## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Hysteroscopic removal of uterine fibroids with power morcellation

Uterine fibroids are non-cancerous growths in or around the womb (uterus). This procedure is done for fibroids inside the womb, using general, local or spinal anaesthesia. A thin tube with a camera on the end (hysteroscope) is inserted through the vagina and cervix and into the womb. Instruments are passed through the hysteroscope to cut the fibroid into small pieces (morcellation). The pieces of fibroid are removed through the hysteroscope. The aim is to reduce symptoms caused by fibroids.

This is a review of NICE's interventional procedures guidance on hysteroscopic morcellation of uterine leiomyomas (fibroids).

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 <u>draft guidance for consultation</u>. 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 The draft guidance may change after this consultation.

IPCD – hysteroscopic removal of uterine fibroids with power morcellation

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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 <u>resolution process</u>
  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 Evidence on the safety of hysteroscopic removal of uterine fibroids with power morcellation shows there are well recognised, infrequent but potentially serious side-effects. Evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out <a href="https://www.what.special.org/what.special.org
- 1.2 Clinicians wishing to do hysteroscopic removal of uterine fibroids with power morcellation should:
  - Inform the clinical governance leads in their healthcare organisation.
  - Give patients (and their families and carers as appropriate) clear written information to support <u>shared decision making</u>, including <u>NICE's information for the public</u>.

IPCD – hysteroscopic removal of uterine fibroids with power morcellation

- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- 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 <u>NICE's interventional</u> <u>procedure outcomes audit tool</u> (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

#### 1.3 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.
- 1.4 The procedure should only be done by clinicians with specific training in this technique, including fluid management.
- 1.5 Further research should report details of patient selection and patient reported outcomes, particularly symptom relief.

# 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 bleeding between periods. They can be associated with fertility problems and miscarriage.

IPCD – hysteroscopic removal of uterine fibroids with power morcellation

#### **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 Hysteroscopic morcellation aims to remove uterine fibroids under visual guidance using a hysteroscope inserted into the uterus through the cervix. Hysteroscopic morcellation is intended to reduce the risks of traumatic injury to the uterus and the risk of inadvertent fluid overload associated with traditional procedures. An intended advantage of the procedure over thermal ablation techniques is avoiding the risk of thermal injury.
- 2.4 Hysteroscopic removal of uterine fibroids with power morcellation is usually done under general or spinal anaesthesia, typically as a day-case procedure. A hysteroscope is inserted into the uterus through the cervix and saline is pumped thorough a small channel in the hysteroscope to distend the uterus. A morcellator is passed through the hysteroscope and used to cut and simultaneously aspirate the morcellated fibroid tissue. The aspirated tissue can be collected for histological analysis.
- 2.5 Different devices are available for this procedure.

#### 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

IPCD – hysteroscopic removal of uterine fibroids with power morcellation

Page 4 of 6

literature search and detailed review of the evidence from 12 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 2 randomised controlled trials (1 is also included in the systematic review and the other compares 2 different healthcare settings), 1 non-randomised comparative study, 3 cohort studies, 2 case series, 1 case report and 1 review of adverse events reported on the US Food and Drug Administration Manufacturer and User Facility Device Experience database. 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: bleeding, uterine perforation, infection and need for a hysterectomy.

#### **Committee comments**

- 3.4 Hysteroscopic morcellation is a different procedure from <a href="https://linear.com/laparoscopic morcellation">laparoscopic morcellation</a>, on which NICE has also produced quidance.
- 3.5 The committee was informed that hysteroscopic morcellation has a potential risk of disseminating malignant tissue through uterine perforation or retrograde flow through the fallopian tubes. The committee noted that this risk is lower than the risk of dissemination in laparoscopic morcellation of fibroids, in which the morcellation takes place within the peritoneal cavity. This potential risk underpins its recommendation that this procedure should only be used with special arrangements.

IPCD – hysteroscopic removal of uterine fibroids with power morcellation

NICE interventional procedures consultation document, March 2021

3.6 The committee was informed that the procedure can be used for other indications including polyps, and for endometrial biopsy.

- 3.7 There is more than 1 device available for this procedure.
- 3.8 The committee was informed that fluid management systems are used with some devices to reduce the risk of causing excessively high uterine pressures and subsequent fluid overload.
- 3.9 It is possible to take a biopsy of the fibroid before or during the procedure.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

March 2021

ISBN: