







Morcellation for Abdominal or Laparoscopic Myomectomy or Hysterectomy

Consent Advice No. 13

October 2019 Updated June 2024

Morcellation for Abdominal or Laparoscopic Myomectomy or Hysterectomy

This guidance is for healthcare professionals who care for women, non-binary and trans people who are premenopausal or aged 50 and below and undergoing abdominal or laparoscopic myomectomy or hysterectomy for non-cancerous conditions, where the use of morcellation is being considered. This guidance does not apply for women, non-binary and trans people who are postmenopausal or over the age of 50.

Within this document we use the terms woman and women's health. However, it is important to acknowledge that it is not only women for whom it is necessary to access women's health and reproductive services in order to maintain their gynaecological health and wellbeing. Gynaecological services and delivery of care must therefore be appropriate, inclusive and sensitive to the needs of those individuals whose gender identity does not align with the sex they were assigned at birth.

This guidance is relevant to those aged 16 years and over with mental capacity, and those under 16 years of age who are Gillick competent,* to help make the decisions that are appropriate for them.

How to use this guidance

This guidance should be used by healthcare professionals to support meaningful discussions tailored to the individual's needs as part of the informed decision-making and consent process, via provision of appropriate and balanced information about the potential benefits, risks and alternative modes of treatment.

There should be careful discussion with the individual, including checks on the following red flag indicators:1-9

- Abnormal uterine bleeding in women of reproductive age/premenopausal.¹⁻⁵
- Suspicious features on imaging there is a limited evidence base (solid masses with inhomogeneous echogenicity, irregular cystic areas, fan shaped shadowing, moderately or very well vascularised on ultrasound); absence of these features does not exclude sarcoma.^{1.6}
- In premenopausal women: fibroids that do not decrease in size after gonadotrophin-releasing hormone (GnRH) agonist treatment (estrogen deprivation) should raise suspicion.⁷
- Family history of breast/ovarian carcinoma (or known BRCA1/2 germline mutation) and/or Lynch syndrome.
- Risk is stratified by age (perimenopause).^{1,2,7}
- History of tamoxifen use.^{1,3,4,8}
- Ethnicity should be considered; as the incidence of fibroids is higher in Black women, so is the incidence of uterine sarcoma. 1,3,9
- History of pelvic irradiation.^{1,3}

It should be ensured that the individual has an up-to-date, normal cervical smear and, if indicated, an endometrial biopsy. 1,3

Discussion of expectant management, medical and surgical management options should have been undertaken and documented.

The aim of this advice is to ensure that all individuals are given consistent information for consent. It is intended for use together with related patient information available from the Royal College of Obstetricians and Gynaecologists: www.rcog.org.uk/en/patients/patients/patient-leaflets/morcellation-myomectomy-hysterectomy/.

Consent Advice No. 13

^{*} Gillick competence outlines whether a child (under 16) can consent to their own medical treatment without the need for parental knowledge or expressed permission. If the child has sufficient maturity and understanding to make informed decisions about their treatment, they would be considered Gillick competent.

Healthcare professionals obtaining consent should be prepared to discuss with the individual any of the points listed on the following pages.

Introduction

Morcellation is a term used to describe the process of cutting tissue into smaller pieces to facilitate its removal from the body. In gynaecology, the practice has been used for over a century. It was first described in the 1890s, when it was employed in vaginal surgery to remove large uteri as a means of reducing the morbidity and mortality associated with abdominal hysterectomies.

In the 1990s, power morcellation was introduced to allow laparoscopic removal of myomas (fibroids) and larger uteri. Owing to the potential dissemination of tissue extracted during the morcellation process, cases of parasitic fibroid development and the inadvertent spread of previously unrecognised malignancies have been described.¹⁻⁴

It is important for clinicians to remember that, even when surgery is being contemplated for presumed non-cancerous conditions, the exact nature of any specimen removed cannot be confirmed until histopathological examination has been undertaken. This is the case when removing fibroids, where there could be undiagnosed uterine sarcoma or in hysterectomy without fibroids, when there could be undiagnosed cervical, endometrial, fallopian tube or ovarian carcinoma.¹⁰

Currently there are no specific biomarkers for uterine sarcoma. 1,11

In the UK, over 400 cases of gynaecological sarcomas are diagnosed each year.¹²

The uterus is the most common anatomical subsite. Leiomyosarcomas are the most common histological subtype.

There is a wide variation in the incidence of undiagnosed leiomyosarcoma in the published literature. Age and menopausal status are very important factors.

Premenopausal women

A number of population-based studies have reported the incidence of unexpected leiomyosarcoma among surgery for uterine fibroids or hysterectomy for whatever cause.

In the largest published database,¹³ risk figures for premenopausal women aged under 50 years range from 1 in 1250 (hysterectomy or myomectomy whatever cause) to 1 in 769 (women with uterine fibroids).

Mathematical modelling for age stratification of risk of an unsuspected uterine sarcoma at the time of surgery for a presumed non-cancerous fibroid **for women under 50 years**² indicates risk figures of 2.5 per 1000 (1 in 400; this is average of all the incidence figures for the five age groups under 49 years from Table 4 in Brohl et al.²).

Perimenopausal women aged 50 and under

Presumed fibroids are more likely to be sarcomas in perimenopausal women if they are rapidly growing and solitary, rather than multiple.^{1-4,6}

The peak age of incidence of uterine sarcoma is between 50 and 55. The risk may be even higher in **women** over the age of 60 ranging from 7.5 to 15.3 per 1000 cases (i.e. 1 in 133² to 1 in 65,¹³ but with less confidence on the incidence figures since the number of procedures is lower in this age group.^{1,2,13}

Table 2 below is derived from risk ranges according to age reported in Mao et al.¹³ and in Table 4 in Brohl et al.²

Table 2. Risk ranges according to age reported in Mao et al.¹³ and Brohl et al.²

Reference	Risk by age range		
	< 50 years	50-59 years	> 60 years
Mao et al. ¹³	1 in 769 to 1 in 1250	1 in 172 to 1 in 303	1 in 65 to 1 in 278
Brohl et al. ²	1 in 304 to 1 in 574	1 in 158 to 1 in 216	1 in 98 to 1 in 157

Before consideration is given to morcellation of a fibroid or breaching of a fibroid capsule (via any route) magnetic resonance imaging (MRI) or ultrasound imaging should have been performed to diagnose a fibroid. Neither ultrasound scan nor MRI are able to definitively exclude sarcomatous change in a fibroid.

Any fibroid that looks suspicious on imaging or where there is concern of uterine sarcoma, should be considered for discussion at a multidisciplinary forum before morcellation is performed. **The guiding principle should be that if sarcoma is suspected then morcellation or breaching of a fibroid capsule should not be undertaken**.^{1,3}

Postmenopausal women

For individuals who are over 50 years of age or postmenopausal this procedure should not be recommended. 15

What abdominal/laparoscopic morcellation involves

Morcellation is only indicated if the uterus (with or without large fibroids) is too big to be removed vaginally once detached laparoscopically, if a subtotal hysterectomy is performed (where the cervix is left intact) or if laparoscopic myomectomy is performed.

Morcellation can be performed laparoscopically, abdominally, or vaginally. Laparoscopically, it involves the insertion of a surgical instrument through a port incision to electrically or mechanically cut a uterus or fibroid into smaller pieces after it has been detached, the fragments are then removed through the instrument. A uterus or fibroid can also be cut into smaller pieces by inserting a specially designed knife through a port incision. Morcellation of an enlarged uterus or fibroid can be performed through the vagina, during vaginal hysterectomy or total laparoscopic hysterectomy. It can also be performed within an abdominal incision.

Because data on complications with regard to laparoscopic or vaginal morcellation have not been reported separately, we recommend that patients are informed in the same manner if either is being considered.

What patient information should be made available?

Women should be provided with both verbal and written information prior to admission for their procedure. This should include information about the risks of laparoscopic morcellation of fibroids or uteri in an easy-to-read format, approved through local governance procedures.

Why is individualisation of care important?

Studies looking at total hysterectomy versus those procedures which injure the tumour, such as myomectomy (either open or laparoscopic), have shown an increased risk of recurrence with morcellation/injury.¹⁶⁻¹⁸ Therefore, en bloc resection with total hysterectomy is recommended if sarcoma is suspected. The closer a woman is to menopause, the more surgeons should recommend hysterectomy over myomectomy.

All patients should receive individualised care, with the risks and benefits of laparoscopic versus open procedures being considered on a case-by-case basis.¹⁹ This will depend on significant past medical and surgical history, in addition to age, venous thromboembolic risks, and the woman's wishes. This is particularly pertinent in modern case law and following the Montgomery ruling.²⁰ All options should be clearly documented. Patients should always be given appropriate time to consider the options, read the recommended leaflets, reflect on any decisions and be encouraged to ask questions.

All women considering this procedure should receive careful explanation of the risks and benefits of laparoscopic versus open hysterectomy or myomectomy.^{21,22} These depend on a range of issues, including local practice and availability of surgical skills, and local interpretation of national guidelines. Audit and review of clinical outcomes of all patients having the procedure is recommended.¹⁵

The use of morcellation should be very carefully considered in women having hysterectomies during the perimenopause years where the risk of uterine sarcoma is higher¹⁻⁵ as per section 4 below.

CONSENT FORM

1. Name of proposed procedure or course of treatment

- Morcellation of uterine tissues or fibroids during laparoscopic myomectomy (which can include mechanical or electrical [using a morcellator], vaginal [through a posterior colpotomy] or through a port using other cutting instruments or devices). It can also be performed abdominally when removing a large fibroid through a smaller incision.
- Morcellation of uterine tissue or fibroids during a laparoscopic hysterectomy (which can include mechanical or electrical [using a morcellator], vaginal [through a posterior colpotomy if a subtotal hysterectomy is performed or vaginally during a total laparoscopic hysterectomy] or through a port using other cutting instruments or devices). It can also be performed abdominally when removing a large uterus through a smaller incision.

2. Proposed procedure

The procedure is designed to remove fibroids or the uterus through small incisions that can facilitate a much quicker recovery, with less serious risks when compared to more traditional open surgery (see section 4).^{4,21,22} The physical outcome for the patient should be good. They may require an overnight stay in hospital and may need a couple of weeks off work depending on the complexity of the operation, blood loss and any postoperative complications.

3. Intended benefits

The main benefit of the use of morcellation is the completion of the entire procedure laparoscopically or vaginally, which is associated with smaller incisions, less pain, reduced risk of infection, reduced risk of thromboembolism, shorter hospital stay and a quicker recovery.

4. Serious and frequently occurring risks

4.1 Unintended morcellation of a uterine sarcoma

There is a wide variation in the incidence of undiagnosed leiomyosarcoma in the published literature and age is an important factor. Larger and solitary lesions which are growing rapidly,¹⁴ those in perimenopausal women,^{1–5} and those not responding to estrogen withdrawal⁷ should raise particular suspicion of a sarcoma rather than a fibroid. Please refer to the data in the Introduction of this consent advice. Mathematical modelling for age stratification of risk of an unsuspected uterine sarcoma at the time of surgery for a presumed non-cancerous fibroid has been reported.²

Risk figures for premenopausal women aged under 50 years range from 1 in 1250 (hysterectomy or myomectomy whatever cause) to 1 in 769 (women with uterine fibroids).

As anatomical relationships are lost in a morcellated specimen, malignant areas may not be sampled and unusual or low grade malignancies may be missed.

4.2 Worsening the prognosis of an existing sarcoma

Morcellation (by any means of disruption or injury at open, vaginal or laparoscopic surgery) of an unexpected uterine sarcoma can potentially disseminate sarcoma into the pelvis and peritoneal cavity. A diagnosis of metastatic sarcoma carries a poor prognosis with a median survival of 18 months. Data from national cancer registries have reported that sarcoma mortality was higher in the morcellated group than in the non-morcellated group (age-adjusted HR 1.90, CI 1.05–3.44; multivariate HR 2.50, 95% CI 0.57–10.9). Age-adjusted 10-year uterine sarcoma survival was 32.2%, risk of 1 in 33 for women treated with morcellation compared with 57.2%, risk 1 in 50 for the non-morcellated group (difference 25.5%; CI –55.7 to 18.1). ^{16,17,23}

4.3 Disseminated fibroids (presence of non-cancerous fibroids within the abdominal and pelvic cavity)

The range of risk is considered to be 1 in 120 (uncommon) to 1 in 1200 (rare). 18

4.4 Damage to bowel, bladder, ureters and blood vessels

There is a risk of damage to the bladder, bowel, ureters and blood vessels with laparoscopic hysterectomy.²⁴ These data were published in 2007. Since then, there have been advances in techniques and equipment, and the possibility that these rates may now be lower has been highlighted.²⁵

Laparoscopic myomectomy, with and without morcellation, also carries a risk of these injuries. However, these risks are unknown because the reported literature is based on case reports rather than large trials. The total number of cases of morcellation of fibroids is also unknown. Surgeons should declare the rate of such injuries from their personal or institutional data where available.

5. Any extra procedures which may become necessary

General additional procedures associated with myomectomy or hysterectomy should be detailed in local procedure specific consent forms where available. A laparotomy may be required if there is a major complication, or, if the surgeon considers that conversion is necessary for safety or access.

6. The benefits and risks of any available alternative treatments, including no treatment

6.1 Open myomectomy or hysterectomy

An abdominal (open) myomectomy or hysterectomy to remove a uterus or fibroid may be performed as an alternative. The benefit is that an unsuspected sarcoma would not be morcellated. However, if this was performed in everyone more harm may be caused overall because of the increased risks of open surgery over laparoscopy. These are an increased risk of thromboembolism, wound infections, blood transfusion and incisional hernias, with a longer hospital stay and recovery.^{4,21,22,26}

It should be noted that when an open myomectomy or vaginal morcellation are performed, simply cutting into the fibroid will cause spillage of cells and if there is an undiagnosed uterine sarcoma, upstaging can still occur.

6.2 Contained retrieval during morcellation

The use of tissue retrieval bags for the contained removal of fibroids or the uterus, once they have been detached has been proposed.²⁷ However, there is no current evidence that bags reduce the incidence of disseminated fibroids or upstaging of an undiagnosed uterine sarcoma. There is also a theoretical risk that the bags obscure the laparoscopic view, with the potential of causing more intra-abdominal injuries.⁴ The decision regarding contained retrieval during morcellation should be based on local practice and individualised patient care. The procedure should only be carried out by a surgeon with specific training in laparoscopic surgery. When an in-bag technique is needed, the surgeon should also have specific training in using containment systems.¹⁵

6.3 Conservative measures and uterine artery embolisation

Any management option, including uterine artery embolisation, MRI-focussed ultrasound, medical management and no treatment that results in uterine preservation, or preservation of some element of fibroid tissue, runs the risk of leaving an undiagnosed uterine sarcoma in situ (see section 4 above).¹

7. Patient statement

The woman should be given the opportunity to state in writing any procedures that should not be performed without further discussion. If other procedures are anticipated to become necessary during the planned procedure these should be discussed preoperatively, and a record of the woman's wishes made.

8. Preoperative information

A record should be made of any sources of information given to the woman prior to surgery (such as <u>RCOG</u> <u>patient information</u> or locally produced information leaflets).

Existing information resources for procedures need to be reviewed to ensure they reflect the available current evidence.

9. Information and support for women and their families

All women should be provided with relevant and up-to-date information sources. Translation services should be sourced if a language-specific leaflet is not available to ensure that a woman has a full understanding of the procedures planned.

10. Acknowledgement

The following reference was used as a resource during preparation of this consent advice: Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review. No. 195. p. 70. Rockville, MD: AHRQ; 2017 [https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-195-uterine-fibroids-final-revision.pdf].

References

- Sizzi O, Manganaro L, Rossetti A, Saldari M, Florio G, Loddo A, et al. Assessing the risk of laparoscopic morcellation of occult uterine sarcomas during hysterectomy and myomectomy: Literature review and the ISGE recommendations. Eur J Obstet Gynecol Reprod Biol 2018;220:30–38.
- Brohl AS, Li L, Andikyan V, Običan SG, Cioffi A, Hao K, et al. Age-stratified risk of unexpected uterine sarcoma following surgery for presumed benign leiomyoma. Oncologist 2015;20:433–439.
- Halaska MJ, Haidopoulos D, Guyon F, Morice P, Zapardiel I, Kesic V; ESGO Council. European Society of Gynecological Oncology Statement on Fibroid and Uterine Morcellation. Int J Gynecol Cancer 2017;27:189–192.
- ACOG Committee Opinion No. 770: Uterine Morcellation for Presumed Leiomyomas. Obstet Gynecol 2019;133:e238– e248.
- Munro MG, Critchley HOD, Fraser IS; FIGO Menstrual Disorders Committee. The two FIGO systems for normal and abnormal uterine bleeding symptoms and classification of causes of abnormal uterine bleeding in the reproductive years: 2018 revisions. Int J Gynaecol Obstet 2018;143:393– 408
- Ludovisi M, Moro F, Pasciuto T, Di Noi S, Giunchi S, Savelli L, et al. Imaging in gynecological disease (15): clinical and ultrasound characteristics of uterine sarcoma. *Ultrasound Obstet Gynecol* 2019;54:676–687.
- Tissue Extraction Task Force; American Association of Gynecology Laparoscopy. Morcellation during uterine tissue extraction: an update. J Minim Invasive Gynecol 2019;25:543– 550.
- Wickerman DL, Fisher B, Wolmark N, Bryant J, Costantino J, Bernstein L, et al. Association of tamoxifen and uterine sarcoma. J Clin Oncol 2002;20:2758–2760.
- 9. Toro JR, Travis LB, Wu HJ, Zhu K, Fletcher CD, Devesa SS. Incidence patterns of soft tissue sarcomas, regardless of primary site, in the surveillance, epidemiology and end results program, 1978–2001: An analysis of 26,758 cases. *Int J Cancer* 2006;119:2922–2930.
- Desai VB, Wright JD, Schwartz PE, Jorgensen EM, Fan L, Litkouhi B, et al. Occult Gynecologic Cancer in Women Undergoing Hysterectomy or Myomectomy for Benign Indications. Obstet Gynecol 2018;131:642–651.
- Peters A, Sadecky AM, Winger DG, Guido RS, Lee TTM, Mansuria SM, et al. Characterization and Preoperative Risk Analysis of Leiomyosarcomas at a High-Volume Tertiary Care Center. Int J Gynecol Cancer 2017;27:1183–1190.
- 12. Sarcoma UK [sarcoma.org.uk]. Accessed 14 May 2024.
- Mao J, Pfeifer S, Zheng XE, Schlegel P, Sedrakyan A. Population-based estimates of the prevalence of uterine sarcoma among patients with leiomyomata undergoing surgical treatment. JAMA Surg 2015;150:368–70.
- Multinu F, Casarin J, Tortorella L, Huang Y, Weaver A, Angioni S, et al. Incidence of sarcoma in patients undergoing

- hysterectomy for benign indications: a population-based study. *Am J Obstet Gynecol* 2019;220:179.e1–10.
- National Institute for Health and Care Excellence. Laparoscopic removal of uterine fibroids with power morcellation. Interventional procedures guidance [IPG703]. NICE; 2021 [www.nice.org.uk/guidance/ipg703]. Accessed 14 May 2024.
- George S, Barysauskas C, Serrano C, Oduyebo T, Rauh-Hain JA, Del Carmen MG, et al. Retrospective cohort study evaluating the impact of intraperitoneal morcellation on outcomes of localized uterine leiomyosarcoma. *Cancer* 2014;120:3154–3158.
- Park J-Y, Park S-K, Kim D-Y, Kim J-H, Kim Y-M, Kim Y-K, et al. The impact of tumor morcellation during surgery on the prognosis of patients with apparently early uterine leiomyosarcoma. Gynecol Oncol 2011;122:255–259.
- Perri T, Korach J, Sadetzki S, Oberman B, Fridman E, Ben-Baruch G. Uterine leiomyosarcoma: does the primary surgical procedure matter? Int J Gynecol Cancer 2009;19:257– 260
- National Institute for Health and Care Excellence. Shared decision making. NICE guideline [NG197]. NICE; 2021 [www.nice.org.uk/guidance/ng197]. Accessed 14 May 2024.
- Montgomery v Lanarkshire Health Board [2015] SC 11 [2015] 1 AC 1430.
- Aarts JWM, Nieboer TE, Johnson N, Tavender E, Garry R, Mol BJ, et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2015;8:CD003677.
- Bhave Chittawar P, Franik S, Pouwer AW, Farquhar C. Minimally invasive surgical techniques versus open myomectomy for uterine fibroids. *Cochrane Database Syst* Rev 2014;10:CD004638.
- Bretthauer M, Goderstad JM, Løberg M, Emilsson L, Ye W, Adami HO, et al. Uterine morcellation and survival in uterine sarcomas. Eur J Cancer 2018;101:62–68.
- National Institute for Health and Care Excellence.
 Laparoscopic techniques for hysterectomy. Interventional procedures guidance [IPG239]. NICE; 2007 [www.nice.org. uk/ipg239]. Accessed 14 May 2024.
- Garry R. Re-evaluating the eVALuate study and the NICE guidelines: a personal review. BJOG 2016;123: 1796.
- Siedhoff MT, Wheeler SB, Rutstein SE, Geller EJ, Doll KM, Wu JM, et al. Laparoscopic hysterectomy with morcellation vs abdominal hysterectomy for presumed fibroid tumors in premenopausal women: a decision analysis. Am J Obstet Gynecol 2015;212:591.e1–8.
- Rousseau M, Morel A, Dechoux S, Bouet PE, Catala L, Lefebvre Lacoeuille C, et al. Can the risks associated with uterine sarcoma morcellation really be prevented? Overview of the role of uterine morcellation in 2018. J Gynecol Obstet Hum Reprod 2018;47:341–349.

Appendix I: Consent to treatment form
Patient identifier/label
Name of proposed procedure or course of treatment
Supplementary consent – morcellation for abdominal or laparoscopic myomectomy or hysterectomy
Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy).
I have explained the procedure to the patient, in particular, I have explained:
The intended benefits
The main benefit of the use of morcellation is the completion of the entire procedure laparoscopically or vaginally, which is associated with smaller incisions, less pain, reduced risk of infection, reduced risk of thromboembolism, shorter hospital stay and a quicker recovery.
Serious risks (as detailed in section 4 above)
 Unintended morcellation of a uterine sarcoma.
 Worsening the prognosis of an existing sarcoma.
 Disseminated fibroids (presence of non-cancerous fibroids within the abdominal and pelvic cavity).
 Damage to bowel, bladder, ureters and blood vessels.
Any additional risks discussed
Any extra procedures which may become necessary
General additional procedures associated with myomectomy or hysterectomy should be detailed in local procedure specific consent forms where available. A laparotomy may be required if there is a major complication, or, if the surgeon considers that conversion is necessary for safety or access.
I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.
The following leaflet has been provided: <u>Information for you: Morcellation for Myomectomy or Hysterectomy</u>
This procedure will involve
General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation
Signed Date
Name (print)
Position
Contact details (if patient wishes to discuss options later)
Statement of interpreter (where appropriate)
I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.
Signed Date
Name (print)

Top copy accepted by patient? Yes / No (please circle)