



Magnetic resonance (MR) image-guided percutaneous laser ablation of uterine fibroids

Interventional procedures guidance Published: 17 December 2003

www.nice.org.uk/guidance/ipg30

1 Guidance

1.1 Evidence on safety and efficacy outcomes of MR image-guided percutaneous laser ablation of uterine fibroids is insufficient to support its use without special arrangements for consent and for audit or research. Clinicians wishing to undertake MR image-guided percutaneous laser ablation should inform the clinical governance leads in their Trusts. They should ensure that women offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's information for the public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

2 The procedure

2.1 Indications

- 2.1.1 MR image-guided percutaneous laser ablation is used to treat uterine fibroids, also known as uterine leiomyomas or uterine myomas. Fibroids are benign tumours of the uterine muscle. They are very common and are often asymptomatic. They may cause abnormal bleeding, pelvic pressure and pain, and reproductive problems.
- 2.1.2 Hysterectomy is the standard treatment for women with fibroids whose symptoms have not resolved with medical treatment. However, in the past decade, there has been increased interest in minimally invasive surgical techniques.

2.2 Outline of the procedure

- 2.2.1 Under MR-image guidance needles are inserted, through an area of skin that has been locally anaesthetised, into the centre of the targeted uterine fibroid. Bare laser fibres are inserted down the centre of each of the needles into the targeted fibroid. Laser energy is then used to destroy the fibroid.
- 2.2.2 A thermal mapping sequence is used to depict the extent of the heated tissue in the target area as the procedure is carried out.
- 2.2.3 A catheter is placed in the bladder before the start of the procedure and women receive intravenous sedation and analgesia throughout.

2.3 Efficacy

2.3.1 The evidence for efficacy was based on four reports published by one UK study group. Some women were included in more than one report. Limited evidence suggested that the procedure resulted in a short-term (3-month) reduction in fibroid volume of around 30%. For more details refer to the sources of evidence section.

2.3.2 The main comment from the Specialist Advisors related to the relatively new nature of the procedure. One Advisor commented on patient selection, stating that the procedure might only be appropriate for fibroids of a certain size, and that it might not be of benefit for women with larger or multiple fibroids.

2.4 Safety

- 2.4.1 Adverse events were reported in a minority of patients. Potential complications included urinary tract infections, skin burns and vaginal bleeding. These events were relatively minor and of a transitory nature. For more details refer to the sources of evidence section.
- 2.4.2 The Specialist Advisors listed the potential adverse effects as infection, burns, uterine damage and bowel or bladder damage.

2.5 Other comments

2.5.1 This is a very specialised procedure and currently only one centre in the UK undertakes it. As such, the evidence available was limited.

3 Further information

- The Institute has issued safety and efficacy guidance on <u>uterine artery</u> <u>embolisation</u> and <u>laparoscopic laser myomectomy</u>, and will issue interventional procedures guidance on laparoscopic total hysterectomy in 2004 [Now published as <u>'Laparoscopic hysterectomy (including laparoscopic total hysterectomy and laparoscopically assisted vaginal hysterectomy) for endometrial cancer'].</u>
- The Institute is also in the process of developing a clinical guideline on hysterectomy and alternative surgical treatments for menorrhagia and other conditions. The expected date of issue of this guideline is September 2005 [Now published as 'Heavy menstrual bleeding: investigation and treatment'].

Andrew Dillon

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Chief Executive December 2003

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 percutaneous laser ablation for uterine fibroids', April 2003.

Information for patients

NICE has produced <u>information on this procedure for patients and carers</u> ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

As part of NICE's work programme, the current guidance was considered for review in May 2009 but did not meet the review criteria as set out in the IP process guide. This guidance therefore remains current.

30 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

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We have produced a <u>summary of this guidance for patients and carers</u>. Information about the evidence it is based on is also available.

Your responsibility

This guidance represents the views of NICE and 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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.