



Photodynamic endometrial ablation

Interventional procedures guidance Published: 24 March 2004

www.nice.org.uk/guidance/ipg47

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 <u>Yellow Card Scheme</u>.

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 Current evidence on the safety and efficacy of photodynamic endometrial ablation does not appear adequate to support the use of this procedure outside formal research. It is suitable for use only within good quality research studies approved by a research ethics committee and with explicit patient consent. 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 Photodynamic endometrial ablation is used to treat heavy menstrual periods, also known as menorrhagia.
- 2.1.2 Menorrhagia is a very common problem. Hysterectomy has been the standard treatment for women with menorrhagia who have not responded to medical therapy. Minimally invasive procedures used to destroy the lining of the uterus (the endometrium) are alternatives to hysterectomy. They include using lasers, radiofrequency waves, electrocautery, microwaves, heated saline or a heated balloon. Photodynamic endometrial ablation is one of these minimally invasive procedures.

2.2 Outline of the procedure

2.2.1 Photodynamic endometrial ablation involves injecting a photosensitive chemical into the uterine cavity through a hysterosalpingography catheter. A probe inserted through the cervix uses a laser to activate the photosensitive chemical, which destroys the endometrium. It can often be carried out under local anaesthetic on a day-case basis.

2.3 Efficacy

- 2.3.1 The evidence relating to this procedure was extremely limited and was based on one very small case series that included two women with menorrhagia and one woman with prolonged postmenopausal bleeding. For more details, see the overview.
- 2.3.2 The Specialist Advisors considered photodynamic endometrial ablation to be an experimental procedure not yet ready for routine clinical use.

2.4 Safety

- 2.4.1 The evidence considered by the Advisory Committee was limited the single study offered no assessment of pain or discomfort during the operation. For more details, see the overview.
- 2.4.2 The Specialist Advisors noted that the photosensitive chemical used in the procedure may cause skin photosensitivity. They commented that the evidence available was too limited to allow accurate assessment of the safety of the procedure.

3 Further information

3.1 NICE has issued <u>interventional procedures guidance on microwave endometrial</u> ablation and free fluid thermal endometrial ablation.

- 3.2 NICE has issued technology appraisal guidance on fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding.
- 3.3 NICE has also produced a guideline 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 Healthcare Improvement Scotland.