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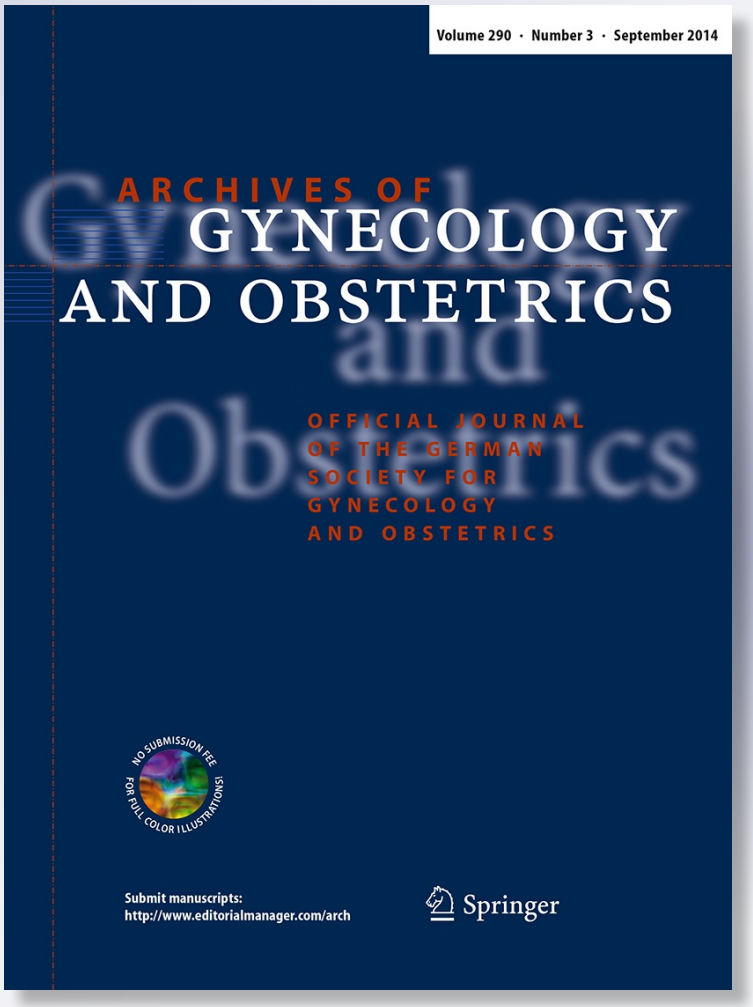

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GENERAL GYNECOLOGY

Randomized comparison of total laparoscopic, laparoscopically assisted vaginal and vaginal hysterectomies for myomatous uteri

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Abstract
Purpose To compare the operative data and early postoperative outcomes of total laparoscopic hysterectomy (TLH), laparoscopically assisted vaginal hysterectomy (LAVH) and vaginal hysterectomy (VH).
Methods One hundred and eight women requiring hysterectomy for enlarged myomatous uterus were randomly allocated into three treatment arms: TLH ($n = 36$); LAVH ($n = 36$); VH ($n = 36$). Randomization procedure was based on a computer-generated list. The primary outcome was the discharge time comparison. The secondary outcomes were operating time, blood loss, paralytic ileus time, intraoperative complications, postoperative pain, and early postoperative complications.
Results The mean discharge time was shorter after VH than after LAVH and TLH ($P = 0.001$). Operating time significantly influenced the discharge time, considered as a dependent variable in general linear model analysis ($P = 0.006$). In contrast, blood loss did not influence the discharge time ($P = 0.55$).The mean operating time was significantly shorter in VH than in TLH and LAVH groups ($P = 0.000$).The intraoperative blood loss was greater during LAVH than during TLH and VH ($P = 0.000$).Paralytic ileus time was shorter after VH than after TLH and LAVH ($P = 0.000$). No intraoperative complications or conversion to laparotomy occurred.
Conclusions VH was the faster operative technique with smaller blood loss and shorter discharge time compared with the others two techniques. So, VH should be considered the preferred approach in patients with enlarged myomatous uteri. When VH is not feasible or salpingo-oophorectomy is required, LAVH or TLH should be considered as valid alternatives. It is necessary to continue prospective comparative studies between the various surgical options to identify the best approach for hysterectomy in each single woman.

Keywords Total laparoscopic hysterectomy · Laparoscopically assisted vaginal hysterectomy · Vaginal hysterectomy · Enlarged myomatous uteri

F. Sesti (✉) · V. Cosi · F. Calonzi · V. Ruggeri · A. Pietropolli · L. Di Francesco · E. Piccione
Section of Gynecology and Obstetrics, Academic Department of Biomedicine and Prevention, Clinical Department of Surgery, Tor Vergata University Hospital, Viale Oxford 81, 00133 Rome, Italy
e-mail: francesco.sesti@uniroma2.it

Introduction

Hysterectomy is a major gynecological operative procedure, whose main indication is symptomatic uterine leiomyoma [1, 2]. Hysterectomy may be performed according to various techniques, but there is not yet an universal agreement between gynecologists about the optimum method of hysterectomy. The route for hysterectomy is based on clinical and technical factors, such as uterine weight or previous vaginal deliveries [3–5]. Total laparoscopic hysterectomy (TLH) offers several advantages in opposition to abdominal hysterectomy (AH), like lower morbidity and faster recovery time [6]. However, it has been reported that TLH takes longer time to perform, and it is associated with a significantly greater rate of complications [1, 7]. Vaginal hysterectomy (VH) offers significant benefits such as reduced hospital stay and improved patient recovery compared with AH, even in patients with enlarged uteri [2, 8]. TLH and VH were associated with similar hospital stay and postoperative recovery times [9–11]. VH was associated with significantly shorter operating time and

lower costs with no detectable difference in quality of life measures or complication rates [12, 13]. Laparoscopically assisted vaginal hysterectomy (LAVH) showed lower postoperative pain and shorter hospital stay in comparison with AH [14, 15]. On the other hand, LAVH took a longer time to perform, and it was more expensive than VH or AH [11, 14, 16]. LAVH can be safely performed for large uterus, despite the increased operating time and blood loss [14].

There are few randomized trials comparing more than two different surgical techniques for hysterectomy [5]. TLH and VH have been compared with traditional AH [10, 17, 18], but nowadays there is only one study in which TLH and VH have been compared with another minimally invasive approach, such as the LAVH [19].

The aim of our prospective trial was to compare the operative data and early postoperative outcomes of TLH, LAVH and vaginal hysterectomy in a consecutive series of patients with symptomatic enlarged myomatous uteri, randomly assigned to each surgical technique.

Materials and methods

The trial was performed at the Section of Gynecology, Department of Surgery, Tor Vergata University Hospital, Rome. Since April 2009–September 2012, all women with symptomatic uterine myomas requiring hysterectomy were considered eligible for the study. Inclusion criteria were: (1) presence of symptomatic or rapidly growing myomas, (2) age <55 years, (3) uterine size ≥12 weeks gestation (12 cm long). Exclusion criteria were: (1) nulliparous women, (2) uterine size ≥16 weeks gestation (16 cm long), (3) previous uterine surgery, (4) suspect malignant gynecological disease.

The study was previously approved by the local ethics committee. There were no conditions that could affect the objectivity of the study. Of 138 women requiring hysterectomy, 128 fulfilled the inclusion criteria and were recruited for the trial. Twenty refused to participate. A written informed consent was obtained from each patient prior to randomization. The enrollment was closed when 108 consecutive patients were included. Thirty-six patients were allocated to each group (Fig. 1). The randomization procedure was based on a computer-generated list using serially numbered, opaque, sealed envelopes. Each patient was blindly allocated by a physician to TLH ($n = 36$) or LAVH ($n = 36$) or VH ($n = 36$). The sequence was concealed until interventions were assigned. Those who performed surgical procedures did not know which operating patients had been included in the study. Those assessing the outcomes were blinded to the group assignments. All procedures were performed by the same equally skilled and experienced surgeons (more than 100 TLH, LAVH or VH surgeries) using an identical technique. Standard preoperative assessment was performed together with abdominal and transvaginal ultrasound (to estimate size, number, site of the myomas and the uterine size), Pap smear and endometrial biopsy. Intraoperative prophylactic antibiotic therapy by cefazolin 2 g was administered to all patients. Gonadotropin-releasing hormone agonists were never administered. For the first 12 h after surgery, pain was controlled with iv administration of ketorolac and tramadol.

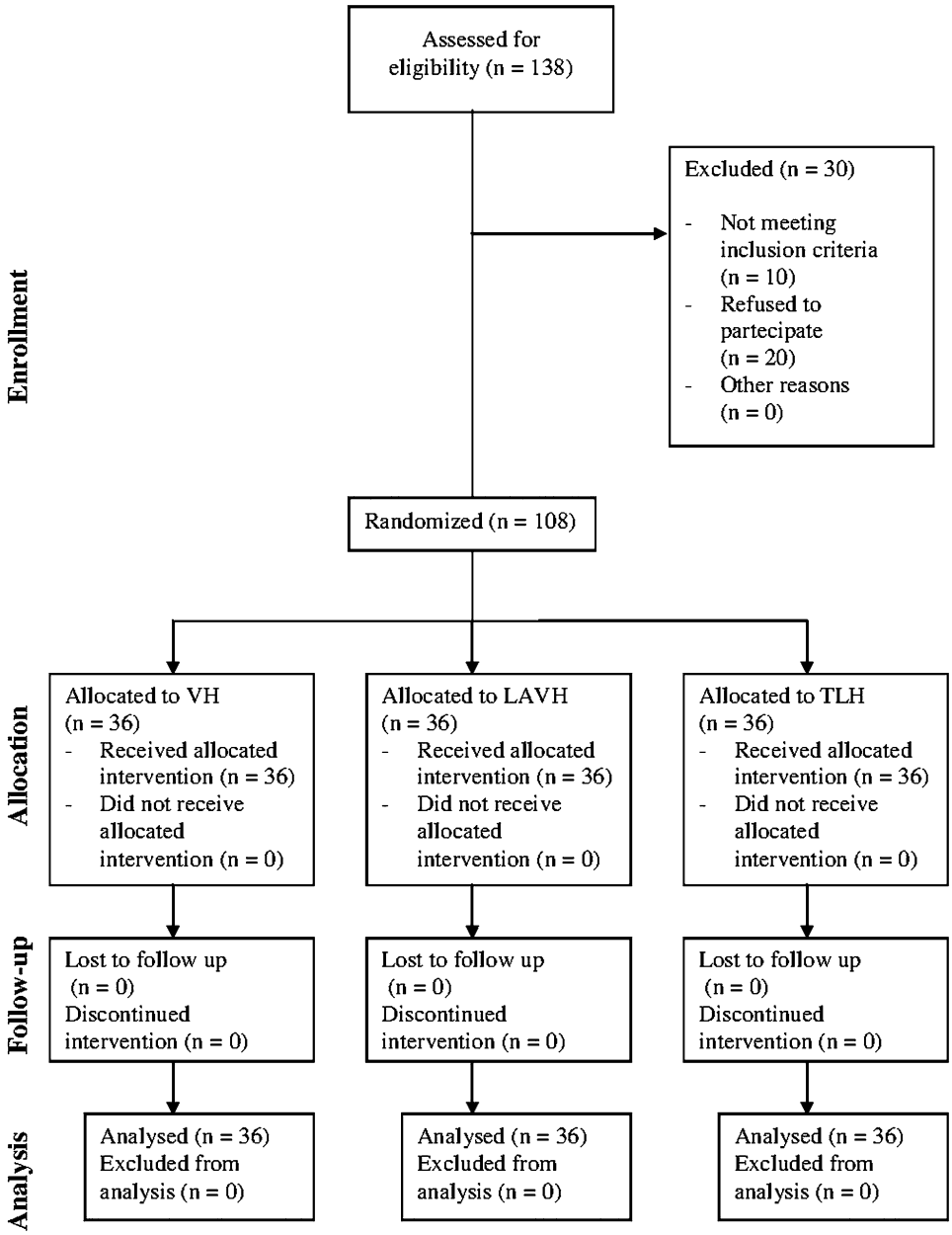
VH was carried out as described by Dargent [20]. If the uterine size did not allow easy exteriorization, bisecting, coring, morcellation, enucleation of myomas or combinations of these volume-reducing techniques were performed [21–23].

LAVH was performed at type ID of laparoscopic assistance, according to the AAGL classification system for laparoscopic hysterectomy [24]. An uterine manipulator was placed into the uterus. Laparoscopy was performed with a 10 mm principal trocar and two ancillary 5 mm trocars. When required, a combined vaginal bisection, coring, morcellation and myomectomy was performed.

The first steps of TLH [6, 24–26] were performed as described for LAVH. After incising the posterior peritoneal leaf of the broad ligament, subsequent steps were performed laparoscopically. The uterus was removed vaginally. When the considerable uterine size demanded, was performed a laparoscopic morcellation.

The primary outcome of the trial was the comparison between the three procedures in terms of discharge time measured in hours after the end of surgery. It was chosen as primary outcome, because it is generally influenced by the main operative data. Before hospital discharge, patients had to tolerate a normal diet, be able to dress themselves, be fully mobile, be apyrexial, be analgesic free, and be satisfied that they could manage at home. The secondary outcome measures were differences in operating time, blood loss, paralytic ileus time, intraoperative complications, intensity of postoperative pain, febrile morbidity (body temperature ≥38 °C in two consecutive measurements ≥4 h apart), early postoperative complications (any unfavorable episode occurring within 30 days from surgery requiring re-admission, blood transfusion, 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 peritoneal 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. Intraoperative complications were considered bowel, urinary or vascular damage. Postoperative abdominal pain was assessed at 24 h by a visual analog scale (VAS), a non-graduated 100 mm line ranging 0 (no pain)–100 (pain as bad as it could be). Women were subdivided

Fig. 1 Flow diagram



in five categories: absence of pain (VAS = 0); mild pain (VAS = 1–25); moderate pain (VAS = 26–50); severe pain (VAS = 51–75); and very severe pain (VAS = 76–100).

For detecting a difference of more than 24 h in discharge time with an alpha error level of 5 % and a beta error of 80 %, it has been estimated that at least 36 patients in each group would have been necessary. The Student's *t* test was used for the analysis of continuous variables. For analyzing discrete variables, χ^2 test or Fisher's exact test was used. The three treatment group outcomes were compared using an one-way analysis of variance followed by Tukey's HSD for post hoc comparison of the mean values. The general linear model (GLM) was used to perform a regression analysis for dependent variables. A *P* value smaller than 0.05 was considered to be statistically significant. All analyses were performed using the statistical software SPSS v15.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Table 1 shows the preoperative patients characteristics. There were no statistically significant differences in age, body mass index (BMI), parity, uterine weight and symptoms between the three groups. Procedures were successfully performed in all patients. Table 2 shows the operative

Table 1 Preoperative patient characteristics

	TLH ($n = 36$)	VH ($n = 36$)	LAVH ($n = 36$)	P
Age (years)	49.7 ± 5.3	49 ± 4.4	48.2 ± 3.3	0.37 (NS)
BMI	27.4 ± 5.8	25.1 ± 3.6	26.2 ± 3.4	0.10 (NS)
Parity	1.9 ± 0.7	2.0 ± 0.9	1.8 ± 0.6	0.54 (NS)
Uterine weight (g)	309.1 ± 88	319.2 ± 107	318.9 ± 100	0.89 (NS)

Values are given as mean ± SD

NS not significant

Table 2 Operative data

	TLH ($n = 36$)	VH ($n = 36$)	LAVH ($n = 36$)	P
Operating time (min)	151 ± 4	70 ± 19	129.6 ± 47	0.000
Blood loss (mL)	204 ± 168	182.8 ± 53	358.3 ± 67	0.000
Conversion to laparotomy	0 (0)	0 (0)	0 (0)	NS
Intraoperative complications	0 (0)	0 (0)	0 (0)	NS

Values are given as mean ± SD or number (percentage)

NS not significant

parameters in the three groups. The mean operating time was significantly shorter after VH (70 min) than after TLH (151 min; $P = 0.000$) and LAVH (129.6 min, $P = 0.000$). In the comparison between TLH and LAVH, there was no statistically significant difference regarding mean operating time ($P = 0.056$), even if the mean operating time (151 vs 129.6 min) was longer after the former procedure. Blood loss had an influence on the operating time considered as a dependent variable in the GLM analysis ($P = 0.002$), and this effect was particularly strong for LAVH ($P < 0.05$). On the contrary, the uterine weight did not have any effect on the operating time considered as a dependent variable in the GLM analysis ($P = 0.21$). Intraoperative blood loss was significantly greater ($P = 0.000$) after LAVH (358.3 mL) than after VH (182.8 mL) and TLH (204 mL). In the comparison between VH and TLH, there was no significant difference regarding blood loss ($P = 0.67$). Uterine weight did not have any effect on the blood loss considered as a dependent variable in GLM analysis ($P = 0.42$). No intraoperative complications occurred, and no case returned to theater in all groups. No conversion to standard laparotomy was necessary.

Regarding the early postoperative outcomes (Table 3), the mean hospital discharge time was significantly shorter after VH (50.7 h) than after LAVH (76.7 h; $P = 0.01$) and TLH (77.3 h, $P = 0.001$). In the comparison between LAVH and TLH, there was no significant difference in terms of mean discharge time ($P = 0.58$). Operating time

Table 3 Early postoperative outcomes

	TLH ($n = 36$)	VH ($n = 36$)	LAVH ($n = 36$)	P
Paralytic ileus time (h)	28.1 ± 8	19.3 ± 3	26.4 ± 3	0.000
Hospital discharge time (h)	77.3 ± 28	50.7 ± 24	76.7 ± 35	0.001
Postoperative complications	1 (2.8)	0 (0)	2 (5.6)	NS

Values are given as mean ± SD or number (percentage)

NS not significant

had an effect on discharge time, considered as a dependent variable in GLM analysis ($P = 0.006$). On the contrary, blood loss did not have any effect on discharge time considered as a dependent variable in GLM analysis ($P = 0.55$). The mean paralytic ileus time was significantly shorter after VH (19.3 h) than after TLH (28.1 h; $P = 0.000$) and LAVH (26.4 h; $P = 0.000$). There was no significant difference regarding this postoperative outcome between TLH and LAVH ($P = 0.32$). The operating time influenced the paralytic ileus time considered as a dependent variable in GML analysis ($P = 0.000$). Figure 2 shows the difference between the three groups regarding the postoperative pain intensity assessed at 24 h using a VAS. Seventeen women (47 %) reported absence of pain (VAS = 0) after VH, 19 (53 %) after TLH, and 5 (14 %) after LAVH. Ten women (28 %) complained of mild pain (VAS = 1–25) after VH, 11 (30 %) after TLH, and 22 (61 %) after LAVH. Four women (11 %) complained of moderate pain (VAS = 26–50), two (6 %) severe pain (VAS = 51–75), and three (8 %) very severe pain (VAS = 76–100) after VH. Two women (6 %) complained of moderate pain after TLH, three (8 %) severe pain, and one (3 %) very severe pain after TLH. Four women (11 %) complained of moderate pain, four (11 %) severe pain, and one (3 %) very severe pain after LAVH. The statistical analysis showed that there were no significant differences among the three techniques considering this variable ($P = 0.32$). Postoperative fever was observed in only three women, one after TLH, one after LAVH, and one after VH, respectively. With regard to early postoperative complications, two cases of bleeding were observed in the LAVH group. Those patients required blood transfusion. In the TLH group, one patient presented transient urinary retention. She was successfully treated using continuous bladder drainage with catheterization for 5 days.

Discussion

The aim of our study was to compare the operative data and early postoperative outcomes of TLH, LAVH and vaginal

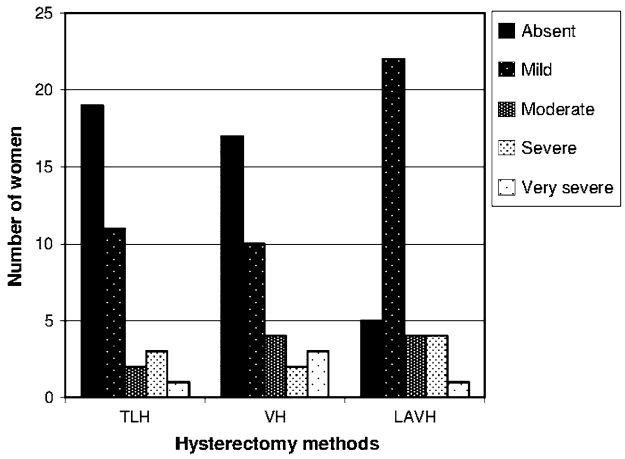


Fig. 2 Postoperative pain intensity

hysterectomy in patients with symptomatic myomas and enlarged uteri. To eliminate eventual bias in our study, we adopted rigid criteria to select the patients into the study. We excluded nulliparous women and patients with previous uterine surgery, like cesarean section, which have been reported to hinder vaginal surgery [27]. Moreover, considering the importance of individual surgeon's experience in laparoscopic and vaginal surgery, all procedures were performed by equally skilled and experienced gynecologic surgeons, using an identical laparoscopic and vaginal technique. In the LAVH group, the level of laparoscopic assistance was decided a priori and limited to judge accessibility and mobility of the uterus excluding the presence of problems, such as adhesions, to secure the round ligaments, and the ovarian or infundibulo-pelvic ligaments, and then to turn to the vaginal part, according to degree ID (dissection up to but not including uterine arteries) of the AAGL classification [24]. To ensure a homogeneous uterine weight in the three groups, we included women with large uterine size between 12 and 16 weeks of gestation. Finally, unlike other studies focused on the same minimally invasive techniques of hysterectomy [5, 19], in our trial we used the GLM analysis allowing the investigation of interactions between variables (regression analysis).

As regards the primary outcome of our trial, the mean hospital discharge time was significantly shorter after VH than after LAVH ($P = 0.01$) and TLH ($P = 0.000$), whereas it was similar in the LAVH and TLH groups ($P = 0.58$). The operating time significantly influenced the discharge time considered as a dependent variable in GLM analysis ($P = 0.006$). On the contrary, the blood loss did not have any effect on the discharge time ($P = 0.55$). In the literature, the data on the discharge time after the three methods of hysterectomy are discordant. Some authors found a longer discharge time after LAVH [37], while other studies showed comparable discharge times for the three methods [1, 5, 10, 18]. The different discharge criteria applied in the different studies could justify these discrepancies. For example, in our study rigid criteria were adopted, so the patients returned home only when they were fully autonomous and felt completely fine.

With regard to the secondary outcome measures analyzed, the mean operating time was significantly shorter with VH ($P = 0.000$) than with TLH and LAVH. Also in the literature, several studies reported that TLH and LAVH required longer operating time than VH [5, 7, 10, 18, 19, 28–31]. In the LAVH group, a laparoscopic check for bleedings was executed at the end of the vaginal procedure and perhaps it may have prolonged the operative time. Another possible explanation may lie in the time of the uterine morcellement that may have been different in the group TLH, where it was carried out laparoscopically, and in the groups LAVH and VH where it was performed by the vaginal route. Unfortunately, we have not calculated the relative times of uterine morcellement performed laparoscopically and vaginally. So, we cannot determine with certainty as this issue may have influenced the operative time.

The mean operating time was strongly influenced by the intraoperative blood loss, particularly for LAVH. In fact, although other studies reported controversial results [10, 18, 32], in our study the LAVH group showed a greater blood loss compared with VH and TLH ($P = 0.000$). Considering that the uterine weight and other surgical factors were analogous in the three groups and that the uterine weight did not have any effect on the operating time considered as a dependent variable in the GLM analysis ($P = 0.21$), as well as on the blood loss ($P = 0.42$), this finding that is in line with another study comparing LAVH, TLH and VH [19] is difficult to be explained. It is not yet clear whether the laparoscopic or vaginal route is better for the division of the uterine vessels. Some authors [33, 34] observed less bleeding during the vaginal step when the uterine vessels were laparoscopically transected, as in the TLH procedure. On the other hand, the transvaginal approach may be associated with retrograde bleeding, especially when an uterine morcellation is necessary, as found by Unger [35].

There was no significant difference ($P = 0.056$) in the comparison between TLH and LAVH regarding operating time, even if the mean operating time was longer after the former procedure, in agreement with a systematic review and meta-analysis on methods of hysterectomy [5] and others studies [19, 36].

Regarding the early postoperative outcome, the VH group showed a mean paralytic ileus time significantly inferior than the other groups ($P = 0.0001$). The extent of the peritoneal opening and the visceral handling were analogous in the three techniques. This finding could be explained by the shorter operating time in the VH group. In

fact, the operating time had an influence on paralytic ileus time considered as a dependent variable in GLM analysis ($P = 0.000$). One could also assume a potential role of pneumoperitoneum, which was present in TLH and LAVH groups, but not in VH in prolonging the duration of paralytic ileus.

Finally, there were no significant differences among the three methods regarding the postoperative pain intensity assessed at 24 h ($P = 0.32$).

With regard to early postoperative complications, like the need of re-admission, blood transfusion, or repeated surgery, we observed two cases of bleeding that required blood transfusion in the LAVH group and one case of transient urinary retention in the TLH group. No significant differences were found among the three groups considering the occurrence of early postoperative complications.

In the literature, the review of the major reports about hysterectomy demonstrates that the vaginal approach is employed more frequently for genital prolapse or small- or medium-sized myomatous uterus. LAVH offers some advantages compared with VH, such as the abdominal–pelvic exploration and the ability to perform salpingo-oophorectomy safely. However, one disadvantage of this procedure is the blood loss, which was higher in patients undergoing LAVH.

Studies about TLH show discrepant results. Some authors [38] reported limited advantages with TLH, while others [39] assert that TLH represents a favorable method because it allows abdomen–pelvic exploration. Our results, in accordance with a recent study [19], did not show a specific advantage of TLH in comparison with the other two techniques. Moreover, the TLH group showed the longest operating time. In our opinion, TLH should be particularly beneficial when VH cannot be performed, for example in case of vaginal stenosis or fixed uteri, and if it is carried out by surgeons highly trained in laparoscopic surgery.

In agreement with the literature [19, 30, 31], our study shows that VH, when there are no contraindications, is the preferred hysterectomy technique, also from the economical point of view. In fact, it was associated with the shortest hospital discharge time and did not need expensive and sophisticated laparoscopic instruments which are employed in TLH or LAVH.

TLH or LAVH permit overcoming some VH contraindications, so they are preferable in patients with endometriosis, adhesions or ovarian cysts because they combine the advantages of both vaginal and laparoscopic approaches.

In conclusion, the specific indications for each surgical approach remain uncertain. The choice depends on the skill and practice of the surgeon, and on the medical conditions. In any case, women must be informed about the various possible alternatives and their respective risks and benefits. VH proved to be feasible even for large uteri. It was the faster operative technique and had a smaller blood loss compared with LAVH and TLH. TLH and LAVH required a longer average hospital stay than VH. The purpose of LAVH and TLH 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. Nevertheless, it needs further prospective comparative studies between the various surgical options aiming to identify the best approach for hysterectomy in each single woman.

Conflict of interest We declare that we have no conflict of interest.

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