**PRE-ASSESSMENT**

Endometrial Ablation for Menorrhagia

Before CCOHTA decides to undertake a health technology assessment, a pre-assessment of the literature is performed. Pre-assessments are based on a limited literature search; they are not extensive, systematic reviews of the literature. They are provided here as a quick guide to important, current assessment information on this topic. Readers are cautioned that the pre-assessments have not been externally peer reviewed.

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**Introduction**

It is estimated that heavy menstrual bleeding or menorrhagia occurs in 9% to 30% of women of reproductive age, with the rate peaking just prior to menopause.\(^1\) In cases where there is no obvious pathology to explain the menorrhagia, the condition is called dysfunctional uterine bleeding (DUB). First-line treatment is usually medical, involving the administration of either hormonal therapies or non-steroidal anti-inflammatory drugs. If medical therapy fails, however, surgery is often the next treatment option. Hysterectomy has long been used as a definitive surgical treatment for heavy menstrual bleeding, ensuring the cessation of blood flow and postoperative patient satisfaction. The procedure, however, is invasive with inherent risks and complications.

Recently, endometrial ablation has been adopted as a less invasive approach for the treatment of menorrhagia. The procedure ensures uterine preservation and in most women also reduces bleeding. The first-generation endometrial ablation techniques include endometrial resection, rollerball ablation (electrocautery) and neodymium: yttrium-aluminum-garnet (Nd:YAG) laser ablation. These techniques are performed hysteroscopically and remove the entire thickness of the endometrium. Although effective, these techniques require specialized training and may be associated with surgical complications. The second-generation endometrial ablation techniques (e.g., balloon thermo-ablation, phototherapy, microwave ablation, radio frequency ablation) have been developed with the intention of reducing the skill required to perform the procedure without compromising effectiveness.

**Research Questions**

1. How does endometrial ablation compare with hysterectomy in terms of safety, clinical effectiveness and patient satisfaction?
2. Is endometrial ablation more cost-effective than hysterectomy?

**Assessment Process**

A preliminary literature search of PubMed, the Cochrane Library and the Centre for Reviews and Dissemination Economic Evaluation Database (EED), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA) was performed in November 2003. The web sites of HTA agencies were also searched.
## Summary of Findings

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• 237 women from US and Canada, whose DUB symptoms were not helped by medicine, were randomized either to hysterectomy or to endometrial ablation; patients are being followed for minimum of 4 years after surgery.  
• Primary endpoints are change in symptoms of bleeding, pain and fatigue; quality of life and cost-effectiveness will also be examined. |
| RCT (ongoing)                        | Fowler SE, Hirst K, Agency for Health Care Policy and Research. Dysfunctional Uterine Bleeding Intervention Trial (DUBIT). Available: http://www.bsc.gwu.edu/studies/dubit.html.³ | • DUBIT is a collaborative, multi-site study comparing effectiveness, costs and outcomes of hysterectomy, endometrial ablation and hormone therapy for women with DUB.  
• Primary objective is to compare effects of three treatments on control of bleeding, patient satisfaction and health-related quality of life.  
• Report is pending.                                                                                                                                 |
| Systematic review (in progress)      | National Coordinating Centre for Health Technology Assessment. Microwave and thermal balloon endometrial ablation for heavy menstrual bleeding: a systematic review. In: Health Technology Assessment Programme. Details of HTA Publications [database online]. Southampton: The Centre; 2002. Available: http://www.ncchta.org/ProjectData/1_project_record_notpublished.asp?Pjtid=1333.⁴ | • RCTs and non-RCTs of microwave or thermal balloon endometrial ablation versus rollerball ablation or endometrial resection or hysterectomy were included.  
• Anticipated publication date is February 2004.                                                                                                                                 |
• Expected date of issue is February 2004.                                                                                                                                 |
### Type of Report

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| *Systematic review*  
A substantive amendment to this systematic review was made on 15 January 1999.  
- Hysterectomy significantly reduces heavy menstrual bleeding when compared with endometrial destruction techniques for up to 4 years post-surgery.  
- No differences between hysterectomy and endometrial ablation groups on quality of life scales.  
- Duration of surgery, hospital stay and recovery time shorter after endometrial destruction.  
- Adverse events (major and minor) significantly more likely after hysterectomy and before hospital discharge; after discharge, only difference is higher rate of infection in patients who had hysterectomy.  
- Repeat surgery for failure of initial treatment more likely for endometrial ablation.  
- Total cost significantly lower for endometrial destruction, but this difference narrowed over time due to high cost of re-treatment. |
| *HTA*  
Report issued July 2003 (guidance to NHS pending)  
- What are effectiveness and cost-effectiveness of microwave and thermal balloon endometrial ablation techniques for heavy menstrual bleeding compared with transcervical resection, rollerball ablation and hysterectomy?  
- Committee agreed that hysterectomy is only option that can guarantee amenorrhea, but also indicated that it should not be offered to patients by default.  
- Based on available evidence, microwave and thermal balloon endometrial ablation are likely as effective as first-generation techniques (transcervical resection and rollerball).  
- Markov analysis suggests that second-generation techniques (microwave and thermal balloon endometrial ablation) are more cost-effective than first-generation techniques; first-generation techniques are more cost-effective than hysterectomy. |
### Endometrial Ablation for Menorrhagia

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) is a non-profit organization funded by the federal, provincial and territorial governments. (www.ccohta.ca)

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|                | • Examined efficacy, safety, acceptability and costs associated with treatment approaches for DUB, including hysterectomy and endometrial ablation techniques.  
• “Endometrial ablation seems to be the surgical treatment of choice for dysfunctional uterine bleeding and should be preferred to hysterectomy. It provides symptomatic relief without the need to remove most of the healthy uterus. One of the drawbacks of endometrial ablation is the risk of persistent or recurrent bleeding, which requires a repeat ablation or possibly a hysterectomy. The reoperation rates given in study reports range from 0 to 38.2%, with the higher rates observed in longer studies or in women under the age of 35.”  
• “The first-generation techniques involve lower costs than a hysterectomy. The cost differential persists for a considerable period of time, although this gap narrows because of the relatively high reoperation rate in the years following endometrial ablation.” |
|                | • Two RCTs were identified that compared outcomes for menorrhagia patients after endometrial ablation (laser ablation or endometrial resection) or hysterectomy.  
• First study found that length of hospitalization and postoperative pain, time to return to normal activities and incidence of postoperative infection were significantly lower in endometrial ablation group compared with hysterectomy group. At one year, 22% of patients who underwent endometrial ablation were amenorrheic.  
• Cost analysis demonstrated that “endometrial ablation by TCRE (transcervical resection of the endometrium) has lower procedural costs than hysterectomy…however, the difference in the costs of endometrial ablation and hysterectomy narrow when repeat ablation procedures, or even hysterectomy, are required.” |
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| Guideline      | Society of Obstetricians and Gynaecologists of Canada. Guidelines for the management of abnormal uterine bleeding [SOGC clinical practice guidelines no 106]. Ottawa (ON): The Society; 2001 Aug. Available: http://www.sogc.medical.org/SOGCnet/sogc_docs/common/guide/pdfs/ps106.pdf. | • Recommendation 7: For women with menorrhagia, “The endometrium can be destroyed by several different techniques but reoperation rate at five years may be up to 40 percent with rollerblade ablation. This should be reserved for the woman who has finished her childbearing and is aware of the risk of recurrent bleeding.” (Evidence obtained from at least one properly conducted RCT.)
|                |           | • Hysterectomy is often best choice for women who have completed childbearing, reviewed alternatives and tried conservative therapy without acceptable results. |
|                |           | • Dilatation and curettage is ineffective for women with heavy menstrual bleeding (grade B).
|                |           | • Endometrium can be destroyed with various techniques, but there may be a 40% re-operation rate after 5 years (grade A).
|                |           | • Women are more likely to be satisfied with endometrial ablation than oral medical therapy (grade A).
|                |           | • There is a similar satisfaction rate and efficacy with endometrial ablation and levonorgestrel intrauterine system (grade A).
|                |           | • Vaginal hysterectomy is associated with reduced operating time, earlier hospital discharge and reduced costs when compared with laparoscopically assisted vaginal hysterectomy (grade A).
|                |           | • Endometrial destruction techniques and vaginal hysterectomy are preferable to abdominal hysterectomy (grade B). |
| Guideline      | Royal College of Obstetricians and Gynaecologists. The management of menorrhagia in secondary care [Evidence-based clinical guidelines no 5]. London: RCOG Press; 1999 Jul. | • Grade A: based on RCTs; grade C: based on more limited evidence, but advice based on experts’ opinion and endorsed by respected authorities.
|                |           | • Endometrial ablative procedures are effective in treating menorrhagia (grade A).
|                |           | • Hysterectomy is an established, effective treatment for menorrhagia (grade A).
|                |           | • Widespread use of hysterectomy as a treatment for menorrhagia should be balanced against its potential mortality and morbidity (grade C). |
**Conclusion**

Several agencies, including AETMIS and the Cochrane Collaboration, have recently reviewed the available information on the various techniques of endometrial ablation as an alternative to hysterectomy for the treatment of menorrhagia. Endometrial ablation appears to be the surgical treatment of choice for DUB and in most cases is preferred to hysterectomy. In the short-term, endometrial ablation techniques (first and second generation techniques) are effective at reducing bleeding and are a cost-effective alternative to hysterectomy. Results from two ongoing RCTs, STOP-DUB and DUBIT, should provide further evidence on this topic.

Given that endometrial ablation techniques are gaining acceptances as a treatment option for DUB, an appropriate question is which endometrial technique is more clinically effective and more cost effective. This question has been addressed by AETMIS.

The long-term outcomes following treatment with the different endometrial ablation methods have not, however, been addressed. An assessment by CCOHTA of the clinical evidence and economic evaluation related to long-term outcomes may be warranted. However, this must first wait the availability of long-term data.

Until further evidence on long-term outcomes becomes available, there may be little value in CCOHTA undertaking a further assessment of the clinical evidence. There may ultimately be a need for an economic evaluation of the cost effectiveness of this procedure and the availability of access to this technology in Canada.

**References**


Endometrial Ablation

for Menorrhagia


