NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA78 fluid filled thermal balloon and microwave endometrial ablation for menstrual bleeding

This guidance was issued in April 2004
The review date for this guidance is January 2010

Recommendation

- The decision to review should be deferred until 2011 when the first of two National Institute for Health Research technology assessments of treatments for heavy menstrual bleeding will be published.

Consideration of options for recommendation:

Options	Comment
A review of the guidance should be planned into the appraisal work programme.	There does not appear to be sufficient new evidence currently to warrant updating the guidance.
The decision to review the guidance should be deferred until 2011.	The review should be deferred until the First of the National Institute for Health Research technology assessments of treatments for heavy menstrual bleeding is published in 2011. The TA review will also help to inform a proposed review of the clinical guideline on heavy menstrual bleeding (CG44).
A review of the guidance should be combined with a review of a related technology and conducted at the scheduled time for the review of the related technology.	There are no reviews of a related technology scheduled.
A review of the guidance should be combined with a new appraisal that has recently been referred to the Institute.	No related appraisals have been referred to NICE.
A review of the guidance should be incorporated into an on-going clinical guideline.	This is not an option. The clinical guideline on heavy menstrual bleeding (CG44; published Jan 2007) was reviewed in January 2010 and the National Collaborating Centre recommended that there is insufficient new evidence to justify a full or partial update of the guideline. This proposal is due to be put to

	Guidance Executive in July 2010.
A review of the guidance should be updated into an on-going clinical guideline.	This is not an option. The clinical guideline on heavy menstrual bleeding (CG44; published Jan 2007) was reviewed in January 2010 and the National Collaborating Centre recommended that there is insufficient new evidence to justify a full or partial update of the guideline. This proposal is due to be put to Guidance Executive in July 2010.
A review of the guidance should be transferred to the 'static guidance list'.	This is not an appropriate option because the evidence base for second generation ablation techniques for heavy menstrual bleeding is evolving and new treatments have become available since TA78 was published.

Original remit(s)

To advise on the clinical and cost-effectiveness of thermal endometrial ablation for heavy menstrual bleeding, in relation to alternative interventions including hysterectomy.

Current guidance

1.1 Fluid-filled thermal balloon endometrial ablation (TBEA) and microwave endometrial ablation (MEA) are recommended as treatment options for women with heavy menstrual bleeding (HMB) in cases where it has been decided (by the woman and the clinician responsible for her treatment) that surgical intervention is appropriate for the management of the condition.

1.2 For heavy menstrual bleeding, the choice of surgical treatment should be made jointly by the woman and the clinician responsible for treatment. The decision should be made after an informed discussion taking into account the desired outcome of the treatment (such as reduced menstrual bleeding or complete cessation of menstrual bleeding [amenorrhoea]), the relative benefits of all other treatment options and the adverse events associated with them, as well as the clinical condition, anatomical suitability and preferences of the woman.

Relevant Institute work

CG44 Heavy menstrual bleeding: NICE guideline. This was issued January 2007, expected review date 2010.

IPG104 Impedance-controlled endometrial ablation for menorrhagia, published 15 December 2004.

IPG51 Free fluid thermal endometrial ablation: guidance published March 2004

IPG104 Impedance-controlled endometrial ablation for menorrhagia published 2004

IPG7 Microwave endometrial ablation published 27 August 2003.

IPG6 Balloon thermal endometrial ablation published August 2003.

Safety information

MHRA (January 2010) Medical Device Alert: Devices used for endometrial ablation. All makes and models (MDA/2010/006)
"The MHRA continues to receive reports of uterine wall injury, wall perforation, or the creation of a false passage following use of endometrial ablation devices. In some cases resection of damaged tissue has been required. The majority of complications occur due to either poor patient selection or endometrial ablation procedures being performed in difficult situations. Patients with either a retroverted uterus or a fixed uterus (e.g. due to significant endometriosis or adhesions), or those that have had previous uterine surgery are at a higher risk."

Details of new products

Device(manufacturer)	Details
Novasure System (Cytyc UK Ltd)	The original appraisal did not include Novasure as it was not available at the time. This device is a second generation ablation techniques but it uses radiofrequency ablation which is not within the remit of TA78.

On-going trials

Trial name and contact	Details
Cavaterm TM vs TCRE in women with DUB (Dysfunctional uterine bleeding) (NCT00549159)	Multicentre randomized clinical trial to evaluate the safety and effectiveness of Cavaterm TM balloon endometrial ablation in women with dysfunctional uterine bleeding compared to transcervical resection of the endometrium. Estimated completion date October 2009.
Effectiveness and Cost-effectiveness of Levonorgestrel containing Intrauterine system in Primary care	This trial will assess the effectiveness, cost effectiveness and acceptability of using the

against Standard treatment for menorrhagia (ISRCTN86566246)	levonorgestrel IUS (Mirena coil) compared to standard medical treatment for women with menorrhagia presenting in primary care. Estimated completion date: December 2014.

Proposed Timing for updating the guidance

If the guidance was agreed by GE, we will consult on the proposal and the decision to review will be deferred until the next review of CG44 in January 2013

New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline(R) In-Process and Embase. References from 2007 onwards were reviewed.

Implementation

A submission from Implementation is attached at the end of this paper.

Equality and diversity issues:
No equalities and diversity issues have been identified.

Appraisals summary:
Technology appraisal guidance 78 (TA78) was initially reviewed in December 2007. It was recommended that the review be deferred for two years at which time the evidence base for TA 78 would be reviewed in conjunction with the review of Clinical Guideline 44 'Heavy menstrual bleeding: investigation and treatment' (published in January 2007). It was anticipated that this would lead to TA78 being updated within the guideline.

CG44 was reviewed in January 2010 and the National Collaborating Centre: Women's and Children's Health (NCC-WCH) recommended that there is insufficient new evidence to justify an update of the guideline currently. The NCC-WCH noted that there is new evidence relevant to the recommendations in the guideline but clinical opinion given to the NCC-WCH indicated that this would not change the recommendations. Clinical guidelines are reviewed on a three-year basis, therefore the next review of CG44 will be in January 2013.

TA78 compared the use of second generation endometrial ablation techniques (fluid-filled thermal balloon endometrial ablation [TBEA] and microwave endometrial ablation [MEA] with first generation techniques (transcervical resection of endometrium, roller-ball ablation and hysterectomy). Second generation techniques, thermal balloon and microwave ablation, were recommended as cost-effective alternatives to hysterectomy for the treatment of heavy menstrual bleeding although there was insufficient evidence to distinguish between the clinical and cost

effectiveness of each technique. The Committee recommended further research directly comparing thermal balloon and microwave ablation and comparing second generation techniques with levonorgestrel releasing intrauterine systems (LNG-IUS).

CG44 recommends pharmaceutical treatment (which includes the LNG-IUS) as first and second line treatment, and, if this fails a range of second generation endometrial ablation techniques including the use of TBEA and MEA techniques (plus impedance-controlled bipolar radiofrequency ablation and fluid free thermal endometrial ablation which do not fall within the original scope of this appraisal). The guideline incorporates and is consistent with the recommendations of TA78. The guideline notes that endometrial ablation is preferable to hysterectomy and all women considering endometrial ablation should have access to a second generation technique. The guideline also evaluates the cost effectiveness of pharmaceutical and endometrial ablation treatment. The guideline recommends that future research be undertaken into the clinical and cost-effectiveness of the various second-generation ablation techniques against one another.

The updated literature search for TA78 identified a number of published studies relevant to this appraisal. These included two RCTs directly comparing thermal balloon ablation with microwave ablation. There was also a small number of studies (two observational studies and one RCT) of an alternative second generation ablation technique which was not available when TA78 was published (Novasure radiofrequency ablation; although this technology was not specifically searched for so it is likely that there is more published evidence). This technology was not within the original remit of TA78 (which included only microwave and thermal balloon ablation); however, if a review was to go ahead it would be appropriate to expand the remit to include all second generation ablation techniques. In addition, the literature search identified a small number of published studies (three RCTs, one systematic review and one cost-effectiveness analysis) comparing second generation ablation techniques with levonorgestrel releasing intrauterine systems which are a recent pharmaceutical alternative to endometrial ablation (this was also recommended as an area for further research in TA78).

In their consideration of the review of CG44, the NCC-WCH noted that there were a number of new studies comparing second generation ablation techniques but clinical opinion was that much more data is still needed to demonstrate the superiority of one technique over another. The NCC-WCH also noted that there are some current research projects underway which may inform a future update of CG44 including two National Institute for Heath Research technology assessments of treatments for heavy menstrual bleeding: one on the effectiveness and cost effectiveness of hysterectomy, microwave endometrial ablation and thermal balloon ablation (due to be published in January 2011), and the other on effectiveness and cost effectiveness of levonorgestrel releasing intrauterine systems and standard medical treatment (due to be published in 2015).

In summary, while there is some new evidence relevant to TA78, it does not appear to be sufficient to warrant a review of the guidance currently. There are ongoing studies including heath technology assessments relevant to this topic that would benefit a future review of the guidance. Therefore, it is proposed that a review of TA78 be deferred until 2011 when the first of the relevant health technology assessments will be published. The review in 2011 will help to inform considerations of the next review of CG44. This is in line with the proposal for the review of CG44 in which the NCC-WCH recommended that there is insufficient new evidence to justify a review of the guideline currently.

GE paper sign off: Dr Frances Sutcliffe, Associate Director, Technology Appraisals, CHTE 6th July & 24th August 2010.

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NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

IMPLEMENTATION DIRECTORATE

Guidance Executive Review

Technology appraisal 78: Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding

1. Hospital Episode Statistics data

1.1 This section provides information on endometrial ablation and hysterectomy procedures for HMB carried out in England. The data are obtained from Hospital Episode Statistics (HES) online. Unfortunately this data does not distinguish between the types of endometrial ablation technique so needs to be treated cautiously in relation to the specific recommendations of the guidance.

Figure 2 Number of procedures performed for HMB in secondary care within the NHS

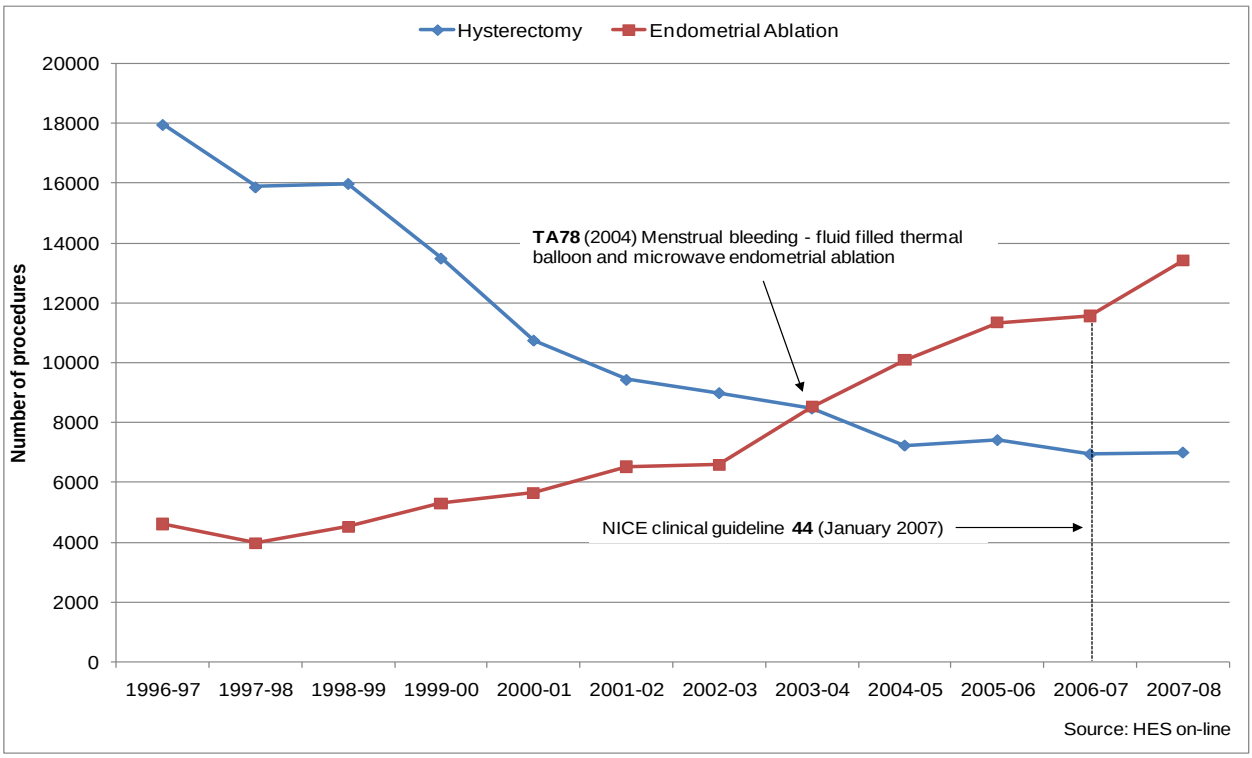
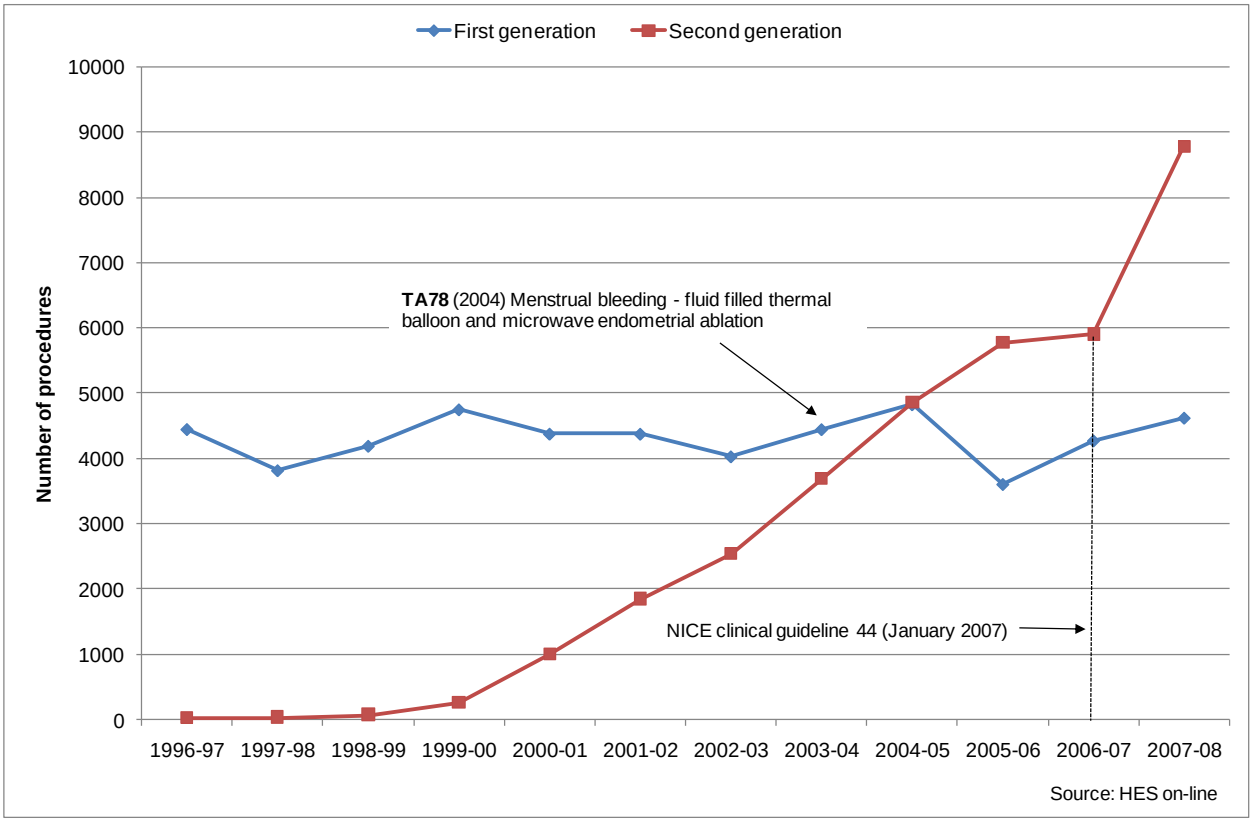


Figure 3 Number of first and second generation endometrial ablation procedures performed for HMB in secondary care within the NHS



2. External literature

An additional literature search was carried out by information services using the following databases:

- ERNIE
- Cinahl (EBSCO Host)
- Embase (Ovid)
- HMIC (Search 2)
- Medline (Ovid)
- Medline in Process (Ovid)

2.1 Hardwick JC, Owen P (Apr. 2004) **Adherence to published guidelines for the management of menorrhagia in women undergoing second generation endometrial ablation**. *Journal of Obstetrics & Gynaecology* 24 (3): 279-280.

Second-generation endometrial ablation techniques provide an effective surgical treatment option for women with menorrhagia. Their ease of use might result in inappropriate surgical treatment without previous medical therapy. The study sought to establish local compliance with national guidelines following the recent introduction of second generation ablation techniques into routine practice. Data were collected at the time of ablation on the preceding medical management of women undergoing either microwave endometrial ablation or thermal balloon ablation. One hundred and thirty-two consecutive women underwent second-generation endometrial ablation. At least one medical treatment (range 1-5) was used before ablation in 86% of women. The majority (86%) of women undergoing a second-generation endometrial ablation technique received at least one effective medical therapy before surgical intervention, indicating a high level of compliance with published guidelines.