Review Current minimal access techniques in the treatment of heavy menstrual bleeding

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Key content:
• Heavy menstrual bleeding remains a major problem for some women.
• Hysterectomy is the leading treatment for this condition but it is recognised to have some serious complications.
• First-generation endometrial ablation techniques have a steep learning curve and are carried out under hysteroscopic visualisation.
• Second-generation techniques are simpler and have lower complication rates, lower analgesia requirements and potential for outpatient use.
• Individual assessment is important in deciding the route and method of treatment for heavy menstrual bleeding, taking clinical factors into consideration.

Learning objectives:
• To know about the various options currently available for endometrial ablation.
• To learn about the clinical application, advantages and limitations of various methods of endometrial ablation.
• To be able to make an informed choice when deciding which modality to use.

Ethical issues:
• Intense competition will continue to drive device manufacturers to make claims of effectiveness based on poor-quality evidence. All users have a responsibility to be well informed and to offer evidence-based advice to women.

Keywords endometrial ablation / levonorgestrel-releasing intrauterine system / menorrhagia / uterine artery embolisation
Introduction

Heavy menstrual bleeding is an important cause of morbidity. It affects 1 in 5 women and leads to 21% of gynaecological referrals from general practitioners. It accounted for £7 million in prescription costs in general practice alone in 1995. It is estimated that 1 in 5 women will have a hysterectomy by the age of 55, mostly for menstrual related illness. In 2004–5 nearly 38,000 hysterectomies took place in England, making it one of the most common major operations performed. Hysterectomy is the gold standard treatment for menstrual problems. It leads to amenorrhoea in almost 100% of women and results in the highest improvements in quality-of-life indices of all the treatments available. However, a hysterectomy is not to be embarked on lightly. It can be associated with serious morbidity or even mortality, as evident from the VALUE study. This study reported a serious complication rate of 3% and mortality in the postoperative period after hysterectomy of 0.38/1000. Hysterectomy is also associated with a relatively long hospital stay and postoperative recovery that can span weeks or longer if there are subsequent complications. This can have serious financial and social implications.

Historically, medical treatment such as combined oral contraceptives, norethisterone, tranexamic acid and mefenamic acid have been offered to women as first-line treatment, with varying degrees of success. Medical treatment is limited by side effects and the need for regular, and possibly long-term, treatment. It may not meet the woman’s expectations and can lead to poor compliance and treatment failure. Recently, the success of the levonorgestrel-releasing intrauterine system has established its place as first-line treatment of menstrual problems. It leads to amenorrhoea in almost 100% of women and results in the highest improvements in quality-of-life indices of all the treatments available. However, a hysterectomy is not to be embarked on lightly. It can be associated with serious morbidity or even mortality, as evident from the VALUE study. This study reported a serious complication rate of 3% and mortality in the postoperative period after hysterectomy of 0.38/1000. Hysterectomy is also associated with a relatively long hospital stay and postoperative recovery that can span weeks or longer if there are subsequent complications. This can have serious financial and social implications.

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Uterine artery embolisation (UAE)

Emboli sion of the uterine arteries is still under evaluation. It involves injecting polyvinyl particles under fluoroscopic guidance to block the blood supply to the fibroids. Studies have shown an 85% improvement in fibroid-related symptoms such as menorrhagia. The mean fibroid volume was found to decrease by 30–60% in trials. Uterine artery embolisation is associated with higher postoperative complications such as vaginal discharge, post-puncture haematoma, post-embolisation syndrome (pain, fever, nausea and vomiting) and readmission rates when compared with hysterectomy. There are also reports suggesting possible premature ovarian failure following uterine artery embolisation. UAE is not currently recommended for women who wish to retain their fertility because of inadequate safety data. Prospective trials are under way to evaluate the effectiveness and safety profile of this intervention.

The levonorgestrel-releasing intrauterine system

The levonorgestrel-releasing intrauterine system (LNG-IUS) (Mirena®, Schering Health, Burgess Hill, West Sussex, UK) was originally developed as a contraceptive. The device releases 20 µg of levonorgestrel in 24 hours and is effective for 5 years (4 years when used for endometrial protection). It has been reported that the LNG-IUS results in an 80–90% reduction in menstrual blood flow and amenorrhoea in 20–30% of users. The device is now licensed in the UK for menorrhagia. Adequate counselling is vital at the time of fitting because most women will continue to have an abnormal pattern of bleeding for a few months following insertion.

The LNG-IUS was compared with cyclical norethisterone in a randomised trial. It was found to be more effective than norethisterone at 1-year follow-up. Although women on the LNG-IUS had more short-term side effects, they were more likely to continue treatment at 12 months (76% versus 22%). Recruitment is now under way for the multicentric ECLIPSE (Effectiveness and Cost effectiveness of Levonorgestrel-containing Intrauterine system in Primary care against Standard treatment for mEnorrhagia) trial. This prospective randomised controlled trial will study the effectiveness, cost effectiveness and acceptability of the LNG-IUS when compared with standard medical treatment in the primary care setting.

A Cochrane review looked at two trials in which the LNG-IUS was compared with transcervical resection of the endometrium (TCRE) and two in which it was compared with balloon ablation. The reviewers found a higher reduction in menstrual blood loss in women who had endometrial ablation. Although there were more side effects in the LNG-IUS group, there was no difference in the perceived quality of life after either intervention. In one interesting study, 50 women who were on the waiting list for a hysterectomy, following failed medical treatment of menorrhagia, were treated with the LNG-IUS. Eventually, 41 of these women were taken off the waiting list because of significant improvement in symptoms. Indeed, there has been a 36% decrease in the number of hysterectomies in England in the decade 1990–2000. This has led to speculation that this reduction might be related partly to the increased use of the LNG-IUS for
contraception during that period. However, caution is advised in interpreting these data, as some studies have shown that over 5 years around 50% of women using the LNG-IUS for menorrhagia will eventually have a hysterectomy. The most recent National Institute of Health and Clinical Excellence (NICE) guideline on the management of heavy menstrual bleeding recommends the use of the LNG-IUS as a first-line intervention, provided that long-term use (for at least 12 months) is anticipated. The ease of application, the lack of need for anaesthesia and the contraceptive and fertility-preserving benefits will ensure that the LNG-IUS will continue to have a prime position in the treatment of heavy menstrual bleeding.

Endometrial ablation
The 1980s heralded a new approach to the treatment of menstrual problems. It had long been recognised that traumatic destruction of the endometrium leads to amenorrhoea. Various methods to destroy the endometrium purposely have been described. These are broadly classified into first- and second-generation devices. The methods now used are listed in Box 1.

First-generation devices
First-generation devices were designed for use under hysteroscopic guidance. In 1981 Goldrath et al. were the first to describe photovapourisation of the endometrium using the neodymium-YAG (Nd:YAG) laser. Laser ablation soon lost its appeal because the device was cumbersome and expensive and suffered frequent mechanical failures. Rollerball ablation was reported by Vancaillie in 1989 and Lin in 1988. The first British results of endometrial resection were published by Magos in 1989, when the procedure was called transcervical resection of the endometrium (TCRE). In the USA the rollerball eventually became the most common device, while British surgeons used a combination of TCRE and rollerball resection. First-generation devices have been extensively evaluated in randomised controlled studies. TCRE is now the gold standard to which newer devices are compared.

First-generation methods are used in the operating theatre with the woman under anaesthesia. A non-ionic, low viscosity fluid (1.5% glycine) is used to distend the uterine cavity. Fluid overload can complicate the procedure, resulting in pulmonary and cerebral oedema, hyponatraemia, seizures, coma and death. Long-term risks include:

- post-ablation pregnancy
- haematometra, with cyclical pelvic pain from cervical stenosis
- uterine synechiae
- occult endometrial carcinoma
- post-ablation tubal sterilisation syndrome (if the procedure is combined with sterilisation).

The MISTLETOE study reported the results of a UK (excluding Scotland) audit into the complications associated with first-generation devices. There were 10 686 women in the study. The authors reported a total complication rate of 4.4%, including 2 directly related deaths. Rollerball ablation was found to be safer than laser and TCRE. Although effective in treating menorrhagia, first-generation techniques have the limitations of needing an experienced surgeon, associated potentially fatal complications, a steep learning curve and a need for anaesthesia and hysteroscopic visualisation of the uterine cavity. In fact, it has been suggested that a surgeon learning the technique of resection should treat 200 cases before they can be considered proficient. These shortcomings paved the way for the development of second-generation devices.

Second-generation devices
Many different methods have evolved over time in an attempt to simplify endometrial ablation and enable it to be performed in the outpatient setting without hysteroscopy. These are collectively known as second-generation techniques.

Hydrothermablation is the only second-generation procedure performed under hysteroscopic guidance. Women with bleeding disorders and those who are high risk for general anaesthesia are not suitable candidates for hysterectomy or TCRE; second-generation devices have proven extremely useful in such situations. Box 2 lists selection criteria and contraindications to the use of second-generation devices. A comparison between second-generation devices is shown in Table 1.

Most studies and trials use subjective improvement and amenorrhoea as outcome measures. The PBAC (pictorial blood loss assessment chart) is a scoring system that requires the woman to match the staining on her pads to a set of standardised

<table>
<thead>
<tr>
<th>First-generation</th>
<th>Second-generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser</td>
<td>Balloon thermal ablation</td>
</tr>
<tr>
<td>TCRE</td>
<td>- Cavitern®</td>
</tr>
<tr>
<td>Rollerball</td>
<td>- Thermachoice®</td>
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<td></td>
<td>- Thermablate®</td>
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<td></td>
<td>- MemoTreat®</td>
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<td></td>
<td>Hydrothermablation (free fluid)</td>
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</table>

- Microwave endometrial ablation
- NovaSure® impedance controlled endometrial ablation system
- Cryoablation (Her Option®)
- Endometrial laser intrauterine thermal therapy (ELITT), Gynelase®
- Photodynamic therapy
- Chemoablation

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Box 1 Types of devices available for endometrial ablation
pictures. A score $>100$ constitutes heavy menstrual bleeding. Improvement in quality of life is assessed by questionnaires such as the Short Form-36 (SF-36). It addition, it is very important that the analysis of data is on an intention-to-treat basis. It is evident that using only amenorrhoea and success rates to evaluate a device is inadequate. The reader is referred to the excellent reviews by NICE and The Cochrane Collaboration.

**Balloon thermal ablation**

Many versions are available, using the same principle. A balloon is positioned within the uterine cavity and hot fluid is circulated within the balloon, leading to endometrial destruction.

**Cavaterm®**

The original Cavaterm® unit (Wallsten Medical SA, Morges, Switzerland) consists of a computerised central unit and a single-use silicone balloon. The balloon size can be adjusted according to the size of the uterine cavity. The fluid used is 1.5% glycine, which is heated from the centre of the catheter to $75^\circ$C and constantly.

### Table 1: Comparison of major second-generation devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Technology</th>
<th>Pre-treatment</th>
<th>Cervical dilatation in mm</th>
<th>Duration of treatment in minutes</th>
<th>Depth of ablation in mm</th>
<th>Percentage amenorrhea rates (%)</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>NICE guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermachoice II</td>
<td>Intrauterine balloon</td>
<td>Optional</td>
<td>5</td>
<td>8</td>
<td>4–5</td>
<td>7–25</td>
<td>Small catheter size, well studied, good safety profile</td>
<td>Post-procedure pain limits outpatient use, used only for normal uterine cavity</td>
<td>PG 6 August 2003</td>
</tr>
<tr>
<td>Cavaterm plus</td>
<td>Intrauterine balloon</td>
<td>None</td>
<td>6</td>
<td>10 minutes</td>
<td>6–8</td>
<td>11–29</td>
<td>Small catheter size, useful in outpatient setting</td>
<td>Used only for normal uterine cavity</td>
<td>PG 6 August 2003</td>
</tr>
<tr>
<td>Thermablate</td>
<td>Intrauterine balloon</td>
<td>Optional</td>
<td>6</td>
<td>2 minutes</td>
<td>4–5</td>
<td>25</td>
<td>Small catheter size and short treatment cycle, extremely portable, potential for outpatient use</td>
<td>Not as extensively reported as others</td>
<td>None yet</td>
</tr>
<tr>
<td>Hydrothermal ablation</td>
<td>Heated 0.9% saline Hysteroscope sheath</td>
<td>Yes</td>
<td>8</td>
<td>10 minutes</td>
<td>2–6</td>
<td>40–53</td>
<td>Useful in the presence of large irregular cavities, performed under direct/hysteroscopic vision</td>
<td>Risk of vaginal burns, painful, needs general anaesthesia, not suitable for outpatient use</td>
<td>PG 51 March 2004</td>
</tr>
<tr>
<td>Microwave endometrial ablation (MEA)</td>
<td>Microwave at 9.2 GHz Probe 8 mm diameter</td>
<td>Optional</td>
<td>8</td>
<td>3–5 minutes</td>
<td>5–6</td>
<td>40</td>
<td>Can be used with larger, irregular cavities, short procedure time, well studied</td>
<td>Painful, hence not well suited to outpatient use, cumbersome unit</td>
<td>PG 7 August 2003</td>
</tr>
<tr>
<td>Novasure (bipolar salpingo-endometrial ablation)</td>
<td>Bipolar diathermy, impedance controlled Catheter 7 mm diameter</td>
<td>None</td>
<td>8</td>
<td>90–120 seconds</td>
<td>41–59</td>
<td>40</td>
<td>Portable and easy to use, short treatment time, device checks for uterine perforation before use</td>
<td>Blind procedure, useful only in smooth, normal sized cavities</td>
<td>PG 104 August 2004</td>
</tr>
<tr>
<td>Cryotherapy (Her Option)</td>
<td>Cryoblation under ultrasound guidance Temperature -90°C Catheter 5.5 mm diameter</td>
<td>Optional</td>
<td>6</td>
<td>10–15 minutes</td>
<td>23</td>
<td>28–40</td>
<td>Done under ultrasound guidance, less painful because of cryoanaesthesia, useful in outpatient setting</td>
<td>Requires operator to have good ultrasound skills</td>
<td>PG 157 March 2006</td>
</tr>
<tr>
<td>Gynelase</td>
<td>Intrauterine diode laser</td>
<td>Yes</td>
<td>6</td>
<td>7 minutes</td>
<td>3.5</td>
<td>50–70</td>
<td>Potential for outpatient use</td>
<td>Blind procedure, not rigorously studied yet</td>
<td>None yet</td>
</tr>
</tbody>
</table>

*aAmenorrhea rates are used in this table for simplicity. It is also important to consider other parameters of success such as patient satisfaction and improvements in PBACs and quality of life.
*bManufacturers (we are working on a more portable unit (personal communication to Rahim Halaab)).
**IPG= interventional procedures guidance*
circulated throughout the system via a pump. The system monitors the pressure within the circuit and maintains it between 220–240 mmHg. The treatment time is 15 minutes and the depth of endometrial ablation 6–8 mm.

The current model, the Cavaterm Plus system (Figure 1), uses 5% dextrose and requires cervical dilatation only to 6 mm. The duration of treatment is 10 minutes and there is no need for hormonal pretreatment of the endometrium. Cavaterm Plus has the advantage of being portable and having a small-diameter probe. This gives it potential for outpatient use. To be effective the balloon needs to achieve intimate contact with the endometrium; hence it is not useful in large, irregular cavities or in the presence of polyps or fibroids.

A single blinded randomised study compared Cavaterm with the Nd:YAG laser. Seventy-two women were randomised (37 to Cavaterm, 35 to laser ablation). The Cavaterm system was as effective as laser ablation in reducing menstrual blood loss, achieving patient satisfaction and improving quality of life. Another trial compared Cavaterm with NovaSure® endometrial ablation. The study enrolled 55 women. Both methods resulted in similar cure and satisfaction rates. However, NovaSure was associated with significantly higher amenorrhoea rates (43% versus 11%).

Thermachoice®
The latest model, Thermachoice® III (Gynecare, Ethicon, Somerville, NJ, USA), consists of a control unit and a disposable 5 mm silicone balloon of fixed length (Figure 2). The fluid used (5% dextrose) is heated externally to 87°C and is passed into the uterus, with the pressure being maintained by the unit between 160–180 mmHg. Once the desired pressure is achieved, ablation takes 8 minutes to complete. The depth of ablation is 4.5 mm.

In a large, multicentre study, 296 women underwent thermal balloon ablation, using the Thermachoice I. Follow-up was at 3, 6 and 12 months. At 12 months, follow-up data were available for 163 women (55%). The success rate over the year ranged between 88–91%. Higher balloon pressure, endometrial pretreatment and greater age were associated with greater success. Women with preoperative pain and longer uterine lengths had more failures. Long-term results from this study (at 5 years) have been published. Seventy-two percent (188 of 260) of women responded to a questionnaire and it was found that 86% did not need a hysterectomy and 75% did not need further surgery for heavy periods. The authors concluded that on long-term follow-up a
A significant number of women had avoided hysterectomy. Thermachoice has been compared with first-generation devices and found to be equally effective and safer.20 Thermachoice has the advantage of an enormous experience base and good safety profile. However, it is useful only in the presence of a normal-sized, smooth uterine cavity. In practice, it is also associated with a high level of postoperative nausea and uterine cramps, probably related to uterine distension and prostaglandin release. This severely limits the outpatient use of this device.

**Thermablate® EAS**
Thermablate® EAS (endometrial ablation system) (MDMI technologies, Richmond BC, Canada) is a more recent device. It consists of a lightweight, reusable, hand-held treatment control unit with a single-use disposable catheter 6 mm in diameter. Following insertion of the prelubricated balloon into the endometrial cavity, the pressure is automatically maintained at 180 mmHg for the treatment cycle of 2 minutes and 8 seconds. Tissue necrosis to a uniform depth of 4–5 mm has been demonstrated. Thermablate has been evaluated by two small studies31,32 (sample size 16 and 54). Amenorrhoea rates of 25% were reported, with success rates of 80%. No major complications were reported in either study. Thermablate has not yet been as rigorously studied as Thermachoice. It has good potential for outpatient use because of its narrow catheter and short application time. There is currently no NICE guidance on the use of Thermablate.

**MenoTreat®**
MenoTreat® (Atos Medical, Hörby, Sweden) is a relatively new device, the use of which seems to be confined to Scandinavian countries at present. The system comprises a disposable silicone catheter, which comes in two balloon sizes, and a control unit. The cervix is dilated to 8 mm for insertion of the 7 mm diameter catheter. The fluid is heated to 85°C in the control unit and circulated from there. The pressure is maintained at 200 mmHg and the treatment time is 11 minutes. There are very few studies on this device in the literature. In a Swedish study,33 51 women underwent treatment. At the 6-month follow-up the treatment was successful in 84.3% of women; amenorrhoea occurred in 10% of women treated. There is no NICE guidance on the use of MenoTreat at present.

**Free fluid endometrial ablation (Hydro Thermablator® [HTA])**
The use of free fluid for endometrial destruction was devised to achieve close contact with the endometrium. By design, this is not possible using a balloon. Hot saline is instilled into the uterine cavity under direct hysteroscopic vision. The hysteroscopic sheath is 7.8 mm in diameter. The pressure is maintained electronically to <55 mmHg to prevent the fluid from flowing through the uterine ostia into the peritoneal cavity. The treatment cycle is 10 minutes at a temperature of 80–90°C. A randomised study34 compared hydrothermal ablation to rollerball ablation: amenorrhoea and patient satisfaction rates were similar for both procedures at 12-, 24- and 36-month follow-up.

The main advantage of the Hydro Thermablator® (HTA) (Boston Scientific, Natick, MA, USA) system is that it is used under hysteroscopic guidance. This method can be used effectively in women who have large or abnormally-shaped uterine cavities and in the presence of uterine septa, submucous fibroids or polyps.35 Limitations of the device include significant pain, which necessitates general anaesthesia. There is also a possible risk of vaginal, perineal and thigh burns if fluid leaks from the cervix.

**Microwave endometrial ablation (MEA®)**
The MEA® (Microsulis Medical Limited, Denmead, UK) system is a device designed to ablate the endometrial lining of the uterus using microwave energy at a fixed frequency. It consists of an MEA control unit with a touch screen and microwave generator housed in a portable cart. A pneumatic foot switch helps the user control the ablation and a graphic output of the individual procedure is produced by an attached printer. The MEA applicator is a reusable instrument to introduce microwave energy at 9.2 GHz into the uterus. The shaft of the applicator measures 8.5 mm in diameter and with graduations along its length in centimetre units; its ceramic tip is 7 mm in length. The probe is inserted into the uterine cavity and moved from side to side (fundal sweep) initially and then gradually removed (Figure 3). The temperature is maintained between 70–80°C by the user. The depth of ablation is 5–6 mm and...
the duration of the treatment is 3 minutes for the normal-sized uterus (75–85 mm cavity length). Endometrial curettage prior to MEA application is not recommended as it increases the risk of unrecognised uterine perforation and subsequent microwave-induced bowel damage.

Microwave endometrial ablation is one of the most robustly studied second-generation techniques. In a major trial in Scotland,acic26 women were randomised (129 to MEA, 134 to TCRE). The mean operating time was significantly shorter with MEA (11.4 minutes) than with TCRE (15 minutes). There was one blunt uterine perforation in both groups and one urgent hysterectomy in the TCRE group. Both procedures led to an improvement in quality-of-life measurements. At 12 months, women were equally satisfied with either procedure. A subsequent paperacic27 reported a 5-year follow-up of the same women. At 5 years, women who had MEA were more satisfied with their procedure (86% versus 74%, a difference of 12%, CI=–2–23%) than with TCRE. The hysterectomy rate was 16% for MEA and 25% for TCRE.

A major drawback of MEA is the extremely bulky and cumbersome unit and the large diameter of the probe. These limit the outpatient application of this useful device. The manufacturers are working on a smaller unit and probe.acic28

**NovaSure** impedance controlled bipolar radiofrequency endometrial ablation

The NovaSure® (Cytyc Corporation, Marlborough, MA, USA) system (Figure 4) has a radiofrequency controller and single-use bipolar probe which incorporates a gold mesh electrode. Once the probe is inside the uterine cavity the electrode array expands to conform to its contours. The device delivers bipolar radiofrequency energy, leading to complete endometrial ablation in just 90–120 seconds. The depth of ablation is controlled by tissue impedance. The endometrium is a low impedance tissue and is vaporised and removed by the suction in the device. The suction also improves the contact of the device with the uterine cavity, increasing the effectiveness of ablation. On reaching the myometrium, the tissue impedance increases, resulting in automatic termination of ablation. The bipolar electrode design provides a tapered zone of ablation. There is shallower ablation (2–3 mm) in the cornual region and lower part of the uterus and deeper ablation (5–7 mm) in the fundus and main body of the uterus. The system can alert the operator to a perforated uterine wall prior to treatment using carbon dioxide (CO2) gas. This is an added safety feature to minimise intra- and postoperative complications.

In one study,acic29 126 women were randomised to either NovaSure (n = 83) or thermal balloon ablation (n = 43). The main outcome measure was amenorrhoea. At 1-year follow-up, amenorrhoea rates were 43% in the NovaSure group and 8% in the balloon group. A significantly greater percentage of women (90%) were satisfied with bipolar ablation when compared with thermal balloon ablation (79%, P = 0.003). In addition, the operating time for bipolar ablation was found to be half that of thermal balloon ablation. As mentioned above, NovaSure has been compared with Cavaterm in a randomised trial.acic30 A small studyacic31 has demonstrated significantly lower pain in women who had NovaSure compared with thermal balloon ablation. This has prompted speculation that, with its short operating time, safety profile and low pain scores, NovaSure might become the ideal office-based procedure.

The blind nature of the procedure is one of NovaSure’s limitations. Also, it cannot be reliably used if the uterine cavity is enlarged or irregular. A further limitation is the need to dilate the cervix to 8 mm, although studies have shown low pain scores with NovaSure use.

**Cryotherapy: Her Option®**

Cryotherapy (Her Option® [American Medical Systems, Minnetonka, MN, USA]) was one of the first techniques to be used for endometrial ablation. Initial enthusiasm was dampened by reports of pelvic abscesses after the procedure. With the advent of newer devices there has recently been a revival of interest in this modality (Figure 5). The device destroys the endometrium by freezing to −90°C. Ultrasound guidance is used to monitor the safety and extent of ablation. The device comprises a 5.5 mm probe and a self-contained unit. The depth (elliptical zone) of the ablation is up to 12 mm and the treatment can take between 10–20 minutes. In a prospective studyacic32 of 15 women at Yale University, amenorrhoea rates of 75% were achieved at 6 months and 50% at 12 months. In a subsequent prospective multicentre trial,acic33 279 women were
randomised (2:1 ratio). One hundred and ninety-three were allotted to cryoablation and 86 to rollerball ablation. At 12 months, 156 women in the cryotherapy group and 76 women in the rollerball group were available for follow-up. Both methods were equally successful in decreasing menstrual bleeding. At 24-month follow-up, 91% (94) of the women available for follow-up were very or extremely satisfied with the treatment.

The use of ultrasound has both advantages and disadvantages. It allows real-time monitoring and control of the depth of ablation. It also demands additional scanning skills, equipment and staff. It is thought that the low temperatures provide anaesthesia, leading to better outpatient tolerance of the device.

Gynelase® endometrial laser intrauterine thermal therapy (ELITT) (Gynelase, Needham, Massachusetts, USA)

The ELITT procedure uses an 830 nm diode laser, emitted from three integrated diffusers that open up after insertion into the uterine cavity. The laser beam undergoes diffusion, leading to uniform heating of the endometrium, including the cornua. The cervix needs to be dilated to 7 mm and the procedure takes 7 minutes to complete. There have been few reported studies evaluating this device. In 2000, Donnez et al.43 reported the outcome of 100 women who underwent this procedure at their centre in Brussels. The main outcome measured was the amenorrhoea rate. At 1-year follow-up this was 71% and 90% had either amenorrhoea or severe hypomenorrhea. No major complications were reported. A similarly high amenorrhoea rate has been reproduced in subsequent studies.44 This device is not currently in widespread use and NICE has not yet produced guidance on its use.

Photodynamic therapy

In this method a photosensitising chemical is injected into the uterine cavity. This pretreatment is followed by laser treatment through a probe, which activates the chemical and results in endometrial ablation. So far, only the results of a preliminary pilot study on 11 women have been published. NICE46 has advised that this modality remains investigational at present.

Chemoablation

Conceptually, this is the most attractive form of endometrial ablation. It involves instilling a chemical into the uterine cavity. One prospective study has been performed in Turkey.47 The chemical used was trichloroacetic acid (TCA); the same agent used to treat papilloma virus warts. The treatment resulted in amenorrhoea and patient satisfaction rates were similar to other second-generation endometrial ablation techniques. It remains to be seen whether such results will be replicated by other investigators and larger studies and, until then, this method remains investigational.

Complications of second-generation devices

Minor complications are common with the use of these devices. They include pain, nausea, vomiting, and urinary and pelvic infection. Although infrequent, serious complications such as uterine perforation and injury to the bladder and bowel have been reported.22 A Cochrane review23 revealed that equipment failure, nausea, vomiting and uterine cramping were more common with the second-generation devices. The second-generation devices were less likely to be associated with fluid overload, uterine perforation, cervical laceration and haematoma when compared with first-generation devices. Sporadic case reports of serious complications are found in the literature. As bad outcomes are notoriously under-reported, there is an urgent need for a study similar to the MISTLETOE study to evaluate the complications associated with second-generation devices. The US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database provides more comprehensive information on serious and rare complications than traditional Medline searches.

Day case or outpatient therapy

Manufacturers of second-generation devices have promoted their use in the outpatient setting using a combination of oral analgesia and paracervical block.
The evidence in the literature has been inconsistent in this regard. Wallage et al. randomized 191 women to undergo MEA under general or local anaesthesia. Sixty-one percent of the women considered treatment under local anaesthesia. The procedure was completed without the need for general anaesthesia in 91% of the local anaesthesia group. Women who had a general anaesthetic were more likely to describe the procedure as totally acceptable and to choose the same anaesthetic again. There is a high incidence of postoperative discomfort, a need for general anaesthesia in 10% of cases and a need for highly trained staff to look after women after the procedure. Consequently, at present it appears prudent to carry out these procedures in dedicated treatment rooms in a day-case setting rather than in the outpatient department.

Good-quality evidence does not exist for the outpatient use of devices other than MEA and Thermachoice. It is essential that claims by manufacturers are backed by high-calibre randomised trials.

Ablation and the myomatous uterus
The presence of myomas in women undergoing endometrial ablation can compromise results. A large myoma in the cavity could interfere with correct placement of the probe or prevent close contact of the balloon with the endometrium. In addition, myomas act as heat sinks and this leads to dissipation of energy, leading to suboptimal ablation. However, the presence of myomas is not a contraindication to endometrial ablation. Indeed, large submucous myomas can be treated with myolysis at the time of endometrial ablation. The addition of endometrial ablation to resection of submucous myomas improves the outcome with regards to heavy menstrual bleeding but does not decrease the likelihood of subsequent hysterectomy. MEA and hydrothermolablation have been used in studies in the presence of small (<3 cm) submucous fibroids and polyps.

Endometrial preparation prior to ablation
Routine endometrial pretreatment with progestogens, danazol or GnRH analogues was the rule with first-generation devices. This leads to an improved hysteroscopic view, less bleeding, less absorption of media and better menstrual related outcomes. However, there is controversy regarding the use of these agents with the newer devices. Studies have confirmed that success and patient satisfaction are not affected by endometrial pretreatment. Hydrothermolablation and ELITT are the only second-generation devices that have shown better outcomes after endometrial pre-thinning.

Factors affecting the success of endometrial ablation
Endometrial ablation is most successful in the presence of a normal-sized uterus and, in the case of first-generation devices, after preoperative thinning of the endometrium (see above). Results are superior whenever an experienced surgeon performs the operation. The coexistence of other gynaecological pathology, such as adenomyosis or myomas, is associated with increased failure rates. The most important effect is that of age: women over the age of 45 are least likely to need further surgery after endometrial ablation and are probably the ideal candidates for this approach.

Cost implications for the National Health Service
NICE estimates that if all hysterectomies were to be replaced by endometrial ablation using second-generation devices, the NHS would save £32 million per year. NICE concedes that this assumption is simplistic, as some women will invariably need or prefer hysterectomy.

In one interesting study, computer software was used to create a hypothetical progression of menorrhagia for 6 cohorts of 1 000 women, each over 10 years. The study considered treatment and re-treatment costs in an NHS hospital setting. Six cohorts of women were created for the following treatment: MEA; thermal balloon ablation; TCRE; rollerball; TCRE with rollerball; and hysterectomy. The model calculated the QALY (cost per quality adjusted life year) for each procedure. The study found that second-generation devices cost less than first-generation devices and that they accrue more QALYS. The estimated costs were as follows: MEA £942, thermal balloon ablation £826, TCRE £1110, rollerball alone £1190, TCRE with rollerball £1027, hysterectomy £2096. Hysterectomy was the most expensive intervention but it resulted in the maximum number of QALYS. The reviewers concluded that where hysterectomy is acceptable it continues to be a very cost-effective method when compared with all forms of endometrial ablation.

Conclusion
Endometrial ablation techniques are evolving over time and devices have become safer, easier to use, more economical and are increasing in popularity. There seem to be no major differences in treatment outcomes with most major second-generation devices. The choice of device is best based on individual preference and availability. Stiff competition has often led manufacturers to claim superiority based on poor-quality research. It is of paramount importance that the user is up to date with current evidence to be able to make an informed choice. Future studies should make more comparisons between second-generation devices and
hysterectomy. The quick recovery and return to work and social activity after endometrial ablation have a significantly reduced impact on the lives of most women treated. Endometrial ablation truly has the potential to empower women and enhance their lives.

Websites

The MAUDE database can be accessed via the FDA website: www.fda.gov

References

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