

Hysteroscopic morcellation of uterine leiomyomas (fibroids)

Interventional procedures guidance

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[nice.org.uk/guidance/ipg522](https://www.nice.org.uk/guidance/ipg522)

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. However, 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.

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.

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.

This guidance replaces IPG486.

1 Recommendations

The National Institute for Health and Care Excellence (NICE) published IPG486 Hysteroscopic morcellation of uterine fibroids in April 2014 but later withdrew the guidance because there was an error in the patient commentary considered by the Committee when it made its recommendations. IPG522 Hysteroscopic morcellation of uterine leiomyomas (fibroids) was published in June 2015 and replaces IPG486 Hysteroscopic morcellation of uterine fibroids.

- 1.1 Current evidence on the efficacy of hysteroscopic morcellation of uterine leiomyomas (fibroids) is limited in quality and quantity. Evidence on safety shows potential for serious complications. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to do hysteroscopic morcellation of uterine leiomyomas (fibroids) should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In particular they should explain the options for treatment and the reasons for considering hysteroscopic morcellation. In addition, the use of NICE's [information for the public](#) is recommended.
 - Audit and review clinical outcomes of all patients having hysteroscopic morcellation of uterine leiomyomas (see [section 7.2](#)).
- 1.3 Hysteroscopic morcellation of uterine leiomyomas (fibroids) should only be done by clinicians with specific training in this technique.
- 1.4 NICE encourages further research into hysteroscopic morcellation of uterine leiomyomas (fibroids) which could include data collection with publication of the findings, particularly of safety outcomes. Patient selection should be clearly described. Outcomes should include symptom relief, quality of life, recurrence rates and information about fertility and subsequent pregnancies. All complications should be documented. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 Uterine leiomyomas (fibroids) are benign tumours of the uterine wall. They can be asymptomatic or cause symptoms including menorrhagia, intermenstrual bleeding, pelvic pressure or pain, and urinary incontinence. They can be associated with subfertility and miscarriage.
- 2.2 Treatment depends on whether the leiomyomas cause symptoms, and on the woman's desire for future childbearing. For symptomatic leiomyomas, treatment options include hysterectomy, myomectomy, uterine artery embolisation and endometrial ablation techniques. Smaller submucous leiomyomas can be removed by hysteroscopic resection.

3 The procedure

- 3.1 Hysteroscopic morcellation aims to remove uterine leiomyomas (fibroids) during a single insertion of a hysteroscope into the uterus. This contrasts with traditional hysteroscopic resection of leiomyomas, in which the instrument is reinserted into the uterus multiple times. Hysteroscopic morcellation is intended to reduce the risk of traumatic injury to the uterus and the risk of inadvertent fluid overload associated with traditional procedures (because the procedure may be completed more rapidly). An intended advantage of the procedure over thermal ablation techniques is avoiding the risk of thermal injury.
- 3.2 Hysteroscopic morcellation of uterine leiomyomas is usually done with the patient 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 through a small channel in the hysteroscope to distend the uterus. A specially designed morcellator is introduced via the hysteroscope and used to cut and simultaneously aspirate the leiomyoma tissue. The aspirated tissue can be collected for histological analysis.
- 3.3 Different devices are available for this procedure.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 A non-randomised comparative study of 200 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported that all patients were symptom free at 3-month follow-up.
- 4.2 A randomised controlled trial of 60 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported mean operating times of 11 and 17 minutes, respectively ($p=0.008$). The non-randomised comparative study of 200 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported mean operating times of 16 minutes (95% confidence interval [CI] 13 to 20) and 42 minutes (95% CI 40 to 45) respectively (p value not stated).
- 4.3 The randomised controlled trial of 60 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported mean total fluid deficits (the amount of distending fluid infused during a procedure minus the amount of fluid recovered) of 409 and 545 ml respectively ($p=0.224$). The non-randomised comparative study of 200 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported mean fluid deficits of 660 ml (95% CI 419 to 901) and 742 ml (95% CI 646 to 838) respectively (p value not stated).
- 4.4 The specialist advisers listed key efficacy outcomes as: proportion of leiomyoma (fibroid) removed by morcellator at first procedure, need for repeat procedures to remove leiomyoma remnants, relief of symptoms (such as reduction in menstrual blood loss and reduction or stopping of intermenstrual bleeding), need for further treatment (including surgery) to manage initial symptoms, reduction in incidence of miscarriage, duration of pregnancy, and live birth rate.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 The majority of the following events were reported in a published review of the Food and Drug Administration (FDA) manufacturer and user facility device experience (MAUDE) database. The review estimated that approximately 180,000 hysteroscopic procedures had been done during the study period, with an overall reported adverse event rate of less than 0.1%.
- 5.2 Bowel damage was reported in 12 patients treated by hysteroscopic morcellation in the review of the FDA MAUDE database: 2 patients had temporary colostomies and were admitted to intensive care units.
- 5.3 Fluid overload needing treatment by intubation and admission to an intensive care unit was reported in 11 patients in the review of the FDA MAUDE database. Uncomplicated fluid overload that resolved spontaneously or with conservative treatment was reported in 19 patients in the same review.
- 5.4 Hysteroscopic morcellation was not completed in 1 patient because of imminent fluid overload, in a randomised controlled trial of 60 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection.
- 5.5 Conversion of the procedure to hysterectomy was reported in 6 patients in the review of the FDA MAUDE database: 3 were because of excessive blood loss, 2 were at the patient's request after the diagnoses of uterine perforation and a failed endometrial ablation, and 1 was due to device failure (also reported in section 5.7).
- 5.6 Uterine perforation that needed no additional surgery or treatment was reported in 28 patients in the review of the FDA MAUDE database.
- 5.7 Device failure (including metal shavings and broken pieces of device visualised in the uterine cavity), poor visualisation, failure of outflow, or a defective device that could not be activated were reported in 25 patients in the review of the FDA MAUDE database. In 1 reported case, the blade fell into the uterine cavity

and could not be retrieved. A hysterectomy was done and the patient recovered well postoperatively.

- 5.8 Pelvic infection was reported in 4 patients in the review of the FDA MAUDE database.
- 5.9 Postoperative bleeding that could be controlled with non-invasive measures was reported in 6 patients in the review of the FDA MAUDE database.
- 5.10 One patient with multiple comorbidities died after the procedure from 'pulmonary embolism and comorbidities'. A second patient, who was an elderly woman described as 'not well', was readmitted the day after her procedure and died shortly after. An exact cause of death was not reported.
- 5.11 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). Information from specialist advisers is provided in [section 6](#), in the context of comments from the Committee.

6 Committee comments

- 6.1 The Committee noted that another procedure, 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 discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids because concerns have been raised about the risk of spreading unrecognised malignant tumours. In light of this, the Committee sought opinion from a number of specialists. Specialist advisers were asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so) and they commented that:
- Laparoscopic morcellation is a different procedure from hysteroscopic morcellation, and has a different risk profile. Laparoscopic morcellation involves inserting a morcellator device through a small incision in the patient's abdomen, and the morcellation of fibroid tissue takes place within the peritoneal cavity. In hysteroscopic

morcellation, the morcellator device is inserted into the uterus through the vagina, and the fibroid tissue is morcellated within the uterus.

- Theoretically, in women with patent fallopian tubes, hysteroscopic morcellation of unrecognised malignant tissue could result in the spread of malignant cells to the peritoneal cavity. Advisers considered that this would be very unlikely and highlighted that, to date, it has not been reported in the peer-reviewed research literature. There is no evidence that the risk is different than for any other transcervical procedure used to remove tissue from the uterus.
- The FDA has stated that the guidance it has issued on laparoscopic power morcellators does not apply to hysteroscopic morcellators, which have a different principle of operation. The FDA guidance states that, 'when used in accordance with current indications and instructions for use, hysteroscopic morcellators do not pose the same risk as [laparoscopic power morcellators] because any sarcomatous tissue present does not enter the peritoneal cavity.'

6.2 Noting the concern about possible unrecognised malignancy within fibroids, the Committee understood that the use of any type of morcellation procedure is contraindicated when malignancy is suspected. The Committee also noted that leiomyosarcoma is very rare in premenopausal women.

6.3 Specialist advisers noted that, in their opinion, hysteroscopic morcellation is most useful for small or pedunculated leiomyomas.

6.4 The Committee noted that available publications contained little information about symptom relief, quality of life or fertility outcomes. This reinforced their consideration that the evidence on efficacy was limited.

7 Further information

7.1 For related NICE guidance, see the [NICE website](#).

7.2 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an [audit tool](#) (which is for use at local discretion).

Information for patients

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced [information for the public](#) explaining this guidance. [Tools](#) to help you put the guidance into practice and information about the [evidence](#) it is based on are also available.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

