

Royal College of Obstetricians & Gynaecologists

Morcellation for Myomectomy or Hysterectomy

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Morcellation for Myomectomy or Hysterectomy

This paper provides advice for healthcare professionals obtaining consent from individuals undergoing myomectomy or hysterectomy for benign conditions, where the use of morcellation is being considered.

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

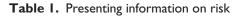
- Post-Menopausal Bleeding (PMB) or abnormal uterine bleeding (AUB) in women of reproductive age/ premenopausal)¹⁻⁵
- Suspicious features on imaging there is a limited evidence base (solid masses with inhomogeneous echogenicity, irregular cystic areas, fan shaped shadowing, moderately or very well vascularised on ultrasound); **absence of these features does not exclude sarcoma**^{1,6}
- Rapidly enlarging fibroid in post-menopausal women¹
- In premenopausal women: fibroids that do not decrease in size after GnRH agonist treatment (oestrogen deprivation) should raise suspicion⁷
- Family history of breast/ovarian carcinoma (or known BRCA1/2 germline mutation) and/or Lynch Syndrome
- Risk is stratified by age (peri and post menopause)^{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/patient-leaflets/morcellation-myomectomy-hysterectomy/.

Health professionals obtaining consent should be prepared to discuss with the individual, any of the points listed on the following pages. Risks may be quantified using the descriptors below.



Term	Equivalent numerical ratio	Colloquial equivalent	
Very common	l in l to l in l0	A person in family	
Common	l in 10 to 1 in 100	A person in street	
Uncommon	l in 100 to 1 in 1000	A person in village	
Rare	l in 1000 to l in 10 000	A person in small town	
Very rare	Less than 1 in 10 000	A person in large town	

The descriptors are based on RCOG Clinical Governance Advice No. 7, Presenting Information on Risk¹⁰ and are used throughout this document.

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 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. Due 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 benign 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.¹¹

Currently there are no specific biomarkers for uterine sarcoma.^{1,12}

In the UK, over 400 cases of gynaecological sarcomas are diagnosed each year.¹³

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,¹⁴ **risk figures for premenopausal women of all ages (<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 benign 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 5 age groups under 49 years from Table 4 in Brohl et al.*²; see Appendix 2).

Peri- and post-menopausal women

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

The risk rises sharply around the menopause, with a summarised figure from several studies of around 6 cases per 1000 procedures (1 in 166) (derived from Brohl et al.,² Mao et al.¹⁴ and Multinu et al.¹⁵).

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 65,¹⁴ but with less confidence on the incidence figures since the number of procedures is lower in this age group.^{1,2,14}

Table 2 below is derived from risk ranges according to age reported in Mao et al.¹⁴ and Brohl et al.² see full table data extracted at Appendix 2.

Reference	Risk by age range				
	<50 years	50–59 years	>60 years		
Mao et al. ¹⁴	I in 769 to I in 1250	I in 172 to I in 303	I in 65 to I in 278		
Brohl et al. ²	I in 304 to I in 574	I in 158 to I in 216	I in 98 to I in 157		

Table 2. Risk ranges according to Mao et al.¹⁴ and Brohl et al.²

Before consideration is given to morcellation of a fibroid or breaching of a fibroid capsule (via any route) MRI or ultrasound imaging should have been performed to diagnose a fibroid. Neither USS 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 multi-disciplinary forum before morcellation is performed. The guiding principle should be that if sarcoma is suspected (e.g. a rapidly enlarging mass in a peri or post-menopausal woman) then morcellation or breaching of a fibroid capsule should not be undertaken.^{1,3}

What 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 in 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 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-toread 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 err towards offering hysterectomy, rather than 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. This will depend on significant past medical and surgical

history, in addition to age and venous thromboembolic risks. This is particularly pertinent in modern case law and following the Montgomery ruling.¹⁹ 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 laparascopic versus open hysterectomy or myomectomy.^{20,21} These depend on a range of issues, including local practice and availability of surgical skills, and, local interpretation of national guidelines.

The use of morcellation should be very carefully considered in women having hysterectomies during the peri and postmenopausal years where the risks of uterine sarcoma are higher¹⁻⁵ as per Section 4 below.

CONSENT FORM

I. 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).
- 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).

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;^{4,20,21} see **Section 4**. The physical outcome for the patient should be good. They may require an overnight stay in the hospital and may need a couple of weeks off work depending on the complexity of the operation, blood loss and any post-operative 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,¹⁵ those in peri and post-menopausal women^{1–5} and those not responding to oestrogen withdrawal⁷ should raise particular suspicion of a sarcoma rather than a fibroid. Please refer to the data in the Introduction section of this consent advice. Mathematical modelling for age stratification of risk of an unsuspected uterine sarcoma at the time of surgery for a presumed benign fibroid has been reported.²

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, Cl 1.05–3.44; multivariate HR, 2.50, 95% Cl 0.57–10.9). Age-adjusted 10-year uterine sarcoma survival was 32.2% for women treated with morcellation compared with 57.2% for the non-morcellated group (difference 25.5%; Cl -55.7 to 18.1).^{16,17,22}

4.3 Disseminated fibroids (presence of benign 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.²³ 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.²⁴

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 due to 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.^{4,20,21,25}

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.²⁶ 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.

6.3 Conservative measures and uterine artery embolisation

Any management option, including uterine artery embolisation, 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;¹ see Section 4 above.

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 RCOG or locally produced information leaflets; https://www.rcog.org.uk/en/patients/patient-leaflets/).

Existing information sheets 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. This consent advice

Please note that the content herein is based on the latest evidence available at the time and will be reviewed again approximately one year from publication.

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Appendix I

Definition of perimenopause referred to in this consent advice is as per https://www.imsociety.org/menopause_terminology.php.

Menopause terminology

The International Menopause Society (IMS) and the World Health Organization (WHO), with the aim of standardising the terminology of menopause have put forward the following definition:

Perimenopause: the period immediately prior to the menopause (when the endocrinological, biological, and clinical features of approaching menopause commence) and the first year after menopause

Appendix 2

The full extracted Table 4 from reference 2: Brohl AS, Li L, Andikyan V, Obi an SG, Cioffi A, Hao K, Dudley JT, Ascher-Walsh C, Kasarskis A, Maki RG. Age-stratified risk of unexpected uterine sarcoma following surgery for presumed benign leiomyoma. *Oncologist*, 2015;20:433–439 [https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC4391766/table/T4/?report=objectonly].

Appendix 3

Reference 27: 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]. This reference has been used as a resource during preparation of the consent advice for morcellation for myomectomy or hysterectomy.

Appendix 4: Consent to treatment form

Patient identifier/label

Name of proposed procedure or course of treatment

Supplementary consent – morcellation for 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 benign fibroids within the abdominal and pelvic cavity).
- Damage to bowel, bladder, ureters and blood vessels.

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: Information for you: Morcellation for Myomectomy or Hysterectomy

This procedure will involve

□ General and/or regional anaesthesia	Local anaesthesia	□ Sedation	
Signed		Date	
Name (print)			
Position			
Contact details (if patient wishes to discuss opt	tions 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 ring)