NICE guidance

Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg704

This guidance replaces IPG522.

1 Recommendations

1.1 Evidence on the safety of hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids 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 what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do hysteroscopic mechanical tissue removal

(hysteroscopic morcellation) for uterine fibroids 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.
- 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 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.

1.3 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.

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.

2.3 This procedure is used for submucosal fibroids, which develop in the muscle layer beneath the inner lining of the uterus and grow into the uterine cavity. This includes pedunculated fibroids, which are attached to the uterus with a narrow stalk of tissue.

The procedure

2.4 Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) aims to remove submucosal uterine fibroids under visual guidance using a hysteroscope inserted into the uterus through the cervix. It is intended to reduce the risk of traumatic injury to the uterus associated with traditional procedures. An intended advantage of the procedure over thermal ablation techniques is avoiding the risk of thermal injury.

2.5 The procedure may be done under local, regional, or general 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.

2.6 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 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.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 Hysteroscopic tissue removal (hysteroscopic morcellation) is a different procedure from laparoscopic morcellation, on which NICE has also produced guidance.

3.6 The committee was informed that hysteroscopic morcellation has a theoretical risk of disseminating malignant tissue through uterine perforation or retrograde flow through the fallopian tubes. The committee noted that this is a theoretical risk in contrast to the

recognised risk of dissemination in laparoscopic morcellation of fibroids, in which the morcellation takes place within the peritoneal cavity.

3.7 The committee was informed that the procedure can be used for other indications, but this guidance is only for treatment of uterine fibroids.

3.8 The committee was informed that automated fluid management systems are used with some devices to reduce the risk of causing excessively high uterine pressures and subsequent fluid overload. It noted the guideline on management of fluid distension media in operative hysteroscopy published by the British Society for Gynaecological Endoscopy and the European Society for Gynaecological Endoscopy.

3.9 It is possible to take a biopsy of the fibroid before or during the procedure.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation