

Magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG231.

1 Guidance

- 1.1 Current evidence on the efficacy of magnetic resonance image (MRI)-guided transcutaneous focused ultrasound for uterine fibroids in the short term is adequate, although further treatment may be required and the effect on subsequent pregnancy is uncertain. There are well-recognised complications but the evidence on safety is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit.
- 1.2 During the consent process clinicians should inform patients that their symptoms may not be relieved, that their symptoms may return, and that further procedures may therefore be required. They should also inform patients about the risk of skin burns. Patients contemplating pregnancy should be informed that the effects of the procedure on fertility and on pregnancy are uncertain.
- 1.3 Patient selection should be carried out by a multidisciplinary team including a gynaecologist and an appropriate imaging specialist.
- 1.4 The procedure should only be carried out by clinicians with specific training in this technique.
- 1.5 NICE encourages further research into the efficacy of MRI-guided transcutaneous focused ultrasound for uterine fibroids. Research studies should report long-term outcomes, including the need for further treatment. Data on the

incidence and outcomes of subsequent pregnancy in patients who choose this procedure because they wish to maintain or improve their fertility are particularly important.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Uterine fibroids are benign tumours of the uterine wall. Fibroids can be asymptomatic or cause symptoms including bleeding, urinary incontinence, pelvic pressure or pain. They can be associated with subfertility and miscarriage.
- 2.1.2 For symptomatic fibroids, treatment options include hysterectomy, myomectomy, uterine artery embolisation and endometrial ablation techniques.

2.2 Outline of the procedure

- 2.2.1 MRI-guided transcutaneous focused ultrasound for uterine fibroids is carried out with the patient lying prone inside an MRI scanner, using imaging and thermal mapping guidance. The patient is usually under intravenous conscious sedation and is able to communicate with the operator about adverse symptoms such as burning sensations or pain. A catheter is inserted to keep the bladder empty during the procedure.
- 2.2.2 The head of the ultrasound device is placed in contact with the skin of the patient's lower abdomen. Low-power ultrasound is first used to target the centre of the fibroid, followed (after the aiming has been confirmed) by high-power pulses to ablate part of the fibroid. The patient may have to lie still for up to 3 hours. After treatment, imaging is used to evaluate the volume of the fibroid ablated.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and 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 [overview](#).

- 2.3.1 A non-randomised comparative study of 192 patients treated by magnetic resonance image (MRI)-guided transcutaneous focused ultrasound or abdominal hysterectomy reported improvements in all Short Form-36 quality of life domains for both treatment groups, although scores at 6 months were better in patients treated by hysterectomy (significant for 5 of 8 domains with p values from 0.004 to 0.05). A case series of 40 patients reported a 40 percentile point improvement from baseline in quality-of-life score (0 to 100 scale) at 3-year follow-up ($p < 0.001$).
- 2.3.2 A case series of 359 patients reported a significantly greater reduction from baseline in symptom severity score (0 to 100; higher scores worse) at 3 months in patients with a non-perfused volume (NPV) ratio greater than 20% versus those with an NPV ratio of 20% or less (31 points versus 24 points, $p < 0.001$). The case series of 40 patients reported a 48 percentile point improvement from baseline in symptom severity score (0 to 100 scale) at 3-year follow-up ($p < 0.01$).
- 2.3.3 Case series of 130 and 80 patients reported that 5% (7 out of 130) and 10% (8 out of 80) of patients respectively had a hysterectomy within 12 months.
- 2.3.4 A case series of 51 women who conceived after the procedure (54 pregnancies) reported that 41% (22 out of 54) of pregnancies resulted in deliveries; miscarriage occurred in 26% (14 out of 54) and 13% (7 out of 54) were electively terminated.
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as quality of life, symptom improvement, avoidance of further surgery, and subsequent fertility.

2.4 Safety

- 2.4.1 Sciatic nerve palsy was reported in 1 of 109 patients (1%) treated by the

procedure in the non-randomised comparative study of 192 patients. The case series of 80 patients reported mild temporary sciatica in 1 patient (1%).

- 2.4.2 The case series of 287 patients reported skin burns in 7% (10 out of 144) of patients treated in 2003–5 compared with 1% (2 out of 143) of patients treated in 2005–6 ($p=0.04$). A full-thickness burn in the lower abdomen was described in a case report (treated by excision and direct closure).
- 2.4.3 Spontaneous vaginal expulsion of treated fibroid tissue requiring hysteroscopic removal was documented in a case report.
- 2.4.4 Bowel perforation following treatment by the procedure was reported in 1 patient (total number treated unknown) in an adverse event report submitted to the US Food and Drug Administration (Manufacturer and User Facility Device Experience [MAUDE] database). Surgical management was required, confirming perforation in 3 bowel sites.
- 2.4.5 The Specialist Advisers considered a theoretical adverse event to be damage to the bladder.

2.5 Other comments

- 2.5.1 The Committee was informed that many women wish to avoid more invasive interventions for symptomatic fibroids, even if this choice carries an increased chance of requiring further treatments. Some women choose this procedure because they wish to preserve their fertility: the lack of evidence on subsequent fertility underlies the recommendation in [section 1.5](#).
- 2.5.2 The Committee noted that there is continuing evolution and development of the techniques used in this procedure.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).