

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# 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.

NICE is looking at laparoscopic removal of uterine fibroids with power morcellation.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 26 April 2021

Target date for publication of guidance: August 2021

## 1 Draft recommendations

- 1.1 For women who are postmenopausal or over 50, evidence on the safety of laparoscopic removal of uterine fibroids with power morcellation shows serious complications. In particular there is an increased risk of spreading undiagnosed malignant tissue. Therefore, this procedure should not be used in these patients. Find out [why NICE recommends not to use some procedures on the NICE interventional procedures guidance page](#).
- 1.2 For women who are premenopausal or 50 or under, evidence on the safety of laparoscopic removal of uterine fibroids with power morcellation shows the potential for serious complications. In particular, the risk of spreading undiagnosed malignant or benign tissue. However, the prevalence of undiagnosed malignant tissue is lower than in women who are postmenopausal or over 50. Evidence on the procedure's efficacy is limited in quantity. Therefore, in these patients 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](#).

- 1.3 Further research should report the details of patient selection, surgical technique (including the use of containment systems) and long-term outcomes.
- 1.4 Clinicians wishing to do laparoscopic removal of uterine fibroids with power morcellation in women 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 procedure outcomes audit tool](#) (for use at local discretion).
  - Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.5 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.

1.6 This procedure should only be done by a surgeon with specific training in both laparoscopic surgery and 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 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 a specially

designed electrosurgical morcellator is introduced through a small incision into the abdomen 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 (pre and post 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 was 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 to reduce the risk of disseminating non-malignant 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.](#)

Tom Clutton-Brock

Chair, interventional procedures advisory committee

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