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Laparoscopic Uterine Vessel Occlusion in the Treatment of Women with Symptomatic Uterine Myomas with and without Adding Laparoscopic Myomectomy: 4-Year Results

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ABSTRACT **Study Objective:** To estimate the necessity of laparoscopic myomectomy (LM) in the treatment of women with symptomatic uterine myomas who are undergoing laparoscopic uterine vessel occlusion (LUVO).
Design: A comparative observational study (Canadian Task Force classification II-3).
Setting: Medical center.
Patients: In all, 163 patients with symptomatic, uncomplicated myomas warranting myomectomy. A total of 95 patients underwent LUVO and 68 underwent LUVO with LM.
Interventions: Symptomatic myomas treated by LUVO with or without LM.
Measurements and Main Results: The outcome was measured by comparing surgical parameters, immediate postoperative parameters, 4-year evaluations of symptom control, and reintervention (hysterectomy or myomectomy) in both groups. The general characteristics of the patients were similar in both groups. No statistical differences existed in complications, success rate, or immediate satisfaction rate between the 2 groups. Compared with LUVO+LM, LUVO had advantages in surgical and immediate postoperative parameters, including less operative time, minimal blood loss, and rapid postoperative recovery; however, LUVO+LM was superior to LUVO in terms of a better and longer duration of symptom relief, a higher level of satisfaction, and avoidance of reintervention. Of the sexually active patients who did not use contraception, 58.8% (10/17) and 66.7% (4/6) became pregnant in groups I and II, respectively (no statistical significance).
Conclusion: Although LUVO is a less invasive procedure in the treatment of most women with symptomatic myomas, it is also less effective for symptom control and has shorter durable symptom relief compared with LUVO+LM. Reoperation can be avoided in most patients who are treated with LUVO+LM. Journal of Minimally Invasive Gynecology (2008) 15, 712–718

Keywords: Myoma; Laparoscopic myomectomy; Laparoscopic uterine vessel occlusion

Uterine leiomyomas are the most common gynecologic tumors in women of reproductive age [1]. Clearly, although many such lesions are asymptomatic [2], symptoms directly attributable to these benign tumors represent the most common reason for laparotomy (LT) in nonpregnant women in the United States [3,4], and in Taiwan [5,6]. Whereas in decades past hysterectomy was seen almost as a panacea for uterine leiomyomas, more recently, attention was paid to the development of pharmaceutical agents and less invasive procedures or those performed by routes that incur less morbidity than does LT [7]. Frequently, such procedures are designed to retain the uterus [7]. Among these, myomectomy

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may be the principal option for women wishing to maintain their fertility [8].

Although the uterine-sparing treatment of choice for symptomatic uterine myomas was myomectomy [9], uterine-artery embolization was introduced in 1995 as an alternative technique for treating myomas [10]. Since then, it has become increasingly accepted as a minimally invasive, uterine-sparing procedure, and studies reported the relief of excessive menstrual bleeding or pressure in 80% to 90% of patients [11–18]. These studies also showed a reduction in leiomyoma and uterine size 3 to 12 months after the procedure [15]. A similar concept, known as laparoscopic uterine vessel occlusion (LUVO), was first reported as a treatment for myomas in 1999 [19,20]. Similar relief of symptoms (89.4% with symptomatic improvement and 21.2% with complete resolution of symptoms) and reduction of uterine and leiomyoma size (average of 46% and 76%, respectively) were reported in 2001 in a 7- to 12-month follow-up of 87 patients after laparoscopic uterine vessel occlusion [21].

Rapid growth occurred in the use of this treatment (LUVO) with various modifications, which included simultaneous accompaniment with myomectomy, and considerable research took place into their outcomes [23–34]. All of the combination therapies are reported to be effective therapy for symptomatic uterine myomas. In addition, we reported that combination LUVO and myomectomy provided the more effective symptom control and minimized the risk of myoma recurrence [22,27]. The question is raised as to what the therapeutic difference is between LUVO alone and the combination of LUVO and laparoscopic myomectomy (LM) (LUVO+LM) in the treatment of women with symptomatic uterine myomas.

The aim of this observational study was to respond to this question by assessing the therapeutic difference between LUVO alone and LUVO+LM in the treatment of women with symptomatic uterine myomas.

Materials and Methods

Patients

This observational study was conducted between March 1999 and December 2002. Women scheduled for uterine-sparing treatment who had symptomatic uterine myomas were invited to participate in the study. All the uterine-sparing treatments for symptomatic uterine myomas, including myomectomy through traditional exploratory LT, mini-LT (MLT), ultra-MLT, laparoscopy, the vagina, or hysteroscopy, and LUVO and combination therapy, are well-accepted procedures in our hospital. All patients had uterine myomas with symptoms, including either menstrual problems such as menorrhagia and pain, or compression syndrome, including a bulge-like sensation and urinary frequency that warranted definite surgical treatment, but these patients wanted to retain their uteri. These women were informed that they could choose to be treated with any (appropriate) one of the above-mentioned procedures, based on their willingness and preference.

The study patients were all thoroughly counseled regarding the potential risks, benefits, curative nature, and fertility issues related to uterine artery occlusion. Written informed consent was obtained from all patients before enrollment in the study. This study was approved by the institutional review board of Taipei Veterans General Hospital, Taiwan.

This study was conducted to evaluate the necessity of LM in the treatment of women with symptomatic uterine myomas who are undergoing LUVO. Only women treated with LUVO alone or a combination of LUVO and LM were enrolled into the study. All patients were followed regularly for at least 4 years after completing therapy. In all, 163 women were finally included in the analysis.

Operative Procedures

Both operations were performed under general anesthesia with the patient in the dorsolithotomy position and with the bladder catheterized.

The detailed procedure used for the women who were treated with LUVO was described before [20,21]. In brief, after establishing a laparoscopic operative field, the anterior leaf of the broad ligament was opened with scissors, keeping the peritoneum at proper tension by shifting the uterus to the opposite side. A vertical 2- to 3-cm incision was made on the triangle enclosed by the round ligament, external iliac artery, and infundibulopelvic ligament, with careful dissection of the ureter and the internal iliac artery, and adequate hemostasis. The bilateral uterine artery and bilateral ovarian suspension ligaments were thoroughly coagulated. In all, 95 women were treated with LUVO only (LUVO group), and the other 68 patients were subsequently treated with LM (LUVO+LM group).

The detailed procedure used in the LM group was reported before [22], with some modification. Myomas were extracted through a 12-mm suprapubic port by morcellation, with the help of an electromechanical morcellator (Ethicon, San Angelo, TX). The myometrial edges were closed in 1 or 2 layers, according to the depth of the uterine wound, by means of polyglactin 0 sutures.

Evaluation Parameters

The parameters we considered for comparing the 2 groups were: operative time (minutes); blood loss, which was estimated by the total volume in the suction container minus the volume of irrigation fluid used intraoperatively; interval between completing surgery and tolerance of food intake; maximal fever; and complications, such as blood transfusion, wound infection, or hematoma. A visual analog 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 nongraduated 10-cm line ranging from ''no pain'' to ''pain as bad as it could be.''

Leiomyoma-related symptoms, either menstrual problems such as menorrhagia and pain, or compression syndrome, including a bulge-like sensation and urinary frequency, were assessed using a yes/no improvement questionnaire at 12, 24, 36, and 48 months after surgery. Recurrence was defined as the presence of any ''no'' in a yes/no improvement questionnaire (different items for evaluation) at 12, 24, 36, and 48 months after surgery. Yes/no questionnaires were used at the discharge date, and at the end of the 12-, 24-, 36-, and 48-month follow-up to evaluate satisfaction. The reproductive outcomes were recorded during the follow-up period.

At each follow-up evaluation, medical or surgical treatment for the myomas was recorded, and included anemia treatment, the use of nonsteroidal antiinflammatory drugs, or intensive surgical procedures, such as hysterectomy, myomectomy, and dilatation and curettage. The follow-up surgical treatments, including hysterectomy or myomectomy, were defined as reinterventions.

Statistical Analysis

SPSS, Version 15.0 for Windows (SPSS Inc., Chicago, IL) was used for statistical analysis. The continuous variables are presented as median, because the Kolmogorov-Smirnov test showed that all of them were skewed. They were compared by nonparametric Mann-Whitney *U* tests. The categorical variables are presented as percentages, and were compared using χ^2 tests or Fisher exact tests, as appropriate. All calculated p values were 2-tailed, and a p value less than .05 was considered statistically significant.

Results

Median age, body mass index, preoperative hemoglobin level, number of myomas, maximum myoma diameter, main tumor location, and obstetric history were similar in the 2 groups; only the symptoms resulting from myoma differed (Table 1). As predicted, operative time in the LUVO group was significantly shorter than in the LUVO+LM group (30 vs 60 minutes); in addition, the amount of blood loss during operation in the LUVO group was less than that in the LUVO+LM group (20 vs 50 mL) (Table 2).

Postoperative recovery was significantly better in the LUVO group compared with the LUVO+LM group, because the mean of the maximal postoperative temperature of the LUVO group was significantly lower than that of the LM group, the VAS score in the LUVO group was significantly lower than that in the LUVO+LM group, and food intake occurred sooner after operation in the LUVO group compared with the LUVO+LM group. The complication rate in both groups was similar (Table 2). However, none of the complications was directly correlated with the operation; 1 complication in the LUVO group was a urinary tract infection and the 3 complications in the LUVO+LM group were patients who received a blood transfusion at the request of the anesthesiologists, although none of these patients had an operative blood loss greater than 200 mL.

Table 1
Baseline characteristics of the enrolled women

	LUVO (n = 95)	LUVO + LM (n = 68)	p
Age (yr)	43 (32–51)	43 (31–49)	.471
Body mass index (kg/m^2)	22.3 (19.5–26.2)	22.3 (18.3–25.7)	.674
Pregnancy history			.831
Nullipara	29.5% (n = 28)	27.9% (n = 19)	
Multipara	70.5% (n = 67)	72.1% (n = 49)	
Preoperative Hgb (g/dL)	9.2 (6.4–12.9)	8.9 (6.2–13.2)	.286
Symptom			
Pain	27.4% (n = 26)	26.5% (n = 18)	1.00
Menorrhagia	57.9% (n = 55)	70.6% (n = 48)	.098
Bulge sensation	57.9% (n = 55)	41.2% (n = 28)	.035
Frequency	46.3% (n = 44)	38.2% (n = 26)	.304
Myoma			
No.	2 (1–5)	2 (1–5)	.905
Maximum diameter (cm)	5 (4–8)	6 (4–7)	.211
Location			.909
Anterior wall (n)	15.8% (n = 15)	17.6% (n = 12)	
Posterior wall (n)	73.7% (n = 70)	70.6% (n = 48)	
Fundal area (n)	10.5% (n = 10)	11.8% (n = 8)	

HgB = hemoglobin; LM = laparoscopic myomectomy; LUVO = laparoscopic uterine vessel occlusion.
Data presented as median/range or percentage/No.

Most patients in the LUVO group and all patients in the LUVO+LM group were reported to have symptom relief (range 87.3%–96.2% in the LUVO group and 100% in the LUVO+LM group, based on different kinds of symptoms), although a trend toward better symptom control was noted in the LUVO+LM group 12 months after surgery (Table 3). Increased hemoglobin levels (11.9 g/dL in the LUVO group vs 12.4 g/dL in the LUVO+LM group) were noted in both groups 24 months after surgery (Table 3). These symptom-improvement effects were maintained in most patients in both groups in this 4-year follow-up (>70% LUVO vs >90% LUVO+LM, respectively).

Table 2
Surgical and postoperative parameters after laparoscopic uterine vessel occlusion and laparoscopic myomectomy

	LUVO (n = 95)	LUVO+LM (n = 68)	p
Operative time (min)	30 (20–50)	60 (40–160)	< .001
Blood loss (mL)	20 (10–35)	50 (30–200)	< .001
Complications[a]	1.1% (n = 1)	4.4% (n = 3)	.309
Maximum fever (°C)	37.4 (37.1–38.1)	37.4 (37.1–38.7)	.487
VAS	3.1 (2.1–3.9)	3.5 (3.2–4.1)	< .001
Tolerance to food intake (hr)	1 (1–12)	8.0 (6–35)	< .001
Satisfaction rate	100% (95/95)	100% (68/68)	–

LM = laparoscopic myomectomy; LUVO = laparoscopic uterine vessel occlusion; VAS = visual analog scale.
Data presented as median/range or percentage/No.
[a] Fisher exact test.

Table 3
Subject characteristics during follow-up

	Group	Baseline	12 mo	24 mo	36 mo	48 mo
Hemoglobin level, median	LUVO	9.2	12.1	11.9	12.1	12.0
	LUVO+LM	8.9	12.1	12.4	12.5	12.5
p		.286	.269	<.001	<.001	<.001
Pain (No.)	LUVO	100% (26)	3.8% (1)	7.7% (2)	30.8% (8)	30.8% (8)
	LUVO+LM	100% (18)	0% (0)	0% (0)	0% (0)	0% (0)
P		.899	1.00	.511	.021	.021
Menorrhagia (No.)	LUVO	100% (55)	12.7% (7)	21.8% (12)	25.5% (14)	25.5% (14)
	LUVO+LM	100% (48)	0% (0)	0% (0)	2.1% (1)	6.3% (3)
p		.098	.042	.001	.004	.039
Bulge sensation (No.)	LUVO	100% (55)	5.5% (3)	9.1% (5)	10.9% (6)	21.8% (12)
	LUVO+LM	100% (28)	0% (0)	0% (0)	0% (0)	0% (0)
p		.035	.266	.076	.041	.001
Frequency (No.)	LUVO	100% (44)	6.8% (3)	9.1% (4)	25.0% (11)	25.0% (11)
	LUVO+LM	100% (26)	0% (0)	0% (0)	0% (0)	3.8% (1)
p		.304	.266	.141	.003	.015
Recurrence (No.)	LUVO	100% (95)	12.6% (12)	17.9% (17)	22.1% (21)	28.4% (27)
	LUVO+LM	100% (68)	0% (0)	0% (0)	1.5% (1)	7.4% (5)
p		–	.001	<.001	<.001	.001
Satisfaction (No.)	LUVO	100% (95)	90.5% (86)	83.2% (79)	83.2% (79)	76.8% (73)
	LUVO+LM	100% (68)	100% (68)	100% (68)	98.5% (67)	97.1% (66)
p		–	.011	<.001	.001	<.001
Reintervention (No.)	LUVO	100% (95)	13.7% (13)			
	LUVO+LM	100% (68)	0% (0)			
p			.001			
Pregnancy rate (No.)	LUVO	(17)	58.8% (10)			
	LUVO+LM	(6)	66.7% (4)			
p			.386			

LM = laparoscopic myomectomy; LUVO = laparoscopic uterine vessel occlusion.

The efficacy of symptom control in the LUVO group seemed to be statistically significantly inferior to that in the LUVO+LM group at 24 months after operation (range 78.2%–92.3% in the LUVO group and 100% in the LUVO+LM group, based on different kinds of symptoms). When the follow-up period was increased to 36 months (3 years), a significant difference occurred in symptom control between the 2 groups. Symptom control in the LUVO group was significantly inferior to that in the LUVO+LM group (range 69.2%–89.1% in the LUVO group and 93.7%–100% in the LUVO+LM group, based on different kinds of symptoms), which contributed to the higher recurrence rate in the LUVO group than in the LUVO+LM group (22.1% vs 1.5% at the end of 3 years, and 28.4% vs 7.4% at the end of 4 years, respectively) (Table 3).

Patients in both groups showed a very high immediate satisfaction rate (100% in both groups). The reintervention rate was 13.7% (n = 13) in the LUVO group, but zero in the LUVO+LM group in this 4-year follow-up, which contributed to the relatively lower satisfaction rate (83.6%) in the LUVO group compared with the very high satisfaction rate (>95%) in the LUVO+LM group (Table 3). Eight patients in the LUVO group had repeat myomectomy and the remaining 5 were treated with hysterectomy.

In terms of the reproductive outcomes in this study, 23 of the 163 patients (17 in the LUVO group and 6 in the LUVO+LM group) were sexually active and did not use contraception methods (Table 3). Fourteen women became pregnant, with a clinical pregnancy rate of 60.9% during the follow-up period. Between the 2 groups, no statistical difference existed in either the clinical pregnancy rate (58.8% [n = 10] vs 66.7% [n = 4]) or the successful delivery rate (100% [n = 10] vs 100% [n = 4]). One (7.1%) woman had a diagnosis of preterm labor, and was treated with various kinds of tocolytic agents.

Discussion

Hysterectomy is the most certain cure for women with symptomatic myomas who do not wish to preserve fertility [35]. The demand for alternative treatments, both by patients and by physicians seeking less invasive procedures, has increased during the last decade [15]. Uterine vessel occlusion has become one such alternative procedure [36–38] and myomectomy as another [39–42]. Uterine vessel occlusion is performed either by radiologists as uterine-artery embolization or by surgeons as uterine vessel occlusion, through either laparoscopy or LT. To treat symptomatic uterine myoma, either LUVO [15,19–21,23,24,29–34] or a combination of LUVO and myomectomy through either laparoscopy or LT [22,25–27] was reported to provide satisfactory results. Furthermore, a comparison of combined LUVO and

myomectomy and myomectomy alone was evaluated and the results showed that combined LUVO and myomectomy was more effective for symptom control and minimized the risk of myoma recurrence in these women with symptomatic uterine myomas (5.8% in the LUVO and myomectomy group vs 36.7% in the myomectomy only group during 42.5-month follow-up) [27]. However, observational studies comparing the therapeutic difference between LUVO alone and LUVO+LM are lacking. In addition, if LUVO can provide adequate symptom control and acceptable satisfaction for these patients, the question is raised as to whether it is necessary to add LM to LUVO in most patients with symptomatic uterine myomas who are undergoing treatment. Therefore, we undertook an observational study comparing LUVO and LUVO+LM in patients undergoing treatment for their symptomatic uterine myomas.

As predicted, and consistent with another report [31], we further confirmed that LUVO is a feasible and less invasive procedure in the treatment of women with symptomatic uterine myomas because of the minimal operative blood loss (median 20 mL), short operative time (median 30 minutes), and relatively low complication rate of 1.1%. By contrast, a subsequent immediate LM operation seemed to be a more invasive procedure compared with LUVO, because the operative time was significantly longer (median 60 minutes), and significantly more operative blood loss occurred (median 50 mL).

In terms of postoperative recovery in both groups [43], it was not surprising that LUVO had significant advantages, including less postoperative pain (lower VAS score), fewer patients with postoperative fever with resultant lower mean temperatures postoperatively, and a shorter interval from surgery to tolerance of food intake compared with LUVO+LM, suggesting that LUVO+LM is a more complicated procedure.

Because LUVO showed better operative and immediate postoperative parameters compared with LUVO+LM, LUVO might be a better choice than LUVO+LM in the treatment of women with symptomatic uterine myomas. However, before reaching this conclusion, therapeutic efficacy should be evaluated. Therefore, a 4-year symptom relief and request for reintervention follow-up was conducted. Symptom control was evaluated at 12, 24, 36, and 48 months after operation, respectively. Almost all myoma-related symptoms in the LUVO+LM group, either menstrual problems such as menorrhagia and pain, or compression syndrome, including a bulge-like sensation and urinary frequency, had disappeared during the 4-year follow-up; however, a few patients had symptom recurrence at 36 months and after. In addition, the anemic state of the patients secondary to the menorrhagia was significantly improved, with an average hemoglobin level of more than 12 g/dL. At the first 12-month visit, and up to the 48-month visit, the hemoglobin level was observed to be maintained at greater than 12 g/dL.

The recurrence rate [44] in the LUVO+LM group was significantly lower than that in LUVO group; as a result, no patient in the LUVO+LM group needed reintervention, such as hysterectomy or myomectomy, secondary to the relapse of symptoms or signs. The better symptom control and lower request rate for reintervention in the LUVO+LM group are not new phenomena. This was also noted in the other available publications [22,26,27]. In fact, nearly all, if not all, patients had significant symptom relief with a mean follow-up ranging from 16.2 to 25.4 months [22,26,27]. The use of LUVO+LM in the treatment of women with symptomatic uterine myomas provides not only excellent symptom relief, but also longer durable symptom control. Of most importance, the recurrence of myomas was reported to be very low, ranging from 0% to 7% during the 36-month follow-up [26].

By contrast, successful symptom control was not such a remarkable finding in the LUVO group, compared with that in the LUVO+LM group. The successful symptom control rate was near 80% at the second year, but decreased to 70% at the end of the third year, and although the hemoglobin level was also significantly improved, the average hemoglobin level was lower than 12 g/dL during the 48-month follow-up. The final reintervention rate was 13.7% in the LUVO group compared with zero in the LUVO+LM group.

This study showed that it was beneficial to add LM in the treatment of women with symptomatic uterine myomas who were undergoing LUVO, but still, many unavoidable limitations exist. First, this study was not a prospective study in nature, although the basic characteristics of both groups were relatively similar. Many confounding factors exist that might interfere with the validation of the outcome measures. Second, we did not enroll all patients (e.g., we excluded those patients who were lost to follow-up, or who were not completely treated with LUVO+LM) who were initially designated to receive LUVO and LM in this period into this study for analysis, which resulted in selection bias. Of course, this limitation further compromised the validation of the outcome measures. For example, an estimated 10% of patients who wished to receive LUVO and LM failed to complete this surgery; although they still received LUVO, these patients were finally treated by conversion to ultra-MLT or MLT for myomectomy in place of the original design of LUVO+LM [45]. Third, we could not compare the myoma changes, in terms of number, size, or disappearance between the 2 groups after treatment. In the LUVO group, the fate of the myomas, including the complete disappearance of the myomas (the decreased number of myomas as a result of tumor shrinkage to invisible status) and the size changes of the myomas could be evaluated. By contrast, the above-mentioned items could not be evaluated in the LUVO+LM group, because the myomas were removed during operation; in theory, reappearance of the myomas in the LUVO+LM group during follow-up meant recurrence or a new lesion.

Concern for the negative impact on pregnancy outcomes of the use of uterine vessel occlusion in the treatment of women with symptomatic uterine myomas has always existed [46,47], and it is still voiced [48–50]. Furthermore,

in comparing reproductive outcomes between uterine-artery embolization and laparoscopic uterine artery occlusion (LUVO) in women with symptomatic uterine myomas, a recent study showed that the pregnancies of women who were treated with uterine embolization were at significantly increased risk of spontaneous abortion when compared with the pregnancies of women treated with laparoscopic uterine artery occlusion [33], suggesting that even using different strategies of uterine vessel occlusion might affect the fertility outcomes of the women. In this study, the fertility outcomes seemed to be good, because the abortion (0%) and preterm labor (7.1%) rates seemed not to be increased compared with the general population in Taipei City, Taiwan [51–53].

Finally, it may be more reasonable to compare women undergoing LM alone with those undergoing combined LUVO+LM to determine the benefits and/or role of LUVO, in terms of reducing the risks of recurrence of myomas and intraoperative bleeding and other complications and/or morbidity parameters, given the fact that myomectomy is generally regarded as the traditional default surgery for those who wish to retain the uterus, rather than LUVO. Although we did not compare the outcomes of the patients treated with myomectomy alone or with the combination of LUVO and myomectomy in this study, in our previous study [22], we clearly showed that LUVO would result in reduced blood loss and, therefore, improve visualization and the need for conversion, and facilitate the rest of the surgical approach, regardless of modality. In addition, our study reported the superiority of LUVO when combined with repeated myomectomy in treating recurrent symptomatic myomas, compared with myomectomy alone, which not only manifested as less blood loss during operation, but also showed a lower recurrence rate during the average follow-up period of 42.5 months [27].

Conclusion

An important point to be emphasized is that this was not a randomized study, but rather one in which the patient chose the method. As such, the result showed the acceptability of LUVO in the treatment of women with symptomatic uterine myomas. However, the therapeutic efficacy of the combination of LUVO+LM was obvious. In addition, reintervention, such as hysterectomy or myomectomy, can be avoided in most women with symptomatic uterine myomas when they are treated with LUVO+LM, although LUVO+LM seems to be a more complicated procedure compared with LUVO alone. This finding is very similar to the result of a comparison study between myomectomy and LUVO+myomectomy [27], suggesting that combination therapy might be more effective than any 1 of the 2 procedures.

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