NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids

Uterine fibroids are non-cancerous growths on the inside or outside of the womb (uterus). In this procedure, a device is put into the vagina and inserted into the womb through the cervix (transcervical). It uses ultrasound to help locate the fibroid, then delivers heat (radiofrequency) energy to destroy it (ablation). The aim is to shrink the fibroid and reduce symptoms.

NICE is looking at transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine 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This document contains the draft guidance for consultation. 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 The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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- prepare a second draft, which will go through a resolution process 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: 22 October 2020

Target date for publication of guidance: March 2021

1 Draft recommendations

1.1 Evidence on the safety of transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids raises no major safety concerns. However, evidence on its efficacy is limited in 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 transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients 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 During the consent process clinicians should tell patients that the procedure may not fully relieve their symptoms and further procedures may be needed.

1.5 Further research should include comparative studies, preferably randomised controlled trials. It should report details of patient selection, disease-specific quality of life and long-term outcomes.

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 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 fertility problems and miscarriage.

Current treatments

2.2 Treatment depends on whether the fibroids cause symptoms, and if the person would like to have children in the future. For symptomatic fibroids, treatment options include medications, 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 Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids is done using general or regional anaesthesia, or sedation. A radiofrequency ablation device with an ultrasound probe at the tip is inserted through the cervix into the endometrial cavity. The ultrasound probe is used to visualise and target the fibroid, which is then ablated with radiofrequency energy. The aim is to shrink the fibroid and reduce symptoms.

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 8 sources, which was discussed by the committee. The evidence included 1 systematic review, 3 case series (6 publications) and 1 case report. 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: quality of life, fibroid-related symptom score, fibroid volume, reintervention rates and future pregnancy.

3.3 The professional experts and the committee considered the key safety outcomes to be: haemorrhage, infection, uterine perforation and hospital readmission.

Committee comments

3.4 The committee noted that there is some evidence of efficacy but that there were no high-quality comparative studies with sufficient numbers of patients to make a definitive evaluation. Fibroids are a common condition and these considerations underpinned the committees request for more data collection including disease-specific quality of life measures and rarer complications

3.5 The committee was informed that the procedure may be an option for people who want to maintain their fertility but noted that the evidence for successful pregnancy after the procedure is limited to case reports.

3.6 The committee noted that all the evidence it reviewed was in women aged under 50.

3.7 The committee noted that all the evidence it reviewed was on fibroid types 1, 2, 3 and 4, and 2 to 5 (transmural), according to the International Federation of Gynecology and Obstetrics (FIGO) classification system.

Colin Howie
Vice chair, interventional procedures advisory committee
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