

Comparative study of vaginal, laparoscopically assisted vaginal and abdominal hysterectomies for uterine myoma larger than 6 cm in diameter or uterus weighing at least 450 g: a prospective randomized study

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Background. The purpose of this study was to compare peri-operative morbidity, preoperative sonographic estimation of uterine weight and postoperative outcomes of women with uterine fibroids larger than 6 cm in diameter or uteri estimated to weigh at least 450 g, undergoing either vaginal, laparoscopically assisted vaginal or abdominal hysterectomies.

Method. Ninety patients who met the criteria of uterine fibroids larger than 6 cm by ultrasonographic examination were included in our prospective study. Patients were randomized into laparoscopic-assisted vaginal hysterectomy (30 patients), vaginal hysterectomy (30 patients) and abdominal hysterectomy (30 patients) groups.

Results. The laparoscopically assisted vaginal hysterectomy group had significantly longer operative times than the abdominal and vaginal hysterectomy groups (109 ± 22 min, 98 ± 16 min, and 74 ± 22 min, respectively, $p < 0.001$). Blood loss for vaginal hysterectomy was significantly lower than for either abdominal or laparoscopically assisted vaginal hysterectomies (215 ± 134 ml, 293 ± 182 ml, and 343 ± 218 ml, respectively, $p = 0.04$). Vaginal hysterectomy and laparoscopically assisted vaginal hysterectomy groups had shorter hospital stays, lower postoperative pain scores, more rapid bowel recovery and lower postoperative antibiotic use than the abdominal hysterectomy group. Uterine weight in the abdominal hysterectomy group was significantly heavier than in the vaginal and laparoscopically assisted vaginal hysterectomy groups (1020 ± 383 g, 835 ± 330 g, and 748 ± 255 g, respectively, $p = 0.02$). We estimated that when a myoma measured between 8 and 10 cm, the uterus weighed approximately 450 g, and the sensitivity of this prediction was 57.5%. For a myoma larger than 13 cm, the estimated uterine weight was more than 900 g and the sensitivity of this prediction was 71%.

Conclusion. The study shows vaginal hysterectomy and laparoscopically assisted vaginal hysterectomy can be performed in women with uterine weight of at least 450 g. Preoperative ultrasonographic examination can provide the surgeon with valuable information on the size of the fibroid and the estimated weight of the enlarged uterus before implementing a suitable surgical method.

Keywords: abdominal hysterectomy; laparoscopically assisted vaginal hysterectomy; morcellation; ultrasonography; vaginal hysterectomy

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Hysterectomy is the second most frequently performed surgical procedure worldwide second only to cesarean section (1, 2). The majority of hysterectomies are performed to manage symptomatic uterine fibroids (3). Surgically speaking, a hysterectomy could be performed via either an abdominal or a vaginal approach, and nowadays with the assistance of laparoscopy. Nonetheless, an enlarged uterus secondary to a huge fibroid often precludes a vaginal or laparoscopic procedure. Instead the abdominal route is used for approximately 70% of surgeries (4), especially when the expected uterine weight exceeds 450 g. Patients undergoing laparoscopically assisted vaginal hysterectomy (LAVH) or vaginal hysterectomy (TVH) experience faster recoveries, fewer complications and shorter hospitalizations compared with patients with abdominal hysterectomy (TAH) (5,6). Unfortunately, TVH and LAVH are less frequently performed or not considered when the weight or size of the uterus and fibroid contribute to additional difficulty during surgery. Recently, this has resulted in surgeons having limited operative skills and patient exposure to effectively perform the critical 'volume reduction' techniques of TVH. Thus, a less than well-trained surgeon may have experience in all three methods of hysterectomy but prefers the abdominal route when performing surgery for enlarged uteri and fibroid.

Several prospective randomized controlled trials have compared the operative time, length of hospital stay, intraoperative complications, postoperative recovery and costs for women undergoing LAVH, TAH and TVH (7–9). However, no prospective randomized study has compared the outcomes between these three alternative methods of hysterectomy for uterine fibroids weighing more than 450 g. It is still difficult to predict uterine weight by pelvic examination and ultrasonography before surgery. Magos et al. (9) reported an observational study of 14 patients with enlarged uteri between 380 and 1100 g who underwent successful TVH but the data were not compared with patients who had undergone LAVH or TAH under similar conditions.

The purpose of this randomized study was to assess the operative time, length of hospitalization and intraoperative blood loss of patients undergoing LAVH, TAH and TVH for uterine size larger than 6 cm or weight more than 450 g. Secondary outcomes evaluated were intraoperative

variables, antibiotics used, correlation of myoma diameter to uterine weight and correlation of ultrasound diagnosis to final pathologic findings.

Materials and methods

Patients were recruited over a two-year period between June 1, 1999 and May 30, 2001 among women scheduled for hysterectomy for uterine fibroids in the Department of Gynecology and Obstetrics at Shin Kong Wu Ho-Su Memorial Medical Center, Taipei, Taiwan. The study was reviewed and approved by the Institutional Review Board of Shin Kong Wu Ho-Su Memorial Medical Center. A transabdominal and/or transvaginal ultrasound was performed one day before surgery to assess the number, location and diameter of the myoma. Patients with a myoma diameter larger than 8 cm and second myoma less than 5 cm or two myomata, both at least 6 cm in diameter but less than 8 cm, entered this study. The total number of uterine fibroids could not be more than three. Patients who were admitted under the indications of adenomyosis, uterine prolapse, chronic pelvic pain, dysfunctional uterine bleeding, cervical dysplasia, or pelvic inflammatory disease were excluded from the study.

Randomization was carried out by opening sealed envelopes containing computer-generated block randomization numbers, with a block size of 10 to ensure roughly equal numbers of patients in each arm at any point in the study. All patients who met the inclusion criteria and agreed to participate in the study signed a written informed consent form and were randomly assigned to undergo one of the operations.

A total of 90 patients (30 women in each group) entered this study. The mean age of the patients was 45.1 years (range 35–54). The majority of the patients (90%) had at least one delivery; nine patients were nulliparous in this study. The mean body mass index was 23.2 kg/m² (range 17.2–32.8). Forty of the 90 patients (44.4%) had uterine fibroids between 8 and 10 cm in diameter, 26 patients (28.9%) had uterine fibroids between 11 and 13 cm, five (5.6%) had fibroids larger than 13 cm, and 19 patients (21.1%) had two fibroids larger than 6 cm but less than 8 cm.

Hysterectomy techniques

All procedures were performed under general anesthesia by the second author, who was experienced in the three surgical methods, with the assistance of the other authors to avoid selection bias of certain patients by certain doctors. Routine soapsuds

Abbreviations:

TVH: vaginal hysterectomy; LAVH: laparoscopically assisted vaginal hysterectomy; TAH: abdominal hysterectomy; UTI: urinary tract infection; URI: upper respiratory infection.

enemas at midnight and in the early morning before the operation was performed on all patients. During abdominal hysterectomy, the abdomen was opened via either a vertical midline or Pfannestiel skin incision. The uterus was removed by the extrafascial technique and the vaginal cuff closed with a continuous interrupted suture followed by reperitonealization. During vaginal hysterectomy, the patients were positioned in a modified Trendelenburg tilt, with their legs in lithotomy position and hips well abducted. Diluted Vasopressin (1:60 cc of normal saline) was injected in increments of 5–10 ml into the utero-vesical fold, bilateral descending uterine artery branches, cardinal ligament and the cul-de-sac of Douglas. An anterior circumferential incision of the cervix and a posterior 'V'-shape incision were performed following the vasopressin injection. The anterior peritoneal cavity was opened after blunt dissection by the index finger with wet gauze. The cul-de-sac of Douglas was entered in the same manner. After uterine artery ligation, volume-reducing techniques including bisecting, coring, morcellation, enucleation or a combination of these methods were performed vaginally. The peritoneum was then closed and the uterosacral ligaments and vaginal vault sutured by 1–0 vicryl. The procedures were carried out according to those described by Joel-Cohen (10). Laparoscopically assisted vaginal hysterectomy was performed in a dorso-lithotomy position using video-monitoring equipment. A 10-mm trocar was inserted into the umbilical position, followed by one 5-mm trocar in each lower quadrant lateral to the inferior epigastric artery, 6–8 cm oblique to the pubic rami. Another 5-mm trocar was inserted 3–4 cm suprapubically. An uterosacral ligament incision was performed in all laparoscopic procedures after identifying the pelvic portion of the ureter. All hysterectomies were compatible to stage five according to the panel described by Richardson with or without ovarian excision (11). Both the round and broad ligaments were excised and dissected after uterosacral ligament excision. An anterior colpotomy was performed after ligation of the bilateral uterine artery. After completing the vaginal phase of the LAVH, the uterus was removed vaginally by volume-reducing techniques. After closing the vaginal cuff with continuous sutures of 1–0 vicryl, a pneumoperitoneum was recreated to confirm hemostasis and recheck for peristalsis of the bilateral ureters.

The duration of the surgery was measured from the first incision until the patient left the operating room, and was additionally separated into those that included or did not include a second procedure including oophorectomy and/or adhesiolysis. The surgical nurse estimated the amount of

bleeding in a routine manner. If a blood transfusion was performed, the number of units of transfused blood was recorded. The specimen weight was obtained immediately after the surgery.

Preoperative ultrasound examination

Transvaginal sonography with a Toshiba SSA-270 A scanner (Toshiba, Tokyo, Japan) employing a 6.25-MHz vaginal probe was applied to measure all myoma sizes in centimeters. The mean diameter of the myoma was determined by the division of the longitudinal (L) plus transverse size (T), i.e. $[(L + T)/2]$. Based on past experience of pelvic examinations a myoma of between 8 and 10 cm or two myomas measuring 6–7.99 cm indicate a uterine size similar to that of approximately 16 weeks' gestational age, and we thus estimated that the uterus weighed more than 450 g. If the myoma was between 11 and 13 cm, the uterine size would be similar to 20 weeks' gestational age and the uterus was estimated to be more than 700 g, and if the fibroid was larger than 13 cm, the uterus was estimated to be more than 20 weeks of gestational or more than 900 g.

Postoperative follow up

All patients received a standardized postoperative protocol of two doses of intravenous meperidine 50 mg every 4 h for pain control followed by acetaminophen 325 mg every 6 h. A tenderness scoring system, with a scale from 1 to 10 (from no pain to most severe pain), was completed by the patient 24 h after the operation. The patient was discharged from the hospital when her pain was mild and could be relieved by oral medication alone, and she could tolerate a soft diet, was ambulatory and was able to self micturate. Hospital stay was defined as the number of days in the hospital.

Complications were recorded as follows: febrile morbidity (defined as a tympanic temperature 38.3 °C or higher 24 h after surgery); an excessive amount of bleeding or hemorrhage requiring transfusion intraoperatively; injury to a major blood vessel or major organ including the bowel, bladder or ureter; and readmission to the hospital during the follow-up period for a problem directly related to surgery.

First-line prophylactic antibiotics, cephalosporin 1.0 g every 8 h (three doses/day) combined with aminoglycoside 80 mg every 12 h (two doses/day), for one day were administered to all patients after the surgery. The antibiotics were continued if tympanic temperature was higher than 37.3 °C after the prophylactic antibiotics. The total doses of antibiotics used were recorded.

Table I. Demographic characteristics of the study group

	LAVH <i>n</i>	TAH <i>n</i>	TVH <i>n</i>	<i>p</i> -value
Age (year)	30	30	30	
Mean $\pm$ SD	44 $\pm$ 5	45 $\pm$ 4	46 $\pm$ 4	0.11*
Range	35.00–52.00	36.00–53.00	36.00–54.00	
College education	30	30	30	0.65†
Nulliparous	30	30	30	0.14†
Had 3 or more pregnancy	30	30	30	0.27‡
Had previous Appendectomy	30	30	30	0.99†
Had previous cesarean section	30	30	30	
Once	3 (10.0%)	1 (3.3%)	1 (3.3%)	0.34†
Twice	0 (0.0%)	1 (3.3%)	3 (10.0%)	
BMI (body mass index)	30	30	30	
Mean $\pm$ SD	23 $\pm$ 3.4	24 $\pm$ 3	22 $\pm$ 2.6	0.14*
Range	17.2–32.8	18.5–30.7	17.3–28.8	

*Based on Kruskal–Wallis test; †Fisher's exact test; ‡Chi-square test.

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

All patients were asked for follow up 6 weeks after surgery and the time return to normal activities was recorded. Final pathologic finding of the specimen was compared with the preoperative ultrasound diagnosis.

Statistical methods

We assumed an SD of 30 min for surgery time as observed from previous studies. The power of analysis was 80% at $\alpha = 0.05$. The randomization schedule was based on computer-generated numbers with use of the SAS statistical software package (SAS Institute, Cary, NC). Statistical analysis was carried out using the Kruskal–Wallis test for continuous values and Fisher's exact test or Chi-square test for categorical variables. Computations were performed using the Statistical Analysis System, Version 8.1 (SAS Institute, Cary, NC). Variables data are presented as mean $\pm$ SD. In all cases, the threshold for significance was taken as $p < 0.05$.

Results

The patients' ages; education; parities; previous surgeries including sterilization, appendectomy and cesarean section; and body mass index are presented in Table I. Overall, there were no differences in terms of patient age, college education, parity, previous surgeries and body mass index.

Comparisons of myoma size and uterine weight are shown in Table II. We estimated that when a myoma measured between 8 and 10 cm, the uterus weighed approximately 450 g, and the sensitivity of this prediction was 57.5%. For a myoma larger than 13 cm, the estimated uterine weight was more

than 900 g and the sensitivity of this prediction was 71%.

Intraoperative and postoperative complications are listed in Table III. Patients who underwent TAH more frequently experienced febrile morbidity (26.7%) compared with those in the LAVH and TVH groups. Hemorrhage requiring transfusion was more common among patients who underwent LAVH, although this was not statistically significant ($p = 0.21$).

Operative time, blood loss, hospital stay, tenderness score, antibiotics used, time return to normal activity and uterine weight are shown in Table IV. The operative time for a hysterectomy without concurrent procedures was significantly longer in the LAVH group than in the TAH and TVH groups ($p = 0.01$). For patients with concurrent procedures (10 adnexectomies and three adhesiolysis in the LAVH group, eight adnexectomies in the TAH group, and two adnexectomies and one posterior colporrhaphy in the TVH group), the operative time was also longer in the LAVH group. Mean estimated blood loss was 343 ± 218 ml in the LAVH group, which was more than both the TAH and TVH groups (293 ± 182 ml and 215 ± 134 ml, respectively, $p = 0.04$). Hospital stays were shorter in the TVH and LAVH groups than in the TAH

Table II. Distribution of myomatous size to uterine weight in the study groups

	450–700 g (<i>n</i> = 33)	701–900 g (<i>n</i> = 20)	≥ 901 g (<i>n</i> = 37)
8–10 cm (<i>n</i> = 40)	23 (57.5%)	7 (17.5%)	10 (25.0%)
11–13 cm (<i>n</i> = 26)	2 (7.7%)	7 (26.9%)	17 (65.4%)
> 13 cm (<i>n</i> = 5)	0 (0.0%)	0 (0.0%)	5 (100%)
Two myomas > 6 cm (<i>n</i> = 19)	8 (42.1%)	6 (31.6%)	5 (26.3%)

Table III. Breakdown of categorical complication rates among women in the study groups

Complication	LAVH (n = 30)	TAH (n = 30)	TVH (n = 30)	P-value
Febrile morbidity				
Source unidentified	0 (0.0%)	6 (20.0%)	2 (6.7%)	0.02*
UTI	1 (3.3%)	0 (0.0%)	0 (0.0%)	
URI	0 (0.0%)	2 (6.7%)	2 (6.7%)	
Vaginal cuff infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	< 0.05*
Pelvic infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Total	1 (3.3%)	8 (26.7%)	4 (13.3%)	
Major organ or vessel injury	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.21*
Intra-op BT	5 (16.7%)	1 (3.3%)	1 (3.3%)	
Rehospitalization	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Total	6 (20%)	9 (30%)	5 (16.7%)	< 0.05*

*Based on Fisher's exact test.

LAVH = laparoscopically assisted vaginal hysterectomy; TVH = vaginal hysterectomy; TAH = abdominal hysterectomy; UTI = urinary tract infection; URI = upper respiratory infection; BT = blood transfusion.

Table IV. Comparison of operative events among women in the study groups

	LAVH n		TAH n		TVH n		p-value
Op. time (min)							
with second procedure	13	119±20 (80–165)	8	117±32 (90–190)	3	93±15 (80–110)	0.12*
without second procedure	17	109±22 (85–75)	22	98±16 (85–150)	27	74±23 (40–120)	< 0.001*
Blood loss (cc)	30	343±218 (50–950)	30	293±182 (50–750)	30	215±134 (50–650)	0.04*
Hospital stay (day)	30	4.7 (3–7)	30	5 (4–8)	30	4.7 (3–7)	0.003*
Post op. tenderness scores after 24 h	30	4 (3–5)	30	6 (4–8)	30	3 (2–5)	< 0.001*
Return to work (days)	30	30±16 (17–42)	30	41±10 (26–65)	30	29±11 (17–50)	< 0.001*
Days of antibiotics used	30	1.3 (1–4)	30	1.7 (1–3)	30	1.3 (1,2)	< 0.001*
Pathological-ultrasound correlation (%)	30	28 (93.3%)	30	100 (100.0%)	30	28 (93.3%)	0.54†
Uterine weight (g)	30	748±255 (450–1450)	30	1020±383 (500–1800)	30	835±330 (450–1700)	0.02*

*Based on Kruskal–Wallis test; †Fisher's exact test.

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

group. The TVH and LAVH groups registered lower pain scores 24 h after surgery and rapid return to normal activities than the TAH group.

Two patients with failed planned TVH (6.6%) had uterine fibroids measuring 15.8 cm and 14 cm in diameter with uteri weighing 1700 g and 1100 g, respectively. The uterine diameter of a patient with failed planned LAVH (3.3%) was 12.5 cm with the uterus weighing 1200 g. All three surgeries were reverted to the abdominal route.

Eighty-four uterine fibroids (95.6%) were correctly diagnosed by transvaginal ultrasound pre-operatively in the study groups. Mean uterine weight was heavier in the TAH group (1020 g) than in the TVH (835 g) and LAVH (748 g) groups.

Discussion

Two important factors determine the success of a TVH for a woman with an enlarged uterus. One factor is vaginal relaxation and uterine mobility, which is important in performing a TVH in a patient with an enlarged uterus without descensus (12). Women who have had many vaginal deliveries have a more relaxed vagina, whereas the vaginal vault can be restricted with difficult access to the uterine vessel in a nullipara. Another factor determining the success of TVH is the surgeon's ability to perform uterine morcellation (9). Uterine morcellation was needed and performed in all patients who underwent TVH and LAVH in this study. Va-

ginal morcellation of an enlarged uterus, although time consuming, is safe and effective. We preferred the technique of applying traction with a tenacula on the cutting end of the uterus followed by a series of wedge resections (9) and vaginal myomectomies (9) in a patient with uterine fibroids. Other techniques such as bisection (9), coring (13), the Pryor technique (14) and the Lash procedure (15) are also effective. The surgeon has to be familiar with all techniques because a combination increases the success of surgery.

Ability to establish an anterior peritoneum and posterior cul-de-sac opening is another important factor in determining the success of TVH, especially in a patient with multiple cesarean sections, pelvic endometriosis or dense pelvic adhesions (16, 17). Injury to the bladder wall will likely occur in patients with multiple cesarean sections who manifest scarring of the anterior peritoneum. On the other hand, endometriosis and dense pelvic adhesions preclude access to the cul-de-sac of Douglas and result in bowel injury. For the enlarged uterus, we find two techniques very helpful for opening the anterior and posterior peritoneum (1): diluted vasopressin 5–10 cc injected into the vesico-uterine fold and cul-de-sac cavity of Douglas. The injected vasopressin solution generates a separation of the bladder base from the cervix, and the plane is more accessible with the index finger applying a rolling motion. In addition, the posterior fornix of the cul-de-sac bulges toward the vagina from the injected vasopressin solution, thus preventing bowel injury in the process of cul-de-sac opening (2). A 'V-shaped' incision posterior to the cervix, as described by Joel-Cohen (10), allows quicker and easier access to the cul-de-sac of Douglas.

Preoperative ultrasound examination correctly diagnosed myoma and was highly compatible with the final pathologic findings. The advantages of ultrasound examination before surgery are (1) excluding the presence of a large ovarian tumor or ovarian endometriosis, as it increases the mechanical difficulty of a TVH and increases the rate of complications (2). Preoperative assessment of the size and position of the myoma and uterus is informative and allows adequate planning of strategy before the hysterectomy. Furthermore, preoperative ultrasound can aid in estimating the weight of the enlarged uterus so the surgeon can decide whether TVH, LAVH or TAH is more appropriate with an enlarged uterus with a large myoma. We prefer to perform TAH for patients with a uterine fibroid greater than 13 cm in diameter. The insertion of trocars becomes increasingly difficult in laparoscopic procedures, and can cause direct injury to the uterus or myoma and lead to

excessive bleeding before the start of the main procedure. Moreover, operative time can be prolonged and the possibility of complications increases when the vaginal route is chosen.

Overall complication rates were lowest in patients in the TVH group. The complication rates were consistent with reports by Kammerer-Dack and Mao (18), Mazdisnian et al. (19) and Darai et al. (20). However, some reports indicate the complication rates are much higher than our study in patients with smaller uteri, undergoing TAH or TVH or LAVH (21, 22).

Total febrile morbidity for the LAVH group was significantly lower than in the TAH and TVH groups in this study, resulting in lower use of post-operative antibiotics in the LAVH group. The major complication rate in our study was extremely low compared with other randomized studies (23, 26). These results show that TVH and LAVH, as well as TAH, can be performed safely in patients with a large uterus. Moreover, rapid recovery and quicker return to normal activities are two advantages of the vaginal and laparoscopic procedures.

Severe pelvic adhesions and adnexectomy are the best indications for laparoscopy in patients with an enlarged uteri (27). Laparoscopically assisted vaginal hysterectomy will likely replace TVH in the treatment of large uterine fibroids with benign ovarian tumors or severe pelvic adhesions, which are more difficult to approach via the vaginal route.

In conclusion, severe pelvic adhesions secondary to endometriosis and uterine fibroids larger than 13 cm were the only contraindications to either VTH or LAVH in the current study. In our experiences, vaginal relaxation and uterine mobility are the determining factors in the success for TVH. Overall, TVH has the shortest operative time, lowest blood loss, shortest hospital stay, lowest risk of infection, fastest bowel recovery and lowest post-operative pain score of the three techniques. Preoperative ultrasonographic findings provide additional information about endometriosis and uterine weight prediction.

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