

GYNECOLOGY

Laparoscopic vs vaginal hysterectomy for benign pathology

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OBJECTIVE: The objective of the study was to compare length of stay, blood loss, operative time, and pain of laparoscopic and vaginal hysterectomy.

STUDY DESIGN: This was a prospective, randomized, controlled comparison between vaginal (VH) and laparoscopic (LH) hysterectomy among 60 consecutive patients with a uterine volume of 300 mL or less and without uterine prolapse. Patients were followed up for 12 months.

RESULTS: The groups were significantly different for mean operative time (VH: 81 ± 30 minutes; LH: 99 ± 25 minutes; $P = .033$) and blood loss (LH: 83 ± 57 mL; VH: 178 ± 149 mL; $P = .004$). Bilateral adnexectomy was performed when preoperatively planned

in 73% of cases of the vaginal arm, whereas it was always performed in the laparoscopic arm ($P = .045$). Postoperative pain on day 0 and the number of days of analgesic request were higher in the vaginal group ($P = .023$ and $P = .017$, respectively). LH was associated with a reduced hospital stay (LH: 2.7 ± 0.5 days; VH: 3.2 ± 0.6 days; $P < .001$). There were no differences between the groups at the follow-up.

CONCLUSION: Laparoscopic hysterectomy results in a shorter hospital stay, less blood loss, and less postoperative pain compared with vaginal hysterectomy.

Key words: hysterectomy, laparoscopy, prospective, randomized, vaginal

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After cesarean section, hysterectomy is the second most frequent gynecological operation:¹ in France it is performed in 60,000 women per year;² in the United States, almost 30-40% of women younger than 65 years have undergone a hysterectomy;^{3,4} and in Italy, the rate of this operation for patients between 40 and 70 years old is 15%.⁵

Traditionally, about 70-80% of hysterectomies have been performed by laparotomy.^{3,6} In the last 10 years, however, several published studies demonstrated that laparotomic hysterectomy, compared with both vaginal and laparoscopic hysterectomy, has a higher inci-

dence of complications, a longer hospital stay, and longer convalescence.⁷⁻⁹ As a consequence, in Western countries, a reduction of 38% of laparotomic hysterectomy was observed, with an increase of laparoscopic and vaginal operations.¹⁰⁻²⁵

There is a paucity of studies, however, that compare vaginal and laparoscopic hysterectomy, but it is still in debate which of these approaches is preferred in case of benign pathology.²⁶⁻³⁴ The aim of the present study was to compare, in a prospective randomized study, the intra- and postoperative outcome of vaginal and laparoscopic hysterectomy, both performed according to standardized techniques, with a 12-month follow-up. The main outcome was to evaluate whether there could be a difference in terms of earlier discharge between the 2 approaches.

MATERIALS AND METHODS

From April 2004 to April 2006, patients referred to the Department of Gynecology and Obstetrics at San Paolo Hospital, University School of Medicine (Milan, Italy), with an indication to vaginal hysterectomy for benign pathology were invited to participate in a randomized

trial to compare vaginal hysterectomy (VH) and laparoscopic hysterectomy (LH).

Exclusion criteria were a uterine volume greater than 300 mL, previous surgery for pelvic inflammatory disease or endometriosis, suspicion of malignancy, the presence of an ovarian cyst greater than 4 cm, and a vaginal prolapse higher than first degree. All the patients underwent a preoperative ultrasound scan, and the uterine volume was estimated according to the ellipsoid formula: longitudinal diameter (apart from cervix) \times transverse diameter \times anteroposterior diameter \times 0.523. The study protocol was approved by the local institutional review board, and all participating patients gave their consent.

All the procedures were performed by 2 skilled surgeons for each group. To minimize the potential confusing effect of the learning curve, only surgeons who had performed at least 50 procedures were involved. The vaginal hysterectomy was performed following Heaney's technique.³⁵ The laparoscopic technique was always a total laparoscopic hysterectomy (IV E in the American Association of Gynecologic

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Laparoscopists [AAGL] classification.^{36,37} The AAGL classification describes the portion of the procedure completed under laparoscopic direction, with 4 types of hysterectomies (types I-IV) arranged according to increasing laparoscopic intervention. Type IV hysterectomy correspond to the complete detachment of cardinal-uterosacral ligament complex. "E" reflects the removal of the entire uterus, the laparoscopic closure of the vaginal cuff and its suspension to the uterosacral ligaments. We used the Clermont-Ferrand uterine manipulator for this type of hysterectomy.

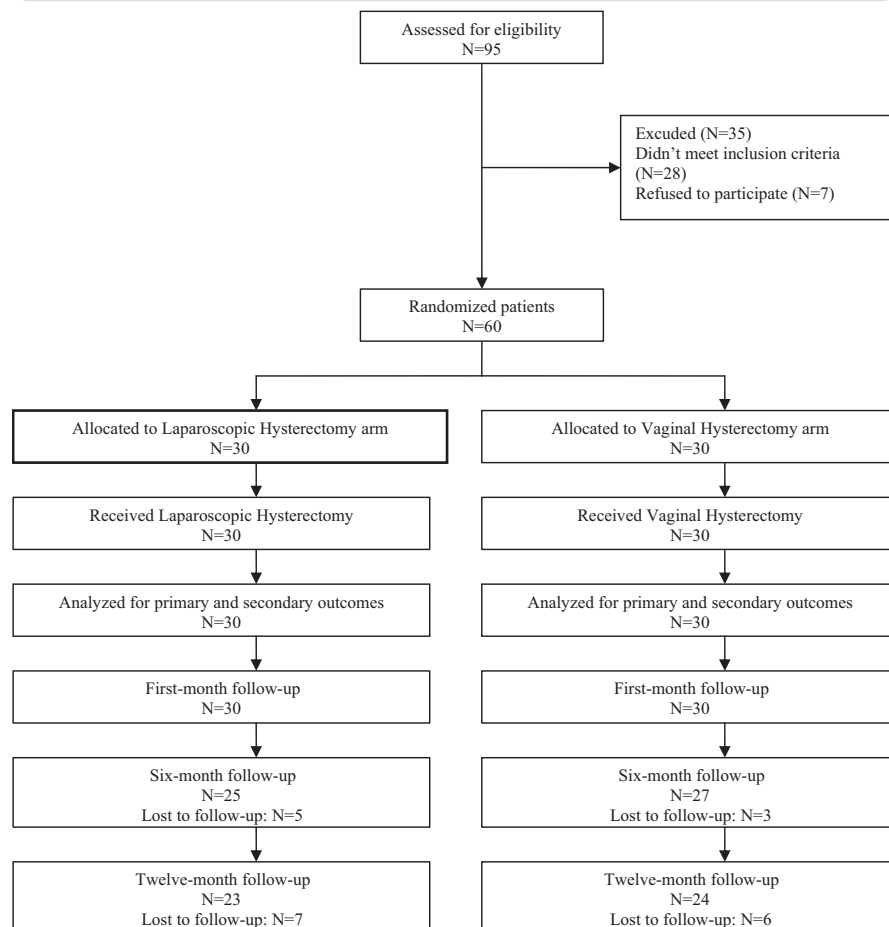
For each patient we recorded anamnestic data, including age; parity; previous surgery; body mass index (BMI); age of menopause or last period; the association of adnexal pathology and the indication to hysterectomy; intraoperative parameters including complications, blood loss, conversion to laparotomy, time of surgery, execution of adnexectomy (if preoperatively planned), correspondence to the ultrasound analysis, additional pelvic pathologies found during the surgery; and postoperative parameters including hospital stay, fever (temperature > 38°C), reduction of hemoglobin at day 1, restarting of bowel activity, infections, urinary dysfunctions, and pelvic pain. Foley's vesical catheter was maintained until the morning of the first day after surgery.

To evaluate postoperative pain, we used the visual analog scale (VAS) score on days 0, 1, 2, and 3 after surgery; the number of analgesic tablets and vials requested by the patients was also recorded. Prophylactic antibiotic was given to all patients at the beginning of the surgery and repeated 12 h later.

During the follow-up at months 1, 6, and 12, we made a clinical and ultrasound evaluation of the patients; we asked for pelvic pain, urinary and bowel dysfunctions, sexual problems, and satisfaction of the patients. We also used a questionnaire,⁷ filled in at home, and delivered during the visits to assess these latest parameters.

The primary endpoint of the trial was the hospital stay. We always used the same parameters to discharge patients:

FIGURE
Flow of participants throughout the study



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restarted bowel motility, regular abdomen and vaginal objectivity, absence of temperature (< 37°C), lack of urinary problems, and patient comfort. The secondary goals included pain, measured by a VAS, analgesic requests, blood loss, and execution of adnexectomy if preoperatively planned.

The sample size was calculated based on the assumption that the expected discharge at day 2 was less than 5% in the vaginal arm and more than 30% in the laparoscopic arm. Based on these assumptions and setting the type I and II errors to the usual levels of 0.05 and 0.20, respectively, the number of cases to be treated per arm was about 30.

Patients were randomized by means of a computer-generated list into 2 groups. Sealed opaque envelopes containing treatment allocation were opened after

inclusion. Patients and physicians were not blinded to the treatment allocation.

The data were analyzed on an SPSS statistical analysis package (SPSS Inc, Chicago, IL), using the Student's *t*-test for comparison of continuous data, and the χ^2 analyses, including the Fisher's exact test, for nominal data. A value of $P < .05$ was accepted as significant.

RESULTS

Sixty patients were recruited; 30 underwent VH and 30 underwent LH. The **Figure** describes the flow of the patients through the trial. All the participants were analyzed for primary and secondary outcomes. Baseline characteristics of the patients and indications to surgery were comparable (**Table 1**).

TABLE 1
Baseline characteristics and indications to surgery

| Baseline characteristics | Laparoscopy | Vaginal | P value |
|-------------------------------|-------------|-------------|---------|
| Age (y) ± SD | 48.96 ± 8.9 | 51.26 ± 8.8 | .364 |
| Menopause, n | 9 (30%) | 9 (30%) | 1.000 |
| Nulliparity, n | 10 (33%) | 3 (10%) | .087 |
| Previous cesarean section, n | 4 (13.3%) | 3 (10%) | .664 |
| Previous pelvic surgery, n | 18 (60%) | 16 (53.3%) | .569 |
| BMI ± SD | 24.4 ± 4.2 | 27.2 ± 6.3 | .057 |
| Mean uterine volume (mL) ± SD | 173 ± 72.5 | 166 ± 66.2 | .729 |
| Indications to surgery, n | | | .204 |
| Myomas | 15 (50%) | 22 (73.3%) | |
| Adenomyosis | 7 (23.3%) | 3 (10%) | |
| Endometrial hyperplasia | 5 (16.6%) | 5 (16.6%) | |
| Ovarian cysts | 3 (10%) | 0 (0%) | |
| Planned surgery, n | | | 1.000 |
| Hysterectomy | 13 (43.3%) | 12 (40%) | |
| H + unilateral adnexectomy | 2 (6.7%) | 2 (6.7%) | |
| H + bilateral adnexectomy | 15 (50%) | 16 (52.3%) | |

BMI, body mass index; H, hysterectomy.

Data are expressed as number (percentage), mean ± SD.

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LH was associated with a longer mean operative time (VH: 82 ± 30 minutes, LH: 99 ± 25 minutes; $P = .033$) and a reduced mean blood loss (LH: 84 ± 57 mL, VH: 178 ± 149 mL; $P = .004$).

Eighteen patients in the vaginal group and 17 in the laparoscopic group were eligible for mono- or bilateral adnexectomy. In the laparoscopic hysterectomy arm, bilateral adnexectomy was performed in 100% of patients, when preoperatively planned, as compared with 73% ($n = 13$) of patients in the vaginal

hysterectomy arm ($P = .045$). The 2 groups were comparable for ultrasound correspondence (95% for each group), additional pathologies found during the operation (6 in vaginal and 7 in laparoscopic arm), intraoperative complications, and unintended laparotomy (none occurred in either group) (Table 2).

Postoperative outcome is illustrated in Table 3. LH was associated with a reduced hospital stay (2.7 ± 0.5 days) as compared with VH (3.2 ± 0.6 days) ($P < .001$). In particular, we found that

more than 33% of patients in the laparoscopic arm could be discharged from the hospital on day 2 vs only 3.3% of patients in the vaginal arm. We described a major complication (thrombosis at day 6) in 1 patient of the vaginal group ($P = .173$), which was treated with heparin and had a spontaneous resolution. Postoperative pain on day 0 according to the VAS (VH: 5.2 ± 3.4 ; LH: 2.7 ± 2.8 ; $P = .023$) and the number of days of analgesic request were higher in the vaginal group (LH: 0.96; VH: 1.65; $P = .017$) (Table 3).

At the first, sixth, and twelfth month of evaluation, there were no significant differences in gynecological and ultrasound objectivity. In addition, no differences in pelvic pain, urinary dysfunctions, sexual activity, vaginal infections, and the resumption of work were observed (Table 4).

COMMENT

There is now a general consensus that vaginal hysterectomy should be considered the gold standard if compared with laparotomic hysterectomy in case of benign uterine pathologies with mobile and no large uterus and without adnexal pathologies.^{7,38} Such a superiority, however, is not so clearly demonstrated over laparoscopic hysterectomy.^{26,34}

In our prospective study, we randomized 60 patients with an indication to vaginal hysterectomy into 2 groups: vaginal and laparoscopic hysterectomy. Baseline characteristics between the 2 arms did not significantly differ. A slight, albeit not significant, difference was observed for BMI. We consider that the difference is due only to randomization. As a matter of fact, we know that the BMI does not have an impact on the time of surgery, the blood loss, the time of hospitalization, and the intra- and postoperative complication rate in laparoscopic surgery.^{39,40} In addition to that, based on previous available data, we decided also to include in the study patients with previous cesarean section,¹⁶ abdominal surgery¹⁹ (apart for endometriosis or pelvic inflammatory disease surgery), and nulliparity.¹⁸

TABLE 2
Intraoperative parameters

| Intraoperative parameters | Laparoscopy | Vaginal | P value |
|--|-------------|---------------|---------|
| Mean operative time ± SD | 99.3 ± 25.4 | 81.95 ± 29.6 | .033 |
| Mean blood loss ± SD | 83.9 ± 57.2 | 178.2 ± 149.4 | .004 |
| Adnexial pathology, n | 9 (30%) | 8 (26.7%) | 1.000 |
| Adnexectomy if preoperatively planned, n | 17 (100%) | 13 (73%) | .045 |
| Complications, n | 0 (0%) | 0 (0%) | |

Data are expressed as number (percentage), mean ± SD.

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TABLE 3
Postoperative parameters and pain (analogic scale)

| Postoperative parameters | Laparoscopy | Vaginal | P value |
|---------------------------------------|--------------|--------------|---------|
| Mean hospital stay (d) ± SD | 2.7 ± 0.53 | 3.2 ± 0.64 | < .001 |
| 2, n | 10 (33.3%) | 1 (3.3%) | |
| 3, n | 19 (63.3%) | 22 (73.3%) | |
| 4, n | 1 (3.4%) | 5 (16.6%) | |
| 5, n | | 2 (6.7%) | |
| Mean delta hemoglobin (g/dL) ± SD | -1.25 ± 0.93 | -1.57 ± 0.72 | .252 |
| Restarting urinary function (mean, d) | 1.64 ± 0.56 | 1.86 ± 0.36 | .132 |
| Temperature (> 38°C) | 10% | 18.8% | .660 |
| Restarting bowel motility (mean, d) | 1.77 | 1.93 | .336 |
| 1, n | 10 (33.3%) | 8 (26.7%) | |
| 2, n | 17 (56.7%) | 16 (53.3%) | |
| 3, n | 3 (10%) | 6 (20%) | |
| Major complications ^a | 0 (0%) | 1 (3.3%) | .173 |
| Pain | | | |
| Day 0 (mean ± SD) | 2.74 ± 2.8 | 5.17 ± 3.4 | .023 |
| Day 1 (mean ± SD) | 3.95 ± 3.2 | 4.00 ± 2.9 | .958 |
| Day 2 (mean ± SD) | 1.95 ± 1.6 | 2.56 ± 2.4 | .370 |
| Day 3 (mean ± SD) | 1.25 ± 1.3 | 1.67 ± 1.2 | .520 |
| Mean days of analgesic request | 0.96 ± 0.92 | 1.65 ± 0.99 | .017 |

Data are expressed as number (percentage), mean ± SD.

^a One patient in the vaginal arm had a major complication (thrombosis at day 6) and was treated with heparin and had a spontaneous resolution.

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In the present series, the operating time was shorter for vaginal hysterectomy. This result is consistent with previous reports. The mean difference in the operating time between the vaginal and laparoscopic hysterectomy, however, was in our experience (18 minutes) clearly lower than the values that have been previously reported by other authors (41 minutes³² and 44.5 minutes⁴¹).

We also observed a significant difference in intraoperative blood loss, confirming the findings of Jugnet et al,⁴² who reported a blood loss of 182 mL during vaginal hysterectomy vs 98 mL during laparoscopic hysterectomy. We failed to observe a difference when considering the decrease in hemoglobin concentration the first day after surgery (VH: -1.57 g/dL; LH: -1.25 g/dL; $P = .252$). In comparison, Ribiero et al³² described a higher intraoperative blood

loss in the vaginal arm and also found a significantly higher reduction in hemoglobin and hematocrit levels ($P = .0001$ and $P = .0023$, respectively). Cosson et al⁴³ reported a reduction of severe hemorrhages in the vaginal hysterectomy (2%) compared with the celioscopic approach (5.3%) ($P = .0001$).

We observed a statistically significant difference in the execution of bilateral adnexectomy when preoperatively planned; this procedure was performed in only 73% of patients in the vaginal arm and in 100% of patients in the laparoscopic arm ($P = .045$).

Our data compare favorably with those previously published. Ballard and Walters⁴⁴ reported 65% of vaginal salpingo-oophorectomy performed in patients with adnexal pathologies or for prophylaxis. Moreover, even if rare, the procedure could produce a higher risk of hemorrhages.^{45,46} Lambaudie et al²⁴ ob-

served that only 51.8% of nulliparous women submitted to a vaginal hysterectomy had a supplementary adnexectomy; the authors concluded that in case of an indication of adnexectomy in nulliparous women, laparoscopic access should be preferred. According to Wilcox et al,³ salpingo-oophorectomy is performed in only 10.3% of patients submitted to vaginal hysterectomy.

These results appear very far apart from what Davies et al⁴⁷ and Kovac and Cruikshank⁴⁸ produced in their studies. The first, in fact, reported that bilateral adnexectomy can be effectively performed in 95-97% of colpohysterectomy. This procedure adds a mean of only 14 minutes to the surgery without any impact on intra- and postoperative complications and time of hospital stay. Kovac and Cruikshank⁴⁸ confirmed the data, emphasizing that 99.9% of ovaries can be removed vaginally. By the analysis of literature,^{3,24,44-46} those percentages⁴⁷⁻⁴⁹ appear excessive.

Bilateral salpingo-oophorectomy is extremely important in peri- and postmenopausal women in which the probability of developing an ovarian cancer is about 1%. This aspect is of particular importance in women with a high risk for that pathology (familiarity for breast or ovarian cancer; previous breast, gastrointestinal, and endometrial cancer). In those groups the probability to detect an occult ovarian cancer is 17%.⁵⁰ Moreover, the execution of prophylactic adnexectomy eliminates the problem of adnexal torsion, benign ovarian pathologies, and prolapsed salpinx (7.91%).⁵¹

In the present series, there were no ureteral injuries, incidental cystotomies, or any other intra- and postoperative complications with the exception of a thrombosis at day 6 in 1 patient in the vaginal group who was treated with heparin and had a spontaneous resolution. Similarly, Johnson et al⁴¹ did not report significant differences between the 2 approaches in this respect. Noteworthy is the fact that the rate of complication does not appear to differ between the 2 procedures after concluding the learning curve.^{30,52-54} In this regard, it must be noted that it has been estimated that

TABLE 4
First-month, 6-month, and 12-month follow-up

| Parameters analyzed | First month | | | Six months | | | Twelve months | | |
|-----------------------|-------------|------------|---------|-------------|------------|---------|---------------|------------|---------|
| | Laparoscopy | Vaginal | P value | Laparoscopy | Vaginal | P value | Laparoscopy | Vaginal | P value |
| N pazienti | 30 | 30 | | 25 | 27 | | 23 | 24 | |
| Genital prolapse, n | | | .141 | | | .185 | | | .516 |
| Absence | 25 (83.3%) | 22 (73.3%) | | 16 (64%) | 14 (51.8%) | | 17 (73.9%) | 15 (62.5%) | |
| I-II degree | 5 (16.7%) | 8 (26.7%) | | 9 (36%) | 13 (48.2%) | | 6 (26.1%) | 9 (31.5%) | |
| III-IV degree | 0 (0%) | 0 (0%) | | 0 (0%) | 0 (0%) | | 0 (0%) | 0 (0%) | |
| Urinary problems, n | | | 1.000 | | | 1.000 | | | 1.000 |
| Absence | 28 (93.4%) | 28 (93.4%) | | 21 (84%) | 21 (77.8%) | | 20 (87%) | 21 (87.5%) | |
| Urgency | 1 (3.3%) | 1 (3.3%) | | 2 (8%) | 3 (11.1%) | | 1 (4.3%) | 1 (4.2%) | |
| IUS | 1 (3.3%) | 1 (3.3%) | | 2 (8%) | 3 (11.1%) | | 2 (8.7%) | 2 (8.3%) | |
| Sexual activity | | | 1.000 | | | 1.000 | | | 1.000 |
| No | 95% | 95% | | 0% | 0% | | 0% | 0% | |
| Yes | 5% | 5% | | 100% | 100% | | 100% | 100% | |
| Resumption of work, d | | | .689 | 100% | 100% | 1.000 | 100% | 100% | 1.000 |
| ≤ 21 | 44% | 50% | | | | | | | |
| ≥ 21 | 56% | 50% | | | | | | | |
| Mean | 25.2 | 22.6 | | | | | | | |

Data are expressed as number (percentage).

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about 30 procedures are required to properly perform the procedure.

Some studies have underlined that the laparoscopic approach is related to a high incidence of ureteral and bladder lesions.⁵¹ In addition, Garry et al,²⁶ in their eVALuate study, reported a similar observation. They presented a concurrent pair of randomized controlled trials to eVALuate the relative roles of Vaginal, Abdominal and Laparoscopic hysterectomy in routine gynecological practice. We believe that their data should be interpreted with caution, because they used different and nonstandardized laparoscopic techniques; in particular, precise information of the technique used is omitted in almost 30% of patients with major complications. Only the standardization of the approach allows the reduction of complications, operative time, and time of learning curve.^{55,56}

We made the evaluation of the postoperative pain (days 0-4) using the VAS score. The results showed a significant difference in the 2 arms at day 0 ($P = .023$), with greater pain referred by the

patients in the vaginal arm (mean 5.17 vs 2.74 of laparoscopy). In the following days there was no significant difference. Moreover, we found a difference in mean days of analgesic request (LH: 0.96 day, VH: 1.65 days; $P = .017$). Also, the number of tablets and vials requested by the patients was higher in the vaginal arm but not significantly ($P = .115$). These data are in line with findings reported by Garry et al²⁶ and by Jugnet et al.⁴² The authors did not detect differences in terms of pain referred but stressed the higher request of analgesics by the patients who underwent vaginal hysterectomy during the first 48 hours ($P < .0005$).^{26,42} These results may be due to the important traction on the uterus required during vaginal hysterectomy and also to the use of vaginal surgical instruments.

The mean hospitalization time, in our study, was 2.7 days in the laparoscopic arm vs 3.2 days in the vaginal arm ($P < .001$). Similar data have been recently reported by Morelli et al⁵⁷ (LH: 2.9 days; VH: 3.3 days). Makinen et al.⁵² also

found a significant reduction of hospital stay in laparoscopic vs vaginal hysterectomies (LH: 3.4 ± 2 days; VH: 5.9 ± 2.7 days; $P < .0001$). On the contrary, other studies in the literature did not confirm a significant difference between the approaches.^{26,31,33,34,41,42,54,58} Of note, we found that, using standardized parameters, more than 33% of patients in the laparoscopic arm could be discharged from the hospital at day 2 after surgery vs only 3.3% of patients in the vaginal arm. This evidence, in our opinion, is important in terms of medical cost, patients' recovery, and satisfaction.

Except for the pain at day 0 and the mean days of analgesic request, there were no significantly different parameters between the 2 groups that could justify a longer stay of the vaginal group patients. Nevertheless, there were some postoperative parameters not individually significant but all in all favorable to a faster discharge for the laparoscopic arm. In particular, we found in vaginal hysterectomies a higher mean of delta hemoglobin (-1.57 vs -1.25); a

slower restart of bowel motility and urinary function (1.93 vs 1.77 and 1.86 vs 1.64, respectively); more cases of temperature greater than 38°C (18.8% vs 10%); a higher mean of pain at days 1, 2, and 3; and a higher number of vials requested.

So, the addition of all these elements has produced a longer hospital stay for the vaginal group and less disease in laparoscopic patients.

The resumption to work was not significantly different between the groups (mean, VH: 22.6 days; LH: 25.2 days; $P = .689$). The result is in line with those published in the literature.^{41,42} These data are well correlated with the absence of differences in pelvic pain evaluated at the first-month follow-up.

Moreover, no differences were observed in terms of satisfaction and sexuality after the operation in the first 12 months. That result is confirmed by other authors.^{26,59} A larger sample size and totally blinded perioperative care would be needed to have the study be more definitive, even if the latter is somewhat difficult.

In conclusion, our study demonstrates that the choice of the vaginal approach to perform a hysterectomy for benign pathologies does not seem to be so obvious. As a matter of fact, it is true that this approach allows a spinal anesthesia and is associated with a reduced mean surgery time as compared with laparoscopy. However, it is also true that laparoscopic hysterectomy is associated with a reduction of blood loss, postoperative pain, and hospital stay. Furthermore, the laparoscopic approach allows the performance of a bilateral adnexectomy, when indicated, in 100% of cases; this could be of great relevance for the choice of the way to approach a hysterectomy. ■

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