A randomised controlled trial of microwave endometrial ablation without endometrial preparation in the outpatient setting: patient acceptability, treatment outcome and costs


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Microwave endometrial ablation (MEA) performed during the postmenstrual phase in an outpatient environment was compared with MEA after drug preparation in a day-case theatre setting. Endometrial preparation was facilitated with either Danazol (200 mg twice daily for 4 to 5 weeks) or one subcutaneous injection of Goseralin (3.6 mg) 5 weeks pre-operatively.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with excessive menstrual loss who agreed to undergo MEA under local anaesthesia. Women were included in the study if they had normal endometrial pathology, a completed family, and a uterine size of 12 weeks or less. Women with non-obstructing sub-mucous fibroids of up to 3 cm in size were included. Hysteroscopy and scanning were not routinely carried out prior to recruitment.

Setting
The setting was secondary care. The economic study was conducted in Aberdeen, UK.

Dates to which data relate
The effectiveness and resource use data were gathered between April 2001 and July 2002. The cost data were taken from personal communication and published and electronic sources that related to 2001 to 2003. The costs were adjusted to 2002 prices.

Source of effectiveness data
The evidence for the effectiveness outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
A power calculation estimated that 180 patients would be needed to achieve 80% power to detect a 20% difference in satisfaction and a 10% difference in acceptability, (p=0.05), assuming a 15% drop-out rate. Women who were eligible
and consented to participate were randomly assigned to one of the two groups. Of 286 eligible patients, 27% declined to enter the study. Two hundred and ten women were recruited to the study, of which 6% subsequently withdrew or were excluded for medical reasons. A total of 197 women started the trial, with 97 assigned to the post-menses group and 100 assigned to the drug preparation group.

**Study design**

The study used a randomised controlled design and was conducted at a single centre. Randomisation was achieved by computer-generated balanced random number blocks. The patients were assigned to the study groups using sealed, opaque, sequentially numbered envelopes at a distant site. There was no indication of blinding. The patients were followed up for one year with a battery of questionnaires. There was no loss to follow-up either postoperatively or at 2 weeks. At 1 month 88.3% of all patients completed questionnaires (86.6% of the post-menses group and 90% of the drug preparation group). At 6 months, 99% of patients in both groups completed follow-up, and at 12 months 96.5% of all patients responded to the questionnaires (95.9% of the post-menses group and 97% of the drug preparation group).

**Analysis of effectiveness**

The primary health outcomes were patient satisfaction with the treatment and acceptability of the treatment. The secondary health measures were menstrual outcomes and quality of life. Acceptability was assessed using a 6-point Likert-type scale (ranging from totally acceptable to totally unacceptable) and a visual analogue scale. Satisfaction was also scored on a 6-point Likert-type scale (ranging from totally satisfied to totally unsatisfied). Patients completed a questionnaire on menstrual detail, the Short Form 12, the Hospital Anxiety and Depression Score, and the modified McGill Pain Questionnaire.

The analysis of effectiveness was conducted on an intention to treat approach for the 197 patients who entered the trial and received treatment. Protocol violations were observed when 3 patients in the post-menses group received drug preparation. However, their data were analysed in their intended treatment group. The demographic and clinical characteristics of the patients in the two groups were presented, but the authors did not report if there were any statistically significant differences between the groups. Baseline anxiety and depression scores for the two groups were compared and found to be similar.

**Effectiveness results**

Satisfaction with the treatment received was compared 12 months after the procedure. In the post-menses group, 92.5% of patients were satisfied with their treatment compared with 88.4% of the drug preparation group (difference in proportions 4.1%, 95% confidence interval, CI: -4.7 - 12.9).

The acceptability of the procedure was assessed at 2 weeks and found to be significantly different between the two groups. In the post-menses group, 89.5% of patients recorded their treatment as acceptable compared with 76.0% of the drug preparation group (difference in proportions 13.6%, 95% CI: 3.0 - 23.9).

The main measure of menstrual outcome was amenorrhoea rates at 1 year. These were similar between the two groups, 55.9% for the post-menses group and 61.9% for the drug preparation group (difference in proportions -5.9%, 95% CI: -19.8 - 7.6).

The quality of life scores showed significant improvement in the physical and mental components at 6 and 12 months for both groups, but found no significant difference between the two groups.

**Clinical conclusions**

The authors concluded that patients who underwent MEA in the postmenstrual phase found the procedure acceptable and were totally satisfied with the treatment they received. In addition, the menstrual outcomes were similar to those for MEA after drug preparation.
Measure of benefits used in the economic analysis
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

Direct costs
The direct costs to the health service and to the patient and her companion were considered. The health service costs included in the analysis were the cost of the drug preparation prior to admission, the costs incurred during hospital admission (overheads, staff costs, capital costs and consumables), and post-discharge costs of MEA-related visits to the general practitioner (GP), clinic and hospital readmission. The non-health service costs included in the analysis were the treatment time associated with admission and travel expenses for the patient, the travel costs for the companion, the cost of caring for the patient's dependants, and other costs associated with the treatment.

The resource use data were derived from the clinical and costing questionnaires, supplemented by information from the clinician who performed most of the procedures. A variety of sources were used to estimate the prices. The costs of the drug preparation, the average cost per procedure for the MEA equipment, and the costs of GP, clinic and subsequent hospital visits, were obtained from the published literature. Anaesthetics, drugs and consumables were valued at local prices although the source was not specified. Staffing costs were derived from personal communications from the Health Technology Board of Scotland. Overheads were taken from Scottish Health Service data. The authors did not specify the source used to estimate the prices of the non-health service costs.

The unit cost estimates and resource use were not reported separately. Since the costs were incurred during less than 2 years, discounting was not applied. The costs were adjusted to 2002 prices, although the method used was not reported. The study reported the average total cost per patient.

Statistical analysis of costs
The cost data were treated stochastically. The range, mean and median values, and the standard deviation of the total cost per patient were reported. Mann-Whitney tests were used for ordinal data and continuous variables that were not normally distributed. Chi-squared or Fisher's Exact tests were applied for independent nominal data.

Indirect Costs
The indirect costs (i.e. productivity costs) were not estimated.

Currency
UK pounds sterling (€).

Sensitivity analysis
A probabilistic sensitivity analysis was used to estimate 95% CIs for normally distributed continuous variables and for differences in proportions for categorical data. A bootstrapping method was used, but the distribution assumptions were not justified.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
At 12 months, the mean total health service cost per patient was 444 for the post-menses group and 568 for the drug preparation group (difference in costs 124, 95% CI: 86 - 194).

At 12 months, the mean total non-health service cost per patient was 190 for the post-menses group and 199 for the drug preparation group (difference in costs -9, 95% CI: -59 - 44).
The cost of adverse events due to treatment was not specifically addressed.

**Synthesis of costs and benefits**
The costs and benefits were not combined as the study was a cost-consequences analysis.

**Authors’ conclusions**
Microwave endometrial ablation (MEA) in the postmenstrual phase produced high satisfaction and acceptability among patients, as well as favourable menstrual outcomes, at a reduced cost to the health service. Treatment post-menses avoided the unpleasant side effects and significant costs associated with drug preparation. Using the outpatient setting will generate an additional benefit by releasing valuable operating time and personnel for other operations.

**CRD COMMENTARY - Selection of comparators**
Although no explicit justification was given for the comparator used, it would appear to represent current practice in the authors’ setting. You should decide if MEA with drug preparation, in a day-case theatre setting, represents current practice for excessive menstrual loss in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a randomised controlled trial, which was appropriate given the study question. The method of recruitment to the study ensured that the study sample was representative of women with excessive menstrual bleeding. The clinical and demographic characteristics of the two patient groups were compared at baseline. However, the authors did not report whether any statistically significant differences were observed. The method of randomisation, length of study and the loss to follow-up were all reported, suggesting that the internal validity of the study is likely to be good. Appropriate statistical analyses appear to have been undertaken, but the results were inadequately presented. Power calculations were reported and an appropriate sample size was used. These facts improve the internal validity of the effectiveness analysis.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of benefit. The analysis was, in effect, a cost-consequences study.

**Validity of estimate of costs**
The authors did not state the perspective from which the costs were estimated. Consequently, it was not possible to determine whether all the relevant categories of costs were included in the analysis. The authors did include the non-health service costs such as travel and time for caring, which suggests that the patient's and/or relative's perspective should have been adopted. However, as the authors’ discussion and conclusions were limited to health service costs, the rationale was unclear.

Neither the unit costs nor resource use were presented, and this will limit the reproducibility of the study in other settings. The method and sources used to estimate the cost of the patient's time were not specified. Consequently, the precision of the cost results was unclear. The statistical analysis of the resource use and costs was not presented. However, CIs for differences in proportions and costs that were estimated using a probabilistic sensitivity analysis were reported. Discounting was not applied, which was appropriate given that the cost analysis was conducted over 1 year. Although unclear, costs (rather than charges) appear to have been used. The price year was reported and this increases the generalisability of the results.

**Other issues**
The authors did not compare their findings with those from other studies, so the extent to which their results agreed with other studies was unclear. The issue of the generalisability of the results to other settings was addressed, the authors noting that the cost results were specific to the UK National Health Service. However, generalisability of the
effectiveness results was enhanced by the avoidance of entry criteria based on menstrual blood scores or predetermined uterine cavity regularity. In addition, the clinician was trained in MEA immediately prior to the study, and the equipment and anaesthetic regimen used are available in most health care facilities in developed countries. The study enrolled women with excessive menstrual loss and this was reflected in the authors' conclusions. The authors do not appear to have presented their results selectively, although the results of statistical tests were not reported. The conclusions reflected the scope of the analysis.

The authors reported one limitation. Patient follow-up should continue for 2 years after treatment as the majority of repeat procedures and hysterectomies following ablation occur in that period. The authors indicated that they intended to continue the patient follow-up.

**Implications of the study**
The authors stated that their findings support the use of MEA, without drug preparation, in the outpatient setting. They recommended that, if other second-generation ablation techniques are to be considered for use with local anaesthesia, randomised controlled trials will be needed to assess their acceptability to the patients.

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