

Impedance-controlled bipolar radiofrequency ablation for menorrhagia

1 Guidance

- 1.1 Current evidence on the safety and efficacy of impedance-controlled bipolar radiofrequency ablation for menorrhagia appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Information is lacking about the long-term results of the procedure. Clinicians are encouraged to collect data on rates of recurrence and late complications, and they should ensure that patients are aware of the uncertainty about long-term safety and efficacy. Use of the Institute's *Information for the Public* is recommended.
- 1.3 It is recommended that the Medicines and Healthcare products Regulatory Agency (formally the Medical Devices Agency) safety notices on endometrial ablation are followed (MDA [1998] SN 9812 *Devices used for endometrial ablation achieved by thermal means*, and MDA [1999] SN 1999(18) *Devices used for endometrial ablation*, available from www.medical-devices.gov.uk). See Section 2.5.2.
- 1.4 Clinicians undertaking this procedure should have had adequate training. The British Society for Gynaecological Endoscopy has agreed to produce standards for training.

2 The procedure

2.1 Indications

- 2.1.1 This procedure is used to treat menorrhagia. The procedure may reduce excessive menstrual bleeding or may result in complete amenorrhoea, an outcome considered desirable by some women.

- 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 treatment. Minimally invasive procedures to destroy the lining of the uterus (the endometrium) are alternatives to hysterectomy. They involve destroying the endometrium using lasers, radiofrequency waves, electrocautery, microwave energy, heated saline, or a heated balloon. Impedance-controlled radiofrequency ablation is one of these minimally invasive procedures.

2.2 Outline of the procedure

- 2.2.1 Under general or local anaesthesia, a sheath containing a bipolar radiofrequency electrode is placed through the cervix. This sheath is pulled back, allowing the electrode to expand and conform to the shape of the uterine cavity. Radiofrequency energy is then delivered into the uterus via the electrode.
- 2.2.2 Fibroids or large polyps inside the cavity of the uterus may interfere with the placement of the device.

2.3 Efficacy

- 2.3.1 Amenorrhoea rates in two randomised controlled trials (RCTs) and two case series ranged from 41% (63/154) to 59% (62/105) at 12 months. In the two RCTs, higher amenorrhoea rates were reported in women undergoing the impedance-controlled procedure than in women undergoing balloon thermal endometrial ablation and rollerball ablation.
- 2.3.2 In one of the RCTs, reduction in bleeding to normal levels or less was almost the same in each group: 91% (140/154) of women following the impedance-controlled procedure, compared with 88% (72/82) of women who underwent rollerball

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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.

ablation. For more information, refer to the Sources of evidence.

2.3.3 In two studies, there was evidence to suggest that the majority of patients were satisfied after the procedure and that quality of life had improved.

2.3.4 The Specialist Advisors commented that this procedure appeared efficacious in the short term in terms of amenorrhoea rates, but that there were little long-term data.

2.4 Safety

2.4.1 Complications following the procedure included pelvic pain, endometritis, urinary tract infection, nausea and vomiting. In the largest study, postoperative adverse events occurred in 13% of women (23 patients). These included nine patients with urinary tract or vaginal infections, two patients with a haematometra and two patients with pelvic inflammatory disease. For more information, refer to the Sources of evidence.

2.4.2 The Specialist Advisors listed potential complications as being infection (endometritis), bleeding and perforation, and damage to the surrounding structures.

2.5 Other comments

2.5.1 The Committee noted that the procedure is not appropriate for the treatment of women with large fibroids and/or an abnormally shaped or displaced uterus.

2.5.2 In 1998 and 1999, the Medical Devices Agency (which became the Medicines and Healthcare products Regulatory Agency [MHRA] in April 2003) made the following recommendations.

- Clinicians should carefully consider the use of thermal endometrial ablation in the following circumstances:
 - a small (thin-walled) uterus
 - pre-operative hormone treatments, or
 - a history of pelvic infections (for example, where fibrosis and bowel adhesions are more likely to be present).
- In cases of suspected uterine displacement, clinicians should verify the correct placement using ultrasound before the device is activated.
- As well as the use of ultrasound for all devices, the use of hysteroscopy prior to the insertion of the ablation device is recommended if the device is not a balloon. This enables a check to

be made that sounding and dilation of the cervix has not caused a perforation or false passage.

- The concurrent use of diathermy during such procedures should not be undertaken because of the risk of the ablation device as a source of alternate site burns.

3 Further information

3.1 The Institute has issued safety and efficacy guidance on microwave endometrial ablation (www.nice.org.uk/IPG007guidance); balloon thermal endometrial ablation (www.nice.org.uk/IPG006guidance); photodynamic endometrial ablation for menorrhagia (www.nice.org.uk/IPG047guidance); free-fluid thermal endometrial ablation (www.nice.org.uk/IPG051guidance).

3.2 The Institute has also issued Technology Appraisal guidance on Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding (www.nice.org.uk/TA078).

3.3 The Institute is developing a clinical guideline on hysterectomy and alternative surgical treatments for menorrhagia and other conditions (expected issue date is September 2005).

Andrew Dillon
Chief Executive
December 2004

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, in English and Welsh, from www.nice.org.uk/IPG104publicinfo.

Sources of evidence

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

Interventional procedure overview of impedance-controlled bipolar radiofrequency ablation for menorrhagia, February 2004.

Available from: www.nice.org.uk/ip227overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0783. *Information for the Public* can be obtained by quoting reference number N0784 for the English version and N0785 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at www.nice.org.uk/IPG104distributionlist

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