

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

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 below.

Interventional Procedure Guidance 30

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. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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 below.

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

3.1.1 The Institute has issued safety and efficacy guidance on uterine artery embolisation (IPG 1) and laparoscopic laser myomectomy (IPG 23), and will issue interventional procedures guidance on Laparoscopic total hysterectomy and hysteroscopic laser myomectomy in 2004.

3.1.2 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.

Andrew Dillon
Chief Executive
December 2003

Information for the Public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. 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/IPG030publicinfoenglish and in English and Welsh from www.nice.org.uk/IPG030publicinfowelsh.

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

Available from: www.nice.org.uk/IP200overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0391. *Information for the Public* can be obtained by quoting reference number N0392 for the English version and N0393 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG030distributionlist

Published by the National Institute for Clinical Excellence, December 2003 ISBN: 1-84257-465-5

© National Institute for Clinical Excellence December 2003. All rights reserved. This material may be freely reproduced for educational and not for profit purposes within the NHS. No reproduction by or for commercial organisations is permitted without the express written permission of the Institute.

National Institute for Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA, website: www.nice.org.uk

N0391 1P 5k Dec 03 (ABA)