VIA MEDICA

ORIGINAL PAPER / GYNECOLOGY

Ginekologia Polska
2022, vol. 93, no. 8, 605–613

ISSN 0017–0011, e-ISSN 2543–6767

DOI 10.5603/GP.a2022.0002

A self-developed contained bag for laparoscopic myomectomy morcellation

Ying Wei[1*], Xuelan Zhou[2*], Qiong-Zhen Ren[1], Qi Ma[3], Xiaomin Tao[1], Minfang Shao[1], Suhong Jia[1]

[1]Department of Obstetrics and Gynecology, The Second Affiliated Hospital of Soochow University, Suzhou, China
[2]Department of Anesthesiology, The Second Affiliated Hospital of Soochow University, Suzhou, China
[3]Department of Ultrasonography, The Second Affiliated Hospital of Soochow University, Suzhou, China
**These authors contributed equally to this study*

ABSTRACT

Objectives: Open power morcellation during a laparoscopic myomectomy (LM) can result in the dissemination of benign or occult malignant tumor cells in the abdominopelvic cavity. The development of a new contained collection bag for power morcellation is now favored by gynecologic surgeons worldwide.

Material and methods: This study was a single-arm trial comprising 20 women who consecutively underwent an LM involving the use of a newly designed contained collection bag for power morcellation between November 3rd 2017 and April 31st 2018. There was also a historical control group consisting of 30 women who underwent open power morcellation during an LM between May 1st 2017 and October 31st 2017. All the essential information concerning the patients and surgically related data, including the myoma size, the operation duration, and the cell count of the intraperitoneal irrigating fluid, were collected and analyzed.

Results: The uterus size and the maximum diameters of the uterus and the myoma of the two groups were not significantly different ($p = 0.65$, $p = 0.71$, and $p = 0.31$, respectively). Pseudopneumoperitoneum was established and clear visualization was guaranteed in all 20 cases in the experimental group. The remaining fragment tissue amount (mean ± SD) and weight (mean ± SD) in the collection bag after morcellation in the experimental group were 5.00 ± 1.48 and 3.87 ± 1.31 (g). All the collection bags were routinely examined after the LM using normal saline, and no leaks or lesions were found. The cell counts of the intraperitoneal irrigating fluid both before and after morcellation were less than 10^5–10^6/L. The pathology of all the tissues confirmed that there were no malignant tumors. The operation of the experimental group was 18 mins longer than that of the historical control group ($p = 0.00$).

Conclusions: This newly designed collection bag system for LM morcellation is effective, feasible, and safe.

Key words: contained morcellation; laparoscopic myomectomy; parasitic myoma; uterine sarcoma

Ginekologia Polska 2022; 93, 8: 605–613

INTRODUCTION

Laparoscopic myomectomy (LM) has lower intraoperative and postoperative morbidity than hysteromyomectomy, and it has become the first choice for most women who wish to preserve their uterus. During the traditional operation, open power morcellation is used in the abdominopelvic cavity to facilitate removal of uterine myomas, but this can lead to the spread of tumor cells and greatly reduces the patient's chances of survival [1–4]. The US Food and Drug Administration (FDA) issued a safety notice in 2014 to discourage the use of power morcellators in gynecology [5]. Afterwards, there was a worldwide reduction in LM surgery [6].

A preliminary attempt was made to address the above problems. After the enucleation of the myoma during the laparoscopic surgery, all the tissue was loaded into a contained bag, and then the myoma was disintegrated in this same contained bag in order to prevent the tumor tissue from

Corresponding author:
Qiong-Zhen Ren
Department of Obstetrics and Gynecology, the Second Affiliated Hospital of Soochow University, No.1055 of Sanxiang Road, Gusu District, Suzhou 215004, China
phone: +86 13912646986, e-mail: rqz102238@163.com
and
Suhong Jia
Department of Obstetrics and Gynecology, The Second Affiliated Hospital of Soochow University, No.1055 of Sanxiang Road, Gusu District, Suzhou 215004, China
phone: +86 15950002238, e-mail: jiasuhongjsh@163.com

Received: 17.12.2021 Accepted: 22.01.2022 Early publication date: 3.03.2022

spreading into the pelvic cavity [7]. In 2014, Chou et al. [8] first reported the Sydney Contained in Bag Morcellation technique, which involves puncturing the inflated bag. Although the design of a contained morcellation system has progressed, there have been no reports of a single bag system that can accommodate the morcellator, with an assistant grasping the forceps, nor one that does not risk needing to change the surgery to single port laparoscopic surgery or puncturing the inflated bag. The purpose of this study is to evaluate the effectiveness, feasibility, and safety of a newly developed contained collection bag for use during an LM.

MATERIAL AND METHODS

This study was a single-arm trial involving 20 women who consecutively underwent an LM with a newly designed contained collection bag for power morcellation between November 3rd 2017 and April 31st 2018. All the eligible subjects were in the experimental group. The historical control group consisted of 30 women who underwent open power morcellation during an LM between May 1st 2017 and October 31st 2017. The patients all had routine follow-ups at three months, six months, one year, and two years after the operation. The chief complaints were recorded, and physical and ultrasonic examinations were performed. This study was approved by the ethics committee of the Second Affiliated Hospital of Soochow University and registered in the Chinese Clinical Trial Registry (registration number: ChiCTR-INR-16009840; 2016/11/13). Both the historical control group patients and the experimental group patients underwent open power morcellation with fully informed consent.

The main inclusion criteria were as follows: patients with a uterine myoma who met the surgical indications; patients wishing to retain their uterus; patients planning to undergo an LM; women aged 20–45 years with a sexual history; patients willing to cooperate with follow-ups and to sign informed consent and with no major visceral diseases. The main exclusion criteria were as follows: patients who could not have the operation because of a serious cardiopulmonary disease; patients who had a procedure besides the LM during the same operation; and patients whose follow-ups could not be maintained.

Bag design

The self-developed collection bag (patent No. ZL 201520384022.2), designed by Dr.Ren Qiongzhen, was produced by Jiangsu Maslech Medical Technology Co., Ltd. It was made of thermoplastic polyurethane membrane, and it was biocompatible and transparent and non-flammable, non-melting, and non-expanding at high temperatures. The average maximum burst pressure was 4.4 kPa (33 mmHg) at a temperature of 23.1°C and a humidity of 50% RH (Reference standard: YY/T0681.3-2010, tested by Shanghai Microspectrum Technology Service Co., Ltd.). The bag was sterilized with ethylene oxide, and the residual amount of ethylene oxide was less than 10 μg/g.

The collecting bag was composed of a main bag body, four pocket ports, and threading wires (Fig. 1). The volume of the main bag body was 1000–3000 mL. The circumference of the first port was 320 mm (equivalent to the circumference of a 100 mm diameter circle), and this port was used to enter the lesion tissue. The edge of the first port could be thread with threading wire. The diameter of the second, the third, and the fourth ports was 16–20 mm, and the neck length was 80–120 mm. The latter three ports could be pulled out of the abdominal cavity through a puncture hole, and a 5–15 mm trocar could be passed inside. The ports were designed with a conical shape to prevent the sheath from slipping. These three ports were used for the morcellator, the optical lens, and the forceps held by the assistant. The whole bag could be entered into the abdominal cavity through a 10 mm trocar after being folded over. Different color bands were used in different ports to facilitate the rapid establishment of a false pneumoperitoneum.

Preoperative preparation

A ThinPrep cytologic test and a human papillomavirus test were performed to exclude cervical lesions. Patients with menstrual disorders, including increased menstrual volume and prolonged menstruation, were treated with diagnostic curettage to exclude endometrial lesions. Ultrasonography and/or pelvic computerized tomography (CT)/magnetic resonance imaging (MRI) were performed to determine the size of the uterus and the size, number, location, and character of the myomas. The operation was performed during the follicular phase after menstruation. The patients were informed of the risks and gave signed consent. Preoperative vaginal sterilizing was performed once a day for three consecutive days before surgery, and unreserve clyster was used for bowel preparation one day beforehand.

Surgical technique

All the operations were performed by the same four experienced senior physicians. The patient was placed in lithotomy position under general anesthesia. Pneumoperitoneum at a pressure of 13–15 mmHg was established with a CO_2 insufflator (KARL STORZ, Germany). A 4-trocar system was used in all the operations: a 10 mm trocar on the umbilicus point for the optical lens; a 5 mm trocar on the right Mc Burney point for the assistant grasping forceps; a 10 mm trocar on reverse Mc Burney point; and a 5 mm trocar on supra-pubic point for the chief surgeon. The LM was performed in a routine manner, and 1–0 synthetic suture was used to suture the uterine wound to stop any bleeding.

The reverse Maxwell's port was extended to 15 mm in order to accommodate the morcellator (KJ-301) (Hangzhou Kangji Medical Instrument Co., Ltd). Before the morcellation, the abdominal cavity and pelvic cavity were rinsed with normal saline, and once all the rinse solution was absorbed a cell count was made. The folded collection bag was inserted into the abdominal cavity through the reverse McDonald's point sheath. Under direct vision, the bag was opened by the assistant, and the tissue was moved into the bag though the first port, which was then tightened and knotted with 2–0 absorbable suture to prevent air leakage. Under direct vision, the second port was pulled out of the reverse Maxwell's point puncture hole, the third port was pulled out of the umbilical puncture hole, the fourth port was pulled out of the Maxwell's point puncture hole, and the sheath was put into the bag mouth. The optical lens was then put into the umbilical trocar, and the morcellator was pushed through the reverse Maxwell's point trocar and the forceps through the Maxwell's point trocar. After all the ports were sealed, a pseudopneumoperitoneum was established using a CO_2 insufflator at the same pressure of 13–15 mmHg. Tissue morcellation and removal were performed under direct vision, with the assistant fixing the myoma in place with the forceps.

After the main tumors were morcellated, the remaining fragments of tissue in the bag were counted under laparoscopy, removed one by one, and weighed. After the morcellation, the air in the bag was discharged. The second and fourth ports were inverted and knotted to prevent tumor contamination, and the collection bag was removed through the umbilical puncture point. The abdominal and pelvic cavity was washed with normal saline and all the rinsing fluid absorbed before a cell count. The collection bag was carefully examined for leakage using normal saline. A cell count was conducted after the red blood cells were lysed using FACS Lysing Solution [Sangon Biotech (Shanghai) Co., Ltd].

Statistical indicators and statistical analysis

The baseline statistical indicators concerning the patients were age, body mass index (BMI), fertility history, and previous abdominal surgery history. The main surgically related indicators were success rate of bag inflation, leakage rate, visual field clarity, operation time, remaining tissue fragment weight and amount, intraperitoneal irrigating fluid before and after morcellation, intraoperative bleeding, intraoperative complications (penetration of intima, injury of important vascular and nerve organs, etc.), post-operative complications, and the amount of hemoglobin before and after the operation. The secondary observation indexes were postoperative morbidity, blood transfusion rate, postoperative hospitalization days and hospitalization expenses,

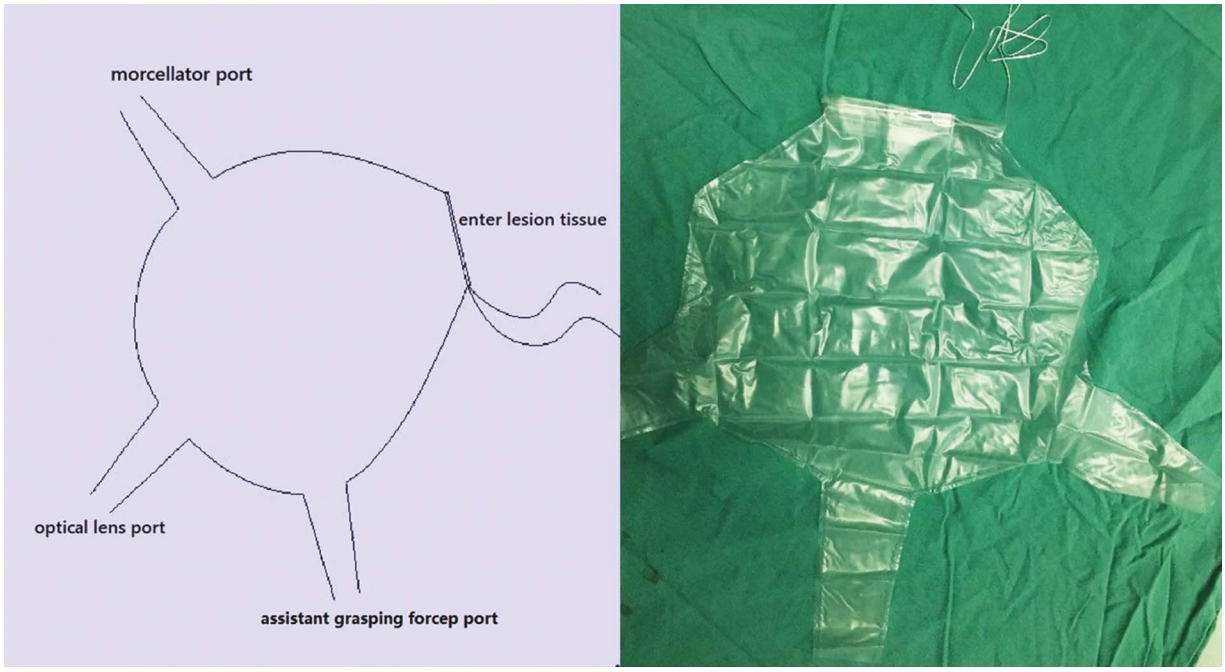

Figure 1. Contained collection bag. The volume of the main bag body is 1000–3000 mL. The circumference of the first port is 320 mm (equivalent to the circumference of a 100 mm diameter circle), which was used for entering the lesion tissue. The edge of the first port could be thread by threading wires. The diameter of the second, the third and the fourth ports was 16–20 mm, and the neck length was 80–120 mm. The latter three ports can be pulled out of the abdominal cavity through puncture hole, and 5–15 mm trocar can pass through inside. The ports was designed in cone shape to prevent the sheath from slipping. The latter three ports was used for morcellator, optical lens and assistant grasping forceps, respectively. The whole bag could enter into the abdominal cavity through a 10 mm trocar after folded

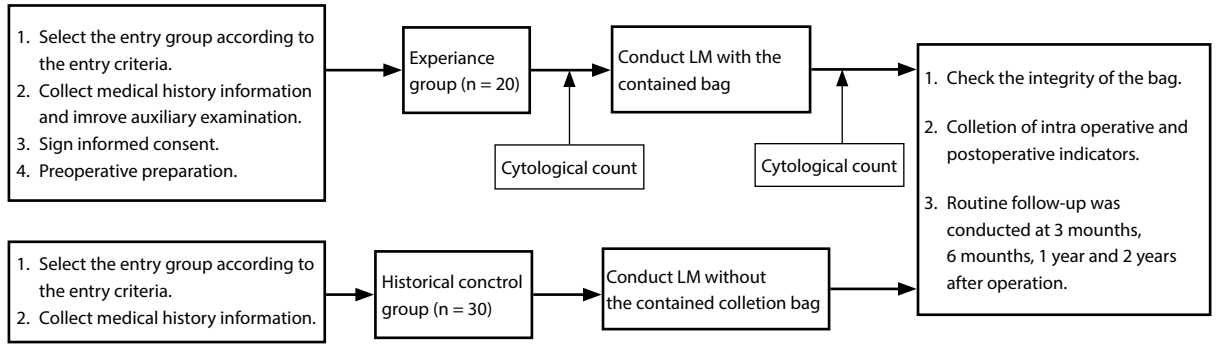

Figure 2. The study flow diagram

Table 1. Demographic and baseline characteristics of the study population

Items	Experiment group (n = 20)	Historical group (n = 30)	T/Z value	p-value
Mean age [years] (SD)	38.17 (5.57)	39.78 (6.07)	T = –0.83	0.41
Mean BMI [kg/m^2] (SD)	23.95 (2.12)	22.33 (2.25)	T = 0.79	0.19
Median number of pregnancies (IQR)	2.5 (2)	2 (3)	Z = –1.15	0.25
Median number of term pregnancies (IQR)	1.0 (0)	1 (0)	Z = –0.60	0.55

SD — standard deviation; BMI — body mass index; IQR — interquartile range

postoperative menstrual recovery, and pregnancy in previously infertile patients.

The SPSS19.0 software package (SPSS Inc., Chicago, IL, USA) was used for data analysis. A Kolmogorov–Smirnov test was used for the normality test, an independent-samples t-test was used for normally distributed data, a Mann–Whitney U test was used for data with non-normally distributed data, and a Chi square test was used for count data. Statistical significance was set at $p < 0.05$.

RESULTS

The demographic and baseline characteristics of the study population

The flow chart in Figure 2 shows that a total of 50 patients were enrolled in the study, 20 in the experimental group and 30 in the historical control group. There was no significant difference in age, BMI, birth history between the two groups (Tab. 1).

The comparison of preoperative medical history and imaging data

The preoperative rates of menorrhagia and/or prolongation of menstruation, abdominal distention and/or abdominal pain, urinary frequency, and infertility were 20%, 25%, 15%, and 5% respectively, in the experimental group, and 17%, 33%, 10%, and 10% respectively, in the historical control group. The p values were all higher than 0.05. Four cases in the experimental group and five cases in the historical control group were complicated with menorrhagia and/or prolonged menstruation. Diagnostic curettage was performed to exclude endometrial lesions before admission. Preoperative imaging (B ultrasound, CT or MRI) showed no significant difference in uterine volume, maximum uterine diameter, and maximum myoma diameter between the two groups. The history of abdominal surgery in the two groups was 50.0% in the experimental group and 53.3% in the historical control group (p = 0.82) (Tab. 2).

The comparison of intraoperative and postoperative conditions

The LM was completed in all 50 patients without the need for it to be converted to a laparotomy. There were no injuries to the intestinal or urinary systems, important blood vessels, or nerves during the operations, and no other surgery was performed besides the LM. In two of the 20 cases in the experimental group and four of the 30 cases in the historical control group, the endometrium was penetrated during the LM (p = 1.00). These six patients were treated with antibiotics 24–48 hours after surgery to prevent infection, and mifepristone tablets 12.5 mg p.o. qd were given on the first day afterwards and for the next three months to prevent adenomyosis formation.

In the experimental group, 20 patients underwent LM with the use of a collection bag. Pseudopneumoperitoneum was successfully established in all the patients, and

the inflation success rate was 100%. The operative field was clear, and the morcellation was performed successfully (Fig. 3), with no rupture of the bag body occurring during the process of morcellation. After the main tumor was morcellated, the number of debris fragments in the bag was counted under laparoscopy. The average number of remaining tissue fragments in the bags of the 20 patients was 5.00 (standard deviation 1.48), and the average weight of the remaining fragments was 3.87 g (standard deviation 1.31). The integrity of the bag was detected by saline injection after operation, and no bag body was damaged. The operation took significantly longer in the experimental

Table 2. A comparative analysis of preoperative complaints, auxiliary examination results and previous abdominal operation history

Items	Experiment group (n = 20)	Historical group (n = 30)	T/Z/X^2 value	p-value
AUB, No. (%)	4 (20.0)	5 (16.7)	$X^2 = 0.00$	1.00
Abdominal distention or pain, No. (%)	5 (25.0)	10 (33.3)	$X^2 = 0.39$	0.53
Frequent micturition, No. (%)	3 (15.0)	3 (10.0)	$X^2 = 0.01$	0.93
Infertility, No. (%)	1 (5.0)	3 (10.0)	$X^2 = 0.01$	0.92
Uterine size [cm^3] (Median, IQR)	144.86, 146.78	122.32, 139.08	Z = –0.50	0.65
Maximum diameter of uterus [mm] (mean ± SD)	73.25 ± 13.94	71.33 ± 16.30	T = 0.37	0.71
Maximum diameter of myoma [mm] (mean ± SD)	62.50 ± 15.07	58.24 ± 12.14	T = 1.03	0.31
Past history of abdominal surgery, No. (%)	10 (50.0)	16 (53.3)	$X^2 = 0.05$	0.82

AUB — abnormal uterine bleeding; Uterine size (B ultrasound /CT/MRI) — long diameter × wide diameter × thickness diameter * 0.523 (cm^3); SD — standard deviation; IQR — interquartile range

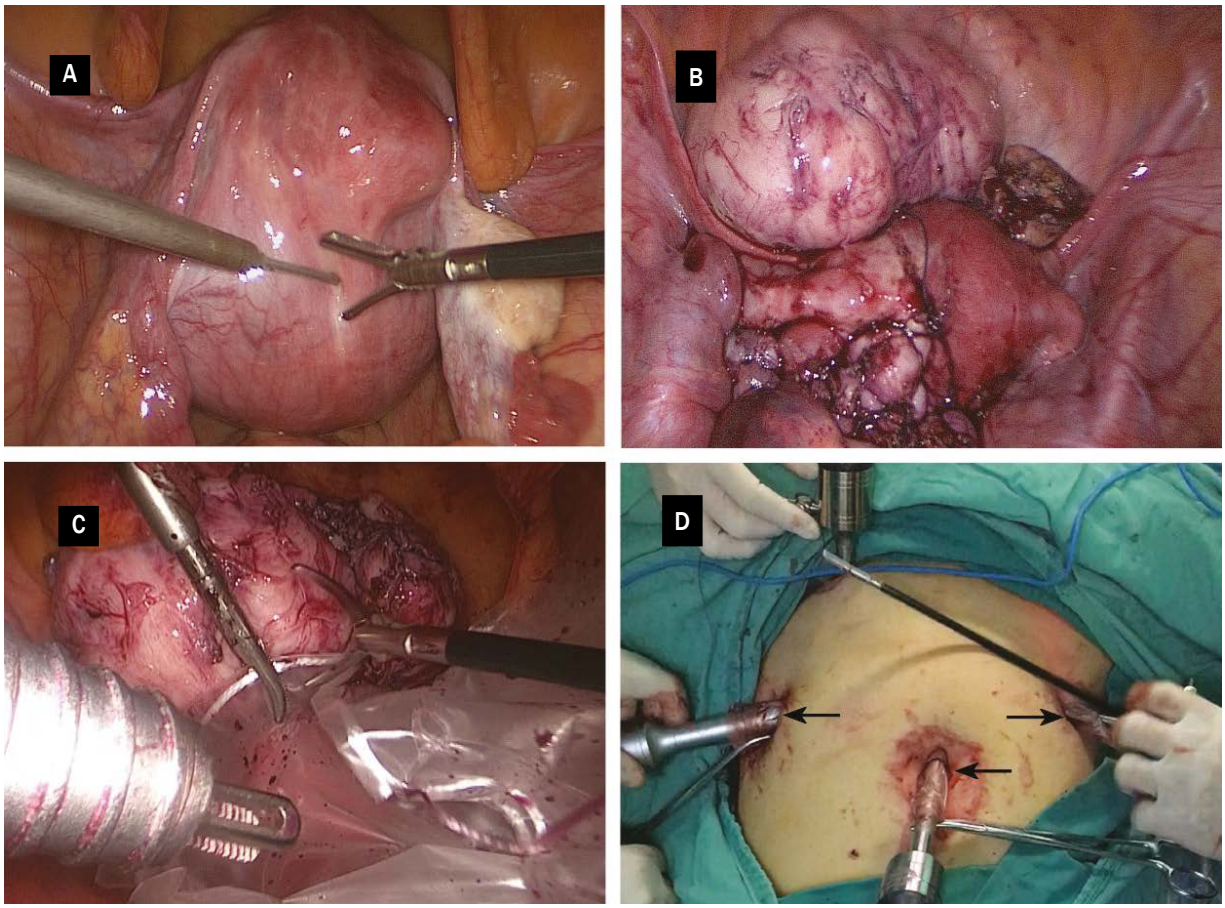

Figure 3. Clear view of contained collection bag in LM; **A.** Estimated diameter of the two myomas were 8 cm and 3 cm; **B.** The actual size of the two myomas were 10 × 8 × 6 cm and 3 × 3 × 3 cm; **C.** The folded collection bag was inserted into the abdominal cavity through the reverse McDonald's point sheath. Under direct vision, the bag was opened with the assistant and the tissue was moved into the bag though first port; **D.** Under direct vision, the second port was pulled out of the reverse Maxwell's point puncture hole, the third port was pulled out of the umbilical puncture hole, the fourth port was pulled out of the Maxwell's point puncture hole, and the sheath was put into the bag mouth respectively

→

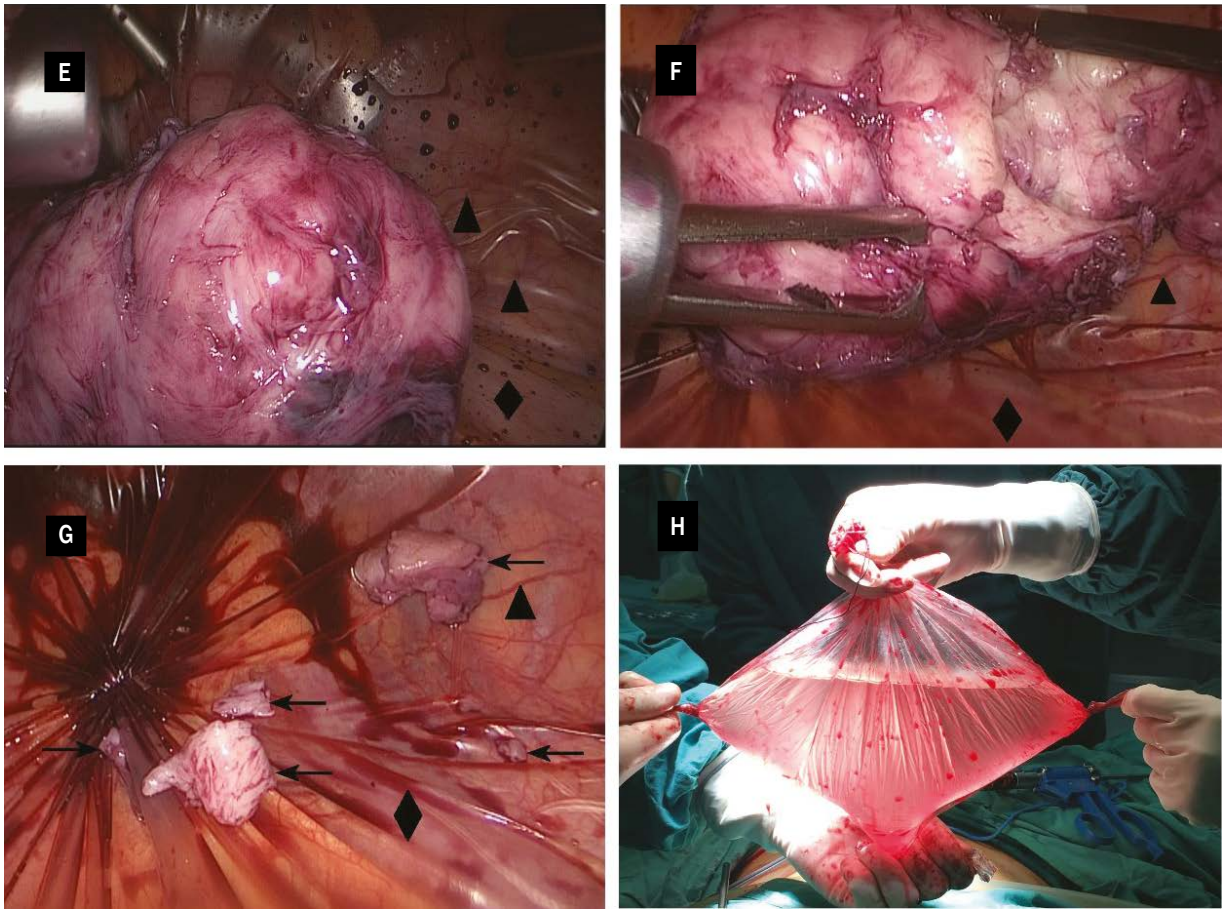

Figure 3. cont. Clear view of contained collection bag in LM; **E.** After the pseudo pneumoperitoneum was established, the intestinal tube and omentum could be pushed away, and the morcellation was performed in a clear field of vision; ▲ represents for vessels and ◆ represents for intestinal tract; **F.** The morcellation conducted with assistant fixing the tumor; **G.** The remaining fragment tissue; **H.** The collection bag were carefully examined for leakage breakage with normal saline

Table 3. Analysis of operative conditions in two groups

Items	Experiment group (n = 20)	Historical group (n = 30)	T/Z value	p-value
Successful cases of pseudo pneumoperitoneum	20/20	—	—	—
Remaining fragment tissue amount (mean ± SD)	5.00 ± 1.48	—	—	—
Remaining fragment tissue weight [g] (mean ± SD)	3.87 ± 1.31	—	—	—
Number of myoma removed during operation(mean ± SD)	1 (1, 5)	1 (1, 7)	Z = –1.19	0.23
Operation duration (min) (median, IQR)	101, 43	83, 35	Z = –3.75	0.00
Intraoperative hemorrhage [mL] (median, IQR)	110, 75	90, 50	Z = –3.55	0.17
Volume of CO_2 [L] (median, IQR)	335, 145	283, 109	Z = –4.24	0.00
Intraoperative penetrating intima, No. (%)	2 (10.0)	4 (13.3)	X^2 = 0.00	1.00
Antibiotic usage rate of class I incision, No. (%)	1 (5.6)	2 (7.7)	X^2 = 0.00	1.00

SD — standard deviation; IQR — interquartile range

group than it did in the control group (p = 0.00), and the median difference between the two groups was 18 min. The intraoperative CO_2 use in the experimental group was also significantly higher than that in the historical control group (p = 0.00), and the median difference between the two groups was 52 L (Tab. 3).

The antibiotic usage rates for class I incisions in the experimental group and the historical control group were 0.05 and 0.08, respectively (p = 1.00). The pathology results of the two groups showed that the myomas were all uterine leiomyomas. There were two cases of cellular leiomyoma in the experimental group, and one case of cellular leiomyoma,

Table 4. Postoperative analysis of two groups

Items	Experiment group (n = 20)	Historical group (n = 30)	T/Z value	p-value
Postoperative Hb decline [g/L] (mean ± SD)	23.50 ± 14.85	18.87 ± 7.54	T = 1.05	0.31
Postoperative hospital stay [d] (mean ± SD)	4.5, 2.0	5.0, 0.5	Z = –0.06	0.95
Postoperative blood transfusion, No. (%)	0	0	—	—
Postoperative morbidity, No. (%)	2 (10.0)	3 (10.0)	X^2 = 0.00	1.00
Postoperative exhaust time [d] (median, range)	2 (1, 2)	2 (1, 3)	Z = –0.14	0.89
Total hospitalization expenses (RMB) (median, IQR)	13257.49, 3102.36	13762.48, 1928.64	Z = –0.63	0.53
Menstrual recovery, No. (%)	4 (100.0)	4 (80.0)	—	1.00

Postoperative morbidity — postoperative body temperature is higher than 38.5°C. Menstrual recovery: refers to patients with preoperative menorrhea (> 80 mL) or prolonged menstrual period (> 7 d) returned to normal menstrual volume (5–80 mL) and normal menstrual period (3–7 d) after surgery. The menstrual recovery in this table was analyzed by Fisher's exact test. There was no statistic (X^2 value), and p-value was bilateral

one case of strange uterine leiomyoma, and three cases of uterine leiomyoma with degeneration in the historical control group (one case of mucinous degeneration and two cases of red degeneration), but none of them was malignant.

In the experimental group, cytological counts of lavage fluid were performed after all the red blood cells were lysed by erythrocyte lysates before and after morcellation. All the cytological counts were less than 10^5–10^6/L. No other cell culture was carried out.

There was no significant difference between the experimental group and the historical control group in postoperative hemoglobin decline, postoperative hospital stays, postoperative blood transfusion, postoperative morbidity, postoperative bowel movement time, and total hospitalization costs. There were three cases of menorrhagia (> 80 mL) and one case of prolonged menstruation (> 7 days) in the experimental group, which all returned to normal after the operation, and three cases of menorrhagia and two cases of prolonged menstruation in the historical control group, four of which returned to normal afterwards. One case of prolonged menstruation did not recover, and previous ultrasonography indicated cesarean scar diverticulum. There was no significant difference in menstrual recovery between the two groups (Tab. 4).

In this study, one patient in the experimental group was infertile, and three patients in the historical control group were infertile (Tab. 1). These patients had still not conceived four years after surgery, and so pregnancy outcome cannot be calculated at present, and further follow-up is needed.

DISCUSSION

Performing a laparoscopic myomectomy rather than a transabdominal myomectomy can reduce trauma and increase patient compliance. However, open power morcellation increases the possibility of spreading potentially malignant diseases and significantly reduces the survival of those patients [9, 10]. The rate of benign myoma is less than 0.50% (0.13–2.02%) and the incidence of potential malignant tumors during hysterectomy and morcellation is 0.10–0.25% [11, 12]. Despite these low rates of malignancy and potential malignancy, the fundamental importance of patient safety means that clinical gynecologists must balance maximum benefit with minimum harm.

There has been some exploration of the technology of improved tumor morcellation. As early as 2003, Landman et al. [13] suggested that in laparoscopic nephrectomy for renal cell carcinoma the affected tissue could be separated in vitro by expanding the body surface incision to 3 cm. The contained morcellation of a uterine myoma during LM has also been studied. This method involves accommodating the morcellation device, while also providing enough space and maintaining clear vision during surgery. The aim of this technique is to isolate and accommodate tissues considered normal before surgery, even if these tissues are subsequently diagnosed as malignant. However, at present, most of the contained morcellation systems require puncturing the bag after the pseudopneumoperitoneum is established in the abdominal cavity, which increases the possibility of bag leakage and tissue splash [14, 15].

In 2016, the FDA approved the Pneumoliner System [16]. This device consists of a sealed bag and a cylindrical plunger, which can be placed in the abdominal cavity. The umbilical incision needs to be wide enough for a cylindrical plunger to be placed in the umbilical puncture hole, as well as a 5 mm diameter fiber lens (convertible direction), a 5 mm morcellator (enhanced bipolar energy), and a pneumoperitoneum system. There is no assistance with fixing the tissue during the morcellation, as well as the More-Cell-Safe system reported in 2017 [17]. However, the Pneumoliner System is like single port laparoscopy, which increases the degree of difficulty of the operation, and it is not suitable for three or four trocars. In addition, the field of vision is relatively limited.

Morcellation techniques with assistants holding the tissue in place can guarantee quicker and safer morcellation

and avoid shaking the tumors with the morcellator, and a clear visual field can reduce the risk of damaging any surrounding vital organs. Nevertheless, it has been reported that with the contained morcellation technique, the morcellator can penetrate the bag and injure the aorta, inferior vena cava, or intestine [18], which can lead to the death of the patient [19]. In the present study, 20 patients in the experimental group had an LM that involved the use of a contained collection bag. Pseudopneumoperitoneum was successfully established in all the operations, and afterwards the intestinal tube and the omentum were pushed away. The morcellation was performed with a clear field of vision and the help of an assistant, thereby reducing the possibility of damaging nearby tissue or enabling the spread of tumor cells. It would appear that morcellation during an LM with a contained collection bag is effective, safe, and feasible.

It has been reported that the average duration of contained power morcellation is 20–26 min. longer than that of open power morcellation, but there is no significant difference in blood loss and length of hospitalization [20]. In this study, the average time increase of the experimental group operations was about 18 min. ($p = 0.00$), and the intraoperative CO_2 use was increased by about 52 L ($p = 0.00$). There was no significant difference between the experimental group and the historical control group in postoperative hemoglobin decline, postoperative hospitalization days, postoperative blood transfusion, postoperative morbidity, postoperative bowel movement time, and total hospitalization costs. The slightly prolonged operation time did not affect the postoperative recovery and total hospitalization costs of the experimental group patients. It is believed that the duration of the operation and the use of CO_2 would decrease if the sample size was increased and the contained power morcellation technique further developed.

This study involved a single-arm trial, and the sample size was relatively small. It is thus necessary to expand the sample size to confirm the validity, safety, and feasibility of the technique. Moreover, in this study, the bags were only used with tumors that were removed during an LM, and further research is necessary regarding their use in patients who are undergoing a laparoscopic hysterectomy.

In this study, the myomas of both the experimental group and the historical control group were pathologically diagnosed as benign and without any malignancy. This means that this study cannot prove that the contained bag technique can reduce the risk of spreading malignant tumors. The efficacy of this bag in preventing abdominal and pelvic dissemination of potentially malignant tumor tissue needs to be further analyzed by enlarging the sample size and increasing the follow-up time. However, this new contained collection bag should not be used in patients with known malignant tumors.

CONCLUSIONS

Morcellation with this newly designed contained collection bag during an LM can be effective, safe, and feasible. It is also economical, practical, and easy to operate. The efficacy of the contained collection bag in preventing the abdominal and pelvic dissemination of potentially malignant tumors requires confirmation.

Funding

This study was funded by the National Natural Science Foundation of China (No. 81270678); Suzhou science and technology planning project (No. SS201633, SYSD2019106, SYS2020134); Jiangsu Provincial Commission of Health and Family Planning (No. F201922) and Suzhou Wumen medical school research special scientific research fund (No.SKJYD2021190).

Ethics approval and consent to participate abstract

The study was conducted in accordance with the Declaration of Helsinki (as was revised in 2013). The study was approved by Ethics Committee of the Second Affiliated Hospital of Soochow University (No.JD-LK-2016-020-03). Written informed consent was obtained from all participants.

Conflict of interest

No potential conflict of interest was reported by the authors.

REFERENCES

1. Tan-Kim J, Hartzell KA, Reinsch CS, et al. Uterine sarcomas and parasitic myomas after laparoscopic hysterectomy with power morcellation. Am J Obstet Gynecol. 2015; 212(5): 594.e1–594.10, doi: 10.1016/j.ajog.2014.12.002, indexed in Pubmed: 25499259.
2. Istre O. Unexpected Uterine Leiomyosarcoma During Laparoscopic Hysterectomy Treated 6 Months With Ulipristal Acetate and Contained Power Morcellation. J Minim Invasive Gynecol. 2017; 24(2): 198, doi: 10.1016/j.jmig.2016.08.004, indexed in Pubmed: 27539216.
3. Park JY, Kim DY, Kim JH, et al. The impact of tumor morcellation during surgery on the outcomes of patients with apparently early low-grade endometrial stromal sarcoma of the uterus. Ann Surg Oncol. 2011; 18(12): 3453–3461, doi: 10.1245/s10434-011-1751-y, indexed in Pubmed: 21541824.
4. Ludwin A, Gawron I, Pityński K. Occult uterine leiomyosarcoma in women undergoing abdominal and minimally invasive surgeries for myomas. Ginekol Pol. 2018; 89(10): 546–552, doi: 10.5603/GP.a2018.0093, indexed in Pubmed: 30393842.
5. Food U S. Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication. Center for Devices & Radiological Health, 2014. https://xueshu.baidu.com/usercenter/paper/show?paperid=3eddca96ea9b38c1b8f9bc741523dc3c (15.12.2021).
6. Lum DA, Sokol ER, Berek JS, et al. Impact of the 2014 Food and Drug Administration Warnings Against Power Morcellation. J Minim Invasive Gynecol. 2016; 23(4): 548–556, doi: 10.1016/j.jmig.2016.01.019, indexed in Pubmed: 26827905.
7. Singh SS, Scott S, Bougie O, et al. Technical Update on Tissue Morcellation During Gynaecologic Surgery: Its Uses, Complications, and Risks of Unsuspected Malignancy. Journal of Obstetrics and Gynaecology Canada. 2015; 37(1): 68–78, doi: 10.1016/s1701-2163(15)30366-2.
8. Kanade TT, McKenna JB, Choi S, et al. Sydney contained in bag morcellation for laparoscopic myomectomy. J Minim Invasive Gynecol. 2014; 21(6): 981, doi: 10.1016/j.jmig.2014.07.005, indexed in Pubmed: 25048568.

9. Park JY, Park SK, Kim DY, et al. The impact of tumor morcellation during surgery on the prognosis of patients with apparently early uterine leiomyosarcoma. Gynecol Oncol. 2011; 122(2): 255–259, doi: 10.1016/j.ygyno.2011.04.021, indexed in Pubmed: 21565389.
10. Oduyebo T, Rauh-Hain AJ, Meserve EE, et al. The value of re-exploration in patients with inadvertently morcellated uterine sarcoma. Gynecol Oncol. 2014; 132(2): 360–365, doi: 10.1016/j.ygyno.2013.11.024, indexed in Pubmed: 24296345.
11. Brölmann H, Tanos V, Grimbizis G, et al. European Society of Gynaecological Endoscopy (ESGE) steering committee on fibroid morcellation. Options on fibroid morcellation: a literature review. Gynecol Surg. 2015; 12(1): 3–15, doi: 10.1007/s10397-015-0878-4, indexed in Pubmed: 25774118.
12. Beckmann MW, Juhasz-Böss I, Denschlag D, et al. Surgical methods for the treatment of uterine fibroids - risk of uterine sarcoma and problems of morcellation: position paper of the DGGG. Geburtshilfe Frauenheilkd. 2015; 75(2): 148–164, doi: 10.1055/s-0035-1545684, indexed in Pubmed: 25797958.
13. Landman J, Venkatesh R, Kibel A, et al. Modified renal morcellation for renal cell carcinoma: laboratory experience and early clinical application. Urology. 2003; 62(4): 632–634; discussion 635, doi: 10.1016/s0090-4295(03)00680-0, indexed in Pubmed: 14550431.
14. Lambat Emery S, Pluchino N, Petignat P, et al. Cell spillage after contained electromechanical morcellation using a specially designed in-bag system for laparoscopic myomectomy: prospective cohort pilot study. J Minim Invasive Gynecol. 2019; 26(7): 1351–1356, doi: 10.1016/j.jmig.2019.01.014, indexed in Pubmed: 30710637.
15. Cheung VYT, Pun TC. Contained morcellation for laparoscopic myomectomy within a specially designed bag. J Minim Invasive Gynecol. 2016; 23(1): 139–140, doi: 10.1016/j.jmig.2015.08.889, indexed in Pubmed: 26391058.
16. Contained Tissue Extraction System. http://medical.olympusamerica.com/products/pneumoliner (15.12.2021).
17. Szymczak P, Sawicki S, Wydra D. Laparoscopic supracervical hysterectomy with the use of the More-Cell-Safe system in a patient with uterine leiomyomas. Ginekol Pol. 2017; 88(2): 113–114, doi: 10.5603/GP.a2017.0020, indexed in Pubmed: 28326522.
18. Rechberger T, Miotła P, Futyma K, et al. Power morcellation for women undergoing laparoscopic supracervical hysterectomy - safety of procedure and clinical experience from 426 cases. Ginekol Pol. 2016; 87(8): 546–551, doi: 10.5603/GP.2016.0042, indexed in Pubmed: 27629127.
19. Milad MP, Milad EA. Laparoscopic morcellator-related complications. J Minim Invasive Gynecol. 2014; 21(3): 486–491, doi: 10.1016/j.jmig.2013.12.003, indexed in Pubmed: 24333632.
20. Vargas MV, Cohen SL, Fuchs-Weizman N, et al. Open power morcellation versus contained power morcellation within an insufflated isolation bag: comparison of perioperative outcomes. J Minim Invasive Gynecol. 2015; 22(3): 433–438, doi: 10.1016/j.jmig.2014.11.010, indexed in Pubmed: 25452122.