

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of laparoscopic removal of uterine fibroids with power morcellation

Uterine fibroids are non-cancerous growths in or around the womb (uterus). In this procedure, which is done using general anaesthesia, the fibroids are cut into small pieces (morcellation) using a specifically designed device and removed using keyhole (laparoscopic) surgery through the abdomen. If a hysterectomy is planned, morcellation could be used to also remove part or all of the uterus. The aim is to reduce symptoms caused by fibroids.

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## Abbreviations

Word or phrase	Abbreviation
Body mass index	BMI
Confidence interval	CI
Computerised tomography	CT
Laparoscopic supracervical hysterectomy	LSH
Laparoscopic hysterectomy	LH
Laparoscopic myomectomy	LM
Laparoscopic total hysterectomy	LTH
Magnetic resonance imaging	MRI
Morcellation operative time	MOT
Randomised controlled trial	RCT
Standard deviation	SD
Total operative time	TOT
Visual analogue scale	VAS

## Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

## Date prepared

This overview was prepared in September 2020 and updated in April 2021.

## Procedure name

- Laparoscopic removal of uterine fibroids with power morcellation

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## Professional societies

- Royal College of Obstetricians and Gynaecologists
- British Society for Gynaecological Endoscopy

## Description of the procedure

### Indications and current treatment

Uterine fibroids (also known as uterine leiomyomas or myomas) are benign tumours of the uterus. They can be asymptomatic or cause symptoms including heavy periods or intermenstrual bleeding. They can be associated with fertility problems and miscarriage.

Treatment depends on whether the fibroids cause symptoms, and if the person would like to become pregnant in the future. For symptomatic fibroids, treatment options include medication, interventional radiology and surgery. Interventional radiology treatments include uterine artery embolisation and MRI-guided focused ultrasound. Surgery includes hysterectomy, myomectomy, endometrial ablation techniques and myolysis.

### What the procedure involves

Laparoscopic surgery with power morcellation allows uterine fibroids to be cut into smaller pieces so they can be removed laparoscopically through a morcellator and without the need for a laparotomy. The procedure aims to reduce symptoms caused by fibroids.

Laparoscopic removal of uterine fibroids with power morcellation is done with the patient under general anaesthesia. During laparoscopic surgery and under direct visualisation an electrosurgical morcellator is introduced through a small incision into the abdomen and used to cut the uterine fibroid into smaller pieces. If a hysterectomy is planned, morcellation can be used to also remove part or all of the uterus. The fragments are then removed through the morcellation cannula. The removed tissue should be sent for histological analysis. To reduce the risk of disseminating benign and malignant uterine tissue, the tissue can be contained in an insufflated sterile bag while being morcellated within the abdomen.

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## Efficacy summary

### Patient-reported symptoms or satisfaction

In a randomised controlled trial of 72 patients, patient-reported symptoms were not statistically significantly different between the laparoscopic myomectomy (LM) with uncontained power morcellation group and the LM with in-bag manual morcellation group (constipation: 42% [16/38] compared with 35% [12/34] of patients respectively,  $p=0.94$ ; urinary frequency: 5% [2/38] compared with 18% [6/34],  $p=0.07$ ; pelvic pain: 74% [28/38] compared with 65% [22/34],  $p=0.82$ ) around 1 week after discharge (Frasca 2017). When comparing the 2 groups at baseline, constipation was reported in 11% (4/38) compared with 6% (2/34) of patients respectively ( $p=0.39$ ), urinary frequency was 0 compared with 6% (2/34,  $p=0.22$ ) and pelvic pain was 32% (12/38) compared with 29% (10/34,  $p=0.84$ ).

In a non-randomised comparative study of 170 patients, aesthetic results were measured using a visual analogue scale (VAS). Results showed a statistically significantly lower acceptance for patients who had standard LM with power morcellation ( $7\pm 2$ , range 5 to 9) than patients who had mini-invasive LM with transumbilical power morcellation ( $9\pm 1$ , range 0 to 10,  $p<0.01$ ) at day 30 after discharge (Ardivino 2013).

A randomised controlled trial of 44 patients compared LM with electromechanical morcellation for attached fibroids (fibroids were enucleated but still attached to the uterus) and LM with electromechanical morcellation for unattached fibroids. Patients in both groups who had symptoms of menorrhagia, pain in the abdomen and a mass in the abdomen reported that their symptoms resolved and they were satisfied with the results of LM with electromechanical morcellation at the end of the 3-year follow up (Sinha 2005).

### Quality of life

In the randomised controlled trial of 72 patients, results from an SF-36 survey were comparable for physical and mental health between the LM with uncontained power morcellation group and the LM with in-bag manual morcellation group 1 month after surgery. Exact data were not reported (Frasca 2017).

### Length of hospital stay

In the randomised controlled trial of 72 patients, mean length of hospital stay was 3.11 days (standard deviation [SD]=0.80) for patients who had LM with uncontained power morcellation compared with 3.41 days (SD=0.93) for patients who had LM with in-bag manual morcellation ( $p=0.21$ ) (Frasca 2017).

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In a randomised controlled trial of 104 patients, mean length of hospital stay was 3.41 days (SD=0.6) for patients who had LM with uncontained power morcellation and 3.24 days (SD=0.6) for patients who had LM with in-bag manual morcellation (p=0.19) (Venturella 2016).

In a non-randomised comparative study of 428 patients, mean length of hospital stay was statistically significantly longer in patients who had 3-port LM with uncontained power morcellation (5.16±1.39 days) than 2-port LM with in-bag manual morcellation (4.73±1.19 days, p<0.001) (Yang 2019).

In a case series of 514 patients with presumed benign fibroids, median length of hospital stay was 2 nights (range 0 to 24) for patients who had LM (16 LM, 496 LM with electromechanical morcellation and 2 open surgeries) (Bean 2017).

In a non-randomised comparative study of 62 patients, median hospital stay was 2 days (range 1 to 3) for the LM with in-bag power morcellation group and the LM with transvaginal extraction group (Boza 2019).

In the randomised controlled trial of 44 patients, mean length of hospital stay was 37.91±5.44 hours (95% confidence interval [CI] 35.74 to 40.10) for patients who had LM with electromechanical morcellation for attached fibroids compared with 39.5±3.63 hours (95% CI 37.91 to 41.09) for patients who had LM with electromechanical morcellation for unattached fibroids (p=0.236) (Sinha 2005).

In a non-randomised comparative study of 85 patients, 92% (33/36) of patients who had laparoscopic in-bag power morcellation (morcellation was done during LM or hysterectomy) did not stay in hospital compared with 86% (42/49) of patients who had laparoscopic uncontained power morcellation (p=0.51) (Vargas 2015). In the same study, 8% (3/36) and 14% (7/49) of patients respectively stayed in hospital for 1 day or more.

## Time to full recovery

In a randomised controlled trial of 72 patients, mean length of full recovery was 11.59 days (SD=5.91) for patients in the LM with uncontained power morcellation group compared with 10.31 days (SD=8.76) for patients in the LM with in-bag manual morcellation group (p=0.11) (Frasca 2017).

## Blood loss

In the randomised controlled trial of 104 patients, there was no statistically significant difference in the change in delta haemoglobin between the LM with uncontained power morcellation group (1.32±0.8 g/dl) and the LM with in-bag manual morcellation group (1.38±0.8 g/dl, p=0.71) 24 hours post-operation and pre-operation (Venturella 2016).

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In the non-randomised comparative study of 428 patients, mean estimated blood loss was statistically significantly more in patients who had 3-port LM with uncontained power morcellation ( $61.8 \pm 58.2$  ml) compared with 2-port LM with in-bag manual morcellation ( $50.2 \pm 52.4$  ml,  $p < 0.001$ ) (Yang 2019). Mean level of haemoglobin between the 2 groups was statistically significantly different at postoperative day 1 ( $10.7 \pm 1.17$  g/dl for 3-port LM with uncontained power morcellation compared with  $11.0 \pm 1.14$  g/dl for 2-port LM with in-bag manual morcellation,  $p = 0.028$ ) but not at day 3 ( $10.5 \pm 1.25$  g/dl compared with  $10.7 \pm 1.16$  g/dl,  $p = 0.127$ ).

In the non-randomised comparative study of 170 patients, change in haemoglobin concentration was not statistically significantly different between the 2 groups ( $0.4$  g/dl for standard LM with power morcellation compared with  $0.3$  g/dl for mini-invasive LM with transumbilical power morcellation) between 24 hours after surgery and the day before surgery (Ardivino 2013).

In the case series of 514 patients, median intraoperative blood loss was 73 ml (range 5 to 3,000) (Bean 2017).

In the non-randomised comparative study of 62 patients, median estimated blood loss was 100 ml (range 10 to 1,000) for patients who had LM with in-bag power morcellation compared with 125 ml (range 20 to 300) for patients who had LM with transvaginal extraction ( $p = 0.85$ ) (Boza 2019).

In the randomised controlled trial of 44 patients, mean blood loss was  $283.9 \pm 229.3$  ml (95% CI 192.20 to 375.72) for patients who had LM with electromechanical morcellation for attached fibroids compared with  $218.5 \pm 110.7$  ml (95% CI 169.96 to 267.04) for patients who had LM with electromechanical morcellation for unattached fibroids ( $p = 0.739$ ) (Sinha 2005).

In a non-randomised comparative study of 720 patients, mean blood loss was  $126.8 \pm 46.3$  ml for patients who had laparoscopic in-bag electromechanical morcellation compared with  $128.6 \pm 58.9$  ml for patients who had laparoscopic uncontained electromechanical morcellation ( $p = 0.711$ ) (Trivedi 2020).

In the non-randomised comparative study of 85 patients, mean estimated blood loss was  $104.3 \pm 129.9$  ml for patients who had laparoscopic in-bag power morcellation compared with  $116.1 \pm 192.7$  ml for patients who had laparoscopic uncontained power morcellation ( $p = 0.74$ ) (Vargas 2015).

## Safety summary

### Presence of malignant tumours

**Uterine leiomyosarcoma** was identified in 1 patient by histological examination in the case series of 514 patients (Bean 2017). The patient had LM converted to open myomectomy, without morcellation, because the fibroid looked suspicious on initial inspection.

**Uterine leiomyosarcoma** was reported in 1 patient after histological analysis and **endometrial carcinoma** in 2 patients in a case series of 239 patients with presumed benign fibroids (Devassy 2019). Because of the suspicious nature of the intraoperative findings, a frozen section was done intraoperatively, and malignancy was found; therefore, laparoscopic radical hysterectomy was done during laparoscopic in-bag morcellation. At 3 years all 3 patients had survived disease free.

### Presence of non-malignant tumours

**Smooth muscle tumour of uncertain malignant potential** was reported in 2 patients after histological examination in the case series of 514 patients (Bean 2017). One patient, who had no desire for future fertility, had a hysterectomy. The histology revealed adenomyosis and benign leiomyomas, with no evidence of malignancy. The other patient had CT and MRI scans, which were both normal. The patient later had in vitro fertilisation and has had 1 successful birth.

**Symplastic tumour with no malignancy** was reported in 2 patients after histopathologic analysis in the non-randomised comparative study of 720 patients who had laparoscopic morcellation of fibroids or uterus with large fibroids (Trivedi 2020).

**Disseminated peritoneal leiomyomatosis** was reported in 14 patients (10 articles) who had LM with uncontained morcellation in a systematic review of 51 articles of patients with fibroids or fibroid uterus (Tulandi 2016).

**Parasitic myoma** was reported in 135 patients (2 systematic reviews) who had laparoscopic uncontained morcellation in the systematic review of 51 articles (Tulandi 2016). In 1 (n=44 studies) of the 2 systematic reviews, the incidence of parasitic myoma ranged from 0.12% to 0.95% after laparoscopic morcellation.

**A combination of parasitic myoma, pelvic endometriosis and adenomyosis** was reported in 1 patient (1 case report) who had laparoscopic supracervical hysterectomy (LSH) with uncontained morcellation in the systematic review of 51 articles (Tulandi 2016).

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**Iatrogenic endometriosis** was reported in 6 patients (3 case reports and 1 non-randomised comparative study) who had laparoscopic morcellation in the systematic review of 51 articles (Tulandi 2016). In the non-randomised comparative study (n=464 patients), the incidence of de novo endometriosis in the LSH group (with morcellation, 1.4% [3/217]) was comparable with that in the non-morcellated group (1.4% [2/145]). Of 3 patients with endometriosis at the LSH who subsequently had another surgery, 2 patients in the morcellated group had recurrent endometriosis.

**Adenomyosis** was confirmed in 12 patients after histological examination in the case series of 239 patients who had laparoscopic in-bag morcellation for presumed benign fibroids (Devassy 2018). **Adenomyosis** was reported in 10 patients (2 case reports and 1 case series) who had LSH with uncontained morcellation in the systematic review of 51 articles (Tulandi 2016). In the case series (1,045 patients), 8 patients (0.57%) had adenomyosis at 2 to 9 years after LSH with morcellation.

**Severe dysplasia of cervix uteri** (confirmed by histology) was reported in 2 patients in the case series of 239 patients who had laparoscopic in-bag morcellation for presumed benign fibroids (Devassy 2018).

## Death

**Death** was reported in 1 patient who had laparoscopic hysterectomy with power morcellation in a systematic review of the medical literature and device-related databases (55 complications identified from 1992 to 2012; Milad 2014).

## Various injuries

**Bowel injury** was described in 22 patients who had laparoscopic power morcellation (myomectomy, n=7; hysterectomy, n=15) in the systematic review of the medical literature and device-related databases (Milad 2014).

**Vascular system injury** was reported in 18 patients who had laparoscopic power morcellation (myomectomy, n=3; hysterectomy, n=15) in the systematic review of the medical literature and device-related databases (Milad 2014).

**Genitourinary tract injury** was described in 4 patients who had laparoscopic power morcellation (myomectomy, n=1; hysterectomy, n=3) in the systematic review of the medical literature and device-related databases (Milad 2014).

**Multiple injuries** were reported in 4 patients who had laparoscopic power morcellation (myomectomy, n=2; hysterectomy, n=2) in the systematic review of the medical literature and device-related databases (Milad 2014).

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## Hernia

Incisional hernia was reported in 1 patient who had the 2-port LM with in-bag manual morcellation in the non-randomised comparative study of 428 patients and the patient had complications with diabetes and morbid obesity with a body mass index (BMI) of 31 kg/m<sup>2</sup> (Yang 2019).

Port site hernia with bowel obstruction was reported in 1 patient in the case series of 514 patients (Bean 2017). This happened through the 15 mm suprapubic port site which was also used for morcellation, despite routine closure of the rectus sheath.

## Blood transfusion

Significant anaemia requiring blood transfusion (postoperative) was reported in 4 patients (2 [5.3%] in the LM with uncontained power morcellation group compared with 2 [5.9%] in the LM with in-bag manual morcellation group, p=0.65) in the randomised controlled trial of 72 patients (Frasca 2017).

Blood transfusion was needed in 4 of the 14 patients whose blood loss was more than 1,000 ml in the case series of 514 patients (Bean 2017).

Intraoperative blood transfusion was reported in 1 patient who had LM with in-bag power morcellation but not found in patients who had LM with transvaginal extraction in the non-randomised comparative study of 62 patients (Boza 2019).

Postoperative blood transfusion was needed in 4 patients whose haemoglobin was less than 11 g/dl in both LM with electromechanical morcellation for the attached fibroids group and the unattached fibroids group in the randomised controlled trial of 44 patients (Sinha 2005).

## Breach in the containment bag

Bag breach was reported in 3 patients who had LM with in-bag power morcellation in the non-randomised comparative study of 62 patients (Boza 2019). This happened during insertion of the bladed optic trocar through the hold on the tail of the bag. In 2 patients, the tail of the bag was further pulled into the trocar port and a new hold was fashioned and used. In the remaining patient, the punctured bag was removed and a new bag was inserted.

The bag was cut because of technical issues in 2 patients followed by uncontained morcellation in the non-randomised comparative study of 720 patients (Trivedi 2020).

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## Pain and analgesia used

Mean postoperative pain score (VAS, with 1 being little pain and 10 being intense pain) was 2.42 (SD=1.33) for patients who had LM with uncontained power morcellation compared with 3.12 (SD=2.14) for patients who had LM with in-bag manual morcellation ( $p=0.36$ ) at 24 hours after surgery in the randomised controlled trial of 72 patients (Frasca 2017). Using analgesic rescue doses (in addition to standard intravenous analgesic therapy) was reported in 47% (18/38) and 24% (8/34) of patients respectively ( $p=0.06$ ). Around 1 week after discharge, mean pain score became 4.97 (SD=2.30) for the LM with uncontained power morcellation group compared with 4.73 (SD=2.36) for the LM with in-bag manual morcellation group ( $p=0.36$ ), and analgesic therapy was needed in 58% (22/38) compared with 29% (10/34) of patients ( $p=0.07$ ).

Mean postoperative pain score (VAS) was 1.62 (SD=0.9) for patients who had uncontained power morcellation compared with 1.56 (SD=0.9) for patients who had in-bag manual morcellation ( $p=0.73$ ) in the randomised controlled trial of 104 patients (Venturella 2016). No statistically significant difference was found in the use of analgesic vials between groups ( $1.57\pm 0.9$  compared with  $1.62\pm 0.9$  respectively,  $p=0.73$ ).

Mean pain score (VAS) was  $6\pm 2$  for patients who had standard LM with power morcellation compared with  $5\pm 2$  for patients who had mini-invasive LM with transumbilical power morcellation ( $p<0.01$ ) at discharge in the non-randomised comparative study of 170 patients (Ardevino 2013).

Additional analgesia used for pain relief was statistically significantly higher in patients who had LM with in-bag power morcellation compared with patients who had LM with transvaginal extraction (72% [23/31] compared with 42% [13/31],  $p=0.01$ ) in the non-randomised comparative study of 62 patients (Boza 2019).

## Other complications

**Pre-pneumoperitoneum**, as a minor complication, was reported in 1 patient who had LM with uncontained power morcellation in the randomised controlled trial of 104 patients (Venturella 2016).

**Asystole with abdominal insufflation** was reported in 1 patient who had laparoscopic uncontained power morcellation in the non-randomised comparative study of 85 patients (Vargas 2015). This was resolved with desufflation.

**Postoperative complications** (anaemia, hemoperitoneum, surgical wound infection, febrile episodes, reintervention) were described in 5% (2/38) of patients who had LM with uncontained power morcellation compared with 6% (2/34) of patients who had LM with in-bag manual morcellation ( $p=0.65$ ) in the randomised IP overview: Laparoscopic removal of uterine fibroids with power morcellation

controlled trial of 72 patients (Frasca 2017). Mild postoperative complications (class 1 and 2 in the Clavien–Dindo classification system) were reported in 5 patients who had laparoscopic in-bag power morcellation and in 4 patients who had laparoscopic uncontained power morcellation ( $p=0.48$ ) in the non-randomised comparative study of 85 patients (Vargas 2015).

## **Anecdotal and theoretical adverse events**

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, a professional expert listed the following anecdotal and theoretical adverse events: internal organ injury and peritoneal leiomyomatosis. If the fibroid turns out to be malignant, morcellation can cause spread of cancer and compromise the prognosis. However, myomectomy itself is likely to compromise the prognosis in the first place.

## **The evidence assessed**

### **Rapid review of literature**

The medical literature was searched to identify studies and reviews relevant to laparoscopic power morcellation of uterine fibroids. The following databases were searched, covering the period from their start to 9 April 2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the [literature search strategy](#)). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The [inclusion criteria shown in the following table](#) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

## Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	<p>Clinical studies were included. Emphasis was placed on identifying good quality studies.</p> <p>Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.</p> <p>Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.</p>
Patient	Patients with uterine fibroids.
Intervention/test	Laparoscopic surgery with power morcellation (also known as electromechanical or electronic morcellation).
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

## List of studies included in the IP overview

This IP overview is based on 2,139 patients from 4 randomised controlled trials (Ardevino 2013; Frasca 2018; Sinha 2005; Venturella 2016), 4 non-randomised comparative studies (Yang 2019; Boza 2019; Trivedi 2020; Vargas 2015) and 2 case series (Bean 2017; Devassy 2019). This overview also includes 2 systematic reviews (Tulandi [2016] reviewed 51 articles but the total number of patients was not reported and Malid [2014] identified 55 laparoscopic morcellator-related complications in the medical literature and device-related databases).

Other studies that were considered to be relevant to the procedure but were not included in the main [summary of the key evidence](#) are listed in the [appendix](#).

## Summary of key evidence on laparoscopic removal of uterine fibroids with power morcellation

### Study 1 Frasca C (2018)

#### Study details

<b>Study type</b>	Randomised controlled trial
<b>Country</b>	Italy (single centre)
<b>Recruitment period</b>	2015 to 2016
<b>Study population and number</b>	n=72 (38 LM with uncontained power morcellation compared with 34 LM with in-bag manual morcellation) Patients with myomas
<b>Age</b>	Mean 37 years for each group
<b>Patient selection criteria</b>	Inclusion criteria: Patients aged between 18 and 50 years, with an ultrasonographic diagnosis of at least 1 myoma measuring between 4 and 10 cm in mean diameter and presenting heavy menstrual bleeding or infertility as indications to laparoscopic myomectomy.  Exclusion criteria: Postmenopausal state, history of malignancies, previous hormonal therapy for at least 6 months before surgery, previous pelvic surgery and presence of uterine mass suspicious for malignancy.
<b>Technique</b>	Laparoscopic myomectomy followed the standard technique.  Uncontained power morcellation: reusable power morcellator Rotocut G1, Storz®.  In-bag manual morcellation: a specimen retrieval bag (Endo Catch II Auto Suture 10 or 15 mm, Covidien®). The edges around the bag's opening were then pulled out through the lower central 10 mm trocar incision, previously enlarged to 20 mm, along with the abdominal fascia. The fibroid was tightly grasped with Schroeder tenaculum and manual morcellation was performed with scalpel or scissors, while the first assistant carefully pulled on the edges of the bag to move it away from the blade, avoiding bag damage. At the end of morcellation, the endoscopic bag was retrieved through the port incision and filled with water to identify eventual bag disruptions.  In both groups, a careful inspection of abdominopelvic cavity was accomplished at the end the procedure, in order to identify and remove residual macroscopic tissue fragments.
<b>Follow-up</b>	1 month
<b>Conflict of interest/source of funding</b>	None

#### Analysis

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Follow-up issues: Patients were followed up at 1 week and 1 month after discharge, but losses to follow-up were not reported.

Study design issues: This RCT evaluated the feasibility and safety of in-bag manual morcellation compared with uncontained power morcellation during laparoscopic myomectomy. The primary end point was the comparison of the 2 techniques in terms of MOT (time was recorded from the moment the fibroid was grasped to be subjected to uncontained morcellation or to be placed within the retrieval bag, to the moment the last tissue fragment was extracted from the abdominal cavity). The secondary end points consisted of the comparison of the 2 procedures in terms of TOT, postoperative haemoglobin drop, intraoperative complication rate and postoperative outcomes.

All eligible patients were randomised 1: 1 by a computer software to 1 of 2 treatment groups. A sample size of 72 patients was calculated, considering an  $\alpha$  of 0.05% and a  $\beta$  of 0.2 (power = 80%). All surgical interventions were performed by an experienced surgeon, highly trained in minimally invasive procedures, who were informed about the patient's treatment arm only at the time of surgery. Also, patients were not blinded, since women in the in-bag manual morcellation group were aware of the larger lower central trocar incision.

Study population issues: There was no statistically significant difference in age, BMI, infertility, myomas diameter, volume, location and type at baseline. There was also no statistically significant difference in symptoms between the LM with uncontained power morcellation and the LM with in-bag manual morcellation (menorrhagia: 57.9% compared with 35.3% of patients,  $p=0.09$ ; pelvic pain: 31.6% compared with 29.4%,  $p=0.84$ ; urinary frequency: 0 compared with 5.9%,  $p=0.22$ ; constipation: 10.5% compared with 5.9%,  $p=0.39$ ).

Other issues: Even though no cases of bag rupture were described, the evaluation of occult tissue leakage fell outside the aims of this study and therefore was not performed. Besides, the study could not assess the efficacy of in-bag morcellation in preventing dissemination of malignant cells, since no patients were diagnosed with a sarcoma at histological examination.

## Key efficacy findings

Number of patients analysed: 72

### Intraoperative outcomes

Parameter	LM with uncontained power morcellation (n=38)	LM with In-bag manual morcellation (n=34)	P value
Mean myomas per patient removed	1.53±0.69	1.65±0.77	0.54
No. of myomas per patient			0.68
1 myoma	22	18	
2 myomas	12	10	
3 myomas	4	6	
MOT, minutes	6.16±7.73	9.47±5.05	0.01
Mean TOT, minutes	96.74±33.51	113.24±28.12	0.01

A strong positive correlation between fibroid size and MOT (Spearman's  $\rho=0.505$ ,  $p<0.05$ )

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Postoperative hospitalisation, mean SD (days): uncontained power morcellation 3.11±0.80 days compared with in-bag manual morcellation 3.41±0.93, p=0.21

### Questionnaire outcomes

Parameter	LM with uncontained power morcellation (n=38)	LM with in-bag manual morcellation (n=34)	P value
Pain intensity (VAS)	4.97±2.30	4.73±2.36	0.36
Analgesic therapy	57.9% (n=22)	29.4% (n=10)	0.07
Symptoms			
Constipation	42.1% (n=16)	35.3% (n=12)	0.94
Urinary frequency	5.3% (n=2)	17.6% (n=6)	0.07
Pelvic pain	73.7% (n=28)	64.7% (n=22)	0.82
Full recovery, days	11.59±5.91	10.31±8.76	0.11

SF-36 survey at 1 month after surgery: Results were also comparable between the 2 groups but exact data were not reported.

### Key safety findings

No intraoperative complications, including laparotomic conversion and endoscopic bag disruption, occurred in either group.

Histological analysis confirmed the diagnosis of myomas in all patients.

### Postoperative complications

Parameter	LM with uncontained power morcellation (n=38)	LM with in-bag manual morcellation (n=34)	P value
Pain intensity (VAS)	2.42±1.33	3.12±2.14	0.36
Analgesic rescue doses (yes/no)	47.4% (n=18)	23.5% (n=8)	0.06
Δ Haemoglobin, g/dL	1.6±0.9	1.8±1.1	0.30
Complications	5.3% (n=2)	5.9% (n=2)	0.65

Postoperative complications included 4 cases of anaemia requiring blood transfusion.

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## Study 2 Venturella R (2016)

### Study details

<b>Study type</b>	Randomised controlled trial
<b>Country</b>	Italy (single centre)
<b>Recruitment period</b>	2014 to 2015
<b>Study population and number</b>	n=104 (51 LM with uncontained power morcellation compared with 53 LM with in-bag manual extracorporeal morcellation) Patients with myomas
<b>Age</b>	LM with uncontained power morcellation: mean 32.45 years LM with in-bag manual extracorporeal morcellation: mean 31.74 years
<b>Patient selection criteria</b>	Inclusion criteria: age between 18 and 40 years, BMI 18 to 40 kg/m <sup>2</sup> , heavy menstrual bleeding, and the presence of at least 1 myoma measuring 4 cm or more in diameter (but no myoma measuring >10 cm, according to the local clinical practice on eligibility for laparoscopy). Exclusion criteria: age over 40 years, presence of uterine neoformation suspicious for malignancy, acute or chronic psychiatric disorders, use of drugs during the 6-month period before enrolment date that affect cognitive ability or state of consciousness and alertness, presence of calcified fibroids at ultrasound examination (for which the effort to morcellate them mechanically may outweigh the amount of time saved), presence of ovarian cysts or adnexal lesions, previous endometrial hyperplasia, abnormal PAP test, positive pregnancy test, previous laparotomic pelvic surgery, major medical conditions, or hepatic, renal, and cardiovascular disorders or other concurrent medical illnesses.
<b>Technique</b>	Laparoscopic myomectomy followed the standard technique but using Monocryl suture CT 0 (Ethicon) instead of Vicryl CT 2-0. Uncontained power morcellation: a power morcellator (Rotocut G1, Storz) was used. In-bag morcellation: each enucleated myoma was placed within a rip-stop nylon specimen bag (Endo Catch Gold Auto Suture 10 or 15 mm, Covidien). The central lower 10 mm trocar incision was upsized to 30 mm, and a 65-mm reusable sterile pessary was placed inside of the bag, between the myoma and pelvic wall, to create a "barrier" between the morcellated portion of the myoma and the bag. After exteriorisation of the fibroid's surface with the aid of Alexis retractors, it was grasped with Schroeder tenaculum, double tooth, or Backhaus towel forceps and subjected to gradual morcellation with scalpel or scissors by cautious C-coring.
<b>Follow-up</b>	At discharge
<b>Conflict of interest/source of funding</b>	Not reported

IP overview: Laparoscopic removal of uterine fibroids with power morcellation

## Analysis

Study design issues: This prospective, unblinded randomised controlled trial (NCT02086435) was to verify whether a “protected extracorporeal in-bag” morcellation by flat knife or scissors coring could be proposed as an alternative to the standard intracorporeal uncontained power technique. The primary endpoint was the comparison of MOT between the 2 groups; it was defined as the time interval beginning from the moment in which, once the haemostasis of the uterine breach had been secured, the myoma was clamped and subjected to intracorporeal morcellation or positioned within a rip-stop nylon specimen bag for extracorporeal morcellation to the moment when the last fragment of myoma was considered removed from the surgical field. The secondary endpoints were the comparisons in terms of TOT; skin-to-skin); simplicity of morcellation (expressed on VAS where 1 defines very bad simplicity and 10 excellent simplicity); intraoperative blood loss (defined as the variation in haemoglobin concentrations between 24 hours postoperative and preoperative blood sample); postoperative hospital stay; postoperative pain (measured on the VAS scale where 1 stands for a little pain and 10 for intense pain); and postoperative complications (blood transfusion and/or laparotomy conversions).

All patients were randomised 1:1 by computer software to 1 of 2 treatment arms by a blinded nurse. All laparoscopic myomectomies were performed by 2 experienced surgeons who were informed about the patient's group only at the time of morcellation. Surgeons followed the same standardised procedures for each intervention. The sample size of 104 was calculated based on a mean morcellation time of 15.0 (SD=5.8) minutes for the standard technique; a clinically significant difference  $\geq 15\%$  in operation time between the 2 techniques; and a dropout rate of 10% to 15%, using 2 sided  $\alpha$  of 0.05% and a  $\beta$  of 0.20 (power of 80%).

Study population issues: At baseline there was no statistically significant difference between groups in terms of BMI, parity, number and dimension of myoma.

## Key efficacy findings

Number of patients analysed: 104

### Intraoperative and postoperative outcomes, mean $\pm$ SD

Parameter	LM with uncontained power morcellation (n=51)	LM with in-bag manual morcellation (n=53)	P value
Mean weight of the surgical specimens, g	312.45 $\pm$ 203.78	336.32 $\pm$ 215.32	0.13
No. of myomas per patient			
1 myoma	36	34	
2 myomas	11	15	
3 myomas	4	4	
MOT, minutes	14.35 $\pm$ 7.8	16.18 $\pm$ 8.1	0.41
TOT, minutes	92.07 $\pm$ 30.1	96.96 $\pm$ 30.2	0.24
Intraoperative blood loss, delta Hb	1.32 $\pm$ 0.8	1.38 $\pm$ 0.8	0.71

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Simplicity of morcellation, VAS scale	7.50±2.1	6.77±2.6	0.27
Hospital stay, days	3.41±0.6	3.24±0.6	0.19

On subanalysis of data, fibroid size represented the principal parameter influencing morcellation time (Pearson coefficient 0.581 compared with 0.484, in the LM with uncontained power morcellation group and LM with in-bag manual morcellation group respectively;  $p < 0.001$ ).

Correlation analysis among variables potentially linked to simplicity of morcellation revealed the most significant factor to be represented by the size of the myoma (Pearson coefficient -0.799;  $p < 0.001$ ) in the uncontained power morcellation group, whereas BMI (Pearson coefficient -0.826;  $p < 0.001$ ) was the most influential factor in the in-bag manual morcellation group.

Using a Kaplan-Meier estimator:

- LM with uncontained power morcellation: patients with a myoma  $< 55$  mm in diameter were assigned a VAS score of 6 or more, while patients with a myoma  $> 65$  mm, the probability of being assigned a VAS score of 5 or less approached 45%.
- LM with in-bag morcellation: patients with BMI  $< 29$  received a VAS score of 6 or more, while patients with BMI  $\geq 29$ , the risk of a VAS score of 5 or less was 30%.

## Key safety findings

### Complications

Parameter	LM with uncontained power morcellation (n=51)	LM with in-bag manual morcellation (n=53)	P value
Complications	2% (n=1)	0	0.30
Postoperative pain, VAS scale	1.62±0.9	1.56±0.9	0.73
Analgesic vials used	1.57±0.9	1.62±0.9	0.73

Only pre-pneumoperitoneum, as a minor complication, was reported in 1 patient who had LM with uncontained power morcellation.

## Study 3 Yang J (2019)

### Study details

<b>Study type</b>	Non-randomised comparative study
<b>Country</b>	South Korea (single centre)
<b>Recruitment period</b>	2011 to 2016
<b>Study population and number</b>	n=428 (248 three-port LM with uncontained power morcellation compared with 180 two-port LM with in-bag manual morcellation) Patients with menorrhagia related to fibroids and symptoms of pelvic pain, pressure and infertility
<b>Age</b>	Three-port LM with uncontained power morcellation: mean 41.3 years Two-port LM with bag-contained manual morcellation: mean 40.5 years
<b>Patient selection criteria</b>	Inclusion criteria: patients who had LM with morcellation.
<b>Technique</b>	Three-port LM with uncontained power morcellation: Incisions were made at the umbilicus, right-and left-lower quadrants of the abdomen. Power morcellation was done using a GYNECARE X-Tract Tissue Morcellator (Ethicon Inc.). The morcellation power was set at between 800 and 1200 Hz. Any contained-bag system was not used during power morcellation. Two-port LM with in-bag manual morcellation: Incisions were made at the umbilicus and the lower-left quadrant of the abdomen. The fibroid(s) was enclosed using a properly sized laparoscopic specimen retrieval bag (Sejong Medical, Korea) before manual morcellation.
<b>Follow-up</b>	at discharge
<b>Conflict of interest/source of funding</b>	This study was supported by a 2-year research grant from Pusan National University. Conflicts of interest: none

### Analysis

**Study design issues:** This retrospective chart review evaluated the feasibility and safety of 3-port LM with power morcellation compared with 2-port LM with bag-contained manual morcellation for patients mainly with menorrhagia related to fibroids. All LMs were done by a single gynaecologic surgeon. Authors stated that because 2-port myomectomy with manual morcellation had been conducted relatively more recently than 3-port myomectomy, the operator's learning curve had an influence on the clinical parameters. This study failed to prove that no actual leakage of the fibroids occurred during manual morcellation.

**Study population issues:** There was no statistically significant difference between the 2 groups in terms of the age, height, and weight of the patients. Concerning the parity, 3-port group (1.45±0.96) experienced statistically significant more parturition than 2-port group (1.18±0.92, p=0.007). However, number of patients who experienced previous caesarean section was not statistically significantly different between groups; 26.2% of patients (n=65) in 3-port group and 25% (n=45) in 2-port group. Previous history of gynaecologic surgeries

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including adnexal operation and myomectomy either by laparotomy or laparoscopy was not significant between groups. Indications for 3-port myomectomy or 2-port myomectomy were menorrhagia related with the fibroids (136 and 93 respectively,  $p=0.581$ ), pelvic pain (58 and 45,  $p=0.786$ ), pressure symptom (21 and 9,  $p=0.231$ ) and infertility (4 and 9,  $p=0.083$ ).

## Key efficacy findings

Number of patients analysed: 428

### Clinical outcomes after laparoscopic morcellation

Parameter	3-port LM with uncontained power morcellation (n=248)	2-port LM with bag-contained manual morcellation (n=180)	P value
Hospital stay, days	5.16±1.39	4.73±1.19	<0.001
Estimated blood loss, mL	61.8±58.2	50.2±52.4	<0.001
Morcellation time, minutes	25.8±9.30	18.9±10.11	<0.001
Total operative time, minutes	82.4±30.19	76.4±25.47	0.047
Fibroids weight, g	124.6±113.76	120.2±125.56	0.297
Preoperative haemoglobin, g/dL	12.3±1.40	12.5±1.44	0.209
Haemoglobin postoperative day 1, g/dL	10.7±1.17	11.0±1.14	0.028
Haemoglobin postoperative day 3, g/dL	10.5±1.25	10.7±1.16	0.127
Change in haemoglobin level at postoperative day 1, g/dL	1.55±1.08	1.44±1.08	0.450

## Key safety findings

**Incisional hernia: n=1 in the 2-port LM with bag-contained manual morcellation** and the patient had complications with diabetes and morbid obesity with a body mass index of 31 kg/m<sup>2</sup>.

Conversion to laparotomy was not reported in either group, and there were no major complications recorded during surgery.

## Study 4 Ardivino M (2013)

### Study details

<b>Study type</b>	Randomised controlled trial
<b>Country</b>	Italy (2 centres)
<b>Recruitment period</b>	2009 to 2011
<b>Study population and number</b>	n=170 (98 standard LM with power morcellation compared with 72 mini-invasive LM with transumbilical power morcellation) Patients with myomas
<b>Age</b>	Standard LM with power morcellation: mean 33.2 years Mini-invasive LM with transumbilical power morcellation: mean 35.3 years
<b>Patient selection criteria</b>	Inclusion criteria: patients with up to 7 intramural myomas and the largest myoma diameter of 8 cm or less. Exclusion criteria: previous uterine surgery, additional diseases requiring surgical treatment (such as endometriosis, tubal surgery or appendicitis), BMI $\geq$ 29 kg/m <sup>2</sup> , contraindications for general anaesthesia and psychiatric disorders precluding informed consent and no medical treatment for ovarian suppression before surgery.
<b>Technique</b>	All procedures were done with patients under general anaesthesia. Standard LM with morcellation: 3 operative ports (left- and right-hand sides and central suprapubic region) were used with a 10-mm intra-umbilical port to introduce the laparoscope. After myoma enucleation and suture of uterine defects, morcellation was done through the 10-mm left-hand-side trocar with a 10-mm morcellator (Rotocut™ G1 tissue morcellator; Karl Storz GmbH & Co. KG, Tuttlingen, Germany). Mini-invasive LM with transumbilical morcellation: 2 5-mm ports in the right and left pelvic region and a 10-mm umbilical port. After myomas enucleation, a 1-Monocryl™ (poliglecaprone 25; Ethicon Endo-Surgery, Cincinnati, OH) (½-circle and 36-mm) needle was introduced into the abdominal cavity directly through the skin breach, while the left iliac trocar was temporarily removed. The surgeon can perform either extra- or intracorporeal knots, introducing laparoscopic instruments directly through the skin breach. The morcellation was done transumbilical using a 10-mm Rotocut G1 tissue morcellator.
<b>Follow-up</b>	30 days after discharge
<b>Conflict of interest/source of funding</b>	None

### Analysis

Follow-up issues: Patients were assessed at 1 day after surgery, discharge and then 30 days thereafter.

Study design issues: This prospective, controlled, randomised study compared a mini-invasive technique of LM with traditional LM, and provided surgical analysis and operative outcomes. Operative times were determined

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by reviewing the surgical procedures using Final Cut Pro (Apple®, Inc., Cupertino, CA) and were calculated from the beginning of the operation (after the insertion of the trocars) until the removal of the trocars.

Computer-based randomisation by a statistician determined into which of the 2 groups patients fell: standard laparoscopic myomectomy (n=98) or mini-invasive technique (n=72). Three surgeons performed the surgical procedures. The power calculation indicated that 22 patients in each group would be necessary to detect a 15% difference in the time required to perform the myomectomy with a power  $\geq 90\%$  at a 1% level of significance.

Study population issues: At baseline the difference in mean BMI was not statistically significant between the 2 groups (  $23.7 \pm 4.1$  kg/m<sup>2</sup> for patients in the standard LM with morcellation group compared with  $23.9 \pm 3.9$  kg/m<sup>2</sup> for patients in the mini LM with morcellation group).

## Key efficacy findings

Number of patients analysed: 170

### Clinical characteristics and outcomes

Parameter	Standard LM with power morcellation (n=98)	Mini-invasive LM with transumbilical power morcellation (n=72)	P value
Main diameter of the myoma, cm	5.3±1.7 (range 2.9 to 7.3)	5.1±1.9 (range 3.1 to 7.2)	>0.05
Localisation			
Anterior	15% (n=21)	15% (n=15)	>0.05
Posterior	19.3% (n=27)	17% (n=17)	>0.05
Lateral	17.9% (n=25)	18% (n=18)	>0.05
Fundal	36.4% (n=51)	37% (n=37)	>0.05
Intrafilamentary	11.4% (n=16)	13% (n=13)	>0.05
No. of myomas per patient	1.5±2.1 (range 1 to 4)	1.4±2.2 (range 1 to 4)	>0.05
Operative time, minutes	58.4±7.1 (range 35.4 to 62.8)	57.2±9.3 (range 34.7 to 70.1)	>0.05
Intraoperative blood loss			
Change in haemoglobin concentration, g/dL	0.4	0.3	>0.05
Degree of surgical difficulty, evaluated by VAS	7±2 (range 5 to 9)	7±3 (range 5 to 10)	>0.05
Aesthetic results by the patient	7±2 (range 5 to 9)	9±1 (range 8 to 10)	<0.01

Haemoglobin concentration was determined on the day before surgery and at 24 hours after surgery; the difference in haemoglobin concentration was calculated to estimate intraoperative blood loss.

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Blood transfusion was not needed in any patients.

### **Key safety findings**

No conversion to laparotomy was required. No major complications, such as ureteric injury, bladder injury or bowel injury, happened in any case.

Postoperative pain (VAS) at discharge, mean $\pm$ SD: 6 $\pm$ 2 (range 4 to 8) for standard LM with morcellation compared with 5 $\pm$ 2 (range 3 to 7) for mini-invasive LM with transumbilical morcellation,  $p < 0.01$ .

## Study 5 Bean EMR (2017)

### Study details

<b>Study type</b>	Case series
<b>Country</b>	UK (single centre)
<b>Recruitment period</b>	2004 to 2015
<b>Study population and number</b>	n=514 (16 LM and 498 LM with electromechanical morcellation) Patients with presumed benign myomas
<b>Age</b>	Mean 38 years
<b>Patient selection criteria</b>	Inclusion criteria: pre-menopausal women with $\leq 3$ intramural/submucous myomas and a dominant myoma measuring 5 to 12 cm in diameter. For subserous myomas, there should be enough room in the abdominal cavity to safely introduce and manoeuvre laparoscopic instruments.
<b>Technique</b>	LM with morcellation: Under general anaesthesia, 4 abdominal ports (1 umbilical port, 2 lateral ports and 1 suprapubic port) were done for most patients. Patients with very large uteri/myomas had an epigastric port instead of the suprapubic port. After enucleating myomas, the myomas were morcellated using a single use electric morcellator (Ethicon Gynecare Morcellex Sigma® Johnson & Johnson, or Kebomed LiNA Xcise™). The technique of a surgical containment bag (Morcellation containment system ECOSAC, Espiner Medical Ltd™) was used for tissue extraction in a few more recent cases.
<b>Follow-up</b>	Not reported
<b>Conflict of interest/source of funding</b>	One author received honoraria from Johnson and Johnson, Olympus, Karl Storz, hospitality from Stryker and consultancy fee from Espiner. One author received honoraria from Johnson and Johnson, Olympus and Gedeon Richter and consultancy fee from Gedeon Richter

### Analysis

Study design issues: This retrospective study reviewed surgical outcomes and histopathological findings following LM. All procedures were done by experienced surgeons, including consultants and senior trainees.

Study population issues: Of the 514 patients, 393 (76.5%) were nulliparous and 121 (23.5%) parous. Four women (0.8%) were post-menopausal. The median time lapse between pre-operative imaging and timing of surgery was 113 days (range 0 to 1807).

### Key efficacy findings

Number of patients analysed: 514 (16 LM, 496 LM with electromechanical morcellation and 2 open surgeries)

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Procedure success: 99.6% (512/514) Two cases were converted to open surgery: 1 because of suspected malignancy, which proved to be a uterine leiomyosarcoma on histological examination and another due to bowel injury at the initial entry.

The location of the dominant fibroid removed was posterior in 31% (n=158), anterior in 24% (n=124), lateral in 19% (n=96), fundal in 14% (n=73) and pedunculated in 11% (n=57) of patients.

Median length of hospital admission (nights): 2 (range 0 to 24)

### Pre-operative ultrasound findings and intraoperative data, median (range)

Number of uterine myomas on ultrasound	2 (range 1 to 13)
Diameter of dominant myomas measured on pre-operative ultrasound (mm)	70 (range 10 to 214)
Number of uterine myomas removed at procedure	1 (range 1 to 12)
Size of largest myomas removed at procedure as assessed subjectively by the operating surgeon (mm)	70 (range 10 to 200)
Blood loss (ml)	73 (range 5 to 3,000)
Breach of endometrial cavity	9.7% (n=50, 95% CI 7.17 to 12.29)
Power morcellation	96.5% (n=496, 95% CI 94.91 to 98.09)
In bag morcellation	1% (n=5, 95% CI 0.12 to 1.82)

## Key safety findings

### Significant complications

Complication		Number	% (95% CI)
Intra-operative complications	Bladder injury	1	0.2% (95% CI -0.19 to 0.57)
	Bowel injury	1	0.2% (95% CI -0.19 to 0.57)
	Blood loss >1,000 ml	15	2.9% (95% CI 1.46 to 4.38)
Wound complications	Port site hernia with bowel obstruction	1	0.2% (95% CI -0.19 to 0.57)

Of the 15 patients who had blood loss >1,000 ml, 1 had open surgery because of suspected malignancy, which proved to be a uterine leiomyosarcoma. Of the 14 patients who had LM and a blood loss >1,000 ml, 4 (28.6%, 95% CI 4.9 to 52.3) needed a blood transfusion. The size, number and location of fibroids were similar in the 14 patients who had an intraoperative blood loss of >1,000 ml and the overall group.

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In the patient who developed a port site hernia, this occurred through the 15 mm suprapubic port site which was also used for morcellation, despite routine closure of the rectus sheath.

There were no cases of undiagnosed uterine malignancies following myoma morcellation.

## Histology

- Benign leiomyoma: n=511
- Smooth muscle tumour of uncertain malignant potential: n=2

One patient, who had no desire for future fertility, had hysterectomy. The histology revealed adenomyosis and benign leiomyomas, with no evidence of malignancy. The other patient had a CT and MRI, which were both normal and subsequent in vitro fertilisation and has had 1 successful birth.

- Uterine leiomyosarcoma: n=1 the patient had conversion to open myomectomy, without morcellation, as the fibroid looked suspicious at initial inspection. The original histology was reviewed and confirmed the initial diagnosis of a benign leiomyomas.

## Study 6 Boza A (2019)

### Study details

<b>Study type</b>	Non-randomised comparative study
<b>Country</b>	Turkey (2 centres)
<b>Recruitment period</b>	LM with in-bag power morcellation (prospective): 2015 to 2017 LM with transvaginal extraction (historical controls): 2014 to 2017
<b>Study population and number</b>	n=62 (31 LM with in-bag power morcellation compared with 31 LM with transvaginal extraction) Patients with myomas
<b>Age</b>	LM with in-bag power morcellation: mean 39.5 years LM with transvaginal extraction: mean 39 years
<b>Patient selection criteria</b>	Not reported
<b>Technique</b>	The intraoperative anaesthesiology protocol was standard in all patients. Additional analgesia was provided according to the patient's request. 4-port technique was used in all patients. The myoma was dissected gently out of its bed using sharp and blunt dissection. Following removal, the myomas bed was closed. After the enucleation of all myomas and reconstruction of the myometrium and the serosa, either the contained power morcellation or transvaginal specimen extractor was placed inside the abdomen. Contained power morcellation: the isolation bag (Morsafe) and the power morcellator (Versator) were used. After all fibroids were placed in the bag, the morcellator was then introduced and morcellation done in the isolation bag under laparoscopic visualisation. Before removing the bag from the abdomen, its tail was tied to prevent leakage. Transvaginal extraction: myomas >6 cm were cut into 2 or 3 pieces, which were then grasped and pulled through the vagina.
<b>Follow-up</b>	LM with in-bag power morcellation: median 13 months (range 4 to 20) LM with transvaginal extraction: median 19 months (range 3 to 28)
<b>Conflict of interest/source of funding</b>	None

### Analysis

Follow-up issues: Median follow-up was 13 months (range 4 to 20) for patients who had LM with contained power morcellation and 19 months (range 3 to 28) for patients who had LM with transvaginal extraction ( $p=0.002$ ).

Study design issues: This study compared the clinical and perioperative outcomes of myomas retrieval after LM using either in-bag power morcellation or transvaginal extraction. All LM was done by 2 expert

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laparoscopists. For comparison of outcomes, patients in both groups were matched 1:1 using the retracted largest myomas diameter.

Study population issues: At baseline no statistically significant difference was found between the 2 groups in terms of age, BMI, history of vaginal delivery and the extracted myoma characteristics.

## Key efficacy findings

Number of patients analysed: 62

### Clinical characteristics and surgery-related outcomes

	LM with in-bag power morcellation (n=31)	LM with transvaginal extraction (n=31)	P value
Total no. of myomas extracted	2 (1 to 9)	1 (1 to 9)	0.33
Main myoma diameter, cm	8 (6 to 12)	8 (6 to 12)	1
Total myomectomy specimen weight, g	120 (65 to 450)	105 (37 to 425)	0.41
Types of myoma			
Sub-serosal	1 (0 to 3)	1 (0 to 8)	0.83
Intramural	1 (0 to 6)	1 (0 to 3)	0.38
Myomas retrieval time, minutes	17 (14 to 42)	10 (3 to 15)	<0.001
Operation time, minutes	110 (65 to 287)	90 (48 to 175)	0.006
Mean instrument placement time, minutes	9.7	0.5	
Estimated blood loss, mL	100 (10 to 1,000)	125 (20 to 300)	0.85
Cul-de-sac obliteration	10% (n=3)	6.5% (n=2)	0.64
Additional analgesia	72% (n=23)	42% (n=13)	0.01
Duration of hospital stay, days	2 (1 to 3)	2 (1 to 3)	0.14

Median (range)

Conversion to laparotomy: n=0

Pathologic specimens contained malignancy: n=0

## Key safety findings

### Intraoperative complications: LM with in-bag power morcellation

- Bag breach: n=3

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This happened during insertion of the bladed optic trocar through the hold on the tail of the bag. In 2 patients, the tail of the bag was further pulled into the trocar port and a new hold was fashioned and used. In the remaining patient, the punctured bag was removed and a new bag was inserted.

- Intraoperative blood transfusion: n=1

There were no postoperative complications within 30 days after the surgery.



## Study 7 Sinha R (2005)

### Study details

<b>Study type</b>	Randomised controlled trial
<b>Country</b>	India (single centre)
<b>Recruitment period</b>	2000 to 2001
<b>Study population and number</b>	n=44 (24 LM with electromechanical morcellation for attached myomas compared with 20 LM with electromechanical morcellation for unattached myomas) Patients with symptomatic myomas
<b>Age</b>	LM with electromechanical morcellation for attached myomas: mean 32.95 years LM with electromechanical morcellation for unattached myomas: mean 33.8 years
<b>Patient selection criteria</b>	Inclusion criteria: symptomatic myomas confirmed by ultrasound examination with uterus larger than 12 weeks on bimanual examination, presence of at least 1 myoma measuring 7 cm or greater, and/or presence of 3 or more myomas greater than 5 cm in size as confirmed by ultrasound examination. Exclusion criteria: patients with submucosal myomas; had associated ovarian lesions or any other pathology discovered by ultrasound examination and a history of surgery.
<b>Technique</b>	All patients were under general anaesthesia. LM with morcellation for attached myomas: laparoscopic myomectomy was done by the technique of enucleation of a myoma by morcellation while it was still attached to the uterus. Three or four ports were needed. The myoma was separated from its capsule to the extent possible with ease in the limited space available. Electromechanical macro-morcellator (Gynecare, Mumbai, Maharashtra, India) was used. The direction of the morcellation was away from the base of the myoma, and both the entry and exit points were under vision to prevent any damage to the uterine wall. In certain cases, when the pseudocapsule was very thinned out as could happen in very large myomas, a part of the pseudocapsule could also be morcellated off along with the myoma. LM with morcellation for unattached myomas: laparoscopic myomectomy was done by the standard technique of laparoscopic myomectomy (complete enucleation of the myoma followed by morcellation).
<b>Follow-up</b>	3 years
<b>Conflict of interest/source of funding</b>	Not reported

### Analysis

Follow-up issues: Patients in both the groups were followed up at 7 days, 1 month, 6 months, and then yearly for a 2-year follow-up period.

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Study design issues: This randomised controlled trial evaluated the feasibility, blood loss, length of surgery, mean hospital stay and complications of enucleation of a myoma by morcellation while it is still attached to the uterus and to compare the technique with the standard technique of LM.

Randomisation was done using a computer-generated random number sequence. The study monitored the operating time, blood loss, patient age, weight, main symptoms and postoperative hospital stay in both groups.

Study population issues: There were initially 24 patients in each group. However, in 4 patients in the LM with morcellation for unattached myomas group, the size and position of the myomas made enucleation by the standard technique very difficult. For ethical reasons, enucleation of the myomas in these patients had to be done by the technique of enucleation of the myoma by morcellation while it was still attached to the uterus; these patients had to be excluded from the study. Hence there were 24 patients in the LM with morcellation for attached myomas group and 20 in the LM with morcellation for unattached myomas group.

The 2 groups were comparable with respect to patient age and weight as well as the mean weight and number of myomas removed. Symptoms included menorrhagia (n=25), infertility (n=17), pain in abdomen (n=7) and mass in abdomen (n=9).

## Key efficacy findings

Number of patients analysed: 44

### Removed myomas

Parameter	LM with morcellation for attached myomas (n=24)	LM with morcellation for unattached myomas (n=20)	P value
Mean weight of myomas (g)	600.5±361.33	584.25±411.17	0.706
Mean number of myomas	2.04±1.54	1.75±1.33	0.562
Mean size of myomas (cm)	7.612±4.295 (range 1 to 20)	7.629±4.570 (range 3 to 19.5)	0.895

### Site of myomas

	No. of myomas	LM with morcellation for attached myomas (n=24)		LM with morcellation for unattached myomas (n=20)		Total no. of myomas in both groups	P value
		No. of patients	No. of myomas	No. of patients	No. of myomas		
Fundal	1	9	9	9	9	18	
	2	2	4	0	0	4	
	3	0	0	2	6	6	
Subtotal (no. of fundal myomas)			13		15	28	0.85

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Anterior	1	10	10	2	2	12	
	2	0	0	3	6	6	
Subtotal (no. of anterior myomas)			10		8	18	0.815
Posterior	1	5	5	7	7	12	
	2	5	10	0	0	10	
Subtotal (no. o posterior myomas)			15		7	22	0.134
Lateral	1	6	6	4	4	10	
Anterior cervical	1	2	2	0	0	2	
Posterior cervical	1	1	1	0	0	1	
Fundal pedunculated	1	1	1	1	1	2	
Posterior pedunculated	1	1	1	0	0	1	
Total			49		35	84	

There were 26 subserous myomas in group A and 21 in group B ( $p=0.796$ ). There were 23 intramural myomas in group A and 14 in group B ( $p=0.273$ ).

### Postoperative clinical outcomes

	LM with morcellation for attached myomas (n=20)	LM with morcellation for unattached myomas (n=20)	P value
Mean blood loss, mL	283.9±229.3 (95% CI 192.20 to 375.72)	218.5±110.7 (95% CI 169.96 to 267.04)	0.739
Mean hospital stay, hours	37.91±5.44 (95% CI 35.74 to 40.10)	39.5±3.634 (95% CI 37.91 to 41.09)	0.236
Mean length of surgery, minutes	97.7±27.06 (95% CI 86.88 to 108.54)	123±38.8 (95% CI 106.93 to 140.57)	0.013

**Patient satisfaction at the end of 3-year follow-up:** The patients in both the groups with symptoms of menorrhagia, pain in abdomen and mass in abdomen reported resolution of their symptoms and were satisfied with the results of the surgery.

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## Key safety findings

There were no intraoperative complications in either group.

Postoperative blood transfusion (when haemoglobin was less than 11 g/dL): n=4 in both the groups.

## Study 8 Trivedi PH (2020)

### Study details

<b>Study type</b>	Non-randomised comparative study (retrospective)
<b>Country</b>	India (single centre)
<b>Recruitment period</b>	Laparoscopic in-bag electromechanical morcellation: 2015 to 2018 Laparoscopic uncontained electromechanical morcellation: 2012 to 2015
<b>Study population and number</b>	n=720 (365 laparoscopic in-bag electromechanical morcellation compared with 355 laparoscopic uncontained electromechanical morcellation) Patients with myomas or uterus with large myomas
<b>Age</b>	Mean 39.4 years
<b>Patient selection criteria</b>	Inclusion criteria: patients with fibroids not responding to medical treatment for infertility or excessive bleeding requiring myomectomy to conserve the uterus; needing hysterectomy with uterus more than 14-weeks size with fibroid or hysterectomy in previous caesarean section, needing bisection, coring or cutting the uterus for vaginal removal; keen for minimal access laparoscopic surgery; no high-risk factors disallowing laparoscopic surgery; consented after duly understanding the pros, cons and risk of spread of pathology by removing tissue laparoscopically after receiving information about alternative techniques.  Exclusion criteria: Any case requiring morcellation for removal of uterus, vaginal or laparoscopic, but with no myomas; any uterus with myomas which was removed intact vaginally, where no morcellation, bisection, coring or cutting of uterus was needed; any uterus with myoma of more than 30 weeks in size or myoma more than 20 cm in the laparoscopic in-bag electromechanical morcellation group.
<b>Technique</b>	All patients were operated under general anaesthesia. Morcellation was done after separation of fibroid or uterine.  Techniques included LM, LH, conventional uncontained morcellation (15-mm reusable morcellator), contained in-bag morcellation (polyurethane stomach-shaped bag).
<b>Follow-up</b>	1 year
<b>Conflict of interest/source of funding</b>	None

### Analysis

Follow-up issues: Patients were discharged in 48 hours, and follow-up was done clinically, with sonography and MRI after 6 months and 1 year in 85% of patients.

Study design issues: This retrospective cohort comparative study evaluated contained bag electromechanical morcellation for removal of myomas and uterus with large myomas, laparoscopically (Study group B), and compare it with uncontained laparoscopic morcellation (Control group A) in patients with similar parameters done earlier.

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Study population issues: The uncontained laparoscopic morcellation group included 151 (42.5%) cases of laparoscopic myomectomy and 204 (57.4%) cases of laparoscopic hysterectomy with more than 14-weeks size uterus. The contained bag electromechanically morcellation group covered 196 (53.6%) cases of laparoscopic myomectomy and 169 (46.4%) cases of laparoscopic hysterectomy with more than 14-weeks size uterus.

## Key efficacy findings

Number of patients analysed: 720

### Clinical characteristics

Parameter	Laparoscopic in-bag electromechanical morcellation (n=365)		Laparoscopic uncontained electromechanical morcellation (n=355)		Total (n=720)
	Myomectomy (n=196)	Hysterectomy (n=169)	Myomectomy (n=151)	Hysterectomy (n=204)	
No. of fibroids	2 (1 to 17)	6 (1 to 12)	2 (1 to 18)	6 (1 to 13)	3.9±2.3 (1 to 18)
Size of fibroids, cm	7.2±1.9	9.0±2.9	7.2±2.3	9.6±3.3	8.3±2.9 (5.5±18.0)
Weight of fibroids/specimen, g	400 (200 to 2100)	1000 (300 to 2100)	350 (200 to 2200)	1000 (300 to 3740)	700.7±433.9 (200 to 3740)
Hb, g/dl	10.7±1.0	11.2±1.1	10.5±0.8	11.1±1.1	10.9±1.1 (8.5 to 14.0)
Medical conditions	4.5% (n=9)	36.2% (n=61)	1.7% (n=3)	31.0% (63)	18.8% (n=98)
Surgical conditions	11.9% (n=23)	2.6% (n=4)	11.3% (n=17)	7.7% (n=16)	8.5% (n=44)
Caesarean section					
No	88.8% (n=174)	55% (n=93)	88% (n=134)	58.7% (n=120)	72.3% (n=376)
One	10.7% (n=21)	36.1% (n=61)	10.4% (n=16)	31.0% (n=63)	22.3% (n=116)
Two	0.5% (n=1)	8.9% (n=15)	0.9% (n=1)	10.3% (n=21)	5.4% (n=28)

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## Clinical outcomes

<b>Total (n=720)</b>	<b>Laparoscopic in-bag electromechanical morcellation (n=365)</b>	<b>Laparoscopic uncontained electromechanical morcellation (n=355)</b>	<b>P value</b>
Duration of surgery, minutes	104.8±30.9	110.3±33.5	0.001
Blood loss, ml	126.8±46.3	128.6±58.9	0.711
<b>Myomectomy (n=347)</b>	<b>Laparoscopic in-bag electromechanical morcellation (n=196)</b>	<b>Laparoscopic uncontained electromechanical morcellation (n=151)</b>	<b>P value</b>
Duration of surgery, minutes	107.4±24.1	107.1±16.2	0.319
Blood loss, ml	130.8±27.2	132.2±14.9	0.053
<b>Hysterectomy (n=373)</b>	<b>Laparoscopic in-bag electromechanical morcellation (n=169)</b>	<b>Laparoscopic uncontained electromechanical morcellation (n=204)</b>	<b>P value</b>
Duration of surgery, minutes	101.7±37.1	112.7±41.9	<0.001
Blood loss, ml	122.2±61.1	125.9±76.8	0.875

Laparoscopic in-bag electromechanical morcellation:

- Mean 17 minutes for insertion of bag, putting specimen in the bag and removal of bag, regardless of size, weight and number of fibroids.
- Bag was cut due to technical issue in 2 patients followed by conventional morcellation and only in 1 patient open surgery was needed to remove very large fibroids.

## Key safety findings

There were no cases of leiomyosarcoma, 2 cases of symplastic tumour with no malignancy were noted.

## Complications

<b>Total (n=720)</b>	<b>Laparoscopic in-bag electromechanical morcellation (n=365)</b>	<b>Laparoscopic uncontained electromechanical morcellation (n=355)</b>	<b>P value</b>
Intraoperative	0	0.5% (n=1)	1.000
Postoperative	1.6% (n=6)	1.1% (n=4)	0.561

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<b>Myomectomy (n=347)</b>	<b>Laparoscopic in-bag electromechanical morcellation (n=196)</b>	<b>Laparoscopic uncontained electromechanical morcellation (n=151)</b>	<b>P value</b>
Intraoperative	Nil	Nil	
Postoperative	1.5% (n=3)	1.7% (n=3)	0.561
<b>Hysterectomy (n=373)</b>	<b>Laparoscopic in-bag electromechanical morcellation (n=169)</b>	<b>Laparoscopic uncontained electromechanical morcellation (n=204)</b>	<b>P value</b>
Intraoperative	0	0.6% (n=1)	1.000
Postoperative	1.7% (n=3)	0.6% (n=1)	0.485

IP overview: Laparoscopic removal of uterine fibroids with power morcellation



## Study 9 Vargas MV (2015)

### Study details

<b>Study type</b>	Non-randomised comparative study
<b>Country</b>	US (2 centres)
<b>Recruitment period</b>	Laparoscopic in-bag power morcellation (prospective): 2014 Laparoscopic uncontained power morcellation (retrospective): 2013 to 2014
<b>Study population and number</b>	n=85 (36 laparoscopic in-bag power morcellation compared with 49 laparoscopic uncontained power morcellation) Patients with myomas and symptoms of abnormal bleeding, pelvic pain/endometriosis and pelvic organ prolapse.
<b>Age</b>	Laparoscopic in-bag power morcellation: mean 49.19 years Laparoscopic uncontained power morcellation: mean 44.06 years
<b>Patient selection criteria</b>	Inclusion criteria: patients had laparoscopic hysterectomy or myomectomy who needed morcellation of uterine tissue for specimen extraction.
<b>Technique</b>	Standard multiport laparoscopic approach was used. The Storz Rotocut G1 electromechanical morcellator (Karl Storz GmbH & Co, Tuttlingen Germany) was used for all patients. Laparoscopic open power morcellation: Morcellation was completed through the umbilical port under direct vision. The abdomen and pelvis were carefully inspected after completion of morcellation, and all visible tissue fragments were extracted. Laparoscopic in-bag morcellation: once the uterus or myoma specimen was detached, it was placed in a specimen retrieval bag that was exteriorised at the umbilicus. The specimen bags used included a 15-mm Endo Catch (Covidien, Mansfield, MA), an Anchor TRS200 (Anchor Products Co, Inc, Addison, IL) tissue retrieval system, and an isolation bag (3M, St Paul, MN). The morcellator was placed through the bag opening at the umbilicus and used to morcellate the specimen under direct laparoscopic vision.
<b>Follow-up</b>	At discharge
<b>Conflict of interest/source of funding</b>	None

### Analysis

Study design issues: This study compared perioperative outcomes, particularly operative time, in historic controls who had laparoscopic surgery with traditional open power morcellation with patients who underwent in-bag power morcellation techniques. All surgeries were performed by 1 of 3 fellowship-trained minimally invasive gynaecologic surgeons using a standard multiport laparoscopic approach. This study included the initial experience with the in-bag morcellation technique, it was possible that operating time could be reduced with further experience and modification. No power calculation was completed to determine an appropriate sample size needed to compare operative outcomes – possibility of type II error. Also, there were no cases of visible bag disruption, but this study did not examine occult leakage of tissue during in-bag morcellation.

IP overview: Laparoscopic removal of uterine fibroids with power morcellation

Study population issues: No patients were excluded from the analyses, but some patients had missing data. The total missing for each variable is race (n=2), body mass index (n=2), gravidity (n=1), parity (n=1), prior abdominal surgery (n=1), operating room time (n=10), estimated blood loss (n=2), and specimen weight (n=5).

Baseline demographics were comparable between the 2 groups although patients who had in-bag morcellation were on average older than the open morcellation group (mean 49.19 [SD=1.12] years compared with 44.06 [SD=8.93] years, p=0.01). Indication for surgery included myomas (n=65), abnormal bleeding (n=19), pelvic pain/endometriosis (n=7), pelvic organ prolapse (n=8) and others (n=2).

## Key efficacy findings

Number of patients analysed: 85

### Baseline characteristics and clinical outcomes

	Laparoscopic in-bag power morcellation (n=36)	Laparoscopic uncontained power morcellation (n=49)	P value
<b>Procedure</b>			
Total hysterectomy	22.2% (n=8)	10.2% (n=5)	0.15
Supracervical hysterectomy	52.8% (n=19)	46.9% (n=23)	
Myomectomy	25.0% (n=9)	42.9% (n=21)	
Operating time, minutes	119.0±55.91	93.33±44.90	0.02
Estimated blood loss, mL	104.3±129.9	116.1±192.7	0.74
Specimen weight, g	433.1±360.2	396.2±328.3	0.64
<b>Length of hospital stay, days</b>			
0	91.7% (n=33)	85.7% (n=42)	0.51
1 or more	8.3% (n=3)	14.3% (n=7)	

### Spearman correlations between operative time and patient/surgical characteristics

	Number	Correlation coefficient	P value
Age	75	0.002	0.99
BMI	73	0.10	0.39
Gravidity	74	-0.24	0.04
Parity	74	-0.27	0.02
Estimated blood loss	74	0.64	<0.0001

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Specimen weight	72	0.36	0.002
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The mean operating time was prolonged in patients who had myomas as their indication for surgery as well as in patients who had a laparoscopic myomectomy or total laparoscopic hysterectomy.

## Key safety findings

### Complications

	Laparoscopic in-bag power morcellation (n=36)	Laparoscopic uncontained power morcellation (n=49)	P value
Intraoperative complication	2.8% (n=1)	2.0% (n=1)	0.99
Postoperative complication	13.9% (n=5)	8.2% (n=4)	0.48

### Intraoperative complications:

- Thermal injury to the bladder before morcellation: n=1 in the in-bag morcellation group. This was oversewn and there were no further related complications.
- Asystole with insufflation: n=1 in the uncontained morcellation group. This was resolved with desufflation.

The postoperative complications in both groups were mild, meeting criteria for class I and II in the Clavien-Dindo classification system. There were no cases of occult malignancy, isolation bag disruption or visible tissue dissemination.

## Study 10 Devassy R (2019)

### Study details

<b>Study type</b>	Case series (retrospective)
<b>Country</b>	Not reported (single centre)
<b>Recruitment period</b>	2014 to 2017
<b>Study population and number</b>	n=239 Patients with presumed benign uterine myomas
<b>Age</b>	Mean 41.4 years
<b>Patient selection criteria</b>	Patients had laparoscopic in-bag morcellation for uterine myomas which were presumed benign after preoperative examinations.
<b>Technique</b>	Laparoscopic in-bag morcellation: the contained morcellation system Morsafe was used during laparoscopic intervention. The bag is pushed through the umbilical port. Fibroids above 5 cm: at least 4 trocars were used. There were 2 to 11mm ports (supraumbilical and umbilical) and 2 or 3 to 5mm ports (left and right inguinal or flanks and suprapubic). Fibroids smaller than 5 cm: the port configuration would be 3 to 4, out of which a 11 mm umbilical and 2 or 3 to 5 mm in the left and right inguinal or flanks and suprapubic.
<b>Follow-up</b>	Not reported
<b>Conflict of interest/source of funding</b>	This study was funded by Veol Medical Technologies P LTD. One author received a grant to perform the retrospective data acquisition.

### Analysis

Study design issues: This retrospective single centre case control study evaluated the feasibility of using contained endobags (Morsafe) in the retrieval of the specimen during laparoscopic surgeries in presumably benign myomatous pathology. The parameters investigated were the time of bag manipulation and the incidence of complications such as bag rupture or herniation at the port sites.

The bags consist of a medical – grade flexible plastic and can be classified into 3 sizes for use, depending on the specimen to be morcellated – small, 23×36.5×12.5 cm; medium, 25×37×13.5 cm; large, 26×39×14.5 cm. In this study, even the large bags enabled trouble – free morcellation of big specimens up to 2805 g. Regarding the practicability of in-bag morcellation, there was no prospective questionnaire evaluated, however the videos were retrospectively reviewed at the conducting time of this study and the overall satisfaction was appreciated by 14 parameters.

Study population issues: Patients weight ranged from 44 to 127.6 kg with a median at 70.8 kg. Laparoscopic interventions included myomectomy (n=148), LSH (n=68), LSH with bilateral salpingectomy (n=7), LSH and bilateral adnexectomy (n=3), LTH (n=3), LTH and bilateral adnexectomy (n=1), radical LTH with lymphonodectomy (n=2), LTH with bilateral salpingectomy (n=1) and adenomyomectomy (n=6).

IP overview: Laparoscopic removal of uterine fibroids with power morcellation

## Key efficacy findings

Number of patients analysed: 239

### Morcellated specimen weight: median 435.5 g (range 30 to 2,805)

- ≤250 g: n=49
- 250 to 500 g: n=72
- 500 to 1,000 g: n=77
- ≥1,000: n=41

### Morcellation time for different interventions

- Mean bag manipulation time: 7 minutes 3 seconds
- Mean morcellation time: 12 minutes 42 seconds

## Manageability and practicability by surgeon

The overall satisfaction was very good in 97.9% of cases (n=234). Only in 2.09% of cases (n=5), laborious manipulation was reported, because of the multiple number of fibroids or the large size/diameter to introduce into the bag.

## Key safety findings

There were no adverse events like rupture or failure of the bag were reported, and no intra or postoperative bag-induced complications such as bleeding, infections or herniations at the port sites.

### Histological examination of the specimens

- Single myoma: n=114
- Multiple myoma: n=68
- Calcified myoma: n=37
- Adenomyosis: n=12
- Uterine leiomyosarcoma: n=1
- Endometrial carcinoma: n=2
- Severe dysplasia of cervix uteri: n=2
- Endometrial hyperplasia with atypia: n=1
- Endometriosis: n=2

In 3 malignancy cases, due to the suspicious nature of the intraoperative findings, a frozen section was intraoperatively done, and malignancy was found; therefore, laparoscopic radical hysterectomy was done during the same session. Disease free survival was reported in all cases over 3 years.

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## Study 11 Tulandi T (2016)

### Study details

<b>Study type</b>	Systematic review
<b>Country</b>	Not reported for individual studies
<b>Search period</b>	Up to 2015
<b>Study population and number</b>	n=51 articles (a total number of patients across all studies was not reported) Patients with uterine myoma or fibroid uterus
<b>Age</b>	Not reported across all the included studies
<b>Study selection criteria</b>	Inclusion criteria: patients had morcellation of uterine myoma or fibroid uterus, with or without bilateral salpingo-oophorectomy. Exclusion criteria: patients with malignancy or found to have malignancy in the postoperative period.
<b>Technique</b>	Laparoscopic myomectomy or hysterectomy with uncontained morcellation
<b>Follow-up</b>	Not reported
<b>Conflict of interest/source of funding</b>	One author was an advisor for Actavis Inc. and Abb-Vie Canada, and 2 authors had no conflicts of interest.

### Analysis

Study design issues: This systematic review evaluated non-malignant sequelae of unconfined morcellation during laparoscopic myomectomy or hysterectomy. The primary outcome was the presence or absence of new benign pathology at the subsequent surgery. Results are presented as proportions.

Comprehensive search terms were used, and the searches were done in 5 electronic databases. Manual search was also performed. The review was conducted in accordance with the preferred reporting items for systematic reviews and meta-analyses statement.

Selected study issues: Most articles were case reports, case series or reviews. Of the 51 articles, 11 articles were related to endometriosis, adenomyosis, and endometrial hyperplasia; 30 articles parasitic myoma; and 9 disseminated peritoneal leiomyomatosis, and 1 disseminated peritoneal leiomyomatosis and endometriosis.

### Key efficacy findings

Number of patients analysed: 44

No efficacy findings were reported.

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## Key safety findings

### Iatrogenic endometriosis, adenomyoma and endometrial hyperplasia after laparoscopic hysterectomy and unconfined morcellation

Author(s)	Age (year)	Initial surgery	No. of patients	Interval to subsequent surgery (year)	Site of iatrogenic endometriosis
Cha et al. 2015	45	LAVH	1	1	Vault endometriosis
Bodur et al. 2012	43	TLH	1	3	Signoid mass
Schuster et al. 2012	40 (mean)	LSH vs TAH and vaginal hysterectomy (control)	3	Not stated	De novo endometriosis in 3/5 reoperated patients in LSH group vs 2/7 in control group Incidence of LSH with morcellation (3/217, 1.4%); hysterectomy without morcellation (2/145, 1.4%)
Kill et al. 2011	55	LSH	1	7	Complex adenomatous endometrial hyperplasia in a peritoneal implant
Salfelder et al. 2010	Not stated	LSH	5	Not stated	One undiagnosed sarcoma: morcellated at LSH. Three parasitic myoma after LSH and LM One endometriotic nodule at the trocar site after LSH
Llewellyn-Bennett et al. 2010	45	TLH	1	1.5	Vaginal vault
Donnez et al. 2007	40 to 48	LSH	8/1,405	2 to 9	Found 0.57% of adenomyoma lateral and retrocervix separated from the uterosacral ligaments
Hilger and Magrina 2006	44	LSH	1	5	Pelvic endometriosis, adenomyosis, and parasitic myoma
Sepilian and Della Badia 2003	30	LSH	1	6/12	Pelvic endometriosis
Wilson and Shaxted 1999	Not stated	LSH	3	Not stated	Not stated

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### Parasitic myomas after laparoscopic hysterectomy and myomectomy with unconfined morcellation

Author(s)	Article type	Mean age (year)	No. of patients	Interval to subsequent surgery (year)	Site of iatrogenic myoma and other findings
Van der Meulen et al. 2016	Systemic review (44 studies)	40.8	69	4 (1/12 to 16)	Mean number of parasitic myoma 2.9 (range 1 to 16); incidence, 0.12 to 0.95%
Pereira et al. 2015	Systemic review (32 studies)	38.4 LM; 44.1 hysterectomy	66	3/12 to 16 after LM	18 parasitic myoma: more frequent after myomectomy 9 adenomyosis: more frequent after hysterectomy 8 endometriosis 22 malignancies

### Disseminated peritoneal leiomyomatosis

Author(s)	No. of patients	Age (year)	Surgery
Yang et al. 2015	1	34	LM: disseminated peritoneal leiomyomatosis and endometriosis
Bogusiewicz et al. 2013	1	42	LSH
Ordulu et al. 2010	1	48	Laparoscopic hysterectomy
Miyaka et al. 2009	1	36	Laparoscope-assisted myomectomy
Takeda et al. 2007	1	33	LM
Kunar et al. 2008	1	24	LM
Thian et al. 2009	1	33	LM
Park et al. 2011	1	36	LM and then hysterectomy
Chin et al. 2014	3	41, 34, 34	LM
Sizzi et al. 2007	3	Not stated	LM with manual morcellation

Laparoscopic hysterectomy or myomectomy with unconfined morcellation is associated with the risk of iatrogenic endometriosis (1.4%), adenomyosis (0.57%), parasitic myoma (0.9%), and rarely DPL. Benign sequelae of uterine or myoma morcellation could be found in up to 1% of cases.

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## Study 12 Milad MP (2014)

### Study details

<b>Study type</b>	Systematic review
<b>Country</b>	US
<b>Search period</b>	1991 to 2013
<b>Study population and number</b>	n=55 events Patients who had laparoscopic power morcellation
<b>Age</b>	Not reported
<b>Study selection criteria</b>	The key words and search terms were: “Blue Endo,” “LiNA,” “Morce,” “morcellator,” “Morcellex,” “Sawalhe,” “SORD,” “Steiner,” and “X-Tract” and keyword combinations of fibroids, laparoscopic, parasitic and retained.
<b>Technique</b>	Laparoscopic morcellation was done in hysterectomy, myomectomy, nephrectomy, splenectomy or other. Morcellators included PKS PlasmaSORD, ROTOCUT G1, Gynecare Morcellex, Gynecare X-Tract, Morce Power Plus, MOREsolution and Xcise.
<b>Follow-up</b>	Not reported
<b>Conflict of interest/source of funding</b>	Not reported

### Analysis

**Study design issues:** This systematic review of the medical literature and device-related databases identified complications, near misses, and device malfunctions associated with the laparoscopic morcellator. Authors searched morcellator-related injuries and all cases that reported to MedSun, the Medical Device Reporting (MDR) and Manufacturer and User Facility Device Experience (MAUDE) databases. In addition, authors screened the medical literature published before and after FDA approval of the electric morcellator in 1993.

**Study population issues:** The types of procedure included hysterectomy, myomectomy, nephrectomy, splenectomy and other, but some outcomes but not all were reported separately for each type.

### Key efficacy findings

Number of patients analysed: 55

No efficacy findings were reported.

### Key safety findings

Laparoscopic morcellator-related complications (all types of procedure) were identified intraoperatively in 37 patients (66%); however, the remainder were not identified until up to 10 days postoperatively. Six patients died of morcellator-related complications.

IP overview: Laparoscopic removal of uterine fibroids with power morcellation

## Procedure type and injury

Procedure	Location of injury					
	Bowel	Vascular system	Genitourinary tract	Other	Multiple	Death
Hysterectomy	15	15	3	2	5	1
Myomectomy	7	3	1	2	1	0

## Contributing factors identified with laparoscopic morcellator-related injuries (n=24)

- Surgeon experience, training and control: n=16
- Lack of visualisation: n=4
- Device malfunction: n=4

A defective device was reported in 39 patients (data not shown) and alternate surgical strategies (such as conversion to laparotomy) or use of additional morcellator devices were needed. In the most extreme case 4 separate handpieces were used.

## Validity and generalisability of the studies

- Where reported, studies were done in various countries and most were conducted in a single centre. UK data were included but only from 1 study.
- Where reported, mean age ranged from 32 to 49 years and the follow-up period ranged from discharge to 3 years.
- Studies 1 to 7 examined the clinical outcomes of laparoscopic myomectomy with morcellation of uterine fibroids and studies 8 to 12 included both laparoscopic myomectomy and hysterectomy techniques.
- There was variation in patient inclusion criteria and techniques in terms of multiport laparoscopic approach, power/manual morcellation, in-bag/uncontained, and attached/unattached fibroids morcellated.
- For contained morcellation, studies 6, 8 to 10 examined the clinical outcomes of in-bag power morcellation and studies 1 to 3 considered in-bag manual morcellation. Different containment bags were used for power morcellation, such as morcellation containment system Morsafe or ECOSAC.
- Different electromechanical morcellation devices were used.
- Surgeon's experience, training and control could affect the outcomes of the procedure, including laparoscopic morcellator-related injuries. The number and size of fibroids and the patient's BMI might have an influence on the simplicity and manageability of the procedure.
- Studies primarily focused on the prevalence or incidence of undetected or occult malignancy during or after laparoscopic morcellation for presumed benign indications were not included in the key summary as they related primarily to diagnostic accuracy in advance of the procedure. However, as they did relate to the longer-term safety profile of laparoscopic morcellation of uterine fibroids, this evidence was included in the appendix and the key relevant papers were also summarised in the 'issues for consideration by IPAC' section (see pp.53-55).

## Existing assessments of this procedure

The American College of Obstetricians and Gynaecologists committee opinion on uterine morcellation for presumed leiomyomas (2019) made the following recommendations and conclusions regarding uterine morcellation (manual or power):

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- *Before considering open morcellation of the uterus, a woman should be evaluated to determine if she is at increased risk of malignancy of the uterine corpus.*
- *Preoperative evaluation includes the appropriate use of imaging, cervical cancer screening, and endometrial tissue sampling to identify malignancy.*
- *The patient should be informed of the possible risk of disseminating an occult uterine malignancy by open morcellation, as well as the risk of disseminating benign uterine tissue.*
- *Although an abdominal hysterectomy or myomectomy may reduce the chance of spreading cancer cells in women with undiagnosed leiomyosarcoma, it is associated with increased morbidity when compared with minimally invasive approaches. These factors must be weighed against the risk of encountering a leiomyosarcoma at the time of surgery for presumed leiomyomas (also called fibroids), as well as the associated morbidity and potential mortality associated with that diagnosis.*
- *Based on the 2017 Agency for Healthcare Research and Quality (AHRQ) report, which used the largest and most comprehensive dataset and rigorous analytic methods to determine estimates of prevalence of leiomyosarcoma, patients may be informed that the risk of unexpected leiomyosarcoma may range from less than 1 in 770 surgeries to 1 in 10,000 surgeries for presumed symptomatic leiomyomas.*
- *The obstetrician–gynaecologist and patient should engage in shared decision making, including informed consent explaining the risks and benefits of each approach to surgery for presumed leiomyomas, the risks and benefits of morcellation, and alternatives to morcellation.*

The Society of Obstetricians and Gynaecologists of Canada (SOGC)/Society of Gynaecologic Oncology of Canada (GOC) clinical practice guideline on morcellation during gynaecologic surgery (2019) made the following recommendations:

- *Preoperative endometrial biopsy and cervical assessment is recommended in order to avoid morcellation of potentially detectable malignant and pre-malignant conditions of the endometrium and cervix (II-2A).*
- *Uterine morcellation should be avoided in hereditary cancer syndromes that increase the risk of uterine malignancy (III-C).*

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- *Techniques for morcellation of a uterine specimen vary, and physicians should consider employing techniques that minimize specimen disruption and intra-abdominal spread (III-C).*
- *Uterine morcellation is contraindicated in women with established or suspected uterine neoplasia (II-2A).*

The International Society for Gynaecologic Endoscopy (ISGE) publication on assessing the risk of laparoscopic morcellation of occult uterine sarcomas during hysterectomy and myomectomy (2018) recommended:

- *Conventional MRI examinations should be performed while the correlation between conventional MRI findings (T1 and T2-weighted images), diffusion weighted imaging (DWI) intensity and corresponding apparent diffusion coefficient (ADC) values and dynamic contrast-enhanced MRI (DCE-MRI) with pharmacokinetic analysis study may also be evaluated in order to exclude or suspect the presence of a LMS (Level C). Only the patients who are considered “low risk” after MRI imaging may undergo minimal invasive surgery involving an intra-abdominal morcellation, unless the morcellation can be carried out in a contained bag (Level C).*

The European Society of Gynaecological Oncology (ESGO) published their statements on fibroid and uterine morcellation in 2017. ESGO recommended:

- *Avoid morcellation if there are suspicious ultrasonographic signs, fast growth within 3 months and rapid postmenopausal growth.*
- *Morcellation should not be used if there is a suspicion of a sarcoma or if a sarcoma is present after endometrial biopsy/resection for uterine bleeding. A hysterectomy with en bloc resection should be the standard approach (by laparotomy for a bulky uterus).*
- *Use power morcellation only for uterine fibroids rather than for the whole uterus, which could be extracted vaginally or by minilaparotomy.*
- *Surgical removal of uterine fibroids by myomectomy should be morcellated in endobag containers.*
- *In case of morcellation in a patient with unrecognised sarcoma the patient should be reported to an online database designed to look at the follow-up of such patients.*

The Asia-Pacific Association for Gynaecologic Endoscopy and Minimally Invasive Therapy (APAGE, 2015) published their statements on laparoscopic morcellation of uterine fibroids in 2015. APAGE concluded:

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- *With minimal access (small incision site), a minimally invasive surgery (MIS) approach would involve a variety of specialised instruments or techniques such as the use of power morcellators during hysterectomy or myomectomy (Wang, 2013; Shiota, 2012). It has not been reported if there is a single technique that is superior or is fully essential to MIS. Therefore, all current techniques should remain available during surgery before evidence-based guidelines are published on this topic.*
- *As the treatment options of tissue extraction continue to grow with emerging technologies, there is a variety of techniques that can be used to divide and remove the specimen. The manual methods of specimen retrieval can be performed through the vagina, through a minilaparotomy (abdominal incision about 5-6 cm), or through the umbilicus port sites (Wang, 2013; Koo 2013; Chern 2012; Shiota, 2012). Power morcellation is one of the surgical techniques that provides a method for removing large tissue without the need for a bigger incision site. However, it does have the potential to disseminate uterine tissue throughout the peritoneal cavity. It is estimated that less than one in 350 women who undergo hysterectomy or myomectomy for uterine fibroids may have an undetected type of uterine malignancy (AAGL Advancing Minimally Invasive Gynaecology Worldwide, 2014; U.S. Food and Drug Administration, 2014).*
- *APAGE believes that there are various options of tissue extraction available and each option has its own benefits. It is not encouraged to convert all surgical cases to laparotomy so as to avoid the use of power morcellators as the incidence of uterine malignancy is very low (1:350) (AAGL Advancing Minimally Invasive Gynaecology Worldwide, 2014; U.S. Food and Drug Administration, 2014; Lee, 2010).*
- *Based on the current evidence, the management of benign and malignant disease with MIS is much preferred over the traditional laparotomy approach. However, surgeons without the requisite training and skills when performing laparoscopic surgeries may lead to morcellator-related injuries and worsen the patient's outcome. Therefore, proper training is required for surgeons when using power morcellation device.*

The Turkish Minimally Invasive Gynecologic Oncology Society (2021) reviewed the existing evidence on morcellation for removal of uterine tissue in gynaecology and suggested:

- *Survival outcomes are worse in uterine sarcomas, even in the early stages, compared to endometrial malignancies. The morcellation of sarcomas can result in disease progression and worsen survival outcomes compared to non-morcellation.*

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- *The peritoneal seeding resulting from morcellation increases the incidence of benign sequelae. These sequelae account for the vast majority of morcellation-related morbidities and should not be ignored.*
- *Although it is assumed that morcellation with tissue containment may be protective against negative outcomes, there is not enough evidence regarding the preventive efficacy of this method. Further studies are needed to establish conclusive data.*
- *Patients should be informed in detail regarding the advantages of minimally invasive surgery and the risks of morcellation. In patients in whom malignancy is suspected, morcellation should be avoided (or not performed at all), regardless of the patient's consent.*

## Related NICE guidance

Below is a list of NICE guidance related to this procedure.

### Interventional procedures

- Ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids. NICE interventional procedures guidance 657 (2019). Available from <https://www.nice.org.uk/guidance/ipg657>
- Hysteroscopic morcellation of uterine leiomyomas (fibroids). NICE interventional Procedures guidance 522 (2015). Available from <https://www.nice.org.uk/guidance/ipg522>
- Magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids. NICE interventional procedures guidance 413 (2011). Available from <https://www.nice.org.uk/guidance/ipg413>
- Uterine artery embolisation for fibroids. NICE Interventional procedures guidance 367 (2010). Available from <https://www.nice.org.uk/guidance/ipg367>
- Magnetic resonance (MR) image-guided percutaneous laser ablation of uterine fibroids. NICE interventional procedures guidance 30 (2003). Available from <https://www.nice.org.uk/guidance/ipg30>
- Laparoscopic laser myomectomy. NICE interventional procedures guidance 23 (2003). Available from <https://www.nice.org.uk/guidance/ipg23>

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- Heavy menstrual bleeding: assessment and management. NICE guideline 88 (2018). Available from <https://www.nice.org.uk/guidance/ng88>

## Additional information considered by IPAC

### Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. One professional expert questionnaire for laparoscopic removal of uterine fibroids with power morcellation was submitted and can be found on the [NICE website](#).

### Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

### Company engagement

A structured information request was sent to 3 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

### Issues for consideration by IPAC

- A consultee has requested that NICE produces guidance to reflect patient information on 'Morcellation for myomectomy or hysterectomy' published by the Royal College of Obstetricians and Gynecologists. The patient information describes the risk of unexpected sarcoma in fibroids and explains that morcellation of an unexpected uterine sarcoma can potentially cause the cancer to spread and worsen the chances of survival.
- In April 2014, the FDA issued a safety communication that discouraged the use of **laparoscopic power morcellation** during hysterectomy or myomectomy for the treatment of women with fibroids. It stated that the FDA is concerned about women undergoing **laparoscopic power morcellation**

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for the treatment of uterine fibroids and the risk of inadvertent spread of unsuspected cancer to the abdominal and pelvic cavities.

- Ongoing trials:
  - Safety and efficacy of using the new tissue containment system during laparoscopic myomectomy morcellation ([NCT04392674](#)); clinical trial (single group assignment); China; estimated enrolment, n=400; estimated study completion date: May 2022.
  - Laparoscopic myomectomy with morcellation or transvaginal extraction of surgical specimens (MYMOTE-1) ([NCT03570879](#)); retrospective observational study (case-control); Italy; estimated enrolment, n=250; estimated study completion date, May 2021.
  - First in human study evaluating the safety and performance of the “LapBox” containment system for laparoscopic tissue morcellation ([NCT04231812](#)); clinical trial (single group assignment); Israel; estimated enrolment, n=10; estimated study completion date, May 2020.
  - Safety and efficacy of using PK morcellator with Pneumoliner bag for laparoscopic morcellation with laparoscopic instrument for tissue containment and removal during laparoscopic supracervical hysterectomy or total laparoscopic hysterectomy (NCT03216772); clinical trial (single group assignment); US; estimated enrollment, n=140.
- Key papers reporting the prevalence or incidence of undetected or occult malignancy during or after laparoscopic morcellation of presumed benign uterine fibroids and/or associated outcomes (including mortality or survival):
  - Bojahr (2015) described that in 10,731 morcellated uteri during LSH only 0.06% sarcoma and 0.07 % endometrial carcinoma were detected but not caused by use of a morcellator. This amounts to a very low uterine malignancy rate of 0.13 %. Median follow-up period for all 6 patients with sarcoma and 7 patients with endometrial cancer was 65.58 months (range 13 to 169). No recurrence was reported for the patients with endometrial cancer and 5 sarcoma patients in the comprehensible follow-up period. One patient died 13 months after LSH surgery due to the diagnosed leiomyosarcoma with peritoneal carcinomatosis and bone metastases.
  - Chen (2018) examined the prevalence, pathology and prognosis of uterine sarcomas in LH or LM with electric power morcellation for presumed leiomyomas. Of the 4,478 patients with LPM for presumed leiomyomas, 24 (0.54%) had unexpected cancer. The patients showed the highest

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- frequency of occult cancers (10/375, 2.6%) at 51 to 60 years and lowest (0/255) before 30 years. The pathology included 14 endometrial stromal sarcomas (ESS) (low grade 12 and high-grade 2), 9 leiomyosarcomas, and 1 malignant mixed mesodermal tumour. The patients had abdominal re-exploration including total hysterectomy with bilateral salpingo-oophorectomy and staging surgery. Three patients were at advanced FIGO stage (IIIb-IVb) and 21 at stage I. Seven patients recurred within 1 to 25 (mean 6.29) months including 5 leiomyosarcomas, 1 high-grade and 1 low-grade ESS. Four recurrent patients with leiomyosarcomas and 1 with high-grade ESS died of disease in 1 to 3 months. Seventeen patients had no relapse and were alive for 6 to 41 (mean 24) months.
- Gitas (2020) assessed the incidence of occult uterine malignancies during laparoscopic myomectomy or hysterectomy with the use of electromechanical power morcellation. They found that of 1,683 patients (the most common indication was symptomatic myomas), 4 had unexpected sarcoma (0.24%). In all cases, the malignancy proved to be a sarcoma and was detected after LSH. All patients with occult sarcomas were older than 45 years and the most common (75%) risk factor was the appearance of a solitary tumour. The patients underwent secondary laparotomy for complete oncological staging, and no histological dissemination of the sarcoma was registered. Two patients had a recurrence. At the final follow-up investigation all 4 patients were in good general health.
  - Kundu (2017) investigated the risk of disseminating uterine malignancy during uterine surgery. They identified 2,825 cases of uterine myometrial surgery. Morcellating procedures were used in 20% of the 1402 hysterectomy procedures (280/1402) and in 13.7% of the 1423 fibroid removals (195/1423). They found a small risk (0.35% [1/280]) of accidental morcellation during hysterectomy with morcellation. They did not observe an occult case of sarcoma after myomectomy with morcellation (0/195) but found 2 cases of accidental sarcoma after myomectomy without morcellation.
  - Pados (2017) studied the prevalence of occult uterine sarcomas and benign atypical leiomyomas after laparoscopic morcellation of presumed benign fibromas in reproductive age women. They found that the prevalence of leiomyosarcomas and atypical leiomyomas was 0% (95% CI 0 to 0.3%) and 0.6% (95% CI 0.23 to 1.18%) (6 atypical-bizarre and 1 mitotically active leiomyoma) respectively. In addition, there were identified 34 cases of adenomyomas, 45 leiomyomas with infarcts, 81 cellular leiomyomas and 133 degenerated leiomyomas. No morcellator associated

complication was recorded and none of the patients included in this study required conversion to laparotomy.

- Raine-Bennett (2016) reported that among 34,728 hysterectomies done for leiomyomas, the incidence of occult uterine sarcoma and leiomyosarcoma was 1 of 278 or 3.60 (95% CI 2.97 to 4.23) and 1 of 429 or 2.33 (95% CI 1.83 to 2.84) per 1,000 hysterectomies performed for leiomyomas. The unadjusted 3-year probability of disease-free survival for no morcellation, power and nonpower morcellation was 0.54, 0.19, and 0.51, respectively (p=0.15); overall survival was 0.64, 0.75, and 0.68, respectively (p=0.97). None of the adjusted risk ratios for recurrence or death were significant except for death at 1 year for power and nonpower morcellation groups combined (6/33) compared with no morcellation (4/76) (5.12, 95% CI 1.33 to 19.76, p=0.02).
- Wright (2016) analysed the prevalence of underlying cancer and precancerous changes in women who had myomectomy with and without electric power uterine morcellation. The total sample was 41,777 patients and included 3,220 (7.7%) who had electric power morcellation. Uterine cancer was identified in 73 (1 in 528) women who had myomectomy without electric power morcellation (0.19%; 95%CI, 0.15% to 0.23%) and in 3 (1 in 1073) women who had electric power morcellation (0.09%; 95% CI 0.02% to 0.27%). The corresponding rates of any pathologic finding (cancer, tumours of uncertain malignant potential, or endometrial hyperplasia) were 0.67% (n=257, 95% CI 0.59% to 0.75%) (1 in 150) and 0.43% (n=14, 95%CI, 0.21% to 0.66%) (1 in 230), respectively. Advanced age was the strongest risk factor for uterine cancer.
- Xu (2019) investigated whether uncontained power morcellation at the time of hysterectomy or myomectomy was associated with increased mortality risk in women with occult uterine cancer. They identified 843 women with occult endometrial carcinoma and 334 women with occult uterine sarcoma who had a hysterectomy or myomectomy for presumed benign indications. They used LSH/LM as a surrogate indicator for uncontained power morcellation. They found that among women with occult uterine sarcoma (n=334), LSH/LM was associated with a higher risk for disease specific mortality than total abdominal hysterectomy (TAH, adjusted hazard ratio [aHR], 2.66, 95% CI 1.11 to 6.37; adjusted difference in 5-year disease-specific survival, -19.4%, 95% CI -35.8% to -3.1%). In the subset of women with leiomyosarcoma, LSH/LM was associated with an increased risk for disease-specific mortality compared with supracervical abdominal hysterectomy (aHR, 3.64, 95% CI 1.50 to 8.86; adjusted difference in 5-year disease specific survival, -31.2%, 95% CI -50.0% to -12.3%) and TAH (aHR, 4.66, 95% CI 1.97 to 11.00; adjusted

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- difference in 5-year disease-specific survival, -37.3%, 95% CI -54.2% to -20.3%). Among women with occult endometrial carcinoma (n=843), there was no significant association between surgical approach and disease specific mortality.
- Yang (2017) described that the proportion of postoperative malignancy after morcellation application was 0.18% (62/33,723) for patients who had LM. Nearly 62.9% (39/62) of patients had demonstrated blood flow signals in the uterine fibroids before surgery. In addition, 23 (37.1%) patients showed rapid growth at the final preoperative ultrasound. With respect to the pathological types, 38 (61.3%) patients had detectable endometrial stromal sarcoma, 13 (21.0%) had detectable uterine leiomyosarcoma, only 3 (3.2%) had detectable carcinosarcoma, and 5 (8.1%) patients with leiomyoma had an undetermined malignant potential. The prevalence of the postoperative morbidity rate was 11.3%.

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10. Devassy R, Cezar C, Krentel H et al. (2019) Feasibility of myomatous tissue extraction in laparoscopic surgery by contained in-bag morcellation: A retrospective single arm study. *International journal of surgery* 62: 22-7
11. Tulandi T, Leung A and Jan N (2016) Nonmalignant sequelae of unconfined morcellation at laparoscopic hysterectomy or myomectomy. *Journal of minimally invasive gynaecology* 23(3): 331-7

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12. Milad MP and Milad EA (2014) Laparoscopic morcellator-related complications. *Journal of Minimally Invasive Gynaecology* 21, 486-91
13. American College of Obstetricians and Gynaecologists (2019) ACOG committee opinion No. 770: Uterine morcellation for presumed leiomyomas. *Obstetrics & Gynaecology*, 133(3): e238-48
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## Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	09/04/2021	Issue 4 of 12, April 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	09/04/2021	Issue 4 of 12, April 2021
International HTA database (INAHTA)	09/04/2021	-
MEDLINE (Ovid)	09/04/2021	1946 to April 08, 2021
MEDLINE In-Process (Ovid)	09/04/2021	1946 to April 08, 2021
MEDLINE Epubs ahead of print (Ovid)	09/04/2021	1946 to April 08, 2021
EMBASE (Ovid)	09/04/2021	1974 to 2021 April 08

### Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

### Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

### Literature search strategy

Number	Search term
1	Uterine Neoplasms/ and Leiomyoma/
2	Myofibroma/
3	((uter* or intrauter*) adj4 (neoplasm* or tumour* or tumor* or growth* or fibroma* or leiomyoma* or leimyoma* or angioleiomyoma* or angiomyoma* or myofibroma* or leyomyoma or lesion*)).tw.
4	(fibromyoma* or fibroleiomyoma).tw.
5	exp Myoma/

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6	(myoma* adj4 (tumour* or tumor* or uter* or intrauter* or submucos* or subseros* or intramural* or pedunculated or cervical)).tw.
7	fibroid*.tw.
8	or/1-7
9	exp Laparoscopy/ and uterine myomectomy/
10	exp Laparoscopy/ and hysterectomy/ (3301)
11	(Laparoscop* adj4 (myomectom* or fibroidectom* or hysterectom*)).tw.
12	((transcervical* or trans-cervical*) adj4 resection*).tw.
13	or/9-12
14	Morcellation/
15	morcellat*.tw.
16	((fibroid* or myoma* or neoplasm* or tumour* or tumor* or growth* or fibroma* or leiomyoma* or leimyoma* or angioleiomyoma* or angiomyoma* or myofibroma* or leyomyoma or lesion*) adj4 (cut* or suck* or suction* or remov* or excis* or shav*)).tw.
17	or/14-16
18	13 and 17
19	8 and 18
20	XCise*.tw.
21	(PK adj2 morcellat*).tw.
22	VersaCut*.tw.
23	(Piranha adj2 morcellat*).tw.
24	or/20-23
25	19 or 24
26	animals/ not humans/
27	25 not 26
28	limit 27 to ed=20200901-20210430

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## Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the [summary of the key evidence](#). It is by no means an exhaustive list of potentially relevant studies.

### Additional papers identified

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
<b>Laparoscopic myomectomy only</b>			
Akdemir A, Taylan E, Zeybek B et al. (2015) Innovative technique for enclosed morcellation using a surgical glove. <i>Obstetrics and Gynaecology</i> 125(5): 1145-9	Case series  n=30	With the innovative technique, a disposable latex glove can be used for an enclosed morcellation that avoids piercing the enclosure container within the abdominal cavity, thereby offering decreased risks related to bag perforation and leakage compared with previous contained power morcellation techniques.	Small sample
Aksoy H, Aydin T, Ozdamar O et al. (2015) Successful use of laparoscopic myomectomy to remove a giant uterine myoma: a case report. <i>Journal of medical case reports</i> 9: 286	Case report  n=1	This case confirms the efficiency, reliability, and safety of a minimally invasive surgical approach to removing a giant uterine myoma. Thus, LM can be considered an alternative to the traditional abdominal myomectomy in patients with large myomas.	Single case report

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Alfaro-Alfaro J, Flores-Manzur MdLA, Nevarez-Bernal R et al. (2016) Complex laparoscopic myomectomy with severe adhesions performed with proper preventive measures and power morcellation provides a safe choice in certain infertility cases. Case reports in obstetrics and gynecology 2016: 4705790	Case report  n=1	Laparoscopic myomectomy, with power morcellation in cases such as these, with proper preventive controls, offers a real benefit for the infertile patient.	Single case report
Anupama R, Ahmad, SZ, Kuriakose S et al. (2011) Disseminated peritoneal leiomyosarcomas after laparoscopic "myomectomy" and morcellation. Journal of minimally invasive gynaecology 18(3): 386-9	Case report  n=1	This case shows that caution should be exercised when selecting patients for laparoscopic myomectomy and stresses the need for a thorough pathologic examination of the specimen retrieved.	Single case report
Asgari, Z., Salehi, F., Hoseini, R. et al. (2020) Ultrasonographic Features of Uterine Scar after Laparoscopic and Laparoscopy-Assisted Minilaparotomy Myomectomy: A Comparative Study. Journal of Minimally Invasive Gynecology 27(1): 148-154	Non-randomised comparative study  n=64 (39 LM compared with 25 LAM)	There were no differences in myometrial scar features after LM compared with after LAM, implying effective suturing via both approaches. One patient in the LM group experienced a bowel injury resulting from morcellation.	Studies with a larger sample or better design were included in the main summary.
Bogani G, Ditto A, Martinelli F et al.	Case report	This case highlights the effects of	Single case report

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<p>(2016) Morcellator's port-site metastasis of a uterine smooth muscle tumour of uncertain malignant potential after minimally invasive myomectomy. Journal of minimally invasive gynaecology 23(4): 647-9</p>	<p>n=1</p>	<p>intraabdominal morcellation, even in low-grade uterine neoplasms. Caution should be used when determining techniques for tissue extraction; the potential adverse consequences of morcellation should be more fully explored</p>	
<p>Bogani G, Uccella S, Cromi A et al. (2014) Electric motorized morcellator versus transvaginal extraction for myoma retrieval after laparoscopic myomectomy: a propensity-matched analysis. Journal of minimally invasive gynaecology 21(5): 928-34</p>	<p>Non-randomised comparative study  n=100 (50 EMM compared with 50 TVE)</p>	<p>Transvaginal extraction upholds the effectiveness of electric motorised morcellator, minimizing the operative time and potentially postoperative pain. Further large prospective studies are needed.</p>	<p>Studies with a larger sample or a better design were included in the main summary.</p>
<p>Bryant-Smith A and Holland T (2018) Laparoscopic myomectomy: a review of alternatives, techniques and controversies. Obstetrician and Gynaecologist 20(4): 261-8</p>	<p>Review</p>	<p>Morcellation should remain available to providers and patients, but a frank discussion of the risk stratification process should occur during preoperative counselling.</p>	<p>Review article</p>
<p>Buckley VA, Nesbitt-Hawes EM, Atkinson P et al. (2015) Laparoscopic myomectomy: clinical outcomes and comparative evidence. Journal of minimally invasive</p>	<p>Review</p>	<p>where the skill set exists, laparoscopic myomectomy is a reasonable alternative to abdominal myomectomy and offers both advantages and disadvantages.</p>	<p>Review article</p>

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gynaecology 22(1): 11-25		Discussion and disclosure with the patient is essential when considering the approach to myomectomy, and continued reporting of complications is advised.	
Chang WC, Huang PS, Wang PH et al. (2012) Comparison of laparoscopic myomectomy using in situ morcellation with and without uterine artery ligation for treatment of symptomatic myomas. Journal of minimally invasive gynaecology 19(6): 715-21	Non-randomised comparative study  n=144 (45 LUAL plus in situ morcellation compared with 99 in situ morcellation)	Laparoscopic myomectomy using an ISM technique with or without simultaneous LUAL may be used in the management of symptomatic uterine myomas; however, LUAL+ISM may result in a better surgical outcome.	Studies with a larger sample or better design were included in the main summary.
Chen SY, Huang SC, Sheu BC et al. (2010) Simultaneous enucleation and in situ morcellation of myomas in laparoscopic myomectomy. Taiwanese journal of obstetrics & gynaecology 49(3): 279-84	Non-randomised comparative study  n=82 ( group A with myomas <150 g n=31; group B with myomas 150 to 349 g n=27; and group C with myomas ≥350 g n=24)	In situ morcellation was an efficient and safe procedure for removal of large uterine myoma during laparoscopic myomectomy.	Studies with a larger sample or better design were included in the main summary.
Chin H, Ng XHA, Chern SMB (2016) Power morcellation- an emerging risk complicating minimally invasive surgery for uterine mesenchymal neoplasms. Gynaecology and	Case series  n=3,013 laparoscopic morcellation  n=7 unsuspected malignancy	Laparoscopic surgery had proven benefits over open surgery, although the dissemination of unexpected malignancy and extrauterine seeding were major concerns. To date, morcellation in the endobag or	This study determined the local incidence and clinical consequences of sarcomas or tumours with atypical features, after intraperitoneal

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Minimally Invasive Therapy 5(3): 109-11		cutting the specimen using a knife or scissors may be alternative surgical techniques.	dissemination via morcellation.
Carter JE and McCarus SD (1997) Laparoscopic myomectomy. Time and cost analysis of power vs. manual morcellation. The Journal of reproductive medicine 42(7): 383-8	Non-randomised comparative study  n=24 (14 electromechanical morcellation compared with 14 manual morcellation)	Electromechanical morcellation results in significant time savings as compared to the manual technique. Financial savings accrue rapidly after the 21 <sup>st</sup> case.	Small sample and limited clinical data were reported.
Chin, Hsuan, Ong, Xiaohui H, Yam, Philip Kwai Lam et al. (2014) Extrauterine fibroids: a diagnostic challenge and a long-term battle. BMJ case reports 2014	Case series  n=6	Authors recommend physicians to make sure that counselling for extrauterine seeding and dissemination of unexpected malignancy is undertaken in cases of minimally invasive surgeries where morcellation is expected. Long-term tumour surveillance is thus essential in such instances.	Small sample
Dubuisson JB and Chapron C (1996) Uterine fibroids: place and modalities of laparoscopic treatment. European journal of obstetrics, gynaecology, and reproductive biology 65(1): 91-4	Case series  n=71	The feasibility of laparoscopic myomectomy has now been proved. This technique requires experienced laparoscopic surgeons with total mastery of endoscopic suture. Although it is a difficult surgical procedure, laparoscopic myomectomy is	Small sample and various techniques used.

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		possible even for large myomas and those that are completely intramural in location.	
Epstein JH, Nejat EJ and Tsai T (2009) Parasitic myomas after laparoscopic myomectomy: case report. Fertility and sterility 91(3): 932e13-4	Case report  n=1	Pieces of initial myoma dispersed within the pelvis during morcellation may have developed into parasitic myomas.	Single case report
Glaser, Laura M, Friedman, Jaclyn, Tsai, Susan et al. (2018) Laparoscopic myomectomy and morcellation: A review of techniques, outcomes, and practice guidelines. Best practice & research. Clinical obstetrics & gynaecology 46: 99-112	Review	Authors advocate for a minimally invasive approach to myomectomy with contained morcellation in appropriate pre-menopausal patients without risk factors or clinical characteristics concerning for occult malignancy. Patients should be thoroughly counselled and should be offered alternative methods of surgery during preoperative counselling.	Review article
Grover A and Bhalla S (2015) Parasitic leiomyoma: A rare complication following laparoscopic myomectomy with review of literature. Current Medicine Research and Practice 5(6): 278-81	Case report and literature review  n=1	Iatrogenic leiomyomas though rare, are diagnostic dilemma for clinicians as they mimic malignancies on imaging and clinically. For pathologist it is important to know the previous history of myomectomy to diagnose an iatrogenic leiomyomas	Single case report

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		occurring in unusual sites.	
Huang PS, Chang WC and Huang SC (2014) Iatrogenic parasitic myoma: a case report and review of the literature. Taiwanese journal of obstetrics & gynecology 53(3): 392-6	Case report and literature review	Parasitic myoma frequently occurs in the dependent part of the abdominal cavity, which suggests seeding of myometrial tissues during morcellation. In situ morcellation and vigorous irrigation with concomitant changes in position may decrease the incidence of retained myoma tissue in the abdomen during surgery.	Single case report
Jan H, Al-Khatib AH, Araklitis G et al. (2014) A 5-mm port-site hernia following a laparoscopic myomectomy resulting in bowel obstruction. Journal of Gynaecologic Surgery 30: 247-250	Case report n=1	Elective closure of the rectus irrespective of port size should be considered in cases of prolonged manipulation through the port or repeated reinsertion of a trocar, both of which may lead to an extension of an initial incision.	Single case report
Kade G, Spaleniak S, Frankowska E et al. (2020) Disseminated peritoneal leiomyomatosis – a rare complication of laparoscopic myomectomy with intraperitoneal morcellation.	Case report n=1	The paper presents a very rare case of multiple myoma metastases to the peritoneal cavity and, most likely, to the lungs. The described case is the first case of benign metastasising leiomyoma with concomitant peritoneal	Single case report

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		metastases and endometriosis.	
Kai K, Aoyagi Y, Nishida M et al. (2020) Port-site implantation of parasitic leiomyoma after laparoscopic myomectomy and its histopathology. SAGE Open Medical Case Reports 8	Case report n=1	Seven years after the primary surgery (laparoscopic myomectomy with power morcellation and ovarian cystectomy), she underwent abdominal myomectomy for a port-site, and peritoneal recurrence of the leiomyoma and intramural leiomyomas was detected.	Single case report
Kavallaris A, Zygouris D, Chalvatzas N et al. (2013) Laparoscopic myomectomy of a giant myoma. Clinical and experimental obstetrics & gynaecology 40(1): 178-80	Case report n=1	Laparoscopic myomectomy can be an option even for giant myomas, with the condition of an expert surgeon and appropriate surgical instruments.	Single case report
Kim SM, Baek JM, Park EK et al. (2015) A comparison of single-, two- and three port laparoscopic myomectomy. Journal of the Society of Laparoscopic Surgeons, 19(4), e2015.00084	Non-randomised comparative study n=191 (single-port n=61, two-port n=37 and three-port n=93)	Single- or two-port myomectomy with transumbilically contained manual morcellation of the myoma, is feasible and safe, with outcomes comparable to those of three-port myomectomy with uncontained power morcellation. These results suggest the potential for minimally invasive management of symptomatic uterine myoma, without the	Studies with a larger sample or better design were included in the main summary.

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		use of a power morcellator.	
Ladke AB, Palaskar PA and Bhivsane VR (2020) Parasitic fibroid: complication of post-laparoscopic morcellation. Journal of Obstetrics and Gynecology of India	Case report n=1	Complications of parasitic fibroid can occur when morcellator is used in laparoscopic surgeries, because of the growth of tissue which have spread in pelvic cavity. To prevent this complication, endobag morcellation should be used.	Single case report
Leal MA, Pinera A, De Santiago J et al. (2017) Novel technique for contained power morcellation through umbilicus with insufflated bag. Gynaecologic and obstetric investigation 82(2): 205-207	Case series n=4	The novel technique for specimen power morcellation seems to be feasible and safe. In addition, it does not seem to be very time consuming; so it could become a new option for laparoscopic myomectomy.	Small sample
Lee JR, Lee JH, Kim JY et al. (2014) Single port laparoscopic myomectomy with intracorporeal suture-tying and transumbilical morcellation. European journal of obstetrics, gynaecology, and reproductive biology 181: 200-4	Case series n=100	Single-port laparoscopic myomectomy (SPLM) is safe and acceptable for various myoma sites and sizes up to 12 cm. Intracorporeal suture-tying and transumbilical morcellation are key technical points of SPLM.	Studies with a larger sample or better design were included in the main summary.
Li B, Zhang S, Ma N et al. (2017) Combining situ-morcellation with continuous-fill-mattress suture in	Non-randomised comparative study	The combining situ-morcellation with continuous-fill-mattress suture shows significant advantages in	Studies with a larger sample or better design were included in

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laparoscopic myomectomy: A surgical approach of choice for patients with large uterine fibroids. <i>Medicine</i> 96(31): e7672	n=116 (62 combining situ-morcellation with continuous-fill-mattress suture compared with 54 conventional LM)	shortening surgery time and reducing blood loss compared with conventional group in laparoscopic myomectomy.	the main summary.
Miyake T, Enomoto T, Ueda Y et al. (2009) A case of disseminated peritoneal leiomyomatosis developing after laparoscope-assisted myomectomy. <i>Gynaecologic and obstetric investigation</i> 67(2): 96-102	Case report n=1	The case report showed that 3 fibroids resected 2 years later and 14 fibroids resected 6 years later were all metastatic tumours originating from the uterine leiomyoma found during the initial surgery, suggesting that morcellation before removal of the leiomyoma nodule during laparoscopic myomectomy may have been associated with the pathogenesis of this case.	Single case report
Nappi L, Sorrentino F, Angioni S et al. (2016) Leiomyomatosis peritonealis disseminata (LPD) ten years after laparoscopic myomectomy associated with ascites and lymph nodes enlargement: A case report. <i>International Journal of Surgery Case Reports</i> 25: 1-3	Case report n=1	Pieces of smooth muscle cell lost in the abdominal cavity during electrical morcellation after laparoscopic myomectomy may progress to leiomyomatosis peritonealis disseminata even after many years (10 years in this case) and it can be associated with ascites and lymph nodes enlargement.	Single case report
Oindi FM, Mutiso SK and Obura T (2018)	Case report	Care should be taken during power	Single case report

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<p>Port site parasitic leiomyoma after laparoscopic myomectomy: a case report and review of the literature. <i>Journal of medical case reports</i> 12(1): 339</p>	<p>n=1</p>	<p>morcellation to prevent excessive fragmentation of the tissues, some of which may become implanted and persist to form parasitic myomas. Moreover, effort should be made to retrieve all myoma fragments by carefully checking the abdominal cavity. Whenever possible, the morcellation should be done in a containment bag.</p>	
<p>Pados G, Tsolakidis D, Theodoulidis V et al. (2017) Prevalence of occult leiomyosarcomas and atypical leiomyomas after laparoscopic morcellation of leiomyomas in reproductive-age women. <i>Human Reproduction</i> 32(10): 2036-41</p>	<p>Case series n=1,216 laparoscopic morcellation  6 atypical-bizarre and 1 mitotically active leiomyomas</p>	<p>Laparoscopic morcellation of unsuspecting leiomyomas after careful preoperative work up seems to be safe in women of reproductive age.</p>	<p>This study identified the prevalence of occult uterine sarcomas and benign atypical leiomyomas after laparoscopic morcellation of presumed benign fibromas.</p>
<p>Pai AHY, Yen CF and Lin SL (2020) Parasitic leiomyoma. <i>Gynaecology and Minimally Invasive Therapy</i> 9: 108-9</p>	<p>Case report n=1</p>	<p>The case described that the tumour most likely arose from the iatrogenic spread of myoma debris by the morcellator. It then obtained its vascular supply from the pelvic tissue. When approaching female patients with abdominal masses, especially those with prior surgical history, parasitic myoma should be included as</p>	<p>Single case report</p>

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		part of her differential diagnoses.	
Paul PG, Thomas M, Das T et al. (2016) Contained morcellation for laparoscopic myomectomy within a specially designed bag. Journal of minimally invasive gynaecology 23(2): 257-60	Case series  n=10	There were no complications related to the in-bag morcellation technique, and there was no visual evidence of damage to the isolation bag. In-bag morcellation using this new bag is a feasible technique for morcellating uterine myomas in a contained manner and may provide an option to minimize the risks of open power morcellation while preserving the benefits of minimally invasive surgery.	Small sample
Park BY, Leslie KO, Chen L et al. (2017) A case of simultaneous benign metastasizing leiomyomas and disseminated peritoneal leiomyomatosis following endoscopic power morcellation for uterine disease. Female Pelvic Medicine and Reconstructive Surgery 23(1): e1-e3	Case report  n=1	Given that the median time to the diagnosis of metastatic leiomyomas can be delayed as long as 23 years from surgery and that the decline of power morcellation use occurred recently in the last 2 years, this phenomenon will likely continue to be found in the coming years.	Single case report
Parkar RB, Chudasama A and Chudasama M (2008) Laparoscopic myomectomy of a large pedunculated fibroid: case report.	Case report  n=1	A laparoscopic myomectomy was successfully undertaken, and the morcellated fragments weighed 1490 grams.	Single case report

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East African medical journal 85(7): 362-4			
Parmar J, Mohan C, Hans D et al. (2017) A diagnostic dilemma of recurrent disseminated peritoneal leiomyomatosis with hypertrophied omental vessels: imaging and embolization of omental branches with positive outcome. Case reports in obstetrics and gynaecology 2017: 8427240	Case report n=1	Uterine morcellation may result in seeding of myometrial tissue throughout the abdominal cavity that leads to serious morbidity and causes diagnostic dilemma. And the disseminated leiomyomatosis can seek blood supply from any nearby vessel.	Single case report
Paul PG and Koshy AK (2006) Multiple peritoneal parasitic myomas after laparoscopic myomectomy and morcellation. Fertility and sterility 85(2): 492-3	Case report n=1	The parasitic myomas could be explained by bits of myometrial tissue being left behind in the peritoneal cavity during the first surgical procedure. The location of these myomas is also suggestive of seeding of myometrial tissues after morcellation.	Single case report
Paul PG, Shintre H, Mehta S et al. (2018) Parasitic myomas: An unusual risk after morcellation. Gynaecology and Minimally Invasive Therapy 7(3): 124-6	Case report n=1	The formation of parasitic myomas was assumed to be due to the myomatous fragments which were left behind during morcellation at the time of initial myomectomy. Methods to prevent this complication are colpotomy, mini-laparotomy, or in-bag morcellation.	Single case report

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<p>Rossetti A, Sizzi O, Chiarotti F et al. (2007) Developments in techniques for laparoscopic myomectomy. JSLS: Journal of the Society of Laparoendoscopic Surgeons 11(1): 34-40</p>	<p>Non-randomised comparative study  n=332</p>	<p>With increased experience, the technical improvements and clinical results have changed our approach and decision making regarding laparoscopic myomectomy. The results and extremely low conversion rate suggest that laparoscopic myomectomy is a safe and reliable procedure even in the presence of multiple or enlarged myomas.</p>	<p>Limited outcomes were reported for laparoscopic morcellation.</p>
<p>Salman S, Ketenci GF, Babaoglu B et al. (2018) Unsuspected diagnosis of uterine leiomyosarcoma after laparoscopic myomectomy in an isolated bag. Case reports in obstetrics and gynaecology 2018: 6342081</p>	<p>Case report  n=1</p>	<p>Although isolation bag is generally reported to be preventive, recurrence of sarcoma was seen at 5th month of follow-up. Even though morcellation within a bag seems to block wide spreading, dispersion of tumour cannot be stopped and more investigations have to be done.</p>	<p>Single case report</p>
<p>Takeuchi H and Kuwatsuru R (2003) The indications, surgical techniques, and limitations of laparoscopic myomectomy. JSLS: Journal of the Society of Laparoendoscopic Surgeons 7(2): 89-95</p>	<p>Case series  n=89</p>	<p>LM appears to offer a number of advantages if the myoma is not larger than 10 cm.</p>	<p>Studies with a larger sample or better design were included in the main summary.</p>

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<p>Tan HL, Koh YX, Chew MH et al. (2019) Disseminated peritoneal leiomyomatosis: a devastating sequela of unconfined laparoscopic morcellation. Singapore medical journal 60(12): 652-654</p>	<p>Case report and literature review  n=1</p>	<p>DPL is a potentially devastating consequence of unconfined laparoscopic morcellation in the surgical management of uterine fibroids. A multidisciplinary approach is recommended in the management of DPL, especially in cases of multivisceral involvement. Clinical caution ought to be exercised when using power morcellators; when unavoidable, confined laparoscopic morcellation offers a promising mitigation and should be adopted if practicable.</p>	<p>Single case report</p>
<p>Tsai, H.-W., Ocampo, E.J., Huang, B.-S. et al. (2015) Effect of semisimultaneous morcellation in situ during laparoscopic myomectomy. Gynaecology and Minimally Invasive Therapy 4(4): 132-136</p>	<p>Non-randomised comparative study  n=122 (54 semisimultaneous morcellation in situ compared with 68 conventional morcellation)</p>	<p>The SSMI technique could shorten surgical time when a laparoscopic myomectomy is performed, but uterine size is also important.</p>	<p>Studies with a larger sample or better design were included in the main summary.</p>
<p>Van der Meulen JF, Pijnenborg JMA, Boomsma CM et al. (2016) Parasitic myoma after laparoscopic morcellation: a systematic review of the literature. BJOG : an international</p>	<p>Systematic review  n=44 studies</p>	<p>The overall incidence of parasitic myomas after laparoscopic morcellation was 0.12% to 0.95%. It is important to discuss the risk of parasitic myoma after laparoscopic morcellation with</p>	<p>Some of the main studies that reported parasitic myoma were included in the main summary.</p>

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journal of obstetrics and gynaecology 123(1): 69-75		women and balance towards alternative treatment options. The duration of steroid exposure after laparoscopic morcellation might be a risk factor for development of parasitic myomas.	
Walid MS and Heaton RL (2010) Laparoscopic myomectomy: an intent-to-treat study. Archives of gynaecology and obstetrics 281(4): 645-9	Case series n=41	Laparoscopic myomectomy is a safe procedure in the hands of an experienced advanced laparoscopic surgeon. Blood loss is dependent on the myoma size and bleeding is the most serious intraoperative complication which may require performing a staged laparoscopic myomectomy, conversion to open myomectomy or blood transfusion.	Small sample and limited outcomes were reported for laparoscopic morcellation.
Wang CJ, Lee JM, Yu HT et al. (2014) Comparison of morcellator and culdotomy for extraction of uterine fibroids laparoscopically. European journal of obstetrics, gynaecology, and reproductive biology 183: 183-7	Non-randomised comparative study n=416 (335 culdotomy compared with 81 electromechanical morcellation)	Fibroid size of 10 cm may be used as a guide for the route of fibroid removal; below 10 cm the morcellator is faster but more expensive, for fibroids 10 cm and above, culdotomy can be considered as it has a similar removal time to the morcellator in multiparae.	Studies with a larger sample or better design were included in the main summary.
Wang CJ, Yuen LT, Lee CL et al. (2006) A prospective	Non-randomised comparative study	There were no significant differences in tumour size, total	Studies with a larger sample or better design

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<p>comparison of morcellator and culdotomy for extracting of uterine myomas laparoscopically in nullipara. Journal of minimally invasive gynaecology 13(5): 463-6</p>	<p>n=78 (32 power morcellation compared with 46 culdotomy)</p>	<p>specimen weight, patient body weight, total operating time, blood loss, and postoperative stay between each group. Uterine myomas can be removed successfully through either port site in nullipara; however, because of reduced removal time, the power morcellator is preferred.</p>	<p>were included in the main summary.</p>
<p>Wright JD, Tergas AI, Cui R et al. (2016) Use of electric power morcellation and prevalence of underlying cancer in women who undergo myomectomy. Oncol. 1(1): 69-77</p>	<p>Non-randomised comparative study  n=41,777 (including 3,220 with electric power morcellation)</p>	<p>The prevalence of cancers and precancerous abnormalities of the uterus in women who undergo myomectomy with or without electric power morcellation is low overall, but risk increases with age. Electric power morcellation should be used with caution in older women undergoing myomectomy.</p>	<p>This study analysed the prevalence of underlying cancer and precancerous changes in women who had myomectomy with and without electric power uterine morcellation.</p>
<p>Yang H, Li XC, Yao C et al. (2017) Proportion of uterine malignant tumours in patients with laparoscopic myomectomy: a national multicentre study in china. Chinese medical journal 130(22): 2661-2665</p>	<p>Case series  n=33,723 LM  n=62 unsuspected uterine sarcoma</p>	<p>The proportion of malignancy is low after using morcellation in patients who undergo laparoscopic myomectomy. Patients with fast-growing uterine fibroids and abnormal ultrasonic tumour blood flow should be considered for malignant potential,</p>	<p>This study examined the incidence of unsuspected uterine sarcoma in patients who are exposed to a power morcellation during laparoscopic myomectomy for presumed benign leiomyoma.</p>

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		and morcellation should be avoided.	
Yang, R., Xu, T., Fu, Y. et al. (2015) Leiomyomatosis peritonealis disseminata associated with endometriosis: A case report and review of the literature. <i>Oncology Letters</i> 9(2): 717-720	Case report and literature review  n=1	The use of laparoscopic power morcellation may contribute to the development of LPD, therefore, the specific surgical approach used in laparoscopic myomectomy should be carefully considered, and protective measures should be taken to prevent myoma fragments spreading if laparoscopic power morcellation is used.	Single case report
Yoon HJ, Kyung MS, Jung US et al. (2007) Laparoscopic myomectomy for large myomas. <i>J Korean Med Sci</i> 22: 706-12	Case series  n=51	With the newly developed screw and the port placement system that was modified from the Choi's 4-trocar method to obtain better surgical vision, LM of large myomas proved to be one of the efficient and feasible methods.	Small sample
Yoshida A, Nii S, Matsushita H et al. (2015) Parasitic myoma in women after laparoscopic myomectomy: A late sequela of morcellation? <i>Journal of obstetrics and gynaecology : the journal of the Institute of Obstetrics and Gynaecology</i> 35(3): 322-3	Case series  n=2	the pathogenesis of parasitic myoma is considered to be multifactorial and accumulation of further cases is needed to fully understand the pathogenesis of parasitic myoma after morcellation. However, it is important that surgeons try to remove all fragments after morcellation	Small sample

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<p>Yoshihiro N, Takahiro S, Kenji S et al. (2019) Retrospective study of collection methods in laparoscopic myomectomy. The Tokai journal of experimental and clinical medicine 44: 54-8</p>	<p>Non-randomised comparative study  n=69 (power morcellation n=37 compared with manual morcellation n=32)</p>	<p>None required allogeneic transfusion or a transition to open surgery and none had surgical or post-surgical complications. At multiple linear regression analysis, which was adjusted by age, body mass index, and intraoperative blood loss, significant difference was not observed in operation time between the power morcellation and manual morcellation groups.</p>	<p>Studies with a larger sample or better design were included in the main summary.</p>
<p>Yoshino Y, Yoshiki N, Nakamura R et al. (2020) Large leiomyomatosis peritonealis disseminate after laparoscopic myomectomy: a case report with literature review. International journal of surgery case reports 77: 866-9</p>	<p>Case report  n=1</p>	<p>A large leiomyomatosis peritonealis disseminata is not always symptomatic. After a laparoscopic myomectomy, especially with power morcellation, long-term follow-up is necessary to detect leiomyomatosis peritonealis disseminata.</p>	<p>Single case report</p>
<p>Yu SP, Lee BB, Han MN et al. (2018) Irrigation after laparoscopic power morcellation and the dispersal of leiomyoma cells: a pilot study. Journal of minimally invasive gynecology 25(4): 632-637</p>	<p>Case series  n=16</p>	<p>In this pilot study myoma cells were disseminated before electromechanical morcellation. Irrigation and suctioning with 3 L normal saline or sterile water after morcellation may reduce myoma cell dissemination.</p>	<p>Small sample, evaluating if copious irrigation and suctioning after power morcellation will reduce myoma cell dissemination.</p>

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<p>Zhang P, Song K, Li L et al. (2011) Application of simultaneous morcellation in situ in laparoscopic myomectomy of larger uterine leiomyomas. Medical principles and practice : international journal of the Kuwait University, Health Science Centre 20(5): 455-8</p>	<p>Case series  n=26</p>	<p>Simultaneous morcellation in situ is an efficient and safe way to remove large uterine myomas (&gt;9 cm) during LM.</p>	<p>Small sample</p>
<p>Zhang J, Zhang J, Dai Y et al. (2015) Clinical characteristics and management experience of unexpected uterine sarcoma after myomectomy. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 130(2): 195-9</p>	<p>Non-randomised comparative study  n=4,248</p>	<p>The overall incidence of unexpected uterine sarcoma after myomectomy was low. Incidental power morcellation of unexpected uterine sarcoma seemed to cause no increase in sarcoma dissemination.</p>	<p>No outcome data were reported for laparoscopic morcellation of uterine fibroids</p>
<p>Zullo F, Venturella R, Raffone A et al. (2020) In-bag manual versus uncontained power morcellation for laparoscopic myomectomy. The Cochrane database of systematic reviews 5: cd013352</p>	<p>Systematic review and meta-analysis  n=176 (2 trials)</p>	<p>We found very low-quality evidence of inconclusive results for total operative time (MD 9.93 minutes, 95% CI - 1.35 to 21.20; 2 studies, 176 participants; IN = 35%), and ease of morcellation (MD - 0.73 points, 95% CI - 1.64 to 0.18; 1 study,</p>	<p>The selected trials were included in the main summary.</p>

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		104 participants). The morcellation operative time was a little longer for the in-bag manual morcellation group, however the quality of the evidence was very low (MD 2.59 minutes, 95% CI 0.45 to 4.72; 2 studies, 176 participants; IN = 0%). There were no postoperative diagnoses of leiomyosarcoma made in either group in either trial.	
<b>Laparoscopic hysterectomy only</b>			
Adelman MR (2015) The morcellation debate: the history and the science. Clinical obstetrics and gynaecology 58(4): 710-7	Review	The risk of inadvertent morcellation of a uterine malignancy, and subsequent dissemination of occult cancer, must be balanced by the risks of increased numbers of laparotomies. Power morcellation should be available to appropriate surgical candidates.	Review article
Agrawal P, Agrawal R and Chandrakar J. (2016) To assess the safety of morcellation for removing uterine specimen during laparoscopic and vaginal hysterectomies for leiomyomas. Journal of Obstetrics and Gynecology of India 66: 567-72	Case series n=232	The risk of occult LMS is extremely low, especially in reproductive age group women. More studies and guidelines are required for Indian women.	The outcomes were not separated for laparoscopic hysterectomy with morcellation.

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Akintobi, A O, Bello, O, Asaolu, O A et al. (2015) Laparoscopic supracervical hysterectomy and uterine morcellation: A case report from Asokoro District Hospital, Abuja, Nigeria. Nigerian journal of clinical practice 18(6): 824-7	Case report  n=1	The case showed that the uterine size is not a limitation to laparoscopic hysterectomy. With proper port placement and adequate skills, LSCH of big size uteri can be safely achieved.	Single case report
Anaf V, Simon P, Govaerts I et al. (1998) Pitfall of the LASH technique: An unsuspected leiomyosarcoma removed after morcellation. Gynaecological Endoscopy 7(1): 47-9	Case report  n=1	Because of the rarity of sarcomas, the laparoscopic approach should not be refused in all cases where this diagnosis is suspected, but intraperitoneal dissemination should be avoided by removing the uterus intact through the vagina, or in a bag without morcellation.	Single case report
Anand N, Handler M, Khan A et al. (2016) Disseminated peritoneal leiomyomatosis status post laparoscopic hysterectomy with morcellation. Journal of radiology case reports 10(12): 12-8	Case report  n=1	One option for hysterectomy due to symptomatic fibroids includes laparoscopic use of power morcellation. If all fragments are not removed, they may parasitise to other blood supplies and present as abdominal or pelvic masses. Intraperitoneal leiomyomas should be included in the differential diagnosis of multiple abdominal and pelvic masses in patients with a history of prior morcellator-	Single case report

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		assisted hysterectomy.	
Brown J, Taylor K, Ramirez PT et al. (2015) Laparoscopic supracervical hysterectomy with morcellation: should it stay or should it go? Journal of minimally invasive gynaecology 22(2): 185-92	Case series n=808  Most common indications: menorrhagia n=472 and leiomyomata n=400	In this cohort of patients who underwent laparoscopic SCH, the risk of hyperplasia or malignancy was low. Laparoscopic SCH with morcellation appears to be a low risk procedure.	The outcomes were not separated for patients with leiomyomata.
Bojahr B, De Wilde RL and Tchartchian G (2015) Malignancy rate of 10,731 uteri morcellated during laparoscopic supracervical hysterectomy (LASH). Archives of gynaecology and obstetrics 292(3): 665-72	Case series n=10,731	In 10,731 morcellated uteri during LASH only 0.06 % sarcoma and 0.07 % endometrial carcinoma were detected. All patients should be informed about the rare possibility of a malignant disease during pre-operative counselling. With a timely follow-up surgery according to the oncologic guidelines, our data suggest a very good prognosis in terms of survival after LASH with morcellation of malignant tumours in the uterus.	Limited outcomes were reported for laparoscopic morcellation of uterine fibroids but rather describing recurrences and follow-up surgery for 8 cases of uterine malignomas which were detected during LASH but not caused by morcellation.
Bojahr B, Raatz D, Schonleber G et al. (2006) Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique. Journal of minimally invasive	Case series n=1,706	Laparoscopic supracervical hysterectomy is a minimally invasive surgical method that should be regarded as an alternative to all other methods of total hysterectomy in benign conditions of the uterus (uterine	Complications were caused by LSH rather than morcellation.

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gynaecology 13(3): 183-9		myomata, dysfunctional uterine bleeding, uterine adenomyosis) as it is associated with a low perioperative morbidity and a rapid period of convalescence.	
Boruta DM and Shibley T (2016) Power morcellation of unsuspected high-grade leiomyosarcoma within an inflated containment bag: 2-year follow-up. Journal of minimally invasive gynaecology 23(6): 1009-11	Case report n=1	Power morcellation within an inflated containment bag may minimise the risk that women undergoing laparoscopic hysterectomy with morcellation have a worse prognosis when diagnosed with an unexpected malignancy.	Single case report
Della B Carl and KH (2010) Endometrial stromal sarcoma diagnosed after uterine morcellation in laparoscopic supracervical hysterectomy. Journal of minimally invasive gynaecology 17(6): 791-3	Case report n=1	Morcellation of leiomyomas at laparoscopic supracervical hysterectomy may potentially increase metastasis if the tumour is a sarcoma.	Single case report
Delbos L, Laberge PY, Lemyre M et al. (2019) Pyomyoma after uterine artery embolization: laparotomy avoided by in-bag morcellation. Journal of minimally invasive gynaecology 26(1): 175-7	Case report n=1	Surgeries for pyomyoma and following UAE can be challenging, but laparoscopy remains a viable option to allow for a minimally invasive approach with contained morcellation. Complications of UAE appear more common with single	Single case report

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		large leiomyomas, which should be kept in mind for optimal counselling and management of women with leiomyomas.	
Dewulf K, Weyns V, Lelie B et al. (2019) Ectopic leiomyoma as a late complication of laparoscopic hysterectomy with power morcellation: a case report and review of the literature. Acta chirurgica Belgica: 1-5	Case report and literature review  n=1	Ectopic leiomyoma is a late and rare complication of a laparoscopic hysterectomy with power morcellation of the uterus.	Single case report
Dioun SM and Soliman PT (2015) Laparoscopic hysterectomy with morcellation for a suspected uterine fibroid resulting in dissemination of cervical adenocarcinoma: A case report. Gynaecologic oncology reports 12: 5-6	Case report  n=1	This is 1 of the first reported cases of an undetected cervical cancer morcellated at the time of surgery for uterine fibroids resulting in wide dissemination of disease and a poor outcome. This case highlights the importance of cervical cancer screening prior to surgery and in particular when morcellation is being considered.	Single case report
Donnez O, Squifflet J, Leconte I et al. (2007) Posthysterectomy pelvic adenomyotic masses observed in 8 cases out of a series of 1405 laparoscopic subtotal	Case series  n=1,405  8 heterogeneous masses	The reported lesions probably result from the growth of missed fragments of uterine corpus after previous morcellation, culminating in the development of symptomatic	This study was included in Tulandi (2016) in the key summary.

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<p>hysterectomies. Journal of minimally invasive gynaecology 14(2): 156-60</p>		<p>iatrogenic adenomyomas. For this reason, the abdominal cavity must be meticulously inspected after electric morcellation, especially in patients with adenomyotic uteri.</p>	
<p>Emoto I, Moriuchi K, Kanbayashi S et al. (2018) Power morcellation-induced dissemination of sarcomatous component arising in leiomyoma. The journal of obstetrics and gynaecology research 44(9): 1843-9</p>	<p>Case report  n=1</p>	<p>Use of power morcellation should be minimized until the advent of novel methods that can perfectly differentiate benign from malignant uterine tumours preoperatively.</p>	<p>Single case report</p>
<p>Hinchcliff EM and Cohen SL (2016) Laparoscopic hysterectomy for uterine fibroids: is it safe? Clinical obstetrics and gynaecology 59(1): 66-72</p>	<p>Review</p>	<p>To mitigate the risks of tissue morcellation, containment system use must be considered when fragmenting a specimen, either with power morcellation or a manual technique via the vagina or minilaparotomy. Advances in technology and devices available to facilitate contained tissue extraction will allow minimally invasive approach to hysterectomy to remain a viable option for most patients.</p>	<p>Review article</p>
<p>Holloran-Schwartz MB, Fierro M and Tritto A (2015)</p>	<p>Case report</p>	<p>Gynaecologic surgeons should be aware of possible</p>	<p>Single case report</p>

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Delayed presentation of a paracytic myoma fragment after laparoscopic supracervical hysterectomy requiring small bowel resection. A case report. The Journal of reproductive medicine 60(12): 75-7	n=1	delayed postoperative complications that can result from parasitic myoma fragments inadvertently left behind following morcellation.	
Holzmann C, Saager C, Mechttersheimer G et al. (2018) Malignant transformation of uterine leiomyoma to myxoid leiomyosarcoma after morcellation associated with ALK rearrangement and loss of 14q. Oncotarget 9(45): 27595-27604	Case report n=1	The case is challenging the current risk estimates for spreading of unexpected malignant uterine tumours due to power morcellation and highlights the relevance of certain genetic alterations for rare malignant transformation of uterine benign smooth muscle tumours.	Single case report
Hutchins FLJ and Reinoehl EM (1998) Retained myoma after laparoscopic supracervical hysterectomy with morcellation. The Journal of the American Association of Gynaecologic Laparoscopists 5(3): 293-5	Case report n=1	When a patient complains of localised, persistent, severe pain after an advanced laparoscopic procedure with morcellation, early imaging studies to localise retained fragments, plus a high index of suspicion, may facilitate management by minimally invasive surgery.	Single case report
Kill LM, Kapetanakis V, McCullough AE et	Case report	The patient with no prior history of	Single case report

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al. (2011) Progression of pelvic implants to complex atypical endometrial hyperplasia after uterine morcellation. Obstetrics and gynecology 117(2pt2): 447-9	n=1	endometrial atypia later developed complex adenomatous endometrial hyperplasia in a peritoneal implant. This finding adds to the list of possible complications after laparoscopic-assisted supracervical hysterectomy and uterine morcellation.	
Krentel H and De Wilde RL (2016) Complications in laparoscopic supracervical hysterectomy(LASH), especially the morcellation related. Best practice & research. Clinical obstetrics & gynaecology 35: 44-50	Review	New techniques like morcellation bags could aid in avoiding the risk of inadvertent tissue dissemination. However, further studies on certain subjects are warranted. Patients must be informed about all possible risks of LASH before surgery: Alternative approaches and extraction techniques should be discussed.	Review article
Kruger PF and Lee P (2014) Disseminated peritoneal leiomyomatosis: A case report and review of current events in the media and the literature. South African Journal of Obstetrics and Gynaecology 20(3): 91-92	Case report  n=1	With the increase in laparoscopic hysterectomies and myomectomies, this case highlights the need for surgical diligence in removal of all morcellated fragments of the specimen. The patient should be made aware of the potential risks of this technique of tissue extraction.	Single case report
LaCoursiere DY, Kennedy J and	Case report	As laparoscopic morcellation is	Single case report

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Hoffman CP (2005) Retained fragments after total laparoscopic hysterectomy. Journal of minimally invasive gynaecology 12(1): 67-9	n=1	performed with increased frequency, the need to understand its sequelae has also increased. A concern of morcellating tissue within the abdomen is the fate of fragments inadvertently left behind.	
Li PC, Lee MH, Wei, YC et al. (2020) Iatrogenic parasitic myoma with two recurrence times after subsequent myomectomy: A rare and complicated case report. Gynaecology and Minimally Invasive Therapy 9(3): 154-158	Case report  n=1	This case study highlights the importance of specimen containment before morcellation in minimally invasive surgery and implies that the pathogenesis of PM recurrence is unknown.	Single case report
Lieng M, Istre O, Busund B et al. (2006) Severe complications caused by retained tissue in laparoscopic supracervical hysterectomy. Journal of minimally invasive gynaecology 13(3): 231-3	Case series  n=2	In addition to adequate tissue morcellating and final inspection of the abdominal cavity, clinicians should be aware of the possible complications related to tissue remnants after surgery involving tissue morcellating.	Small sample
Narasimhulu DM, Eugene E and Sumit S. (2015) Torsion of an iatrogenic parasitic fibroid related to power morcellation for specimen retrieval. Journal of the Turkish German	Case report  n=1	Iatrogenic parasitic fibroids are rare complications after previous uterine surgery, and an acute presentation due to torsion is even rarer. Most of these patients present with severe pain and	Single case report

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Gynaecology Association 16(4): 259-62		peritoneal signs. Low-grade fever and leukocytosis may be present. MRI is the best tool to evaluate these lesions. Awareness of this potential complication will reduce the delay in diagnosis and facilitate appropriate management.	
Oh SJ, Lee SY, Kim WY et al. (2020) Comparison between transumbilical and transvaginal morcellation of a large uterus during single-port-access total laparoscopic hysterectomy. Obstetrics & gynecology science 63(3): 379-86	Non-randomised comparative study  n=57 (30 TUM compared with 27 TVM)	TUM during SPA-TLH is a feasible technique for extracting large uteri weighing $\geq 500$ g. This procedure is suitable for patients without a history of vaginal delivery or a narrow vaginal cavity.	Studies with a larger sample or better design were included in the main summary.
Sepilian V and Della Badia C (2003) Iatrogenic endometriosis caused by uterine morcellation during a supracervical hysterectomy. Obstetrics and Gynaecology 102: 1125-7	Case report  n=1	Spillage and implantation of viable endometrial tissue might occur during uterine morcellation during laparoscopic supracervical hysterectomy. This case emphasises the importance of minimizing spillage and vigorous irrigation of the abdomen and pelvis before closing the incisions.	Single case report
Raine-Bennett T, Tucker LY, Zaritsky E et al (2015) Occult uterine sarcoma and leiomyosarcoma: Incidence of and	Case series  n=125 patients with occult uterine sarcomas	Morcellation is associated with decreased early survival of women with occult leiomyosarcomas.	Studies with a larger sample or better design were included in the main summary.

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survival associated with morcellation. Obstetrics & gynaecology 127: 29-39			
Rechberger T, Miotla P, Futyma K et al. (2016) Power morcellation for women undergoing laparoscopic supracervical hysterectomy - safety of procedure and clinical experience from 426 cases. Ginekologia polska 87(8): 546-51	Case series  n=426	The incidence of unintended endometrial carcinoma in morcellated uterus after LASH was relatively small. However, careful pre-operative counselling should be undertaken in order to exclude the possibility of any malignant disease in uteri among women scheduled to power morcellation.	Studies with a larger sample or better design were included in the main summary.
Rimbach, S., Holznecht, A., Schmedler, C. et al. (2016) First clinical experiences using a new in-bag morcellation system during laparoscopic hysterectomy. Archives of Gynaecology and Obstetrics 294(1): 83-93	Non-randomised comparative study  n=14 (7 contained in-bag morcellation compared with 7 uncontained morcellation)	This study proved evidence of technical feasibility of More-Cell-Safe in the clinical setting of laparoscopic hysterectomy. Instruction and training may be favourable to avoid technical difficulties. Further development should aim to allow, as well, morcellation of extremely large specimens.	Small sample
Rimbach S and Schempershofe M (2017) In-bag morcellation as a routine for laparoscopic hysterectomy. BioMed research international 2017: 6701916	Case series  n=49	The technique presented here allows in-bag power morcellation during laparoscopic hysterectomy in a usual multiport approach with proven feasibility. Preventive effectiveness against	Small sample

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		spilling from morcellated tissue is suggested by reproducible results of negative peritoneal washings.	
Ruan JY, Chen HQ, Gong Y H et al. (2016) Laparoscopic subtotal hysterectomy due to giant uterine fibroids: a case report. Clinical and experimental obstetrics & gynaecology 43(1): 134-6	Case report n=1	It was the first time authors did the LSH for so giant uterus, but if the operation space and visual field could be enlarged effectively, giant uterus like this case can also be removed successfully. The practiced hands and good cooperation are both important for the operation which can shorten operation time and reduce injuries.	Single case report
Sinha R, Sundaram M, Lakhotia S et al. (2009) Total laparoscopic hysterectomy for large uterus. Journal of Gynaecological Endoscopy and Surgery 1(1): 34-9	Case series n=173	Total laparoscopic hysterectomy is a technically feasible procedure. It can be performed by experienced surgeons for large uteri regardless of the size, number or location of the myomas	Studies with a larger sample or better design were included in the main summary.
Sanneh A, Murdock T, Wethington SL et al. (2020) Low-grade endometrial stromal sarcoma diagnosed 8 years after hysterectomy with morcellation. Obstetrics and gynaecology 136(2): 365-8	Case report n=1	Morcellation of the uterus can hinder an accurate pathologic diagnosis of uterine stromal neoplasms.	Single case report
Szymczak P, Sawicki S and Wydra D	Case report	The statement of the FDA has encouraged	Single case report

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<p>(2017) Laparoscopic supracervical hysterectomy with the use of the More-Cell-Safe system in a patient with uterine leiomyomas. <i>Ginekologia polska</i> 88(2): 113-4</p>	<p>n=1</p>	<p>scientists to look for new procedures which would allow to morcellate in a safer way, decreasing the risk of unsuspected malignant dissemination. The More-Cell-Safe system could be an acceptable and feasible alternative form of tissue delivery during laparoscopic procedures.</p>	
<p>Takahashi T, Ugajin T, Imai N et al. (2019) Leiomyosarcoma after total laparoscopic hysterectomy with power morcellation. <i>Case reports in obstetrics and gynaecology</i> 2019: 9381230</p>	<p>Case report n=1</p>	<p>Even if the initial pathologic evaluation suggests a benign mass, parasitic myoma and even sarcoma can occur after TLH with power morcellation. Considering the risk of dissemination and occult malignancy, the use of power morcellation should be avoided if there are alternative options to remove the tumour.</p>	<p>Single case report</p>
<p>Tchartchian G, Dietzel J, Bojahr B et al. (2010) No more abdominal hysterectomy for myomata using a new minimally-invasive technique. <i>International Journal of Surgery Case Reports</i> 1(1): 7-8</p>	<p>Case report n=1</p>	<p>The minimally invasive hysterectomy has already proven to be the more effective surgical technique in larger studies. The LACH seems to be a feasible alternative to the laparotomy in the described group and promising regarding the possibility to</p>	<p>Single case report</p>

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		extend minimal-invasive procedures.	
Turner T, Secord, AA, Lowery WJ et al. (2013) Metastatic adenocarcinoma after laparoscopic supracervical hysterectomy with morcellation: A case report. <i>Gynaecologic Oncology Reports</i> 5: 19-21	Case report n=1	The case illustrates the potential risk of metastatic adenocarcinoma diagnosed after hysterectomy with uterine morcellation. Definite causal relationship of metastatic disease as a result of morcellation cannot be proven; however, in the setting of an unknown cancer diagnosis at time of morcellation, subsequent widespread dissemination in the pelvis may result.	Single case report
Van Wijngaarden WJ and Filshie GM (2001) Laparoscopic supracervical hysterectomy with Filshie clips. <i>Journal of the American Association of Gynaecologic Laparoscopists</i> 8(1): 137-42	Case series n=12	LSH is a valid addition to gynaecologic procedures. Of all techniques used, we found the optimal combination to be an endoscopic swivel head stapling device to the infundibulopelvic or ovarian ligaments, Filshie clips to the uterine arteries, cutting diathermy to transect the cervix, and motorised morcellator to remove the uterine body.	Small sample
Wilkie GL, Reus E, Leung K et al. (2018) Occult malignancy incidence and preoperative	Non-randomised comparative study	The risk of occult malignancy noted during hysterectomy was low overall. Preoperative	Outcomes were not separated for laparoscopic morcellation.

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assessment in hysterectomies with morcellation. Journal of Gynaecologic Surgery 34(1): 18-26	n=2,309	evaluation of patients undergoing hysterectomy with morcellation was similar to those without morcellation, except for lower rates of endometrial assessment by biopsy or D&C. Given the concern for possible dissemination of occult malignancy with morcellation, one may consider preoperative assessment with endometrial biopsy prior to surgery or contained morcellation.	
Wilson NM, Faber L, Lidang M et al. (2016) Unexpected uterine malignancy following laparoscopic hysterectomy with morcellation. Acta oncologica 55(7): 932-4	Case series n=4	These cases are all examples of unexpected malignancy discovered after LH with morcellation despite preoperative evaluation according to existing guidelines. For women at risk for uterine sarcoma morcellation should be avoided. However, our cases were not informed of the risk for sarcoma, as they had none of these risk factors, so better diagnostic tools are warranted.	Small sample
Wu CQ, Woo LY, Giede KC et al. (2019) Occult leiomyosarcomas in a Canadian province:	Case series n=26,212 hysterectomies	The prevalence of uterine LMS is estimated to be 1 in 853. There were 5 cases of unintended	Of the total sample, it was unclear how many were for

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a retrospective cohort study. Journal of obstetrics and gynaecology Canada 41(1): 46-51		morcellation (1 power, 4 mechanical). Survival outcomes were comparable in women with unintended morcellation of occult disease and in those without morcellation.	laparoscopic morcellation.
<b>Both laparoscopic myomectomy and laparoscopic hysterectomy</b>			
Brolmann HA, Sizzi O, Hehenkamp, WJ et al. (2016) Laparoscopic power morcellation of presumed fibroids. Minerva ginecologica 68(3): 352-63	Review	If the small risks associated with morcellation can be avoided by using the sterile bag to morcellate in, then this is by far to prefer over increasing the number of laparotomies which has been reported in the USA already.	Review article
Clark NV and Cohen SL (2018) Tissue extraction techniques during laparoscopic uterine surgery. Journal of minimally invasive gynecology 25(2): 251-256	Review	Contained morcellation is a promising approach that may reduce the risks associated with tissue extraction, although many unanswered questions remain regarding the level of protection and long-term outcomes. Further research and innovation is warranted to continue morcellation in minimally invasive surgical approaches.	Review article
Chen Q, Shi H, Lu WG et al. (2018) Unexpected uterine sarcomas in 4478 patients with electric power morcellation	Case series n=4,454 laparoscopic	In conclusions, we identified 24 unexpected cancers in 4478 patients with leiomyomas who were treated by	Limited outcomes were reported for laparoscopic morcellation of uterine fibroids but instead

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<p>for leiomyomas. European journal of obstetrics, gynaecology, and reproductive biology 230: 85-9</p>	<p>power morcellation</p> <p>n=24 unexpected uterine sarcomas</p>	<p>hysterectomy or myomectomy with morcellation. Our study suggests that LPM is possibly associated with adverse prognosis in patients with unexpected high-grade sarcomas rather than in the low-grade ESS. Absence of endometrial carcinoma in our study addresses the necessity of pre-operative endometrial sampling in high risk women.</p>	<p>detailed second surgery and prognosis for the 24 patients with unsuspected uterine cancers which were treated by LPM.</p>
<p>Cohen SL, Hariton E, Afshar Y et al. (2016) Updates in uterine fibroid tissue extraction. Current opinion in obstetrics &amp; gynaecology 28(4): 277-82</p>	<p>Review</p>	<p>Although the incidence of occult leiomyosarcoma is low, outcomes are poor and may be worsened by morcellation. By addressing risk factors for malignancy and incorporating evolving surgical techniques into practice, gynaecologists can continue to offer patients a minimally invasive approach for fibroid management.</p>	<p>Review article</p>
<p>Cohen SL, Einarsson JI, Wang K C et al. (2014) Contained power morcellation within an insufflated isolation bag. Obstetrics and gynecology 124(3): 491-7</p>	<p>Case series</p> <p>n=73</p>	<p>Morcellation within an insufflated isolation bag is a feasible technique. Methods for morcellating uterine tissue in a contained manner may provide an option to minimize</p>	<p>Studies with a larger sample or better design were included in the main summary.</p>

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		the risks of open power morcellation while preserving the benefits of minimally invasive surgery.	
Cohen SL, Morris SN, Brown DN et al. (2016) Contained tissue extraction using power morcellation: prospective evaluation of leakage parameters. American journal of obstetrics and gynaecology 214(2): 257e1-e6	Case series n=76	Findings are consistent with prior work demonstrating the feasibility of contained tissue extraction; however, further refinement of this technique is warranted.	Studies with a larger sample or better design were included in the main summary.
Cohen A and Tulandi T (2017) Long-term sequelae of unconfined morcellation during laparoscopic gynaecological surgery. Maturitas 97: 1-5	Review	Morcellation of uterus and myoma can also lead to iatrogenic endometriosis, parasitic myoma and, albeit rarely, disseminated peritoneal leiomyomatosis. These benign sequelae of morcellation occur more often than malignant dissemination of sarcomatous tissue. Accordingly, confined morcellation should be performed with a minimally invasive technique while eliminating tissue dissemination inside the abdominal cavity. The ideal technique and device remain to be determined.	Review article

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<p>Cucinella G, Granese R, Calagna G et al. (2011) Parasitic myomas after laparoscopic surgery: an emerging complication in the use of morcellator? Description of four cases. Fertility and sterility 96(2): e90-6</p>	<p>Case series  n=4</p>	<p>Laparoscopic myomectomy with the use of a morcellator is associated with an increased risk of developing of parasitic myomas. A thorough inspection and washing of the abdominopelvic cavity at the end of the surgery should be performed to prevent this rare complication.</p>	<p>Small number of parasitic myomas reported.</p>
<p>Czarkowski K, Chetty N, Berkes E et al. (2014) Role and risks of morcellation associated with laparoscopic management of myomas. Current Obstetrics and Gynaecology Reports 3(3): 201-206</p>	<p>Review</p>	<p>This article highlights the importance of patient education and preoperative counselling regarding morcellation-associated complications and doctor awareness for meticulous specimen retrieval. In patients with suspicious findings, avoidance of morcellation is the key and consideration of hysterectomy instead of myomectomy should be outlined.</p>	<p>Review article</p>
<p>Damasco MR, Chan PWK, Slonim Me et al. (2017) Incidence of malignancy and myoma variants at surgery for presumed benign symptomatic myomas. Journal of minimally invasive gynaecology 24(4): 659-64</p>	<p>Case series  n=1,878 myomectomy or hysterectomy for myomas  73 benign variants, 8 STUMPs and 11 unexpected malignancy.</p>	<p>There were no confirmed cases of leiomyosarcoma over the 10-year period in women requiring surgery for presumed benign disease in the presence of myomas. There was a low but significant rate of unexpected gynaecologic malignancy and a</p>	<p>This study focused on the incidence of LMS or other uterine pathologies in patients who having hysterectomy or myomectomy (with morcellation) for benign myomas.</p>

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		higher than expected rate of clinically significant adverse outcomes with manually morcellated cellular myoma variants.	
Dixit N, Jesner O and Modarres M (2016) Endoscopic treatment and power morcellation of uterine fibroids. Current Obstetrics and Gynaecology Reports 5(2): 94-105	Review	There is no evidence-based consensus on what is the best surgical treatment, and the choice will finally rest with the individual surgeon or surgical unit taking into account a patient's symptoms and needs, findings and availability of local resources and skills.	Review article
Ebner F, Friedl TWP, Scholz C et al. (2015) Is open surgery the solution to avoid morcellation of uterine sarcomas? A systematic literature review on the effect of tumour morcellation and surgical techniques. Archives of gynaecology and obstetrics 292(3): 499-506	Systematic review n=7 studies	There is no reliable diagnostic tool to differentiate a fibroid from a uterine sarcoma preoperatively. Tumour morcellation occurs in various open and closed surgical techniques and is not limited to laparoscopic surgery only. There is an urgent need for a presurgical diagnostic parameter.	Outcomes for laparoscopic morcellation were not separated.
Einarsson JI, Cohen SL, Fuchs N et al. (2014) In-bag morcellation. Journal of minimally invasive gynaecology 21(5): 951-3	Case series n=12	Contained electromechanical morcellation will become standard practice and that these techniques will most certainly continue to evolve rapidly in the near future. Innovative	Small sample

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		devices specifically designed for contained morcellation are already being developed and once they are commercially available, open mechanical morcellation will probably be a thing of the past.	
Erenel H, Temizkan O, Mathyk BA et al. (2015) Parasitic myoma after laparoscopic surgery: A mini-review. Journal of the Turkish German Gynaecology Association 16(3): 181-6	Review	Parasitic myoma is a rare condition resulting from the small fibroid fragments left after morcellation and can be either asymptomatic or symptomatic. Although it is rare, patients should be informed about the risk of this condition after laparoscopic surgery. It is important for surgeons to look for small fibroid fragments during and after morcellation and make an effort to remove every piece of tissue.	Review article
Gao ZhZh; Li LA; Meng YG (2016) A retrospective analysis of the impact of myomectomy on survival in uterine sarcoma. PloS one 11(2): e0148050	Non-randomised comparative study  n=59 (30 fibroid morcellation compared with 29 total hysterectomy)	Fibroid morcellation during laparoscopic surgery (including laparoscopic, transvaginal and transabdominal approaches) had no significant impact on RFS and OS time in patients. However, the 5-year RFS and	Small sample (laparoscopic morcellation n=6)

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		OS rates were both lower in the FM group than in the TH group. Grade level was a significant risk factor for the prognosis of patients with uterine sarcoma.	
Gitas G, Alkatout I, Mettler L. et al. (2020) Incidence of unexpected uterine malignancies after electromechanical power morcellation: a retrospective multicentre analysis in Germany. Archives of Gynaecology and Obstetrics 302(2): 447-53	Case series  n=1,683  n=4 occult sarcomas	Occult malignancies are liable to spread after EMM, although the overall risk of being diagnosed with an occult malignancy and the risk of dissemination appear to be low. Once the preoperative diagnostic investigation has yielded no suspicious findings, laparoscopic morcellation may be considered a safe method, especially LM in patients of reproductive age.	This study estimated the incidence of occult uterine malignancies during LM or LH with the use of EMM but these cases were not caused by EMM.
Hall T, Lee SI, Boruta DM et al. (2015) Medical device safety and surgical dissemination of unrecognized uterine malignancy: morcellation in minimally invasive gynaecologic surgery. The oncologist 20(11): 1274-82	Review	In light of the scrutiny on morcellation practices, a new standard of care in minimally invasive gynaecology is emerging. Common themes among statements by the FDA, the SGO, ACOG, and AAGL are recognition of the risk of disseminating an otherwise contained malignancy, the importance of informed consent for this risk, appropriate preoperative	Review article

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		evaluation for malignancy, and the need for alternatives to intracorporeal morcellation.	
Hanekom G, Siebert I, Hugo L et al. (2018) Controversies in laparoscopic morcellation of Uterine leiomyoma. Obstetrics and Gynaecology Forum 28(1): 22-7	Review	The incidence of occult malignancy is much higher than traditionally reported and in contrast to previous beliefs of it being a very rare event. The total banning of power morcellation will however deny a large number of patients the proven benefits of minimal access surgery exposing them to the morbidity of open surgery. Instead it is proposed that a thorough preoperative assessment and risk stratification. The choice of procedure and indication should also be considered along with the risk factors especially the age.	Review article
Kriplani A, Mahey R, Gupta M et al. (2018) Complications of laparoscopic morcellation: two cases and a review of the literature. Journal of Gynaecologic Surgery 34(1): 31-5	Case series and literature review n=2	Reducing accidental spread of uterine malignancy and, at the same time, preserving the benefits of a minimally invasive approach requires careful patient selection, counselling of patients, informed consent, and alternative methods of tissue extraction.	Small sample

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		These methods include contained morcellation.	
Kundu S, Zachen M, Hertel H et al. (2017) Sarcoma risk in uterine surgery in a Tertiary University Hospital in Germany. International Journal of Gynaecological Cancer 27(5): 961-6	Case series  n=2,825 myomectomy or hysterectomy  n=23 sarcoma or carcinosarcoma	small risk (0.35% [1/280]) of accidental morcellation during hysterectomy with morcellation was found in the study. Authors did not observe an occult case of sarcoma after myomectomy with morcellation (0/195) but found 2 cases of accidental sarcoma after myomectomy without morcellation. For these reasons, minimally invasive surgery with morcellation should not be excluded a priori. The patient should be well informed about the risks and various options. The advantage of laparoscopic surgery should be balanced against the risk of the unknown spread of malignant tissue.	Limited outcomes were reported for laparoscopic morcellation of uterine fibroids but instead focusing on the 23 patients with sarcoma or carcinosarcoma identified during the surgery.
Lete I, Gonzalez J, Ugarte L et al. (2016) Parasitic leiomyomas: a systematic review. European journal of obstetrics, gynaecology, and reproductive biology 203: 250-9	Systematic review  n=274 patients with parasitic leiomyomas n=108 using power morcellation	While parasitic leiomyoma was first described a century ago, the recent introduction of laparoscopic power morcellation has increased the number of reported cases.	Various surgical techniques and indications were included.
Leren V, Langebrekke A and Qvigstad E (2012)	Case series	Three patients were diagnosed with parasitic leiomyomas	Similar incidence of parasitic leiomyomas was

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<p>Parasitic leiomyomas after laparoscopic surgery with morcellation. Acta obstetrica et gynecologica Scandinavica 91(10): 1233-6</p>	<p>n=2,470  n=3 parasitic leiomyomas</p>	<p>within 8 years, representing an incidence of 0.12% after morcellation procedures in the department. Increased awareness of this serious late complication requires thorough inspection and repeated washing after the morcellation procedure. Physicians should be aware of the possibility, and patients should be informed about the risk, which is uncertain but may be as high as 1%.</p>	<p>covered by Tulandi (2016) in the main summary</p>
<p>Lieng M, Berner E and Busund B (2015) Risk of morcellation of uterine leiomyosarcomas in laparoscopic supracervical hysterectomy and laparoscopic myomectomy, a retrospective trial including 4791 women. Journal of minimally invasive gynecology 22(3): 410-4</p>	<p>Case series  n=1,846 laparoscopic morcellation  n=26 uterine LMS</p>	<p>The incidence of uterine LMS in the population of women referred for anticipated benign fibroids was 0.0054 (1 in 183 women). The rate of unintended morcellation of a LMS in the study was 0.0002 (1 in 4791 women).</p>	<p>This study focused on the incidence of uterine LMS in patients who had laparoscopic morcellation for benign fibroids.</p>
<p>Liu C, Chen B, Tang X et al. (2020) Disseminated peritoneal leiomyomatosis after uterine artery embolization, laparoscopic surgery, and high intensity</p>	<p>Case report  n=1</p>	<p>In the case, the occurrence of DPL is most likely associated with laparoscopic myomectomy using power morcellation. In addition, it should be noted whether</p>	<p>Single case report</p>

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focused ultrasound for uterine fibroids: a case report. International Journal of Hyperthermia 37(1): 925-928		some other factors played a role in stimulating the growth of the multiple nodules.	
Liu FW, Galvan-Turner VB, Pfaendler KS et al. (2015) A critical assessment of morcellation and its impact on gynaecologic surgery and the limitations of the existing literature. American journal of obstetrics and gynaecology 212(6): 717-24	Review	Specific guidelines for the use of power morcellation may be of benefit while awaiting advances in preoperative diagnosis of sarcomas. The impact of minimally invasive surgery on patient quality of life and the economic benefits of shorter recovery time and improved pain management should not be overlooked in gynaecologic surgery.	Review article
Lu B, Xu J and Pan Z (2016) Iatrogenic parasitic leiomyoma and leiomyomatosis peritonealis disseminata following uterine morcellation. The journal of obstetrics and gynaecology research 42(8): 990-9	Case series n=6	Laparoscopic hysterectomy with tumour morcellation may increase the chance of tumour implantation and dissemination. Both clinicians and pathologists should be alert to this rare complication.	Small sample
Martinez-Zamora, M Angeles, Castelo-Branco, Camil, Balasch, Juan et al. (2009) Comparison of a new reusable gynecologic laparoscopic electric morcellator with a disposable	Non-randomised comparative study n=29 (Gynecare morcellex n=15 versus Olympus VarioCarve n=14)	the Olympus VarioCarve morcellator seems to be a safe and effective instrument for laparoscopic myomectomy and supracervical hysterectomy, offering a shorter	Small sample

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<p>morcellator: a preliminary trial. Journal of minimally invasive gynecology 16(5): 595-8</p>		<p>operation time for removal of morcellated tissue compared with a conventional device and low risk of injury to surrounding organs and tissue.</p>	
<p>Mettler, L., Maass, N., Abdusattarova, K. et al. (2017) Frequency of uterine sarcomas in patients admitted for uterine fibroid surgery. Journal of the Turkish-German Gynecological Association 18(2): 62-6</p>	<p>Case series n=2,269</p>	<p>The results showed that the frequency of unsuspected uterine sarcomas was 1/2269 (0.044%) among women who had myomectomies and hysterectomies to treat presumed benign uterine fibroids.</p>	<p>Outcomes were not separated for laparoscopic morcellation.</p>
<p>Meurs EAIM, Brito LG, Ajao MO et al. (2017) Comparison of morcellation techniques at the time of laparoscopic hysterectomy and myomectomy. Journal of minimally invasive gynaecology 24(5): 843-9</p>	<p>Non-randomised comparative study  n=297 (electronic power morcellation n=146, manual morcellation via vagina n=33, or manual morcellation via minilaparotomy n=118)</p>	<p>The study did not reveal a significant difference between the 3 morcellation techniques when comparing the perioperative complications although the longest operative times were noted for the minilaparotomy approach. All 3 morcellation techniques represent viable options for tissue extraction at the time of minimally invasive surgery.</p>	<p>Studies with a larger sample or better design were included in the main summary.</p>
<p>Mowers EL, Skinner B, McLean Karen et al. (2015) Effects of morcellation of uterine smooth muscle tumour of uncertain malignant potential and</p>	<p>Case series  n=8</p>	<p>Surgical re-exploration procedures after morcellation of a uterine STUMP or ESS have a high likelihood of detecting peritoneal implants,</p>	<p>Small sample</p>

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endometrial stromal sarcoma: case series and recommendations for clinical practice. Journal of minimally invasive gynaecology 22(4): 601-6		which can be benign or malignant.	
Odejinmi F, Agarwal N, Maclaran K et al. (2015) Should we abandon all conservative treatments for uterine fibroids? The problem with leiomyosarcomas. Women's health 11(2): 151-9	Review	The risks from morcellation of occult malignancy may have been previously underestimated but overall risk remains low. This has to be balanced against the risk associated with alternative options and patients should be given the appropriate information to make informed choices.	Review article
Parker WH, Pritts EA and Olive DL (2016) What is the future of open intraperitoneal power-morcellation of fibroids? Clinical obstetrics and gynaecology 59(1): 73-84	Review	Although the possibility of occult LMS should be considered by women and their gynaecologists, authors suggest that current morcellation techniques be continued for women who wish to benefit from minimally invasive surgery. Investigation into new and, hopefully, better morcellating devices may make the procedure safer for women.	Review article
Perkins RB, Handal-Orefice R, Hanchate, AD et al. (2016) Risk of undetected cancer	Case series	Approximately 1 in 350 women undergoing LSH had an undiagnosed	This study determined the incidence of undetected

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<p>at the time of laparoscopic supracervical hysterectomy and laparoscopic myomectomy: implications for the use of power morcellation. Women's health issues : official publication of the Jacobs Institute of Women's Health 26(1): 21-6</p>	<p>n=17,903 laparoscopic procedures</p>	<p>uterine cancer, with higher risks among older women. Approximately one-half of women had endometrial biopsies documented before hysterectomy. Safer alternatives, such as contained morcellation, should be evaluated to reduce the risk of complications after morcellation procedures.</p>	<p>cancer at the time of laparoscopic procedures.</p>
<p>Pereira N, Buchanan TR, Wishall KM et al. (2015) Electric morcellation-related reoperations after laparoscopic myomectomy and nonmyomectomy procedures. Journal of minimally invasive gynaecology 22(2): 163-76</p>	<p>Systematic review n=66 electric morcellation-related reoperation (32 studies)</p>	<p>Twenty-four (36.4%) patients underwent laparoscopic myomectomies, of which 19 (79.2%) and 5 (20.8%) patients needed a second surgical procedure because of new clinical symptoms and the diagnosis of malignancy in the morcellated surgical specimen, respectively. Forty-two (63.6%) patients had laparoscopic hysterectomies; of these, 25 (59.5%) patients needed a second surgical procedure because of the onset of new clinical symptoms, whereas the remaining 17 (40.5%) patients had a second surgical procedure because of the diagnosis of malignancy in the morcellated surgical</p>	<p>Initial pathology included leiomyoma, uterine leiomyosarcoma, low-grade endometrial stromal sarcoma, etc.</p>

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		specimen. The most common benign pathology was parasitic leiomyomata (22 patients, 33.3%). The most common malignant pathology was leiomyosarcoma (16 patients, 24.2%).	
Perri T, Korach J, Sadetzki S et al. (2009) Uterine leiomyosarcoma: does the primary surgical procedure matter? International journal of gynaecological cancer : official journal of the International Gynaecological Cancer Society 19(2): 257-60	Non-randomised comparative study  n=37	In patients with stage I LMS, primary surgery involving tumour injury seems to be associated with a worse prognosis than total hysterectomy as a primary intervention.	Small sample
Pezzuto A, Serboli G, Ceccaroni M et al. (2010) Two case reports of bowel leiomyomas and review of literature. Gynaecological endocrinology : the official journal of the International Society of Gynecological Endocrinology 26(12): 894-6	Case series and literature review  n=2	Care needs to be taken to remove all pieces of myomas after morcellation, being careful to look if there are small pieces throughout the abdomen to prevent side effects like bowel-occlusions.	Small sample
Purohit P, Datta S and Narvekar N (2015) Open power morcellation. Obstetrics, Gynaecology and Reproductive Medicine 25(7): 208-9	Review	A clear local evidence-based policy on the use of power morcellation should be developed. Surgeons using a power morcellator should be experienced with the device operation,	Review article

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		aiming to retrieve all specimen fragments from the peritoneal cavity following morcellation. A focus on innovation in preoperative screening for uterine malignancies as well as advanced morcellating technology is critical to improve patient outcomes.	
Raspagliesi F, Maltese G, Bogani G et al. (2017) Morcellation worsens survival outcomes in patients with undiagnosed uterine leiomyosarcomas: A retrospective MITO group study. Gynaecologic Oncology 144(1): 90-5	Non-randomised comparative study  n=125 patients with undiagnosed uterine sarcoma	The results suggest that morcellation increase the risk of death in patients affected by undiagnosed LMS. Further prospective studies are warranted in order to assess the risk to benefit ratio of power morcellator utilisation in patients with apparent benign uterine myomas.	This study investigated the impact of morcellation on survival outcomes of patients affected by undiagnosed uterine sarcoma but not for uterine fibroids.
Rodriguez AM, Zeybek B, Asoglu MR et al. (2016) Incidence of occult leiomyosarcoma in presumed morcellation cases: a database study. European journal of obstetrics, gynaecology, and reproductive biology 197: 31-5	Case series  n=13,964	Our analysis shows the overall risk of being diagnosed with occult leiomyosarcoma is 12.9 per 10,000 in laparoscopic-assisted supracervical hysterectomy and myomectomy for patients younger than 49. There is no evidence of occult leiomyosarcoma 1 year after operation for patients younger than 40 who had laparoscopic myomectomy.	This study focused on the risk of occult leiomyosarcoma.

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<p>Rousseau M, Morel A, Dechoux S et al. (2018) Can the risks associated with uterine sarcoma morcellation really be prevented? Overview of the role of uterine morcellation in 2018. Journal of gynaecology obstetrics and human reproduction 47(8): 341-9</p>	<p>Review</p>	<p>There is a risk of morcellating an occult sarcoma when performing a myomectomy or hysterectomy for fibroids. Implementing the use of morcellation containment bags should be the norm. The use of minimally invasive surgery (laparoscopic or vaginal) and the associated benefit-risk ratio compared to a laparotomy should also be discussed with the patient before the operation.</p>	<p>Review article</p>
<p>Seidman MA, Oduyebo T, Muto MG et al. (2012) peritoneal dissemination complicating morcellation of uterine mesenchymal neoplasms. PLoS ONE 7(11): e50058</p>	<p>Case series n=1,091</p>	<p>While additional study is warranted, these data suggest uterine morcellation carries a risk of disseminating unexpected malignancy with apparent associated increase in mortality much higher than appreciated currently.</p>	<p>This study determined the frequency and clinical consequence of intraperitoneal dissemination of uterine mesenchymal neoplasms. Data on laparoscopic removal of uterine fibroids with power morcellation were limited.</p>
<p>Senapati S, Tu FF, Magrina JF (2015) Power morcellators: a review of current practice and assessment of risk. American journal of obstetrics and gynecology 212(1): 18-23</p>	<p>Review</p>	<p>Providers performing minimally invasive hysterectomies and myomectomies should consider offering contained morcellation, whether via laparotomy, laparoscopically, or vaginally, but with the</p>	<p>Review article</p>

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		caveats that it needs significant further study. Reducing accidental spread of uterine malignancies whereas preserving benefits from MIS, requires urgent studies of patient preferences, contained morcellation, and alternative methods of tissue extraction.	
Shim J, Kenton K and Abernethy MG (2018) Pathology of power morcellation: a 12-year retrospective analysis. Journal of Gynaecologic Surgery 34(1): 27-30	Case series n=456	The incidence of occult malignancy discovered on pathology following power morcellation of the uterus and/or fibroids is low in women. These data can be used to counsel patients prior to consideration of power morcellation. Given the limitations in preoperative diagnosis of sarcoma and potential complications of morcellation even of benign pathology, controlled morcellation should be a goal with established guidelines.	Studies with better design were included in the main summary.
Springborg HH and Istre O (2015) Complete plastic lining of the abdominal cavity during laparoscopic electromechanical morcellation-a promising technique.	Case series n=21	The presented improved contained morcellation technique is feasible in laparoscopic hysterectomy and myomectomy. Larger studies will however be required before	Small sample

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Gynaecological Surgery		the general introduction of the method.	
Tan A, Salfinger S, Tan J et al. (2015) Morcellation of occult uterine malignancies: an Australian single institution retrospective study. The Australian & New Zealand journal of obstetrics & gynaecology 55(5): 503-6	Case series n=734 myomectomy or hysterectomy with morcellation  n=3 occult malignancies	The risk of unintended morcellation of uterine malignancy in the study is higher than that estimated by the Australian TGA and highlights the urgent need for further studies in Australia.	This study reported the incidence of occult uterine malignancy in morcellated surgical specimens.
Taylan E, Sahin C, Zeybek B et al. (2017) Contained morcellation: review of current methods and future directions. Frontiers in Surgery 4	Review	There is currently no available method for tissue extraction that completely eliminates the risk of cellular dissemination. Therefore, further investigations and technological developments are needed to improve morcellation technique.	Review article
Torrent-Colomer A, Claret AR, Vicens-Vidal M et al. (2019) Parasitic myomas and leiomyomatosis peritonealis disseminata after laparoscopic surgery with power morcellation: a report of four cases. Journal of Gynaecologic Surgery 35(1): 24-9	Case series n=4	Laparoscopic morcellation of myomas without containment techniques is associated with an increased risk of parasitic myomas or LPD, mainly in reproductive-age women. Techniques for contained morcellation of the uterine tissue should be performed in an attempt to prevent this complication.	Small sample
Trivedi PH, Patil SS, Parekh NA et al.	Case series	The in-bag morcellation	Small sample

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<p>(2015) Laparoscopic morcellation of fibroid and uterus in-bag. Journal of Obstetrics and Gynaecology of India</p>	<p>n=21</p>	<p>technique handles the issue of ULMS and makes laparoscopic myomectomy and hysterectomy possible with fair safety. Further studies should be directed toward identifying patients at high risk of ULMS prior to presumed leiomyoma resection in order to reduce the risk of inadvertent tumour morcellation.</p>	
<p>Wong M, De Wilde RL, Isaacson K (2018) Reducing the spread of occult uterine sarcoma at the time of minimally invasive gynaecologic surgery. Archives of Gynaecology and Obstetrics 297(2): 285-93</p>	<p>Review</p>	<p>During a minimally invasive surgery, there is a risk of disseminating an occult sarcoma during tissue extraction. Minimally invasive gynaecologists are tasked with balancing taking a minimally invasive approach, which is shown to result in better patient outcomes, with minimizing the risk of spreading an occult sarcoma.</p>	<p>Review article</p>
<p>Xu X, Lin H, Wright JD et al. (2019) Association between power morcellation and mortality in women with unexpected uterine cancer undergoing hysterectomy or myomectomy. J Chin Oncol 37: 3412-24</p>	<p>Non-randomised comparative study  n=843</p>	<p>Uncontained power morcellation was associated with higher mortality risk in women with occult uterine sarcoma, especially in those with occult leiomyosarcoma.</p>	<p>This study determined whether uncontained power morcellation at the time of hysterectomy or myomectomy is associated with increased mortality risk in</p>

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			women with occult uterine cancer.
Zhao WC, Bi FF, Li D et al. (2015) Incidence and clinical characteristics of unexpected uterine sarcoma after hysterectomy and myomectomy for uterine fibroids: A retrospective study of 10,248 cases. OncoTargets and Therapy 8: 2943-8	Case series  n=10,248  Laparoscopies n=1,792	A laparoscopic supracervical hysterectomy was the first operation, and morcellation was applied. She underwent a second operation for recurrence after 240 days, and the greater omentum, peritoneum, and mesentery had multiple metastatic lesions. The stage had progressed from stage I to stage III. The result may be related to morcellation, and the patient's prognosis also decreased.	Outcomes were not reported separately for laparoscopic morcellation.
Zullo F, Falbo A, Iuliano A et al. (2010) Randomized controlled study comparing the Gynecare Morcellex and Rotocut G1 tissue morcellators. Journal of minimally invasive gynaecology 17(2): 192-9	Randomised controlled trial  n=74	No difference was detected between groups in any parameters assessed, whereas a significant difference ( $p < 0.05$ ) in handling score was detected in the experimental group compared with the control group. The Gynecare Morcellex is an effective instrument with excellent safety and handling.	This study compared the effectiveness of 2 morcellators and RCTs with a larger sample were included in the main summary.