

# A prospective short-term evaluation of uterine leiomyomas treated by myomectomy through conventional laparotomy or ultraminilaparotomy

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**Objective:** To evaluate the short-term therapeutic outcome of myomectomy through conventional laparotomy in the treatment of uncomplicated uterine myomas compared with myomectomy through ultraminilaparotomy.

**Design:** Controlled, nonrandomized clinical study.

**Setting:** University-affiliated tertiary care referral center.

**Patient(s):** One hundred thirteen patients with symptomatic and uncomplicated uterine myomas warranting surgical treatment, who expressed a strong desire to retain their uterus. Seventy-two patients underwent myomectomy by laparotomy and 41 by ultraminilaparotomy.

**Intervention(s):** Myomectomy through laparotomy or ultraminilaparotomy access.

**Main Outcome Measure(s):** The outcome was measured by comparing blood loss, need for blood transfusion, operative time, postoperative febrile morbidity, time of flatus passage after operation, and postoperative pain (visual analogue scale score and anesthesia use) in both groups.

**Result(s):** General characteristics of the patients were similar in both groups. There were no statistical differences in mean operative time, blood loss, febrile morbidity, insurance pay, and therapeutic efficacy (symptom relief) between the two groups. However, postoperative recovery seemed to be better and more rapid in the ultraminilaparotomy group compared with that in the laparotomy group, including rapid and early bowel movement, lower scores on the visual analogue scale, and shortened postoperative hospital stay.

**Conclusion(s):** This study demonstrates the superiority of ultraminilaparotomy in treating uncomplicated uterine myomas, compared with laparotomy, during this 1-year short-term follow-up. (*Fertil Steril*® 2008;90:2361–6. ©2008 by American Society for Reproductive Medicine.)

**Key Words:** Conventional laparotomy, ultraminilaparotomy, myomectomy, uncomplicated myoma

Uterine leiomyomas, the most common benign uterine tumors, may be present in 20% to 40% of women of reproductive age (1). The use of myomectomy rather than hysterectomy to treat uterine myoma has become popular because it can relieve the symptoms successfully and maintain the reproductive potential (2). The development of new and innovative laparoscopic instruments has allowed a greater number of gynecologic surgeons to use laparoscopy in place of laparotomy (3). In addition, laparoscopic myomectomy was claimed to have decreased the risks of postoperative adhesions compared with abdominal myomectomy, which is a considerable advantage in infertile patients (4). Many other alternative surgical techniques (5), such as laparoscopically

assisted myomectomy (6), laparoscopic ultraminilaparotomic embolized myomectomy (7), laparoscopically assisted transvaginal myomectomy and hand-assisted laparoscopy (8), the morcellation technique (9), and isobaric (gasless) laparoscopy (10), have recently been introduced for the management of uterine myomas, and these modified procedures also have been performed in our hospital.

However, the problem of the uterine incision and the suture created by laparoscopic myomectomy being as strong as those made by conventional laparotomy is of deep concern. Bleeding is also difficult to control and sometimes necessitates advancing to abdominal myomectomy. Uteroperitoneal fistula formation and uterine dehiscence, even rupture, are risks after laparoscopic myomectomy (11–13). In addition, we are faced with an expensive operation in terms of the dedicated and used-and-wasted (disposable) instruments and the lengthy training of surgeons who must acquire new and relatively unfamiliar manual skills (14, 15), although the modern trend favors laparoscopy in place of laparotomy in the majority of gynecologic surgeries (3, 16, 17). Minilaparotomy, frequently adopted by general surgeons, could be a valid and

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cost-effective alternative to laparoscopy (18–24). It does fulfill the criteria of minimally invasive surgery because of the better economy without compromising the postoperative recovery of the patients, compared with laparoscopy (2, 18). The question that we were concerned with, however, is whether myomectomy performed through conventional laparotomy could be replaced by ultraminilaparotomy completely.

Therefore, the aim of this controlled, nonrandomized prospective study was to assess the short-term outcome of myomectomy through laparotomy and ultraminilaparotomy.

## MATERIALS AND METHODS

### Patients

Between January 2004 and December 2005, 113 patients were enrolled in this controlled, nonrandomized clinical study. Each woman gave her informed consent to be included in the study, which was previously approved by the local ethics committee and Institutional Review Board. All patients fulfilled the following criteria to comply with the definition of uncomplicated myomas of the National Health Insurance Bureau in Taiwan: [1] symptomatic myoma, [2] a wish to receive myomectomy, [3] a wish to retain their uterus, [4] absence of previous abdominal or pelvic surgery, [5] a number of visible uterine masses (myomas) less than or equal to five intramural or subserous myomas (without peduncle), [6] a maximum diameter of no more than 8 cm, and [7] an absence of prominent or significant pelvic adhesion on clinical evaluation. The phrase 'symptomatic' included either menstrual problems such as menorrhagia and pain or compression syndrome, including a bulgelike sensation and frequency. A few of the patients were also classified as having unexplained infertility (25). On the basis of the willingness of the patients, 72 women (63.7%) received myomectomy through laparotomy (the laparotomy group), and the remaining 41 (36.3%) underwent myomectomy through ultraminilaparotomy (the ultraminilaparotomy group). To make this study even more uniform and consistent, the general characteristics of the patients in the two groups were evaluated continuously during the study period with use of a limited number of evaluated items, such as age, body mass index, and biochemical blood data.

### Operative Procedures

Both operations were performed with the patient under general anesthesia in the Trendelenburg position and the bladder catheterized. Diluted vasopressin (1:60) was injected into the myometrium around the myoma nodules and into the myoma tissue in both groups to decrease intraoperative bleeding.

In the ultraminilaparotomy group, a 2 to 4 cm (nearer to 3 cm) transverse skin incision (modified Pfannenstiel incision) along the preoperative mark was made 1 to 2 cm below the pubic hair line and 2 to 4 cm above the pubic symphysis. The subcutaneous fat was opened 2 to 3 cm above the skin incision. The abdominal fascia was opened transversely 2

to 3 cm above the skin incision to a width of 5 to 6 cm. We defined the final incision wound as not extending to 4 cm in the ultraminilaparotomy group. A final incision wound extending to 4 cm was considered as a complication and was calculated as a failure.

To prevent bowel and bladder injuries, the peritoneum was opened manually and dissected caudocranially. When required, the bowel and the uterus were packed upward with warm, wet pads. One or two small Deaver retractors (width, 2.5 cm) or thyroid retractors (width, 1.5 cm) replaced the traditional self-retaining retractor. The small end of the abdominal retractor (width, 3 cm) was inserted just barely into the wound. Continuous repositioning of the retractors permitted the operative window to be focused always on the surgical field. The "picking" of the fibroid and the suture of the uterine wound were completed inside the abdominal incision. The instrument, the Backhaus Towel Clamp (Robbins Instruments, Inc., Chatham, NJ), was applied as traction to the myoma during dissection. Enucleation was done along the cleavage plane separating the myoma nodule and the surrounding myometrium. Larger myomas were "pared" with use of a piece-by-piece procedure through a smaller wound, similar to peeling an apple. Horizontal sutures followed by locking sutures were used to close the myometrium, leaving as little dead space as possible. The serosa was closed with a continuous inverting suture of 5-0 poliglecaprone 25 (Monocryl; Ethicon, Somerville, NJ) to minimize raw surfaces on the uterus. Finally, copious peritoneal irrigation with a 1:10,000 dilution of heparin-containing normal saline solution was used to clean debris and blood clots within the abdominal cavity (26).

In the laparotomy group, the operative procedure was similar to that in the ultraminilaparotomy group, with some differences, including [1] an 8- to 12-cm suprapubic incision (Pfannenstiel incision), [2] the myomectomy and uterine reconstruction procedures done outside the abdomen, [3] the use of a different retractor such as the Balfour retractor to support the larger wound incision, and [4] removal of the intact uterine leiomyomas.

### Evaluation Parameters

The parameters we considered for comparing the two groups were operation time (minutes), blood loss, duration of postoperative ileus, days of hospitalization, maximal fever and duration of fever (body temperature  $>37.5^{\circ}\text{C}$ ), postoperative use of analgesics, blood transfusion, and percentage of paralytic ileus. A visual analogue scale (VAS) applicable to the wound of each group was used to evaluate postoperative pain for 24 hours after surgery. The VAS consisted of a non-graduated 10-cm line ranging from "no pain" to "pain as bad as it could be."

Cost for every patient was based on the final payment from the National Health Insurance Bureau. Leiomyoma-related symptoms, either menstrual problems such as menorrhagia and pain or compression syndrome, including a bulgelike

sensation and frequency, were assessed with use of a presence-or-absence questionnaire. If the patients with unexplained infertility could conceive successfully after surgery, this meant there was a decrease in unexplained infertility. At 12 months after surgery, all patients underwent transvaginal ultrasonography, and symptom recurrence was determined.

### Statistical Analysis

SPSS (version 12.0; SPSS Inc., Chicago, IL) statistical software was used to analyze the patient data. Data were presented as the mean  $\pm$  SD. A parametric-independent samples *t*-test was used to compare differences between the two groups, and  $\chi^2$  analysis was used for categorical variables. For all statistical evaluations,  $P < .05$  was used to reject the null hypothesis.

### RESULTS

Mean age, body mass index, symptoms resulting from myoma, number of myomas, and maximum myoma diameter were similar in the two groups (Table 1). It was not surprising to see that the suprapubic wound size was significantly smaller in the ultraminilaparotomy group compared with the laparotomy group (3.4 cm vs. 9.5 cm) (Table 2). Operation time, blood loss, maximal postoperative fever, and duration of fever were similar between the two groups. Significantly, fewer patients in the ultraminilaparotomy group received continuous pain-control anesthesia for postoperative pain control than in the laparotomy group (17.1% vs. 41.7%); by contrast, more patients ( $n = 31$ , 75.6%) requested meperidine hydrochloride for postoperative pain control in the ultraminilaparotomy group, compared with 58.3% in the laparotomy group. However, the accumulated dose of meperidine hydrochloride seemed to be less in the laparotomy group (108.6 mg vs. 131.3 mg), although without statistical significance. The VAS score at the wound was sig-

nificantly lower in the ultraminilaparotomy group (3.3 vs. 4.8). The time of removal of the close wound vacuum reservoir was significantly earlier in the ultraminilaparotomy than in the laparotomy group (2.5 days vs. 3.4 days). Time of bowel recanalization (interval between operation and normal bowel movement) after ultraminilaparotomy was significantly shorter than after laparotomy ( $1.32 \pm 0.57$  days vs.  $1.76 \pm 0.86$  days,  $P < .005$ ). The hospital stay was shorter in the ultraminilaparotomy group than in the laparotomy group (4.0 days vs. 5.3 days). Average costs (in New Taiwan [NT] dollars) for every hospitalization were NT\$56,693 in the laparotomy group and NT\$53,561 in the ultraminilaparotomy group, with an average saving of NT\$3,132 for each case. Two patients in the laparotomy group needed blood transfusion after operation, and another two patients in the laparotomy group had a significant paralytic ileus (Table 3). Four patients with a final incision wound ranging from 4.1 cm to 4.3 cm in the ultraminilaparotomy group (9.8%) were considered as having a complication. The success rate of the completed operation was 90.2%, compared with 100% in the laparotomy group. The majority of patients in both groups were reported to have symptom relief (ranging from 87.5% to 100% in the ultraminilaparotomy group and 92.3% to 100% in the laparotomy group, based on different kinds of symptoms) and satisfaction at the end of the 1-year follow-up (92.7% in the ultraminilaparotomy group vs. 95.8% in the laparotomy group), as seen in Table 4, without statistical difference. All patients (four in the laparotomy group and one in the ultraminilaparotomy group) with unexplained infertility conceived spontaneously during the follow-up period. They would be given treatment with a cesarean section procedure thereafter (data not shown).

### DISCUSSION

Besides laparoscopy, one of the choices for gynecologic and reproductive surgery is the use of minimal access surgery, such as ultraminilaparotomy or minilaparotomy, because both can be considered less traumatic surgery. In recent years,

**TABLE 1**

**Baseline characteristics of the enrolled women.**

	Laparotomy (n = 72)	Ultraminilaparotomy (n = 41)	P value
Age (y)	39.3 $\pm$ 6.3	39.8 $\pm$ 7.7	.714
Body mass index (kg/m <sup>2</sup> )	22.9 $\pm$ 3.4	22.1 $\pm$ 4.0	.303
Symptom (%)			
Pain	59.7	41.5	.061
Menorrhagia	63.9	68.3	.636
Frequency	18.1	19.5	.848
Bulge sensation	15.3	14.6	.927
Unexplained infertility	5.6	2.4	.439
Myoma			
No.	2.1 $\pm$ 1.3	1.9 $\pm$ 1.1	.344
Maximum diameter (cm)	6.1 $\pm$ 1.6	6.3 $\pm$ 1.3	.525

Wen. Myomectomy by ultraminilaparotomy. Fertil Steril 2008.

**TABLE 2****Surgical parameters following myomectomy by laparotomy and ultraminilaparotomy.**

	Laparotomy (n = 72)	Ultraminilaparotomy (n = 41)	P value
Incision length (cm)	9.5 ± 2.0	3.4 ± 0.8	<.001 <sup>a</sup>
Operation time (min)	99.3 ± 25.9	97.9 ± 28.7	.797
Blood loss (mL)	106.9 ± 11.2	87.3 ± 7.5	.330
Maximal fever (°C)	38.19 ± 0.20	38.15 ± 0.18	.628
Duration of fever (h)	3.9 ± 3.3	3.5 ± 2.6	.336
Use of analgesic			
Patients with pain-control anesthesia (%)	41.7	17.1	.007 <sup>a</sup>
Patients treated with meperidine hydrochloride (%)	58.3	75.6	.065
An accumulated dose of meperidine hydrochloride (mg)	131.3 ± 79.6	108.6 ± 57.5	.178
Use of drainage (close wound vacuum reservoir)			
Time of removal (d)	3.4 ± 0.8	2.5 ± 0.7	.013 <sup>a</sup>

<sup>a</sup> Success rate (see Materials and Methods).

Wen. Myomectomy by ultraminilaparotomy. *Fertil Steril* 2008.

the concept has been applied in the management of uterine myomas and other gynecologic disease (18–24). In addition, there is an urge to reduce intraoperative and postoperative complications, to increase the compliance of patients, and to reduce cost.

Myomectomy is advisable for women who wish to preserve their childbearing capabilities (27), and it is needed when myomas are either asymptomatic, growing rapidly and causing infertility or recurrent abortion, or symptomatic and causing abnormal uterine bleeding or pain. The surgical mode of access usually used in myomectomy is laparotomy or its modification—minilaparotomy (6), though recently laparoscopy (4, 6) or a combination of laparoscopy and minilaparotomy (6), and vaginal surgery (28) have represented valid alternatives.

Because of the fixed National Health Insurance payment per case for myomectomy in Taiwan, including the standard payment for myomectomy procedures, and the standard hospital stay of 6 days, many strategies have been tried to achieve better economy. Ultraminilaparotomy may be one of the choices. In this study, data from the comparison of the two groups showed many significant advantages when ultraminilaparotomy was used for the management of uncomplicated uterine myomas, including significantly less postoperative pain (lower VAS score, less usage of pain-control anesthesia without an increased accumulated dose of meperidine hydrochloride) and better recovery (shortened time between operation and bowel recanalization, shortened period for removing the close wound vacuum reservoir, and earlier discharge and shortened hospital stay). In addition,

**TABLE 3****Postoperative details of the two groups of women.**

	Laparotomy (n = 72)	Ultraminilaparotomy (n = 41)	P value
Time of bowel recanalization (d)	1.8 ± 0.9	1.3 ± 0.6	.004 <sup>a</sup>
Duration of hospitalization (d)	5.3 ± 0.9	4.0 ± 0.9	<.001 <sup>a</sup>
Blood transfusion (mL)	500 (n = 2)	0	—
Paralytic ileus (%)	2.8 (n = 2)	0	—
Wound infection (%)	1.4 (n = 1)	0	—
VAS score	4.8 ± 0.8	3.3 ± 0.9	<.001 <sup>a</sup>
Cost (NT\$)	56,693 ± 8,883	53,561 ± 10,621	.450
Success rate (%) <sup>a</sup>	100	90.2 (n = 37)	—

<sup>a</sup> Success rate (see Materials and Methods).

Wen. Myomectomy by ultraminilaparotomy. *Fertil Steril* 2008.

**TABLE 4****One-year postoperative follow-up of the two groups of women.**

	Laparotomy (n = 72)	Ultraminilaparotomy (n = 41)	P value
Satisfaction rate (%)	95.8 (69/72)	92.7 (38/41)	.423
Relief of symptoms (%)			
Absence of pain	95.3 (41/43)	94.1 (16/17)	—
Absence of menorrhagia	97.8 (45/46)	96.4 (27/28)	—
Absence of frequency	92.3 (12/13)	87.5 (7/8)	—
Absence of bulge sensation	100 (11/11)	100 (6/6)	—
Absence of unexplained infertility	100 (4/4)	100 (1/1)	—
Recurrence rate of myomas	0	0	—

*Wen. Myomectomy by ultraminilaparotomy. Fertil Steril 2008.*

ultraminilaparotomy appeared to provide better economy, with savings of NT\$3,132 (NT\$56,693 [US\$1,718] vs. NT\$53,561 [US\$1,623]), though the difference was not statistically significant. Other complications, such as requests of blood transfusion, paralytic ileus, and wound infection occurred only in the laparotomy group, although there was no statistical significance between the two groups. The short-term therapeutic outcome, which was evaluated regularly up to 1 year, showed a 92.7% satisfaction rate in the ultraminilaparotomy group and 95.8% in the laparotomy group. Taken together, the data in this study strongly support the advantages of using ultraminilaparotomy in place of laparotomy for uncomplicated uterine myomas.

Several randomized prospective studies have compared the early outcome of myomectomy by laparotomy with that obtained with minilaparotomy (5, 21, 24). Our data were consistent with the results from Benassi et al., including similar blood loss and hemoglobin difference and fewer days of spontaneous recanalization and postoperative hospital stay (21). Similar advantages were observed in another randomized prospective study on the early outcome of myomectomy by laparotomy, minilaparotomy, and laparoscopically assisted minilaparotomy (6). In evaluating the costs of minilaparotomy and laparotomy, many studies found a significant economic benefit for the minilaparotomy group (21), although our study only suggested that the use of ultraminilaparotomy might be less costly. A multicenter randomized, controlled study provided more evidence showing similar advantages, such as minimal invasiveness, high feasibility, and safety, in minilaparotomy compared with laparoscopy (24). In addition, the reproductive outcome was evaluated in the same series and showed that minilaparotomic and laparoscopic myomectomy improves the reproductive outcomes in patients with unexplained infertility in a similar manner, although the authors found that the laparoscopic approach provides the best benefits in fertile patients with symptomatic leiomyomas (29).

It is noteworthy that the ultraminilaparotomy technique in this study differs from that in the above studies. First, the incision wound was significantly smaller; the average incision wound was only 3.4 cm. Because the minilaparotomy ap-

proach was considered a minimally invasive procedure (24) and the average incision wound was approximately 5 cm (ranging either from 4 to 9 cm or from 4 to 6 cm in length in different studies) (19–24), the ultraminilaparotomy approach is a minimally invasive procedure even though the wound extended to 5 cm and even though the latter condition (wound length  $\geq 5$  cm) should not be considered as a ultraminilaparotomy. In this study, none of the ultraminilaparotomy incision wounds was  $>5$  cm in length. However, up to four patients (9.8%) in the ultraminilaparotomy group did not meet the criteria of ultraminilaparotomy, in which the final incision should be  $\leq 4$  cm, because the final wound length in these four patients ranged from 4.1 to 4.3 cm. Based on this fact, which violated our original definition of ultraminilaparotomy, the success rate of the completed operations was only 90.2%. Therefore, the ultraminilaparotomy approach for myomectomy might be another choice when the minilaparotomy approach for myomectomy is planned, although this suggestion needs further proof. Second, the non-custom-made instrument, the Backhaus Towel Clamp, placed in the major myoma, was used to force the myoma and the uterus near the small incision wound. Third, larger myomas were “pared” piece by piece through a smaller wound. Using this strategy, we avoided enlarging the wound and were able to remove bigger leiomyomas successfully. Finally, diluted vasopressin was used to decrease intraoperative bleeding, and the myometrial defect was carefully closed with a standard three-layered closure.

The main limitation of this study is the short follow-up period (1 year). We failed to provide the long-term outcome after operation (ultraminilaparotomy), including the risk of uterine dehiscence, recurrent uterine leiomyomas, and other possible future sequelae, such as adhesion formation.

Another limitation brought to our attention in this study should be mentioned because it may significantly affect the results. There is a fundamental discrepancy in the surgical techniques, with the use of uterine externalization versus intraperitoneal repair at myomectomy in the laparotomy group and ultraminilaparotomy group, respectively, which may contribute to some differences of outcomes based on studies

of cesarean section (30–32). In a review of extra-abdominal versus intra-abdominal repair of the uterine incision during cesarean section, there were no statistically significant differences between the groups in most of the outcomes identified, but the following differences, febrile morbidity and length of hospital stay, might be present.

With extra-abdominal closure of the uterine incision, febrile morbidity was lower (relative risk 0.41, 95% confidence interval 0.17 to 0.97) and the hospital stay was longer (weighted mean difference 0.24 days, 95% confidence interval 0.08 to 0.39) (30). Finally, the average hospital stay was relatively longer in both groups in this study (4.0 days in the ultraminilaparotomy group and 5.3 days in the laparotomy group). The culture of hospitalization in Taiwan might contribute to this finding, because patients who received myomectomy uneventfully had a 6-day standard hospital stay.

In conclusion, the ultraminilaparotomy technique for myomectomy offers advantages for patients, including less pain, quicker recovery of bowel function, and a reduction in days of hospitalization without compromising the therapeutic effects, including the successful excision of uncomplicated leiomyomas and the resolution of symptoms, compared with laparotomy, if a proper selection of patients is made. Ultraminilaparotomy is a feasible approach in the surgical treatment of uncomplicated uterine leiomyomas.

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