NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids

Uterine fibroids are non-cancerous growths on the inside or outside of the womb (uterus). In this procedure, the woman lies face down with an ultrasound scanning device placed on the skin of the abdomen immersed in water. This scans the womb to show where the fibroids are. A separate device is used to deliver a precisely focussed dose of high-intensity ultrasound energy through the skin of the abdomen (transcutaneous). This heats the fibroid until most or all of it is destroyed. The woman may have to lie still for up to 3 hours during the procedure. The aim is to reduce symptoms caused by the fibroids.

The National Institute for Health and Care Excellence (NICE) is looking at ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

Issue date: March 2019

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are 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 developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please 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 we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 18 April 2019

Target date for publication of guidance: July 2019

1 Draft recommendations

1.1 Current evidence on the safety of ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids shows there are well-recognised complications including skin burns. The evidence on efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these and provide them with clear written information to support shared decision making. In addition, the use of NICE's information for the public *[URL to be added at publication]* is recommended.
- Audit and review clinical outcomes of all patients having ultrasound-guided high intensity transcutaneous focused ultrasound for symptomatic uterine fibroids. 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.

1.3 During the consent process clinicians should tell patients that their symptoms may not be fully relieved and may return, and that further procedures may be needed. They should also tell patients about the risk of skin burns. Patients considering pregnancy should be told that the effects of the procedure on fertility and future pregnancy are uncertain.

1.4 Patient selection should be done by a multidisciplinary team including a gynaecologist and an appropriate imaging specialist.

1.5 The procedure should only be done in specialised centres by clinicians with specific training in this technique.

1.6 NICE encourages further research and prospective data collection. Studies comparing ultrasound-guided high-intensity focused ultrasound with other therapies such as uterine artery embolisation and MRI-guided high-intensity transcutaneous focused ultrasound would be useful. Studies should report patient selection (including size, location and number of fibroids), patient-reported outcome measures, long-term outcomes and subsequent pregnancy rates.

2 The condition, current treatments and procedure

The condition

2.1 Uterine 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 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 and surgery. Surgery includes hysterectomy, myomectomy, uterine artery embolisation, endometrial ablation techniques, MRI-guided focussed ultrasound and myolysis.

The procedure

2.3 Ultrasound-guided high-intensity transcutaneous focused ultrasound (HIFU) for symptomatic uterine fibroids is done with the patient lying face down, with the abdominal wall immersed in degassed water. Intravenous sedation may be used to help minimise body movement. A urinary catheter is inserted to keep the bladder empty during the procedure. Continuous sonographic imaging is used to identify the fibroid(s) with a real-time diagnostic ultrasound scanner integrated into the centre of a therapeutic ultrasound transducer. After the target fibroid has been confirmed, it is ablated by high-intensity ultrasound energy. The patient may have to lie still for up to 3 hours.

2.4 Ultrasound-guided HIFU uses grayscale or echogenicity changes to determine the adequacy of ablation. After treatment, imaging (by

ultrasound or MRI scan) is used to evaluate the volume of the fibroid ablated.

3 Committee considerations

The evidence

3.1 To inform the committee, 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 9 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 4 non-randomised comparative studies, 3 case series and 1 case reports, and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: patient-reported outcome measures, quality of life, fibroid size, subsequent pregnancy rates and need for further intervention.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: pain, skin burns, vaginal discharge and bleeding, and damage to adjacent structures (including bowel injury).

Committee comments

3.4 Most evidence came from studies done outside the UK and there was some uncertainty about the generalisability of this evidence to the UK setting.

3.5 There may be additional safety concerns in patients who have had previous abdominal surgery (including caesarean section); in

patients who are obese; and in patients who have a retroverted uterus.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

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