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Outcomes of in-bag transvaginal extraction in a series of 692 laparoscopic myomectomies: results from a large retrospective analysis

Concise title: *In-bag transvaginal extraction after laparoscopic myomectomy*

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Institutional Review Board approval

The study was approved by the independent Institutional Review Board (IRB) "Comitato Etico dell'Insubria" (approval ID: 352020; November 17, 2020).

Data availability statement

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

Word count: 3750.

Abstract

Study Objective: Transvaginal extraction is feasible method to remove surgical specimen. In this study, we aim to report our experience with in-bag transvaginal specimen retrieval after laparoscopic myomectomy over the last 15 years.

Design: Single-center retrospective analysis.

Setting: Academic hospital.

Patients: Women who underwent laparoscopic myomectomy from January 2005 to April 2021.

Intervention: Posterior colpotomy and in-bag transvaginal extraction of the surgical specimen.

Measurements and Main Results: We collected and analyzed data about patients' characteristics, main indication for surgery, intra- and post-operative (within 30 days) complications.

Results: A total of 692 women underwent transvaginal specimen retrieval after laparoscopic myomectomy (mean largest myoma diameter: 6.64 ± 2.21 cm; mean specimen weight: 177 ± 140 grams; mean operative time: 84.1 ± 37.1 minutes; mean blood loss: 195 ± 191 ml). Within 30-days, we reported the following colpotomy-related complications: 4 (0.6%) cases of vaginal bleeding, which resolved spontaneously in 3 cases (one case required readmission with new colporrhaphy under general anesthesia); 2 (0.3%) cases of vaginal pain, with no underlying cause identified on physical examination and pelvic ultrasound. Specimen weight was positively correlated with longer operative time, intraoperative blood loss and length of hospital stay.

Conclusion: Posterior colpotomy and in-bag transvaginal extraction can be considered a feasible option for retrieval of surgical specimens after laparoscopic myomectomy.

Keywords: Laparoscopic myomectomy; In-bag transvaginal extraction; Posterior colpotomy; Surgical specimen retrieval; Complications.

Introduction

Uterine myomas are the most common benign gynecological tumor during reproductive age [1]: according to a recent systematic review [2], black women seem to have two-threefold increased risk of developing myomas. In addition, other risk factors such as age, premenopausal state, hypertension, family history, time since last pregnancy, food additive and soybean milk consumption as well as epigenetic changes [3] may all play a role. On the one hand, myomas represent one of the most common indications for hysterectomy in women not desiring future fertility [4,5]; on other hand, the presence of large intramural and submucosal myomas has been associated with infertility and increased risk of spontaneous abortion, fetal malpresentation, placenta previa, preterm birth, cesarean section, and peripartum hemorrhage [6].

Myomectomy is considered the treatment of choice in women who desire uterine and fertility preservation, in case of symptoms, infertility or failed pharmacological treatments [7]. To date, minimally invasive surgical approach for uterine myomas is widely preferred [8], since it is associated with reduced morbidity when compared to abdominal myomectomy. Indeed, a Cochrane systematic review which included more than 800 women who underwent myomectomy reported that laparoscopic treatment was associated with less postoperative pain, less postoperative fever, and shorter hospital stay than open abdominal myomectomy [9].

Following laparoscopic/robotic myomectomy, three main options are available for specimen retrieval [10]: mini-laparotomy, in-bag-contained morcellation after enlargement of one of the ancillary trocar ports, and in-bag-contained transvaginal extraction through posterior colpotomy. In our Institution, we usually adopt the latter technique, since it is feasible, reproducible, cost-effective, and avoids the enlargement of skin scars.

The objective of our research is to report our experience with in-bag transvaginal specimen retrieval after laparoscopic myomectomy over the last 15 years.

Materials and methods

Patients, pre-operative work-up, data collection

Consecutive patients who underwent laparoscopic myomectomy with in-bag transvaginal extraction and manual morcellation (when necessary) of the surgical specimen at Women's and Children's Hospital of Varese (University of Insubria) between January 2005 and April 2021 were included in this retrospective study. Data were retrieved from our Institutional surgical database, that was developed for research purposes, with baseline real-time collection of data concurrent to hospital admission.

Inclusion criteria were: a) women undergoing myomectomy for single or multiple symptomatic uterine myomas; b) surgery performed by laparoscopic approach; c) specimen retrieval performed by in-bag transvaginal extraction through posterior colpotomy. We excluded cases of malignancies suspected during the pre-operative work-up, virgin women (who are not scheduled for transvaginal specimen extraction to preserve the integrity of the hymen), and cases with obliterated Douglas pouch (for instance, in case of deep infiltrating endometriosis of the posterior compartment).

In the work-up phase, women underwent bimanual pelvic examination and preoperative mapping (number, position, size of the myomas) by transvaginal 2D sonography, whereas magnetic resonance imaging (MRI) and/or transabdominal ultrasound scan were used in selected cases (for instance, in case of virgin patients who could not undergo pelvic examination and transvaginal sonography).

Prior to surgery, all patients were counselled that the specimen would be removed transvaginally. They gave written informed consent for laparoscopic myomectomy and in-bag transvaginal extraction through posterior colpotomy. After 2014, women scheduled for myomectomy were provided with both verbal and written information about the possibility of in-bag transvaginal morcellation of fibroids in an easy-to-read format, approved through local governance procedures. Alternatives to morcellation and associated morbidity were also discussed. Moreover, on admission, each patient signed informed consent to allow data collection for research purposes.

The design, analysis, interpretation of data, drafting, and revisions conform the Helsinki Declaration, the Committee on Publication Ethics (COPE) guidelines (<https://publicationethics.org/>), the REporting of studies Conducted using Observational Routinely-collected Data (RECORD) statement [11], available through the Enhancing the QUALity and

Transparency Of health Research (EQUATOR) network (www.equator-network.org). This retrospective data analysis was approved by the Institutional Review Board “Comitato Etico dell’Insubria” (approval ID: 352020; November 17, 2020).

The study was not advertised, and no remuneration was offered to the patients to enter or continue the study. Over the study period, there were no significant differences in the facilities available for patient care and in the referral patterns of our service. Other aspects of patient management unrelated to surgical approach remained consistent over time. All the operations were performed by gynecologic surgeons with extensive experience in advanced minimally invasive surgical techniques (more than 500 major gynecological laparoscopic procedures per surgeon).

For each patient, we recorded age, Body Mass Index (BMI), parity, main indication for the myomectomy, diameter of the largest myoma removed from a single patient (measured on preoperative ultrasound/MRI examination), surgical specimen weight, operative time (defined as beginning with the initial skin incision and ending when the last skin stitch was applied), estimated blood loss (calculated at the end of surgery from the contents of the suction devices and reported in ml, before to rinse), length of hospital stay, intraoperative and perioperative complications (including estimated blood loss > 500 ml), as well as complications occurred within 30-days from surgery. Patients were advised to avoid intercourses during the first 15 days after surgery to allow proper healing of the posterior colpotomy.

Laparoscopic myomectomy

The intraoperative anesthesiology protocol was standardized and followed in all cases: patients underwent general endotracheal anesthesia; after induction, patients received preemptive analgesia (ketorolac 30 mg) and prophylaxis for postoperative nausea and vomiting (dexamethasone 4 mg). Each woman received a single intravenous dose of prophylactic antibiotic (ampicillin sodium/sulbactam sodium 3 grams), 1 hour before the surgery. The surgical steps of the myomectomy were performed in standard fashion. In brief, a multiport laparoscopic technique was used: a 5-mm trocar was placed at the umbilicus and two or three additional 5- or 3-mm accessory trocars were positioned laterally in the right and/or left lower quadrants and 2 cm above the pubis.

In our Center we routinely use 5-mm camera, and this allows to easily switch its position from umbilical to lateral trocars, when necessary. Subserosal pedunculated myomas were removed by coagulating and cutting the stalk, using bipolar coagulation and suturing of serosa, if necessary. In case of intramural myomas, the surgeon incised the overlaying serosa using a monopolar hook and extended the incision until the pseudocapsule. Myoma enucleation was performed using a 5-mm screw or laparoscopic single-toothed tenaculum, applying traction with monopolar hook, bipolar forceps or suction-irrigator to isolate the cleavage plan by blunt dissection. After careful electrocoagulation of the bleeding points, uterine incision was approximated by using 1-0 polyglactin sutures, using a single- or multi-layered closure technique, as appropriate, with intra- or extracorporeal knot tying. Anti-adhesive barriers and hemostatic agents were not routinely used.

In-bag transvaginal extraction of the surgical specimen

In-bag transvaginal specimen retrieval was performed as previously described by our group [12]. Following myomectomy, a posterior 1–2 cm transverse colpotomy was performed laparoscopically at the level of the posterior fornix between the utero-sacral ligaments. A 10- or 15-mm polyurethane specimen pouch, along with its support (Endo Catch II; Covidien Surgical, Mansfield, MA, USA) was used as a guide (**Figure 1A and 1B**). The specimen pouch was then opened into the abdominal cavity (**Figure 1C**). Once the fibroid(s) was/were placed into the bag using a laparoscopic grasper (**Figure 1D**), the specimen bag was tightened and pulled out for transvaginal removal: in this way, the vaginal walls and the vulvar region were covered by a layer of resistant material (**Appendix, A**). In case of large fibroids, in-bag protected manual morcellation have been required (**Appendix, B**) to avoid any enlargement of the incision of the posterior colpotomy. In the early phase of implementation of contained tissue morcellation following laparoscopic myomectomy, we consistently assessed the integrity of the bag after morcellation with gross inspection, to be confident that the procedure was feasible. In 2017 our group has published a collaborative study showing bag integrity in a large cohort of women undergoing laparoscopic myomectomy [13]. Since then, assessment of bag integrity was left to the discretion of the surgeon, filling the bag with saline solution after the end of the procedure. The colpotomy was then

closed transvaginally using a running 1-0 polyglactin suture (**Appendix, C and D**). A video of one procedure is available as **supplementary data** (in this video, the myoma extraction resulted in a slight extension of the colpotomy).

Perioperative management

Postoperative pain was treated with paracetamol 1 g intravenously every 6 hours for 3 times (starting from approximately 30 minutes before the end of surgery). Rescue analgesia (morphine 10 mg subcutaneously or ketorolac 30 mg intravenously) was provided according to the patient's request. Preemptive infiltration of trocar sites with a local anesthetic was not routinely performed: indeed, according to a previous study from our group [14], pain scores using only 5 mm instruments (i.e. without enlarging one port-site to introduce the morcellator) were very low, therefore it is implausible that local anesthetic injection at the trocar sites could give a tangible further improvement of postoperative pain.

Statistical analysis

Conventional descriptive statistics reported patients' clinical and demographic characteristics and surgical data. Continuous variables were expressed as mean and standard deviation, or median and interquartile range, based on the distribution. Categorical variables were expressed as frequency and percentage. In addition, we stratified the cohort in three groups according to age (< 30 years, 30-40 years, > 40 years) and in four groups according to specimen weight (< 50 gr, 50-150 gr, 150-250 gr, > 250 gr), and used one-way analysis of variance (ANOVA) to determine whether there were any statistically significant differences among these groups. In addition, we performed post-hoc analysis to check for any significant difference between paired groups, for all the parameters for which ANOVA test reported overall significant differences among the groups.

Finally, we performed a trend analysis to evaluate whether specimen size (largest diameter measured in cm/mm during pre-operative ultrasound scan by sonographers trained in pre-operative mapping of myomas) and weight increased over years. For this purpose, to take into account how both specimen weight and largest diameter would have varied over the time, density

was calculated as the ratio between the specimen weight in grams and the approximated volume of the specimen, represented like a sphere-shape object with a radius of its maximum length.

A p value <0.05 was considered statistically significant. All analyses were performed in IBM SPSS Statistics 23.0 (IBM, Armonk, NY, USA).

Results

We analyzed data of 692 women who underwent laparoscopic myomectomy with in-bag transvaginal extraction of the surgical specimen through posterior colpotomy, from a total of 936 laparoscopic myomectomies. As summarized in **Table 1**, median age was 36.3 ± 6.83 , median BMI was 22 ± 3.2 and 317 (45.81%) women were nulliparous. The main indication for myomectomy was abnormal uterine bleeding in 509 (73.6%) cases, pain in 63 (9.1%) cases and subfertility/infertility in 120 (17.3%) cases.

The mean largest myoma diameter (i.e. mean maximum diameter measured during pre-operative ultrasound scan) was 6.64 ± 2.21 cm (34 myomas ≥ 10 cm and < 12 cm; 14 myomas ≥ 12 cm), and the mean myoma(s) weight was 177 ± 140 grams. Almost one half of the patients had a myomectomy for fibroids weighing 50-150 grams (n= 341; 49.3%) and the other half for fibroids weighing > 150 grams (n= 314; 45.4%), while only 37 (5.3%) for fibroids weighing < 50 grams.

Regarding surgical outcomes, mean operative time was 84.1 ± 37.1 minutes, and mean intraoperative blood loss was 195 ± 191 ml. We registered 11 (1.5%) intraoperative complications, including 6 (0.9%) cases of intraoperative blood loss > 500 ml, requiring transfusion in 2 (0.3%) cases, and 5 (0.7%) conversions to laparotomy. No bowel, bladder, major vessels, or other organs injuries were reported. Among the cases where the integrity of the endo-bag was checked (n= 54; 7.8%), micro-perforations were detected in 2 inspections (3.7%). Mean hospital stay was 1.91 ± 1.13 days.

Within 30-days from surgery, 34 (4.9%) post-operative complications occurred: 22 (3.2%) cases of fever occurred within one week from surgery, without any sign of pelvic abscess at ultrasound or sign of infection at level of colpotomy, treated with antibiotics and antipyretics; 6 (0.9%) cases of hemoperitoneum diagnosed by ultrasound during emergency room visit (all these patients

complained about abdominal/pelvic pain), which resolved spontaneously after expectant management in 5 cases (readmission and surgical drainage by laparoscopy was required in only one case); 4 (0.6%) cases of vaginal bleeding (without any apparent associated hemoperitoneum at ultrasound performed during emergency room visit), which resolved spontaneously in 3 cases (one case required return to the operating room for colporrhaphy); among the four cases with vaginal bleeding, one occurred within 10 days (this patient did not engage in vaginal intercourse during days 1-15 of the postoperative period, according to our recommendations), two cases occurred during days 16-30 of the postoperative period in women who engaged in vaginal intercourse, one case occurred during days 16-30 of the postoperative period in a woman who did not engage in vaginal intercourse; 2 (0.3%) cases of vaginal pain of unknown cause reported during emergency room visit. One case of vaginal pain occurred during days 1-15 of the postoperative period, the other one during days 16-30 of the postoperative period. None of these two cases engaged in vaginal intercourse during the follow-up period. In these two cases, physical examination, blood test and pelvic ultrasound were normal and no extension or infection of the posterior colpotomy has been recorded. Vaginal pain resolved after one week of oral treatment with painkiller. The maximum diameter of the largest removed fibroid in these two cases was 6.4 and 7.1 cm, respectively. According to operative reports, the colpotomy was not noted to have extended during closure in the patients who had vaginal bleeding and pain. We did not find any case of misdiagnosed malignancy (leiomyosarcoma) or uncertain malignant potential.

After stratification by age categories (**Table 2**), the main indications for surgery in the group of women < 30 years were abnormal uterine bleeding (62.9%) and subfertility/infertility (31.9%). In the group of women between 30 and 40 years, as well as over 40 years, the main indication for surgery was abnormal uterine bleeding (74.2% and 80.3%, respectively). We did not find significant differences for specimen weight ($p=0.747$), operative time ($p=0.457$), estimated blood loss ($p=0.639$) and hospital stay ($p=0.736$) after stratification by age.

After stratification by categories of specimen weight (< 50 gr, 50-150 gr, 150-250 gr, > 250 gr) we found a significant increase in operative time ($p < 0.001$), estimated blood loss ($p < 0.001$) and longer hospital stay ($p < 0.001$) with increasing weight of removed fibroid(s) (**Table 3**).

Finally, the trend analysis (**Figure 2**) showed that specimen size and weight of the removed myomas increased over time.

Discussion

The retrieval of surgical specimens has paramount importance in minimally invasive surgery. To the best of our knowledge, this is the largest dataset analysis of in-bag contained specimen retrieval by posterior colpotomy after laparoscopic myomectomy, with manual morcellation when necessary. The rate of intraoperative and postoperative complications reported in our study is in line with those reported in a previous large multicenter data analysis [15]. Of note, within 30 days from surgery, we did not observe infections at the level of colpotomy or pelvic abscesses, which are the most concerning around the use of transvaginal extraction for specimen retrieval. Unfortunately, due to the retrospective study design, we have to highlight that we were not able to record the rate of unintentional extension of the colpotomy during the procedure and its mean length when it occurred, so these elements should be further investigated in future analysis.

As expected, we found that main indications for surgery were strictly correlated with age, with a prevalence for both abnormal uterine bleeding and subfertility/infertility in women younger than 30 years, whereas in older women the most common indication was abnormal uterine bleeding. Interestingly, we did not find significant differences for specimen weight, operative time, estimated blood loss and hospital stay after stratification by age categories. About this point, we stratified patients by age categories aiming to check whether a particular subset of women would take more benefit compared to other subsets: from a hypothetical point of view, older women may have less vaginal elasticity compared with younger women, and this could potentially affect the outcomes of transvaginal extraction. This was not confirmed by our data analysis, suggesting that this variable is not likely to play a key role in intra- and postoperative outcomes after transvaginal extraction. In addition, although significant differences were not detected for specimen weight among age groups, we acknowledge that a trend of increasing specimen weight was noted with increasing age categories. This could be due, at least in part, by the sample size that was unable to detect the small differences between age categories: from this point of view, it makes clinical sense that

increasing age allows for increased fibroid burden that may correlate with increased fibroid size and/or specimen weight.

After stratification by categories of specimen weight, we found significant differences for operative time, estimated blood loss and hospital stay among the four groups (< 50 gr, 50-150 gr, 150-250 gr, > 250 gr): in particular, we found that these parameters followed a parallel increase with the specimen size and weight. Overall, our results suggest that transvaginal extraction of fibroids could be considered an effective and feasible option for specimen retrieval, confirming our previous findings [13] in a larger dataset. The feasibility of posterior colpotomy was also confirmed by Nezhat et al. [16], in a previous study in which the authors did not find adhesions in the cul-de-sac in 22 women who had undergone posterior colpotomy. We acknowledge that a surgeon who is not skilled in bag-contained transvaginal extraction can find this technique challenging, and this may lead to longer operative time and potential complications compared with other approaches. However, transvaginal route of specimen extraction may be considered a strategy to further reduce incisional morbidity. For adnexal masses, it has been shown that vaginal extraction is associated with less postoperative pain compared to transabdominal extraction [14]. Therefore, if future studies will confirm that the vaginal route for fibroids removal confers advantages or non-inferiority compared with other techniques for surgical specimen retrieval, this technique should be added to the gynecologic surgeon's armamentarium. The safety of contained morcellation in terms of tissue dissemination is crucial in minimally invasive surgery. In myomectomy, tissue may spread both during and after the excision of the myoma, even before morcellation is performed. Although future research is needed to definitely confirm the safety of contained morcellation, we acknowledge that there is no available method for tissue extraction that completely eliminates the risk of cellular dissemination.

In our study, the rate of endobag micro-perforation was found lower compared with another case series [17]; this may be due, at least in part, to the large experience gained in this technique by our group and to the different methods in the two studies: indeed, Solima et al. investigated bag integrity after transvaginal in-bag manual morcellation of uteri at the end of total laparoscopic hysterectomy, filling the bag with diluted methylene blue; differently, we tested bag integrity after

in-bag transvaginal manual morcellation of myomas after laparoscopic myomectomy, using saline solution. For these reasons, we take the opportunity to solicit further studies to investigate bag integrity, taking into account different procedures for testing as well as different surgical approaches [18].

The consistency of the surgical approach over the years in a single setting and the high number of collected cases represent the main strength points of our study. Nevertheless, some potential limitations should be considered for a proper data interpretation of our findings. First, the median diameter of the largest myoma removed from a single patient was 6.64 ± 2.2 cm. Although we did not set an upper size limit to the myomas that could be removed laparoscopically (in this cohort, 48 women had a dominant myoma equal to or larger than 10 cm), we cannot exclude that larger myomas have been removed by open surgery due the concern with the ability to complete the extraction through the culdotomy incision. Second, we acknowledge that the lack of a standardized prospective validated questionnaire and the short term follow up do not allow to draw a robust conclusion about the development of *de novo* dyspareunia; indeed: 1) sexual activity and partner status were not ascertained prior to and following surgical treatment; 2) women might not have brought the complaint of sexual pain to the attention of the health care providers, either because they were not expressly interviewed for this purpose or because they had not yet resumed sexual activity given the short investigated time interval since surgery; 3) validated sexual function questionnaire scores were not used, therefore we are unable to determine whether sexual dysfunction develops after posterior colpotomy for specimen retrieval. In addition, the procedures were performed by senior surgeons skilled in minimally invasive approach, in a setting recognized as Center of Excellence in Minimally Invasive Gynecology (COEMIG) according to the criteria adopted by the Surgical Review Corporation, so the results of our analysis may be not directly translated in a clinical setting without the proper skills for this technique. Nevertheless, the trend analysis highlighted that specimen weight/size extracted by transvaginal approach increased over the years, suggesting that proficiency with this technique increased with the number of performed cases.

Another main limitation is the short follow-up: indeed, we did not investigate potential long-term (i.e., after the first 30 days) complications. In addition, we could not differentiate between coitus-induced vs surgery-related colpotomy complications, since patients were monitored for complications within 30 days from surgery, but they were counseled to avoid intercourse for only 15 days after surgery. Finally, we acknowledge that our technique (as the other available ones) could not avoid the peritoneal dissemination in case of unsuspected malignancies, since the risk of cell spread may occur during the enucleation of a misdiagnosed benign myoma. Indeed, in case of uterine mass enucleation (regardless of the surgical technique used to perform the procedure), the surgical specimen is already exposed within the abdominal/pelvic cavity before the extraction: on the one hand, this does not prevent cells (or even small debris) to disseminate within the abdominal/pelvic cavity, and this can occur for benign [19], uncertain or overt malignant diseases [20]; on the other hand, bag-contained tissue morcellation allows to avoid, at least macroscopically, tissue spread within the abdominal/pelvic cavity [21]. Nevertheless, microscopic tissue spread should be taken into account even if the bag is used, regardless of transvaginal or port-site extraction.

Conclusions

According to our large dataset analysis, posterior colpotomy and in-bag transvaginal extraction can be considered a feasible option for surgical specimen retrieval after laparoscopic myomectomy.

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Author's contribution

A.S.L. was responsible for the study design and manuscript writing; S.G. and R.G. performed data collection; J.C. and F.D.F. performed the data analysis; S.U. and A.C. edited the manuscript for intellectual content; F.G. supervised the study development and gave approval for the final version of the manuscript.

All the authors conform the International Committee of Medical Journal Editors (ICMJE) criteria for authorship, contributed to the intellectual content of the study and gave approval for the final version of the article.

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Ethical Approval:

This study was approved by the Institutional Review Board "Comitato Etico dell'Insubria" (approval ID: 352020).

Informed consent: Each patient enrolled in this study was informed about the procedures and signed consent to allow data collection and analysis for research purposes.

Data sharing: The dataset generated during the current study is available from the corresponding author on reasonable request.

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Figure, Table and Appendix Legend

Figure 1. Colpotomy and extraction of myoma. A) Exposure of posterior vaginal fornix and uterosacral ligaments with an endo-bag; B) Posterior colpotomy using the monopolar hook; C) Introduction of the endo-bag into the abdominal cavity; D) Introduction of myoma in the endo-bag and extraction.

Figure 2. Specimen density (y axis) over time (x axis, expressed in years). Density was calculated as the ratio between the specimen weight in grams and the approximated volume of the specimen, represented like a sphere-shape object with a radius of its maximum length.

Table 1. Demographic data, surgical and post-operative outcomes in women who underwent laparoscopic myomectomy with in-bag transvaginal extraction.

Continuous variables are expressed as mean and standard deviation. Categorical variables were expressed as frequency and percentage.

Table 2. Main indication for surgery and surgical outcomes stratified for age.

Continuous variables are expressed as mean and standard deviation. Categorical variables were expressed as frequency and percentage. Not significant: n.s.; post-hoc analysis:

* p <0.05 for < 30 years Vs 30-40 years; p <0.001 for < 30 years Vs > 40 years; n.s. for 30-40 years Vs > 40 years.

** n.s. for < 30 years Vs all the other groups, and for 30-40 years Vs > 40 years.

*** p <0.001 for < 30 years Vs 30-40 years, and for < 30 years Vs > 30 years; n.s. for 30-40 years Vs > 40 years.

Table 3. Main indication for surgery and surgical outcomes stratified for specimen weight.

Continuous variables are expressed as mean and standard deviation. Categorical variables were expressed as frequency and percentage. Post-hoc analysis:

* p <0.05 for < 50 gr Vs all the other groups, and for 50-150 gr Vs 150-250 gr and > 250 gr.

** p <0.05 for < 50 gr Vs all the other groups, for 50-150 gr Vs > 250 gr, and for 150-250 gr Vs > 250 gr.

¶ p <0.05 for < 50 gr Vs 150-250 gr and > 250 gr, for 50-150 gr Vs 150-250 gr and > 250 gr, and for 150-250 gr Vs > 250 gr.

° p <0.05 for < 50 gr Vs all the other groups, for 50-150 gr Vs 150-250 gr and > 250 gr.

p <0.05 for 50-150 g Vs 150-250 gr and > 250 gr, and for 150-250 gr Vs > 250 gr.

Supplementary data. Video of a laparoscopic myomectomy and in-bag transvaginal extraction by posterior colpotomy.

Appendix. Transvaginal morcellation and colporrhaphy. A) Exposure of the myoma contained in the endo-bag; B) Transvaginal manual morcellation; C) Colporrhaphy; D) Final result.

Age (years)	36.3 ± 6.83
Body Mass Index	22 ± 3.2

Nulliparity	317 (45.81%)
Indication for surgery	
Abnormal uterine bleeding	509 (73.6%)
Pain	63 (9.1%)
Subfertility/infertility	120 (17.3%)
Myoma diameter (cm)*	6.64 ± 2.21
Myomas ≥ 10 cm and < 12 cm	34 (4.9%)
Myomas ≥ 12 cm	14 (2%)
Specimen weight (gr)	177 ± 140
Operative time (minutes)	84.1 ± 37.1
Estimated blood loss	195 ± 191
Hospital stay	1.91 ± 1.13
Intra-operative complications	11 (1.5%)
Early post-operative complications	34 (4.9%)

Table 1. Demographic data, surgical and post-operative outcomes in women who underwent laparoscopic myomectomy with in-bag transvaginal extraction (n= 692).

Continuous variables are expressed as mean and standard deviation. Categorical variables were expressed as frequency and percentage.

* Maximum diameter measured during pre-operative ultrasound scan.

	< 30 years (n=135)	30-40 years (n=384)	> 40 years (n=173)	p
Main indication for surgery				
Abnormal uterine bleeding	85 (62.9%)	285 (74.2%)	139 (80.3%)	<0.05*
Pain	7 (5.2%)	36 (9.4%)	20 (11.6%)	n.s.**
Subfertility/infertility	43 (31.9%)	63 (16.4%)	14 (8.1%)	<0.001***
Specimen weight (gr)	162 ± 98	177 ± 143	188 ± 161	0.747
Operative time (minutes)	80 ± 28	86 ± 39	82 ± 38	0.457
Estimated blood loss	175 ± 148	205 ± 208	189 ± 182	0.639
Hospital stay	1.88 ± 0.681	1.93 ± 1.329	1.88 ± 0.904	0.736

Table 2. Main indication for surgery and surgical outcomes stratified for age.

Continuous variables are expressed as mean and standard deviation. Categorical variables were expressed as frequency and percentage. Not significant: n.s.; post-hoc analysis:

* p <0.05 for < 30 years Vs 30-40 years; p <0.001 for < 30 years Vs > 40 years; n.s. for 30-40 years Vs > 40 years.

** n.s. for < 30 years Vs all the other groups, and for 30-40 years Vs > 40 years.

*** p <0.001 for < 30 years Vs 30-40 years, and for < 30 years Vs > 30 years; n.s. for 30-40 years Vs > 40 years.

	< 50 gr (n=37)	50-150 gr (n=341)	150-250 gr (n=184)	> 250 gr (n=130)	P
Main indication for surgery					
Abnormal uterine bleeding	25 (4.9%)	253 (49.7%)	125 (24.6%)	106 (20.8%)	<0.001*
Pain	9 (14.3%)	29 (46.0%)	13 (20.6%)	12 (19.0%)	0.002
Subfertility/infertility	3 (2.5%)	59 (49.2%)	46 (38.3%)	12 (10.0%)	<0.001**
Operative time (minutes)	76 ± 47	75 ± 30	90 ± 35	103 ± 45	<0.001 [¶]
Estimated blood loss	117 ± 156	154 ± 158	221 ± 172	287 ± 257	<0.001 [°]
Hospital stay	2.05 ± 3.472	1.73 ± 0.737	1.99 ± 0.810	2.22 ± 0.948	<0.001 [#]

Table 3. Main indication for surgery and surgical outcomes stratified for specimen weight.

Continuous variables are expressed as mean and standard deviation. Categorical variables were expressed as frequency and percentage. Post-hoc analysis:

* p <0.05 for < 50 gr Vs all the other groups, and for 50-150 gr Vs 150-250 gr and > 250 gr.

** p <0.05 for < 50 gr Vs all the other groups, for 50-150 gr Vs > 250 gr, and for 150-250 gr Vs > 250 gr.

[¶] p <0.05 for < 50 gr Vs 150-250 gr and > 250 gr, for 50-150 gr Vs 150-250 gr and > 250 gr, and for 150-250 gr Vs > 250 gr.

[°] p <0.05 for < 50 gr Vs all the other groups, for 50-150 gr Vs 150-250 gr and > 250 gr.

[#] p <0.05 for 50-150 g Vs 150-250 gr and > 250 gr, and for 150-250 gr Vs > 250 gr.

Figure 1

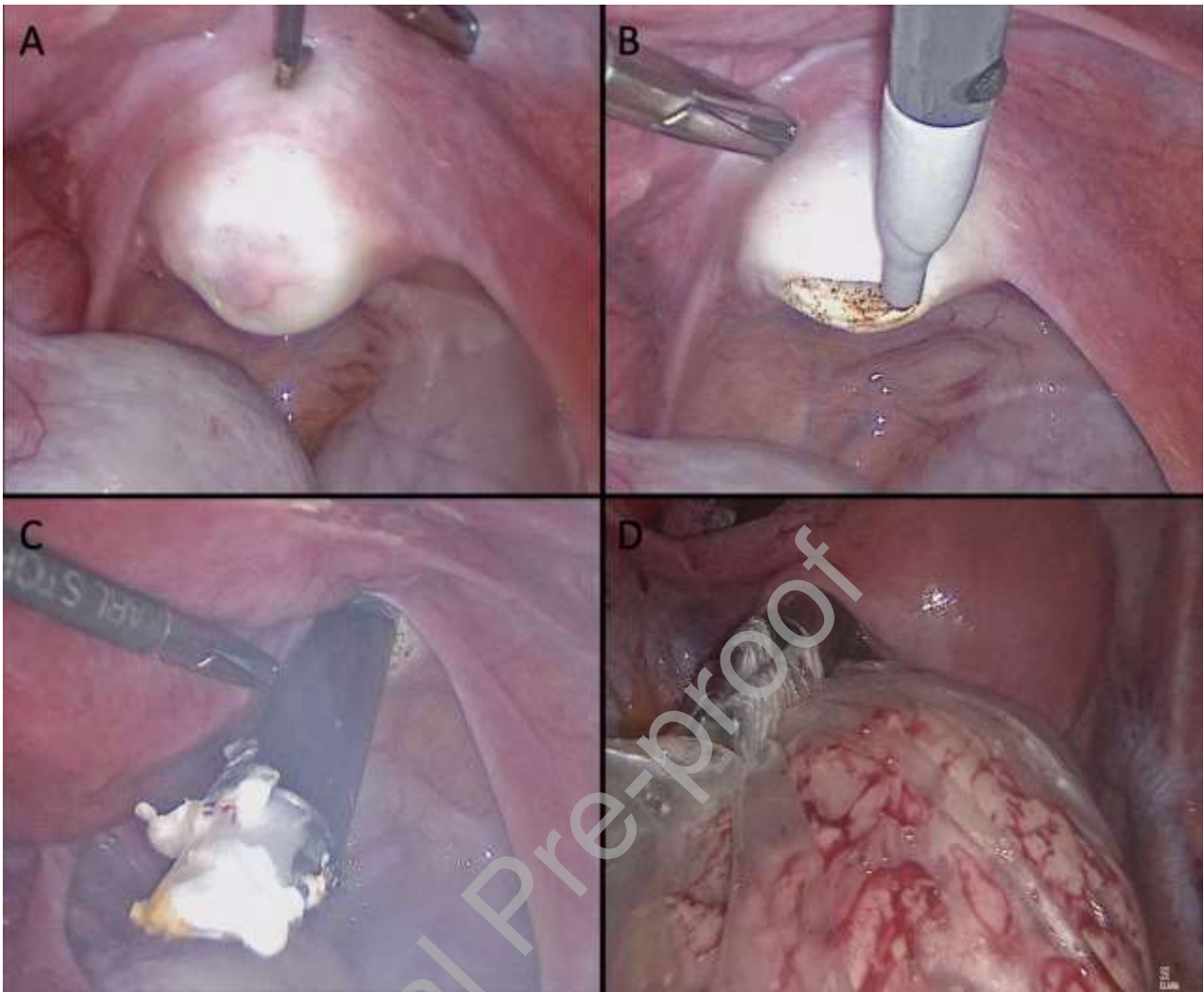


Figure 2

