Effective HEALTH CARE

Menorrhagia - excessive regular menstrual blood loss - accounts for a significant proportion of gynaecological referrals and over half of all hysterectomies.

A large proportion of women who complain of heavy periods and who receive treatment have menstrual blood loss within the normal range.

Diagnostic dilatation and curettage (D&C) should not be performed on women aged under 40 and its use in older women could be replaced by cheaper and safer methods of endometrial sampling.

One of the most commonly prescribed drugs in primary care, norethisterone, is possibly the least effective. Evidence suggests that tranexamic acid and mefenamic acid are among the most effective and acceptable of first line treatments. The hormone releasing intra-uterine device appears to be highly effective but is not yet licensed for use in menorrhagia.

Endometrial resection and laser ablation are cheaper than hysterectomy and generally effective in the short term but a significant proportion of women require further surgery on one or more occasions.

Surgeons must have the necessary training and skills before using less invasive surgical techniques such as endometrial resection and laser ablation.

Women report high levels of satisfaction with hysterectomy which is totally effective; however, it is more expensive and involves a longer recovery period.

Since no management option is superior in all respects, women should be assisted to make informed choices about how to be treated.

Research is needed to compare the relative effectiveness and cost effectiveness of the most promising forms of interventions in terms of blood loss, quality of life and patient acceptability.

The Management of Menorrhagia

What are effective ways of treating excessive regular menstrual blood loss in primary and secondary care?

August 1995    Number 9

A BULLETIN ON THE EFFECTIVENESS OF HEALTH SERVICE INTERVENTIONS FOR DECISION-MAKERS
Nuffield Institute for Health, University Leeds, and the NHS Centre for Reviews and Dissemination, University of York, Research Unit, Royal College of Physicians. It is funded by the Department of Health. The views expressed are those of the authors and not necessarily those of the DoH.
B. Management Options

Reassurance may be offered to the woman about levels of blood loss.

Menorrhagia is treated by drugs including non-steroidal anti-inflammatory drugs, anti-fibrinolytics, hormones and intrauterine devices, and surgery, in particular dilatation and curettage, hysterectomy and removal of the lining of the womb (endometrial ablation). There is considerable variation in practice and uncertainty about the most appropriate management strategies.

B.1 Reassurance: It is difficult for women to compare their experience of menstrual blood loss with that of other women. While the woman’s perception of the heaviness of her loss and its effect on her quality of life is the major reason for seeking medical help, she might benefit from being reassured that her experience is not abnormal, or from counselling. The effectiveness of reassurance and counselling is not known; it is currently being studied in a randomised controlled trial in Oxford.

B.2 Drug Treatment: Menorrhagia can be treated by drugs in primary care. A wide variety of drugs are used, ranging from non-steroidal anti-inflammatory drugs, anti-fibrinolytics, hormones and intrauterine devices. Each year around £7m is spent in the UK on primary care prescribing to treat menorrhagia. However, there is uncertainty about the effectiveness of many of the drug therapies.

Box 2: Consultation and Treatment for Menorrhagia

5% of women aged 30-49 consult their GP for excessive menstrual blood loss in a year.

822,000 prescriptions were written for this condition in England and Wales in 1993.

About 73,000 hysterectomies and 10,000 endometrial ablations were performed in England in 1992/3, of which about two thirds were undertaken for women presenting with menorrhagia.

Most women undergoing hysterectomy for menorrhagia have normal haemoglobin levels.

By the age of 43 one in 10 women have undergone a hysterectomy and 15% have had at least one D&C. Women with less educational qualifications have higher rates of hysterectomy.

B.3 Diagnosis: Dilatation and curettage (D&C) is often carried out on women with menorrhagia for diagnostic purposes, primarily to exclude the rare possibility of an endometrial malignancy. In 1993/4, 106,145 D&Cs were performed in England; however data are not available to distinguish between D&Cs performed to remove retained products of conception after miscarriage and those for menorrhagia.

The Effective Health Care bulletins are based on a systematic review and synthesis of literature on the clinical effectiveness, cost-effectiveness and acceptability of health service interventions. Relevant and timely topics for review are selected by a Steering Group comprising managers, directors of public health and academics. Selection of topics takes into account the following criteria: resource implications, uncertainty about effectiveness, and the potential impact on health. The review and synthesis of the literature is carried out by a research team using established methodological checklists, with advice from expert consultants for each topic. The bulletins represent the views of the Effective Health Care research team.

A. Menorrhagia

Menorrhagia - excessive regular menstrual blood loss - is one of the most common reasons for women to be referred to gynaecologists. It is the main presenting problem in at least half of those who undergo hysterecomies.

In routine clinical practice, there is rarely any objective measurement of menstrual blood loss. Clinicians rely on the woman’s assessment of blood loss, but this is often an inaccurate indicator of actual loss.

The main aim of treatment is to alleviate symptoms and thus improve the woman's quality of life.

DEFINITION, CAUSE, MEASUREMENT, TREATMENT AIMS

A.1 Menorrhagia is defined as ‘excessive’ regular menstrual blood loss. It is one of the most common conditions referred to specialist outpatient clinics, accounting for 12% of all gynaecology referrals. Menorrhagia is also the main presenting problem in at least half of all women who undergo hysterecomies. However, there is considerable uncertainty about whether and how the problem should be treated; this is reflected in wide national and international variations in referral and surgical rates.

A.2 Most women treated for menorrhagia have no apparent organic pathology. When no gynaecological or systemic cause of the reported heavy bleeding is found, the condition is labelled 'dysfunctional uterine bleeding'. Several possible causes of menorrhagia have been identified (Box 1). Particularly high regular menstrual blood loss may be accompanied by anaemia.

A.3 The widely accepted clinical definition of menorrhagia is blood loss of 80 ml or more per period. This figure is derived from population studies which have shown that average blood loss is between 30 and 40 ml, and 90% of women have losses of less than 80 ml. While objective measurement of blood loss is possible, it is confined to research and not currently considered feasible in routine clinical practice.

A.4 In a national survey, 31% of women described their blood loss as heavy. However, many women who seek treatment for heavy menstural bleeding do not actually have greater losses than average. In one population study, 26% of those with losses well within the normal range (below 60 ml) considered their periods heavy, while 40% of those with objectively heavy losses (over 80 ml) considered their periods to be moderate or light. Over half of women referred for endometrial ablation for dysfunctional uterine bleeding had menstrual blood losses of less than 80 ml.

A.5 Treatment for menorrhagia has two related goals:

- to control menstrual blood loss - either by reducing or stopping it altogether
- to improve quality of life.

Box 1: Possible Causes of Menorrhagia

<table>
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<tr>
<th>Pathological</th>
<th>iatrogenic</th>
<th>Other</th>
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<tbody>
<tr>
<td>biochemical factors</td>
<td>intra-uterine devices</td>
<td>genetic</td>
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<td>fibroids</td>
<td>sterilisation</td>
<td>number of children</td>
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<td>adenomyosis</td>
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<td>obesity</td>
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<td>systemic disorders</td>
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Table 1: Hospital statistics for the management of menorrhagia (England)¹⁷

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<tr>
<td>Q07</td>
<td>Abdominal Hysterectomy</td>
<td>64,084</td>
<td>60,554</td>
<td>57,747</td>
<td>58,446</td>
<td>59,607</td>
<td>59,376</td>
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<td>Q08</td>
<td>Vaginal Hysterectomy</td>
<td>13,959</td>
<td>12,726</td>
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<td>13,562</td>
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<tr>
<td></td>
<td>ALL HYSSTERECTOMIES</td>
<td>78,007</td>
<td>73,280</td>
<td>70,675</td>
<td>71,630</td>
<td>73,169</td>
<td>73,517</td>
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<tr>
<td>Q17</td>
<td>Therapeutic Endoscopic Operations on the Uterus</td>
<td>649</td>
<td>1,699</td>
<td>4,224</td>
<td>7,707</td>
<td>9,982</td>
<td>9,945</td>
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<tr>
<td></td>
<td>ALL THE ABOVE</td>
<td>78,656</td>
<td>74,979</td>
<td>74,899</td>
<td>79,337</td>
<td>83,151</td>
<td>83,462</td>
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<td>Q10</td>
<td>Curettage of Uterus</td>
<td>168,404</td>
<td>169,295</td>
<td>149,772</td>
<td>140,356</td>
<td>126,636</td>
<td>106,146</td>
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<tr>
<td>Q18</td>
<td>Diagnostic Endoscopic Examination of Uterus</td>
<td>3,385</td>
<td>4,312</td>
<td>7,349</td>
<td>12,718</td>
<td>17,931</td>
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<tr>
<td></td>
<td>ALL DIAGNOSTIC</td>
<td>171,789</td>
<td>173,607</td>
<td>157,121</td>
<td>153,074</td>
<td>144,567</td>
<td>127,999</td>
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</table>

Other methods of investigating the womb lining by sampling the endometrium have become available, such as the use of narrow curettes, vacuum curettes, catheters or cannulae, endometrial washing, and endometrial scraping or aspiration. Hysteroscopy - the insertion of a small magnifying instrument via the vagina and cervix to allow viewing of the inside of the uterus - can be used on its own or with one of the sampling techniques to achieve a more accurate diagnosis.¹⁸⁻²⁰ In 1993/4, 21,853 hysteroscopies were carried out in NHS hospitals in England,²¹ an increase of 22% on 1992/3 (Table 1). These newer methods of endometrial sampling are frequently performed in outpatient clinics or general practice surgeries.

B.4 Surgical Treatment: Three types of surgical procedures are used to treat menorrhagia: D&C, removal of the uterus and cervix (hysterectomy), and removal of the lining of the womb (endometrial ablation). Hysterectomy is the most commonly used surgical treatment. It can be performed through an incision in the abdomen or via the vagina. Recently, laparoscopic hysterectomy has been developed. Hysterectomy may be accompanied by removal of one or both ovaries (total hysterectomy plus salpingo-oophorectomy). Myomectomy (surgical removal of fibroids) can also be performed, leaving the uterus intact.²² The new procedures of endometrial ablation or resection using laser surgery or diathermy are designed to remove as much as possible of the womb lining. Choice of surgical procedure has depended largely on the preference of the surgeon.²³

B.5 Despite considerable debate about the appropriate use of hysterectomy,²⁴ it is one of the most commonly performed surgical operations. In England in 1993/4, 73,517 women had this operation in NHS hospitals (Table 1),²⁵ but since many hysterectomies are performed in private hospitals, the total number of women undergoing the procedure is considerably higher. There are large socio-economic variations in the likelihood of having a hysterectomy for menstrual reasons; women who leave school without qualifications are fifteen times more likely to have a hysterectomy than women with a University degree.²⁶⁻²⁷

B.6 The majority of hysterectomies performed in the UK are abdominal.²⁸⁻²⁹ In 1993/4 19.2% of hysterectomies were performed vaginally.¹¹ Hysterectomy in the UK almost always involves inpatient admission and about one week's hospital stay, although vaginal hysterectomies are sometimes performed as day cases in the USA.²⁸⁻²⁹ Routine hospital episode statistics from a Thames Region showed that oophorectomy was carried out in 59% of abdominal hysterectomies.³⁰ In the majority of cases, both ovaries are removed.²⁹

B.7 Rates of endometrial ablation and resection are increasing. Figures from an audit undertaken by the Royal College of Obstetrics and Gynaecology of endometrial resection/ablation in the UK (NHS or private sector) indicate that in the period 1 April 1993 to 31 October 1994 about 10,200 of these procedures were undertaken, 82% of which used diathermy (either transcervical resection of the endometrium, rollerball or a combination), 16% used laser alone and 2% radiofrequency or cryoaulation.³¹

C. Diagnosis

Diagnostic dilatation and curettage (D&C) should not be performed on women aged under 40 years as the risks outweigh the benefits. D&C in older women could be replaced by cheaper, safer and probably more accurate alternative methods of endometrial sampling in outpatients. The accuracy of these approaches needs to be rigorously compared.

C.1 The main diagnostic investigations of the uterus are:

- dilatation and curettage (D&C)
- outpatient endometrial sampling
- hysteroscopy
- vaginal ultrasonography

C.2 Women complaining of excessive menstrual bleeding who are referred to gynaecological clinics commonly undergo dilatation and curettage primarily to exclude the possibility of cancer of the endometrium.³² In Britain, the operation normally involves a general anaesthetic and a two-day hospital stay, although the Audit Commission has estimated that up to 86% of D&Cs could be performed as day cases.³³

C.3 The use of D&C for diagnosing endometrial malignancy is not cost-effective in women at least under 40 years because serious pathology and the prevalence of endometrial cancer is so uncommon in these women.³⁴⁻³⁵ Based on estimates of endometrial cancer incidence of 0.66 per 100,000 women aged 30-34, Vessey, Clarke and MacKenzie³⁶ calculated that 3,000-4,000 D&Cs would have to be performed to detect one endometrial cancer in women aged under 35. This minimal potential benefit needs to be considered in the context of the risks associated with D&C, such as general anaesthetic, uterine perforation and laceration of the cervix.³⁷⁻³⁸

C.4 The usefulness of D&C as a diagnostic tool in general has been repeatedly questioned.³⁹⁻⁴⁰ Several studies have indicated that a significant proportion of endometrial lesions are not detected by D&C.³⁵⁻⁴¹⁻⁴²

C.5 The newer methods of endometrial sampling appear to be at least as accurate as D&C, have high levels of patient acceptability, lower complication rates and do not require inpatient admission and general anaesthesia.³⁵⁻⁴³ However, no randomised controlled trial has been carried out to compare outpatient endometrial sampling and D&C.

C.6 There has been only one economic assessment of the diagnostic technologies - a cost analysis of hysteroscopy versus D&C in the Australian health service.⁴⁵ This study found that if out-patient hysteroscopy were to replace D&C performed either as day case or in-patient, there would be a significant cost saving to the health service. However, these savings are unlikely to be fully realised if there is an increase in the rate of investigation.
D. Evaluating the Effectiveness of Treatment

Well-designed randomised controlled trials (RCTs) provide the most reliable evidence for the effectiveness of interventions. While there are many trials of drug therapies in the management of menorrhagia, there are only three for surgical treatments and none comparing drug and surgical interventions. Few studies examined the effect of any intervention on quality of life. There are a number of major problems in the design and conduct of available drug trials.

D.1 Nature of the Evidence. Well-designed randomised controlled trials (RCTs) provide the most reliable evidence for the efficacy of interventions as any observed differences between the groups can be more confidently attributed to differences in treatment. Searches were undertaken on Medline and Embase in order to identify the relevant research literature supplemented by consultation with experts and manual cross-checking of reference lists. Drug trials without objective measures of menstrual blood loss were excluded. The searches identified 31 randomised controlled trials of drug therapies which included objective measurement of menstrual blood loss among the outcome measures and 3 randomised controlled trials of surgical interventions, comparing abdominal hysterectomy with hysteroscopic surgical procedures. The comparisons of the RCTs that have been undertaken are shown in Figure 1.

D.2 The surgical trials that have been published are too small to provide reliable estimates of rare events such as mortality and of too short duration to give information on longer-term outcomes. Information on complication rates and risks of ill-health associated with surgery for menorrhagia is based on published observational studies including case series.

D.3 Outcome measures. A range of outcome measures are reported in the literature. For the drug therapies, objectively measured menstrual blood loss is the only consistent measure of outcome presented. For the surgical treatments, outcomes are commonly explored in the form of mortality, post-operative complications, effect on menstrual symptoms (including blood loss), risk of other diseases, and emotional and psycho-sexual outcomes. Few studies of any treatment modality examined the effect of the intervention on quality of life.

D.4 Quality of the drug trials. A number of methodological problems were identified with the drug trials:

a) entry criteria: Whereas some trials included only patients with a blood loss greater than 80 ml, others used lower thresholds such as 50 ml or 75 ml, and some entered all patients complaining of excessive menstrual blood loss.

b) side effects: In some trials side effects were not reported at all or actual numbers of patients experiencing side-effects were not given.

c) dosages: Some trials compared the effects of different dosages. For some drugs, the doses varied from study to study.

d) baseline pre-treatment observation and placebo comparison: Many of the trials include a baseline pre-treatment cycle. The baseline needs to be derived from at least 2 cycles to take account of the natural variation in menstrual blood flow from cycle to cycle. This is essential for the examination of any placebo effect.

e) short length of follow-up: The follow-up in the trials is at most 6 months, usually 2 months on each treatment. An average should be taken over more than 2 cycles to allow for natural variations in menstrual blood flow.

f) statistical issues: Most studies report mean blood loss. However, since the distribution of menstrual blood loss is skewed, the median would provide a more appropriate summary measure.

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Figure 1: Comparison of the Drug and Surgery-Randomised Controlled Trials

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<tr>
<th>Drug</th>
<th>Placebo</th>
<th>Other</th>
<th>Dichlofenac</th>
<th>IUD</th>
<th>Noradrenaline</th>
<th>Naproxen</th>
<th>Ethenosytrole</th>
<th>Ibuprofen</th>
<th>Danazol</th>
<th>Transaminic Acid</th>
<th>Mefenamic Acid</th>
<th>Hysteroscopic Surgery</th>
<th>Abdominal Hysterectomy</th>
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Note: An entry of one drug against # indicates a comparison of different doses of the same drug.
E. Drug Treatments

There is no evidence to support the continued use of norethisterone, the most popular drug prescribed for menorrhagia by GPs, at low doses and for short duration. The evidence suggests that tranexamic acid is the most effective and acceptable of the currently available drug treatments. Mefenamic acid also appears effective. There is also evidence that the hormone releasing intra-uterine device is effective, but this is not yet licensed for use for the treatment of menorrhagia in the UK. Further research is required to compare the relative effectiveness of the most promising drugs, exploring their effects on blood loss and the woman's quality of life.

GPs should offer at least one course of effective drug therapy prior to referral for surgical treatment.

E.1 A wide variety of drugs is used to treat menorrhagia (Box 3). A summary of the features of the drug trials can be found in Appendix 1.

E.2 Comparative Analysis: The menstrual blood loss reduction reported for each arm of the drug trials is shown in Figure 2. Since these results are derived from different trials, comparison across the trials, while suggestive, is not a reliable indicator of relative effectiveness since the participating patients are not always comparable. These comparisons indicate that the levonorgestrel releasing intra-uterine device, danazol, tranexamic acid, mefenamic acid, and naproxen may be the most efficacious in reducing menstrual blood loss. Norethisterone, particularly at low doses and used for short duration, appears the least efficacious and may be ineffective for reducing blood loss.

E.3 Of the more efficacious drugs, the hormone releasing coil is not yet registered for use in the UK as a treatment for menorrhagia. Danazol has well known, serious and distressing side-effects which make it unacceptable for long-term use; it is also very expensive. Early reports of an increase in risk of thromboembolic clots following use of tranexamic acid, which led to restrictions of its use in the UK, have now been discounted. Mefenamic acid has fewer side-effects and offers the advantage of alleviating menstrual pain.

E.4 This evidence is only suggestive because insufficient RCTs directly compare the top ranking drugs (Table 1). In one RCT, tranexamic acid produced a 58% reduction in menstrual blood loss, compared with 28% for mefenamic acid. In another RCT, tranexamic acid produced a 45% reduction in menstrual blood loss compared with a 20% increase with low doses of norethisterone. Further research, examining effects on blood loss and the woman's quality of life, is required to compare the most promising drugs.

E.5 Current prescribing practices: A total of 821,700 prescriptions were issued in the UK in 1993 to 345,225 patients for menorrhagia at an annual cost of £7,176,595. A national sample

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### Box 3: Drugs Used to Treat Menorrhagia

- Non-steroidal anti-inflammatory drugs (prostaglandin synthetase inhibitors, cyclo-oxygenase inhibitors)
  - mefenamic acid
  - naproxen
  - indomethacin
  - ibuprofen
  - flurbiprofen
  - meclofenamic acid
  - diclofenac
  - etamsylate

- Anti-fibrinolytics
  - tranexamic acid
  - epsilon-aminoacaproic acid

- Hormones
  - progestogens:
    - norethisterone
    - medroxyprogesterone
    - dydrogesterone
    - combined oestrogen/progestogen:
      - oral contraceptives
      - hormone replacement therapy

- Other:
  - danazol
  - gestrinone
  - clomifene
  - LHRH / GnRH analogues

- Other drugs:
  - anti-heparin agents
  - gamelonic acid

- Intra-uterine devices
  - levonorgestrel IUD *
  - prostaglandin releasing IUD *

Key: * now available in the UK as a contraceptive device
of 518 general practitioners who treated 4,603 patients complaining of menorrhagia revealed that norethisterone, prescribed to 38% of these patients, was the most commonly used drug, followed by mefenamic acid (27%), combined oral contraceptives (11%), combined hormone replacement therapy (8%), dydrogesterone (6%), danazol (6%), ethamsylate (6%) and tranexamic acid (5%).

E.6 Primary use of drug therapies: Some of the drug therapies are effective, have few or mild side-effects and acceptable treatment regimes. GPs should consider offering at least one course of an effective drug therapy prior to referral for surgical treatment. If the more effective drugs such as tranexamic acid were used in primary care, there might be a substantial reduction in the number of women referred for surgery.

E.7 Cost implications: Currently norethisterone is prescribed to 38% of women receiving medical treatment for menorrhagia, at a cost of £654,538 nationally, whereas tranexamic acid is used by about 5% of women at a cost of £285,105. A shift in prescribing from norethisterone to a more effective drug such as tranexamic acid could result in a 20% increase in menorrhagia drug costs. However, since short-term use of norethisterone has been found to be no more effective than placebo in the treatment of menorrhagia, money spent on it may be wasted. In addition, many women treated in this way would be referred for more expensive surgical treatment. If tranexamic acid were to replace all other drugs used for menorrhagia, there could be a net saving of at least 10% on the total drug bill for menorrhagia.

F. Surgical Treatments

Women require a shorter period in hospital for transcervical endometrial resection or ablation than for hysterectomy, and they resume normal activities earlier. However, re-treatment rates of up to 23% in two years have been reported for endometrial resection, offsetting its cost advantage relative to hysterectomy. In addition, little is known about the long-term effects of endometrial resection or ablation.

High levels of satisfaction have been reported for surgical procedures, particularly for hysterectomy.

There is no evidence for a therapeutic effect of dilatation and curettage (D&C).

F.1 Three randomised controlled trials compared abdominal hysterectomy with newer, less invasive surgical interventions for menorrhagia. The results of the studies of the outcomes of the different types of endometrial resection or ablation have been combined in the following analysis. Table 2 and Appendix 2 summarise the key results of these studies.

F.2 The process of care. Abdominal hysterectomy requires more theatre time and results in a longer length of stay in hospital than the less invasive approaches.

F.3 Post-operative complications. Abdominal hysterectomy has a high complication rate of around 45%, including pain, haemorrhage, wound infection, urinary retention, urinary tract infection and vaginal discharge. This compares with a rate of 0-15% for transcervical endometrial resection or ablation, with reported complications of uterine perforation, fluid overload, haemorrhage and urinary tract infection. Lower complication rates have been reported for vaginal hysterectomy in uncontrolled studies.

To reduce the rate of serious post-operative infections, pre-operative antibiotics should be used routinely. A meta-analysis of 25 trials of antibiotic prophylaxis during abdominal hysterectomy suggests a possible reduction in post-operative infections from 21% to 9%.

F.4 Resumption of normal activities. A woman undergoing abdominal hysterectomy can expect to convalesce for two to three months before she is able to resume her normal activities. Estimates of the time taken to recover from the operation itself range from 8 to 11 weeks, compared to 2 to 3 weeks for resection or ablation. Patients who have a hysterectomy are more likely to require

Table 2: Comparative Results of the Three Surgical RCTs

<table>
<thead>
<tr>
<th>Study</th>
<th>Reading Study&lt;sup&gt;49&lt;/sup&gt;</th>
<th>Bristol Study&lt;sup&gt;22,40&lt;/sup&gt;</th>
<th>Aberdeen Study&lt;sup&gt;11&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>Abdominal Hysterectomy</td>
<td>Endometrial Ablation</td>
<td>Abdominal Hysterectomy</td>
</tr>
<tr>
<td>Study Size:</td>
<td>26</td>
<td>25</td>
<td>97</td>
</tr>
<tr>
<td>Follow up time</td>
<td>av. 12 mth</td>
<td>av. 12 mth</td>
<td>4 mth (2.2 yrs)</td>
</tr>
<tr>
<td>Process of Care:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating Time</td>
<td>50</td>
<td>30</td>
<td>45</td>
</tr>
<tr>
<td>(median mins)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of Stay</td>
<td>7</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>(median days)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-op Complications</td>
<td>46%</td>
<td>0%</td>
<td>47%</td>
</tr>
<tr>
<td>Duration of anaesthesia (median weeks)</td>
<td>1</td>
<td>0</td>
<td>14%</td>
</tr>
<tr>
<td>No pain at 7 days</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Time to Resume Daily</td>
<td>8</td>
<td>2-3</td>
<td>4</td>
</tr>
<tr>
<td>Activities (median weeks)</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Menstrual Outcomes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No bleeding</td>
<td>100%</td>
<td>64%</td>
<td>190%</td>
</tr>
<tr>
<td>Light bleeding</td>
<td>-</td>
<td>16%</td>
<td>-</td>
</tr>
<tr>
<td>Menstrual pain</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Emotional Outcomes:</td>
<td>GHO score &lt;25%</td>
<td>-</td>
<td>25%</td>
</tr>
<tr>
<td>Satisfaction:</td>
<td>Very satisfied with improvement</td>
<td>-</td>
<td>94%</td>
</tr>
<tr>
<td>Insufficient improvement</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Re-operation rate</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
post-operative analgesia and to need it for a longer period than those who undergo resection or ablation.

F.5 Effect on menstrual symptoms. Since the uterus is removed in hysterectomy, the woman will totally cease to have periods. Endometrial resection or ablation is not always successful in reducing menstrual loss. Estimates vary from 13-64% for no menstrual bleeding and 62-77% for a light flow. These figures are similar to those arising from earlier case series data. However, menstrual blood loss and menstrual pain may increase with time after endometrial ablation. An ongoing cohort study of patients who had undergone an endometrial resection has shown that, even in those patients for whom menstruation returned, it was usually light. However, 13% reported increased menstrual pain.

F.6 Re-operation rate. Relatively high rates of re-operation - repeat resection or ablation and/or hysterectomy - have been reported following initial treatment with endometrial resection or ablation, ranging from 6-23%, with the higher rates found in studies with longer follow-up. Another cohort study estimates the cumulative probability of requiring a hysterectomy four years after endometrial resection to be 12% following total resection and 40% following repeat total resection.

F.7 Emotional and psycho-sexual outcomes. Hysterectomy appears to have a beneficial effect on mental well-being. In contrast to earlier studies which suggested an increased incidence of depression, a lower prevalence of depression and improved mood and vigour after hysterectomy has been found in more recent studies. Recent reviews have suggested that the subgroup of women at higher risk of depression is composed of women with pre-operative psychopathology; thus the operation is unlikely to be the cause of subsequent psychiatric problems. For sexual functioning the evidence is more varied, with some patients reporting increased sexual enjoyment and others reduced libido.

Endometrial resection or ablation may also have a beneficial effect on depressive symptoms, enjoyment of sex, and general health. Dwyer, Hutton and Stirrat found that 26% patients undergoing endometrial resection had improved scores on the General Health Questionnaire at 4 months after surgery, and 22% of patients reported improved enjoyment of sex at 4 months. Finion et al. found similar results at 12 months, with 51% of the patients indicating that their general health was better after the operation.

F.8 Satisfaction. High levels of patient satisfaction have been reported for both surgical procedures, but higher after hysterectomy than resection or ablation. However, the initial advantage at one month after endometrial resection, in terms of health-related quality of life as measured by the rating scale of the EuroQol, is offset by a non-significant difference four months after the operation.

F.9 Hysterectomy with oophorectomy. Oophorectomy is often performed at the same time as abdominal hysterectomy in order to eliminate the risk of ovarian cancer. Whether this practice is justified depends on the balance of risks and benefits in terms of years of life gained and quality of life. If the ovaries are removed, a pre-menopausal woman will undergo a 'surgical menopause', with a consequent increased risk of osteoporosis and cardiovascular disease. However, the removal of the ovaries appears to reduce the risk of breast cancer. Overall, oophorectomy reduces average life expectancy in younger women by at least five years if they do not take hormone replacement therapy. Since many women do not comply with long term hormone replacement therapy, the routine removal of healthy ovaries in women who are not at high risk of ovarian cancer is hard to justify.

F.10 Long-term risk of disease and pregnancy. Hysterectomy has been implicated in the development of urinary symptoms, bowel disorders and osteoarthritis. Evidence on urinary symptoms and bowel disorders is conflicting and the evidence on the development of osteoarthritis following hysterectomy is inconclusive. The lack of long-term studies of endometrial resection or ablation means that little is known about their effect on disease risk. The chances of pregnancy following endometrial resection or ablation are unknown and sterilisation is often recommended for those who do not want any more children.

F.11 Mortality. Apart from individual case reports, there is no evidence on mortality following endometrial ablation. Estimates of the risk of operative mortality for patients undergoing hysterectomy vary from 0.4 to 2 per 1000 women, depending on the definition of operative mortality and type of study. In a population registry study of about 30,000 Danish women who underwent hysterectomy for non-cancer indications, mortality within 30 days of hysterectomy for women under the age of 50 was 4.2 per 10,000. For vaginal hysterectomy, mortality appears to be lower (1 per 1,000) than for patients who undergo abdominal hysterectomy (2 per 1000), but this probably reflects the selection of healthier patients for the vaginal operation.

F.12 Relative Costs. As endometrial resection requires less operating theatre time and has a shorter length of stay, its health service costs are less than abdominal hysterectomy. However, this initial cost advantage may diminish over time. Four months after surgery, on average the total cost of endometrial resection (including the cost of complications and re-treatments) was 47% lower than that for abdominal hysterectomy. However, after follow-up for an average of 2.2 years this had fallen to 29%, mainly because about a quarter of the women initially randomised to resection subsequently received a repeat resection and/or a hysterectomy. It should be noted that these costs do not include the cost to the woman, her family and the community of the relatively long period of convalescence required after hysterectomy.

F.13 Costs of alternative surgical options: A range of other surgical alternatives to hysterectomy exist, including laser ablation and radiofrequency. However, these treatments involve higher capital costs for specialist equipment.

The use of other types of hysterectomy than abdominal hysterectomy might reduce the cost gap relative to transcervical resection of the endometrium. Vaginal hysterectomy usually involves a shorter length of hospital stay and has been found to be less costly than abdominal hysterectomy. However, vaginal hysterectomy is contra-indicated in some women. It may be possible to use the new technique of laparoscopic-assisted vaginal hysterectomy on most women who would have received abdominal hysterectomy. The effect on costs is unclear and will vary depending on whether surgeons use disposable or re-usable surgical instruments. However, laparoscopic-assisted vaginal hysterectomy remains to be evaluated properly in terms of clinical effectiveness and cost to the NHS.

F.14 Dilatation and curettage: D&C has been widely used as a possible treatment option for menorrhagia but has never been shown to be effective. There are no published reports of randomised controlled trials of this procedure against placebo. Reports from uncontrolled case studies claiming a beneficial effect lack objective measurement of blood loss and are probably detecting a placebo effect. The only study to measure blood loss before and after D&C found a reduction in menstrual blood loss immediately after the procedure, but losses returned to previous levels or higher by the second menstrual period.

G. Other Treatment Options

It has been suggested that there are relationships between exercise and aspects of nutrition, for example vitamin A status, and the duration and extent of menstrual bleeding. However, no controlled trials assessing the effectiveness of altering nutrition and the amount of exercise have been identified.
H. Advice to Commissioners of Services and Research

Women with menorrhagia should be provided with sufficient information about the risks and benefits of drug and surgical interventions to enable them to make an informed choice about management options.

Purchasers should monitor indications for treatment, the use of D&C in diagnosis and therapy, and prescribing patterns of less effective drugs.

Further research is needed on the relative effectiveness of drug therapy and surgical interventions in terms of blood loss, quality of life and patient acceptability. Research on the possible role of nutritional and other lifestyle interventions is also needed.

H.1 Recommendations to Purchasers: Available research evidence suggests that:

(a) Because many women complaining of heavy periods may not in fact have excessive menstrual blood loss, every attempt should be made to ascertain whether blood loss is indeed high. However, this is difficult without a routinely available objective method. It is also important to determine what particular problems their heavy periods cause the woman. Reassurance may help to improve her subjective assessment of blood loss, pain and discomfort, and reduce the need for unnecessary treatment.

(b) All the options should be discussed with the woman, giving her sufficient information about the risks and benefits of drug and surgical interventions for her to make an informed decision about her treatment.

(c) GPs should consider offering a course of effective drug therapy such as tranexamic acid and mefenamic acid as a first line treatment. Drug use should be monitored to identify prescribing of relatively ineffective drugs such as mefenamic acid.

(d) Hysteroscopic examination is likely to be the most cost-effective method of diagnosing uterine pathology in older women. This can be carried out in outpatients. D&C should generally not be offered to women under the age of 40 years for diagnosis.

(e) There is no obvious best surgical treatment for all women. The advantage of conservative surgery over abdomino hysterectomy in the short term appears not to be sustained in the longer term. D&C should not be used as a treatment for menorrhagia.

(f) If newer less invasive surgical techniques are used, it is important to ensure that the surgeons have the necessary training and skills.

H.2 Purchasers should monitor indications for treatment amongst their providing units, the use of D&C, and prescribing patterns.

H.3 New Technologies: Evidence from Scandinavian countries points to the effectiveness of the hormone releasing intra-uterine device as a first line of treatment for menorrhagia; however, it is not yet licensed for this indication in the UK. New technologies should not be purchased unless there is good evidence on their efficacy or unless they are part of a high quality evaluative study.

H.4 Recommendations for Further Research: Further research is needed in the following areas:

(a) To evaluate different strategies to help women cope with their perceived heavy periods in order to avoid unnecessary drug or surgical treatment (for example, reassurance, counselling and the development of coping strategies).

(b) To develop an accurate, objective and effective method for the routine measurement of menstrual blood loss.

(c) To compare the relative effectiveness and cost effectiveness of the most promising medical and surgical interventions in terms of blood loss, quality of life and patient acceptability.

(d) To examine the potential effects of changes in exercise, diet and the use of nutritional supplementation on menorrhagia.

(e) To explore different mechanisms and approaches to providing information to the woman (for example, in the form of patient leaflets and videos) in order to help her decide which treatment option is more appropriate.

References


<table>
<thead>
<tr>
<th>Trial</th>
<th>Selection Criteria</th>
<th>Intervention</th>
<th>Outcome Measures</th>
<th>Duration</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vernyth, Verheugen-Deelstra, Verstraete et al. (1968)</td>
<td>Women with a history of menorrhagia. Subjective. Trial: cross-over, double blind. Size: N=16.</td>
<td>Transaxamic acid (500mg 4 hourly from day 1 till bleeding stops) Placebo</td>
<td>mean hemoglobin loss, pads used, side-effects.</td>
<td>6 months 36% dropout</td>
<td>Transaxamic acid reduced mbl by 35%. No blood loss reported, just percentage. Side-effects: no difference between active and placebo groups.</td>
</tr>
<tr>
<td>Nilsson &amp; Rybo (1967)</td>
<td>Women aged 15-40 with suspected menorrhagia. Subjective. Trial: cross-over, double blind. Size: N=26</td>
<td>Low dose transaxamic acid (250mg 4 hourly) High dose transaxamic acid (500mg 4 hourly) Placebo</td>
<td>mbl, side-effects.</td>
<td>3 months 0% dropout</td>
<td>Low dose of transaxamic acid reduced mbl by 38%, high dose by 51% and the placebo by 8%. Side-effects: 7 in low dose group, 13 in high dose group, and 8 in placebo group (mainly diarrhoea and abdominal pain).</td>
</tr>
<tr>
<td>Ylikorkala &amp; Vinikka (1963)</td>
<td>Women with IUDs and mbl &gt;70mL. Trial: cross-over, double blind. Size: N=19.</td>
<td>Transaxamic acid (1.5g tid s for 5 days) Diclofenac sodium (50mg 8 tid s for days 1 and 25mg tid s for 4 days) Placebo</td>
<td>mbl, duration, intermenstrual bleeding, side-effects, restricted activity, pelvic pain, subjective assessment.</td>
<td>5 months 10% dropout</td>
<td>Transaxamic acid reduced mbl by 56%, diclofenac sodium by 24%. Side-effects: 12 women in transaxamic acid group, 5 in diclofenac sodium group.</td>
</tr>
<tr>
<td>Andersch, Miloon &amp; Rybo (1986)</td>
<td>Women aged 34-49 with mbl &gt;80mL. Trial: cross-over, open. Size: N=15.</td>
<td>Transaxamic acid (1.5g tid s for 3 days, 1g bd during days 4 and 5) Flurbiprofen (100mg bd for 5 days) Placebo</td>
<td>mbl, duration, side-effects.</td>
<td>4 months 0% dropout</td>
<td>Transaxamic acid reduced mbl by 53%, flurbiprofen by 24%. Side-effects: 7 in transaxamic acid group, 4 in flurbiprofen group.</td>
</tr>
<tr>
<td>Milssen, Andersen, Andersch and Rybo (1991)</td>
<td>Women with mbl &gt;80mL and no pelvic pathology. Trial: First 20 women given IUD, next 15 randomised to cross-over design. Size: IUD=16, drugs=15.</td>
<td>IUD Group: Levonorgestrel IUDs (release rate of 20ug per day) Drugs Group: Flurbiprofen (100ug bd for 5 days) cross-over with Transaxamic acid (1.5g tid s for days 1-3, then 1g bd for days 4 and 5)</td>
<td>mbl, side-effects.</td>
<td>4 months 11% dropout</td>
<td>IUD group: at 3 months gave 82% reduction, at 6 months 86% reduction and in 12 months 96% reduction in mbl Drugs: Flurbiprofen reduced mbl by 21% and transaxamic acid by 44%. Side-effects: 7 transaxamic acid, 4 flurbiprofen.</td>
</tr>
<tr>
<td>Chihaba, Andersen, Nasli et al. (1989)</td>
<td>Women referred to gynaecology outpatient clinics with mbl &gt;60mL. Trial: single-blind. Size: A:8, B:16, C:16.</td>
<td>Group A: placebo Group B: danazol (200mg od for 12 weeks) Group C: danazol (100mg od for 12 weeks) cross-over with Transaxamic acid (1.5g tid s for days 1-3, then 1g bd for days 4 and 5)</td>
<td>mbl, duration, side-effects.</td>
<td>5 months 0% dropout</td>
<td>30mg of danazol reduced mbl by 86%, 100mg of danazol reduced mbl by 75%, and no change for the placebo group. Side-effects: thickness 5, musclekelletal pain 4, skin rash 3, headache 6, irritability 3, vomiting 3, average weight gain 2.3kg.</td>
</tr>
<tr>
<td>Makarikangas and Ylikorkala (1986)</td>
<td>Women complaining of excessive menstrual bleeding and primary menorrhagia over 70mL mbl. No pre-treatment control cycle. Trial: double-blind, cross-over. Size: N=13.</td>
<td>High dose: Ibuprofen (400mg tid s) Low dose: Ibuprofen (200mg tid s) Placebo</td>
<td>mbl, duration, pain, side-effects.</td>
<td>3 and 6 months 23% dropout</td>
<td>High dose Ibuprofen reduced mbl by 25% and low dose by 16%. Side-effects: 5 on high dose, 6 on low dose, included head ache, dizziness, nausea, diarrhoea, and dyspepsia on high dose.</td>
</tr>
<tr>
<td>Roy and Show (1981)</td>
<td>Healthy volunteers who had used IUD for at least 5 months with no side-effects. Subjective. One pre-treatment control cycle. Trial: double-blind, cross-over. Size: N=20.</td>
<td>Ibuprofen (400mg qds) Placebo</td>
<td>mbl.</td>
<td>2 months 0% dropout</td>
<td>Overall percentage reduction in mbl 32% for Ibuprofen, and 6% increase for the placebo group. Means values not given. Side-effects: 2 on Ibuprofen (swelling around eyes and mouth &amp; mild stomach cramps), 2 on placebo (mild stomach cramps &amp; nausea headaches and dizziness).</td>
</tr>
<tr>
<td>Kusende and Bonar (1975)</td>
<td>Women complaining of excessive menstrual bleeding while using IUDs. Trial: open. Size: A:11 B:12.</td>
<td>Group A: ethamsylate (500mg qds during period) Group B: EACA (5g qds during period)</td>
<td>mbl.</td>
<td>4 months 8% dropout</td>
<td>Ethamsylate reduced mbl by 7%. EACA by 50%. Side-effects not reported.</td>
</tr>
<tr>
<td>Hanson and Campbell (1976)</td>
<td>Women with primary menorrhagia. IUD users also recruited. One pre-treatment control cycle. Trial: double-blind, cross-over. Size: A=9, B=13.</td>
<td>Ethamsylate (500mg qds 5 days before onset and for 10 days) Placebo Group A: primary menorrhagia Group B: IUD users</td>
<td>mbl, side-effects.</td>
<td>4 months 29% dropout</td>
<td>Ethamsylate reduced mbl by 50% in the primary menorrhagia group, 19% in the IUD group, and no change for the placebo group. Side-effects: reported in 18 out of 53 ethamsylate cycles and 17 out of 50 placebo cycles - but reportedly not serious.</td>
</tr>
<tr>
<td>Rybo, Nilsson, Sjöström and Nygren (1981)</td>
<td>Women with primary menorrhagia. Women without primary menorrhagia were fitted with IUD Trial: double-blind, cross-over. Size: A=4, B=5, C=5.</td>
<td>Progesterone (500mg in morning, then 250mg in afternoon for 2 days, then 250mg bd for up to 7 days) Placebo Group A: Primary menorrhagia Group B: IUD &amp; mbl &gt;80mL Group C: IUD &amp; mbl &lt;80mL</td>
<td>mbl.</td>
<td>4 months 0% dropout</td>
<td>In primary menorrhagia group progeserone reduced mbl by 24%. Group with IUD &amp; &gt;80mL reduced by 38% and IUD group with mbl &lt;80mL reduced by 9%; reduction in placebo of 2-4%. Side-effects: not reported.</td>
</tr>
<tr>
<td>Trial</td>
<td>Selection Criteria</td>
<td>Intervention</td>
<td>Outcome Measures</td>
<td>Duration</td>
<td>Results</td>
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</tr>
<tr>
<td>Davies, Anderson and Tombell (1987)</td>
<td>Women using IUDs and mbl &gt;80ml</td>
<td>High dose: naproxen (500mg bd. plus 250mg od for 5 days) Low dose: naproxen (500mg loading dose plus 250mg tds for 5 days)</td>
<td>mbl, pads &amp; tampons reused, intensity of bleeding, assessment of drug effect, side-effects.</td>
<td>4 months 29% dropout</td>
<td>High dose reduced mbl by 32%, low dose reduced mbl by 32%. Side-effects: no adverse reactions to naproxen, 1 patient with nausea/vomiting.</td>
</tr>
<tr>
<td>Ylikorkala and Piekkonen (1986)</td>
<td>Women with mean mbl &gt;80ml.</td>
<td>Naproxen (250mg qds for days 1-5 of cycle) Placebo</td>
<td>mbl, duration, side-effects.</td>
<td>4 months 0% dropout</td>
<td>Naproxen reduced mbl by 36% and 11% increase in mbl for the placebo group. Side-effects: 1 patient on placebo showed mild side-effects, but none on naproxen.</td>
</tr>
<tr>
<td>Colles, Arnot, Meristo and Guiter (1978)</td>
<td>Women volunteers selected from those requesting an IUD. Mbl measured but all c &lt; 80ml. One or two pre-treatment control cycles.</td>
<td>Group A: UPS-40 (release 40mg per day of progesterone) Group B: UPS-65 (release 65mg per day of progesterone) Group C: Norplant IUD (release 10ug per day of progesterone) Group D: Levonorgestrel IUD (release 2ug per day of progesterone)</td>
<td>mbl.</td>
<td>6 months 0% dropout</td>
<td>UPS-40 increased mbl by 34% (but not significant increase), UPS-65 reduced mbl by 40%, norplant releasing IUD reduced mbl by 35%, and levonorgestrel releasing IUD reduced mbl by 47%. Side-effects: not given.</td>
</tr>
<tr>
<td>Nilsson (1977)</td>
<td>Women volunteers from hospital staff, not menstruating.</td>
<td>Group A: i-norgestrel-releasing IUD (releasing 25ug daily) Group B: copper IUD</td>
<td>mbl.</td>
<td>3 months 0% dropout</td>
<td>The i-norgestrel-releasing IUD reduced the pre-insertion mean mbl by 60%. Side-effects: none given.</td>
</tr>
<tr>
<td>Vargyas, Caureau and Mishell (1987)</td>
<td>Women aged 16-42 with mbl &gt; 60ml.</td>
<td>Meclofenamate sodium (100mg tds for 6 days or until bleeding ceased) Placebo</td>
<td>mbl, duration, dysmenorrhea, side-effects, pads &amp; tampons used.</td>
<td>4 months 9% dropout</td>
<td>Meclofenamate sodium reduced mbl by 49%; a 4% reduction for the placebo group. Side-effects: dysmenorrhea, backache, headache less severe on active drug. Nausea and vomiting no difference between groups.</td>
</tr>
<tr>
<td>Higham and Shaw (1991)</td>
<td>Women aged 20-50 with proven menorrhagia.</td>
<td>Group A: danazol (dose reduced each cycle: 200mg, 100mg, 50mg od) Group B: danazol (200mg od) Group C: Noriprost (5mg tds days 19-26)</td>
<td>mbl, duration, interval between cycles, dysmenorrhea, subjective assessment, side-effects.</td>
<td>3 months 14% 24% dropout</td>
<td>Danazol reduced mbl by 28% as the reducing dose and by 40% on the 200mg dose. Side-effects: 15 women on reducing dose, 17 on 200mg dose, 11 on placebo.</td>
</tr>
<tr>
<td>Ingemanson, Silberman, Rybo and Bjorkman (1981)</td>
<td>Women using IUDs and mbl &gt;80ml</td>
<td>Danazol (500mg tds for 5 days of drug) Placebo.</td>
<td>mbl, duration, subjective assessment, side-effects.</td>
<td>4 months 0% dropout</td>
<td>Danazol reduced mbl by 29% and a 4% reduction for the placebo group. Side-effects: None attributed to danazol.</td>
</tr>
<tr>
<td>Preston, Cameron, Adams and Smith (1995)</td>
<td>Patients complaining of menorrhagia, with clinical mbl &gt;80ml.</td>
<td>Group A: tranexamic acid (1g qds days 1-4) Group B: norplant (5mg od on days 19-26)</td>
<td>mbl, subjective assessment, side-effects.</td>
<td>2 months 9% dropout</td>
<td>Tranexamic acid reduced mbl by 45%, norplant increased mbl by 20%. Side-effects: 8 headaches &amp; 3 GI on tranexamic acid, 10 headache &amp; 7 GI on norplant.</td>
</tr>
</tbody>
</table>

**Key:**
- mbl = menstrual blood loss
- od = once a day
- qd = twice a day
- qds = three times daily
- qhs = four times daily
- mg = milligrams
- GI = Gastro-intestinal

Note: All trials included at least 2 pre-treatment control cycles except if otherwise indicated.
## Appendix 2: Overview of Surgical Randomised Controlled Trials

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<tr>
<th>Study</th>
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<th>Follow-up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannes et al (1991)⁷⁷</td>
<td>Women aged 29-51 (median of 40) awaiting abdominal hysterectomy for menorrhagia at the Royal Berkshire Hospital Reading, found suitable after history, physical examination, and pelvic ultrasound with a vaginal probe. Exclusions: women known to have leiomyomata, endometrial or cervical neoplasia, concomitant ovulation pathology, pelvic inflammatory disease or endometriosis. 51 of 78 women without pelvic pathology on the waiting list and consenting to participate, allocated at random to 2 groups:</td>
<td>Requirement for analgesia; complications; post-operative recovery time; menorrhagia status. Diary record of symptoms after discharge from hospital, noting first day without analgesic drugs, date felt fit to return to work. Women requiring hysterectomy or a repeat hysteroscopic procedure.</td>
<td>9-16 months, with a mean of 12 months. Loss to follow-up not reported.</td>
<td>Recovery after endometrial resection was substantially shorter (median 16 days) than for hysterectomy (median 58 days). 2 women (4%) in the hysterectomy group had complications, and none of the women who had endometrial resection. 4 (16%) of the women who had endometrial resection required any post-operative analgesia. 4 women (16%) had repeat resections; no woman required a hysterectomy within the mean follow-up of one year. The mean theatre and ward cost for endometrial resection was £607 and £1270 for hysterectomy. Authors point to the need for larger numbers and longer follow-up to estimate complications and long-term efficacy of endometrial resection.</td>
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<td>Dwyer, Hutton and Sieradzki (1993)⁷⁸</td>
<td>Women aged under 52 (mean of 40) complaining of menorrhagia which could not be controlled by conservative means and who were candidates for hysterectomy, attending the gynaecological department of Bristol’s teaching hospital. Exclusions: women with uterine size &gt; 12 weeks, additional symptoms or other pathology made hysterectomy the preferred treatment. 4 histological assessment of the endometrium was undertaken if hyperplasia due to anovulatory menstruation was suspected. 196 of 216 women found suitable and agreeing to participate, allocated at random to 2 groups:</td>
<td>Requirement for analgesia; complications; post-operative recovery time; menorrhagia status; sexual activity; psychiatric morbidity using the 60 item General Health Questionnaire (GHQ). Self-recording of degree of pain each day for a week, booklet recording post-operative problems, amount and duration of vaginal bleeding, date of return to work and normal daily activities. Follow-up rate of endometrial resection, as assessed by the number of women not satisfied or who had severe synchnées. Degree of satisfaction with their operation 4 months after operation. Restricted version of the EuroQol health questionnaire, completed a minimum of 4 months after the operation: asking the women to value their health on average, one month prior to and 2 weeks after the operation, and at the time of completing the questionnaire. SF-36 as part of longer term follow-up together with the EuroQol.</td>
<td>4 months, with a 2% drop-out rate. 69% completed the EuroQol health questionnaire sent at 4 months after the operation. At an average of 2.2 years, lost to follow-up: Group A: 25%; Group B: 17%. Post-operative morbidity, length of stay and time taken to return to work, normal daily activities and sexual intercourse were significantly lower in the endometrial group. Postmenstrual symptoms, symptoms of dysmenorrhea, bleeding and breast tenderness were less frequent after hysterectomy. After endometrial resection, 13 women were amenorrhoeic while 7% had hypo-menorrhoea. 46% (47%) of the women having a hysterectomy had complications compared to 4 (4%) of those having an endometrial resection. Only 1 woman having a hysterectomy did not require analgesia for post-operative pain compared to 39 of the endometrial resection group. After 4 months, there was a statistically significant difference in satisfaction in favour of hysterectomy with 94% (vs 85%) being very satisfied or satisfied with the results of their treatment, and no statistical difference in EuroQol scores. At 4 months, there was failure rate of at least 10-15% in those in whom endometrial resection appeared complete. At 2.8 years, the cumulative probability of a repeat resection was 12% and of a hysterectomy 16%, leading to an overall 23%</td>
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<td>Priski et al (1994)⁷⁹</td>
<td>Women attending general gynaecological clinics at Aberdeen’s teaching hospital, aged under 50, weighing under 100 kg, a clinical diagnosis of dysfunctional uterine bleeding (tumors less than size of a pregnancy of 10 weeks, and normal endometrial history), and who would otherwise have undergone a hysterectomy. 204 women allocated at random to 3 groups:</td>
<td>Requirement for analgesia; complications; post-operative recovery time; menorrhagia status; urinary incontinence, premenstrual and menstrual symptoms and dyspareunia. Women’s grading of heaviness and pain for each day of the period. Patient satisfaction - how does your health compare with that a year ago? what effect has the operation had on their symptoms? how satisfied are you with the effect of treatment. Women requiring hysterectomy or a repeat hysteroscopic procedure. Data collected before randomisation, and at 1, 6 and 12 months after treatment.</td>
<td>12 months. Nine-attenders for follow-up: At 1 month: 5%; At 6 months: 12%; At 12 months: 9%. Women treated by hysteroscopic surgery had less morbidity and a significantly shorter recovery period than those treated by hysterectomy. Five women in the hysterectomy group had major complications: 2 from the anaesthesia, 1 from intro-abdominal bleeding, and 2 pelvic abscesses. One woman given hysterectomy had a small bowel obstruction. 10% of the women in the hysterectomy group had an infection, compared with 0% in the hysterectomy group. 45% were amenorrhoeic or had only a brown discharge, and 33% had light periods. After 12 months, 89% of the hysterectomy group (and 78% of the hysterectomy group) were very satisfied with the effect of surgery; 95% (90%) thought they had been an acceptable improvement in symptoms: 73% (48%) indicated that their health was much better than a year before.</td>
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