

Safety and efficacy of contained manual morcellation during laparoscopic or robotic gynecological surgery

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Abstract

Objective: To assess the safety and efficacy of contained manual morcellation (CMM) with a tissue pouch during minimally invasive robotic or laparoscopic surgeries.

Methods: A retrospective cohort study included women who underwent robotic or laparoendoscopic single-site surgery at a tertiary referral center between February 2014 and April 2017. The specimen was postoperatively contained, sliced into one or more long strips, and then pulled out. The surgical type, specimen containment time, containment failure rate, specimen weight, manual morcellation time, and overall CMM speed (g/min) were recorded. Surgical complications related (bowel or bladder injury, ureteral injury, vascular injuries, and tumor dissemination) or not related (delayed wound healing, infection, and hernia) to CMM were also documented. The patients were followed up for 2 years.

Results: A total of 165 cases were recorded, comprising 149 cases that underwent laparoscopic and 16 that underwent robotic gynecological surgeries. The average time for specimen containment and manual morcellation in CMM was 6.7 ± 5.0 and 13.2 ± 11.2 min, respectively. The mean morcellation speed was 25.1 ± 8.5 g/min. Among the specimens, those of the uterus with adenomyosis had the lowest CMM speed (21.4 ± 8.0 g/min), whereas those of the uterus with myoma had the highest speed (27.5 ± 8.9 g/min). The pouch perforation rate after CMM was 13.3% and no pouch-related complication was noted.

Conclusion: CMM is an efficient method for specimen removal.

KEYWORDS

Contained morcellation; Manual morcellation; Specimen removal

1 | INTRODUCTION

Minimally invasive surgery has developed vigorously; however, removal of specimens during surgery remains challenging, particularly when it involves a tumor with a large size or undetermined characteristics. Surgical removal of specimens using a power morcellator during laparoscopic surgery is reportedly responsible for spreading cancerous tissue within the abdomen and pelvis in women with unsuspected

uterine sarcoma.¹⁻³ An increasing number of non-malignant sequelae of unconfined morcellation, such as iatrogenic parasitic myoma during hysterectomy, have been reported recently.^{4,5} Therefore, a safe and effective method of specimen removal is required during laparoscopic or robotic surgery.

A retrospective study⁶ revealed that the number of laparoscopy-assisted vaginal hysterectomies increased and no laparoscopic supracervical hysterectomy was performed after the study hospital

withdrew power morcellation. According to an online questionnaire study,⁷ doctors changed the surgical technique to a larger wound-involving, open, or vaginal surgery for hysterectomy after a warning from the U.S. Food and Drug Administration. On the contrary, a retrospective study⁸ revealed that contained power morcellation could be a safe technique for the removal of specimens. However, 12.3% of patients were readmitted due to urine retention and gastrointestinal distress. Nonetheless, a different study⁹ reported another contained power morcellation system (Morsafe) that could safely and effectively remove specimens. Furthermore, a retrospective study¹⁰ showed that manual morcellation is safe and feasible during laparoscopic surgery. In addition, no contained morcellation reportedly carries the risk of tumor dissemination. Contained specimen removal could be achieved by minilaparotomy and a transvaginal approach.¹¹

Contained manual morcellation (CMM) is an innovative method of specimen removal with a tissue pouch and it involves bagging the whole target tissue before removal. CMM was first used in a case of difficult laparoscopic subtotal hysterectomy in 2014.¹² After gaining initial experience,¹³ the use of CMM was extended to other single-site laparoscopic or robotic gynecological surgeries.¹⁴ The aim of the present study was to demonstrate the safety and efficacy of CMM in minimally invasive surgeries and to share related experiences.

2 | MATERIALS AND METHODS

The present retrospective study was approved by the Research Ethics Committee of Hualien Tzu Chi Hospital (IRB 106-153-B). A total of 165 women were included, comprising 149 who underwent laparoscopic surgeries and 16 who underwent robotic surgeries from February 2014 to April 2017 at the Hualien Tzu Chi Medical Center. The inclusion criteria were women at any age undergoing surgeries such as robotic or laparoendoscopic single-site (LESS) surgery with or without additional supracervical hysterectomy (SCH) with a 5-mm port approach, cervical ligament-sparing hysterectomy (SCH plus internal and external conization),^{13,15} myomectomy, and ovarian/adnexal tumor resection (e.g. large teratoma and ovarian tumor with irreversible torsion or unknown characteristic/suspect of early-stage malignancy) (Table 1). Conversely, the exclusion criteria were women who did not undergo the abovementioned surgeries and had incomplete records.

Cases meeting the inclusion criteria using procedure codes were retrieved and the medical records of the hospital were reviewed. The procedure codes were as follows: 80420C, laparoscopic adnexectomy; 80425C, laparoscopic bilateral adnexectomy; 80402B, laparoscopic myomectomy; 80416B, laparoscopic hysterectomy; and 80424B, laparoscopic staging surgery.

Data on the surgical type, specimen containment time, containment failure rate, specimen weight, manual morcellation time, and overall CMM speed (g/min) were collected. Surgical complications related (bowel or bladder injury, ureteral injury, vascular injuries, and tumor dissemination) or not related (delayed wound healing, infection, and hernia) to CMM were also recorded. According to the routine

TABLE 1 Surgery with CMM usage in this study (n=165).^a

Surgery	Number
Approach method	
LESS	69.7 (115/165)
LESS + additional port	30.3 (50/165)
Laparoscopic surgery	149
SCH	59
CLSH	50
Myomectomy	9
Ovarian tumor/cyst resection	31
Robotic surgery	16
SCH	4
CLSH	4
Myomectomy	7
Ovarian tumor/cyst resection	1

Abbreviations: CLSH, cervical ligament sparing hysterectomy; CMM, contained manual morcellation; LESS, laparoendoscopic single-site; SCH, supracervical hysterectomy.

^aValues are given as number or percentage (ratio).

follow-up schedule set at the department, patients were followed up at the following schedules: postoperative 1 week, 1 month, 3 months, 6 months, 1 year, and 2 years.

The LESS port setting was performed as described in previous studies.^{12,16} In brief, the umbilical area was incised (2.0–2.5 cm), followed by the incision of the fascia down to the abdominal cavity. For patients with a large uterus or adnexal tumors, LESS was set at the Lee–Huang point.¹⁷ After the specimen was placed into the tissue bag intra-abdominally (Fig. 1A), the pouch was closed by pulling up the drawstring and then pulled out via the umbilical LESS wound site (Fig. 1B). After wrapping the pouch opening outward to shorten the working distance of CMM (Fig. 1C), the specimen was grasped with Allis tissue forceps and then sliced into one or more long strips using a sharp scalpel blade (Fig. 1D).

2.1 | Measurement and statistical analysis

The materials used in CMM were: (1) the LapSac[®] surgical tissue pouch (COOK Medical Inc., Bloomington, IN, USA); (2) a wound retractor and surgical glove or any single-port set; and (3) a No. 11 sharp scalpel blade (Albion, UK). Additionally, one or two ports sized 5 mm were inserted at the lower abdomen as necessary.

The specimen containment time was calculated from the moment the tissue pouch was inserted into the abdominal cavity until the specimen was contained in the pouch. When the specimen containment time was longer than 25 min, a containment failure occurred according to the set definition by the authors. Failure cases were proceeded without CMM and were thereby excluded from this study. Meanwhile, the manual morcellation time refers to the time used to morcellate all specimens out of the pouch. The morcellation time was calculated from the first incision to the

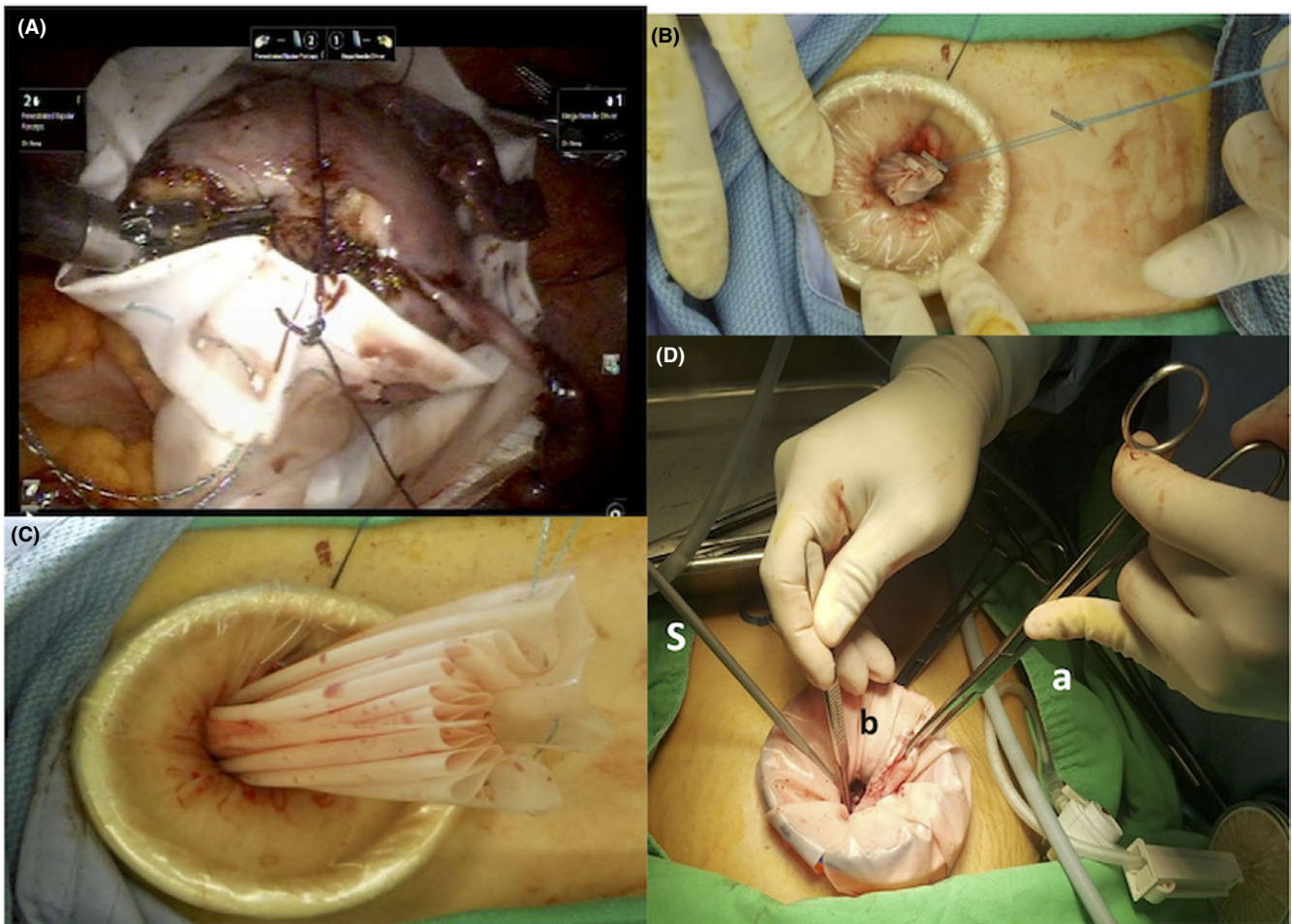


FIGURE 1 Procedures of specimen containment and manual morcellation. (A) A specimen was contained after robotic surgery with flexible arms. (B) The pouch was pulled out via the umbilical port site. (C) The blue drawstring was cut and removed, and the pouch opening was wrapped outward to shorten the working distance of manual morcellation. (D) During containment, the specimen was grasped with Allis tissue forceps (a) and sliced into strips using a scalpel blade (b). Suction is on standby to aspirate tissue fluid.

removal of all specimens out of the pouch. The weight of the specimen was recorded immediately after the surgery. The CMM rate of the ovarian/adnexal tumor was omitted because its weight could not be calculated accurately preoperatively or after CMM. All tissue fragments or fluids would be contained in the pouch after CMM. To check whether a tissue bag was ruptured after CMM, the surgeon filled the pouch with water dyed with methylene blue.

The results are expressed as mean \pm standard deviation. Differences between groups (i.e. myoma [MM], adenomyosis [ADE], uterus with myoma [M], and ovarian cyst [C]) were determined by one-way ANOVA and post-hoc test with Bonferroni's correction. $P < 0.05$ denotes statistical significance. The SPSS software was used for this analysis (version 24, IBM, Armonk, NY, USA).

3 | RESULTS

A total of 165 women were included in this study, comprising 149 who underwent laparoscopic surgeries and 16 who underwent robotic surgeries (Table 1). Approximately 70% (115/165)

of these women completed their treatment by LESS, whereas the remaining 30% (50/165) needed one or two additional 5-mm ports for assistance.

The average time for specimen containment and manual morcellation in CMM was 6.7 ± 5.0 and 13.2 ± 11.2 minutes, respectively (Table 2). The C group needed the significantly shortest time for containment (4.6 ± 2.5 min), followed by the M group (6.3 ± 2.7 min) and ADE group (7.5 ± 5.5 min) ($P = 0.017$). Meanwhile, the containment failure rate was 1.2% (2/165) wherein two cases could not be contained within 25 minutes due to large tumor size. Moreover, the median specimen weight was 288.6 g (range 60–1357). The weight of myoma was significantly less than that of the uterus (137.1 ± 65.3 vs 306.2 ± 202.6 g, $P = 0.004$). The mean speed of CMM was 25.1 ± 8.5 g/min. Among the specimens, those of the uterus with adenomyosis had the lowest CMM speed (21.4 ± 8.0 g/min). In contrast, those of the uterus with myoma alone had the highest CMM speed (27.5 ± 8.9 g/min), followed by myoma (26.5 ± 2.8 g/min) and the uterus with myoma and adenomyosis (25.9 ± 9.2 g/min). The speed of CMM was significantly lower in adenomyosis than in uterine myoma (21.4 ± 8.0 vs 27.5 ± 8.9 g/min, $P < 0.008$).

TABLE 2 Efficacy of CMM with the tissue pouch.^a

Events (n=165)	Results	P value	Post-hoc test
Overall specimen containment time (min)	6.7 ± 5.0	0.017 ^b	C<M, ADE, M + ADE ^c
Myoma(s) (n=16)	6.3 ± 2.7		
Uterine body (n=117)	7.5 ± 5.5		
Ovarian tumor/adnexal cyst (n=32)	4.6 ± 2.5		
Specimen containment failure rate	1.2% (2/165)		
Overall specimen weight (g)	288.6 (60–1357)	0.004 ^b	MM<M, ADE, M + ADE ^d
Myoma(s)	137.1 ± 65.3		
Uterine body	306.2 ± 202.6		
Overall manual morcellation time (min)	13.2 ± 11.2	0.006 ^b	MM<M, ADE, M + ADE ^d
Myoma(s)	6.1 ± 2.8		
Uterine body	14.2 ± 11.5		
Overall CMM Speed (g/min)	25.1 ± 8.5	0.008 ^b	ADE<M ^e
MM (myoma(s)) (n=16)	26.5 ± 2.8		
M (uterine body with myoma(s) only) (n=39)	27.5 ± 8.9		
ADE (uterine body with adenomyosis only) (n=39)	21.4 ± 8.0		
M + ADE (uterine body with myoma and adenomyosis) (n=39)	25.9 ± 9.2		

Abbreviations: ADE, adenomyosis; C, ovarian cyst; CMM, contained manual morcellation; M, uterus with myoma; MM, myoma.

^aValues are given as mean ± SD or mean (range).

^bOne-way ANOVA test (post-hoc test was Bonferroni's correction).

^cC<M, ADE, M + ADE: the overall specimen containment time in ovarian cyst (C) group was shorter than ADE and M + ADE groups.

^dMM<M, ADE, M + ADE: the overall specimen weight and overall manual morcellation times in MM group was less weighted and shorter than M, ADE, M + ADE groups.

^eADE<M: Overall CMM speed in ADE group was shorter than M group.

The pouch perforation rate after CMM was 13.3% (Table 3) and no pouch-related complication was noted. In the present study, CMM helped avoid some adverse events in three cases (Table 3). In one case of uterine myoma, the surgeon was unaware of the presence of an intrauterine device (IUD), which was incidentally found in the tissue pouch during CMM. If this IUD remained undetected in the abdomen, peritonitis may have occurred. In another case, a frozen section revealed a borderline ovarian serous cystadenoma. The third case was of mucinous adenocarcinoma (pT1aNOM0), which

was diagnosed with a frozen section; hence, laparoscopic staging surgery was performed instead. The second and third patients have been followed up for more than 2 years and are still alive without evidence of recurrence.

No wound infection was observed, but delayed umbilical wound healing was noted in three cases. Two cases of umbilical hernia were also found after 2-year follow-up (Table 3).

4 | DISCUSSION

The reported method of specimen removal, i.e. CMM, is basically suitable for a patient undergoing laparoscopic or robotic surgery for benign gynecological diseases. CMM is simple and safe because it is performed with direct visualization and manual cutting without pneumoperitoneum. All fragments of a specimen, missed foreign body, pus, or tissue fluid can be safely contained in the tissue pouch during morcellation. Patients will benefit mainly from the prevention of parasitic myoma, i.e. scattering of inflammatory or infectious tissues/foreign bodies. The tissue pouch used in CMM is available in different sizes. The largest one has an opening diameter of 20 cm; therefore, this method is feasible for women with a large uterus. Unlike the other method of in-bag morcellation that needs two or more ports for assistance, CMM can be mostly performed using only a single site.

TABLE 3 Safety profiles of CMM with the tissue pouch.^a

Pouch perforation rate (any)	13.3 (22/165)
CMM-related complication	0 (0/165)
CMM usage prevents potential adverse event	1.8 (3/165)
Uterine with unknown missed IUD	1
Borderline serous cystadenoma of ovary	1
Mucinous adenocarcinoma (pT1a)	1
Umbilical wound infection	0 (0/165)
Umbilical wound delayed healing	1.8 (3/165)
Umbilical hernia	1.2 (2/165)

Abbreviations: CMM, contained manual morcellation; IUD, intrauterine device.

^aValues are given as percentage (ratio) or case number.

Complications of morcellation performed using a vaginal or an abdominal approach include bowel or bladder injury, ureteral injury, vascular injury, and tumor dissemination.¹⁸ In this study, no CMM-related complications were reported.

The pouch perforation rate of CMM is 13.3%. In fact, only one tiny perforation was found at the upper portion of the pouch caused by the tip of a scalpel blade that occurred because of the perpendicular cutting force of manual morcellation. This perforation did not compromise the waterproof containment of tissue fragments or fluid. The tissue pouch used in CMM is a waterproof nylon bag containing a polyurethane inner layer that is relatively resistant to tearing and cutting. Hence, the pouch presented herein is less likely to be perforated following manual morcellation.

The rate of electromechanical morcellation performed with a power morcellator is 8.6–14.0 g/min.¹⁹ In a recent study on manual morcellation without specimen containment,¹⁰ the mean morcellation rate was 39.8 g/min. The results of this study indicate that CMM has an efficacy that lies between those of power morcellation and manual morcellation. A subgroup analysis showed that the rate of CMM depends on lesion characteristics; this rate is slower for adenomyoma than for myoma. More importantly, CMM represents a more well-controlled method that may minimize the risk of the dissemination of potential inflammatory/regenerative tissues or occult cancer cells caused by electrical or non-contained manual morcellation.^{20–22} The techniques of specimen containment and manual morcellation are not difficult as long as the user follows the step-by-step procedures mentioned previously. In addition, CMM can potentially be widely used in minimally invasive surgeries such as those involving ovarian tumors of unknown characteristics and robotic surgery.¹⁴

In the present study, specimens of adenomyoma required more time to morcellate than those of myomas. Adenomyosis is endometrial invasion of the myometrium that results in an enlarged uterus,²³ whereas myoma is characterized by smooth muscle cell proliferation and is the most common benign uterine tumor.²⁴ Adenomyoma is harder than myoma when morcellated. The hard consistency of adenomyoma may be caused by the ectopic endometrial gland and menstrual blood accumulated in the myometrium; therefore, more time is consumed during morcellation.

However, this study has several limitations. The present study has a retrospective cohort design. In addition, although CMM is a new method of specimen removal, it has limitations for large specimens. When a specimen has a maximum diameter larger than 15 cm, the containment would be difficult and time-consuming. Preoperative abdominal ultrasound may be helpful to determine whether a minimally invasive surgery with CMM is safe and feasible.

CMM is an efficient method of specimen containment and removal. It is safe and effective, and it can potentially be widely used for a large specimen during robotic or laparoscopic gynecological surgeries.

AUTHOR CONTRIBUTIONS

MKH: study concepts, design and manuscript preparation; JHW: data analysis and manuscript preparation; YCW and TYC: study design,

acquisition of data, and manuscript preparation; DCD: study concepts, design and manuscript preparation, and revision.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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