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Original Article

A case-control study to compare the outcome of women treated by two minimally invasive procedures-ultraminilaparotomy myomectomy and laparoscopic myomectomy

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ABSTRACT

Objective: Ultraminilaparotomy myomectomy (UMLT-M with less 4 cm transverse skin incision) and conventional 3-port wound laparoscopic myomectomy (LM) approaches were proposed as alternative minimally invasive procedures in the management of women with symptomatic uterine myomas but few studies have compared the outcomes of both procedures.

Materials and methods: Between January 2002 and December 2003, 71 patients undergoing UMLT-M were compared with those 71 women undergoing LM. The last data collection for all patients was done on 31 December 2016. The parameters for comparison included the characteristics of the uterine myomas, surgical parameters, morbidities, and outcomes. Surgical parameters included the operative time (minutes), estimated blood loss (milliliters), time for removal of drainage, percentage of blood transfusion and co-morbidities.

Results: Mean operative time in the LM group was significantly longer than that in the UMLT-M group (208.7 ± 65.9 *vs.* 98.0 ± 28.2 min, $p < 0.001$). Intra-operative blood loss was significantly higher in the LM group than that in the UMLT-M group (210.9 ± 184.5 *vs.* 111.7 ± 108.4 ml, $p < 0.001$). However, more patients had postoperative fever in the UMLT-M group (39.4% *vs.* 8.5%, $p < 0.001$). The recurrence rate of myoma at 5-year follow-up was significantly different between two groups (35.2% of UMLT-M *vs.* 57.7% of LM, $p = 0.007$), but there was no difference when follow-up time was over ten years. The location of the myoma recurrence was different between two groups with higher recurrence rates in the fundal and lateral sides of uterus in the UMLT-M group and in the anterior wall of uterus in the LM group. However, the overall symptom control, the need of repeated myoma-related surgery and subsequent pregnancy outcome of both groups seemed to be similar in both groups.

Conclusions: More operative time and more blood loss reflected that LM demanded skills, experience and equipment. Therefore, UMLT-M might be a feasible alternative choice in the management of uterine myomas, since it is an easy-to-perform and familiar technique, especially in the absence of suitable equipment or skilled operator. A large and randomized study is needed to confirm the above findings.

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Introduction

Uterine fibroids (myomas or leiomyomas) are the most common benign tumors of the uterus [1,2], and majority of them are asymptomatic; therefore, no further intervention is needed [3–6]. Sometimes, uterine myomas result in abnormal uterine bleeding, pelvic pain, infertility, and miscarriage [7–10]. Myomectomy, rather than hysterectomy, can be one of the best options in the management of women with symptomatic uterine fibroids, who wish to preserve their childbearing capabilities or avoid hysterectomy for reasons other than fertility [11–16]. Currently, women have much concern of cosmetic benefits and low-traumatic procedures, which prompts the search for more conservative and minimally invasive surgical methods when surgical intervention is unpreventable [17–22].

The feasibility, safety and cosmetic advantages of laparoscopic myomectomy (LM) have been confirmed in the literature [23–26]. However, LM is still more complicated and technically challenging with a longer learning curve, and sometimes associated with catastrophic problems [27,28]. The minilaparotomy (MLPT with 4–8-cm transverse skin incision) myomectomy (MLPT-M) and ultraminilaparotomy (UMLT with less 4 cm transverse skin incision) myomectomy (UMLT-M) approaches were proposed as alternative minimally invasive procedures for LM [29–31]. Short hospital stay, rapid recovery and good cosmetic effects were also apparent in both procedures compared to conventional laparotomy [29,31]. Several studies have compared MLPT-M with LM [32–36], but only a small number of studies have been available to compare the outcome of UMLT-M and LM [37]. One study from Ciavattni and colleagues to show that LM seems to be the preferable approach for the treatment of large myomas of $\geq$5 cm, providing more rapid recovery compared to the UMLT-M, but the postoperative outcome, such as recurrence rate did not be mentioned [37].

The current study aimed to evaluate the outcomes of UMLT-M and LM in the management of women with symptomatic uterine fibroids.

Materials and methods

Between January 2002 and December 2003, 71 patients undergoing UMLT-M treatment and 71 multivariable-matched women undergoing LM (1:1) were enrolled into the current study. The last data collection for all patients was done on 31 December 2016. This study was approved by the institutional Review Board of Taipei Veterans General Hospital.

These patients had to fulfill the criteria of uncomplicated myomas provided by the National Health Insurance Bureau in Taiwan, including (1) absence of previous abdominal or pelvic surgery, (2) a number of visible uterine masses (myomas) $\leq$5 intramural or subserous myomas (without peduncle), (3) a maximum diameter of not $\leq$8 cm, and (4) an absence of prominent or significant pelvic adhesion on clinical evaluation [29–31]. In addition, the patients had to fulfill the following 3 basic requirements: absence of preoperative or postoperative adjuvant therapy, absence of other pelvic pathologies, except fibroids, and a final follow-up in December 2015. The phrase “symptomatic” meant any disturbance induced by fibroids that troubled one's life, which has been described previously [29–31].

Operative procedures

All operations were performed under general endotracheal anesthesia with the patients in the Trendelenburg position and the bladder catheterized. Diluted vasopressin (1:80) was injected into the myometrium around the fibroid nodules and directly into the fibroid tissue of the patients to decrease intraoperative bleeding during both procedures.

Ultraminilaparotomy myomectomy (UMLT-M)

The operative procedure for the UMLT-M group was similar to that in the conventional laparotomy group with some differences. First, a 2–4 cm (near 3 cm) transverse incision (modified Pfannenstiel incision) along the preoperative mark was made below the pubic hairline. The abdominal fascia was opened transversely to a width of 5–6 cm. Second, the self-retaining retractor was replaced with small Deaver retractors (width 2.5 cm) or thyroid retractors (width 1.5 cm). The small end of the abdominal retractor (width 3 cm) was inserted only slightly into the wound. During dissection, the instrument, the Backhaus towel clamp (Robbins Instruments Inc, Chatham, NJ), was applied for traction of the fibroid toward the incision wound. Third, removal of the intact fibroid was not as easy as in conventional laparotomy. Larger fibroids were pared piece-by-piece through a smaller wound [29–31]. The combination waste vent (CWV) drain was placed in the cul-de-sac region and pulled out from the wound in the left lower abdominal region. Then, the CWV drain was fixed on the abdominal wall.

Laparoscopic myomectomy

A 10-mm port was inserted through the umbilicus to introduce the video-laparoscopic system and pneumoperitoneum was established. Another three accessory 5-mm trocars were inserted into the abdomen in the left lower quadrant, right lower quadrant, and suprapubic area for operative instruments and in the suction irrigator for the cannula. The fibroid was grasped and pulled with a second needle to infiltrate Pitressin. Next, we incised the myometrium and removed fibroids. After that step, we extended the wound over the left lower quadrant up to 1.2 cm for insertion of an electronic morcellator (Karl Storz, Tuttlingen, Germany). Fibroids were removed using the morcellator. The myometrial defects were repaired through a standard laparoscopic suture with 1-0 and 2-0 vicryl, and bleeding of the uterus was later checked. The CWV drain was placed in the cul-de-sac region and pulled out from the wound in the left lower abdominal region. Next, the CWV drain was fixed on the abdominal wall. After completing this procedure, the CO_2 insufflator and video laparoscopic system were turned off temporarily.

Evaluation parameters

The parameters we considered for comparing the 2 groups were the characteristics of the uterine fibroids, surgical parameters, morbidities, and outcomes. Surgical parameters included the operative time (minutes), estimated blood loss (milliliters), time for removal of drainage, percentage of blood transfusion and co-morbidities. Co-morbidities included percentage of febrile morbidity (body temperature >37.5 °C), maximal temperature, duration of febrile morbidity, and percentage of paralytic ileus, hospital stay (days), visual analog scale scores, postoperative use of analgesics, and accumulative dosage of meperidine hydrochloride. The outcome evaluation primarily focused on recurrence, either the occurrence of symptoms or detection of any uterine fibroids. The parameters, including recurrence rate, interval between operation and detection of recurrence, number, maximal size, and location, were recorded. Recurrence was defined as any detected tumor with a minimal diameter >1 cm after operation.

All patients received >4 semiannual follow-ups and were subsequently followed up annually or when symptoms or signs

recurred. Routine pelvic examinations and ultrasound were used for every patient.

Statistical analysis

Statistical analysis was carried out using the PASW computer program package (PASW Statistics V18, Chicago, IL, USA). Data are presented as the mean ± SD. The parametric—independent samples t-test was used to compare the differences between the two groups, and the chi-square analysis was used for categorical variables. For all statistical evaluations, $p < 0.05$ was used for significant.

Results

Women undergoing UMLT-M had shorter operative time and less blood loss than those undergoing LM

Baseline characteristics are shown in Table 1. Since this was a case-controlled study, the age, body mass index (BMI), number and maximum diameter of uterine leiomyoma and indication for myomectomy were similar in both groups. Both groups successfully completed the intended operative procedure.

Comparing the surgical parameters, mean operative time in the LM group was significantly longer than that in the UMLT-M group (208.7 ± 65.9 *vs.* 98.0 ± 28.2 min, $p < 0.001$; Table 2). Intraoperative blood loss was significantly higher in the LM group than that in the UMLT-M group (210.9 ± 184.5 *vs.* 111.7 ± 108.4, $p < 0.001$; Table 2). More patients received a blood transfusion in the LM group than those in the UMLT-M group did (16.9% *vs.* 0%, $p < 0.001$; Table 2). The average amount of blood transfused was 585 ml in the LM group. The duration of using a postoperative drainage system was similar in both groups.

For postoperative pain control, more LM patients (95.8%) than UMLT-M patients (70.4%) received an intramuscular injection of meperidine hydrochloride, but the accumulated dose was higher in the UMLT-M group than that in the LM group (113.0 ± 58.1 *vs.* 58.2 ± 29.6 mg, $p < 0.05$). The pain score (visual analog scale score) was significantly higher in the LM group than that in the UMLT-M group (5.9 ± 1.6 *vs.* 3.5 ± 0.9, $p < 0.05$; Table 2).

Patients in the UMLT-M group had shorter hospital stay

Maximal body temperature was higher in the UMLT-M group than that in the LM group (38.1 ± 0.1 *vs.* 37.9 ± 1.9 °C, $p < 0.001$), contributing to more patients in the UMLT-M group having postoperative fever (39.4% *vs.* 8.5%, $p < 0.001$; Table 3). Period of fever was not statistically different between two groups, but the trend of longer period of fever was noted in the UMLT group (3.6 ± 2.5 *vs.* 1.8 ± 1.4 days, $p = 0.082$). Four patients had postoperative paralytic ileus in the LM group compared with none in the UMLT-M group. UMLT-M groups had shorter hospital stay than LM did (4.1 ± 0.8 *vs.* 5.5 ± 1.4, $p < 0.001$).

Recurrent rate of myomas in the UMLT-M group was lower than that in the LM group at the end of 5-year follow-up but this difference disappear when follow-up time was over 10 years

Patients in the LM group had higher recurrence rates of uterine myomas than those in the UMLT-M group did (35.2% *vs.* 57.7%, $p = 0.007$; Table 4), but this difference between two groups disappeared when the follow-up period was more than 10 years (Table 5). The location of recurrent fibroids was different in both groups, including higher recurrence rates at the anterior wall of

Table 1
Clinical characteristics of women with symptomatic uterine myomas.

	UMLT-M (n = 71)	LM (n = 71)	*p* value
Basic data			
Age (years)	39.8 ± 7.7	39.9 ± 6.3	0.934
Body mass index (kg/m^2)	22.5 ± 4.5	23.2 ± 4.3	0.390
Myoma data			
Number (n)	1.9 ± 1.1	2.1 ± 1.5	0.060
Max diameter (cm)	6.9 ± 2.0	6.1 ± 2.6	0.309
Indication for myomectomy			
Pain (%)	30 (42.3)	39 (54.9)	0.179
Uterine bleeding (%)	43 (60.6)	44 (62.0)	0.864
Pressure (%)	18 (25.4)	19 (26.8)	0.894
Mass (%)	10 (14.1)	14 (19.7)	0.372
Infertility (%)	3 (4.2)	1 (1.4)	0.300

Data are presented with mean ± standard deviation or number (percentage).
UMLT-M: ultraminilaparotomy myomectomy, LM: laparoscopic myomectomy.

Table 2
Surgical parameters.

	UMLT-M	LM	*p* value
Surgical parameter			
Operative time (mins)	98.0 ± 28.2	208.7 ± 65.9	<0.001
Use of drainage	5.6% (4)	100% (71)	0.002
Time to remove drainage (days)	2.5 ± 0.6	2.4 ± 1.4	0.928
Blood loss (ml)	111.7 ± 108.4	210.9 ± 184.5	<0.001
Blood transfusion (%)	0 (0)	12 (16.9)	<0.001
Mean blood transfusion (ml)	0	585	
Post-operative pain			
Visual analog scale	3.5 ± 0.9	5.9 ± 1.6	<0.001
Pain control (%)	16 (22.5)	3 (4.2)	<0.001
Meperidine hydrochloride (%)	50 (70.4)	68 (95.8)	<0.001
Meperidine hydrochloride dose (mg)	113.0 ± 58.1	58.2 ± 29.6	<0.001

Data are presented with mean ± standard deviation or number (percentage).
UMLT-M: ultraminilaparotomy myomectomy, LM: laparoscopic myomectomy.

Table 3
Postoperative morbidity.

Parameters	UMLT-M	LM	*p* value
Fever cases (%)	28 (39.4)	6 (8.5)	<0.001
Max fever (°C)	38.1 ± 0.1	37.9 ± 1.9	<0.001
Duration of fever (h)	3.6 ± 2.5	1.8 ± 1.4	0.082
Paralytic ileus (%)	0 (0)	4 (5.6)	0.120
Days of bowel recanalization	1.3 ± 0.6	1.5 ± 0.6	0.079
Hospitalization (days)	4.1 ± 0.8	5.5 ± 1.4	<0.001

Data are presented with mean ± standard deviation or number (percentage).
UMLT-M: ultraminilaparotomy myomectomy, LM: laparoscopic myomectomy.

Table 4
Accumulative outcome of 5-year follow-up.

Parameters (n)	UMLT-M n (%)	LM n (%)	*p* value
Relief of symptoms	65 (91.5)	62 (87.3)	0.413
Recurrence rate of myoma (%)	25 (35.2)	41 (57.7)	0.007
Location			
(1) Anterior	7 (28)	24 (58.5)	0.016
(2) Fundal	8 (32)	4 (9.8)	0.023
(3) Posterior	18 (72)	30 (73.1)	0.917
(4) Lateral	16 (64)	9 (22)	0.001
Repeated myoma-related surgery	4 (5.6)	5 (7)	0.731
Attempt pregnancy	6	7	–
Term pregnancy	2	2	–
Preterm pregnancy	1	1	–
Abortion or EP	0	1	–

Data are presented with mean ± standard deviation or number (percentage).
UMLT-M: ultraminilaparotomy myomectomy, LM: laparoscopic myomectomy, EP: ectopic pregnancy.

Table 5
Accumulative outcome of 10-year follow-up.

Parameters (n)	UMLT-M n (%)	LM n (%)	*p* value
Relief of symptoms	55 (77.5)	56 (78.9)	0.839
Recurrence rate of myoma (%)	35 (49.3)	42 (59.2)	0.238
Location			
(1) Anterior	8 (22.9)	25 (59.5)	0.001
(2) Fundal	10 (28.6)	4 (9.5)	0.031
(3) Posterior	22 (62.9)	30 (71.4)	0.424
(4) Lateral	22 (62.9)	15 (35.7)	0.018
Repeated myoma-related surgery	5 (7.0)	5 (7.0)	–
Attempt pregnancy	7	7	–
Term pregnancy	3	2	–
Preterm pregnancy	1	1	–
Abortion or EP	0	1	–

Data are presented with mean ± standard deviation or number (percentage).
UMLT-M: ultraminilaparotomy myomectomy, LM: laparoscopic myomectomy, EP: ectopic pregnancy.

uterus in the LM group and higher recurrence rates at the fundal and lateral wall of uterus in the UMLT-M group, respectively (Table 4). This difference persisted even more than 10 years after initial myomectomy for these enrolled patients (Table 5).

Symptom control, the need of repeated surgery, and pregnancy outcome were similar in both groups

However, the recurrence rates of uterine myomas in both groups did not influence the therapeutic outcome, including symptom relief rates and the need of repeated myoma-related surgery in two groups. The symptom control rate was similar in both groups, even after more than 10 years postoperatively (Tables 4 and 5). No patients needed to undergo a second repeated surgery for early postoperative complications. Some patients underwent repeated surgery for recurrence of myoma-related symptoms or signs, but there was no difference between two groups, and no difference of 5-year and 10-year follow-up in both groups (Tables 4 and 5). Pregnancy outcome was also similar in both groups without statistically significant difference (Tables 4 and 5). All patients with pregnancy were treated with cesarean section, regardless of which myomectomy was done.

Discussion

Myomectomy, unlike hysterectomy, not only maintains fertility but also successfully relieves uterine fibroid-related symptoms [12,17,38–40]. Conventional laparotomy is most commonly used for myomectomy. Several modified procedures for myomectomy, including minilaparotomy (MLPT with 4–8-cm transverse skin incision) and ultraminilaparotomy (UMLT with less 4 cm transverse skin incision), laparoscopy, laparoscopically assisted laparotomy, natural orifice laparoscopy, and single-port laparoscopically assisted-transumbilical UMLT, have been developed [41,42]. Our previous report showed the superiority of the use of UMLT-M in the management of women with uncomplicated uterine fibroids, including less operative pain, rapid recovery and better cosmetic results compared to the use of laparotomy; however, previous study only followed up by one year [29]. Another study found that UMLT approach with or without laparoscopy could be used successfully in place of conventional laparotomy in the management of women with symptomatic uterine fibroids [31]. The current study further supported the potential benefits of UMLT-M in the management of women with symptomatic uterine fibroids compared with LM, including shorter operative time, less blood loss and a lower recurrence rate. UMLT-M might be another option for women who would like to preserve the benefits from the small incision wound but are relatively not suitable for LM, such as those with intra-abdominal adhesion or a compromised cardiopulmonary system.

With no difference of operative time in the Ciavattini's study (77.7 *vs.* 86.1 min) [37], our study showed that LM needed more operative time than UMLT-M did. The reason was much longer operative time of LM needed in the current study (median 200 min), which was significantly higher than those studies in the literature (median 100 min, ranging from 30 to 330 min) [24,26,38]. Since the current study enrolled the study subjects between 2002 and 2003, LM was still a new technology at that time, with following limitation, such as unfamiliar techniques, or inadequate equipment support.

With the above reason, there was no surprise to find more blood loss in the LM group. Three patients in the LM group needed a blood transfusion, but none in the UMLT-M group. Several studies disclosed the increased risk of delayed bleeding and future uterine rupture after LM [41–44]. However, this limitation might be often neglected in the modern technology to perform LM, since continuous barbed suture or medical material has been available now [24,26,45–49]. With a significant improvement of surgical material, LM is much more easy and feasible.

With comparison between LM and UMLT-M, it is relatively surprising to find that the pain intensity VAS score was higher in the LM group than that in the UMLT-M group. The reason was uncertain, and possibly explained by few patients (4.2%) in the LM group who received continuous pain control anesthesia after the operation. This further supported by higher dosage of meperidine hydrochloride needed in the UMLT-M group. Alessandri's study showed MLPT-M had more severe pain than LM did (VAS score, 6.5 *vs.* 4.1) [41]. In the current study, the use of other analgesic drugs, such as non-steroid anti-inflammatory drugs (NSAIDs) had not been recorded, contributing to uncertain results in term of pain evaluation between UMLT-M and LM.

In the current study, it is surprising that women undergoing UMLT-M had a high risk of fever than patients undergoing LM did (39.4% *vs.* 8.5%). In terms of postoperative fever, the results are relatively conflicted. Ciavattini's [37] and Fanfani's studies [44] did not show any difference of febrile morbidity between UMLT-M or MLT-M and LM, but Seracchioli's study showed risk of postoperative fever was higher in the abdominal myomectomy compared to LM (26% vs. 12%) [50]. In theory, postoperative levels of the inflammatory cytokines have been consistently lower after laparoscopic procedures, and the functions of the peritoneal macrophages are better preserved when laparotomy is avoided [51,52]. Evidence suggested that laparoscopic procedures altered the host response, significantly contributing to better postoperative outcome, including lower incidence of postoperative fever [53–55]. Other gynecological surgeries, such as surgery for benign ovarian tumor also showed the lower febrile morbidity in the laparoscopic procedures compared to conventional laparotomy [56].

A longer hospital stay was found in the LM group. The reason might be related to payment system from the National Health Insurance in Taiwan, since the Diagnosis Related Groups (DRG) system for myomectomy accepted 6 days of standard hospitalization. More patients in the LM group stayed for 6 days and even one patient stayed for 15 days.

Patients in the LM group had a higher recurrence rate of uterine myoma than those in the UMLT-M group did in the short-term follow-up (5 years), but the difference was absent when follow-up time is more than 10 years. However, this difference did not affect the therapeutic outcome of the patients either treated with UMLT-M or LM, because the symptom control, the need of repeated myoma-related surgery, and subsequent pregnancy outcomes

seemed to be not difference between two approaches. This finding supported that long-term follow-up might provide much more information for the surgical outcomes of both procedures.

In the current study, the recurrence location of myomas seemed to be different between two groups. It is an interesting finding. The possible explanation might be secondary to surgical exposure and limitation of the surgical technology of the surgery itself.

The main limitation of the current study was not randomized, and also compromised by the "beginning" of using LM in the management of women with uterine myomas. However, our study confirmed the feasibility of UMLT-M in the management of women with symptomatic uterine fibroids. UMLT-M is an easy-to-perform and familiar technique.

Conflict of interest

The Authors declare that there are no conflicts of interest.

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