

Laparoscopic removal of uterine fibroids with power morcellation

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Evidence on the safety of laparoscopic removal of uterine fibroids with power morcellation shows potentially serious complications. In particular there is a risk of spreading undiagnosed malignant tissue, which has higher prevalence in people who are postmenopausal or over 50. Evidence on the procedure's efficacy is limited in quantity. Therefore:
- For people who are postmenopausal or over 50, this procedure should not be used. Find out why NICE recommends not to use some procedures on the NICE interventional procedures guidance page.
 - For people who are premenopausal or 50 or under, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Further research should report details of patient selection, surgical technique (including any containment system used) and long-term outcomes.
- 1.3 Clinicians wishing to do laparoscopic removal of uterine fibroids with power morcellation in people who are premenopausal or 50 or under should:
- Inform the clinical governance leads in their healthcare organisation.
 - Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public. Also see the Royal College of Obstetricians and Gynaecologists' advice on obtaining consent from women having this procedure.

- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these. Also see the [Royal College of Obstetricians and Gynaecologists' information for patients who may be considering this procedure](#).
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedures outcomes audit tool](#) (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.4 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.5 This procedure should only be done 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.

2 The condition, current treatments and procedure

The condition

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

Current treatments

- 2.2 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.

The procedure

- 2.3 Laparoscopic surgery with power morcellation allows uterine fibroids to be cut into smaller pieces so they can be removed laparoscopically and without the need for a laparotomy. The procedure aims to reduce symptoms caused by fibroids.
- 2.4 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 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.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 12 sources, which was discussed by the committee.

The evidence included 4 randomised controlled trials, 4 non-randomised comparative studies, 2 case series and 2 systematic reviews. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: symptom relief, effective removal of fibroids and preservation of the ability to become pregnant.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: spread of malignant and benign tissues, organ injury, bleeding, hernia and pain.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that the risk of developing uterine malignancy increases with age (before and after menopause).
- 3.6 The committee was informed that all patients should be risk assessed before the procedure for the presence of malignancy. If malignancy is considered, this should be discussed with a gynaecological multidisciplinary team.
- 3.7 The committee was informed that myomectomy without morcellation is also associated with a risk of disseminating previously undiagnosed malignancy.
- 3.8 The committee was informed that containment systems (the in-bag technique) were increasingly used in this procedure with the aim of reducing the risk of disseminating benign or malignant cells.
- 3.9 The committee was informed that using containment systems adds complexity to the procedure and requires additional training. If the bag is punctured by the morcellator it would leak fibroid material and potentially injure the surrounding organs.

- 3.10 The committee noted that laparoscopic power morcellation for the treatment of fibroids is the subject of a safety communication from the US Food and Drug Administration (FDA). In this communication, the FDA encourages the use of additional labelling on laparoscopic power morcellator devices to warn of the risks of disseminating malignant and benign uterine tissue. It also advises using containment systems.
- 3.11 The committee noted that laparoscopic morcellation is a different procedure from hysteroscopic morcellation, on which NICE has also produced guidance.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.