**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Interventional procedure consultation document**

**Hysteroscopic morcellation of uterine leiomyomas (fibroids)**

Uterine leiomyomas (fibroids) are non-cancerous (benign) growths that occur in the womb and can be associated with heavy menstrual bleeding, and with problems becoming pregnant and during pregnancy. Hysteroscopic morcellation is performed with anaesthesia. A special instrument is passed through the vagina and through the neck of the uterus to cut the leiomyoma into small pieces (morcellation), which are then removed by suction.

The National Institute for Health and Care Excellence (NICE) is examining hysteroscopic morcellation of uterine leiomyomas (fibroids) and will publish guidance on its safety and efficacy to the NHS. NICE’s Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about hysteroscopic morcellation of uterine leiomyomas (fibroids).

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

**Note that this document is not NICE’s formal guidance on this procedure. The recommendations are provisional and may change after consultation.**

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE’s guidance on the use of the procedure in the NHS.

For further details, see the Interventional procedures programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest
groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE’s duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 26 November 2014
Target date for publication of guidance: February 2015

1 Provisional recommendations

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, and 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 leiomyomas (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 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 (fibroids) (see section 7.2).

1.3 Hysteroscopic morcellation of uterine leiomyomas (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 leiomyomas (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. 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 published literature reported limited significant safety issues. The majority of the following events were 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 31 patients: 2 patients were treated by hysterectomy, 2 patients were treated by laparoscopy and 13 reports stated that no treatment was needed.

5.3 Bowel perforation was reported in 9 patients: 1 patient had a temporary colostomy, 1 patient had a bowel resection, 3 patients had surgical repair, 3 reports stated that it was unknown whether intervention was needed and in 1 patient there was no further information.

5.4 Fluid deficit (that is, fluid overload in the patient) needing intervention was reported in 23 patients. Of these, 7 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 and 1 patient had a hysterectomy. One of these reports noted that the excessive fluid loss was attributed to error by nurses. In addition, hysteroscopic morcellation was aborted prematurely in 1 patient because of imminent fluid overload in a randomised controlled trial of 60 patients.
5.5 Pulmonary oedema was reported in 9 patients: 5 reports stated that the patients were treated with diuretics, and 3 patients were admitted to the intensive care unit.

5.6 Bleeding needing intervention was reported in 6 patients; 1 patient had a hysterectomy.

5.7 One patient with ‘remarkable hypertension, rheumatoid arthritis and obesity’ died after the procedure from ‘pulmonary embolism and comorbidities’.

5.8 There were 6 reports of metal shards breaking off into the uterine cavity.

5.9 The FDA MAUDE database also contained single case reports of the following adverse events: tubo-ovarian abscess (no further information); seizure during the procedure (which was aborted); endometritis (endometrial ablation was also done after the morcellation procedure); infection (the type of infection was not stated, and the patient was treated with antibiotics); and a contraceptive implant sucked into the cutting window of the morcellator (the implant and the device were removed together and the patient had no injury or clinical sequelae).

5.10 The specialist advisers described 2 anecdotal adverse events: moderate vaginal bleeding that resolved spontaneously; and blade detachment from the machine. Morcellation of malignant tissue and spreading and upstaging of endometrial cancer were described as theoretical adverse events by 2 specialist advisers.

6 Committee comments

6.1 The Committee noted that laparoscopic 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 advice from a number of specialists and was advised 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.
- It is theoretically possible that unrecognised malignancy could be spread into the peritoneal cavity by hysteroscopic morcellation in a woman with patent fallopian tubes, but advisers considered this would be very unlikely. To date, this has not been reported in the peer-reviewed research literature.

6.2 The Committee noted that the use of morcellation is contraindicated when malignancy is suspected. The Committee also noted that leiomyosarcoma is very rare in premenopausal women. In addition, the Committee noted that unexpected malignancy has been diagnosed as a result of histologic analysis of tissue removed by hysteroscopic morcellation and then successfully treated.

6.3 The Committee was advised that hysteroscopic morcellation is most useful for small or pedunculated leiomyomas.

6.4 The Committee noted that 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.

7 Further information

7.1 For related NICE guidance, see the NICE website.
7.2 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

Bruce Campbell
Chairman, Interventional Procedures Advisory Committee
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