The surgical management of menorrhagia

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Surgical treatment of menorrhagia is likely to be both successful and satisfactory to the patient. Correct diagnosis of the cause of menorrhagia is essential, and management should be directed to the specific cause of the problem. The question of which treatment is best is a complex one and involves balancing patient wishes, expected outcomes, complications, cost-effectiveness and quality of life issues. For the subset of women in whom dysfunctional uterine bleeding is diagnosed, the literature suggests that there is a hierarchy of treatments that, in descending order for both efficacy and patient acceptability, are: (i) hysterectomy; (ii) endometrial ablation (either first- or second-generation); (iii) the levonorgestrel intrauterine system; and (iv) medical treatments. All four of these options should be discussed with the patient and the relative advantages and disadvantages considered before a treatment decision is made. For patients in whom a pathological cause is diagnosed, specific treatments should be aimed at removal of the lesion and observation of the effect on menstrual status. In addition to the treatment options above, specific treatments such as hysteroscopic, laparoscopic or open excision of the lesion need to be considered. For interventional radiological procedures such as uterine artery embolization, further study is recommended before it can be considered as a safe and effective treatment for menorrhagia.

Keywords: endometrial ablation/hysterectomy/menorrhagia/surgery/uterine artery embolization

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Introduction

Menstruation is arguably one of the most amazing biological processes of the human body. Each month that fertilization does not occur, the entire endometrium is shed and then completely regenerated, without scarring. This process is often repeated several hundred times in a woman’s lifetime. There is no other tissue that undergoes such rapid and dramatic alterations with such relentless regularity.

Given the complexities of this process, it is not surprising that disorders are common and account for 33% of referrals to gynaecological practice (Coulter et al., 1989), and that the perceived loss of excessive blood during menstruation causes 5% of women aged 20–39 years to consult their gynaecologist each year (Vessey et al., 1992; Royal College of General Practitioners and Department of Health, 1995). This common problem then, accounts for a significant proportion of gynaecological healthcare costs, and is estimated to account for 1% of total healthcare costs (Smith, 1999).

In an objective study measuring menstrual loss, it was determined that the mean menstrual loss for the studied population is 43 ml per cycle. However, 10% of women may lose more than 100 ml of blood each cycle (Hallberg et al., 1966). This means that sufferers of menorrhagia may lose over 40 l of blood during their reproductive lifetime! Effective intervention improves quality of life for these patients and reduces health costs for the community.

This review presents the data on clinical outcomes of various surgical treatments for menorrhagia.

Defining the problem

It has been suggested that excess menstruation should be considered present when more than 80 ml of blood is lost per
cycle (Hallberg et al., 1966; Cole et al., 1971). The initial complaint of menorrhagia is a subjective one, and comes from the woman’s perceived menstrual loss. There is a marked variation in a woman’s sensitivity to this degree of loss, with many women either over- or under-reporting their menstrual loss. One study has shown that 40% of women with an objectively measured menstrual loss of greater than 80 ml report that their periods are either light or moderate (Hallberg et al., 1966). In a study in women with iron-deficiency anaemia due to menorrhagia, only 15% described their periods as heavy (McKenna et al., 1989). At the other end of the spectrum, it has been reported that 26–38% of women complaining of heavy periods had objective menstrual losses of less than 80 ml per cycle (Hallberg et al., 1966; Fraser et al., 1984). Studies using subjective measurements of diagnosis have reported that 22–30% of women complained of heavy periods (Gath et al., 1987; Rees, 1991), this being a much greater figure than the 10% defined by objective blood loss.

The ideal investigation for diagnosing menorrhagia would be: (i) readily available; (ii) inexpensive; and (iii) to measure actual blood loss. However, no such test exists. Currently available objective measures of menstrual loss include the alkaline haematin method, which is generally considered to be a research tool and is not available for everyday gynaecological consultation. Attempts have been made to increase the accuracy of diagnosing menorrhagia using pictorial blood loss assessment charts (PBLAC). Initial studies demonstrated a sensitivity and specificity of >80% for a PBLAC score of >100 (Higham et al., 1990). Other reports have demonstrated that the same sensitivity and specificity can be achieved, but with a cut-off point of 185 (Janssen et al., 1995); still more recently one study has reported that there is no correlation between the observed PBLAC and actual measured blood loss (Reid et al., 2000). With improved technology in sanitation protection, there will be a change in the reliability of this score over time, though it is suggested that such a scoring system is an unreliable tool that adds little to the subjective complaint. The advantage of the PBLAC is that it does provide semi-objective comparative information in the absence of a more valid and reliable test. There have been a number of other questionnaire-based tools developed to assist in the diagnosis of the problem, though these are not widely utilized and suffer similar problems to the PBLAC (Lampling et al., 1998; Shaw et al., 1998; Chadha et al., 2000).

There are many areas in gynaecology such as urogynaecology and reproductive medicine, where patients present with problems that affect their quality of life, and which do not cause them any physical harm directly; however, the treatments that we prescribe for them can cause harm. Women must be counselled appropriately as to this fact, and both non-surgical and surgical options offered. The woman suffering with menorrhagia has a specific complaint that is affecting her quality of life, though this complaint may not affect her medical well-being, since she may not become anaemic as a consequence.

Aetiology

When a woman presents with menorrhagia, consideration must first be given to diagnosis. This requires an appropriate history and clinical examination, complemented by suitable investigation. Anaemia should be detected with a full blood count and iron studies. Ultrasonography, sonohysterography and hysteroscopy are additional investigations that may diagnose a structural problem and should be utilized depending on their availability and the experience of the surgeon. Common causes of menorrhagia include local pathology such as fibroids, polyps, adenomyosis or infection. Rarer but important causes include genital malignancy (cervical, endometrial or myometrial) and systemic disorders such as thyroid disease and bleeding disorders. In over 50% of cases no cause is found and the diagnosis of dysfunctional uterine bleeding is made (Coulter et al., 1995).

It is important to clarify here that dysfunctional uterine bleeding (DUB) and menorrhagia are not interchangeable terms. DUB is a specific diagnosis and is a subset of menorrhagia, though not all treatments for DUB can be utilized for other diagnoses of menorrhagia. The term DUB in this review is used as a specific diagnosis based on the following criteria: (i) the complaint of excessive menstrual blood loss (recognizing the limitations of measuring actual menstrual blood loss); and (ii) the adequate exclusion of pathology that may otherwise cause menorrhagia.

This definition of DUB is used, rather than the objective measurement of >80 ml blood loss per cycle, as none of the published studies has used the more scientific definition for diagnosis, owing to the clinical difficulties previously discussed.

The surgical treatment of menorrhagia will be discussed with particular reference to endometrial ablation in its various forms, hysterectomy and uterine artery embolization. Reference to associated and important areas such as the use of the levonorgestrel intrauterine system, pre-operative treatment for ablation or hysterectomy, quality of life issues and economic considerations will also be made.

Surgical destruction of the endometrium

It is now 20 years since laser energy was first used to destroy the full thickness of the endometrium as a treatment for menorrhagia (Goldrath et al., 1981). This followed many unsuccessful attempts at endometrial destruction by the application of chemicals including methyleneaocrylate and quinacrine, the insertion of radium pessaries into the uterine cavity, the application of steam or heated metal rods, and cryotherapy. Following Goldrath’s description of endometrial destruction, there has been an ongoing interest in hysteroscopic destruction by laser or electrical energy.

Endometrial ablation is not suitable for all types of menorrhagia, and women must undergo adequate evaluation before its use is considered. Women must have a benign cause for their menorrhagia and have no desire for future fertility. Endometrial ablation is most commonly used in the treatment of DUB, though small submucosal fibroids up to 2 cm in diameter, or pedunculated intracavitary fibroids or polyps can be treated with either the resection technique or endometrial laser ablation (Garry, 1990; Vancaillie, 1993). The treatment of larger non-pedunculated fibroids is associated with a higher incidence of complications (Neuworth, 1978; Baggish et al., 1989; Donnez, 1993; Hamou, 1993) and should only be treated by expert hysteroscopists.

For the specific treatment of DUB, surgical destruction of the endometrium is one therapeutic management (Hart and Magos, 1999; Reich et al., 1999). Guidelines from the Royal College of
Obstetricians and Gynaecologists (RCOG) state that medical therapy should be tried prior to undertaking surgery for DUB. This recommendation has been made, despite the fact that the only randomized trial in the literature comparing medical and surgical treatments for menorrhagia reported overall satisfaction following surgical treatment as 76%, compared with 27% in the medical group at 4 months follow-up (Cooper et al., 1997). There was a statistically significant reduction in pain and bleeding parameters in those women who had surgery compared with medical treatments. Moreover, a significantly greater number of women found surgery more acceptable and would have chosen it again compared with medical treatment (93 versus 31% and 36% 36% respectively). These results were maintained at 2 years, with a significantly higher proportion of patients in the surgical group being satisfied with their initial treatment (Cooper et al., 1999a). Some 59% of women in the medical group had undergone surgery for menorrhagia during the follow-up period. This study suggested that surgical interventions were much more effective than medical treatments of menorrhagia.

It is possible that for appropriately screened and counselled patients, surgery offers an improved clinical outcome and better quality of life, and may also have a cost advantage over medical treatments. The results of this study indicated that further investigation by randomized trials would assist in defining the exact role for surgery in the management of DUB with consideration of clinical outcome, quality of life issues and cost-effectiveness issues.

Progestogen-releasing intrauterine systems

While the use of progestogen-releasing intrauterine systems for the treatment of menorrhagia is, strictly speaking, a medical management, it is mentioned here both for completeness and as a comparison with surgery. There is a Cochrane review of the subject (Lethaby et al., 2000a), to which the reader is directed for more information. Comparisons of these systems against other treatments for menorrhagia report that they are more effective than 21 days of oral progestagens for the treatment for menorrhagia. Women are more satisfied and are more likely to continue with this system than with medical treatments. They are, however more likely to suffer side effects than with medical treatments.

Compared with surgery, women are more likely to be amenorrhoeic following transcervical resection of the endometrium than with the progestogen-releasing intrauterine system. There was a trend to improved satisfaction in the surgery group, though studies were all underpowered for this outcome measure and the results did not reach statistical significance. There was a significantly greater number of women who suffered side effects using the progestogen-releasing intrauterine system.

First-generation endometrial ablation techniques (FEAT)

The surgeon requires three essential components to undertake a FEAT: (i) a uterine distension medium (fluid or gas); (ii) an operative hysteroscope with inputs for light, distension medium and operative instrumentation as well as outputs for distension medium and optics; and (iii) a power source for endometrial ablation—this may be laser energy or electrical energy delivered via a rollerball or resector loop.

Most surgeons prefer to use fluid distension as it provides excellent vision and allows for instant and accurate control (Garry et al., 1992; Garry, 1993; Loffer, 1993). If electrical energy is being used, then the fluid must be electrolyte-free, to allow current conduction. Glycine, sorbitol and Dextran 70 have all been used with this energy source, though these fluids are each associated with a number of problems (Baumann et al., 1990; Botto et al., 1990; Istre et al., 1992; Baggish et al., 1993; Broadbent and Margos, 1993; Witz et al., 1993). Pulmonary complications due to fluid absorption may result in pulmonary oedema. Expert management by a trained anaesthetist using diuretics and monitoring is essential once diagnosed.

A number of complications have also been recognized, including: (i) metabolic complications, where dilution of plasma and electrolytes may lead to hyponatraemia and hypokalaemia that cause cardiac arrhythmia and arrest; (ii) cerebral oedema may also occur because of hypo-osmolarity problems—the use of hypo-osmotic glycine can result in profound osmotic changes that may produce coma or death; (iii) glycine is ultimately metabolized to ammonia, and this may cause alterations in consciousness or coma; and (iv) anaphylactic complications caused by the use of Dextran 70 solution.

If laser energy is employed, a physiological solution may be used, and although many of the complications listed above may be avoided, fluid overload with resulting pulmonary oedema may still occur (Garry and Erian, 1990; Goldrath, 1990). No matter which fluid type is used to distend the cavity, it is essential that a monitoring system be utilized for checking fluid deficit. This may be either automated (Hawe et al., 1998) or manual, though the automated system is much less labour-intensive and may give a continuous readout of the amount of fluid intravasated. It is recommended that if non-physiological solutions are used, evaluation should occur at a fluid deficit of 1000 ml, and the procedure should be terminated at a fluid deficit of 1500 ml. The risks of hyponatraemia require an evaluation of serum electrolytes, monitoring of the patient’s fluid balance, and may require expert consultation with anaesthetists and the administration of diuretics (Garry, 1995).

Predicting clinical outcome following endometrial ablation has proved difficult, though success is less likely in women with large uterine cavities or deep adenomyosis, or when an intramural fibroid is present (Lomano, 1991; Dequesne et al., 1993; Garry, 1995; Shamonki et al., 2000). The use of endometrial laser ablation (ELA) in the presence of submucosal fibroids has been reported to increase the chance of success (Phillips et al., 1998), but the use of electrosection has been reported to reduce overall success (Hart and Magos, 1997). It is unclear why there is this discrepancy. The age of the patient at ablation, dysmenorrhoea, premenstrual syndrome or the method of endometrial preparation do not appear to be predictive factors of success (Phillips et al., 1998).

Complications of FEAT

As a surgical alternative to hysterectomy in the treatment of menorrhagia, endometrial ablation (with or without resection of pathology) is a safe procedure with an overall complication rate of 1.25–4.58% (Overton et al., 1997). The risks are significantly
less than with hysterectomy, where complication rates of 30–40% are quoted. In the MISTLETOE study, which reported on over 10,500 endometrial ablations performed by 690 surgeons over an 18-month period, the risk of fluid overload was reported to be approximately 4%, with ELA being associated with the greatest risk of fluid absorption. The risk of perforation has been reported as 0.65–2.47% (O’Connor et al., 1997; Overton et al., 1997), with the risk being greater with transcervical resection of the endometrium (TCRE) than with either ELA or rollerball ablation (Garry et al., 1995; Overton et al., 1997). The risk of intraoperative hysterectomy is 1% (Rankin and Steinberg, 1992; Dwyer et al., 1993; Overton et al., 1997). In one series of 1000 ELAs there were no intraoperative hysterecories (Phillips et al., 1998). Both intrauterine and ectopic pregnancies have been reported (Lam et al., 1991; Rogerson et al., 1997; Opperman et al., 1998) following endometrial ablation, and patients should be encouraged to continue barrier contraceptives or have concomitant sterilization. Mortality from endometrial ablation, as quoted in the MISTLETOE study is 2 in 10,000 for ELA or rollerball ablation, and 3 in 10,000 for loop TCRE.

Other possible long-term complications include haematometra, the development of new pain post-operatively, and the possibility of endometrial malignancy being missed. There have been isolated reports of malignancy following ablation, but the true incidence of this last complication is unlikely to be known for many years (Dwyer and Stirrat, 1991; Copperman et al., 1993).

Pre-operative preparation prior to surgical treatment

For women who have a diagnosis of submucosal fibroids or dysfunctional uterine bleeding as a cause of their menorrhagia, surgical treatment may be made safer and more effective by pre-operative endometrial preparation. There is a Cochrane review of this subject which reports decreased operative times and decreased fluid absorption when endometrial pretreatment with either danazol or GnRH analogues is used (Lethaby et al., 2001). The amenorrhoea rate has been reported to be higher in a number of endometrial ablation trials group, 1999). In the largest series with the longest follow-up, the clinical outcomes were similar with all three of the first-generation procedures. Published data on outcome following FEAT are summarized in Table I. In the largest series of over 1000 ELAs published to date (Phillips et al., 1998), 37% remained amenorrhoeic with up to 6-year follow-up. Of those women who continued to menstruate, 86% stated that their periods were lighter, and there was an overall satisfaction rate of 89%. Dysmenorrhoea and premenstrual tension was reported to be improved in 77 and 57% respectively. The hysterectomy rate calculated by life-table analysis, was 21% over a 7-year period following ELA. Having a repeat ablation increased the subsequent risk of hysterectomy, but the presence of intrauterine pathology such as polyps or fibroids decreased the risk of hysterectomy. Satisfaction was linked to the need for hysterectomy, with those women who required surgery reporting a 57% dissatisfaction rate compared with 4.3% in those who did not.

Table I. Summary of published data for outcome following first-generation endometrial ablation techniques (FEAT)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Patients</th>
<th>Evidence class</th>
<th>Follow-up</th>
<th>Amenorrhoea</th>
<th>Satisfaction</th>
<th>Further surgery</th>
<th>Hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>O’Connor and Magos (1996)</td>
<td>525 (TCRE)</td>
<td>B</td>
<td>5</td>
<td>32</td>
<td>80</td>
<td>20</td>
<td>9</td>
</tr>
<tr>
<td>Phillips et al. (1998)</td>
<td>746 (ELA)</td>
<td>B</td>
<td>6.5</td>
<td>37</td>
<td>80</td>
<td>NR</td>
<td>21</td>
</tr>
<tr>
<td>Chullaparam et al. (1996)</td>
<td>142 (RB)</td>
<td>B</td>
<td>4.2</td>
<td>28</td>
<td>84</td>
<td>15</td>
<td>8.5</td>
</tr>
<tr>
<td>Vilos et al. (1996a)</td>
<td>800 (Comb)</td>
<td>B</td>
<td>1</td>
<td>60</td>
<td>NR</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Meyer et al. (1998)</td>
<td>117 (RB)</td>
<td>A</td>
<td>1</td>
<td>27</td>
<td>87</td>
<td>NR</td>
<td>2</td>
</tr>
<tr>
<td>Crosignani et al. (1997)</td>
<td>38 (TCRE)</td>
<td>A</td>
<td>2</td>
<td>23</td>
<td>87</td>
<td>NR</td>
<td>10</td>
</tr>
<tr>
<td>Bhattacharya et al. (1997)</td>
<td>372 (Comb)</td>
<td>A</td>
<td>1</td>
<td>47</td>
<td>90</td>
<td>18</td>
<td>10</td>
</tr>
</tbody>
</table>

*a: evidence from randomized controlled trials; B: evidence from prospective non-randomized trials. Comb = combination of ablation techniques; ELA = endometrial laser ablation; NR = not reported; RB = rollerball ablation; TCRE = transcervical resection of the endometrium.

Surgical management of menorrhagia

One study has been performed which examined the costs associated with endometrial thinning agents prior to endometrial ablation (Sculpher et al., 2000). The results of the analysis suggested that danazol was a cheaper thinning agent than GnRH analogues, but this was offset by a reduced amenorrhoea rate in the danazol group. It is unclear what impact this has on the overall analysis, since the cost of amenorrhoea, compared with menstrual improvement is impossible to quantify. If women treated with danazol needed further surgery owing to decreased operative efficacy, then this cost advantage may be diminished. Further research is required to answer this question.

Progestogens do not appear to offer any improvement in outcome at this time (Serden and Brooks, 1992; Rich et al., 1995; Alford and Hopkins, 1996). There does not appear to be any difference in complication rates in women who are treated before surgery, though this may be a reflection of low overall complication rates (Overton et al., 1997).

Outcomes after FEAT

The FEAT procedures have now been through the ‘four phases of a revolutionary technique’ (Garry, 1997), and have had sufficient long-term follow-up and validation in randomized trials and a large national audit (Sculpher et al., 1996; Bhattacharya et al., 1997; Crosignani et al., 1997; Overton et al., 1997; Aberdeen endometrial ablation trials group, 1999). In the largest series with the longest follow-up, the clinical outcomes were similar with all three of the first-generation procedures. Published data on outcome following FEAT are summarized in Table I.

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not have subsequent hysterectomy. These results are similar to other series using ELA (Erian, 1994; Goldrath, 1995; Baggish and Sze, 1996).

Following TCRE, amenorrhea rates have been reported as between 26 and 40% (O'Connor and Magos, 1996; Hart and Magos, 1997), with an 85% improvement in those continuing to menstruate. Dysmenorrhoea and satisfaction were reported at 80 and 84% respectively. At 5 years follow-up, 91% of women had avoided hysterectomy and only 20% of women had required any additional surgery. This technique differed from the report by Phillips in that women who had submucosal fibroids had an increased risk of hysterectomy following ablation rather than a decreased risk (Hart and Magos, 1997). Treatment failures appear to peak at about 3 years following the initial surgery, and the patient was unlikely to require additional surgery beyond this time.

Rollerball ablation seems to offer similar results, with amenorrhea rates ranging from 25 to 60% with 6-month to 3-year follow-up (the higher amenorrhea rate being reported with the shortest follow-up) (Phillips, 1994; Chullapram et al., 1996; Vilos et al., 1996a,b; Meyer et al., 1998). An earlier study which combined rollerball ablation with post-operative progestagens reported a 100% amenorrhea rate (Townsend et al., 1990), though this has never been repeated by any other author.

There has been at least one randomized trial (Bhattacharya et al., 1997) and a further retrospective study (Phillips, 1994) to compare the clinical outcomes of FEAT. These showed no significant difference in outcome for any of the FEAT procedures.

Second-generation endometrial ablation technologies (SEAT)

Following Neuwirth’s description of balloon ablation in 1994 (Neuwirth et al., 1994), there have emerged a number of new technologies available to ablate the endometrium. These include non-hysteroscopic techniques such as balloon technologies (Hawe et al., 1999), microwave endometrial ablation (Hodgson et al., 1999), bipolar technology (Abbott, 2000), diode laser (Donnez et al., 1996), monopolar energy (Soderstrom et al., 1996), radiofrequency (Phipps et al., 1990), cryotherapy (Pittrof et al., 1994) and photodynamic therapy (Gannon and Brown, 1999). There is one technique using freely circulating hot water that has hysteroscopic control (Goldrath et al., 1997).

SEAT technologies have been promoted as safer and requiring less technical skill than FEAT. This is despite the findings of the MISTLETOE study which clearly demonstrate the safety of FEAT, and show that surgical experience has little impact either on the complication rate or on clinical outcome. Some 31% of operators using endometrial resection or ablation had no formal training in the procedure, and 59% of physicians in the study had performed fewer than 10 operations. There was no overall level of experience at which complications were more likely to occur with these procedures.

Based on this evidence, SEAT must satisfy one of the following criteria in order to replace FEAT: (i) better clinical outcome; (ii) reduced risk of injury; (iii) reduced risk of further surgery; (iv) improved quality of life; and (v) improved cost-effectiveness.

Initial reports of amenorrhea rates for some of these technologies which range from 68 to 80% in case series (Hawe et al., 1999; Abbott, 2000) have not yet been confirmed in rigorous randomized trials. A number of trials have reported that some of these techniques are equal to FEAT in randomized studies (Cooper et al., 1999b; Bongers et al., 2000), but none has yet shown a significant improvement in either outcome or complication rate. A review of endometrial ablation using radiofrequency technology has demonstrated a worrying number of complications, including vesicovaginal fistulae, visceral, vaginal, cervical and skin burns (Thijssen, 1997). Consequently, this technology cannot be recommended given these current problems. Published data on outcome following SEAT are listed in Table II.

The advantage of these techniques may be in their ease of use and speed, with some techniques requiring an average of 2 min treatment time. Some may be performed in an outpatient setting with local anaesthesia and analgesia, with or without sedation. This may provide a definite cost advantage to health

Table II. Summary of published data for outcome following second-generation endometrial ablation techniques (SEAT)

<table>
<thead>
<tr>
<th>Reference</th>
<th>SEAT</th>
<th>Patients (n)</th>
<th>Evidence class*</th>
<th>Follow-up</th>
<th>Amenorrhea (%)</th>
<th>Satisfaction (%)</th>
<th>Further surgery (%)</th>
<th>Hysterectomy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hodgson et al. (1999)</td>
<td>MEA</td>
<td>43</td>
<td>B</td>
<td>3 years</td>
<td>37</td>
<td>84</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>Cooper et al. (1999b)</td>
<td>MEA</td>
<td>129</td>
<td>A</td>
<td>1 year</td>
<td>40</td>
<td>77</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Thijssen (1997)</td>
<td>RFA</td>
<td>1280</td>
<td>B</td>
<td>6-58 months</td>
<td>14</td>
<td>84</td>
<td>22</td>
<td>21</td>
</tr>
<tr>
<td>Vilos et al. (1997)</td>
<td>ThermaChoice</td>
<td>121</td>
<td>B</td>
<td>6-12 months</td>
<td>12</td>
<td>NR</td>
<td>19</td>
<td>4</td>
</tr>
<tr>
<td>Meyer et al. (1998)</td>
<td>ThermaChoice</td>
<td>128</td>
<td>A</td>
<td>1 year</td>
<td>15</td>
<td>87</td>
<td>NR</td>
<td>1</td>
</tr>
<tr>
<td>Amso et al. (1998)</td>
<td>ThermaChoice</td>
<td>300</td>
<td>B</td>
<td>3-12 months</td>
<td>14</td>
<td>NR</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Bongers et al. (2000)</td>
<td>ThermaChoice</td>
<td>77</td>
<td>B</td>
<td>3 years</td>
<td>17</td>
<td>60</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Grainger et al. (2000)</td>
<td>ThermaChoice</td>
<td>128</td>
<td>A</td>
<td>2 years</td>
<td>13</td>
<td>86</td>
<td>NR</td>
<td>3</td>
</tr>
<tr>
<td>Hawe et al. (1999)</td>
<td>Cavaterm</td>
<td>50</td>
<td>B</td>
<td>6-24 months</td>
<td>58</td>
<td>96</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Weisberg et al. (2000)</td>
<td>HTA</td>
<td>20</td>
<td>B</td>
<td>1 year</td>
<td>56</td>
<td>NR</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Donnez et al. (2000)</td>
<td>ELITT</td>
<td>100</td>
<td>B</td>
<td>1 year</td>
<td>71</td>
<td>91</td>
<td>NR</td>
<td>2</td>
</tr>
<tr>
<td>Corson et al. (1999)</td>
<td>VestaBlate</td>
<td>122</td>
<td>A</td>
<td>1 year</td>
<td>31</td>
<td>88</td>
<td>NR</td>
<td>5</td>
</tr>
</tbody>
</table>

*A, evidence from randomized controlled trials; B, evidence from prospective non-randomized trials.

ELITT = endometrial laser intrauterine thermoablation; HTA = hydrothermal ablation; hyst = hysterectomy; MEA = microwave endometrial ablation; NR = not reported; RFA = radiofrequency ablation.
providers, though with patient acceptability and satisfaction being very high with FEAT it is unlikely that this will be significantly improved.

A further advantage of SEAT is that it may be used in patients in whom there is a need to avoid fluid absorption or haemorrhage. Such treatment may be used for patients with cardiac or renal disorders, or those receiving anticoagulant therapy where SEAT can be performed without the need to withhold any such medication (Cooper et al., 1999b; Hawe et al., 1999).

The results of randomized trials evaluating the long-term clinical effectiveness, complication rate, long-term outcome and need for further surgery, quality of life data and cost-effectiveness are awaited before statements can be made regarding where these technologies will lie in the treatment of menorrhagia. From the available evidence, they appear comparable with FEAT, and for the surgeon who is competent with FEAT there is no evidence to suggest that he/she should change to SEAT. Few gynaecologists regularly undertake any form of FEAT, and the new devices may increase the number of those able to perform an endometrial ablation satisfactorily.

Hysterectomy

Hysterectomy is second only to Caesarean section as the commonest major surgery in premenopausal women. DUB accounts for between 35 and 64% of the 70,000 hysterectomies performed each year in the UK (Grant and Hussein, 1984; Vessey et al., 1992; Hospital Episode Statistics, 1995). Hysterectomy for menorrhagia is one of the few surgical treatments with a 100% primary success rate. The completed VALUE study from the UK will provide data on the relative costs and benefits of hysterectomy and FEAT in treating DUB. Controversy persists over the best method of performing hysterectomy (Richardson et al., 1995; Langenbrekke et al., 1996; Summitt et al., 1998; Falcone et al., 1999; Marana et al., 1999; Ferrari et al., 2000), though the recently completed EVALUATE study, the largest randomized trial comparing vaginal, abdominal and laparoscopic hysterectomy to date should answer this question.

Currently in the UK, 74% of hysterectomies are performed by the abdominal route, 21% vaginally, and <5% laparoscopically (Ray Garry Value Study, personal communication). There have been a number of randomized studies that have examined different types of hysterectomy, though as yet none has shown any clear difference in complication rates. The efficacy and patient satisfaction rate of hysterectomy for menorrhagia are the highest of any treatment (Dwyer et al., 1993; Vanciaillie, 1993; Crosignani et al., 1997; O’Connor et al., 1997; Kjerulff et al., 2000). This is despite hysterectomy being associated with a complication rate of up to 67% (Dicker et al., 1982; O’Connor et al., 1997; Kjerulff et al., 2000), and concern over the long-term effect of oophorectomy without estrogen replacement (Siddle et al., 1987; Hammond, 1994; Griffiths and Convery, 1995). Current published reports indicate that laparoscopically assisted vaginal hysterectomy may have a longer operative time, but reduced analgesia rates, hospital stay and recovery time when compared with abdominal hysterectomy. There is no clear evidence that one method of hysterectomy (vaginal, abdominal or laparoscopic) offers reduced complication rates, lower costs, or quality of life advantage over any other. Data available on comparative hysterectomy studies are summarized in Table III.

What is clear, is that the hysterectomy rate has not fallen, despite the introduction of endometrial ablation techniques. Several authors heralded these new techniques as a ‘revolution in treatment’ (Garry and Erian, 1990; Magos, 1990; Ke and Taylor, 1991; Coulter, 1993), though the best expectations of this technique replacing hysterectomy have not been realized (Bridgeman and Dunn, 2000). It would appear that instead of replacing hysterectomy, endometrial ablation has only served to increase the number of surgical procedures for the problem of menorrhagia. This most likely reflects a lower threshold for treatment of the problem, and more women who may not wish to have a hysterectomy now have a greater choice about their treatment (Coulter, 1993; Bridgeman and Dunn, 2000).

Hysterectomy versus ablation

A number of studies have compared hysterectomy and endometrial ablation, as well as there being a Cochrane review on the subject (Gannon et al., 1991; Lethaby et al., 2000b). The results of these studies have suggested that both treatments are efficacious and have high patient satisfaction rates. In the short term, there are reduced operative time, recovery time, hospital stay and post-operative complications with endometrial ablation. In the long term, women having endometrial ablation have an increased risk of further surgery, though 76% of patients in these trials avoided hysterectomy. For a full review on this issue, the reader is directed to the Cochrane review (Lethaby et al., 2000b).

Fibroids as a cause of menorrhagia

Neuwirth first described the use of hysteroscopic resection of fibroids to relieve menorrhagia in 1976 (Neuwirth and Amin, 1976). Since then, there have been many reports on the safety and efficacy of hysteroscopic surgery to remove submucous myomas (Valle, 1990; Corson and Brooks, 1991; Goldrath and Husain, 1997). There are reports of up to 140 myomas being removed from a single uterus for menorrhagia, with relief of symptoms (Goldrath and Husain, 1997). For women with documented submucous fibroids who have repeated pregnancy wastage or who are unable to conceive, then surgery offers them an opportunity to conceive (Torpin et al., 1942; Goldrath and Husain, 1997). Conservative hysteroscopic surgery alone, without associated ablation, may be adequate treatment for menorrhagia and avoid further surgery. The combination of endometrial ablation and myomectomy has been reported with varying levels of success. It has been reported that following ELA and submucous myomectomy, there was a greater chance of avoiding hysterectomy (Phillips et al., 1998), though this is in opposition to another report (Hart and Magos, 1999) which suggested that submucous fibroids increase the chance of hysterectomy, as previously discussed.

For women who have completed their family and who have intramural or subserous fibroids, hysterectomy is a common treatment (Vessey et al., 1992; Sutton, 1996; Vercellini et al., 1998). Hysterectomy is one of the few surgical procedures that has a 100% primary success rate for the presenting problem of menorrhagia. The advantage of one type of hysterectomy
compared with another is not yet clear, though all techniques have been employed. The Cochrane review of pre-operative GnRH analogues prior to hysterectomy or myomectomy concludes that 3–4 months of treatment with a GnRH analogue pre-operatively significantly reduces fibroid size and uterine volume. If the woman is anaemic, then this may be corrected pre-operatively and intra-operative blood loss is reduced. For patients initially scheduled for abdominal surgery, following treatment, a vaginal procedure is more likely. The use of GnRH analogues should be selective and related to the improvements that they may cause, such as increasing pre-operative haemoglobin levels or possibly converting an abdominal to a less invasive vaginal procedure (Weeks et al., 2000; Lethaby et al., 2001).

Uterine artery embolization (UAE)

Uterine artery embolization is not a new procedure, having been available for over 20 years, although it has usually been utilized for the treatment of acute haemorrhage (Rosenthal and Colapinto, 1985; Greenwood et al., 1987; Gilbert et al., 1992). The first report for treating menorrhagia secondary to fibroids by this technique was published in 1994 (Ravina et al., 1994), with the first case series (Ravina et al., 1995a) reporting a success rate of 89% and an average shrinkage of 70%. Further series since have reported volume reductions of 40–50% (Goodwin et al., 1997; Worthington-Kirsch et al., 1998; Hutchins et al., 1999) and control of menorrhagia in 80–90% (Ravina et al., 1995b; Worthington-Kirsch et al., 1998). In total, over 4000 cases have been performed to date world-wide (Broder et al., 2000).

The technique involves catheterization of the femoral artery and selective occlusion of the uterine arteries with polyvinyl alcohol (PVA) particles, gelfoam pledgets, gelfoam powder or microcoils (Goodwin and Walker, 1998). These particles selectively occlude the hypervascular capsule of the fibroid and cause ischaemia. Following the procedure, pain is moderate to severe and often requires admission for analgesia—the only reason for hospital admission (Goodwin and Walker, 1998; Hutchins et al., 1999).

Approximately 40% of women will suffer with post-embolization syndrome characterized by pain, fever and leukocytosis.

Table III. Summary of published data for comparative trials of hysterectomy

<table>
<thead>
<tr>
<th>Reference</th>
<th>Patients (n)</th>
<th>Comparators (Evidence class)</th>
<th>Complication rate (%)</th>
<th>Time of surgery (min)</th>
<th>Hospital stay (days)</th>
<th>Recovery time (days)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summitt et al. (1992)</td>
<td>56</td>
<td>LH 29 A</td>
<td>3</td>
<td>120</td>
<td>0.5</td>
<td>NR</td>
<td>Longer operative time, greater expense, greater blood loss and higher analgesia requirements in the LH group. No differences in complication rates or hospital stay.</td>
</tr>
<tr>
<td>Raju and Auld (1994)</td>
<td>80</td>
<td>LH 40 A</td>
<td>5</td>
<td>100</td>
<td>3.5</td>
<td>21</td>
<td>Longer operative time in the LH group, shorter hospital stay, convalescence and overall costs in the LH group. No difference in complications.</td>
</tr>
<tr>
<td>Richardson et al. (1995)</td>
<td>98</td>
<td>LH 75 B</td>
<td>36</td>
<td>131</td>
<td>3.2</td>
<td>23</td>
<td>VH quicker, complication rates similar laparotomy and additional surgery rate similar, 6.9% laparotomy rate LH, 8.7% VH group, all other comparisons the same.</td>
</tr>
<tr>
<td>Langenbrekke et al. (1996)</td>
<td>100</td>
<td>LH 46 A</td>
<td>21</td>
<td>100</td>
<td>2</td>
<td>20</td>
<td>Same time, significantly less hospital stay and faster return to work with LH, same blood loss, similar complication rates</td>
</tr>
<tr>
<td>Olsson et al. (1996)</td>
<td>143</td>
<td>LH 71 A</td>
<td>27</td>
<td>148</td>
<td>2</td>
<td>16</td>
<td>Reduced blood loss, hospital stay, post-operative pain,convalescence. There is greater operative time for LH. No difference in complications.</td>
</tr>
<tr>
<td>Summitt et al. (1998)</td>
<td>65</td>
<td>LH 34 A</td>
<td>20</td>
<td>180</td>
<td>2.1</td>
<td>28</td>
<td>Increased operative time in LH group, decreased hospital stay and recovery, no difference in costs, no difference in complication rates.</td>
</tr>
<tr>
<td>Falcone et al. (1999)</td>
<td>48</td>
<td>LH 24 A</td>
<td>43</td>
<td>180</td>
<td>1.5</td>
<td>21</td>
<td>Operative time and blood loss significantly greater in LH group, decreased hospital stay, analgesia usage, recovery time in the LH group. No difference in costs.</td>
</tr>
<tr>
<td>Marana et al. (1999)</td>
<td>116</td>
<td>LH 58 A</td>
<td>5</td>
<td>91</td>
<td>4</td>
<td>NR</td>
<td>No difference in operative time, reduced blood loss in the LH group, reduced post-operative pain and reduced hospital stay after LH</td>
</tr>
<tr>
<td>Ferrari et al. (2000)</td>
<td>62</td>
<td>LH 31 A</td>
<td>NR</td>
<td>135</td>
<td>3.8</td>
<td>NR</td>
<td>Decreased operative time in the AH group, shorter hospital stay and decreased analgesic usage, no major complications reported.</td>
</tr>
</tbody>
</table>

*aA, evidence from randomized controlled trials; B, evidence from prospective non-randomized trials. Abd = abdominal hysterectomy; LH = laparoscopic hysterectomy; NR = not reported; VH = vaginal hysterectomy.
Initially, this caused considerable concern and led to a number of ‘unnecessary hysterectomies’ being performed (Hutchins et al., 1999). The treatment of this condition is conservative, though the difficulty is to differentiate it from true sepsis, which has led to at least one death (Vashisht et al., 1999), a number of emergency hysterectomies, and at least one bowel resection. These procedures are significantly more difficult than primary procedures owing to the presence of pyometra and or peritonitis (Ravina et al., 1995b).

Complications from procedural arteriography such as haemorrhage requiring surgery, puncture site thrombosis, and aneurysm formation are rare. Other rare but important complications from the embolization procedure include neurological damage (Hare and Holland, 1983), leg ischaemia (Jander and Russinovich, 1988) and bladder necrosis (Hietala, 1978). The overall ischaemic complication is reported as <1% (Vedantham et al., 1997). Premature menopause is reported in approximately 5% of patients having UAE, compared with approximately 1% of women following hysterectomy (Broder et al., 2000).

Pregnancy following UAE has been reported, and live births have resulted (Ravina et al., 1995a). It is unclear whether there is a significant risk from rupture of the uterus, and there are no reports of this complication in the literature at this time. It is possible that for women wishing to preserve fertility who have symptomatic fibroids, UAE offers an alternative to myomectomy by laparoscopy or laparotomy. It remains for this relatively new approach to be assessed by the rigours of a randomized trial against established techniques in the management of fibroids, before its true role in management can be ascertained. At present, caution should be applied when considering this procedure, particularly in women who wish to conceive in the future. Case series have reported high patient satisfaction rates, though this should be regarded with caution given the likely biases that may be involved in patients involved in the initial studies. A further concern is that UAE has been reported to be twice as expensive as hysterectomy (Medicare physician fee schedule, 1998). The same process for assessing this technique applies as previously discussed for SEAT; that is, an assessment of clinical outcome, cost-effectiveness and quality of life/patient satisfaction.

Quality of life

Menorrhagia has a detrimental impact on quality of life, and can adversely affect physical and mental health of the sufferer. It is also associated with disruption to vocational, family and social life (Coulter et al., 1994a; Shaw et al., 1998). Although women present frequently to general practitioners or gynaecologists, they are often not aware of treatment options, and two-thirds do not make a choice of treatment despite discussing their options (Shaw et al., 1998). It is difficult to assess the importance of the above disruptions to an individual patient, and therefore to tailor the best treatment to her needs.

What is apparent is that quality of life is improved after any treatment for menorrhagia, with this improvement being least with medical interventions (Coulter et al., 1994b; Cooper et al., 1997) and greatest with hysterectomy, as discussed earlier. Endometrial ablation offers significant improvement in quality of life with either first-generation or second-generation techniques, though less than hysterectomy. The improvement in quality of life from the use of a medicated intrauterine device lies between that achieved with medical and ablation treatments.

Costs of treating menorrhagia

Each year in the UK, £7 million is spent on drug treatments for menorrhagia in the primary care setting (Coulter et al., 1995). In addition to pharmaceutical costs, endometrial ablation procedures cost a further £1 million each year, and hysterectomies over £7 million (Sculpher et al., 1996). A number of publications have reported endometrial ablation as being more cost-effective treatment than abdominal, vaginal or laparoscopic hysterectomy in the treatment of menorrhagia (Sculpher et al., 1993; Ransom et al., 1996; Vilos et al., 1996a,b). When assessed per procedure, the costs of endometrial ablation are 40–70% less than for hysterectomy with 2-year follow-up. It remains to be seen if the cost advantage is maintained over a longer time frame. It is estimated that 55% of ablations would need to fail for the cost advantages of this technique to be lost (Sculpher et al., 1996). Evidence from the literature supports the cost advantages of endometrial ablation, with hysterectomy being avoided in 79% (Phillips et al., 1998), 91% (O’Connor and Magos, 1996) and 95% (Paskowitz 1995) of women following ELA, endometrial resection and rollerball ablation at 6.5, 5 and 1.5 years estimated by life-table analysis respectively. It has been reported that the likelihood of further surgery is minimal after 3 years (Shamonki et al., 2000), and therefore it is likely that these economic advantages will be maintained. Direct assessment is required however.

To date, there has been no economic evaluation of SEAT, though with shorter operative times and similar clinical outcomes, a further cost advantage may be obtained over FEAT. This is an area for future evaluation.

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