Hysteroscopic morcellation of uterine fibroids

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guidance.nice.org.uk/ipg486

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1 Recommendations

1.1 Current evidence on the efficacy of hysteroscopic morcellation of uterine fibroids is limited in quality and quantity. Evidence on safety shows potential for serious complications, but the incidence of these is unknown. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake hysteroscopic morcellation of uterine fibroids should take the following actions.

- 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 explain 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 fibroids (see ).

1.3 Hysteroscopic morcellation of uterine fibroids should only be carried out by clinicians with specific training in this technique.

1.4 NICE encourages further research into hysteroscopic morcellation of uterine fibroids. 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.

1.5 NICE will review the procedure on publication of further evidence.

2 Indications and current treatments

2.1 Uterine fibroids are benign tumours of the uterine wall. Fibroids 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 fibroids cause symptoms, and on the woman’s desire for future childbearing. For symptomatic fibroids, treatment options include hysterectomy, myomectomy, uterine artery embolisation and endometrial ablation techniques. Smaller submucous fibroids can be removed by hysteroscopic resection.

3 The procedure

3.1 Hysteroscopic morcellation aims to remove uterine fibroids during a single insertion of a hysteroscope into the uterus. This contrasts with traditional hysteroscopic resection of fibroids, 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 fibroids 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 fibroid 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 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 patient satisfaction, recurrence, reoperation, pregnancy and live birth rates.

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 published literature did not report any significant safety issues. The following events were all reported on the Food and Drug Administration (FDA) manufacturer and user facility device experience (MAUDE) database. The denominator for these data (the total number of procedures performed) is unknown and therefore it is not possible to calculate incidence rates.
5.2 Uterine perforation (found or suspected) was reported in 8 patients (1 patient was treated by hysterectomy, 2 patients had laparoscopy and 3 reports stated that no treatment was needed).

5.3 Bowel perforation was reported in 3 patients (2 were repaired at laparoscopy and 1 patient had a mini-laparotomy).

5.4 Fluid deficit (that is, fluid overload in the patient) needing intervention was reported in 16 patients. Of these, 6 patients were admitted to the emergency room or intensive care unit (4 reports stated that patients needed to be intubated), 2 patients needed temporary ventilator support, 1 patient had a laparoscopy and 1 patient had a hysterectomy. One of these reports noted that the excessive fluid loss was attributed to error by nurses.

5.5 Pulmonary oedema was reported in 6 patients: all were treated with diuretics, and 4 patients were admitted to the intensive care unit.

5.6 Bleeding needing intervention was reported in 3 patients; 1 patient had a hysterectomy.

5.7 The FDA MAUDE database also had a record of 1 procedure in which the blade of the morcellator fell off into the uterine cavity and a hysterectomy was done. Another procedure was abandoned after shards of metal were cut off the shaft by the device blade – the uterine cavity was irrigated with saline to try to recover all the pieces of metal (the patient made a full recovery).

5.8 The specialist advisers did not describe any additional adverse events.

6 Committee comments

6.1 The Committee was advised that hysteroscopic morcellation is most useful for small or pedunculated fibroids and that the risks are greater with fibroids deep in the wall of the uterus.

6.2 In debating its recommendation, the Committee noted that the available publications contained very little information about symptom relief, quality of
life or fertility. This underpinned the conclusion that the evidence on efficacy was inadequate and the recommendation about outcomes from future research.

6.3 The Committee received a number of patient commentaries, which were mostly supportive of the procedure.

7 Further information

7.1 This guidance requires that clinicians undertaking 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 a summary of this guidance for patients and carers. 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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