



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

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www.nice.org.uk/guidance/ipg30

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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

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 NICE'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 1 UK study group. Some women were included in more than 1 report. Limited evidence suggested that the procedure resulted in a short-term (3-month) reduction in fibroid volume of around 30%. For more details, see the <u>overview</u>.
- 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, see the overview.

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 1 centre in the UK undertakes it. As such, the evidence available was limited.

3 Further information

- 3.1 NICE has issued guidance on uterine artery embolisation, laparoscopic laser myomectomy, and laparoscopic hysterectomy (including laparoscopic total hysterectomy and laparoscopically assisted vaginal hysterectomy) for endometrial cancer.
- 3.2 NICE has also published guidance on heavy menstrual bleeding: assessment and management.

Sources of evidence

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

Information for patients

NICE has produced <u>information for the public on this procedure</u>. 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 <u>Healthcare Improvement Scotland</u>.