NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg657

1 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. Find out what special arrangements mean on the NICE interventional procedures guidance page.

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 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 has developed an audit tool (which is for use at local discretion).

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, 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 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 report, 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).

3.4 One commentary from a patient who had experience of this procedure was received, which was discussed by the committee.

Committee comments

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

3.6 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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation