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Original Articles

Measures to improve the safety of power morcellation in laparoscopic surgery: IMELDA technique

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Summary

The objective of this study was to explore measures to improve the safety of power morcellation in laparoscopic surgery. In this study of 50 patients, the IMELDA technique for specimen morcellation is presented. This is the first in-bag morcellation study to demonstrate cytologically, and with postoperative blue dye tests, that no intraperitoneal spilling occurs using this morcellation technique. IMELDA stands for inked margins in-bag morcellation extracorporeally ligated for dual port access. IMELDA morcellation enables surgeons to change from intraperitoneal power morcellation to contained bag power morcellation, without making larger incisions, and without changes in port placement and visualization angles. Inked margins enable the pathologist to determine where the section margins were in case of an unexpected malignant or premalignant lesion, even though the specimen is morcellated. IMELDA morcellation uses a self-construction technique avoiding the need for expensive commercially available in-bag morcellation kits, for which there still is no scientific proof that they are spill proof. Most standard specimen extraction bags can be used to self-construct an IMELDA bag. The port placement can be adjusted to the surgeon's habits and any available morcellator can be used. For very low resource settings, a surgical glove can be used to construct an endobag for this frugally innovative morcellation technique.

Key words: Morcellation; Power morcellation; Laparoscopy; Hysterectomy; Myomectomy; In bag; Leiomyoma uteri; Leiomyosarcoma uteri; IMELDA.

Introduction

A large specimen, such as a uterus, cannot be removed in toto during laparoscopic surgery. Therefore, a reduction in specimen size is required. A power morcellator is a surgical instrument consisting of a hollow cylindrical knife through which a grasper can be used to pull the selected mass into the cylinder to obtain size reductions [1]. In a laparoscopic supracervical hysterectomy (LASH), the uterus is morcellated into smaller units in order to extract it from the abdominal cavity.

There is an association between power morcellation and the spread of fragments of the tissue that has been morcellated [2]. These fragments can cause parasitic fibroids by implanting both on the peritoneum and the abdominal wall. This can lead to seeding fibroids. A fibroid or uterine leiomyoma is a benign smooth muscle tumor of the myometrium.

In cases where a sarcoma, a malignant smooth muscle tumor of the myometrium, was misdiagnosed on ultrasound to be a leiomyoma, power morcellation can cause upstaging of the tumor. The United States' Food and Drug Administration (FDA) published a press release on April 17th, 2015, discouraging the use of laparoscopic power morcellation due to the risk of upstaging uterine sarcoma [3].

It is difficult to preoperatively make a distinction between a benign leiomyoma and a malignant sarcoma, even for experienced gynecologists and radiologists. The typical features characterizing a uterine sarcoma, such as central necrosis, increased vascularity and noticeable growth, also characterize a benign fibroid [2, 4].

The estimated incidence of uterine fibroids is 20-40% in women during the reproductive stage of their lives [5, 6]. Leiomyosarcoma is rare by comparison, with an occurrence of only 0.64/100,000 women [7]. The incidence of smooth muscle tumor of unknown potential (STUMP) is much more difficult to assess due to lack of proper documentation [2].

It is estimated that in 0.14% of all fibroids, there is in fact a previously undetected sarcomatous change. This signifies that in up to 1/700 laparoscopic hysterectomies, a sarcoma is missed in preoperative screening [2].

The impact of the FDA press release was enormous and the possibility of upstaging uterine sarcoma by power morcellation has been heavily discussed. A literature review by Pritts *et al.* stated that the studies reporting this risk were not of the best quality and thus lowered the potential threat

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of upstaging [8].

Suggestions have been made for improving the safety of morcellation in minimally invasive surgery by performing manual morcellation of the specimen in an endobag or by using a power morcellator in a contained bag.

Manual morcellation in an endobag has the disadvantage that one of the incisions needs to be enlarged. This increases the invasiveness of the procedure, as well as the risk of herniation and that of the formation of endometriosis at the site of the umbilicus [9, 10]

Different techniques of power morcellation in an endobag have been described [11-18]. Analysis of the different techniques led to the detection of the following weaknesses in these techniques. Most techniques assume that contained bag power morcellation prevents spilling into the peritoneal cavity. Particularly in dual port techniques, with two openings in the endobag, there is a theoretical risk of spill through one opening when removing the bag from the peritoneal cavity. Some techniques even perforate an inflated endobag with a trocar to create a second access. Breaking the integrity of the bag intraperitoneally with a second trocar increases the theoretical risk of spilling.

The theoretical risk of spilling when removing the bag from the peritoneal cavity at the end of the procedure seems lower in single port techniques. Having only one opening in the bag prevents the need to pull another opening through the peritoneal cavity.

Single port techniques however also require enlarging one of the incisions, increasing the invasiveness of the procedure and the risk of herniation. Secondly, single port power morcellation can be technically more challenging than dual port morcellation for surgeons who are not experienced in single port surgery.

All types of morcellation make it difficult for the pathologist to judge section margins. For example where a STUMP is detected in one myoma in a LASH specimen: if the STUMP is located centrally in the uterus and the entire specimen is morcellated in a contained bag without spilling, the risk of spilling to the peritoneal cavity should be very low. If however, the STUMP was located next to the site where the cervix was transected, there is likely to have been cellular spilling when the surgeon placed the specimen into the endobag. Finally, the use of endobags increases the cost of morcellation, which can be an obstruction to implementing these safer morcellation techniques in low resource settings. This study aims to assess whether the abovementioned problems can be overcome and attempts to find answers to the following questions: 1) Can the risk of spilling in contained bag power morcellation be reduced, without increasing the invasiveness of the surgery by enlarging incisions? 2) Can we provide evidence for this with cytological testing? 3) Can the evaluation of section margins of morcellated specimens be improved? 4) Can the cost of commercially available contained bag morcellation kits be avoided?

Materials and Methods

Rigorous examination of files of patients who underwent a laparoscopic supracervical hysterectomy or a myomectomy between March 2014 and March 2015 at Imelda Hospital in Bonheiden, Belgium was undertaken. The surgical and anatomical pathology reports were analyzed. The collection of these data was made in September 2015, a year and a half after the start of the study. Patient BMI, morcellation technique, weight of the uterus, and the anatomical pathology reports were considered.

A standard laparoscopic supracervical hysterectomy was performed in all patients. A pneumoperitoneum was created using a Verress needle. After insufflation of 3 liters of CO2, a standard reusable 10-mm trocar was placed in the umbilicus, and two reusable trocars were placed in the left iliac fossa and suprapubically. Using reusable bipolar forceps and cold scissors, the uterus was dissected until just below the isthmus. The cervix was transected using a monopolar instrument. The cervical section margin of the resected uterus was dyed using methylene blue (in 18 out of 50 patients). The specimen was placed in an endobag. The endocervix was coagulated using a bipolar forceps. Haemostasis was checked and the peritoneal cavity was rinsed. In ten patients the umbilical incision was enlarged, the opening of the endobag was pulled through the enlarged umbilical incision, and the specimen was manually morcellated in the endobag. In 40 patients the IMELDA (inked margins in-bag morcellation with extracorporeal ligation for dual port access) technique was used. A Vicryl -1 suture was attached to the opposite end of the opening of the endobag. The bag was inserted through the umbilical trocar. The specimen was placed in the bag and the purse string of the endobag was closed. The purse string was partially pulled through the suprapubic trocar. The suprapubic incision was made to the size of the morcellator. The purse string was completely pulled through the suprapubic incision, externalizing the open part of the endobag. The morcellator was inserted through the opening in the endobag and the purse string was tightened. The bag was closed around the morcellator using a suture (extracorporal ligation). The Vicryl-1 suture on the opposite end of the endobag was pulled through the umbilical trocar and the trocar was removed. This part of the endobag was now externalized, and a small opening was cut in the externalized part of the endobag. The umbilical trocar was placed in the umbilicus through the opening in the endobag, and the bag was closed around it using a suture (extracorporeal ligation).

A closed system had now been created, with the specimen in the endobag, one 10-mm trocar for the standard optic in the umbilicus with part of the bag closed around the trocar with a suture out of the peritoneal cavity, and the morcellator trocar suprapubically with part of the bag closed around this trocar with a suture out of the peritoneal cavity (dual port access) (Figure 1). The intraperitoneal part of the bag was completely intact. CO2 was insufflated into the endobag through the umbilical trocar and the specimen was morcellated. The content of the bag was then rinsed and aspirated through the suprapubic port.

After morcellation the suprapubic trocar was removed. To remove the endobag, one of the open ends of the endobag needed to be pulled through the peritoneal cavity, potentially allowing cells to spill from the endobag into the peritoneal cavity. Therefore a small swab was placed in the umbilical opening of the bag and tied in the opening with a Vicryl-1 suture to seal that end of the bag (extracorporeal ligation) (Figure 2).

To prove that no spilling occurred out of the bag, cytological ex-

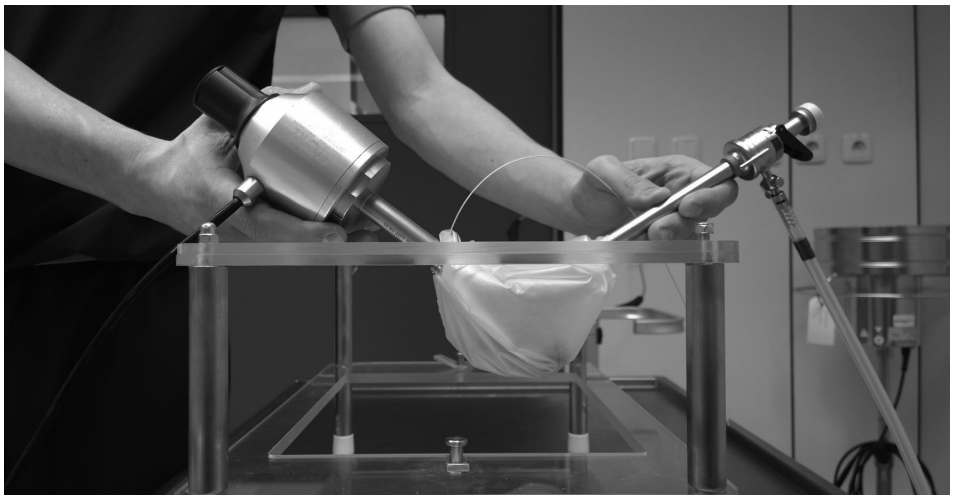

Figure 1. — The specimen is morcellated in the insufflated endobag in the peritoneal cavity. Both trocars (for laparoscope and morcellator) are extracorporeally inserted into the endobag and ligated with a suture.

Figure 2. — A small swab is placed in the umbilical opening of the bag and tied in the opening with a Vicryl-1 suture to seal that end of the bag.

amination was necessary. There is always spilling of myometrial cells into the peritoneal cavity when transecting the cervix. Therefore cytological examination of peritoneal washings at the end of the procedure was not an option. The authors aimed to demonstrate that no cells inside the endobag were spilled into the peritoneal cavity. Therefore a second endobag with a small swab inside it was tied around the already sealed umbilical end of the bag (Figure 3). Then the endobag was pulled from the suprapubic opening and through the umbilical opening, the peritoneal cavity and the suprapubic opening. Now the second endobag was opened and the swab was removed and sent for cytological examination to prove that there had been no spillage from the first endobag. The second endobag had served to prevent intraperitoneal cells from contaminating the swab. The first endobag was now filled with methylene blue dye to test its integrity (Figure 4).

In two out the total of 50 cases, a size 8 powder free surgical glove was used instead of an endobag. This was done in order to offer a low-cost alternative to the more expensive containment bags. The LASH specimen was placed into the glove, the arm end of the glove was used for the umbilical port, and the middle finger was used for the suprapubic port (Figure 5).

Results

The files of 50 patients were analyzed. None of these 50 patients were excluded from the study. The mean BMI of all patients was 27 kg/m², the mean weight of the uterus was 141 grams. In 40 cases, the uterus was power morcellated, and manually morcellated in ten patients. In the power morcellation group, the mean BMI was 27 kg/m² and the mean weight of the uterus 126 grams, whereas in the manually morcellation group, the mean BMI was 26 kg/m² and mean weight of the uterus was 199 grams (Table 1).

Out of the 40 patients who underwent power morcellation with the containment bag technique as described above, 26 uteri were power morcellated in a containment bag of which ten bags were tested for integrity. In these 26 cases, the mean BMI was 27 kg/m² and the mean uterine weight 116 grams.

In ten out of the 26 cases, bag integrity was tested by filling the bag with methylene blue dye at the end of the proce-

Figure 3. — A second endobag with a small swab inside it is tied around the already sealed umbilical end of the bag.

Figure 4. — The endobag is filled with methylene blue dye to test its integrity.

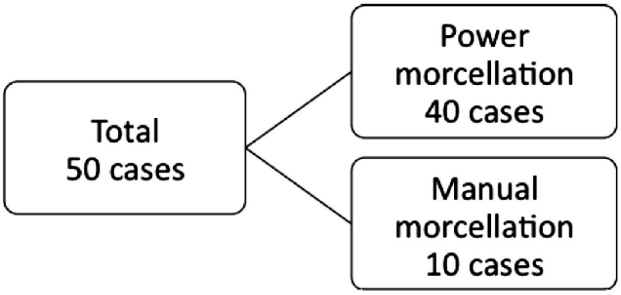

Figure 5. — General flowchart.

Table 1. — *Population traits.*

	Number of cases (n)	Mean BMI (kg/m²)	Mean uterine weight (grams)
Power morcellation	40	27	126
Manual morcellation	10	26	199
Total	50	27	141

dure. There was no leakage. The pathological examination of these 26 uteri showed benign myomatous uteri.

In two out of the 40 cases, the uterus was power morcellated in a surgical glove instead of an endobag. The mean BMI of these two patients was 29 kg/m² and the mean uterine weight was 72 grams. In both cases, bag integrity was tested by filling the glove with methylene blue dye at the end of the procedure. There was no leakage. The pathological examination of both these uteri showed benign myomatous uteri.

In the remaining 12 cases, as well as the power morcellation in a containment bag as described before, the resection planes were also dyed with methylene blue. In ten of these 12 cases, the double bag technique was performed. Cytological examination of the swab in the second bag of all ten cases showed no myometrial or endometrial tissue, confirming that no spilling had occurred when removing

Table 2. — *Population traits of the power morcellation group.*

	Number of cases (n)	Mean BMI (kg/m²)	Mean uterine weight (grams)
In-bag morcellation	26	27	116
Morcellation in glove	2	29	72
Resection planes marked	12	27	157
Total	40	27	126

Table 3. — *Population traits of the manual morcellation group.*

	Number of cases (n)	Mean BMI (kg/m²)	Mean uterine weight (grams)
In-bag morcellation	4	27	215
Resection planes marked	6	26	189
Total	10	26	199

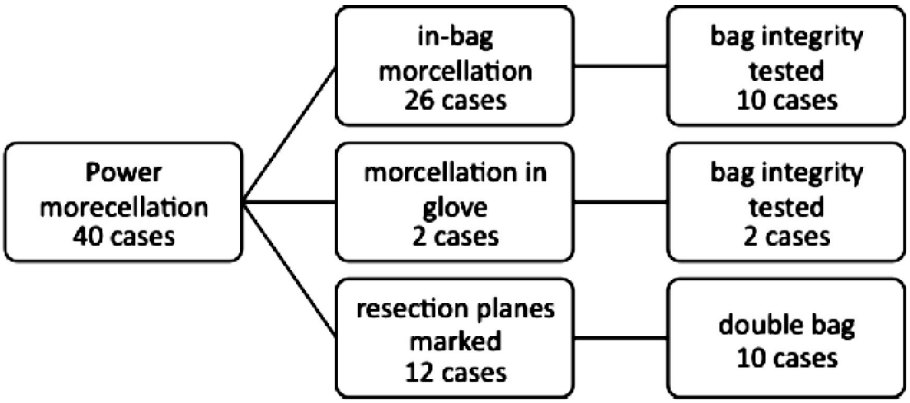

Figure 6. — Power morcellation flowchart.

Figure 7. — Manual morcellation flowchart.

the endobag. In these 12 cases, the mean BMI was 27 kg/m² and the mean uterine weight was 157 grams. The pathological examination of these 12 uteri showed 11 myomatous uteri and one STUMP (Figure 6, Table 2).

A total of ten patients underwent manual morcellation of the uterus in a containment bag. The manual morcellation was performed through an enlarged umbilical incision (Figure 7). In four out of these ten cases, the uterus was manually morcellated as described above. The mean BMI in these four cases was 27 kg/m² and the mean uterine weight was 215 grams. The pathological examination of these four uteri showed a benign myomatous uterus. In the remaining six cases, in addition to the manual morcellation technique as described above, the resection planes were also dyed with methylene blue. The mean BMI in these six was 26 kg/m² and the mean uterine weight was 189 grams.

Pathological examination of these six uteri showed four benign myomatous uteri, one STUMP, and one leiomyosarcoma (Table 3).

Discussion

The dual port contained bag morcellation technique described offers the advantage that surgeons can morcellate using the same technique that they are accustomed to, without using endobags: one camera port and one port for the morcellator. Visualization and handling are the same as when not using a bag, as opposed to the single-port, in-bag techniques.

Proof that no spilling occurs from the endobag needs to be provided for both dual port and single port techniques. No evidence of this is presented in current literature. In addition dual port techniques are confronted with an extra challenge. As there are two openings in the bag, proof is also needed that no spilling occurs through the second opening, as it is pulled through the peritoneal cavity for extraction. To the best of the present authors' knowledge, this has not been demonstrated until now. In particular, techniques where the endobag is perforated by a trocar in the peritoneal cavity to place the second port, seem to be at higher risk of spilling. Therefore the IMELDA technique uses extracorporeal ligating of the bag: both ends of the endobag are opened outside of the body before placing the trocars into it. The bag is ligated to the trocars extracorporeally. After morcellation a swab is sutured into one of the openings to prevent residual bag content from spilling, as this opening enters the peri-

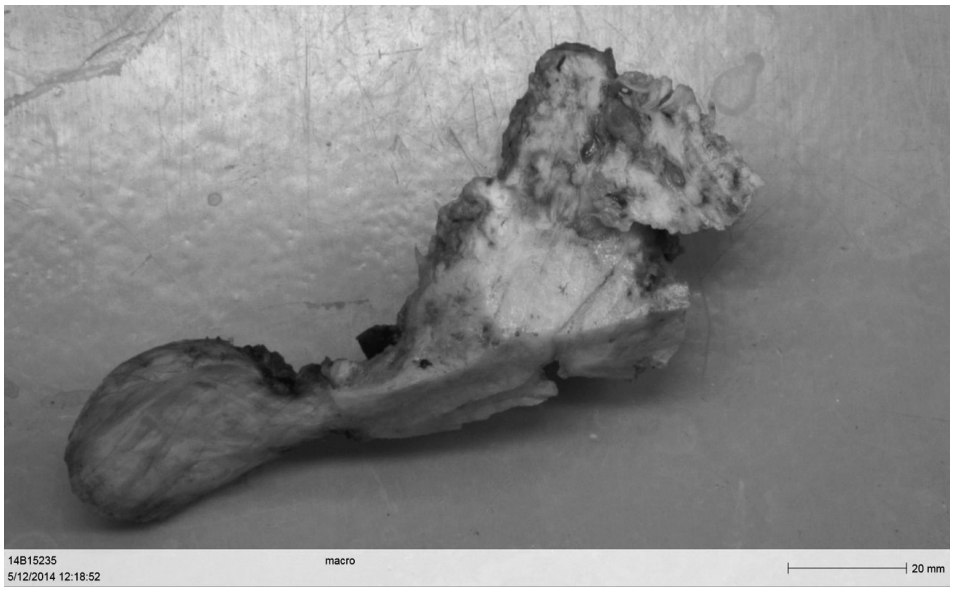

Figure 8. — Fragment of morcellated uterus with leiomyosarcoma (LMS): the LMS is situated 1 cm from the section margin (blue).

toneal cavity before removing the bag through the suprapubic port. This ensures that every part of the bag that is ever in contact with the peritoneal cavity is sealed.

To prove that suturing a swab in the opening of the bag provides sufficient seal, a second bag containing a second swab was tied around the first bag before pulling it through the peritoneal cavity. The second bag was necessary for the study as the swab could get contaminated by peritoneal fluid containing myometrial tissue from the transection of the cervix.

In all ten patients, the cytology of the second swab indicated no myometrial or endometrial cells, illustrating that suturing the first swab into the opening of the bag, provides sufficient seal to safely pull the bag through the peritoneal cavity without spilling.

This technique enables surgeons to change from intraperitoneal power morcellation to contained bag power morcellation, without making larger incisions and without changes in port placement. The bags were also filled with methylene blue dye to demonstrate their integrity at the end of the procedure.

The second goal of this study was to determine whether evaluation of the section margins of the morcellated specimen could be improved. When an unexpected diagnosis of STUMP or sarcoma is made, it is important to know whether it was contained centrally in the corpus uteri when it was placed in the endobag, or whether it was transected at the level of the cervix and intra-abdominal spilling occurred causing upstaging.

To demonstrate the resection plane to the anatomical pathologists, this resection plane was colored using methylene blue ($C_{16}H_{18}N_3SCl$), a heterocyclic aromatic compound. In case of spilling, a non-permanent ink was chosen, to prevent staining the peritoneal cavity. The uterus was then morcellated and extracted from the abdominal cavity and the tissue fragments were sent to the anatomical pathologists. Methylene blue however, is insufficient to use as a dye for pathological examination. The use of alcoholic solvents in analyzing the tissue fragments would wash the ink away. Therefore, the anatomical pathologists used permanent India ink to re-ink the sites that were colored with methylene blue. The pathologist could then examine the specimen and orientate the myoma, STUMP or sarcoma in relation to the section margin (Figure 8).

The third goal of this study was to assess whether the cost of commercially available contained bag morcellation kits could be avoided. Two different brands of bags (Teleflex and Cook) and a powder free surgical glove (Gammex) were tested in this study to create a self-constructed dual port bag for contained power morcellation. This avoids the need for expensive commercially available kits and enables the surgeon to use any type of power morcellator he has available. The use of a glove instead of an endobag enables surgeons in low resource setting to use this frugally innovative technique to increase the safety of their morcellations.

Conclusion

In-bag morcellation is said to reduce the risk of spilling, which potentially leads to myoma seeding, or upstaging, in cases of unexpected premalignant or malignant lesions. This is the first in-bag morcellation study to demonstrate cytologically and with postoperative blue dye tests that no intraperitoneal spilling occurs using this morcellation tech-

nique. IMELDA, enables a surgeon to change from intraperitoneal power morcellation to contained bag power morcellation, without making larger incisions and without changes in port placement and visualization angles. Inked margins enable pathologists to determine where the section margins were in case of an unexpected malignant of premalignant lesion, even though the specimen is morcellated.

Extracorporeal ligation of the trocars and the swab into the endobag reduces the risk of spilling. Cytological examination indicated that ligating a swab into the open end of the bag prevents spilling of residual microscopic post morcellation bag content into the peritoneal cavity. Methylene blue tests of the bags after morcellation indicated the integrity of the bags at the end of the procedure.

IMELDA morcellation uses self-constructed materials avoiding the need for expensive, commercially available, in-bag morcellation kits, for which there still is no scientific proof that they prevent spilling. Most standard specimen extraction bags can be used to self-construct an IMELDA bag. The port placement can be adjusted to the surgeon's habits and any available morcellator can be used. For very low resource settings, a surgical glove can be used to construct an endobag for this frugally innovative morcellation technique.

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