

Laparoscopically Assisted Vaginal Hysterectomy Versus Vaginal Hysterectomy for Enlarged Uterus

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ABSTRACT

Objectives: To compare the surgical and immediate postoperative outcomes for vaginal hysterectomy (VH) with those for laparoscopically assisted vaginal hysterectomy (LAVH) in patients with enlarged myomatous uterus.

Methods: Eighty women requiring hysterectomy for an enlarged myomatous uterus were randomly allocated into 2 treatment arms: VH (n=40) and LAVH (n=40). The randomization procedure was based on a computer-generated list. The primary outcome was a comparison of the discharge times between the 2 procedures. Continuous outcome variables were analyzed using the Student *t* test. Discrete variables were analyzed with the chi-square test or Fisher's exact test. $P < 0.05$ was considered statistically significant.

Results: The mean discharge time was longer for LAVH than for VH (72 ± 4.2 vs 48 ± 2.6 h; $P = 0.00$). VH resulted in shorter times for paralytic ileus (19 ± 3 vs 26 ± 3 h; $P = 0.00$) and surgery (71 ± 3 vs 129 ± 7 min; $P = 0.00$). The intraoperative blood loss was less with VH (186.0 ± 52 vs 362.7 ± 65 mL; $P = 0.00$). No intraoperative complications occurred, and no patient was returned to the operative theater in either group.

Conclusions: Several surgical and immediate postoperative outcomes were significantly better in the VH group than in the LAVH group. However, further controlled prospective studies are required for identifying the best approach for hysterectomy in patients with enlarged uterus.

Key Words: Enlarged uterus, Uterine myomas, Vaginal

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hysterectomy, Laparoscopically assisted vaginal hysterectomy.

INTRODUCTION

Hysterectomy is a major gynecological operative procedure that is often performed for symptomatic leiomyomas. However, there is no universal agreement among gynecologists about the optimal method of hysterectomy in patients with an enlarged myomatous uterus. Generally, the surgical route for hysterectomy is selected on clinical and technical factors, such as uterine weight or previous vaginal deliveries.¹ In the studies comparing the operative techniques of hysterectomy in patients with enlarged uteri, it has been documented that vaginal hysterectomy (VH) offers significant benefits in terms of reduced hospital stay and more rapid recuperation compared with abdominal hysterectomy (AH).²⁻⁴ VH was associated with significantly shorter operating time and lower costs with no detectable difference in quality of life measures or complication rates.^{5,6} Laparoscopically assisted vaginal hysterectomy (LAVH) resulted in less postoperative pain and a shorter hospital stay compared with AH.^{7,8} However, LAVH resulted in increased operating time and blood loss, and it was more expensive than VH or AH.⁸⁻¹¹

In the literature, few randomized trials compare the operative and early postoperative outcomes for VH with those for LAVH.^{6,8,9,12} Therefore, our randomized trial aimed to compare the surgical and immediate postoperative outcomes of vaginal hysterectomy (VH) with those of laparoscopically assisted vaginal hysterectomy (LAVH) in a series of patients with symptomatic myomas and enlarged uteri.

METHODS

Patients

The trial was performed at the Section of Gynaecology, Department of Surgery, Tor Vergata University Hospital, Rome. From April 2003 to June 2005, all women with symptomatic uterine myomas requiring hysterectomy

were considered eligible for the study. Inclusion criteria were¹ presence of symptomatic or rapidly growing myomas²; age <55 years³; uterine size ≥ 12 weeks gestation. Exclusion criteria were¹ nulliparous women²; uterine size ≥ 16 weeks gestation³; previous uterine surgery⁴; suspect malignant gynecological disease.

The local ethics committee previously approved this study, and the Italian Ministry of Education provided research funds. None of the authors have a financial interest in or any arrangement with the companies producing the instruments used in the study or with competing companies. There also was no direct payment to the authors from any source for the purpose of financing the writing of the manuscript, nor were there any other financial connections, direct or indirect, or other situations that might raise the question of bias in the work.

Of the 145 women requiring hysterectomy, 89 fulfilled the inclusion criteria and were recruited for the trial. Nine refused to participate. A written informed consent was obtained from each patient before randomization. The enrollment was closed when 80 patients were included, and 40 patients were allocated to each group. The patients were randomized the day before surgery. The randomization procedure was based on a computer-generated list using serially numbered, opaque, sealed envelopes. A blinded physician randomly assigned each patient to either VH (n = 40) or LAVH (n = 40). The sequence was concealed until interventions were assigned. Those who performed surgical procedures did not know which patients undergoing surgery had been included in the study. Those assessing the outcomes were blinded to the group assignments.

All procedures were performed by the same surgeons (EP, FS) using the same technique. Standard preoperative assessment was performed together with an abdominal and transvaginal ultrasound to estimate the size, the number, the site of the myomas, and the uterine size. Intraoperative prophylactic antibiotic therapy by an ampicillin sodium/sulbactam sodium combination was administered to all the patients. Gonadotropin-releasing hormone agonists (GnRH-a) were never administered.

Surgical Technique

VH was carried out as described by Dargent.¹³ After detaching the ventral vaginal wall and mobilizing the bladder, an incision was made in the so-called bladder groove; the supravaginal septum was divided in order to reach the utero-vesical space, avoiding opening the peritoneum at this stage. Successively, after detaching the dorsal vaginal

wall and entering the pouch of Douglas, a posterior colpotomy was made, and the "posterior supravaginal septum" was opened entering the peritoneal pouch of Douglas. A gaze roll was placed in the peritoneal cavity to avoid descent of the intestinal loops. After protecting the bladder in front and the rectum behind, the broad ligaments were divided. The paracervical or suspensory ligaments (that include the lower part of the bladder pillar, parametrium, and uterosacral ligament) were identified and sutured before dividing. The utero-vesical peritoneal fold was opened. Adnexal pedicles were clamped and divided. If at this time the uterine size did not allow easy exteriorization, bisecting, coring, morcellation, enucleation of myomas, or combinations of these volume-reducing techniques were performed.¹⁴ Finally, the vagina was closed, while at the same time approximating the pedicle stumps of the suspensory ligaments.

LAVH was performed at type ID (dissection up to but not including uterine arteries + anterior structures and posterior culdotomy) of laparoscopic assistance, according to the AAGL Classification System for Laparoscopic Hysterectomy.¹⁵ A uterine manipulator was placed into the uterus. Laparoscopy was performed with a 10-mm principal trocar introduced through the umbilicus. Under direct visualization, 2 lower incisions lateral to the rectus muscles were executed placing 2 ancillary 5-mm trocars. The operation began with the dissection of bilateral round ligaments and adnexa. After the course of ureters was identified, the round ligaments were grasped with a bipolar forceps, 2 cm to 3 cm distal to their uterine insertion, and desiccated for a length of about 1.5 cm. This desiccated area was divided with scissors. If adnexa were to be conserved, hemostasis and dissection of the ovarian ligaments were performed. If the tubes and ovaries were to be removed with the uterus, the infundibulopelvic portion of the broad ligaments was coagulated and dissected. The anterior fold of the broad ligaments was opened and incised using scissors at the level of the vesico-uterine pouch. The posterior leaf of the broad ligament was cut on each side, parallel to the lateral side of the uterus, down to the point of origin of the uterosacral ligaments behind the cervix. The subsequent steps were performed vaginally. A circular colpotomy was carried out by means of a scalpel. The cardinal and uterosacral ligaments, and the uterine vessels were clamped, cut, and sutured. The detached uterus was removed vaginally. When required, a combined vaginal bisection, coring, morcellation, and myomectomy was performed. After the closure of the vaginal cuff, pneumoperitoneum was re-established, and all pedicles were inspected to ensure hemostasis.

The primary outcome of the trial was the comparison between the 2 procedures in terms of discharge time. Discharge time was chosen as a primary outcome because it is generally influenced by the main operative data (operative time, blood loss, paralytic ileus time, early postoperative complications). Discharge time was measured in hours after surgery. The patients were discharged from the hospital when they were tolerant of a normal diet, able to dress themselves, fully mobile, afebrile, and not requiring analgesics. The secondary outcome measures were differences in operation time, blood loss, paralytic ileus time, febrile morbidity (body temperature $\geq 38^{\circ}\text{C}$ in 2 consecutive measurements ≥ 4 hours apart), intensity of pain, early postoperative complications (any unfavorable episode occurring within 30 days after surgery requiring readmission, blood transfusion, or repeat surgery).

The operation time was calculated from skin or vaginal incision to closure. Blood loss was estimated by calculating the blood volume of the suction machine during surgery, excluding liquid utilized for intraperitoneal washing, and by weighing swabs. Paralytic ileus time was calculated in hours from the end of the procedure to the ability to pass stool or gas. Postoperative pain was assessed at 24 hours by using a visual analog scale (VAS) that consisted of a nongraduated 10-cm line ranging from 0 (no pain) to 100 (pain as bad as it could be). Women were subdivided into 5 categories: absence of pain (VAS=0); mild pain (VAS=1 to 25); moderate pain (VAS=26 to 50); severe pain (VAS=51 to 75); and very severe pain (VAS=76 to 100).

Statistical Analysis

A power calculation verified that more than 26 patients in each group would be necessary to detect a difference of more than 24 hours in discharge time with an alpha error level of 5% and a beta error of 80%. Statistical analysis was performed using the Statistical Program/SPSS for Windows, version 10 (Chicago, IL, USA). Continuous outcome variables were analyzed using the Student *t* test. Discrete variables were analyzed using the chi-square test or Fisher's exact test. The 2 treatment groups were compared using a one-way analysis of variance (ANOVA) followed by Tukey's HSD for post hoc comparison of the mean values. A general linear model (GLM) procedure also was used to investigate interactions between variables (regression analysis). $P < 0.05$ was considered statistically significant.

RESULTS

Age, BMI, parity, uterine weight, and symptoms were similar in the 2 groups (**Table 1**). Procedures were successfully performed for all the patients in both groups. **Table 2** shows the operative parameters in the 2 groups. The mean operating time was significantly shorter after VH than after LAVH (71 ± 3 vs 129 ± 7 min; $P = 0.00$). The intraoperative blood loss had an influence on the operating time considered as a dependent variable in the GLM analysis ($P = 0.02$), and this effect was particularly strong for LAVH ($P = 0.00$). On the contrary, uterine weight did not have any effect on the operating time considered a dependent variable in the GLM analysis ($P = 0.50$). Intraoperative blood loss was less than with VH (186.0 ± 52 vs 362.7 ± 65 mL; $P = 0.00$). Uterine weight did not have any effect on the blood loss considered as a dependent variable in the GLM analysis ($P > 0.05$). No intraoperative complications occurred, and no case was returned to the theater in either group. No conversion to laparotomy was necessary.

With regard to the early postoperative outcome (**Table 3**), the mean discharge time was longer with LAVH than with VH (72 ± 4.8 vs 48 ± 2.4 hours; $P = 0.000$). Neither operating time nor blood loss had any effect on the discharge time considered as a dependent variable in the GLM analysis ($P > 0.05$). The paralytic ileus time was significantly shorter after VH (19 ± 3 vs 26 ± 3 h; $P = 0.00$). The operating time had an influence on the paralytic ileus time considered as a dependent variable in the GLM analysis ($P = 0.00$). Regarding the postoperative pain intensity at 24 hours, 20 patients (50%) reported absence of pain (VAS=0) after VH, and 6 (15%) after LAVH. Patients undergoing LAVH had more postoperative pain compared with patients undergoing VH. Postoperative fever was observed only in one woman after LAVH. No early postoperative complications requiring readmission, blood transfusion, or repeat surgery were observed in either group.

Table 1.
Patient Characteristics

	VH (n = 40)	LAVH (n = 40)	P
Age (years)*	48.8 ± 0.7	48 ± 0.5	0.60
BMI*	25.4 ± 0.6	25.8 ± 0.6	0.84
Parity*	2.2 ± 0.2	2.1 ± 0.2	0.86
Uterine weight (g)*	320 ± 17	335 ± 18	0.80

*Mean \pm SD.

Table 2.
Operative Data

	VH (n = 40)	LAVH (n = 40)	P†
Operating time (min)*	71 ± 3	129 ± 7	0.000
Blood loss (mL)*	186.0 ± 52	362.7 ± 65	0.000
Conversion to laparotomy, No. (%)	0 (0)	0 (0)	NS
Intraoperative complications, No. (%)	0 (0)	0 (0)	NS

*Mean ± SD.
†NS = not significant.

Table 3.
Early Postoperative Outcomes

	VH (n = 40)	LAVH (n = 40)	P†
Paralytic ileus time (h)*	19 ± 3	26 ± 3	0.000
Discharge time (h)*	48 ± 2.6	72 ± 4.2	0.000
Postoperative complications, No. (%)	0 (0)	0 (0)	NS

*Mean ± SD.
†NS = not significant.

DISCUSSION

Our randomized trial aimed to compare the surgical and immediate postoperative outcomes for vaginal hysterectomy (VH) with those for laparoscopically assisted vaginal hysterectomy (LAVH) in a series of patients with symptomatic myomas and enlarged uterus. To eliminate eventual bias in our study, we adopted strict criteria for patient selection for inclusion in the study. So, we excluded nulliparous women and patients with previous uterine surgery, such as caesarean delivery, which has been reported to hinder vaginal surgery.¹⁶ Moreover, considering the importance of the individual surgeon's experience in laparoscopic and vaginal surgery, all procedures were performed by the same surgeons using the identical laparoscopic and vaginal technique. In the LAVH group, the level of laparoscopic assistance was decided a priori and limited to the type ID (dissection up to but not including uterine arteries + anterior structures and posterior culdotomy) of laparoscopic assistance, according to the AAGL Classification System for Laparoscopic Hysterectomy,¹⁵ ie, to evaluate the accessibility and mobility of the uterus, to exclude the presence of problems, such as adhesions, to secure the round ligaments, the ovarian or

infundibulopelvic ligaments, and to dissect the structures located anterior and posterior to the uterus. Finally, we included patients with uterine size between 12 and 16 weeks gestation to ensure homogeneity of the uterine weight in the 2 groups.

In the literature, several studies report that operation time is longer with LAVH than with VH.¹⁷⁻²² Also in our study, the mean operating time was significantly shorter after VH (P=0.00), and this variable was strongly influenced by intraoperative blood loss, particularly for the LAVH group. Therefore, the set up for LAVH may cause a longer operative time than the set up for VH. Although other studies reported controversial results,^{17,19,21} in our study the LAVH group had more blood loss compared with VH (P=0.00). Considering that the uterine weight and the other surgical factors were homogeneous in the 2 groups, and that the uterine weight did not have any effect on the operating time considered as a dependent variable in the GLM analysis (P=0.50), and on the blood loss (P>0.05), it is difficult to explain this finding. It is not clear whether the laparoscopic or transvaginal route is better for the division of the uterine vessels. Some authors observed less bleeding during the vaginal step when the uterine vessels were transected laparoscopically.^{23,24} On the other hand, the transvaginal approach may be associated with retrograde bleeding, especially when a uterine morcellation is necessary.²⁵⁻²⁷ So, the approach to the uterine vessels, vaginal or laparoscopic, could explain the different blood loss in the various studies. To elucidate this issue, it would be interesting to compare the blood loss associated with type I (not involving laparoscopic occlusion and division of the uterine arteries) and type II (involving laparoscopic occlusion and division of the uterine arteries) LAVH.¹⁵

With regard to the early postoperative outcome, the paralytic ileus time was significantly shorter after VH (P=0.00). This finding could be explained with the shorter operation time in the VH group taking into account that the operating time had an influence on the paralytic ileus time considered as a dependent variable in the GLM analysis (P=0.00). The mean discharge time was significantly longer with LAVH than with VH (P=0.000). Neither the operating time nor the blood loss had any direct effect on the discharge time considered a dependent variable in the GLM analysis (P>0.05), but the longer paralytic ileus time could have influenced the longer discharge time with LAVH. Postoperative pain was greater in patients undergoing LAVH than those undergoing VH, probably because of the pneumoperitoneum and the small abdominal incisions.

In the literature, the data on the discharge time after the 2 methods of hysterectomy are discordant. Some authors found a longer discharge time with LAVH,²⁰ while other studies showed comparable discharge times with the 2 methods.^{1,17,19,22} The different discharge criteria applied in the diverse studies could justify these discrepancies. In our study, for example, rigid criteria were adopted, so the patients returned home only when they were tolerant of a normal diet, able to dress themselves, fully mobile, afebrile, and not requiring analgesics.

In the literature, the review of the major reports on hysterectomy for myomatous uteri demonstrates that the vaginal approach is used more frequently for small- or medium-sized uteri. With the LAVH, the abdominal-pelvic exploration and the ability to perform oophorectomy safely represent the major advantages compared with VH. The specific indications for each of the hysterectomy techniques remain uncertain. However, the purpose of LAVH and total laparoscopic hysterectomy is not to replace VH, but rather to increase the abilities of the gynecological surgeon to perform minimally invasive surgery for more extended indications, avoiding the need of an abdominal hysterectomy also in the presence of ovarian tumors, tubo-ovarian adhesions, endometriosis, or previous pelvic surgery. Although the selected surgical technique is essentially based on the surgeons' experience, all the patients must be informed about the various feasible surgical alternatives, and about their respective risks and benefits.

CONCLUSION

Several surgical and immediate postoperative outcomes were significantly better in the VH group than in the LAVH group. However, further controlled prospective studies are required to identify the best approach for hysterectomy in patients with enlarged myomatous uterus.

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