Original Article

An analysis of the surgical outcomes of laparoendoscopic single-site myomectomy and multi-port laparoscopic myomectomy

Shi-Fang Zhou, Hai-Yan Wang, Kun Wang

Department of Integrated Traditional Chinese and Western Medicine, Obstetrics and Gynecology Hospital Affiliated to Fudan University, Shanghai, China

Contributions: (I) Conception and design: SF Zhou, HY Wang; (II) Administrative support: HY Wang; (III) Provision of study materials or patients: SF Zhou, HY Wang; (IV) Collection and assembly of data: SF Zhou, K Wang; (V) Data analysis and interpretation: SF Zhou; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Professor Hai-Yan Wang. Obstetrics and Gynecology Hospital of Fudan University, No. 128, Shenyang Road, Shanghai 200090, China. Email: haiyanwang2002@163.com.

Background: This study sought to compare the surgical results of patients undergoing a laparoendoscopic single-site myomectomy (LESS-M) and a conventional laparoscopic myomectomy (CLM) at our hospital.

Methods: The basic data of 233 patients undergoing LESS-M and 233 patients undergoing CLM at the Obstetrics and Gynecology Hospital Affiliated to Fudan University were collected from January 2018 to January 2020, and the results of the operations were compared by evaluating a number of factors, including operation time, intraoperative bleeding, postoperative fever, and postoperative maximum body temperature.

Results: The operation times of the LESS-M and CLM groups were 83.9±33.4 and 75.2±26.7 min, respectively; the difference between the groups was statistically significant. The surgical blood loss of the LESS-M group was 86.1±76.9 mL, and that of the CLM group was 83.8±79.9 mL (P>0.05). When the diameter of a fibroid was ≥8 cm, a fibroid was located in the posterior wall or the number of fibroids was ≥4, the operation time of the CLM group was shorter than that of the LESS-M group. When the diameter of a fibroid was ≥8 cm, the blood loss of the CLM group was less than that of the LESS-M group.

Conclusions: LESS-M is safe and feasible. If the diameter of a fibroid is ≥8 cm, the fibroid is located in the posterior wall, or the number of fibroids is ≥4, the utility of single-port surgery should be carefully considered.

Keywords: Fibroids; single-site laparoscopy; laparoscopic myomectomy; retrospective studies

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Introduction

Uterine fibroids are extremely common benign neoplasms of the uterus and are especially common in women of reproductive age (1-3). Research has shown that 51% of premenopausal women receive a new diagnosis of fibroids (4). Pathological examinations of surgical specimens showed that the prevalence of fibroids is 77% (5). Uterine fibroids can induce menorrhagia, dysmenorrhea, pelvic compression, infertility, miscarriage, and other symptoms. Treatment plans for fibroids depend on the size, location, number, symptoms, age of the patient, and fertility requirements. Common treatment methods include surgery, interventional embolization, ultrasound ablation, and drug therapy. At present, myomectomy is still the most commonly used treatment. Compared to laparoscopy surgery, laparoscopic myomectomy has less bleeding, a quick recovery time post-surgery, better cosmesis, and less surgical complications (6,7).

In November 2014, the United States Food and Drug Administration (FDA) issued a safety communication severely restricting the use of power morcellators during minimally invasive surgery for women with uterine

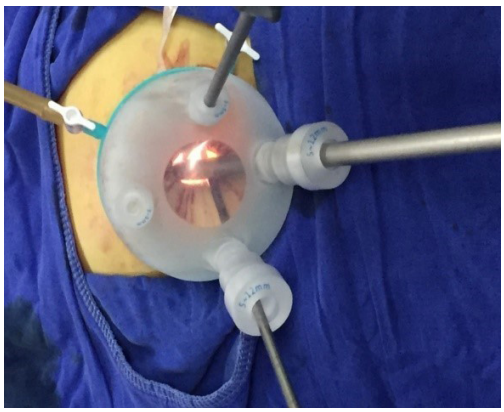

Figure 1 The 12-mm trocar was used for the 10-mm flexible 3D laparoscope, and the other two 5-mm trocars were inserted into conventional laparoscopic instruments.

leiomyomas (8). Won *et al.* (9) found that the use of in-bag power morcellation in a laparoscopic myomectomy was feasible and safe. As the risks of open power morcellation are minimal, there was no change in the selection of myomectomy to treat leiomyoma after the FDA communication (10). However, many clinicians remain concerned that the fibroid morcellator can cause the intra-abdominal dissemination of sarcoma, and the expansion of the right lower abdominal incision can cause subcutaneous hematoma, incision infection, abdominal scars and other adverse surgical outcomes. In recent years, clinical studies on the use of laparoendoscopic single-site myomectomy (LESS-M) to remove fibroids have been carried out abroad (11-15), and LESS-M is considered safe and reliable. To assess the exact feasibility and safety of LESS-M, we conducted a retrospective study to compare the surgical outcomes of LESS-M with those of conventional laparoscopic myomectomy (CLM).

We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/atm-21-1862).

Methods

Subjects

All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Ethics Committee of the Obstetrics and Gynecology Hospital Affiliated to Fudan University (2019-07). Informed consent was obtained from all individual participants included in the study. Data were collected from the medical records of patients who underwent a LESS-M or a CLM from January 2018 to January 2020 at the Obstetrics and Gynecology Hospital Affiliated to Fudan University. In order to reduce bias and confounding variable, all the data of operations is treated by using Propensity Score Matching. Observational samples are matching by similar characteristics including age, number of births, operation history, and degree of intraoperative adhesion. A total of 466 patients who underwent LESS-M or CLM were included in the study; the LESS-M group comprised 233 patients, and the CLM group comprised 233 patients.

Patients were eligible to participate in the study if they met the following inclusion criteria: (I) underwent received laparoscopic surgery at our hospital; (II) had a pathological operation diagnosis of uterine leiomyoma; (III) the maximum diameter of their fibroids was ≤12 cm; and (IV) the number of fibroids was ≤7. Patients were excluded from the study if they had suspected or confirmed uterine malignant tumors (including endometrial or cervical lesions).

Operation techniques

For LESS-M, the skin of the umbilical orifice, the fascia layer and the peritoneum layer were cut medially at about 1.5 cm. A wound retractor and a multichannel single port (Beijing Aerospace Kadi Technology Development Institute) were inserted through the umbilicus, and the airway was inflated to maintain a pneumoperitoneum pressure of 14 mmHg. A 12-mm trocar was used for the 10-mm flexible three-dimensional (3D) laparoscope, which was controlled by an assistant, and the other two 5-mm trocars were inserted into conventional rigid laparoscopic instruments by the attending surgeon (see *Figure 1*). After irrigation with normal saline and the removal of any clots that had formed, the peritoneum, fascia, and subcutaneous tissue were then approximated and closed layer by layer using the 2-0 Polysorb suture (VICRYL, ETHICON); skin adhesive (Mepore) was used to close the skin incision (see *Figure 2*). With the exception of port placement and the method for myoma morcellation, the operative procedures of the CLM and LESS-M did not differ between the two groups. A 12-mm trocar in the intraumbilical area and 3 ancillary 5-mm trocars were placed in the parumbilical area and both lower lateral abdomens (see *Figure 3*). After the bleeding was completely stopped, the umbilical hole was sutured with absorbable thread (see *Figure 4*).

Figure 2 The peritoneum, fascia, subcutaneous tissues were closed layer by layer.

Figure 3 The 5-mm trocar was placed at the left and right Mai's point, and 5 cm to the left of the umbilicus; the 12 mm trocar was placed at the umbilical hole.

Figure 4 The closed abdomen at the end of the operation in CLM. CLM, conventional laparoscopic myomectomy.

Observation index

We collected patients' baseline data, including age, birth history, surgical history (e.g., appendix surgery or cesarean section), body mass index (BMI), maximum average diameter of fibroids, position of uterine fibroids (i.e., anterior, posterior, fundus, or sidewall), fibroid location (i.e., intermural or subserosal), and number of fibroids.

The main safety indicator was operation time. Total operation time was defined as the time interval from skin incision to suture completion. These safety indicators were bleeding volume, average hospital stay, postoperative maximum body temperature, exhaust time, surgical complications (intestinal injury, urinary tube injury, large blood vessel injury) and 24 h visual analogue scale (VAS). VAS scores were routinely recorded on the nursing record sheet. On the VAS, 0 represents no pain, 1 to 3 represents mild pain that does not affect sleep, 4 to 6 represents moderate pain, which affects sleep and requires the use of analgesics, and 7 to 10 represents severe pain, which seriously affects sleep. The amount of blood loss during surgery was calculated by the anesthesiologist. The length of hospital stay was defined as the time from the day of surgery to the day of discharge.

The laboratory indicator was the hemoglobin change value. The long-term surgical results evaluation indicator was patients' satisfaction with the surgical incision. We telephoned the patients and asked them to indicate their satisfaction on a 5-point scale ranging from very dissatisfied to very satisfied (very dissatisfied =1, dissatisfied =2, generally satisfied =3, satisfied =4, and very satisfied =5).

We conducted a stratified analysis of the operation time and bleeding volume between the LESS-M and CLM groups according to the type of fibroid (i.e., intramural or subserosal), the number of fibroids (1, 2, 3, 4, and ≥5), the location of the fibroid(s) (i.e., the anterior wall, posterior wall, lateral wall, or fundus of the uterus), and the diameter of the fibroid(s) (<8 and ≥8 cm).

Statistical method

SPSS 25.0 was used for the statistical analysis. The continuous variables were compared using Student *t*-tests or Mann-Whitney U tests. The categorical variables were compared using Chi-square or Fischer's exact tests. The results were considered statistically significant when the P values were <0.05.

Results

The study collected information on 233 LESS-M patients and 233 CLM patients. *Table 1* sets out the results of the analysis of patients' basic data. There was no statistically significant differences between the two groups in terms of age, BMI, surgical history, and parity. The average diameter of the largest fibroids in the LESS-M group was

Table 1 Baseline characteristics ($\bar{x} \pm s$, or n)

Variable	LESS-M (n=233)	CLM (n=233)	P
Age (y)	39.8±6.2	40.0±6.6	0.182
Parity (n)	155	167	0.229
Surgery history (n)	45	62	0.061
BMI (kg/m^2)	22.1±1.9	22.0±3.0	0.518
Number of uterine fibroids (n)	1.7±1.1	1.8±1.3	0.366
Diameter of largest myoma (cm)	6.8±1.7	7.0±1.8	0.654
Location of largest myoma			0.158
Anterior	104	102	
Posterior	71	74	
Fundus	45	33	
Lateral	13	24	
Fibroid type			0.065
Intermural	161	159	
Subserosa	72	74	
Number of fibroids			0.456
1	134	118	
2	59	66	
3	28	28	
≥4	12	19	
Number of fibroids <8 and ≥8 cm (n)			0.842
<8 cm	161	159	
≥8 cm	72	74	

LESS-M, laparoendoscopic single-site myomectomy; CLM, conventional laparoscopic myomectomy; BMI, body mass index.

Table 2 Intraoperative data ($\bar{x} \pm s$, or n)

Variable	LESS-M (n=223)	CLM (n=223)	P
Total operative time (min)	83.9±33.4	75.2±26.7	0.002
Blood loss (mL)	86.1±76.9	83.8±79.9	0.072
Transfusion (n)	4	3	0.703
Surgical complications			
Intestinal injury	1	2	
Urinary tube injury	0	0	
Large blood vessel injury	0	0	

LESS-M, laparoendoscopic single-site myomectomy; CLM, conventional laparoscopic myomectomy.

6.8±1.7 cm, and that of the CLM group was 7.0±1.8 cm; the difference between the 2 groups was not statistically significant. The average number of fibroids in the LESS-M group was 1.7±1.1, and that in the CLM group was 1.8±1.3; the difference between the 2 groups was not statistically significant. The number of anterior wall fibroids in the LESS-M group was 104, the number of posterior wall fibroids was 71, the number of fundus fibroids was 45, and the number of lateral wall fibroids was 13. The number of anterior wall fibroids in the CLM group was 102, and the number of posterior fibroids was 74, the number of fundus fibroids was 33, and the number of lateral fibroids was 24. There was no statistical difference between the 2 groups. The largest number of myomas in the LESS-M group was 161 intermural fibroids and 72 subserosal fibroids, while the largest number in the CLM group was 159 intramural fibroids, and 74 subserosal fibroids; there was no statistical difference between the two groups.

Intraoperative data

As *Table 2* shows, the operation times of the LESS-M and CLM groups were 83.9±33.4 and 75.2±26.7 min, respectively; the difference between the groups was statistically significant. The surgical blood loss of the LESS-M group was 86.1±76.9 mL, and that of the CLM group was 83.8±79.9 mL; the difference between the 2 groups was not statistically significant. Four patients in the LESS-M group received blood transfusion due to extensive bleeding during the operation. There is no difference in postoperative complications between the two groups.

Postoperative and follow-up data

As *Table 3* shows, the value of hemoglobin reduction in the LESS-M group was 10.5±6.1 g/L, and that of the CLM group was 12.2±8.9 g/L; the difference between the 2 groups was not statistically significant. The length of hospital stay in the LESS-M group was 4.9±1.6 days, and that of the CLM group was 4.9±1.9 days; the difference between the 2 groups was not statistically significant. The exhaust time of the LESS-M group was 30.4±12.7 hours, and that of the CLM group was 29.7±12.9 hours; the difference between the two groups was not statistically significant. The postoperative 24 h VAS score in the LESS-M group was 1.4±0.8 points, and that in the CLM group was 1.5±0.6 points; the difference between the 2 groups was not statistically significant. The satisfaction

Table 3 Postoperative data ($\bar{x} \pm s$, or n)

Variable	LESS-M (n=233)	CLM (n=233)	P
Maximum postoperative body temperature (℃)	37.6±0.3	37.6±0.5	0.866
Length of hospital stay (d)	4.9±1.6	4.9±1.9	0.308
Hemoglobin drop (g/dL)	10.5±6.1	12.2±8.9	0.415
Exhaust time (h)	30.4±12.7	29.7±12.9	0.236
24 h VAS	1.4±0.8	1.5±0.6	0.471
Level of satisfaction	4.4±0.8	3.6±0.8	0.022

LESS-M, laparoendoscopic single-site myomectomy; CLM, conventional laparoscopic myomectomy; VAS, visual analogue scale.

Table 4 Analysis of differences in operation times ($\bar{x} \pm s$, or n)

Variable	Classification	LESS-M	CLM	P
Diameter of largest myoma	<8 cm	74.0±25.9	70.0±25.8	0.358
	≥8 cm	97.0±37.2	85.0±25.4	0.033
Location of largest myoma	Anterior	79.7±34.5	74.4±23.6	0.285
	Posterior	83.9±30.0	74.9±25.9	0.021
	Fundus	92.9±40.0	82.2±35.2	0.271
	Lateral	76.4±26.1	73.2±26.4	0.626
Number of fibroids	1	78.6±29.4	72.5±27.9	0.090
	2	86.4±29.6	76.8±25.6	0.128
	3	84.3±36.3	86.0±28.9	0.496
	≥4	130.1±50.7	83.8±25.2	0.000
Fibroid type	Intermural	85.4±34.4	77.2±26.4	0.127
	Subserosa	60.5±24.6	57.5±24.4	0.221

LESS-M, laparoendoscopic single-site myomectomy; CLM, conventional laparoscopic myomectomy.

level of surgical incision in the LESS-M group was 4.4±0.8, and that of patients in the CLM group was 3.6±0.8; the difference between the 2 groups was statistically significant.

Stratified analysis of the difference in operation times

Table 4 sets out the data analysis results for the 2 groups. When the diameter of a fibroid was <8 cm, the average LESS-M operation time was 74.0±25.9 min, and the average CLM operation time was 70.0±25.8 min; the difference was not statistically significant. Conversely, when the diameter of a fibroid was ≥8 cm, the average LESS-M operation time was 97.0±37.2 min, and the average CLM operation time was 85.0±25.4 min; the difference was statistically significant (P=0.033). There was no statistical difference in the operation times of the anterior and lateral wall and fundus fibroids between the 2 groups. The average operation time of posterior fibroids in the LESS-M group was 83.9±30.0 min, and that of the CLM group was 74.9±25.9 min; the difference between the 2 groups was statistically significant (P=0.021). When the number of fibroids was <4, there was no statistically significant difference in the operation times between the 2 groups. However, when the number of fibroids was ≥4, the average operation time of the LESS-M group was 130.1±50.7 min, and that of the CLM group was 83.8±25.2 min; the difference between the 2 groups was statistically significant.

Table 5 Analysis of differences in operative blood loss ($\bar{x} \pm s$, or n)

Variable	Classification	LESS-M	CLM	P
Diameter of largest myoma	<8 cm	79.8±75.8	75.0±48.3	0.172
	≥8 cm	113.1±74.9	102.1±90.9	0.001
Location of largest myoma	Anterior	85.2±67.3	80.9±68.0	0.086
	Posterior	89.0±84.2	88.1±66.7	0.820
	Fundus	84.4±80.7	83.7±76.2	0.919
	Lateral	90.4±100.3	76.9±28.2	0.404
Number of fibroids	1	81.7±76.3	80.7±95.0	0.133
	2	87.4±72.1	83.3±42.0	0.879
	3	89.9±93.3	87.9±78.6	0.162
	≥4	90.0±35.3	89.3±45.2	0.659
Fibroid type	Intermural	87.8±78.4	85.4±83.0	0.139
	Subserosa	66.3±54.3	64.3±38.0	0.872

LESS-M, laparoendoscopic single-site myomectomy; CLM, conventional laparoscopic myomectomy.

Stratified analysis of differences in the amount of bleeding

Table 5 shows the results of the data analysis of the 2 groups of patients. When the diameter of a fibroid was <8 cm, the average bleeding volume of the LESS-M group was 79.8±75.8 mL, and that of the CLM group was 75.0±48.3 mL; the difference was not statistically significant. However, when the diameter of a fibroid was ≥8 cm, the average bleeding volume of the LESS-M group

was 113.1±74.9 mL, and that of the CLM group was 102.1±90.9 mL; the difference was statistically significant (P=0.001).

The difference in the operative blood loss of the anterior, posterior, lateral wall and fundus fibroids between the 2 groups was not statistically significant. Whether the number of fibroids was <4 or ≥4, there was no statistical difference of blood loss between the 2 groups.

Discussion

In the past 10 years, LESS-M has developed rapidly, and studies have shown that LESS-M is safe and feasible (16-19). Park *et al.* (16) studied 515 cases of single-port laparoscopic gynecological surgeries, including total hysterectomies, adnexal surgeries, ovarian cystectomies, and salpingectomies. Of the 515 cases, only 17 cases of myomectomy were performed, and the operations were successful without surgical complications. However, it should be noted that Park *et al.* did not compare the advantages and disadvantages of LESS-M and multi-port surgery. The LESS-M operation is difficult and the operation time is long. To date, only 8 clinical studies [comprising 2 randomized controlled trials (13,20), and 6 cohort studies (11,21-24)] have compared the results of LESS-M and CLM operations. The results of the 8 clinical studies all found evidence that LESS-M is safe and feasible, but the conclusions on total operation time, blood loss, postoperative hemoglobin reduction, and average hospital stay were inconsistent, and only 1 study analyzed morcellation time, suturing time, and removal time.

Choi *et al.* (23) found that operation time was less in the LESS-M group compared with the CLM group. Conversely, Han *et al.* (24) found that operation time was longer in the LESS-M group compared with the CLM group. Song *et al.* (13) found no difference in operation time, enucleation time, suturing time, and morcellation time. The present study found that LESS-M surgery takes longer than CLM surgery. Further, when the diameter of a fibroid is ≥8 cm, or a fibroid is located in the posterior wall or the number of fibroids is ≥4, the operation time of the CLM is shorter than that of the LESS-M. However, when the diameter of a fibroid is <8 cm, the number of fibroids is <4, or a fibroid is located on the anterior wall, lateral wall, or the fundus of the uterus, there is no statistical difference in the operation times between the 2 groups. Various studies have drawn different conclusions about the number of fibroids removed and the maximum diameter of fibroids. The inclusion criteria for Choi *et al.*'s (23) and Han *et al.*'s (24) studies were that the largest diameter be no more than 10 cm and the number of fibroids be less than 3. Korean scholars believe that LESS-M is suitable for patients who have fibroids ≤5 with a diameter <12 cm (11). To choose an appropriate surgical approach, surgeons need to assess the location and size of each fibroid, patient fertility, and the risk of uterine rupture.

The inclusion criteria for the present study were that the largest diameter of a fibroid be ≤12 cm, and the number of fibroids be <7. The operations were all successful. There were no differences in postoperative fever, postoperative hemoglobin changes, average hospital stay, or exhaust time between the 2 groups. In the process of the operations, the diameter and number of fibroids were related to the smooth completion of the operation, and the location of the fibroids also determined the difficulty of the operation. When the diameter of a fibroid was ≥8 cm, the fibroid was located in the posterior wall or the number of fibroids was ≥4, the operation time of the CLM group was better than that of LESS-M group. In terms of fibroid removal, anterior wall fibroids were easily removed; however, fibroids located in the lower uterine segment and in the deep uterine muscles were difficult to remove, as it was necessary to suspend the uterus or lift the uterus to assist the progress of the operation.

Operation time is related to the choice of surgical incision and suture time. Han *et al.* (24) used a transverse incision to cut the myometrium, while Song and Lee *et al.* (13,21) used straight incisions. We elected to use a barbed suture to prevent tissue retraction and combined interlocking suturing with mattress suturing. Using a barbed suture to close uterus wall after laparoscopic myomectomy results in shorter operative times and less blood loss (25). Jeong *et al.* conducted 246 LESS-M operations using 2 suturing methods and compared the surgical outcomes. The result suggested that the interrupted suture method was more effective in relation to operating time and estimated blood loss than the continuous interlocking method (26).

The satisfaction level of surgical incision in the LESS-M group was 4.4±0.8, and that of patients in the CLM group was 3.6±0.8; the difference between the 2 groups is statistically significant. Lee *et al.* (20) found that the observer scar assessment scale was lower in the LESS-M group than that of CLM after 1 week and 8 weeks from discharge. Several studies also have evaluated the cosmetic satisfaction of single port and multi-port laparoscopic surgery. For example, two prospective studies conducted abroad found that the cosmetic score

of single-site laparoscopic hysterectomy was higher than that of traditional laparoscopy, indicating that single-site laparoscopy has outstanding cosmetic effects (27,28).

The limitations of LESS-M cannot be ignored. First, the operation is difficult and there is a certain learning curve. The current study indicated that proficiency for LESS-M was achieved after about 45 operations (29). You *et al.* reported that surgeons need to operate on 20 patients to reach technical competency in hysterectomy (30). However, after achieving competency, surgeons conducting LESS-M operations can reach the same operation speed as that for CLM operations. Second, the port used in single-site laparoscopic surgery is expensive, which increases the cost of the surgery. Many scholars at home and abroad have reported that self-made ports, most of which are made of incision protective sleeves, medical gloves, and laparoscopic trocars, reduce the cost of medical consumables, enable more primary hospitals to carry out LESS-M, and have more benefits for patients. We also use improved lengthened instruments, such as lengthened needle holders. Barbed suture and self-fixing knot-free absorbable suture can also shorten the operation time and reduce the difficulty of suture (31). Finally, this study focused on the effects of surgery; however, there is still a lack of research on long-term recovery, especially in relation to reproduction. A prospective study should be conducted to collect large samples of clinical data and analyze the long-term safety and effectiveness of LESS-M.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Ethics Committee of the Obstetrics and Gynecology Hospital Affiliated to Fudan University (2019-07). Informed consent was obtained from all individual participants included in the study.

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