prolapse, and certain cancers such as atypical endometrial hyperplasia or adenocarcinoma endometrioid grade 1. A history of cesarean section and nulliparity were not considered as contraindications. Before the surgery, all patients underwent preoperative assessments, including a detailed medical history, a pelvic examination, and imaging, usually and ultrasound or Magnetic Resonance Imaging (MRI) when indicated. The risks of surgery were explained to the patients, including the potential need to switch to laparoscopy or laparotomy during the

operation and the risks of intraoperative bleeding, transfusion or adjacent organ injury. In the V-NOTES group, adnexal procedures were planned for all patients preoperatively. The choice of adnexectomy over salpingectomy was based on age, hormonal status and oncological risk factors. In the VH group, some operators removed the fallopian tubes whenever possible, others did not propose it systematically because of potential technical difficulties.

Preoperative clinical and demographic characteristics recorded included age, body mass index (BMI), number of vaginal and cesarean deliveries, and pelvic surgery history. Similarly, operating time (minute), blood loss (mL), associated intraoperative procedures (involving pelvic statics or the adnexa for example), uterus weight (in grams), perioperative complications, number of post-operative nights and number of re-admissions after surgery were recorded.

The main outcome assessed was outpatient management. Secondary endpoints were uterine weight, intraoperative and postoperative complications.

The Institutional Review Board of the College of Obstetrics and Gynaecology, approved the research protocol of the present study (CEROG 2020-GYN-1103). All patients gave consent for their data to be used for research at the time of their initial management.

Surgical procedure

(1) Routine management

Under general anesthesia, the patient was positioned in the lithotomy. Prophylactic intravenous cephalosporin was given just before surgery. A Foley catheter was inserted through the urethra in order to empty the bladder, and a speculum was used to expose the operative field. At the beginning of the surgery, a paracervical injection of adrenaline xylocaine diluted to 50% was performed to prepare the dissection planes

and to reduce bleeding. In both groups, the surgeon had the possibility to use a bipolar vessel sealing system device (BSL). In the VH group, it was possible to use a BSL and/or a conventional suture ligature (CSL). This choice was at the surgeon's discretion.

(2) Hysterectomy by V-NOTES

The first operative steps are quite similar to a VH until the ligature sectioning of the utero sacral ligaments after the opening of the Douglas pouch and the vesicouterine pouch. At that moment, we inserted the gel point patch device (Applied) and initiated an insufflation at 8 mmHg. We used a 10 mm rigid laparoscopy and two standard rigid laparoscopic 5-mm graspers. The exploration of the peritoneal cavity was carried out. Thereafter, we performed the coagulation and the section of the uterine pedicles. Then we opened the broad ligaments. We coagulated and sectioned the utero ovarian ligament if we preserved the ovaries, the mesosalpinx, the infundibulo ovarian, and then the round ligament. If an adnexectomy was scheduled, we coagulated and cut the infundibulo pelvic ligament under visual guidance. After controlling hemostasis, the gel point Patch device was removed. Finally, vaginal closure was done by a Vicryl n°1 suture.

Statistical Analysis

Categorical variables were displayed as numbers (percentage). Quantitative variables were displayed as means (\pm standard deviation, SD) in the case of normal distribution or medians [range] otherwise. Normality of distribution was assessed using histograms and the Shapiro-Wilk test. Comparisons in patients' characteristics and surgical outcomes between the two study groups (V-NOTES and VH) were done using Chi-square tests for categorical variables, and Student t or Mann-Whitney U tests (depending on the normality of distributions) for quantitative variables; no statistical

comparisons were done for categorical variables with a frequency <5. Statistical testing was done at the two-tailed α level of 0.05. Data was analyzed using SAS software package, release 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Study population

The baseline characteristics are shown in [Table 1](#). There was no difference between the two groups concerning age, BMI, parity, and history of cesarean section and pelvic surgery. The main complaint for patients was menorrhagia.

Surgical outcomes

Results are shown in [Table 2](#). There was no difference concerning the length of hospitalization ($p=0.14$). The rate of outpatient success rate was similar between the two groups ($p=0.85$). In the V-NOTES group, 39 patients of 50 (78%) were scheduled as outpatients. The outpatient success rate in this group was 77% since 9 of the 39 patients (13%) were converted from outpatient to conventional hospitalization. The reasons were as follows: 1 for metrorrhagia, 1 for postoperative pain, 1 for conversion to laparoscopy, and 3 for an operating time of more than 3 hours (2 were operated on by young doctors, the other concerned a uterus weighing more than 1 kg). In the VH group, 32 of 50 (64%) patients were scheduled as outpatients with a success rate of 75%. Indeed, 8 of the 32 patients (15%) spent one night in hospital: 2 for intraoperative bleeding greater than 500cc, 1 for nausea and vomiting, 1 for hematuria at the end of the operation requiring monitoring of the diuresis, 2 for leaving the operating theatre at a late hour.

There was no difference between the two groups in terms of surgical outcomes, except for the rate of salpingectomies or adnexectomies which was significantly higher in the V-NOTES group, with 100% of patients undergoing one of these procedures compared to 60% of patients in the VH group ($p<0.001$). It should be noted that in the VH group, 2 patients had already undergone adnexal surgery: a 45-year-old patient with a history

of bilateral salpingectomy who did not require oophorectomy; and a patient with history of a bilateral adnexectomy for recurrent serous cystadenomas. In the V-NOTES group, a 43-year-old patient had already undergone a left adnexectomy, which did not prevent them from undergoing a contralateral salpingectomy. In the V-NOTES group, there were 8% (n=4) of patients who were nulliparous and 12% (n=6) who had never delivered vaginally with no intraoperative bleeding or postoperative complications. In the VH group, there were 2% of patients who were nulliparous (n=1) and 8% who had never delivered vaginally (n=4). Out of these 4 patients, 2 had intraoperative bleeding estimated at 500 and 900mL. The median operative time was 81 minutes [33 ; 229] in the V-NOTES group and 70.5 minutes [32 ; 158] in the VH group (p=0.089). Six associated procedures were performed during the intervention in the V-NOTES group: 1 pelvic statics procedure (consisting of a sacrospinofixation, an anterior colporrhaphy and a colectomy), 1 adnexal cyst cytopuncture, 1 ureterolysis in a case of deep pelvic endometriosis, 1 digestive adhesiolysis, 1 condyloma removal and 1 sentinel node procedure (in context of hysterectomy performed for endometrioid adenocarcinoma grade 1) . Concerning the VH group, 7 associated procedures were performed: 6 pelvic statics procedures (5 posterior sacrospinofixation, and 1 uphold prosthesis) and 1 adnexal cyst cytopuncture. For V-NOTES and VH, the median uterus weight was 156 grams [122 to 370] and 154 grams [104 to 252], respectively (p=0.31). More uteruses weighed more than 280 grams in the V NOTES group with 32% of patients compared to 20% in the VH group, without reaching the significance level (p=0.17). There were no intra operative complications in the V-NOTES group. However, there was one switch to laparoscopy due to abundant bleeding in a context of polyfibromatous uterus weighing 1428g. In the VH group, there were no intra operative complications and no switches to laparoscopy or laparotomy with a maximum uterine weight of 743 grams.

In terms of postoperative complications, one patient in the V-NOTES group consulted the emergency department the day after the operation for laparoscopic gas pain. In the VH group, 1 prolonged hospitalization for elevated post-void residual volumes and 1 urinary tract infection were reported. Furthermore, there were two cases of re-admission in the month following the intervention in the VH group (0 cases in the V-NOTES group) because of a hematoma of the vaginal scar and an acute urinary retention because of a urinary tract infection. The two patients who had an acute urinary retention had also undergone a posterior sacrospinofixation.

DISCUSSION

In our study comparing hysterectomy by V-NOTES to VH, outpatient care did not differ between the two surgical procedures. Similarly, there was no difference regarding the surgical outcomes except for the rate of salpingectomy or adnexectomy which was significantly higher in the V-NOTES group.

The current issues of public health-care, bed occupancy and cost management are all arguments in favor of the rise of ambulatory care. Hysterectomy is a surgical procedure that meets the eligibility criteria for outpatient care: short duration (<1h30), low risk of hemorrhage, and reduced postoperative pain. VH is already performed on an outpatient basis with a high rate of patient satisfaction ^(1,6,21). It has been proven that the post-operative stays are shorter after V-NOTES hysterectomy than TLH ^(17,20,22). This could be explained by a shorter operative time ⁽²²⁾ and the difference in insufflation pressures (8mmHg for V-NOTES versus 12mmHg for THL). Thus, the patients present lower postoperative pain scores ^(17,20), which is the limiting factor for successful outpatient treatment ⁽⁵⁾. In our study, the outpatient success rate was 77% in the V-NOTES group, which is consistent with the rate found by Baekelandt et al, in their randomized controlled trial comparing V-NOTES hysterectomy and TLH (77% for V-NOTES versus 43% for TLH p= 0.007) ⁽²⁰⁾.

We compared VH which has a well-established technique to the first V-NOTES, and thus to our V-NOTES learning curve. In spite of this, there were no further complications apart from one conversion to laparoscopy in the V-NOTES group. This is particularly encouraging since it was only the fifth hysterectomy performed using this new technique in our center and that it involved a large polyfibromatous uterus weighing 1428g. Our operative time of 92.7minutes for a mean uterus weight of 288.8 grams, is consistent or even lower than those found in the literature. Yang et al ⁽¹⁷⁾ in

their retrospective study of 183 patients published in 2020 showed a mean time of 129.3 minutes with an average uterus weight of 219.9 grams (\pm 148.4) ; Baekelandt reported in his first feasibility study on 10 patients a mean operative time of 97 min for an average uterine weight of 132 grams [51 – 353] ⁽¹⁸⁾. However, in their more recent series of 1000 patients, the average time for V-NOTES hysterectomy was 46 minutes for an average uterine weight of 172 grams [20 – 3361], showing promising learning curve ⁽²³⁾ .

The higher rate of salpingectomy and adnexectomy highlight the fact that V-NOTES, like TLH, could provide a better visibility and access to the adnexa than VH. This is a considerable advantage as it is recommended to perform salpingectomy at the same time as the hysterectomy in order to decrease the risk of ovarian cancer ⁽²⁴⁾. Aharoni et al. in their study which compared hysterectomy associated with suspension of the uterosacral ligament by V NOTES to HV have made the same observation ⁽²⁵⁾. Moreover, they showed a reduction in the number of ureteral obstructions with the V-NOTE technique ⁽²⁵⁾.

Another difficulty with vaginal surgery has typically been nulliparity, since the vaginal access thus be difficult. It has also been described that the risk of bleeding could be greater compared with the women who are primiparous or multiparous ⁽²⁶⁾. Nulens et al. in a feasibility study on 9 virgin patients, showed 100% of V-NOTES hysterectomy without any bleeding complications ⁽²⁷⁾. Moreover, a series of V-NOTES hysterectomies have been described with a nulliparity rate consistent with our results without any bleeding complications ⁽¹⁴⁾. It should be noted that in the HV group, 2 of the 4 patients who had never delivered vaginally had intraoperative bleeding estimated at 500 and 900mL.

Like VH, the V-NOTES technique could overcome some of the disadvantages of TLH by allowing fewer requirements for blood transfusions, lower post-operative pain, better post-operative recovery, no abdominal wall complications and an aesthetic advantage^(2,17,20). Moreover, in case of large uteruses, the vaginal access offered by the V-NOTES technique allows direct access at the beginning of the procedure in order to coagulate the vessels, especially at the isthmus, in contrast to laparoscopy. It could result in a reduction of intraoperative bleeding⁽¹⁹⁾. But, the V NOTES technique also provides some of the advantages of TLH such as an ergonomic position for the surgeon and his operating assistants. Bekker et al. showed that V NOTES hysterectomy performed since 2019 allowed a good surgeons satisfaction due to a better ergonomic position compared to TLH or VH⁽²⁸⁾. This is very interesting as these are factors that have been detrimental to the vaginal route since the rise of laparoscopy in the 1990s⁽²⁾.

Performing hysterectomy can be a difficult procedure for large uteruses which is defined as a polomyomatous uterus and/or a weight greater than 280 g⁽²⁹⁾. With an average uterine weight of 288 grams, V-NOTES seems to be perfectly adapted for large uteruses and a safe alternative to TLH or laparotomy. Nulens et al.⁽³⁰⁾ in their series of 114 patients with uterine weight varying between 281g to 3361, found no conversions to laparoscopy and one conversion to laparotomy for specimen extraction no matter if the patient had a history of cesarean section, obesity, or nulliparity.

This is the first study that compares V-NOTES hysterectomy to the reference approach. Even though we compared a newly learned technique with a well-honed one, the rate of outpatient surgery remains high and is comparable to that of the vaginal route, with no added complications. This shows the feasibility and rapid learning of this approach. However, we caution that the present findings come from an observational,

non-randomized design with a limited sample size and we therefore cannot exclude confusion and selection bias like any observational study.

CONCLUSION

Hysterectomy by V-NOTES is an innovative technique in the field of MIS which can be performed as a safe and adequate alternative to VH. It adds the advantages of the vaginal surgery while avoiding their disadvantages such as the impossibility to properly explore the peritoneal cavity, a difficult access to the adnexa, and the challenges involved with large uteruses and/or nulliparous women. This surgical route could also allow daycare surgery, which is an important component of our current health policies. However, more studies need to be conducted, for instance multicenter randomized trials, in order to confirm these results and define the position of this surgical approach in the treatment strategy.

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Table 1. Patient characteristics

Characteristics	V-NOTES hysterectomy (n=50)	VAGINAL hysterectomy (n=50)	p
Age (year)	48.6 ± 7.4	49.5 ± 8.5	0.57
Body mass index (kg/m ²)	27.5 ± 6.4	25.6 ± 5.2	0.11
Parity (through vaginal delivery)	2.0 [0 ; 5]	2.0 [0 ; 5]	0.20
0	6 (12.0)	4 (8.0)	
1	13 (26.0)	7 (14.0)	
2	18 (36.0)	24 (48.0)	
3	7 (14.0)	8 (16.0)	
4	5 (10.0)	5 (10.0)	
5	1 (2.0)	2 (4.0)	
Caesarean section history	4 (8.0)	8 (16.0)	0.22
History of pelvic surgery	7 (14.0)	12 (24.0)	0.20
Surgical indication			0.57
Menorrhagia	26 (52.0)	32 (64.0)	
Uterine myoma symptomatic by compression	9 (18.0)	5 (10.0)	
Essure	6 (12.0)	6 (12.0)	
Others	9 (18.0)	7 (14.0)	

Values are expressed as mean ±standard deviation, median [range] or numbers (percentage)

Table 2. Surgical outcomes

Characteristics	V-NOTES hysterectomy (n=50)	VAGINAL hysterectomy (n=50)	P
Operative time (minute)	81.0 [33 ; 229]	70.5 [32 ; 158]	0.089
Blood loss (mL)	10 [10 ; 600]	10 [10 ; 900]	0.81
Surgical gesture on adnexa	50 (100.0)	30 (60.0)	< 0.001
Salpingectomy	38 (76.0)	25 (83.3)	
Adnexectomy	12 (24.0)	5 (16.7)	
Others surgical gesture	6 (12.0)	8 (16.0)	0.56
Uterus weight (g)	156 [36 ; 1428]	154 [24 ; 743]	0.31
Weight range (g)			0.17
< 280	34 (68.0)	40 (80.0)	
>= 280	16 (32.0)	10 (20.0)	
Intraoperative complication	0 (0.0)	0 (0.0)	ND
Post-operative complications	1 (2.0)	4 (8.0)	ND
Number of post-operative nights	0 [0 ; 3]	1 [0 ; 4]	0.14
0	30 (60.0)	24 (48.0)	
1	18 (36.0)	19 (38.0)	
2	1 (2.0)	6 (12.0)	
3	1 (2.0)	0 (0.0)	
4	0 (0.0)	1 (2.0)	
Outpatient surgery	30 (60.0)	24 (48.0)	0.23
• Scheduled outpatient	39 (78.0)	32 (64.0)	0.12
• Conversion to conventional hospitalization	9 (13.0)	8 (15.0)	0.85
Outpatient success rate	77.0	75.0	
Re-admission	0 (0.0)	2 (4.0)	ND

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

ND: indicates not done for categorical variables with frequency less than 5 patients

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Date de soutenance : 15/10/2021

Titre de la thèse :

- **“IS V-NOTES HYSTERECTOMY AS SAFE AND FEASIBLE IN DAY CARE SURGERY AS VAGINAL HYSTERECTOMY ? ”**

Thèse - Médecine - Lille 2021

Cadre de classement : Gynécologie chirurgicale

DES + spécialité : Gynécologie-Obstétrique

Mots-clés : *chirurgie endoscopique transluminale par orifice naturel transvaginal (vNOTES), hystérectomie vaginale, résultats chirurgicaux, chirurgie ambulatoire*

Résumé :

Introduction : L'hystérectomie est une intervention chirurgicale largement réalisée en gynécologie et concerne jusqu'à 80 000 femmes par an en France. La voie vaginale apparaît comme la voie préférentielle dans la prise en charge des pathologies bénignes de par ses meilleures suites opératoires et de son faible taux de complications. Cependant, elle présente certaines limites, notamment dans les utérus poly fibromateux avec un contrôle parfois délicat des artères utérines et des pédicules annexiels. L'hystérectomie par chirurgie endoscopique transluminale transvaginale à orifice naturel (V-NOTES) est une technique innovante qui permettrait de surmonter les limites de la chirurgie vaginale en permettant une exploration complète de la cavité péritonéale et un contrôle visuel constant des structures adjacentes. L'objectif de cette étude est de montrer la faisabilité et la sécurité de l'hystérectomie selon la technique V NOTES en comparaison à la voie d'abord de référence qu'est la voie vaginale (HV).

Matériel et méthodes : Les données des 50 premières hystérectomies V-NOTES réalisées à Jeanne de Flandre au CHU de Lille ont été incluses successivement puis comparées aux 50 dernières (HV). Les caractéristiques de base et les résultats chirurgicaux ont été comparés entre les deux groupes. Le critère de jugement principal était le succès d'une prise en charge en ambulatoire. Les critères de jugement secondaires concernaient les complications peropératoires et postopératoires ainsi que le poids utérin.

Résultats : La durée d'hospitalisation ainsi que le succès de l'ambulatoire ne différaient pas selon la technique chirurgicale ($p=0.23$). Il n'y avait pas de différence concernant les caractéristiques chirurgicales à l'exception du taux de gestes annexiels qui était significativement plus élevé dans le groupe V-NOTES avec un taux à 100% contre 60% dans le groupe HV ($p<0.001$).

Conclusion : L'hystérectomie par V-NOTES est une technique innovante dans le domaine de la chirurgie mini-invasive qui peut être réalisée comme une alternative sûre et adéquate à l'HV. Elle couple les avantages de la voie vaginale à ceux de la voie coelioscopique. De plus cette voie d'abord est une bonne candidate à la prise en charge en ambulatoire. Cependant, d'autres études doivent être menées pour confirmer ces résultats et définir la position de cette voie d'abord dans la stratégie thérapeutique.

