

Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg689

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.

1 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 procedures 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 become pregnant 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 9 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 cohort studies (6 publications), 1 case series 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.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 There is some evidence of efficacy but there were no high-quality comparative

studies with sufficient numbers of patients to make a definitive evaluation. Fibroids are a common condition. These considerations underpinned the committee's request for more data collection including disease-specific quality of life measures and rarer complications.

- 3.6 The committee was informed that the procedure may be an option for people who want to maintain their fertility but the evidence for successful pregnancy after the procedure is limited to case reports.
- 3.7 All the evidence reviewed was in women aged under 50.
- 3.8 All the evidence reviewed was on fibroid types 1, 2, 3 and 4, and 2 to 5 (transmural), using the International Federation of Gynecology and Obstetrics (FIGO) classification system.
- 3.9 The committee was informed that there is a limit to the size of fibroid that can be treated using this procedure.

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Endorsing organisation

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