

GYNECOLOGY

Contained tissue extraction using power morcellation: prospective evaluation of leakage parameters

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BACKGROUND: Safe tissue removal is a challenge for minimally invasive procedures such as myomectomy, supracervical hysterectomy, or total hysterectomy of a large uterine specimen. There is concern regarding disruption or dissemination of tissue during this process, which may be of particular significance in cases of undetected malignancy. Contained tissue extraction techniques have been developed in an effort to mitigate morcellation-related risks.

OBJECTIVE: The objective of the study was to quantify perioperative outcomes of contained tissue extraction using power morcellation, specifically evaluating parameters of tissue or fluid leakage from within the containment system.

STUDY DESIGN: This was a study including a multicenter prospective cohort of adult women who underwent minimally invasive hysterectomy or myomectomy using a contained power morcellation technique. Blue dye was applied to the tissue specimen prior to removal to help identify cases of fluid or tissue leakage from within the containment system.

RESULTS: A total of 76 patients successfully underwent the contained power morcellation protocol. Mean time for the contained morcellation procedure was 30.2 minutes (± 22.4). The mean hysterectomy specimen weight was 480.1 g (± 359.1), and mean myomectomy specimen weight was 239.1 g (± 229.7). The vast majority of patients (73.7%) were discharged home the same day of surgery. Final pathological diagnosis was benign in all cases. Spillage of dye or tissue was noted in 7 cases (9.2%), although containment bags were intact in each of these instances.

CONCLUSION: Findings are consistent with prior work demonstrating the feasibility of contained tissue extraction; however, further refinement of this technique is warranted.

Key words: hysterectomy, in-bag morcellation, laparoscopic surgery, myomectomy

Minimally invasive procedures that require tissue extraction pose a unique challenge to gynecological surgeons. To extract an intact uterine or fibroid specimen, it must be small enough to fit through a colpotomy or minilaparotomy incision. Otherwise, morcellation techniques are required, which may result in the disruption or dissemination of tissue. Particularly, there is concern regarding spread of fragments of morcellated tissue in cases of occult malignancy.¹⁻¹⁰

There has been a shift in the standard of care from a liberal use of open, or uncontained, power morcellation to more restricted use following the US Food and Drug Administration review of the topic in 2014. In an updated safety communication, the Food and

EDITORS' CHOICE

Drug Administration specified that laparoscopic power morcellators should not be used to remove fibroid tissue in the majority of women who undergo hysterectomy or myomectomy.¹¹

As a result, contained tissue extraction techniques are being modified in an effort to minimize the risk of tissue dissemination while allowing for a minimally invasive mode of access and accompanying morbidity advantages. Early reports have documented the feasibility of contained power morcellation within an insufflated specimen bag as one approach to this task.¹²⁻¹⁴

Techniques for contained tissue extraction using power morcellation are in the early phases of development; therefore, it is important to evaluate potential issues such as the risk of tissue leakage from within the containment system. Although a small in vitro pilot study showed no cytological or visual evidence of fluid or tissue leakage when an isolation bag was used for contained power morcellation,¹⁵ similar findings are yet to be demonstrated on a larger scale.

The goal of this work was to quantify perioperative outcomes of contained tissue extraction, specifically evaluating parameters of tissue or fluid leakage from within the containment system.

Materials and Methods

This is a multicenter prospective cohort study of adult women scheduled to undergo minimally invasive hysterectomy or myomectomy using contained tissue extraction techniques. Participating institutions in the greater Boston, MA, area included the following: Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, Massachusetts General Hospital, Newton-Wellesley Hospital, and Lahey Hospital and Medical Center.

Thirteen surgeons, all experienced laparoscopic surgeons, enrolled patients in this study. The majority of surgeons are fellowship trained in either minimally invasive gynecologic surgery or reproductive endocrinology and infertility. Institutional review board approval was obtained at all institutions, and the Brigham and Women's Hospital Institutional Review Board served as the data and safety monitoring board for this study.

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The primary outcome measure was leakage of dye or tissue fragments during specimen removal using contained power morcellation. Secondary outcomes included operative time, time required for contained power morcellation, and perioperative complications. Inclusion criteria for enrollment were women 18 years of age or older eligible to undergo laparoscopic or robot-assisted laparoscopic myomectomy or hysterectomy, as determined clinically by the operating surgeon. Exclusion criteria included suspected malignancy, medical illness precluding laparoscopy, inability to give informed consent, allergy to either indigo carmine or methylene blue dye, or morbid obesity. Routine preoperative testing was performed at the discretion of the operating surgeon and included a Papanicolaou smear, endometrial biopsy, imaging with pelvic magnetic resonance imaging or ultrasound, and blood work as indicated.

The following demographic variables were collected: patient age, race, obstetrical history, body mass index (BMI), past surgical history, and indication for surgery. Perioperative variables that were collected included the following: mode of access, type of procedure(s) performed, operative time (defined as time from incision to closure), time for morcellation procedure (defined as time from placing containment bag into abdomen to complete specimen removal), estimated blood loss (defined as surgeon estimate that was recorded in the operative record), specimen weight, number of fibroids removed in cases of myomectomy, type of containment bag used, intact status of the containment bag as visually inspected by surgical team at the end of the procedure, the presence of dye or tissue leakage outside the containment bag, intraoperative complications (defined as visceral, vascular, or nerve injury; estimated blood loss greater than 1000 mL; or serious anesthesia complication), postoperative complications (graded on Clavien-Dindo 5 point scale),¹⁶ length of hospital stay, readmission, reoperation, and pathological results.

Eligible patients were offered enrollment and, if interested, signed informed consent to participate in the study

Characteristics	Completed morcellation (n = 76)	No morcellation (n = 10)	Unsuccessful morcellation (n = 3)
Procedure, n, %			
Hysterectomy	42 (55.3%)	6 (60.0%)	1 (33.3%)
Myomectomy	34 (44.7%)	4 (40.0%)	2 (66.7%)
Subtype of hysterectomy, n, %^a			
Total	13 (31.0%)	3 (50.0%)	1 (100.0%)
Supracervical	29 (69.0%)	2 (33.3%)	0 (0%)
Radical	0 (0%)	1 (16.7%)	0 (0%)
Approach, n, %			
Laparoscopic multiport	66 (86.8%)	7 (70.0%)	1 (33.3%)
Robotic, multiport	10 (13.2%)	3 (30.0%)	2 (66.7%)
Additional procedure, n, %			
No	26 (34.2%)	3 (30.0%)	2 (66.7%)
Yes	50 (65.8%)	7 (70.0%)	1 (33.3%)
Age			
Mean (SD)	43.16 (8.53)	44.50 (8.06)	40.67 (6.66)
Race, n, %			
White	50 (65.8%)	8 (80.0%)	2 (66.7%)
Black	12 (15.8%)	1 (10.0%)	0 (0%)
Hispanic/Latino	6 (7.9%)	0 (0%)	0 (0%)
Asian/Pacific Islander	6 (7.9%)	1 (10.0%)	1 (33.3%)
Other	1 (1.3%)	0 (0%)	0 (0%)
Declined	1 (1.3%)	0 (0%)	0 (0%)
BMI			
Mean (SD)	26.47 (5.93)	25.59 (8.54)	27.80 (5.56)
Parity, n, %			
Nulliparous	38 (50.0%)	5 (50.0%)	2 (66.7%)
1-2 live births	30 (39.5%)	5 (50.0%)	1 (33.3%)
> 2 live births	8 (10.5%)	0 (0%)	0 (0%)
Prior abdominal surgery, n, %			
None	43 (56.6%)	5 (50.0%)	1 (33.3%)
Laparotomy	16 (21.1%)	1 (10.0%)	0 (0%)
Laparoscopy	11 (14.5%)	3 (30.0%)	1 (33.3%)
Both	6 (7.9%)	1 (10.0%)	1 (33.3%)

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(continued)

protocol. Patients who declined participation were offered other standard methods of tissue extraction including specimen removal via a colpotomy or

minilaparotomy incisions. The contained power morcellation was performed according to a technique that has previously been described.¹³

The laparoscopic or robot-assisted laparoscopic myomectomy or hysterectomy was performed in standard fashion: a 5 or 12 mm port was placed at the umbilicus with additional ports on the abdomen as per surgeon discretion. Following hysterectomy or myomectomy, a tightly rolled containment bag was inserted into the abdomen. Specimen containment bags used for this purpose included the following: EcoSac (Espiner Medical, North Somerset, United Kingdom), 50 × 50 cm isolation bag (3, St Paul, MN), Anchor tissue retrieval system (Anchor Products Co, Addison, IL), and Endocatch (Covidien, Minneapolis, MN).

These containment bag options were chosen from among hospital stock, and the use of a particular bag type was based on surgeon preference. The bag was then opened and the specimen placed into the bag. The bag edges were brought out through the umbilical site, and once the entire rim of the bag was outside the abdominal cavity, a laparoscopic trocar was replaced through the orifice of the bag. Next, the abdominal cavity was desufflated by opening an ancillary port, and the insufflation tubing was connected to the trocar inside the containment bag. After visual inspection to confirm that the inflated bag contained the tissue specimen, a lateral trocar was redirected to pierce the bag. A balloon-tipped trocar (Kii Advanced Fixation, Applied Medical, Irvine, CA) was recommended for this purpose to maintain the trocar position within the bag. The laparoscope was then placed via the lateral port and insufflation tubing connected at this site as well.

At this time, 5 mL of either indigo carmine or methylene blue dye were injected into the bag, and then a power morcellator device (Rotocut G1; Karl Storz, Tuttlingen, Germany) was introduced at the umbilicus. This small volume of blue dye was sufficient to stain the specimen and coat the tissue and associated fluids. The specimen was then morcellated under continuous laparoscopic vision.

At the end of morcellation, the specimen bag was desufflated, the abdominal

TABLE 1
Patient characteristics by success of contained tissue extraction (continued)

Characteristics	Completed morcellation (n = 76)	No morcellation (n = 10)	Unsuccessful morcellation (n = 3)
Indication for surgery ^b			
Pain/endometriosis	14 (18.4%)	2 (20.0%)	0 (0%)
Abnormal bleeding	23 (30.3%)	1 (10.0%)	0 (0%)
Fibroids	59 (77.6%)	8 (80.0%)	3 (100%)
Pelvic organ prolapse	6 (7.9%)	2 (20.0%)	0 (0%)
Other indication	4 (5.3%)	0 (0%)	0 (0%)

Missing data as follows: BMI, n=1. BMI, body mass index.
^a Among those who had a hysterectomy; ^b Categories not mutually exclusive.
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cavity reinsufflated, and, if using a balloon-tipped trocar, the pneumatic anchor device of the trocar deflated and removed from the bag. This was done in sequence in an effort to avoid the exit of liquids and gas under pressure inside the bag into the abdominal cavity. Following removal of the containment bag, the abdomen and pelvis was carefully examined for any signs of spillage of blue dye, fluid, or tissue.

The integrity of the containment system was also examined by the surgeon. Precautions were outlined such that if a bag tear or leakage was noted at any time prior to or during morcellation, the procedure would be halted and either a new containment bag would be utilized or alternative extraction techniques undertaken.

Given the lack of existing data on the incidence of leakage with contained tissue extraction, a formal power analysis was not performed. The enrollment goal was set at 400 patients in an attempt to comprehensively evaluate this technique, with plans for interim analyses. Specifically, a plan was outlined to halt the study at the time of interim analysis if any complications related to the use of the containment bags were noted or if blue dye leakage was observed in greater than 5% of cases.

Descriptive statistics were calculated using SAS statistical software. Median and range or mean and SD are presented for continuous variables; categorical variables are presented using frequency.

Results

Eighty-nine patients signed informed consent for contained power morcellation of uterine or myoma tissue and were enrolled in this study. Seventy-six patients successfully underwent the contained power morcellation protocol. There were three cases in which the contained power morcellation was not performed as planned because the surgeon found the specimen size too large for either placement of the tissue into a bag or adequate visualization. There were ten cases in which the contained power morcellation was found to be unnecessary and not attempted, most often because of small specimen size or surgeon preference. Following an interim analysis, the decision was made to close the study early because of seven observed instances of fluid or tissue leakage.

Table 1 outlines the patient and procedural characteristics of all cases, separated into completed, unsuccessful, or no contained power morcellation categories. Hysterectomy was performed in 55% of cases; supracervical hysterectomy was performed most often (69% of hysterectomy cases). The most common mode of access was multiport laparoscopy. Among the completed morcellation cases, the mean patient age was 43 years (±8.53). The majority of patients were of white race with a mean BMI of 26.47 (±5.93). Half of the patients were nulliparous and 43% had undergone prior surgery. The predominant indication for surgery was uterine fibroids.

Perioperative outcomes for the 76 patients who completed the contained power morcellation protocol are listed in Table 2. Mean operative time was 174.9 minutes (± 84.9), whereas the mean time for the contained morcellation procedure was 30.2 minutes (± 22.4). Mean estimated blood loss was 164.7 mL (± 435.1). There was one intraoperative complication, which was a case with an estimated blood loss of 3600 mL and intraoperative conversion to open radical hysterectomy because of the size of the uterine fibroid and the degree of anatomic distortion. The mean hysterectomy specimen weight was 480.1 g (± 359.1), and the mean myomectomy specimen weight was 239.1 g (± 229.7), with 26% of myomectomies involving removal of more than 5 fibroids.

Seven postoperative complications were observed, including two urinary tract infections, two blood transfusions for symptomatic anemia, one allergic reaction to abdominal preparation solution, one incisional seroma and one pelvic infection. The vast majority of patients (73.7%) were discharged home the same day of surgery. There were no reoperations. Final pathological diagnosis was benign in all cases, with fibroids as the most common diagnosis. There was one case performed for presumed uterine fibroids in which the final diagnosis returned a smooth muscle tumor of uncertain malignant potential tumor. Of note, there was no evidence of any tissue leakage outside the containment bag during the morcellation of the smooth muscle tumor of uncertain malignant potential tumor.

Regarding issues with containment bag integrity, there was one case wherein a containment bag tear was noted prior to morcellation because of manipulation of the bag with insertion, and one case when a tear was created during removal of the containment bag. As reported by surgeon visual assessment, no bag tears occurred during the morcellation process.

Spillage of dye or tissue was evaluated by careful abdominopelvic survey after the morcellation and was noted in seven cases (9.2% of contained morcellation procedures). All identified tissue

TABLE 2	
Perioperative outcomes among cases with completed contained tissue extraction	
Variable	Completed morcellation
OR time, incision to close (minutes)	
Mean (SD)	174.9 (84.94)
Time for morcellation procedure, bag in to bag out (minutes)	
Mean (SD)	30.15 (22.38)
Intraoperative complications, n, %	
No	75 (98.7%)
Yes	1 (1.3%)
EBL > 1000 mL	
No	75 (98.7%)
Yes	1 (1.3%)
EBL, mL	
Mean (SD)	164.7 (435.1)
Hysterectomy specimen weight by pathology, g	
Mean (SD) ^a	480.1 (359.1)
Myomectomy specimen weight by pathology, g ^b	
Mean (SD)	239.1 (229.7)
Postoperative Clavien-Dindo complication rating (1-5)	
0	69 (90.8%)
1	2 (2.6%)
2	5 (6.6%)
Length of stay, d	
0	56 (73.7%)
1	17 (22.4%)
2	3 (3.9%)
Pathology findings ^c	
Fibroids	64 (84.2%)
Adenomyosis	17 (22.4%)
Endometriosis	2 (2.6%)
Ovarian or Fallopian tube cyst	3 (3.9%)
Other benign finding	10 (13.2%)
Cancer	0 (0.0%)

Missing data as follows: time for morcellation procedure, n = 1. EBL, estimated blood loss; OR, operating room.

^a Among those who had a hysterectomy; ^b Among those who had a myomectomy; ^c Categories not mutually exclusive.

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fragments or fluid droplets were removed from the abdomen. Containment bags were visually intact in each of these instances aside from intentional puncture with lateral trocar. Table 3

summarizes key factors for these seven cases of dye or tissue spillage.

Of note, patient BMI ranged from 19 to 31 kg/m² in these cases of spillage. From review of operative notes, there

TABLE 3
Description of cases with tissue or dye spillage (n = 7)

Case	Specimen size, g	Pathology	Dye spillage	Tissue spillage	Bag type	Surgeon's explanation, if given
LM	66	Fibroids	x		EcoSac	Blue dye introduced through lateral trocar and then dripped during removal of trocar from bag
LSH	40	Fibroids and adenomyosis		x	Endocatch	< 1 cm piece of blue tissue may have escaped out of the lateral puncture site or lateral trocar itself
RALM	87.3	Fibroids	x		Endocatch	Dye spill likely from side port during removal of bag
LM	464	Fibroids	x		EcoSac	Specimen and blue dye placed in Endocatch bag. Bag noted to be too small, and switch made to a larger bag. Dye obviously spilled when removing specimen from first bag
LM	83.2	Fibroids	x	x	EcoSac	
LM	349	Fibroids	x		EcoSac	Blue dye got on laparoscope from lateral trocar site and dripped into abdomen after bag was removed
LSH	250	Fibroids	x	x	EcoSac	

LM, laparoscopic myomectomy; LSH, laparoscopic supracervical hysterectomy; RALM, robot-assisted laparoscopic myomectomy.
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were no identifiable risk factors for the spillage. Surgeon explanation of these events included dye droplets from the lateral port into the abdomen at the time of the containment bag removal, escape of a small tissue fragment from the lateral puncture site, and dye spill during the replacement of larger containment bag prior to morcellation; the remainder of leakage events were unexplained.

Comment

The use of minimally invasive surgical techniques allows for decreased morbidity, length of hospitalization, and recovery time in addition to marked improvement in patient quality of life compared with open approaches.¹⁷⁻²⁰ One limitation to minimally invasive management of certain uterine lesions is the need for tissue disruption to avoid laparotomy for specimen removal. In cases in which a preoperative workup was unable to detect a malignant lesion, it is possible that the malignancy may be disseminated or upstaged by the use of uncontained tissue morcellation; this may occur whether or not a power morcellator device is used.^{10,21,22} Therefore, it is desirable to investigate alternatives for safe removal of resected tissue using a closed containment system.

We present findings from enrollment of 89 patients in a contained power

morcellation protocol for uterine and fibroid specimen extraction at the time of minimally invasive surgery. Contained tissue extraction was successfully used in 76 cases, with only three cases requiring alternate extraction technique for reasons of technical difficulty. There were no instances of containment bag tear during the morcellation process and no complications related to the morcellation technique. Ninety percent of the cases were characterized by complete tissue and fluid containment, with no evidence of tissue or dye spill upon a postmorcellation abdominopelvic survey.

Whereas our results are consistent with prior work demonstrating the feasibility of contained tissue extraction and a pilot study evaluating leakage parameters in vitro,¹²⁻¹⁵ further refinement of this technique is warranted based on the leakage of tissue or dye that was observed. As a result of the leakage events that did occur, we do not advise performing perforation of the containment bag system during contained tissue extraction. This leakage may have occurred at the time of the bag removal, placement/removal of the lateral trocar or via microperforation.

It is unclear whether the tissue and fluid leakage that was observed in this study (seven of 76 patients) holds any

clinical significance, although these instances do represent potential opportunities for tissue dissemination. Even in cases of open surgery and intact specimen extirpation, there may be uterine tissue disruption and fluid spread, particularly in cases of supracervical hysterectomy or myomectomy. Regardless, the authors decided to close the study at the time of interim analysis to allow for further refinements in technique, which may minimize such concerns and enhance reproducibility.

Strengths of this study include the involvement of a large number of surgeons and medical centers, which lends support to the generalizability of the contained tissue extraction technique. Additionally, the use of a dye marker to evaluate for fluid leakage is an improvement on reliance on surgeon gross visual assessment for this measure. Limitations include the fewer than planned number of completed morcellation cases and lack of information about long-term postoperative outcomes. Future studies may benefit from incorporating an objective measure of bag integrity after morcellation as well, in addition to gross inspection by the surgical team, which was used in this study.

Despite the instances of tissue or fluid leakage that were observed in this study, our results provide additional support

for the feasibility of contained tissue extraction and justify continued efforts toward improving such a system. Further refinements of the technique and equipment available for this process will afford additional advantages in efficiency and system integrity. As improvements to the contained morcellation process evolve, it is important that the gynecological surgical community continues to rigorously evaluate potential complications and outcomes. ■

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