

Magnetic resonance image-guided transcutaneous focused ultrasound ablation for uterine fibroids

1 Guidance

1.1 Current evidence on the safety and efficacy of magnetic resonance image (MRI)-guided transcutaneous focused ultrasound for uterine fibroids is such that this procedure should only be used with special arrangements for consent and for audit or research.

1.2 Clinicians wishing to use MRI-guided transcutaneous focused ultrasound ablation for uterine fibroids should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG231publicinfo).
- Audit and review clinical outcomes of all patients having MRI-guided transcutaneous focused ultrasound ablation for uterine fibroids (see section 3.1).

1.3 Further research on the procedure and publication of long-term outcomes would be useful. The Institute will review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Uterine fibroids, also known as leiomyomas or myomas, are benign nodules of smooth muscle cells and fibrous tissue that develop within the wall of the uterus.

2.1.2 Uterine fibroids occur in approximately one third of all women. In many cases they are

asymptomatic, but they can cause abnormal uterine bleeding and a feeling of pelvic pressure or pain. Uterine fibroids may also be associated with reproductive problems such as infertility and miscarriage.

2.1.3 Treatment depends on whether the fibroids are symptomatic, and on the woman's desire to become pregnant. Treatment will rarely be required after the menopause. Asymptomatic fibroids (often discovered incidentally) require no treatment other than monitoring. Symptomatic fibroids can be removed surgically by hysterectomy or myomectomy. Uterine artery embolisation may also be a treatment option for some women.

2.2 Outline of the procedure

2.2.1 Focused ultrasound is carried out under MRI guidance, with a thermal mapping sequence to monitor the extent of tissue heating. A catheter is inserted to keep the bladder empty during the procedure. Sonication (ultrasound) is delivered through the skin, initially at low power. Once the centre of the fibroid has been correctly targeted, higher power sonication is delivered to ablate the fibroid. The patient is under conscious sedation and is therefore normally able to communicate with the operator about any adverse symptoms such as burning sensations or pain.

2.3 Efficacy

2.3.1 The evidence on efficacy is based on four case series. In a study of 160 women, the first 96 were treated using the original protocol and the last 64 were treated with a modified protocol allowing expanded treatment. At 6 months, 74% and 88% of each group, respectively, had a 10-point reduction in symptom severity (measured by the

Interventional procedure guidance 231

This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

Uterine Fibroid Symptom and Quality of Life questionnaire). In another case series of 109 women, 71% had the same outcome at 6 months.

- 2.3.2 A case series of 49 women reported that mean symptom severity score was 48% lower at 12 months compared with baseline. Another case series of 42 women reported that mean duration of menstrual bleeding decreased from 6.1 days to 4.9 days and frequency of tampon/pad changes increased from 1.7 hours to 2.25 hours (minimum follow-up of 6 months).
- 2.3.3 All four case series reported that a percentage of women (34% [40 of the 116 women remaining at 12 months in the study of 160 women], 28% [23 of the 82 women remaining at 12 months in the study of 109 women], 12% [6/49] and 26% [11/42]) required alternative treatments such as hysterectomy. For more details, refer to the 'Sources of evidence' section.
- 2.3.4 The Specialist Advisers stated that symptomatic response was the key efficacy outcome. One Adviser stated that there was limited reduction in fibroid volume following the procedure.

2.4 Safety

- 2.4.1 The evidence on safety is based on four case series and one case report. In the case series of 160 women, 290 adverse events were reported; however, none were considered serious. Pain or discomfort related to the procedure was reported in 51% of patients. One patient had paraesthesia at the cannulation site which resolved within 6 weeks. Another patient had mild sonication-related leg pain which resolved within 2 days.
- 2.4.2 In the study of 109 women, 5% reported skin burns, and 1 woman developed skin ulceration. In the study of 49 women, 2 (4%) experienced small, superficial skin burns and 1 (2%) experienced a full-thickness burn. Two studies each reported one case (1/109; 1/42) of sciatic nerve pain, which resolved within 12 months. Other complications included mild diarrhoea, fatigue and backache. For more details, refer to the 'Sources of evidence' section.
- 2.4.3 The Specialist Advisers listed theoretical complications as skin burns, reversible neural damage, and thermal damage to adjoining structures.

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1337. 'Understanding NICE guidance' can be obtained by quoting reference number N1338.

The distribution list for this guidance is available at www.nice.org.uk/IPG231distributionlist

Published by the National Institute for Health and Clinical Excellence, September 2007; ISBN 1-84629-481-9

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

© National Institute for Health and Clinical Excellence, 2007. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute.

2.5 Other comments

- 2.5.1 The Committee noted that there were a significant number of consultee comments from patients.
- 2.5.2 It was noted that there was no evidence on the efficacy of the procedure as treatment for sub-fertility associated with uterine fibroids.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion), available from www.nice.org.uk/IPG231
- 3.2 The Institute has published interventional procedures guidance on magnetic resonance (MR) image-guided percutaneous laser ablation of uterine fibroids (www.nice.org.uk/IPG030) and uterine artery embolisation for the treatment of fibroids (www.nice.org.uk/IPG094).
- 3.3 Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding have been appraised as part of the Institute's technology appraisal work programme and full guidance was issued in April 2004 (www.nice.org.uk/TA078). The Institute has issued a clinical guideline on heavy menstrual bleeding (www.nice.org.uk/CG044).

Andrew Dillon
Chief Executive
September 2007

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG231publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of magnetic resonance image-guided transcatheter focused ultrasound ablation for uterine fibroids', November 2006.

Available from: www.nice.org.uk/ip343overview