


## CLINICAL ARTICLE

## Gynecology

# Comparison of perioperative surgical outcomes between contained and free manual vaginal morcellation of large uteruses following total laparoscopic hysterectomy

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## Abstract

**Objective:** To compare contained and free manual vaginal morcellation of large uteruses after total laparoscopic hysterectomy (TLH) in women at low risk of uterine malignancy in terms of feasibility and safety.

**Methods:** A single-center, observational, retrospective, cohort study was carried out including all patients undergoing TLH requiring manual vaginal morcellation for specimen extraction of large uteruses from January 2015 to August 2021 at the Division of Gynecology and Human Reproduction Physiopathology, IRCCS Azienda Ospedaliero-Universitaria of Bologna, Bologna, Italy. Patients were divided into two groups according to the type of manual vaginal morcellation (contained or free), and compared in terms of demographic, clinical, and perioperative data.

**Results:** In all, 271 patients were included: 186 (68.6%) in the contained morcellation group and 85 (31.4%) in the free morcellation group. The mean operative time was significantly lower in the contained morcellation group compared with the free morcellation group (median [interquartile range] 130 [45] vs. 155 [60] min;  $P < 0.001$ ). No significant difference was found in complications related to the morcellation step, overall, intraoperative and postoperative complications, estimated blood loss, length of hospital stays, uterine weight, and rate of occult malignancy between the two groups.

**Conclusion:** Contained vaginal manual morcellation of the uterus after total laparoscopic hysterectomy using a specimen retrieval bag appears to be a safe procedure with significantly lower operative time than free vaginal manual morcellation.

## KEYWORDS

benign gynecologic pathology, hysterectomy, large uteruses, minimally invasive surgery, morcellation, operative times, perioperative outcomes, retrieval bag

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## 1 | INTRODUCTION

Hysterectomy is one of the most frequent gynecologic surgeries, preceded only by cesarean section.<sup>1</sup> Hysterectomies are increasingly conducted laparoscopically as a result of advancements in technology, materials and training skills. Laparoscopic hysterectomy is the preferred choice among women with benign gynecologic pathology, especially in the presence of pelvic adhesions and limited vaginal access.<sup>2</sup> The laparoscopic route has been associated with less intraoperative blood loss, shorter hospital stays and faster postoperative recovery times than laparotomy.<sup>3,4</sup>

Advances in surgical techniques have allowed laparoscopic surgery even for large uteruses.<sup>3,5</sup> In these cases, the minimally invasive approach implies the need for specimen reduction by morcellation during vaginal extraction.<sup>6</sup> From 2014, the use of electromechanical morcellation has been discouraged to minimize the risk of cell dissemination into the peritoneal cavity in case of occult malignancies.<sup>5–10</sup> Although it is not possible to totally exclude the risk of occult uterine malignancies during preoperative workup, diagnostic algorithms differentiating between cases at low and high risk are recommended by international guidelines to counsel patients and direct surgical planning.<sup>9</sup> Moreover, vaginal morcellation with cold scalpel (i.e., manual morcellation) plus or not in-bag insertion of the specimen (i.e., contained or free morcellation, respectively) was proposed to minimize the risk of intra-abdominal spread of cells.<sup>7,8,10,11</sup>

Despite several reports demonstrating good perioperative outcomes of vaginal manual morcellation with or without the use of an endoscopic bag after laparoscopic hysterectomy,<sup>11–13</sup> no study directly compared contained and free vaginal morcellation using cold scalpel following total laparoscopic hysterectomy for large uteruses.

The aim of the present study was to compare contained and free vaginal morcellation using cold scalpel after total laparoscopic hysterectomy in symptomatic women with large uteruses at low risk of malignancy in terms of feasibility and safety.

## 2 | MATERIALS AND METHODS

### 2.1 | Study protocol and selection criteria

The study was performed according to an a priori defined study protocol and was designed as a single-center, observational, retrospective, cohort study. The whole study was reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines and checklist.<sup>14</sup>

Medical records and surgical charts were searched for all consecutive patients undergoing total laparoscopic hysterectomy requiring manual vaginal morcellation for specimen extraction of large uteruses between January 2015 and August 2021 at the Division of Gynecology and Human Reproduction Physiopathology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, University of Bologna, Bologna, Italy. We excluded women younger than 18 years,

with a certain diagnosis of or at high risk of gynecologic malignancies and/or requiring laparotomic conversion.

In our routine clinical practice, all patients underwent preoperative evaluation including medical history collection, bimanual examination, and transvaginal ultrasound with color Doppler assessment according to the international guidelines.<sup>15,16</sup> If endometrial carcinoma was suspected, patients underwent endometrial sampling by hysteroscopy to exclude malignancy. In the presence of any sonographic feature suggestive of uterine sarcoma, magnetic resonance imaging was performed;<sup>9,17,18</sup> patients who were considered at low risk after magnetic resonance imaging underwent minimal invasive surgery.<sup>19</sup> During preoperative evaluation, all patients were counseled about the risk of vaginal morcellation and of occult cancer, including uterine sarcoma. After surgery, follow-up evaluations at 1 and 3 months were performed in all patients.

Patients included for study analyses were divided into two groups according to the type of manual vaginal morcellation: contained or free. For each patient, we collected demographic, anthropometric, clinical, and perioperative data. In particular, clinical and perioperative data included total operative time (defined as the time period between skin incision and suture in minutes), successful contained morcellation attempt, associated surgical procedures, estimated blood loss, uterine weight, length of hospital stay, intraoperative complications (bowel, bladder, vascular, or nerve injury), postoperative complications according to the Clavien–Dindo classification<sup>20</sup> within 90 days after surgery, and histologic diagnosis of occult malignancy.

### 2.2 | Types of manual vaginal morcellation

After colectomy, vaginal manual morcellation comprised using a cold-blade scalpel with (contained) or without (free) an endoscopic bag. Before contained vaginal manual morcellation, the edges of the endoscopic bag were exteriorized through the vagina. Manual morcellation was performed by expert surgeons using a scalpel under direct visualization and at the end of the procedure, the specimen retrieval bag was removed and its integrity was assessed by visual inspection.<sup>11,21</sup> Due to the lack of strong evidence in favor of one of the two approaches, the choice to perform contained or free vaginal morcellation was based upon surgeon discretion.

### 2.3 | Study outcomes

Primary outcome was the difference in mean total operative time between contained and free vaginal morcellation.

Secondary outcomes were the comparisons between contained and free vaginal morcellation in term of rate of complications related to the morcellation step, overall complications, intraoperative complications, and postoperative complications according to the Clavien–Dindo classification,<sup>20</sup> estimated blood loss, length of hospital stays, uterine weight, and rate of occult malignancy.

## 2.4 | Statistical analysis

Continuous data were expressed as mean  $\pm$  standard deviation (SD) or median (interquartile range), as appropriate. Categorical variables were expressed as numbers and percentages. Student *t* test or Mann–Whitney *U* test and chi-squared or Fisher exact test were used for continuous and categorical data, respectively, as appropriate. A *P* value less than 0.05 was considered significant for all tests. Statistical analysis was carried out using the SPSS software version 24.0 (IBM Corp., Armonk, NY, USA).

## 2.5 | Sample size estimation

Hypothesizing a significance level of 5%, a power of 80%, and a standard deviation of operative times equal to 40 min, we estimated that at least 85 patients per group were required to exclude a difference above 20 min between surgeries with and without the use of an endoscopic bag.<sup>22</sup>

## 2.6 | Ethics statement

The study received approval from the Institutional Review Board of the IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy (No. 49/2022/Oss/AOUBo) and was performed in accordance with the Declaration of Helsinki. All patients signed an informed consent for the use of their data for the study.

# 3 | RESULTS

## 3.1 | Study population

Based on the selection criteria, 271 patients were included in the study: 186 (68.6%) patients in the contained morcellation group and 85 (31.4%) in the free morcellation group.

The baseline characteristics of the overall population and by study groups are shown in Table 1. No significant difference was found in terms of age, body mass index (calculated as weight in kilograms divided by the square of height in meters), previous abdominal surgery, and clinical symptoms. Fibroids were the most common indication for surgery (257 patients, 94.8%), whereas abnormal uterine bleeding was the most frequent symptom (205 patients, 75.6%).

## 3.2 | Study outcomes

Surgical data of the overall population and by study groups are illustrated in Table 2. Contained morcellation attempts were successful in all cases.

The mean total operative time  $\pm$  SD was statistically lower in the contained group compared with the free morcellation group

(130  $\pm$  45 min vs. 155  $\pm$  60 min, *P* < 0.001). At the end of surgery, no macroscopic leakage of the specimen retrieval bag was reported.

Overall surgical complications occurred in 21 (11%) and 6 (7%) patients of the contained and free morcellation groups, respectively, without a significant difference (*P* = 0.28). Four (2.2%) patients of the contained group showed intraoperative complications: two urinary bladder perforations and two rectosigmoid tract superficial lesions on the adventitia (4/186 in the contained group versus 0/85 in the free group, *P* = 0.31). None of the intraoperative complications occurred during the morcellation step in both groups. No dropouts occurred during follow up. Postoperative complications occurred in 17 (9.1%) and in 6 (7%) patients of the contained and free groups, respectively, without a significant difference (*P* = 0.57). Details of postoperative complications according to the Clavien–Dindo classification of the overall population and by study groups are shown in Table 3. Among the overall study population, five patients (5/271, 1.8%) underwent reoperation. Four (4/186, 2.2%) patients belonged to the contained group (one hemoperitoneum requiring laparoscopic wash, one bladder perforation needing laparoscopic suture, one right hydroureteronephrosis treated with temporary ureteral stent positioning, and one rectal perforation resolved through Hartmann procedure) and one patient (1/85, 1.2%) belonged to the free morcellation group (temporary right ureteral stent placement for ureteral stenosis).

No significant difference was found in estimated blood loss, length of hospital stays, and uterine weight.

Lastly, the rate of occult malignancy did not differ between the two groups (1% in the contained group compared with 1.2% in the free group, *P* = 0.58). In the contained group, one ovarian cystadenocarcinoma (0.5%) and one endometrial endometrioid adenocarcinoma (0.5%) were reported, and in the free morcellation group, only one patient showed uterine endometrial stroma sarcoma at histologic evaluation (1.2%). Malignant histologic cases were discussed by a multidisciplinary team and these patients underwent complete staging surgery and adjuvant treatment when necessary; at 1-year follow up no recurrence was diagnosed.

# 4 | DISCUSSION

To the best of our knowledge, our study may be the first to directly compare contained and free manual vaginal morcellation after laparoscopic total hysterectomy for large uteruses in terms of feasibility and safety. Compared with free vaginal manual morcellation, contained morcellation after total laparoscopic hysterectomy of large uteruses seems to reduce total operative time and showed similar rates of complications.

Since the US Food and Drug Administration produced their safety communication and warning note against the use of laparoscopic power morcellators, several studies have been published investigating different morcellation techniques. In a retrospective cohort study, Meurs et al.<sup>23</sup> compared power intraperitoneal morcellation, manual vaginal morcellation, and manual mini-laparotomic morcellation after

TABLE 1 Baseline characteristics of the overall population and by study groups.

Characteristics	All patients (n = 271)	Contained morcellation group (n = 186)	Free morcellation group (n = 85)	P value
Age, years	48.3 ± 4.8	48.4 ± 4.7	47.9 ± 5.2	0.41
BMI groups				0.39
<18.5	11 (4.1)	7 (3.8)	4 (4.7)	
18.5 to <25	167 (61.6)	119 (64.0)	48 (56.5)	
25 to <30	63 (23.2)	38 (20.4)	25 (29.4)	
≥30	30 (11.1)	22 (11.8)	8 (9.4)	
Previous deliveries				0.42
0	81 (29.9)	60 (32.3)	21 (24.7)	
1	110 (40.6)	74 (39.8)	36 (42.4)	
≥2	80 (29.5)	52 (28.0)	28 (32.9)	
Menopausal status	21 (7.7)	14 (7.5)	7 (8.2)	0.81
Previous abdominal surgery	168 (62)	114 (61.3)	54 (63.5)	0.72
Hormonal therapy				0.47
None	191 (70.5)	133 (71.5)	58 (68.2)	
Estroprogestinic	21 (7.7)	17 (9.1)	4 (4.7)	
Progestinic	17 (6.3)	10 (5.4)	7 (8.2)	
GnRH-a	17 (6.3)	9 (4.8)	8 (9.4)	
Ulipristal	14 (5.2)	9 (4.8)	5 (5.9)	
LNG-IUS	11 (4.1)	8 (4.3)	3 (3.5)	
Symptoms, n (%)				
Abnormal uterine bleeding	205 (75.6)	143 (76.9)	62 (72.9)	0.54
Constipation	68 (25.1)	48 (25.8)	20 (23.5)	0.76
Pelvic pain	61 (22.5)	42 (22.6)	19 (22.4)	1
Dysmenorrhea	51 (18.8)	36 (19.4)	15 (17.6)	0.87
Pollakiuria	41 (15.1)	31 (16.7)	10 (11.8)	0.36

Note: Data are presented as mean ± standard deviation or as number (percentage).

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); GnRH-a, gonadotropin-releasing hormone agonist; LNG-IUS, levonorgestrel-releasing intrauterine system.

laparoscopic or robot-assisted laparoscopic hysterectomy or myomectomy with and without the use of an endoscopic bag. They found no significant difference among approaches in terms of estimated blood loss, length of stay, and perioperative complications; manual mini-laparotomic morcellation independently from the use of a bag seemed to imply a longer operative time compared with other techniques. However, the authors remarked on the small number of vaginal morcellations and did not report any data comparing contained and not contained vaginal morcellation (11% of the total study population).<sup>23</sup>

The present study showed that contained manual vaginal morcellation was successful in all cases. In contrast, Serur et al.,<sup>11</sup> reporting on a series of 104 patients treated with contained manual morcellation by the abdominal or vaginal route after laparoscopic hysterectomy for large uteruses, found that in five cases the vaginal morcellation failed at the insertion into the bag and extraction of the specimen due to the uterus size. For this reason, they suggested that the vaginal route could be more difficult in nulliparous women and in the presence of severe vaginal stenosis.<sup>11</sup>

In our series, contained manual morcellation appeared to save operative time compared with free morcellation. The two study groups did not differ in variables potentially affecting total operative time (e.g., body mass index, positive history for previous surgery, uterine weight). Based on our results, we hypothesized that the use of a specimen retrieval bag enveloping the uterus during morcellation allows adequate mobilization and rotation of the tissues and avoids their sudden detachment regardless of their consistency and size. This time-saving procedure could guarantee a reduction of hospital costs for patients and healthcare systems.<sup>24–29</sup>

As a result of the retrospective nature of the present study we failed to report the interval time for the morcellation steps. However, few studies focused on this variable. In a retrospective study, Gil-Gimeno et al.<sup>30</sup> compared feasibility and safety of contained and free morcellation in 106 patients after total laparoscopic hysterectomy requiring specimen fragmentation. In particular, they mostly considered analyses of contained or free

TABLE 2 Surgical data of the overall population and by study groups.

	All patients (n = 271)	Contained morcellation group (n = 186)	Free morcellation group (n = 85)	P value
Total operating time, min	134 (55)	130 (45)	155 (60)	<0.001
Estimated blood loss, mL	100 (0)	100 (0)	100 (200)	0.38
Length of hospital stay, days	4 (1)	4 (1)	4 (1)	0.021
Intraoperative complications, n (%)	4 (1.5%)	4 (2.2%)	0 (0.0%)	0.31
Postoperative complications within 90 days from surgery, n (%)	23 (8.5%)	17 (9.1%)	6 (7.0%)	0.57
Uterine disease at pathologic examination, n (%)				
Fibroids	252 (93.0%)	174 (93.5%)	78 (91.8%)	0.61
Adenomyosis	42 (15.5%)	25 (13.4%)	17 (20.0%)	0.21
Uterine weight, g	386 (345)	371 (332)	395 (358)	0.82

Note: Values are expressed as median (interquartile range) or as number (percentage).

TABLE 3 Postoperative complications according to Clavien–Dindo classification of the overall population and by study groups.

Classification	All patients (n = 271)	Contained morcellation group (n = 186)	Free morcellation group (n = 85)	P value
Grade I	4 (1.5)	3 (1.6)	1 (1.2)	0.78
Grade II	15 (5.5)	10 (5.4)	5 (5.9)	0.86
Grade III	7 (2.6)	6 (3.2)	1 (1.2)	0.32

Note: Values are expressed as number (percentage).

intraperitoneal power morcellation (71.7%). The authors found that total operative time was longer in the overall contained morcellation group compared with the free one (mean  $\pm$  SD [range]: 170  $\pm$  48 min [77–344 min] vs. 130  $\pm$  43 min [60–271 min], respectively;  $P < 0.01$ ).<sup>30</sup> The authors stated that this difference could be due to the higher uterine size observed in the contained morcellation group compared with the free group.<sup>30</sup> Notably, among a subset of 16 videos showing contained power intraperitoneal morcellation, the authors reported a mean time of 17 min for bag insertion, 25 min for morcellation, and 4 min for bag extraction. These data are in line with those from other studies.<sup>31,32</sup> In contrast, in a prospective pilot study on 12 women undergoing manual vaginal morcellation after total laparoscopic hysterectomy, Solima et al.<sup>21</sup> reported a mean morcellation time of about 6 min (range 4–19 min). It is likely that the use of contained manual vaginal morcellation compared with intraperitoneal power morcellation requires a lower operative time. Indeed, the use of contained power morcellation systems requires additional steps to set-up and disassemble instrumentation, potentially even requiring a greater learning curve compared with that of the manual vaginal technique.<sup>30,33</sup>

Concerning the complication rate, the present study did not show significant differences between the two study groups. Although several studies reported a direct correlation between the duration of a surgical procedure and the risk of complications,<sup>24,29</sup> we did not find any significant difference between the two groups in terms of complications despite the lower operative time reported for the contained group. However, the small number of events limited the power of this analysis. Further larger studies

are needed to assess the risk of iatrogenic complications associated with the use, or not, of a specimen retrieval bag during vaginal manual morcellation.

Among oncologic outcomes, in three cases (1.1%) an occult malignancy was detected in our series. We did not observe any significant difference between the two study groups for this study outcome. These results are in line with those previously reported by Seidman et al.,<sup>34</sup> who observed a rate of unexpected leiomyoma variants or atypical and malignant smooth muscle tumors of 1.2% after power morcellation of uteruses or “fibroids”. Similarly, Wasson et al.<sup>35</sup> reported a low incidence of occult uterine malignancy following 611 vaginal hysterectomies requiring morcellation (0.82%), including endometrial adenocarcinoma ( $n = 3$ ; 0.49%) and low-grade stromal sarcoma ( $n = 2$ ; 0.33%). Unfortunately, even if preoperative evaluation is optimized, it does not seem possible to eliminate the risk of occult malignancy, with particular regard to leiomyosarcoma.<sup>10,15,16</sup> Several studies proposed that the extraction of specimens by in-bag morcellation could be oncologically safe.<sup>29,36–39</sup> Indeed, it can reduce the risk of disseminating uncertain cells and destroying the uterus surface, allowing the adequate staging in case of malignancy.<sup>30</sup> Contained morcellation systems have also been used in cases of suspected endometrial carcinoma: indeed, some prospective studies reported no local recurrences at 18-month and 24-month follow up after contained vaginal morcellation of uteruses in women with endometrial cancer.<sup>29,36</sup> Despite the use of a bag reducing the gross spillage of tissue, it cannot avoid microscopic leakages. Solima et al.,<sup>21</sup> in a pilot study of 12 patients undergoing vaginal contained morcellation after total laparoscopic hysterectomy, used diluted methylene blue to investigate any minimal bag

damage of containment bags. Although the authors remarked on the small number of cases as the main study weakness, they found a leakage of methylene blue in 33% of cases even if surgeons did not notice a rupture in any bag at visual evaluation after morcellation.<sup>21</sup>

Despite an a priori defined study protocol, a large sample size, and the novelty of the study question, some limitations might affect the generalizability of our findings. First, a possible selection bias might be due to the retrospective design; however, the two study groups did not significantly differ in terms of baseline characteristics. Second, possible differences in findings might be found with non-tertiary centers because of the single tertiary center setting of our study; nevertheless, management of complex surgical scenarios such as large uteruses requires skilled laparoscopic surgeons and high-volume centers.

In conclusion, contained vaginal manual morcellation seems to reduce total operative time compared with free vaginal manual morcellation, without adding to the risk of complications. This advantage might add to the widely described decrease in the risk of peritoneal dissemination of specimen cells. Further studies are needed to confirm our findings.

#### AUTHOR CONTRIBUTIONS

**Diego Raimondo:** study conception, study design, study methods, data extraction, data analysis, manuscript preparation, methods supervision; whole study supervision. **Antonio Raffone:** study conception, study design, study methods, data analysis, manuscript preparation, methods supervision; whole study supervision. **Camilla Franceschini:** study conception, study design, study methods, data extraction, data analysis, manuscript preparation. **Agnese Virgilio:** study design, study methods, data extraction, data analysis, manuscript preparation. **Roberto Palermo:** data extraction, data analysis, manuscript preparation. **Giulia Borghese:** methods supervision, study supervision, manuscript preparation. **Manuela Maletta:** study conception, data analysis, manuscript preparation. **Alessandra Borgia:** study conception, study design, study methods, data analysis, manuscript preparation. **Daniele Neola:** methods supervision, study supervision, manuscript preparation. **Antonio Travaglino:** study design, methods supervision, manuscript preparation, whole study supervision. **Jacopo Lenzi:** data extraction, data analysis. **Maurizio Guida:** study design, methods supervision, manuscript preparation, whole study supervision. **Renato Seracchioli:** study conception, study design, methods supervision, manuscript preparation, whole study supervision. All authors approved the final version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

#### CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author (AR) upon reasonable request.

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