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Laparoendoscopic Single Site Myomectomy: Without the Use of a Single Port Access Device

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Abstract

Objective: Herein we described our experience with laparoendoscopic single site mymectomy (LESS-M) without the use of a single port access device and compared the clinical outcomes between LESS-M and conventional laparoscopic mymectomy (LM).

Methods: From January 2012 to December 2014, 32 patients with leiomyomas underwent LESS-M in our hospital were enrolled in this prospective observational case-control study, and were 1:1 matched and compared with 32 patients who underwent LM by the same operative team for leimyomas of similar size and location. Patients and surgical data, and follow-up information were analyzed.

Results: The operating time in the LESS-M group was significantly longer than that in the LM group (98 ± 9 min vs 56 ± 7 min, *P*=0.000), but the patients returned to work significantly earlier (2.9 ± 0.5 week vs 3.7 ± 1.1, *P*=0.001), and the cosmetic satisfaction score was significantly higher (9.3 ± 0.6 vs 8.4 ± 0.7, *P*=0.000). There was no significant difference of the mean intraoperative blood loss, hemoglobin change, return of bowel activity, postoperative fever, operation cost and total cost between the two groups.

Conclusion: LESS-M is a feasible, safe, and efficacious procedure with shorter recovery and increased cosmetic satisfaction in selected patients with leiomyoma, and it can be cost-effectively performed without the need for a single port access device.

Keywords: Myomectomy; Laparoendoscopic single-site surgery; Uterine leiomyomas; Laparoscopic surgery

Introduction

Leiomyomas are the most frequent benign tumors of the uterus and affect approximately 25-40% of women of reproductive age. Laparoscopic myomectomy (LM) is a surgical procedure that has been performed frequently in the gynecological field.

Laparoendoscopic single site surgery (LESS) has been used for hysterectomy, adnexal surgery, myomectomy, and gynecologic cancer surgery [1]. Some reports have demonstrated the feasibility and safety of SPLS and the improvement in outcomes over conventional laparoscopy in terms of pain, recovery time, cosmesis, and duration of hospital stay [2-5].

Laparoscopic myomectomy (LM) is a surgical procedure that has been performed frequently in the gynecological field. In an attempt for further improvement, laparoendoscopic single site myomectomy (LESS-M) has been recently introduced. This surgical approach is still in evolution, as only a small number of patients have been reported so far [6-13]. This technique is evolving quickly, nevertheless, there is insufficient data regarding whether it has advantages over conventional LM.

The technique for laparoendoscopic single-site myomectomy reported before described the use of disposable transumbilical single port access devices or a glove- disposable wound retractor system [6-13], a flexible tip laparoscope along with curved and articulating working instruments. Utilization of such instruments and disposable access ports or disposable wound retractors can impose a significant cost burden on patients in developing countries.

We recently performed LESS-M using conventional laparoscopy instruments and a flexible tip laparoscope, without the need for single port laparoscopy access devices. We herein report our modifications and feasibility of this cost-effective technique of LESS-M, and present a matched case-control retrospective study comparing LESS-M and LM with respect to perioperative outcomes and cosmetic satisfaction.

We recently performed LESS-M using conventional laparoscopy instruments and a flexible tip laparoscope, without the need for single port laparoscopy access devices. We herein report our modifications and feasibility of this cost-effective technique of LESS-M, and present a prospective observational matched case-control study comparing LESS-M and LM with respect to perioperative outcomes and cosmetic satisfaction.

Materials and Methods

Patients

Between January 2012 and December 2014, 32 patients with leiomyoma were selected to undergo LESS-M in the Obstetrics and Gynecology Hospital of Fudan University. The patients were selected consecutively, based on their ultrasonographic characteristics, and the data were collected.

The inclusion criteria included the presence of a symptomatic leiomyoma measuring 8 cm or less on ultrasonographic examination, and intramural or subserosal type of myoma. Patients whose myomas

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measured > 8 cm on ultrasonographic examination or with a submucosal type were excluded from this study. LESS-M was suggested to all the patients who fulfilled the inclusion criteria, and was performed with the consent of the 32 patients.

The LESS-M group was matched to a control group (n=32) who underwent LM by the same operative team during the same period. The patients were 1:1 matched prospectively on the basis of size, location and type of leimyomas. This study was approved by the Obstetrics and Gynecology Hospital of Fudan University Institutional Review Board.

Operative technique

The patients were placed in a dorsal lithotomy position under general anesthesia with endotracheal intubation. A 3 cm long vertical transumbilical incision is made. The rectus sheath is laterally dissected underneath the skin flaps, as described by Dubey et al. in laparoendoscopic single-site radical nephrectomy [14]. Carbon dioxide was insufflated to maintain the intra-abdominal pressure at 14 mmHg. 3 separate home-made metalic 5mm trocar are inserted through this single incision (Figure 1). The metalic trocars are different in length, so that the interference between different trocars during operation is minimized. A LTF-VP deflectable tip video laparoscope (Olympus, Center Valley, Pennsylvania) is used through one of the 5mm ports.

The dilute solution of pituitrin (6 IU/20 ml normal saline) was injected into the uterine muscle. The serosa and myometrium covering the myoma was opened with a monopolar hook. Conventional laparoscopic claw forceps were used to grasp the myoma and create countertraction. The cleavage plane between the fibroid and the uterus was identified, and the myoma was dissected out of the uterus. Roticulator for manipulation of the uterus was not needed in our procedure.

A running suture using 1/0 PDS II delayed absorble material (Ethicon, Somerville, NJ, U.S.A) and conventional needle holder repaired the defect in the myometrial and serosal layers. An additional mattress suture following running suture completed the closure of the uterine wall. The needle was directly inserted into the pelvic cavity using a needle holder and was returned outside the body using a laparoscopic needle holder at the left lower quadrants of the abdomen. Prior to myoma mocellation, one of the 5mm ports is enlarged to a 15 mm port, and the myoma was morcellated by conventional laparoscopic morcellation (Figure 2). Finally, the skin incision is closed with interrupted 1/0 vicryl sutures.

Clinical outcome measurement

Patients' perioperative data, including operative time, estimated blood loss, hemoglobin decreases, the return of bowel activity, postoperative fever, postoperative hospitalization length, intra- and postoperative complications were recorded. The postoperative fever was defined as a body temperature equal to or higher than 38°C on two consecutive occasions at least 6h apart, except during the first 24 h.

The patients were regularly followed up at 1 and 3 months after surgery. Figure 3 showed the appearance of the umbilical scar in one patient 3-month post surgery. For cosmetic satisfaction assessments, the visual analog scale (VAS) was used, which ranges from 0 (completely unsatisfied) to 10 (fully satisfied). And all patients completed the assessments [15] at their 3-months follow up.

Statistical analysis

Statistical analyses were performed using SPSS 16.0 software (SPSS, Inc, Chicago, IL). Data are expressed as the mean ± standard deviation (SD). Student's *t*-test or chi-square tests were used, as appropriate. Differences were considered to be significant at $P<0.05$

Results

Thirty two patients who underwent LESS-M were 1:1 matched and compared with 32 patients who underwent LM by the same operative team for leimyomas of similar size, location and type. The detailed patient characteristics of the two groups are shown in (Table 1). No statistically significant ($P>0.05$) differences in age, parity, body mass index (BMI) were noted between the two groups.

LESS-M was successfully completed in all 32 patients. The final length of the skin incision was 3 cm in all cases. None of the patients required extension of the skin incision during surgery.

Compared with control group, the operating time was significantly longer (98 ± 9 min vs. 56 ± 7, $P=0.000$). There was no significant difference of the mean intraoperative blood loss, hemoglobin change, return of bowel activity, postoperative fever, operation cost and total cost between the two group (Table 2). The patients underwent LESS-M return to work significantly earlier than those underwent LM (2.9 ± 0.5 week vs 3.7 ± 1.1, $P=0.001$). There were no surgical or wound complications and no transfusion in any patient, and the histopathological result was leiomyoma in all the cases.

Figure 1: Technique of Port insertion. (a) A 3cm vertical transumbilical incision were made, and rectus sheath dissected under skin flaps. (b) The home-made mental trocar with different lengths. (c) Configuration of conventional laparoscopy instruments without the use of a single port access device in LESS-M.

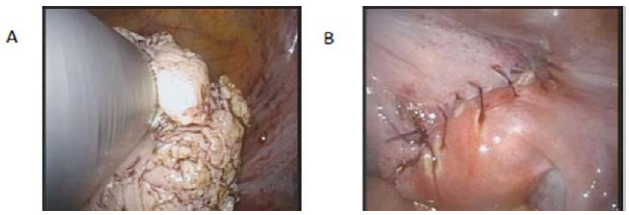

Figure 2: Laparoendoscopic single site mymectomy. (a) The myoma was morcellated by conventional laparoscopic morcellation. (b) Uterus at the completion of the hysterotomy closure.

Figure 3: Appearance of the umbilical scar 3 month post surgery.

Parameter, mean ± SD or n	LESS-M (n=12)	LM (n=24)
Age (y)	30.5 ± 3.5	32.9 ± 5.0
Parity (n)	0.3 ± 0.5	0.5 ± 0.6
BMI (kg/m2)	21.4 ± 1.4	21.6 ± 1.5
Size of myomas (cm)	5.5 ± 0.7	5.5 ± 0.7
Location of myomas (n)		
Anterior	5	10
Posterior	3	6
Fundal	3	6
Lateral	1	2
Type of myomas (n)		
Subserosal	3	6
Intramural	9	18
Previous abdominal surgery	2	5
Abbreviations: SD, standard deviation; LESS-M, laparoendoscopic single site mymectomy; LM, laparoscopic mymectomy; BMI, body mass index		

Table 1: Clinical characteristics of the two groups.

Parameter, mean ± SD or n (range)	LESS-M (n=12)	LM (n=24)	*P* value
Operating time (min)	103 ± 12	56 ± 7	0.000
Estimated blood loss (ml)	48.3 ± 18.5 (30-100)	45 ± 19.3 (30-100)	>0.05
Hemoglabin change (g/dL)	1.2 ± 0.9 (0-4)	1.0 ± 1.0 (0-4)	>0.05
Return of bowel activity (h)	28.6 ± 5.2 (20-36)	24.8 ± 4.8 (14-32)	>0.05
Postoperative fever	0	1	>0.05
Return to work(week)	3.0 ± 0.5 (2-4)	4.0 ± 1.0 (3-6)	0.005
Hospital stay post surgery (d)	3.1 ± 0.3 (3-4)	3.1 ± 0.3 (3-4)	>0.05
Complications (n)	0	0	>0.05
Transfusion (n)	0	0	>0.05
Cosmetic satisfaction score	9.4 ± 0.5 (9-10)	8.4 ± 0.8 (7-10)	0.000
Operation Cost ($)	1,043 ± 39	1,037 ± 34	>0.05
Total Cost ($)	1,774 ± 150	1,751 ± 108	>0.05
Abbreviations: SD, standard deviation; LESS-M, laparoendoscopic single site mymectomy; LM, laparoscopic mymectomy; BMI, body mass index			

Table 2: Perioperative data of the two groups.

For the cosmetic satisfaction investigation by VAS scoring 0-10, 10 patients in the LESS-M group and 1 patients in the LM group expressed "negligible attention to the cosmetic influence of the skin scar", and gave the full score 10. The mean cosmetic satisfaction score was significantly higher in the LESS-M group than that in the LM group (9.3 ± 0.6 vs. 8.4 ± 0.8, P=0.000).

Discussion

This prospective case-control study described our experience with LESS-M without the use of a single port access device and compared the clinical outcomes between LESS-M and conventional LM. Our matched pair study showed that the operating time in the LESS-M group was significantly longer than that in the LM group, but the patients returned to work significantly earlier, and the mean cosmetic satisfaction score was significantly higher. There was no significant difference of the mean intraoperative blood loss, hemoglobin change, return of bowel activity, postoperative fever and hospital stay post surgery between the two group. So LESS-M was an efficacious procedure with shorter recovery and increased cosmetic satisfaction in selected patients with leiomyoma, and that it could be cost-effectively performed without the need for a single port access device.

Studies of laparoendoscopic single site surgery, also known as single-port laparoscopic surgery, embryonic natural-orifice transumbilical endoscopic surgery (E-NOTES), and single-incision laparoscopic surgery, have been actively undertaken. It is also called E-NOTES, because it is an approach through the umbilicus that is patent during the embryonic and fetal periods [7]. Because LESS surgery is expected to improve cosmesis and reduce incisional morbidity relative to those of muliport laparoscopic surgery, early studies of LESS have been reported in various areas [16-19].

Einarsson reported embryonic natural-orifice transumbilical endoscopic myomectomy and unique surgical string for the first time [10]. And then various types of LESS-M have recently been performed in the gynecological field. Nevertheless, up to now, there is still limited data regarding the benefit of LESS-M over conventional LM. Han et al. [13] compared LESS-M with conventional LM, and concluded that despite the increased operating time, LESS-M offers comparable surgical outcomes and superior cosmesis compared with traditional LM.

Our results were in accordance with the Han et al.'s results that LESS -LM had longer operating time, but our results showed that the LESS-LM had the advantages of improved recovery times, and moreover, gave further data on better cosmetic outcomes by using the cosmetic satisfaction score. In women, LESS-M approach is more attractive in terms of body image with minimized scarring.

Disadvantages of LESS include longer operating times and learning times, and the need for specialized instruments including disposable transumbilical single port access devices and curved and articulating working instruments [20,21]. These instruments are high cost, high maintenance devices and require familiarization to work with. Rising cost owing to use of new disposable articulating instruments could be one of the potential barriers for popular use of LESS surgery in developing countries.

We have used standard rigid laparoscopy working instruments except a flexible tip laparoscope, thereby decreasing the amount of investmentrequired for setting up infrastructure, which cost more than twenty thousand dollar, for starting a LESS program. In most western countries, the operation cost increases with the prolonged operation time. But in China, the cost depends on the instruments used, so the operation cost and total hospital cost of the 2 groups was almost the same in our study. However, the hospital might have decreased number of operations due to the prolonged operating time of LESS-LM, and thus possibly lose some income. With the development of the experience with the LESS procedure, the operating time will become significantly shorter, so that this problem might be solved.

And we did not use a single port access device, about a thousand dollar each, as described by the previous authors, which further decreased the cost of the surgery. Our technique does not impose an added cost burden on patients, is ergonomically balanced, and can be performed with minimal added inconvenience to surgeons.

The real challenge of LESS is to avoid conflict between the operative instruments and the videoscope and to maintain pneumoperitoneum. During operation, every movement of the one can interfere with the other. In our study, we used multiple fascial punctures from a single umbilical skin incision to insert multiple ports for operation. This method can help to maintain pneumoperitoneum. And the different length homemade metal trocar were helpful to minimize this interference between the instruments.

Before surgery, all the patients were carefully evaluated by ultrasonographic examination to make sure that the leiomyomas were single, no more than 8 cm in diameter and was not located on the isthmus or cervix of the uterus. So all the fibroids were removed and none was left behind in the LESS procedure.

The limitation of this study is the limited sample size, and that the grouping of the patients was based on their choice. Therefore, a large, prospective, randomized study is needed to achieve solid conclusions on the benefits and disadvantages of LESS surgery.

Conclusion

This study demonstrated the feasibility of LESS-M with conventional laparoscopic instrumentation, and suggested shorter recovery of the patients and a definitive cosmetic advantage. We believe that LESS-M is potentially applicable to selected patients with myoma. Further large-sized randomized prospective trials will be required to confirm the true place of LESS-M.

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