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Original Research Article

Hysterectomy in Women with Benign Uterine Disease. A Prospective Randomized Comparison of three Minimally Invasive Procedures

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Objectives: **To compare the clinical results of three minimally invasive hysterectomy techniques: vaginal hysterectomy (VH), laparoscopically assisted vaginal hysterectomy (LAVH), and total laparoscopic hysterectomy (TLH).** ***Study design:*** **A prospective, randomized study was performed at our gynecologic surgery center between January 2008 and December 2013. A total of 176 women indicated to undergo hysterectomy for benign uterine disease were randomly assigned to three different groups VH (n=57), LAVH (n=61), and TLH (n=58).** ***Results:*** **TLH had the longest operating time (135minutes) and severe complications occurred only in this group. The lowest consumption of analgesics was observed in TLH patients. VH had the shortest operating time (65 min). However, febrile complications rate and the increase in CRP were significantly higher. LAVH had an acceptable operating time (110 min), a low complication rate, lack of severe post-operative complications and smallest drop in hemoglobin. Conversion rate was comparable between VH, LAVH and TLH. The follow-up of patients within 1, 6 and12 months does not show significant differences between the three groups.** ***Conclusion:*** **VH is the most suitable method for women for whom the shortest duration of surgery and anesthesia is optimal. LAVH is preferable in cases when oophorectomy is required. TLH did not appear to offer any significant benefits over the other two methods apart from less consumption of analgesics and should be indicated in women where neither VH nor LAVH are feasible.**

Keywords: Benign uterine disease, Laparoscopy, Vaginal hysterectomy.

INTRODUCTION

Hysterectomy for benign lesions, excluding prolapse and neoplastic processes, is the most frequently performed surgery in women outside pregnancy [**1**,**2**]. However, hysterectomy should be proposed after failure of alternative conservative treatments, and after evaluating the risk-benefit ratio. Therefore, efforts to reduce intra- and post-operative morbidity of hysterectomy, focus on reducing the total number of hysterectomies performed and developing surgical alternatives to abdominal hysterectomy.

Currently, there are several minimally invasive techniques such as vaginal hysterectomy (VH), laparoscopicallyassisted vaginal hysterectomy (LAVH), total laparoscopic hysterectomy (TLH), and more recently robotic hysterectomy. Several studies have compared the minimally invasive techniques in abdominal hysterectomy [**3-8**], the majority of them were retrospective studies. However, studies comparing minimally invasive techniques are less numerous, making it difficult to determine the most beneficial procedure to patients. The objective of this study is to compare the intra- and post-operative morbidity associated with the three minimally invasive hysterectomy techniques (VH, LAVH, TLH).

MATERIAL AND METHODS

Study settings

A randomized prospective study was conducted in our center of gynecological surgery between January 2008 and December 2013. A total of 176 women undergoing hysterectomy for benign disease were included in the study and randomized into three groups: vaginal hysterectomy (VH, n=57), laparoscopically assisted vaginal hysterectomy (LAVH,

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n = 61) and total laparoscopic hysterectomy (TLH, n = 58). Randomization was performed using computer-generated random numbers to distribute patients equitably between groups. All participants gave informed consent according to the protocol approved by the ethics review board.

Study population

Patients who should undergo a hysterectomy for benign disease and gave their informed consent were included in the study. Patients were excluded from this study if they had a contra-indication for vaginal hysterectomy (severe endometriosis, virginity, serious spinal pathology hampering installation), or laparoscopy (including contra-indications for anesthetics and medical problems that can be aggravated by pneumoperitoneum or the Trendelenburg position).

Moreover, patients with a confirmed or suspected gynecologic cancer, except for cervical intraepithelial neoplasia (CIN III), or a uterine volume greater than 300 ml were excluded. Urinary incontinence, or the urogenital prolapse higher than 1st degree, or the need for another concomitant surgical procedure were also exclusion criteria.

Study procedures and data collected

All patients had a pelvic ultrasound and the uterus size was estimated using the following formula: longitudinal diameter (starting from the neck) x transverse diameter x anteroposterior diameter x 0.523. The same standard preparation before surgery was done for all patients, including antibiotic prophylaxis (intravenous cefazolin 2 g) and digestive preparation. All operations were performed under general anesthesia with endotracheal intubation.

VH was performed using Heaney's technique [**9**]. Laparoscopic hysterectomy was always total (E IV according to the classification of the American Association of GynecologicLaparoscopists (AAGL) [**10**], using the uterine manipulator from Clermont-Ferrand. LAVH was performed according to a standardized protocol: laparoscopic time associated with hemostasis and section of the round ligaments and adnexal pedicles, a vesico-uterine detachment and electrocoagulation section of uterine vessels. Hysterectomy was then continued by vaginal approach.

For each patient, the following information were recorded before the surgery: age, body mass index (BMI), parity, previous history of intra-abdominal surgery, pre-operative baseline hematology exams (blood type, hemoglobin, platelets, prothrombin time, APTT, Fibrinogen, urea, creatinine) and microbiology tests (urine culture, a vaginal swab and C-reactive protein [CRP]). The intra- and post-operative evaluation included operative time (the first incision to the last suture), unilateral or bilateral oophorectomy, uterine fragmentation, weight of the uterus, frequency of intra-operative complications, conversion rate, blood loss (measured using two different methods, the intra-operative assessment of blood loss and the difference between the hemoglobin level before surgery, one and three days later), and transfusion rate. On the third post-operative day, CRP levels were evaluated.

We also evaluated the infectious morbidity (temperature > 38°C for more than 24 hours after surgery), the rate of early and late post-operative complications, the length of hospital stay and the analgesics use defined by the number of analgesics use (1 unit = 1g of paracetamol IV) administered during hospitalization at the patient's request for pain relief (no other analgesic was administered during this time). On the third post-operative day, an ultrasound examination was performed in all patients in search of intra-pelvic hematoma. Remote monitoring was provided to outpatients by clinical examination and ultrasound. Patients were convened every month for the first 6 months and then every 3 months for 1 year.

We used a questionnaire to evaluate the following parameters: pelvic pain (visual analog scale [VAS] from 0 to 10 on a horizontal line: 0: no pain; 1-3: low, 4-6: moderate; 7-10: severe), urinary problems (absence, urge incontinence, stress urinary incontinence [SUI]), pelvic floor disorders (absence, stages I, II, III, and IV according to Baden and Walker [11]), sexual activity (yes/no), patient satisfaction (VAS; 0: very disappointed; 10: very satisfied).

The results of the questionnaire were reported on one, 6 and 12 months. The surgical team that participated in the study included all active gynecological surgeons within the service without being limited to specialists in vaginal or laparoscopic procedures. All surgeons were able to perform one of three procedures evaluated in this study, avoiding thus personal preferences. Four experienced surgeons participated in the study.

Statistical analysis

Statistical analysis was performed using ANOVA and Duncan test for continuous variables, the $\chi 2$ test and Kruskal-Wallis test for non-continuous variables. A p-value < 0.05 was considered statistically significant. All statistical analyzes were performed with SPSS software, version 13.0.

RESULTS

There was no significant difference between the three groups in terms of age, BMI, gender or history of abdominal-pelvic surgery (Table 1). Among the 176 patients, 26 (14.8%) have already had a laparotomy is 14.8% (Table 2). The two main indications for hysterectomy were uterine fibroids and abnormal uterine bleeding. The majority of patients had more than one indication, a maximum of two indications have been reported (Table 3).

The main parameters assessed during surgery are summarized in Table 4. There was a significant difference in terms of operative time between the three groups; the shortest duration was observed in the VH group (65 minutes), the longest in the TLH group (135 minutes). We reported three bladder injuries, two occurred in the VH group while the third occurred in the LAVH during laparoscopy. Surgical repair took place by vaginal approach in the first two cases and by laparotomy in the third case. Centimeter wound hail occurred in one patient in the TLH group during the introduction of the central trocar, repair took place at the same time by an intraperitoneal suture of the bowel wall.

When a technique for reducing uterine volume was necessary (whatever the procedure of hysterectomy), the mean uterine weight was 295 g against 211 g in the remaining cases. The VH was associated with the highest rate of uterine fragmentation (36.8%), without significant difference between the three groups. Indeed, the tilt of the uterine body could not be obtained in 56.2% of cases (n=32) and required the use of fibroid enucleation nuclei in 19.3% of cases (n=11) and performing a uterine hemisection in 24.5% of cases (n=14). In the LAVH and TLH groups, the rates of uterine fragmentation were 29.5% and 32.7% respectively. The rate of conversion to another type of hysterectomy was comparable between the three groups.

Table 1. Pre-surgery characteristics of the patients

	LAVH n=61	HC n=58	HV n=57	p-value*
Age (years)	52.8	51.5	51.7	NS
BMI	26.5	27.5	28.3	NS
Parity	2.7	2.9	2.8	NS
Abdominal- pelvic surgery; n (%)	17 (27.8%)	15 (25.9%)	13 (22.8)	NS
Laparotomy; n (%)	10 (16.4%)	9(15.5%)	7 (12.3%)	NS
Coelioscopy; n (%)	7(11.4%)	6(10.4%)	6 (10.7%)	NS

Abbreviations: BMI=body mass index; LAVH=laparoscopically assisted vaginal hysterectomy; NS=not significant; TLH=total laparoscopic hysterectomy; VH=vaginal hysterectomy.
* Significance level set at 5%.

Table 2. Surgical history that required a laparotomy

	n	%
Ovarian cyst	3	1.7
Intestinal occlusion	1	0.5
Myomectomy	4	2.3
Salpingectomy	2	1.1
Cesarean	12	6.8
Appendectomy	2	1.1
Endometriosis	2	1.1
Total	**26**	**14.8**

Table 3. Indications of hysterectomy

Indications	n	%
Menometrorrhagia	13	7.4
Menometrorrhagia + endometrial hyperplasia	22	12.5
Menometrorrhagia+ adenomyosis	12	6.8
Menometrorrhagia+ uterine myoma	65	36.9
Uterine myoma	11	6.2
Uterine myoma+ chronic pelvic pain	8	4.5
Uterine myoma+ endometrial hyperplasia	9	5.1
Chronic pelvic pain	14	7.9
Chronic pelvic pain + adenomyosis	7	3.9
Endometrial hyperplasia	9	5.1
Cervical intraepithelial neoplasia	6	3.4
Total	**176**	

Table 4. Parameters assessed in intraoperative

	LAVH n=61	TLH n=58	VH n=57	p-value*
Operative time(minutes)	110 [65–185]	135 [90–220]	65 [45–175]	0.0001*
Adnexectomy(%)	65.5%	43.1%	40.3%	NS
Uterine fragmentation(%)	29.5%	32.7.8%	36.8%	NS
Blood loss (ml)	173 [42–950]	186 [20–680]	199[30–530]	NS
Bladder injury (n)	1	0	2	NS
Ureteral wound (n)	0	0	0	NS
Digestive wound (n)	0	1	0	NS
Conversion (n[%])	3 (4.9) Laparotomy	4 (6.8) LAVH	3 (5.2) LAVH	NS -

Abbreviations: LAVH=laparoscopically assisted vaginal hysterectomy; NS=not significant; TLH=total laparoscopic hysterectomy; VH=vaginal hysterectomy.
* Significance level set at 5%.

Table 5. Parameters assessed in post-operative

	LAVH n=61	TLH n=58	VH n=57	p-value*
Uterine weight (g)	224 [90–850]	201 [75–650]	199 [65–542]	NS
Post-operative fever (%)	3.2%	6.8%	21.0%	0.016
Transfusion (%)	1.6%	1.7%	1.8 %	NS
Hospital stay (days)	4.7 [3–8]	4.1 [2–6]	5.2 [3—10]	NS
Analgesic use(g Perfalgan)	5.1	4.2	8.2	0.011
Mean difference in hemoglobin, D1 (g/L)	13.7 [6-98]	15.1 [5-36]	16.4 [8-48]	NS
Mean difference in hemoglobin, D3 (g/L)	9.3 [14–26]	14.2[2–49]	16.1[2–51]	0.040
C-reactive protein	7.4	8.3	15.3	0.013
Major complications				
Vesico-vaginal fistula (n)	0	1	0	NS
Uretero-vaginal fistula (n)	0	1	0	NS
Minor complications				
Urinary infection	2	3	1	NS
Vaginal vault hematoma (n)	3 (4.9%)	4 (6.8)	8 (14%)	NS
Vaginal scar dehiscence (n)	1	1	0	NS
Functional occlusion (n)	0	2	0	NS
Urinary retention (n)	0	0	1	NS

Abbreviations: D=day; LAVH=laparoscopically assisted vaginal hysterectomy; NS=not significant; TLH=total laparoscopic hysterectomy; VH=vaginal hysterectomy.
* Significance level set at 5%.

Table 6. Follow-up at 1, 6 and 12 months in post-operative

Parameter assessed	1 month in post-operative				6 months in post-operative				12 months in post-operative			
	LAVH n=61	TLH n=58	VH n=57	p-value*	LAVH n=59	TLH n=55	VH n=56	p-value*	LAVH n=57	TLH n=54	VH n=52	p-value*
Genital prolapse				NS				NS				NS
Absence-stage (%)	96.7	98.2	98.2		89.8	87.3	92.8		89.5	92.6	94.2	
Stage II (%)	3.3	1.8	1.8		10.2	12.7	7.2		10.5	7.4	5.8	
Stage III-IV (%)	0	0	0		0	0	0		0	0	0	
Urinary disorders												
Absence (%)	93.4	96.5	96.4		88.1	87.3	89.3		87.7	81.4	86.5	
Urge incontinence (%)	3.3	3.4	1.8		6.8	9	8.9		7	12.9	9.6	
SUI (%)	3.3	0	1.8		5.1	3.6	1.7		5.3	5.6	3.8	
Sexual activity				NS				NS				NS
Yes (%)	1.6	3.4	0		96.6	94.6	92.8		100	98.1	100	
No (%)	98.4	97.6	100		3.4	5.4	7.2		0	1.9	0	
Pain				NS				NS				NS
Absence (n)	45.9	48.2	43.8		83.1	85.4	89.3		89.5	94.4	96.2	
Low (%)	50.8	46.6	54.4		15.2	14.5	8.9		7	3.7	3.8	
Moderate (%)	1.6	5.2	1.7		1.6	0	1.8		3.5	1.9	0	
Severe (%)	1.6	0	0		0	0	0		0	0	0	
Satisfaction score (%)	79.1	73.2	76.3	NS	82.5	75.2	79.1	NS	85.9	81.4	82.6	NS

Abbreviations: LAVH=laparoscopically assisted vaginal hysterectomy; NS=not significant; SUI=stress urinary incontinence; TLH=total laparoscopic hysterectomy; VH=vaginal hysterectomy.
* Significance level set at 5%.

Three conversions (4.9%) to laparotomy were reported in the LAVH group because of bleeding during laparoscopy in 2 cases and following a bladder injury in 1 case. In the VH group, conversions occurred in 3 cases (5.2%) in the LAVH group, due to uncontrollable bleeding after oophorectomy in 1 case, and due to inaccessible ovariesin 2 cases. Finally, in the TLH group, the 4 (6.8%) reported conversions were all in LAVH due to anesthetic complications related to the pneumoperitoneum in all cases.

In post-operative, the mean uterus weight (as provided by the anatomopathologists) was224 g [90–850] in the LAVH group *versus*201 g [75–650] in TLH and199 g [65–542] in VH with no significant difference. The shortest hospital stay was reported in the TLH group without any significant difference with the two other groups. The lowest use of analgesics was

observed in TLH with a significant difference with the LAVH and VH groups (p=0.011). The rate of post-operative fever was significantly higher in the VH group (21%) compared to the LAVH (3.2%) and TLH (6.8%) groups. The increase in CRP (biological marker of inflammation) was also significantly greater in the VH group compared to the other two groups, without difference between the TLH and LAVH groups.

The decrease in hemoglobin at the first post-operative day was comparable between the three groups. However, in the third post-operative day, the drop in hemoglobin was significantly lower in the LAVH group compared to the other two groups (9.3 g/l *versus* 14.2 and 16.1, p=0.04); while the comparison between the VH and TLH groups showed no significant difference. Only three of the 176 patients needed transfusions of total blood, one patient in the LAVHgroup and one in the VH group because of low hemoglobin levels before surgery; the third patient was in the TLH group due to a significant intra-operative bleeding upon ligation section of uterine pedicle.

However, the differences between the groups in terms of blood transfusions were not significant. We noted only two (1.1%) major post-operative complications which occurred in the TLH group: one patient developed a vesicovaginal fistulae, another developed an uretero-vaginal fistula. Both patients were managed in the urology department with a favorable evolution. Nevertheless, the incidence of major complications were not statistically significant between the three groups. The most common post-operative complication was minor vaginal vault hematoma observed, especially in the VH group (n=8) followed by TLH (n=4) and LAVH (n=3), but the difference was not statistically significant (Table 5).

The follow-up of patients at one, 6 and 12 months was not significantly different between the three groups in terms of urinary disorders, sexual activity, pelvic pain, and occurrence of genital prolapse. The satisfaction score was comparable between the three groups (**Table 6).**

DISCUSSION

In our study, the VH group had the shortest procedure time and the TLH group, the longest time. This is consistent with other studies that have reported a shorter operative time for VH compared LAVH [12-15] and LAVH compared to TLH [16]. The average blood loss and the decrease in hemoglobin levels at the end of the first post-operative day were comparable between the three groups, which is consistent with other studies [14,17].

However, on the third post-operative day, we found significant differences; the lowest variation was seen in the LAVH group and the largest decrease in hemoglobin was in the VH group. Analgesic use was lower in patients who underwent TLH and greater in those who underwent VH. The results in the literature are highly variable, some authors have shown an equivalent analgesic use between the two groups [18], while others revealed a lower need for analgesics in the LAVH group [19].

Regarding the inflammation markers, our study shows that the VH group had a significant rise of CRP and post-operative fever compared to the TLH and LAVH groups.These results contradict those of Ribeiro *et al.* [**20**], who found a smaller increase in CRP in the HV group *versus* laparoscopic and abdominal hysterectomy when assessing the post-operative inflammatory response. However, in agreement with our findings, Holub*et al.* [**21**] found no difference in inflammatory response between the TLH and LAVH groups. In our study, the elevated inflammatory response in the VH group could be due to the increased frequency of small vaginal vault hematomas observed in this group (14% *versus* 4.9 and 6.8%, not significant difference). Indeed, a study showed that vaginal vault hematomas were more frequent in the VH compared to LAVH [**8**].

In our series, the choice of conversion was dependent on the surgeon and not predefined in the study. The total number of conversions from one procedure to another was comparable between the three groups. Conversion to abdominal hysterectomy took place only in the LAVH group, while the VH and TLH were converted into LAVH (although vaginal hysterectomy laparoscopy was converted after completion of the vaginal time, it was classified as a conversion to LAVH). Conversions of VH in laparoscopy were due to the inaccessibility of the annexes or hemorrhagic complications during the salpingo-oophorectomy.

The four TLH cases were converted into vaginal hysterectomy due to anesthetic complications related to pneumoperitoneum in all cases. We observed a similar number of conversions in the LAVH and VH groups, while some studies have shown a higher conversion rate in the LAVH group compared to VH [**8,22**]. The short and medium follow-up of our patients (1, 6 and 12 months) showed a comparable profile of patients in the three groups in terms of pelvic pain, urinary problems, sexual activity and occurrence of urogenital prolapse.

One of the study strengths is that all women were candidates to undergo one of three methods of hysterectomy and that the groups had comparable characteristics before surgery. This study was designed with exclusion criteria that would eliminate most of the factors that would favor one type of surgery over the other (e.g., vagina accessibility and the estimated size of the uterus). This point is different from several published series that had compared the different methods of hysterectomy despite the differences that existed between the groups in terms of pre-operative patient characteristics. Some series often include hysterectomies with concomitant surgeries [**23,24**] or do not limit the size of the uterus [**8,25**]. Others have also compared the results across different indications [**22,26]**.

Contrary to published series comparing VH and LAVH [**17,22**], we did not find any advantage of VH compared to LAVH. In our study, LAVH had an acceptable operative time, low rate of intra- and postoperative complications, low blood loss and the lowest prevalence of febrile complications. However, the satisfaction score in the short and medium term was comparable between the two groups. Also, LAVH seems to be the most universal method, as demonstrated by the fact that, in case of complications or technical difficulties in the other two groups, operations were converted to LAVH. LAVH is also more beneficial when a salpingo-oophorectomy is necessary, which has been technically difficult in 3 of 57 (5.2%) patients who underwent VH.In some randomized trials [**27,28**], VH was identified as a preferred method of hysterectomy, if it can be done safely. However, VH has some limitations as we found a moderate increase in the risk of post-operative inflammatory complications and technical difficulties with salpingo-oophorectomy. However, due to the short operative time, it could be the procedure of choice in older patients with a particular medical condition, especially since we could embrace the benefits of spinal anesthesia.

Regarding TLH, the conclusions are contradictory; some studies report limited use of this surgical approach [**10**], while others highlight its advantage for the exploration of the intra-abdominal cavity and in situations where additional surgery may be necessary [**29,30**]. Our results do not show a specific

advantage of TLHover the other two procedures, except for the lower use of analgesics. In addition, two major post-operative complications (one case of vesicovaginal fistula and one case of uretero-vaginal fistula) occurred only in the TLH group. Therefore, we believe that the laparoscopic approach should be reserved for specific indications, especially in situations that do not allow the VH such as a tight vagina, and only by highly skilled surgeons in laparoscopic surgery.

CONCLUSION

Based on our results, LAVH and VH seem to be the preferred techniques of hysterectomy in case of benign disease of the uterus. Each gynecologist surgeon should be familiar with these procedures. VH has the advantage of a shorter operating time, making it a suitable method of hysterectomy when the shortest length of the surgery and anesthesia are preferable. LAVH will be reserved for cases requiring oophorectomy because it combines the benefits of vaginal and laparoscopic approaches.

We have not found significant benefits for TLH outside a lower use of analgesics, major complications occurred only in this group. In our view, TLH is not the technique for wider application including a population of relatively older women who often have comorbidities. It will instead be reserved for cases where VH is not possible (due to a narrow vaginal access, pelvic adhesions resulting in a rise of the cervix and the uterus, endometriosis, large uterus ...), as an alternative to laparotomy and only by highly skilled surgeons in laparoscopic surgery.

DECLARATION OF INTEREST

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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