

Balloon thermal endometrial ablation

1 Guidance

- 1.1 Current evidence on the safety and efficacy of balloon thermal endometrial ablation appears adequate to support the use of this procedure, provided that the normal arrangements for consent, audit and clinical governance are in place.
- 1.2 It is recommended that 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 point 2.5.4.

2 The procedure

2.1 Indications

- 2.1.1 Balloon thermal 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 that has 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, microwaves, heated saline, or a heated balloon. Balloon thermal endometrial ablation is one of these minimally invasive procedures.

2.2 Outline of the procedure

- 2.2.1 Thermal balloon endometrial ablation is a technique that involves inserting a balloon into the uterine cavity through the cervix. The balloon is inflated with a pressurised solution that is then heated to destroy the endometrium. It can often be carried out using local anaesthesia on a day-case basis.

2.3 Efficacy

- 2.3.1 The Committee considered evidence from a Cochrane systematic review of endometrial destruction techniques. The systematic review concluded that women undergoing thermal ablation techniques (transcervical resection of endometrium, laser ablation, rollerball ablation, saline irrigation, microwave ablation, radiofrequency ablation, heated balloon, photodynamic therapy and cryoablation) had a similar reduction in bleeding to, and were as satisfied as, women having hysteroscopic resection of the endometrium. The advantages of thermal ablation techniques were that general anaesthesia was not required and the procedures were quicker and easier to perform. The systematic review did not come to any conclusions about the relative advantages and disadvantages of the different thermal endometrial destruction techniques.
- 2.3.2 Other studies found treatment to be 'successful' or patient satisfaction to be 'good' or 'excellent' in more than 90% of cases. Rates of amenorrhoea varied from 30 to 60%. For more details, refer to the overview (see below).
- 2.3.3 The Specialist Advisors believed the procedure to be established and that it might offer benefits similar to those of microwave endometrial ablation. They commented that there was a lack of long-term data, making long-term efficacy hard to judge.

2.4 Safety

- 2.4.1 The evidence highlighted a number of side effects and complications of balloon thermal endometrial ablation. These included endometritis, urinary tract infection and haemorrhage, although they were all uncommon. For more details, refer to the overview (see below).

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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.

2.4.2 The Specialist Advisors noted risks, including uterine perforation and bowel injury. They commented on the lack of data in this area.

2.5 Other comments

2.5.1 The Committee noted that the temperature and pressure of the fluid inside the balloon varies between devices, and these differences are likely to give rise to different results and side-effect profiles.

2.5.2 Long-term efficacy data were lacking.

2.5.3 Endometritis and perforation are possible complications, but further data on side effects are needed.

2.5.4 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.
- The concurrent use of diathermy during such procedures should not be undertaken due to the risk of the ablation device as a source of alternate site burns.

The US Food and Drug Administration (FDA) recently issued similar recommendations.

2.5.5 Evidence was presented to the Committee on the use of only two devices for this procedure (Cavaterm[®] and Gynecare[®]) as in the Safety and Efficacy Register of New Interventional Procedures. If data relating to other devices become available, the procedure may be reviewed by the Committee.

3 Further information

3.1 NICE has issued interventional procedures guidance on microwave endometrial ablation and will issue interventional procedures guidance on free-fluid thermal endometrial ablation and photodynamic endometrial ablation for menorrhagia in the future.

3.2 Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding have been appraised as part of the Institute's technology appraisal work programme. Guidance is being prepared.

3.3 NICE is 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
August 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/IPG006publicinfoenglish.

Sources of evidence

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

- *Interventional procedure overview of balloon thermal endometrial ablation (Cavaterm[®])*, November 2002.
- *Interventional procedure overview of balloon thermal endometrial ablation (Gynecare[®])*, November 2002.

Available from:
<http://www.nice.org.uk/IP099overview1>
<http://www.nice.org.uk/IP099overview2>

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference: N0256. *Information for the Public* can be obtained by quoting reference number N0257 for the English version and N0258 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/IPG006distributionlist

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