Morcellation for Laparoscopic Myomectomy or Hysterectomy

This is the first edition of this guidance.

This document provides guidance for doctors obtaining consent for women undergoing laparoscopic myomectomy or hysterectomy, where the use of morcellation is being considered.

Which consent form should be used for morcellation?

It is important that women receive thorough, consistent and evidence-based information to assist in their decision-making and consent process. Due to the potential additional risks with morcellation, it is advised that any consent form specifically obtains consent for morcellation if it is expected to be part of the procedure.

Individual clinicians can therefore decide whether to use:

- A procedure-specific consent form (laparoscopic myomectomy or laparoscopic hysterectomy) and supplement it with a relevant patient information leaflet on morcellation.
- A procedure-specific consent form (laparoscopic myomectomy or laparoscopic hysterectomy) in addition to a supplementary morcellation consent form and to provide a relevant patient information leaflet on morcellation.

Examples of a morcellation-specific consent form can be found in Appendix I. This, alongside the British Society for Gynaecological Endoscopy (BSGE)/Royal College of Obstetricians and Gynaecologists (RCOG) patient information leaflets on morcellation, may be adapted for local use.

What patient information should be available?

Women should have access to 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.

How should clinicians keep up to date?

Surgeons performing laparoscopic morcellation must be familiar with the European Society for Gynaecological Endoscopy (ESGE) paper *Options on fibroid morcellation: a literature review*.

This paper summarises the currently perceived small additional risks. While this was an exhaustive review performed in 2014, it is also important that the operating surgeon remains aware of new data as they appear and also of the opinions of regulatory authorities, such as the National Institute for Health and Care Excellence, the Medicines & Healthcare Products Regulatory Agency and the Food and Drug Administration, as well as specialist organisations, such as the RCOG, BSGE, ESGE and American Association of Gynecologic Laparoscopists.

Consent should also be taken with consideration of the general guidance provided by the RCOG on consent in women’s healthcare.

Why is individualisation of care important?
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 the Montgomery ruling. 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 must receive careful explanation of the risks of laparoscopic hysterectomy or myomectomy versus the additional risks of open hysterectomy or myomectomy (namely increased risk of thromboembolism).

Individualisation of care is particularly important when considering morcellation. As the mean age of presentation of leiomyosarcoma is 69 years, the role of laparoscopic morcellation should be very carefully considered in women during the postmenopausal years.

Consent Form

1. Name of proposed procedure or course of treatment

- Morcellation of 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. Intended benefits

- Use of morcellation to enable the removal of large pieces of tissue at laparoscopic hysterectomy or myomectomy through a laparoscopic incision or vaginal incision (present already during total hysterectomy or made in addition during myomectomy or subtotal hysterectomy) avoiding the planned need for open surgery (abdominal incision).
- The main benefit of this is completion of the entire procedure laparoscopically, which is associated with smaller incisions, less pain, reduced risk of infection, reduced risk of thromboembolism, shorter hospital stay and a quicker recovery.

3. Serious and frequently occurring risks

- The main risks associated with laparoscopic myomectomy and hysterectomy are detailed in the local procedure specific consent forms.

3.1 Serious risks associated with morcellation

Unintended morcellation of a sarcoma (type of uterine cancer)

- The range of risk is considered to be 1 in 700 (uncommon) to 1 in 7400 (rare).
- The risk in women aged under 40 years is considered to be less than 1 in 1000.
Parasitic fibroids (implantation of small portions of fibroids within the abdominal wall and pelvic cavity)

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

Worsening the prognosis of an existing sarcoma

- There are some studies which suggest that en bloc removal of a fibroid uterus (total abdominal hysterectomy) may result in improved 5-year survival and less risk of recurrence. However, these data are biased, retrospective (in most cases) and of poor quality. There is a lack of high-quality reliable data to suggest that morcellation (of any type, i.e. vaginal, open incision, laparoscopic with or without the use of a morcellator [electrical or mechanical]) significantly results in tumour upstaging.

Damage to bowel, bladder and blood vessels

- The risk is unknown.
- The risks of serious complications 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.

Other considerations

- A diagnosis of malignancy may be missed in morcellated tissue. This may occur if the histological analysis misses a small portion of tumour within a specimen, and may delay or alter treatment.
- No clear data currently exists about the risks versus benefits, or risks versus diagnostic accuracy, of needle biopsy of fibroids prior to laparoscopic myomectomy or hysterectomy.

Contained retrieval during morcellation

- There are several tissue retrieval bags in use for the contained removal of fibroids or the uterus once they have been detached. Current research suggests that they are feasible and safe to use. Some studies have shown that they add some time to the overall surgery although as experience increases, this is not likely to be significant. There is no current evidence that bags reduce the incidence of parasitic fibroids or reduce the worsening or upstaging of an undiagnosed sarcoma.

4. Any extra procedures which may become necessary

- General additional procedures associated with laparoscopic myomectomy or hysterectomy are detailed in the local procedure specific consent forms.
- Morcellation-specific procedures include:
  - During laparoscopy a laparotomy may become necessary prior to starting morcellation if the surgeon has concerns about malignancy.

5. What laparoscopic morcellation involves

Morcellation is a technique that is used to facilitate the removal of large benign tissues through small laparoscopic or vaginal incisions during laparoscopic procedures. Morcellation can involve the insertion of a surgical instrument, through one of the laparoscopic incisions, to electrically or mechanically cut in to smaller pieces large tissues (like a uterus or fibroid) once it has been detached.
(thus removing it through this device). Alternatively, the tissue is cut into smaller pieces through a port incision or vaginal incision using other cutting devices. No additional vaginal incision is required when a total laparoscopic hysterectomy with vaginal morcellation is performed (as the specimen is removed vaginally anyway).

It should be noted that morcellation is only indicated if the uterus (with or without large fibroids) is too big to be removed vaginally once detached laparoscopically or if a subtotal hysterectomy is performed (where the cervix is left intact).

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

6.1 Open myomectomy or hysterectomy

A laparotomy as an open myomectomy or hysterectomy to facilitate the removal of a uterus or fibroid can be performed as an alternative. However, if this was performed in everyone more harm would be caused overall due to the increased risks of open surgery over laparoscopy, namely an increased risk of thromboembolism.

It must be noted that when an open myomectomy is performed, simply cutting into the fibroid will cause spillage of cells and if there is an undiagnosed sarcoma, theoretical upstaging can still occur.

6.2 Conservative measures and uterine artery embolisation

Any procedure that results in uterine preservation, or preservation of some element of fibroid tissue, runs the risk of leaving a sarcoma present. This would apply to procedures like uterine artery embolisation. However, this is not reported to result in a worse prognosis and patients deemed suitable for uterine artery embolisation should still have this treatment option offered to them.

7. Patient statement

The woman must 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. Information and support for women and their families

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

References


Appendix I: Consent to treatment form

Patient identifier/label ...........................................................................................................................................................................

Name of proposed procedure or course of treatment
Supplementary consent for morcellation of fibroids with/without a uterus (womb).

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
To remove fibroids and/or uterus with morcellation, to reduce surgical and postoperative complications and ensure a quicker recovery compared with an open operation.

Serious risks
- Unintended morcellation of a cancerous fibroid (leiomyosarcoma): 1 in 700 (uncommon) to 1 in 7400 (rare). Less than 1 in 1000 in those under 40 years old.
- Spreading of small particles of benign noncancerous fibroid material throughout the abdomen (parasitic fibroids): 1 in 120 (uncommon) to 1 in 1200 (rare).

Any extra procedures which may become necessary
- Blood transfusion.
- Other procedures: laparotomy; repair of damage to bowel, bladder, uterus, blood vessels.

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 Morcellation of fibroids or fibroid uterus.

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 ring)
This Consent Advice was produced on behalf of the Royal College of Obstetricians and Gynaecologists by: 
Dr E Saridogan FRCOG, London and Dr F Shakir MRCOG, London

and peer reviewed by: BSGE; Dr S Karavolos MRCOG, Aberdeen; RCOG Guidelines Committee

The Joint Standing Committee for Patient Safety lead reviewer was: Mr A Pickersgill FRCOG, Cheshire.

The chair of the Joint Standing Committee for Patient Safety was: Mr A Pickersgill FRCOG, Cheshire.

All RCOG guidance developers are asked to declare any conflicts of interest. A statement summarising any conflicts of interest for this Scientific Impact Paper is available from: https://www.rcog.org.uk/en/guidelinesresearch-services/guidelines/XX/

The final version is the responsibility of the Joint Standing Committee for Patient Safety of the RCOG.

The guideline will be considered for update 3 years after publication, with an intermediate assessment of the need to update 2 years after publication.

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces Consent Advice as an aid to good clinical practice. The ultimate implementation of a particular clinical procedure or treatment plan must be made by the doctor or other attendant after the valid consent of the patient in the light of clinical data and the diagnostic and treatment options available. The responsibility for clinical management rests with the practitioner and their employing authority and should satisfy local clinical governance probity.