

## NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

### INTERVENTIONAL PROCEDURES PROGRAMME

#### Interventional procedure overview of magnetic resonance image-guided percutaneous laser ablation for uterine fibroids

##### Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

##### Date prepared

This overview was prepared in April 2003

##### Procedure name

Magnetic resonance image-guided percutaneous laser ablation  
MRI guided percutaneous laser ablation for uterine fibroids  
MR guided percutaneous laser ablation for uterine fibroids

##### Specialty society

*British Society of Interventional Radiology*  
*Royal College of Obstetricians and Gynaecologists*

##### Description

###### Indications:

Uterine fibroids (also known as uterine leiomyomas or uterine myomas) are the most common pelvic tumours in women and the most common indication for hysterectomy. They are present in around 30% of all women and 40% of premenopausal women <sup>[1]</sup>.

Only 20-30% of leiomyomas are symptomatic resulting in symptoms such as excessive menstrual bleeding, pelvic discomfort and pain.

###### Current Treatments and Alternatives:

The treatment for uterine fibroids has traditionally been hysterectomy or other surgery. However over the past decade there has been increased interest in minimally invasive surgical techniques.

**What the procedure involves:**

A catheter is placed in the bladder prior to the start of the procedure. Patients are given intravenous sedation and analgesia.

Under magnetic resonance image guidance needles are inserted into the centre of the targeted uterine fibroid through an area of skin that has been anaesthetised. 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.

A thermal mapping sequence is then used to depict the extent of the heated tissue in the target area as the procedure is carried out.

Each procedure may involve up to three successive power applications in an overlapping manner to cover as much of the target fibroid as possible whilst monitoring the exact site of heat deposition with thermal mapping.

The technique is described as an outpatient procedure.

It is important to note that this procedure differs from other interstitial laser techniques for uterine fibroids in that a laparoscope is not used in the procedure.

**Efficacy:**

- The evidence for efficacy is based on four papers published by one UK study group. There is some evidence to suggest that the procedure results in a short-term (3 month) reduction of fibroid volume of around 30%. Evidence however is limited with some of the same women being included in the studies.
- The main comment from Specialists Advisors related to the relatively new (emerging) nature of the procedure. One Advisor commented on patient selection; stating that the procedure may only be appropriate for fibroids of certain size and not of benefit for women with larger or multiple fibroids.

**Safety:**

- Adverse events were reported in a minority of patients. Potential complications include urinary tract infections, skin burns and vaginal bleeding. These events were relatively minor and of a transitory nature.
- There is the possibility that adjacent organs such as the bowel or bladder could be damaged due to either penetration at the time of needle placement or due to heat damage from uncontrolled power application. This however is a theoretical concern since to date complications of this nature have not been reported.
- Specialist Advisors listed potential adverse effects as infection, burns, uterine damage and bowel or bladder damage.

## Literature review

### Rapid Review of Literature

The medical literature was searched to identify studies and reviews relevant to image guided laser treatment for uterine fibroids. Searches were conducted via the following databases from commencement to February 2003: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1 ) was applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved

**Table 1 Inclusion criteria for identification of relevant studies**

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality comparative studies. Abstracts were excluded where no clinical outcomes were reported; the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded due to the difficulty in appraising methodology.
Patient	Women with uterine fibroids
Intervention/test	Image guided (MRI) percutaneous laser ablation
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy
Language	Non-english language articles will be excluded unless they are thought to add substantively to the English language evidence base.

### List of Studies Found

Four relevant papers were identified (see below). Members of the same study group have written all four papers.

It was decided to treat this evidence as two separate studies, despite the results of some of the same women being included in more than one paper.

**Table 2 Summary of key efficacy and safety findings from case series papers**

<b>Authors, location, date, number of patients</b>	<b>Key efficacy findings</b>	<b>Key safety findings</b>	<b>Comments</b>
Hindley et al (2002) <sup>[2]</sup> MRI Case series 66 patients with symptomatic fibroids	<p><b>Mean volume reduction of fibroids</b> 3 month follow-up (47 pts) fibroid volume had decreased by 31% (significant) 1 year follow-up (24 pts) fibroid volume had decreased by 41% (significant) 6/20 patients had a substantial increase at 12 months</p> <p><b>Menstrual blood loss (8 pts)</b> Post treatment 121.2ml 3 months 81.2ml</p> <p><b>Menorrhagia Outcomes Questionnaire (MOQ) 35/37</b> Compared to a historical group undergoing hysterectomy patients undergoing MRI laser ablation reported a worse total outcome score.</p>	3 patients required antibiotic therapy for urinary tract infections 2 patients sustained minor skin burns	Lost to follow-up - unclear.  Very small sample size for menstrual blood loss  Description of patients is lacking
Law et al 1999 & Law and Regan 2000 <sup>[3-5]</sup> MRI Case series  12 patients symptomatic fibroids who had not responded to medical management  Mean ablation was 15 mins	<p><b>Mean volume reduction of fibroids (7pts)</b> 3 month follow-up (7pts) fibroid volume had decreased by 37.5%</p> <p>Women reported subjective improvement in symptoms (objective measures in progress)</p> <p>Four women went on to have subsequent surgery</p>	No complications were reported 2 patients experienced vaginal bleeding	Small sample size  Short term follow-up  In the paper by Law and Regan it notes that 30 women with symptomatic fibroids are included

In a paper by Chapman (1998)<sup>[6]</sup> reference is also made to five patients with large leiomyomas in whom CT was used to confirm the position of laser fibres. However no safety or efficacy has been published on these patients.

## **Validity and generalisability of the studies**

- Very limited information is available on image guided percutaneous laser ablation for uterine fibroids. To date four papers have been published describing this procedure in women with uterine fibroids. The same study group has undertaken all these studies, with some of the same women being included in the studies.
- Patient selection was reported as being conservative. This suggests that patients with a greater probability of positive outcomes would have been selected for inclusion into the study.
- Many of the endpoints were measured on a small number of patients, for example menstrual blood loss was measured in 8 out of 66 patients.
- There is also a question regarding the validity of using the Menorrhagia Outcomes Questionnaire (MOQ) for women undergoing percutaneous laser ablation, as the MOQ was developed for women who have undergone a hysterectomy.
- There is little long-term data and limited follow-up.

## **Specialist advisor's opinion / advisors' opinions**

*Specialist advice was sought from the British Society of Interventional Radiology, and the Royal College of Obstetricians and Gynaecologists*

- This procedure is very new.
- Only one centre is undertaking the procedure.
- The procedure requires specialised equipment and as such the diffusion of the technology is likely to be slow.
- It has the potential to have a significant benefit for some patients.
- Potential adverse events include infection, burns and damage to adjacent organs.

## **Issues for consideration by IPAC**

- To date only one centre in the UK is undertaking this procedure. The group had initially proposed carrying out a randomised controlled trial comparing myomectomy with thermal ablation Law and Regan (2000) <sup>[5]</sup> however were unable to obtain funding for this process (personal communication 31st March 2003 Gedroyc,W.).

## **References**

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- (3) Law P, Gedroyc WM, Regan L. Magnetic resonance-guided percutaneous laser ablation of uterine fibroids. *J Magn Reson Imaging* 2000; 12(4):565-570.
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