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Original Article

Cell Spillage after Contained Electromechanical Morcellation Using a Specially Designed In-Bag System for Laparoscopic Myomectomy: Prospective Cohort Pilot Study

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ABSTRACT **Study Objective:** Few reports have investigated the use of endoscopic retrieval bags in the context of laparoscopic myomectomy with electromechanical morcellation. We performed a leak test of a specially designed endoscopic bag system in women undergoing laparoscopic myomectomy with contained electromechanical morcellation.

Design Classification: Prospective study.

Setting: University hospital.

Patients: Thirty-one women undergoing laparoscopic myomectomy with contained electromechanical morcellation.

Interventions: Electromechanical morcellation was introduced for large specimen extraction during laparoscopic procedures. Complications such as retained/disseminated parasitic tissue were documented.

Measurements and Main Results: Systematic peritoneal washings were performed at 3 specific times: at baseline, T1, once the peritoneal cavity was accessed laparoscopically; T2, when the myometrial incision was closed after myomectomy; and T3, after contained electromechanical morcellation. After retrieval of the endoscopic bag from the abdominal cavity, visual inspection and water test on the bag with NaCl infiltration were performed to detect leaks attributed to intraoperative perforations. A pathologist performed cytologic analyses on the 3 washings. The mean endoscopic bag procedure duration was 9 minutes. The use of a specially designed endoscopic bag system was found to be easy in 45% of cases, and no complications were reported. Cytologic washings were positive for smooth muscle cell detection in 8 cases (25.8%) at T2 and 3 cases (9.7%) at T3. All positive cases at T3 already had detectable smooth muscle cells at T2. After retrieval from the abdominal cavity, perforations on the optic access of the endoscopic bag were observed in 3 cases.

Conclusion: The results from this pilot study are encouraging. The use of a specially designed endoscopic bag system could be an adjuvant to reduce the risk of disseminating cells during myomectomy. Journal of Minimally Invasive Gynecology (2019) 26, 1351−1356. © 2019 AAGL. All rights reserved.

Keywords: Endoscopic bag; Laparoscopic myomectomy; Minimally invasive surgery; Electromechanical morcellation

Electromechanical morcellation was introduced in the 1990s for large specimen extraction during laparoscopic procedures [1]. Today, this technique is used in minimally invasive surgery to facilitate removal of large specimens of the uterus or leiomyoma that previously required laparotomy. It provides faster recovery and decreases morbidity and mortality [2].

Nevertheless, complications such as retained or disseminated parasitic tissue have been documented in the medical literature [3]. In rare occasions parasitic tissue may implant itself in the abdominal cavity and become symptomatic for patients [4]. In addition, the risk of unexpected malignancy such as uterine sarcoma is debated but has been reported as high as approximately 1 in 350 (.29%), and, if disseminated, uterine sarcoma progression-free survival and overall survival may be worsened [5]. Therefore, morcellation is contraindicated by the American Congress of Obstetricians and

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Gynecologists in cases of proven or suspected malignancies of the uterus [6].

Endoscopic bags were introduced in gynecologic surgery for oophorectomy and/or ovarian cystectomy to limit the risk of spreading misdiagnosed malignant or borderline tumors [7]. Few studies have investigated the use of endoscopic bags during laparoscopic myomectomy with morcellation, which could represent an adjuvant in reducing intraperitoneal tissue dissemination [8−11].

The aim of this study was to leak test a specially designed endoscopic bag system for contained electromechanical morcellation in women undergoing laparoscopic myomectomy. Such an endoscopic bag system would decrease the risk of unintended tissue dissemination, therefore increasing patient safety and becoming a useful adjuvant in minimally invasive surgery using the morcellation technique.

Methods

All patients undergoing laparoscopic myomectomy with electromechanical morcellation in the Department of Gynaecology of the Geneva University Hospitals, between July 2017 and July 2018 and who did not meet exclusion criteria, were offered to participate in this study. In our institution since the 2014 US Food and Drug Administration alert discouraging the use of electromechanical morcellation to remove leiomyoma, the current standard is a procedure using a specially designed endoscopic bag system.

Exclusion criteria were proven or assumed malignancies of the uterus (cervix or corpus). Preoperative screening comprised cervix cytology, endometrial biopsy, pelvic ultrasound, and magnetic resonance imaging if the ultrasound exam was incomplete or nonconclusive. Patients diagnosed with atypical cells at the endometrial biopsy or Pap smear test, postmenopausal women, patients previously treated with tamoxifen or pelvic radiation, and those diagnosed with genetic diseases (Lynch syndrome or hereditary leiomyomatosis and renal cell cancer) were also excluded.

Eligible women were given information about the study, and women who agreed to participate signed a written consent form. The study protocol was approved by the cantonal ethics committee of Geneva (CCER 2016-01495).

Patient characteristics (age, ethnicity, body mass index [BMI], history of abdominal surgery, uterine volume based on imaging) were collected prospectively. Laparoscopic myomectomy was performed according to previously described techniques [12], and a specially designed endoscopic bag system (More-Cell-Safe; A.M.I., Feldkirch, Austria), which does not need additional punctures for accessory ports, was used for contained electromechanical morcellation (Video 1). Operative data, including total operative time, endoscopic bag insertion duration (calculated from the insertion of the endoscopic bag until its removal from the abdominal cavity), number and weight of removed leiomyoma, blood loss (estimated by the volume of blood in the suction container), and surgeon's opinion on the difficulty of use of the endoscopic bag on a 3-point Likert scale (*How do you rank the difficulty of use of endoscopic retrieval bags? 1 = Difficult, 2 = Neutral, 3 = Easy*) were obtained via a case report form prospectively completed by the surgeon. All surgeons were experienced with the use of the specially designed endoscopic bag system (More-Cell-Safe), with each having fulfilled more than 10 procedures.

Peritoneal washings were performed at 3 specific times during surgery, using 200 mL NaCl to irrigate the peritoneal cavity. T1 corresponded to baseline/first peritoneal washing and was performed at the beginning of the surgery once the peritoneal cavity was laparoscopically accessed. T2 corresponded to the second washing and was performed after myomectomy, when the myometrial incision was closed. T3, the third and last washing, was done after contained electromechanical morcellation. No supplementary washing was authorized.

Upon retrieval of the endoscopic bag from the abdominal cavity, 1000 mL NaCl was infiltrated into the bag to test eventual leaks (water test). Visual inspection was also systematically performed to detect potential bag damages. Conventional cytology, cell block histology, and immunostaining sections from the peritoneal cavity washings and the postoperative histology of the specimen removed were obtained from the pathologist report.

We planned to include 30 patients to report the proportion of contamination during myoma enucleation and electromechanical morcellation with a precision of ±10% and to have a reasonable chance of detecting problems with the system and significant adverse events. This sample size is similar to that used by Toubia et al [13], who studied peritoneal washings after electromechanical morcellation in laparoscopic myomectomy. Simple descriptive statistics were used to analyze our data. Given the small sample size and low statistical power and the pilot nature of this study, we reported mainly descriptive statistics.

Results

We included 32 patients operated by 4 senior surgeons within a year (July 2017 to July 2018). Of patients invited to participate, 1 declined. One patient was excluded from the analysis because the leiomyoma size required a laparotomy conversion during surgery.

Patient mean age was 37 years old, with 42% originating from Europe, 29% from Africa, 16% from Asia, 10% from South America, and 3% from North America (Table 1). The mean BMI was 25 kg/m^2, with 12 overweight women (BMI, 25−29.9 kg/m^2), 3 with grade 1 obesity (BMI, 30−34.9 kg/m^2), and 1 with grade 2 obesity (BMI, 35−39.9 kg/m^2). The mean estimated uterine volume was 188 cm^3. Five patients had prior abdominal surgery, of which 3 had 1 prior abdominal surgery and 2 more than 2 prior abdominal surgeries.

Table 1

Patients and operative characteristics

Variable	No. of patients or mean	Percentage or standard deviation
Mean age, yr	37	6
Origin		
Europe	13	42
Africa	9	29
Asia	5	16
South America	3	10
North America	1	3
Mean BMI, kg/m^2	25	4
Normal (18.5−24.9 kg/m^2)	15	48
Overweight (25−29.9 kg/m^2)	12	39
Obesity grade 1 (30−34.9 kg/m^2)	3	10
Obesity grade 2 (35−39.9 kg/m^2)	1	3
Prior abdominal surgeries	5	16
1	3	
2	1	
3	1	
Mean uterine volume, cm^3	188	161
Mean total operative duration, min	149	43
Mean endoscopic bag procedure duration, min	9	6
Mean number of leiomyomas retrieved	2	1
Mean weight of leiomyomas retrieved, g	95 (min 10 to max 313)	77
Mean estimated blood loss, mL	200	229
Endoscopic bag use		
Easy	14	45
Neutral	12	39
Difficult	5	16
Endoscopic bag perforation (optic access only)		
Positive	3	10
Negative	28	90

The mean operative duration was 149 minutes. The mean endoscopic bag procedure duration was 9 minutes. An average of 2 leiomyoma were removed with a mean weight of 95 g. The mean blood loss was 200 mL. Surgeons' opinions on the difficulty of using the endoscopic bag were easy in 45%, neutral in 39%, and difficult in 16% of cases. The difficulties in the use of the endoscopic bag were mainly found when introducing the camera to the optic access of the endoscopic bag and to create a pneumoperitoneum in the bag.

Postoperative histology of removed specimens confirmed the diagnosis of leiomyoma in 31 patients. One specimen was diagnosed as an endometrial stromal nodule. This patient underwent hysterectomy 2 weeks later. She had no evidence of residual tumor, and peritoneal washings were negative at all time periods in the initial surgery and at the time of hysterectomy.

For the 31 patients with leiomyoma diagnosis, cytologic washings did not detect any smooth muscle cells at T1 (Table 2). Cytologic washings were positive in 8 cases (25.8%) at T2 and 3 cases (9.7%) at T3. All cases positive at T3 had already detectable smooth muscle cells at T2.

Patients were further divided in 3 groups according to smooth cell detection: group 1, no detectable smooth muscle cells at T1, T2, or T3; group 2, smooth muscle cells only at T2; and group 3, smooth muscle cells at T2 and T3. Patient and operative characteristics of group 2 did not differ from group 1 except for the mean weight of retrieved leiomyoma (126 g in group 2 compared with 88 g in group 1) (Table 3). Patient and operative characteristics of group 3 were notable for a mean uterine volume of 217 cm^3; a mean weight of leiomyoma retrieved of 100 g; a mean total operative procedure duration of 183 minutes, of which the mean endoscopic bag procedure duration was 17 minutes; and a mean estimated blood loss of 450 mL. Surgeons' opinions on the insertion of the endoscopic bag were evaluated as difficult in 1 case and neutral in 2 cases.

Although the water test did not show any direct leaks on endoscopic bags, perforations were detected on the optic access of endoscopic bags in 3 cases. Cytologic washings were positive at T2 and T3 in only 1 of these 3 cases. In the other 2 cases cytologic washings were negative at all times (T1−T3).

Discussion

To our knowledge this is the first prospective study investigating the risk of smooth muscle cell spillage during

Table 2

Cytologic washing: smooth muscle cells detection at T1, T2, and T3

	T1	T2	T3	T2 and T3
Yes	0	8	3	3*
No	31	23	28	28

T1 = at the beginning of the surgery, once the peritoneal cavity was laparoscopically accessed; T2 = after the myomectomy, once the myometrial incision was closed; T3 = after the contained power morcellation.
* These 3 patients are the same as in the T3 column.

contained electromechanical morcellation of leiomyoma. We did not detect any increased risks using this bag, and the use of a bag may decrease the risk of cell dissemination during electromechanical morcellation.

We observed smooth muscle cells at T2 but not at T3 in 5 cases. This may be due to the enucleation of larger leiomyoma. Indeed, the mean weight of myoma in group 1 (negative washings at all 3 times) was 88 g compared with 126 g in group 2 (smooth muscle cells only at T2).

Three cases had positive washings at T2 and T3, after contained electromechanical morcellation. Given that the bag was intact in all 3 cases, we suspect that smooth muscle cells found at T3 may be residual cells from the positive washings at T2. If this is true, that no patients had smooth muscle cells found only at T3 suggests the endoscopic bags do reduce the spread of cells. When compared with patients of group 2 (smooth muscle cells only at T2), these 3 cases had a longer operative duration of 49 minutes, 10 additional minutes for bag insertion, and an extra 290 mL of blood loss. These observations suggest that the surgery procedure was probably more difficult. Another argument in favor of smooth muscle cell contamination at T3 is that no smooth muscle cells were found only at T3, which if it had been the case would have shown the endoscopic bags to be non −leak-proof and hence unsafe.

After removing the endoscopic bag from the abdominal cavity, leakages were observed in 3 cases only. These leakages, attributed to intraoperative punctures, were not noticed by the surgeons during the procedure and were observed on the optic access of the endoscopic bag. The operators did not perceive these punctures during the procedure. It is possible that the pressure induced during insertion or withdrawal of the camera at the beginning of the procedure played a role in these punctures. Although this approximate 10% leakage rate is concerning, that punctures were found only on the optic access of the endoscopic bags could explain why no smooth muscle cells were found in the cytologic washings at T3 in those 3 cases; this is reassuring. Regardless, this emphasizes the importance of strengthening these endoscopic bags by the manufacturers, especially on optic access.

Very few reports have studied leaks of endoscopic bags. Paul et al [14] described contained morcellation for laparoscopic myomectomy within a specially designed bag. The technique was described as safe, and no visual evidence of damage was found on the isolation bag. However, intact status of the bag was determined by visual inspection only, potentially omitting infraclinical leakage. Furthermore,

Table 3

Patient and operative characteristics in function of smooth muscle cell detection at T1, T2, and T3

Variable	Group 1 (n = 23)	Group 2 (n = 5)	Group 3 (n = 3)
Mean age, yr	38	36	37
Origin			
Europe	10	2	1
Africa	6	1	2
Asia	5	0	0
South America	2	1	0
North America	0	1	0
Mean BMI, kg/m^2	25	23	27
Mean prior abdominal surgery, no. of patients	5	0	0
Mean uterine volume, cm^3	180	208	217
Mean total operative duration, min	148	134	183
Mean endoscopic bag procedure duration, min	9	7	17
Mean number of leiomyomas retrieved	2	2	2
Mean weight of leiomyomas retrieved, g	88	126	100
Mean estimated blood loss, mL	176	160	450
Endoscopic bag use			
Easy	11	3	0
Neutral	8	2	2
Difficult	4	0	1

Group 1 = no smooth muscle cells at T1, T2, and T3; group 2 = smooth muscle cells only at T2; group 3 = smooth muscle cells at T2 and T3.

peritoneal washings were not performed to detect spillage in that study. Another study by Cohen et al [15] evaluated bag leakages during myomectomy and hysterectomy morcellation procedures by using blue dye applied to tissue specimens before removal. Spillage of dye or tissue was noted in 4 cases of laparoscopic myomectomy (5.3%), where blue dye had contaminated the abdominal cavity via the endoscope or the port in 3 of 4 cases. To date, the only study that evaluated endoscopic bag leakage, and hence safety by comparing peritoneal washings throughout surgery, was reported by Toubia et al [13]. Peritoneal washings were performed at the same 3 specific times during the surgery as in our study. Although their study had a smaller sample size (n = 20), they found positive washings at T3 in 6 cases, of which 3 also had positive washings at T2. One limitation of the study by Toubia et al is that the morcellation procedure was not totally contained.

These findings are encouraging for further investigation on the use of a specially designed endoscopic bag system for contained electromechanical morcellation. The difference in findings between our study and Toubia et al suggests that the number and size of retrieved leiomyoma could be limiting factors, increasing cell spillage risk during leiomyoma enucleation. Even though no cell spillage seems to be related to electromechanical morcellation using endoscopic bags, the question of potential cell dissemination before morcellation and after enucleation remains. Indeed, 3 of the 8 cases with positive washings at T2 still had positive cytology at T3, corresponding to 10% of our total sample. Furthermore, because cell dissemination was noted in 25% of patients before morcellation, it is reasonable to assume that this would occur with myomectomy performed by both open and minimally invasive routes, and if the goal is to have no risk of spread, then hysterectomy is the only acceptable option.

Our preoperative screening comprised cervix cytology, endometrial biopsy, pelvic ultrasound, and/or magnetic resonance imaging, and patients diagnosed with atypical cells at the endometrial biopsy or Pap smear test, postmenopausal women, patients previously treated with tamoxifen or pelvic radiation, and those diagnosed with genetic diseases were excluded. To reduce the cumulative risk of spreading undetected malignancy such as sarcoma, a preoperative patient selection is mandatory but cannot completely exclude the risk estimated at less than .3% [5].

The results from our pilot study are promising, but further research on larger and multicentric cohorts needs to be undertaken to confirm our findings and evaluate the safety criteria for the use of endoscopic bags. As noted earlier, strengthening the bag at the optic access would be potentially beneficial. We did not test any bags before surgery and so cannot rule out that the 3 perforations pre-existed.

In conclusion, the use of a specially designed endoscopic bag system in women undergoing laparoscopic myomectomy is a simple, fast, and safe technique for contained electromechanical morcellation. In most cases bag insertion was found to be easy, and no complications related to the usage of endoscopic bags were reported. No spillage of smooth muscle cells directly related to electromechanical morcellation was observed. Smooth muscle cell spillage was exclusively due to leiomyoma enucleation before morcellation. In view of the US Food and Drug Administration's recommendation limiting the use of electromechanical morcellation for removing leiomyoma, the use of a specially designed endoscopic bag system could be a safe, minimally invasive alternative; however, spreading of an undetected malignancy cannot be excluded after enucleation. Reinforcing the endoscopic bags by manufacturers is needed to avoid unnoticed punctures during their manipulation through endoscopic ports.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.jmig.2019.01.014.

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