

Laparoscopic in-bag morcellation — a comparison of two tissue extraction systems

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ABSTRACT

Objectives: Morcellation is an integral part of laparoscopic procedures related to uterine fibroids, which consist of the mechanical fragmentation of the tumor and its extraction outside the abdominal cavity. To avoid the risk of tissue dissemination, special extraction systems have been developed, which allow morcellation of the specimen under visual control and its removal without contact with the abdominal organs. The aim of the paper is to compare the two systems for laparoscopic morcellation.

Material and methods: The study included 33 premenopausal women with symptomatic leiomyomas or adenomyosis, who were qualified for laparoscopic surgery with contained power morcellation. Patients were allocated alternately to a different tissue extraction system's group. According to the study protocol, selected operative parameters were prospectively recorded. Finally, an assessment of bag use was performed. The data was statistically analyzed.

Results: There were significant differences between the two tested systems in terms of introducing and positioning the bag, its removal from the peritoneal cavity, as well as optic trocar insertion and establishing the pseudo-peritoneum.

Conclusions: Despite the minor design differences and some ergonomic aspects, both presented systems proved to be safe and feasible tools for laparoscopic contained morcellation. This technique both reduces the risk of tissue dissemination and preserves the advantages of minimal invasiveness.

Key words: morcellation; leiomyoma; endoscopy; hysterectomy

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INTRODUCTION

Uterine fibroids are the most common benign gynaecological tumours. They occur in approximately 25% of women of reproductive age [1]. The main clinical symptoms of uterine fibroids include abnormal bleeding, pain, or limited fertility. Some uterine fibroids remain asymptomatic [2]. Despite the availability of conservative methods (pharmacotherapy, thermoablation, embolization), surgical treatment remains the basic form of fibroid management [3, 4]. Advancements in instrumentarium and systematic progress in surgical techniques resulted in most fibroid surgeries previously carried out via laparotomy (myomectomy, supracervical and total hysterectomy) can be currently performed via laparoscopy. The advantages of laparoscopy,

which triggered the change in surgery management, are well-known and include minor physical trauma (minimal invasiveness), a relatively uneventful post-operative course, a short convalescent period and very good cosmetic effect.

Excluding cases of laparoscopic hysterectomy with transvaginal uterine extraction, morcellation is an integral part of all other laparoscopic procedures related to uterine fibroids. This technique, consisting of the mechanical fragmentation of organs or larger tissue fragments and their extraction outside the abdominal cavity, was introduced by Steiner in 1993 [5]. Since then, various types of morcellators have been widely used in surgical gynaecology, becoming a permanent element of advanced laparoscopic surgery kits. For several years, intra-abdominal morcellation has

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been the subject of intense discussions due to the risk of intraperitoneal spread of previously undiagnosed uterine sarcoma [6, 7]. The above concerns even led to the US implementing a prohibition in 2014 of using power morcellators in a case of uterine mass during menopause and perimenopause [8]. On the other hand, it was a stimulus to work both on improving the quality of pre-operative diagnostics and on methods of removing the specimen from the peritoneal cavity [9–13]. The result of a new approach to power morcellation are different tissue extraction systems, which allow morcellation of the specimen under visual control and its removal without contact with the abdominal organs.

Objectives

The aim of the paper is to compare two tissue extraction systems for laparoscopic morcellation, that differ from each other in terms of volume, material, and detailed technological solutions.

MATERIAL AND METHODS

The study was approved by the Bioethics Committee of Rzeszow University, Poland (Resolution No.19/04/2016) and conformed to the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008). After receiving an explanation of the study, each subject provided written informed consent to enrol in the study. It is a single-center comparative trial that was conducted at the Clinical Department of Obstetrics and Gynaecology of Provincial Clinical Hospital No 2, Rzeszow, Poland between October 2016 and June 2019.

The study included 33 premenopausal women with symptomatic leiomyomas or adenomyosis, who were qualified for laparoscopic surgery (myomectomy or supracervical hysterectomy) with contained power morcellation. After written informed consent was obtained, patients were allocated alternately to a different tissue extraction system's group in the order of their admission to the hospital.

Preoperative diagnosis was based on vaginal speculum examination including Pap smear, bimanual examination and the transvaginal ultrasonography of the uterus. The previously performed endometrial biopsy was negative for malignancy. Immediately before surgery, all patients underwent laboratory tests, electrocardiography and anaesthesia consultation. During the operation patients were placed in a steep Trendelenburg position (35° tilt), with knees flexed and legs abducted. Foley's catheter was inserted in the bladder and peri-operative antibiotic prophylaxis was administered. Pneumoperitoneum (intra-abdominal pressure of 15 mmHg) was created in a typical way. An optical trocar was inserted in the umbilical recesses and three 6 mm ports were placed in the abdomen (two on the left side and one on the right side). Initially, the abdominal cavity and pelvis were thoroughly examined. All the operative

procedures were performed by the same gynaecologist, according to professional standards. The surgery was followed by contained power morcellation using an alternately allocated tissue extraction system.

The first bag is made of polyurethane. This material is transparent, impermeable to cellular elements and liquids, has no pro-inflammatory properties and is resistant to the thermal effect of light used during endoscopic procedures [14, 15]. The dimensions of the bag (340 x 250 mm), dictated by human anatomy and the average volume of gas (2.5 L) required to produce the pneumo-peritoneum, so that morcellation of the specimen under visual control is possible without the need to modify the surgical technique during laparoscopy. The bag has two independent openings. The main opening of 160 mm allows the operator to even put a specimen considered to be large into it. This opening has been designed so that after it is pulled from the abdominal cavity, a morcellator could be inserted through it.

A second, 190 mm in length, 16 mm wide tubular double-layered bag opening (sleeve), after extraction outside the abdominal wall through the umbilical incision, is used to insert an optical trocar and to insufflate the bag. In order to protect the optical tool against contamination, an additional, 250 x 11 mm rigid shield was created with a transparent window at its top. Once morcellation is complete, the trocar is removed from the bag along with the shield, and then the shield - being potentially contaminated — is disposed of. Next, the sleeve is turned inside out and closed by tying a double knot. Thanks to the above procedures, the potentially contaminated part of the bag remains protected, while its other elements that encounter the peritoneal cavity during removal of the bag from the abdominal wall should remain oncologically sterile.

The second system for contained laparoscopic power morcellation is also sterile and single use. The bag is made of unique Superamide66 fabric, which is a polyurethane-coated "ripstop" nylon fabric. According to the manufacturer, this material prevents the bag from bursting or rupturing. The dimensions of the bag are a mouth diameter of 140 mm, length of 325 mm, and volume of 2000 mL. It also features an accessory sleeve as an independent secondary access into the bag. After isolation of the specimen, the bag is inserted through a 12 mm left lateral trocar. Once inside the abdominal cavity, the bag is opened and placed by grasping the easily identifiable colored tabs on the edge of the main opening of the bag. The specimen is then placed into the bag. The mouth is closed by pulling the drawstring and the bag is extracted from the abdomen. Next, the accessory sleeve is pulled out through the umbilical incision. The working tip of the morcellator is placed through the mouth of the bag, and the laparoscope with insufflation tubing inserted via the accessory sleeve. After morcellation,

Table 1. Demographic data and perioperative parameters in the study group

	First arm (n = 16)	Second arm (n = 17)	p-value
	mean (SD)		
Mean age	44.8 (4.8)	44.4 (3.9)	0.794 ^{a)}
Mean BMI [kg/m ²]	25.22 (3.55)	26.47 (6.11)	0.480 ^{a)}
Time from start of bag use to start of morcellation [min]	13.81 (5.47)	12.29 (2.54)	0.323 ^{b)}
Time of morcellation [min]	9.56 (4.18)	7.94 (3.07)	0.212 ^{a)}
Time of removal of the bag [min]	2.94 (1.12)	2.41 (1.66)	0.061 ^{c)}
Amount of morcellated tissue [g]	270.25 (142.29)	221.41 (89.34)	0.313 ^{c)}
Residual tissue and/or fluid in bag after removal [g]	32.06 (9.90)	36.24 (14.47)	0.552 ^{c)}
Estimated blood loss [mL]	56.25 (59.90)	66.47 (34.45)	0.075 ^{c)}

^{a)} Student's t-test for independent samples; ^{b)} t-test with independent variance estimation (Welch); ^{c)} U Mann-Whitney test; BMI — body mass index

the laparoscope with the trocar is removed, the sleeve is closed by pulling the drawstring and secured by tying a knot. The bag and remaining contents are extracted through the left lateral incision, using a “rocking motion”. To observe the bag removal and avoid the risk of contamination a new laparoscope should be taken. After removal of the bag, the operating field was finally inspected for haemostasis and prospective complications. Finally, the bag walls were checked for their tightness by visual inspection and fluid filling.

According to the study protocol, selected operative parameters were prospectively recorded, *e.g.*, time from inserting the bag into the peritoneal cavity to positioning the specimen, time of morcellation, time of bag removal, amount of morcellated tissue, residual material in bag after its removal, damage to the bag, bag and morcellation associated complications, other intraoperative and postoperative complications. Finally, a subjective assessment of bag use was performed according to a self-developed 0–10 rating scale (0 = not feasible for clinical use, 5 = acceptable, 10 = perfect for clinical routine).

The data was analyzed using TIBCO Software Inc. (2017). Statistica (data analysis software system), version 13. <http://statistica.io>. Quantities are given for categorical variables, while for measurable variables the mean and standard deviation are given. The normality of the distribution of measurable variables was tested using the Shapiro-Wilk test. In order to compare the two groups, the student's t-test for independent samples or the t-test Welch with an independent estimation of variance (when the distributions of the variables were normal distributions) or the Mann-Whitney U test (in the case of non-normality of the distribution) was used. The level of statistical significance was $p < 0.05$.

RESULTS

A total of 33 patients initially qualified for laparoscopic surgery with power morcellation, were considered eligible, and were enrolled in the study. Sixteen women were allo-

cated to the first arm (a bag of 2500 mL volume) and 17 to the second arm (a bag of 2000 mL volume). Mean patient age in the whole group was 44.5 years (range 37–52), mean \pm SD BMI [kg/m²] was 25.87 ± 4.99 . The main indication for operation was symptomatic myomas (31 patients). Adenomyosis was only found in two patients. The prevailing type of procedure was supracervical hysterectomy (LASH) with bilateral salpingectomy. Laparoscopic myomectomy was carried out in two patients (1 procedure in each group).

There were no significant differences between both groups regarding demographic data and perioperative parameters (Tab. 1). In two patients from the second group, minor complications occurred during bag removal, *e.g.*, minor peritoneal bleeding from the trocar canal. They required routine haemostasis using bipolar forceps. The entire usage of the first system was without complications.

The mean total time of bag use (from insertion of the bag to start of morcellation plus bag removal) was 14.71 (± 3.39) min in the case of second arm and 16.75 (± 5.92) min in the first arm. These differences were not statistically significant ($p = 0.397$). Table 2 shows the results of the assessment of bag use, divided into stages of the procedure.

There were significant differences in favour of the first system regarding introducing and positioning the bag inside the peritoneal cavity as well as bag removal. The second system significantly outperformed the first one in terms of optic trocar insertion and establishing the pseudo-peritoneum. No damages to the bags were observed. All patients were discharged on the second postoperative day. In all cases, a histopathological examination confirmed the preoperative diagnosis.

DISCUSSION

Starting from 2014, several tissue extraction systems were described (EndoCatch bag, Covidien; Anchor TRS-200, Anchor Surgical; LapSac Surgical Tissue Pouch, Cook

Table 2. Assessment of bag use [mean value, rating scale 0–10]

	First arm	Second arm	p-value
	mean (SD)		
Insertion of the bag	9.9 (0.3)	8.6 (1.4)	0,005 ^{a)}
Deployment and positioning of the bag inside the peritoneal cavity	9.1 (0.4)	8.5 (0.6)	0,020 ^{a)}
Placement of the specimen into the bag	9.2 (0.7)	9.4 (0.5)	0,407 ^{a)}
Optic trocar insertion	8.7 (0.7)	9.6 (0.6)	0,002 ^{a)}
Creation of the pseudo-peritoneum	8.6 (1.0)	9.3 (0.5)	0,026 ^{a)}
Introduction of morcellator	9.7 (0.5)	9.8 (0.4)	0,517 ^{a)}
In-bag morcellation	9.0 (0.6)	8.7 (0.5)	0,249 ^{a)}
Withdrawal of the bag	10.0 (0.0)	9.4 (0.9)	0,046 ^{a)}

^{a)} U Mann-Whitney test; SD — standard deviation

Medical; Steri-Drape Isolation Bag, 3M), which reflected a new approach to power morcellation. The above-noted bags allowed morcellation of the specimen under visual control and then removal without contact with the abdominal organs. An important disadvantage of the above technique was the possible risk of tissue dissemination associated with intra-abdominal puncture of the bag containing a specimen.

The two tissue extraction systems used in our series are completely different solutions. Although they differ slightly from each other, both have two independent openings. The larger opening is designed to place a specimen and after it is pulled from the abdomen — to insert a morcellator. The second opening, a lateral sleeve, after extraction through the umbilical incision, is used to place an optical trocar with telescope and insufflate the bag. This innovative technique efficiently reduces the risk of tissue dissemination.

As demonstrated above, both presented tissue extraction systems proved to be safe and feasible tools for laparoscopic contained morcellation. Introducing and positioning the bag in the peritoneal cavity was easier in the case of the first system, despite its bigger volume. This bag is rolled-up beforehand and placed in a special protective cover which perhaps explains these observations. On the other hand, optic trocar insertion and subsequently establishing the pseudo-peritoneum was simpler for the second system. A possible elucidation is that the accessory sleeve in the first bag is longer than in the second system (190 mm vs 100 mm), which requires more time and manual skills to travel through it.

Comparing the mechanical properties of the material from both systems is worth emphasizing, that the second bag is slightly stiffer, which theoretically can be more traumatizing while being pulled from the abdomen. This may also be a possible explanation for the minimal peritoneal injuries of the trocar canal which we recorded in our series. However, it should be clearly highlighted, that

the above-mentioned complications were nonmeaningful and neither influenced the course of the operation, nor the convalescence.

In 2015, Winner et al. compared the duration of laparoscopy with uncontained and contained morcellation, stating laparoscopy with a bag took on average 20 minutes longer. At the same time, there were no significant differences in the duration of hospitalization for patients, the weight of the tissue specimen, the amount of intraoperative blood loss and postoperative complications [16]. In the presented material, regardless of the system used, activities related to the insertion of the bag, placement of the specimen into it, creation of the pseudo-peritoneum and removal of the bag after morcellation lasted a total of about 16 minutes. This time was largely compensated by eliminating the stage of searching for small tissue fragments remaining after open morcellation along with repeated rinsing of the peritoneal cavity.

CONCLUSIONS

The tested tissue extraction systems differed in terms of introducing and positioning the bag, its removal from the peritoneal cavity, as well as optic trocar insertion and establishing the pseudo-peritoneum. Despite the differences, both presented systems proved to be safe and feasible tools for laparoscopic contained morcellation.

Detailed instructions and training may help to avoid complications and overcome technical difficulties. However, more studies with a greater number of patients are still necessary to confirm its efficiency and determine the place of contained morcellation in routine laparoscopic surgery.

Conflict of interest

All authors declare no conflict of interest.

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