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## A Multicenter Randomized Comparison of Laparoscopically Assisted Vaginal Hysterectomy and Abdominal Hysterectomy in Abdominal Hysterectomy Candidates

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**Objective:** To compare intraoperative and postoperative outcomes between laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy among patients who are not eligible for vaginal hysterectomy.

**Methods:** Study subjects were randomly assigned to undergo laparoscopically assisted vaginal hysterectomy or standard abdominal hysterectomy. Intraoperative and postoperative management was similar for each group. Surgical characteristics, complications, length of hospital stay, charges, and convalescence were analyzed.

**Results:** Sixty-five women at three institutions underwent laparoscopically assisted vaginal hysterectomy ( $n = 34$ ) or abdominal hysterectomy ( $n = 31$ ). Three patients in the laparoscopic group required conversion to abdominal hysterectomy.

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Mean operating time was significantly longer for laparoscopically assisted vaginal hysterectomy (179.8 versus 146.0 minutes). There were no differences in blood loss or incidence of intraoperative complications. There was a higher incidence of wound complications in the abdominal hysterectomy group, but no significant difference in the frequency of postoperative complications. Laparoscopically assisted vaginal hysterectomy required a significantly shorter mean hospital stay (2.1 days) and convalescence (28.0 days) than abdominal hysterectomy (4.1 days and 38.0 days, respectively). There were no significant differences in mean hospital charges between the study groups (laparoscopic \$8161, abdominal \$6974).

**Conclusion:** Except for operating time, there are no differences between laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy regarding intraoperative characteristics among abdominal hysterectomy candidates. Postoperatively, laparoscopically assisted vaginal hysterectomy requires a shorter hospital stay and convalescence. Hospital charges are similar between the procedures. A larger number of cases will help determine the indications for laparoscopically assisted vaginal hysterectomy. (Obstet

Laparoscopically assisted vaginal hysterectomy is currently advocated as an alternative to abdominal hysterectomy. Some physicians recommend laparoscopically assisted vaginal hysterectomy as an alternative to simple vaginal hysterectomy.<sup>1</sup> Reported benefits of laparoscopically assisted vaginal hysterectomy, when compared with the standard methods, include shorter hospital stays and convalescence, less postoperative pain, lower morbidity, and, in some series, greater cost-effectiveness.<sup>1-5</sup>

In 1992, we reported the results of a randomized comparison of laparoscopically assisted vaginal hysterectomy and standard vaginal hysterectomy performed in an outpatient setting.<sup>6</sup> There were no differences with regard to length of hospital stay or intraoperative or postoperative morbidity. Operating times and use of postoperative pain medication were greater for laparoscopically assisted vaginal hysterectomy. In addition, the laparoscopic route incurred significantly higher costs than the vaginal route.

Because of the lack of randomized comparative investigations of laparoscopically assisted vaginal hysterectomy and considering the findings from our initial study, we elected to perform a randomized multicenter comparison of laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy. We tested the feasibility and safety of laparoscopically assisted vaginal hysterectomy in candidates for abdominal hysterectomy only. Using these criteria, we hoped to identify indications for laparoscopically assisted vaginal hysterectomy. The procedures were compared for technical operative difficulty, complications, postoperative recovery, and hospital charges.

### *Materials and Methods*

This study was a multicenter randomized comparison of the outcomes of laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy among women judged to be candidates for abdominal hysterectomy only. The three participating research centers were The University of Tennessee, Memphis; Bowman Gray School of Medicine, Winston-Salem, North Carolina; and The University of North Carolina, Chapel Hill. Indications for abdominal hysterectomy were determined from standard surgical texts,<sup>7,8</sup> the practices in the communities surrounding the participating institutions, and the experiences of the authors.

Indications for abdominal hysterectomy only included the following: 1) documented visual diagnosis

of pelvic endometriosis; 2) documented pelvic adhesions; 3) three or more previous laparotomies (mini-laparotomies were excluded); 4) uterine leiomyomata 12-18 gestational weeks in size; 5) previous tubo-ovarian abscess or two documented episodes of pelvic inflammatory disease requiring intravenous (IV) antibiotic therapy; 6) adnexal mass in the presence of an indication for hysterectomy, or the need for total ovariectomy; and 7) indicated hysterectomy with lack of mobility and unfavorable vaginal introitus (defined as a pubic arch less than 90 degrees or a narrow introitus).

Because all patients participating in the study were allowed to leave the hospital as soon as they were able, including same-day discharge, the following inclusion criteria were met: 1) age at least 18 years, 2) a working telephone in the home, 3) an available support person in the home for 48 hours after surgery, and 4) an understanding of the postoperative instructions. Patients were excluded from participation in the study if they required a concomitant colporrhaphy, urethropexy, vaginal vault suspension, or a nongynecologic major operation. Patients were also excluded for medical conditions requiring in-hospital monitoring (eg, diabetes mellitus, organic heart disease) or if they had known cervical or endometrial cancer. Finally, candidates were excluded if they had absolute contraindications to operative laparoscopy, including: 1) uterine leiomyomas or pelvic masses greater than 18 gestational weeks in size, 2) conditions making them intolerant to anesthesia, 3) severe bleeding disorders, 4) acute peritonitis of the upper abdomen with severe distention, or 5) a midline abdominal hernia.<sup>9</sup>

Eligible patients were offered entry and were fully aware that they would be randomly assigned to one of the procedures. Women participating signed a consent form approved by the institutional review boards of each participating institution. After the consent was signed, the coordinating secretary (at The University of Tennessee) was contacted for randomization. Each study site had a computer-generated randomization list, with each surgical assignment placed in consecutive sealed envelopes. The study secretary opened the appropriate envelope for each site and informed the investigator of the assigned procedure. The patient was made aware of her assignment before hospitalization.

Before surgery, each woman received IV antibiotic prophylaxis with cefazolin 2 g, or with doxycycline 200 mg if she was allergic to penicillin. General anesthesia was administered for laparoscopically assisted vaginal hysterectomies. The choice of regional or general anesthesia was left to the anesthesiologists and patients for abdominal hysterectomies.

The surgical procedures were performed similarly at all institutions, following technical steps agreed upon at

a prestudy meeting. All operations were performed by gynecology residents, with attending physicians (investigators) assisting. A modified Richardson technique<sup>7</sup> was used for abdominal hysterectomies. Laparoscopically assisted vaginal hysterectomies were performed through three 12-mm trocars using a general technique described previously.<sup>6</sup> A combination of endoscopic staples (U.S. Surgical Corp., Norwalk, CT) and bipolar coagulation was used for the laparoscopic operation. Anesthesia time, operating time, estimated blood loss, uterine weight, and intraoperative complications were recorded.

Anticipating differences in immediate recovery between the study groups, we managed the patients similarly to offer the earliest possible discharge. Abdominal hysterectomy patients returned to their hospital rooms with an indwelling bladder catheter in place. They were encouraged to ambulate and consume a liquid diet as soon as they wished. To allow discharge as soon as the patients were able, we followed these criteria: 1) tolerance of diet, 2) no need for intramuscular (IM) pain medication, 3) ability to ambulate, 4) ability to void, and 5) stable hematocrit. Women undergoing laparoscopically assisted vaginal hysterectomy returned from the recovery area to their hospital rooms without bladder catheters. We anticipated that more of the patients in this surgical group would satisfy the criteria for same-day discharge. Those who had same-day discharge met the criteria described in our earlier reports and were followed using that protocol for outpatient hysterectomy.<sup>6,10</sup> Those who were unsuitable or did not wish same-day discharge were discharged according to the criteria used for abdominal hysterectomy.

Each patient had hematocrits measured upon arrival to her hospital room after surgery and 5 hours later. Complete blood count and electrolytes were obtained on the first 2 postoperative days. For patients discharged before the second postoperative day, a licensed home health agency nurse obtained laboratory studies and vital signs. All patients were seen 2 and 6 weeks postoperatively in the outpatient office.

Febrile morbidity (temperature at least 38°C on two occasions) and other postoperative complications were recorded.<sup>11</sup> Pain control was assessed by analyzing the use of IM narcotics and oral pain medications. The numbers of days hospitalized and days until returning to work or normal activity (as determined by the patients) were recorded.

Nominal variables were analyzed by  $\chi^2$  or Fisher exact test when appropriate. Continuous variables were analyzed using a two-tailed *t* test. *P* < .05 was considered statistically significant.

Table 1. Study Group Demographics

Characteristic	TAH (n = 31)	LAVH (n = 34)
Age (y)	41.5 ± 5.7 (28-49)	38.3 ± 7.3 (26-61)
Gravidity	2.4 ± 1.7 (0-6)	3.1 ± 1.8 (0-8)
Parity	1.7 ± 1.3 (0-4)	2.3 ± 1.6 (0-8)
Weight (lb)	178.1 ± 43.1 (109-273)	168.3 ± 41.0 (97-248)

TAH = total abdominal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy.

Data are presented as mean ± standard deviation (range).

## Results

Sixty-five eligible women underwent randomly assigned operations. Two other women who were randomized refused their assigned procedure; they were removed from the study and their random numbers were discarded. Thirty-one (47.7%) women had abdominal hysterectomies and 34 (52.3%) women had laparoscopically assisted vaginal hysterectomies. Three patients in the laparoscopically assisted vaginal hysterectomy group required conversion to an abdominal hysterectomy because uterine fibroids found during the laparoscopy were too large for proper dissection. All three patients remained in the laparoscopic group for the purposes of data analysis.

The groups were similar demographically (Table 1). There were no differences in menopausal status or preoperative uterine mobility. A significantly greater number of women in the laparoscopically assisted vaginal hysterectomy group had undergone previous abdominal surgery (28 versus 19; *P* = .033). Table 2 lists the preoperative indications for surgery in both groups. The most common indication was large leiomyomata uteri.

The intraoperative characteristics of operating time, estimated blood loss, and uterine weight are presented in Table 3. Mean operating time was significantly longer for laparoscopically assisted vaginal hysterectomy. There were no statistical differences in the incidences of

Table 2. Indications for Surgery

Indication	TAH (n = 31)	LAVH (n = 34)
Endometriosis	1 (3.2%)	1 (3%)
Adhesions	2 (6.5%)	0
Leiomyomata uteri	23 (74.1%)	23 (68%)
Prior laparotomies	2 (6.5%)	0
Prior TOA/PID	1 (3.2%)	1 (3%)
Adnexal mass	0	2 (6%)
No mobility	† 2 (6.5%)	7 (20%)

TAH = total abdominal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; TOA = tubo-ovarian abscess; PID = pelvic inflammatory disease.

Data are presented as n (%).

**Table 3. Intraoperative Characteristics**

Characteristic	TAH (n = 31)	LAVH (n = 34)	P
Operating time (min)	146.0 ± 69.9 (52-325)	179.8 ± 56.4 (80-270)	NS
Estimated blood loss (mL)	660.5 ± 610.0 (100-3000)	568.0 ± 394.0 (50-1600)	NS
Uterine weight (g)	383.9 ± 227.8 (70-954)	336.8 ± 276.0 (54-1550)	NS

TAH = total abdominal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; NS = not significant ( $P > .05$ )  
Data are presented as mean ± standard deviation (range).

intraoperative complications between the groups. Two patients in the laparoscopically assisted group had incidental cystotomies; these were repaired laparoscopically without further occurrence. One patient in the laparoscopic group had an injury to the abdominal-wall inferior epigastric artery that was controlled with suture ligation. Two patients in the laparoscopically assisted group and two in the abdominal group had intraoperative hemorrhage greater than 1000 mL. The two women in the abdominal group received intraoperative transfusions.

A statistically greater number of patients in the abdominal hysterectomy group (30 of 31 patients) required IM narcotics on the day of surgery compared with patients in the laparoscopic group (26 of 34 patients;  $P = .018$ ). No patient in the laparoscopic group, except for those who underwent laparotomy, required IM narcotics after the day of surgery. There were no differences in preoperative and postoperative hematocrit values between the study groups (Table 4).

The study groups did not differ significantly with regard to postoperative complications. One patient in each group developed pelvic cellulitis after the operation.<sup>11</sup> Seven patients in the abdominal group and one in the laparoscopic group had some form of wound complication, ranging from wound infection to simple superficial wound separation.

Statistically significant differences were noted in total number of days hospitalized and total number of convalescent days (reported by the patient) (Table 5). If a

patient was discharged on the day of surgery, the total number of hospital days was considered to be one. Table 5 demonstrates the lack of a statistically significant difference in total hospital charges ( $P = .15$ ).

### Discussion

It is generally accepted that when a vaginal hysterectomy can be performed, even when it is difficult, laparoscopically assisted vaginal hysterectomy provides no benefit.<sup>4,6</sup> However, when compared with abdominal hysterectomy, compelling evidence suggests that laparoscopically assisted vaginal hysterectomy provides specific benefits.<sup>2,3,12</sup> The greatest potential benefit is the ability to convert an abdominal hysterectomy to the vaginal route, thus leading to lower morbidity, less pain, shorter hospital stay and convalescence, and cost savings.<sup>2,3,5,12</sup> To prove these benefits, study populations must consist of candidates for abdominal hysterectomy only.

Our study attempted to evaluate laparoscopically assisted vaginal hysterectomy by randomized comparison of the procedure with abdominal hysterectomy in a strictly selected group of abdominal hysterectomy candidates. Because of regional variations in choosing the abdominal route for hysterectomy, indications for abdominal hysterectomy in this study were developed to encompass the practices of the majority of physicians in this country. Because the practices of the institutions participating in this investigation might differ in some respects, the data obtained must be interpreted in light of this compromise.

In contrast to earlier retrospective investigations,<sup>4,5</sup> uterine weights in our study were similar between study groups, demonstrating a common selection population with regard to uterine size and operative difficulty. There was no statistical difference in mean estimated blood loss, however, laparoscopically assisted vaginal hysterectomy entailed a significantly longer mean operating time.

Although there were no differences in the incidence of intraoperative complications, bladder injuries occurred only in the laparoscopically assisted vaginal hysterectomy group. This may have been the result of

**Table 4. Preoperative and Postoperative Hematocrit**

Time	Mean hematocrit		P
	TAH (n = 31)	LAVH (n = 34)	
Preoperative	35.8 ± 4.2 (25.0-42.3)	36.9 ± 3.9 (28.6-44.9)	NS
5 h postoperative	32.5 ± 4.5 (23.1-39.9)	32.6 ± 4.4 (18.0-38.8)	NS
Postoperative day 1	30.3 ± 3.9 (22.2-38.4)	30.2 ± 4.9 (18.3-37.9)	NS
Postoperative day 2	29.3 ± 4.3 (21.3-36.4)	29.3 ± 4.8 (19.7-37.5)	NS

TAH = total abdominal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; NS = not significant ( $P > .05$ )  
Data are represented as mean ± standard deviation (range).

**Table 5. Postoperative Recovery and Hospital Charges**

Variable	TAH (n = 31)	LAVH (n = 34)	P
Hospital days	4.13 ± 1.6 (2-9)	2.12 ± 1.3 (1-6)	<.001
Convalescent days	38.0 ± 10.8 (15-55)	28.0 ± 13.3 (9-70)	.002
Hospital charges (\$)	6974 ± 2843 (3183-16,086)	8161 ± 3600 (3061-23,591)	NS

TAH = total abdominal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; NS = not significant ( $P > .05$ )  
Data are presented as mean ± standard deviation (range).

resident surgeons' performing the dissections, and this complication could be less common with more experienced surgeons. Hemorrhage was the only intraoperative complication noted in the abdominal hysterectomy group, and all cases occurred when the indication for surgery was leiomyomata uteri.

Patients undergoing laparoscopically assisted vaginal hysterectomy had significantly less need for IM narcotics, indicating less postoperative pain. Although this certainly benefits the patients' comfort, it also allows earlier ambulation with fewer attendant problems of remaining bedridden.

Although there were no significant differences in the incidences of postoperative complications, one type of complication deserves note. Seven patients in the abdominal hysterectomy group, but only one in the laparoscopic group, developed some form of wound complication, ranging from simple skin separation to frank wound infection requiring debridement. Although this difference did not reach statistical significance, the increased incidence of wound complications after abdominal hysterectomy is a concern, especially when considering potential consequences, such as longer hospital stays and long-term outpatient care.

In previous studies, laparoscopically assisted vaginal hysterectomy was associated with shorter hospital stays and convalescence than abdominal hysterectomy.<sup>2,4,5,13</sup> Investigators suggested that these shorter stays and recovery times would be associated with cost savings. However, the differences noted were documented in uncontrolled trials or retrospective reviews, in which the length of stay could be influenced by practice bias. In our study, the criteria for discharge were standardized. As with previous studies, statistical differences were found between the laparoscopic and transabdominal routes. It is probable that the shorter hospital stays for laparoscopically assisted vaginal hysterectomies were partially responsible for the lack of statistical differences in mean hospital charges. In our previous study comparing laparoscopically assisted vaginal hysterectomy and standard vaginal hysterectomy, the numbers of hospital days were similar, and the differences in charges resulted from disposable-equipment costs and longer operating times.<sup>6</sup> Longer hospital stays

and relatively similar operating times for the abdominal hysterectomy group in this study eliminated statistical differences in charges. This is contrary to a recent report showing statistically higher costs for the laparoscopically assisted approach despite shorter hospital stays.<sup>14</sup> This discrepancy might be due to the prospective design of our study and the rigid controls placed on postoperative management. However, the lack of differences in charges and in complications must be interpreted cautiously; a type II error might have been introduced by the limited number of study subjects. To achieve a  $\beta$  of 0.8 with a difference in means of \$1000.00 and a standard deviation (SD) of \$1500.00, 37 patients must be included in each group. If the cost of disposable equipment were further reduced or if reusable equipment were emphasized, laparoscopically assisted vaginal hysterectomy might show significantly lower hospital charges in abdominal hysterectomy candidates.

We hoped to shed light on the proper indications for laparoscopically assisted vaginal hysterectomy by performing this study. To date, we are unable to define the total spectrum of indications for laparoscopic assistance. Most patients (74.1%) in this study underwent surgery for uterine fibroids. Only two patients had endometriosis, two had documented adhesions, and two had an adnexal mass. Larger patient numbers in the other indication categories could clarify indications.

All three cases converted to abdominal hysterectomy in this study were done because of uterine leiomyomata obstructing access to the upper pedicles. This is consistent with the primary reasons for conversion in other studies.<sup>15</sup> We do not believe that conversion to the transabdominal route was operator dependent because each site reported one patient converted to an abdominal hysterectomy. Limiting the size of uterine fibroids approached with laparoscopy to 16 or 18 gestational weeks seems wise, but we still consider that many cases of uterine fibroids up to 16 weeks' size can be approached vaginally.

Greater patient numbers will be necessary to identify the proper indications for laparoscopically assisted vaginal hysterectomy given our difficulties encountered with recruitment for indications other than fibroids. Potential benefits to patients and health care savings

appear encouraging based upon our data. Addressing savings in indirect costs will require further investigation.

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