A pragmatic randomised comparison of transcervical resection of the endometrium with endometrial laser ablation for the treatment of menorrhagia


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
Endometrial laser ablation (ELA) and transcervical resection of the endometrium (TCRE) in the treatment of menorrhagia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Women aged under 50 years of age, weighing less than 100 kg and with a clinical diagnosis of dysfunctional uterine bleeding (uterus less than the size of a pregnancy of 10 weeks and normal endometrial histology).

Setting
Hospital (the gynaecology department of a large teaching hospital). The economic study was performed in the UK.

Dates to which data relate
Effectiveness data were from 1994. 1994 prices were used.

Source of effectiveness data
Effectiveness data were derived from a randomised controlled trial.

Study sample
Women with menorrhagia were randomised to either endometrial laser ablation (n=188) or transcervical resection of the endometrium (n=184). The randomisation was generated by a computer and the study was powered to yield a 90% chance of detecting at the 5% significance level, a difference of 15% (between 70% and 85%) between ELA and TCRE on the basis of reported satisfaction rates of 78% after hysteroscopic surgery. This necessitated the recruitment of at least 350 women.

Study design
The study design was a single-centre randomised controlled trial. The subject allocation was stratified according to one of three consultants and the women were recruited at two separate time periods, eight months apart. The earlier recruitment for a study comparing hysteroscopic surgery with hysterectomy involved 105 women (ELA n=53, TCRE n=52); and the later recruitment involved 267 women (ELA n=135, TCRE=132). After 6 months and 12 months, the
overall loss to follow-up was 11% and 14% respectively.

**Analysis of effectiveness**
The analysis was performed on an intention to treat basis. The primary analysis was based on all randomised women while secondary analysis was stratified according to recruitment time period and consultant. The primary outcomes included operative complications, post-operative recovery, relief of menstrual and other symptoms, need for further surgical treatment, and patient satisfaction. Two questionnaires were completed at trial entry and at 6 and 12 months following treatments, in which menstrual and other symptoms were assessed using a clinical questionnaire and psychological outcome was measured by the Hospital Anxiety and Depression Scale.

**Effectiveness results**
Perioperative morbidity was low and similar for both ELA and TCRE. At 12 months, outcomes were also similar: 45% in the ELA group versus 49% in the TCRE group had either amenorrhea or brown discharge; 49% versus 46% had lighter periods; 5% versus 4% had no change and 1% versus 1% had heavier periods. In terms of re-treatment, 16% in the ELA group and 20% in the TCRE group received further surgical treatment (of which 5% in the ELA group versus 14% in the TCRE group had a hysterectomy and 11% versus 6% received repeat ablation). Anxiety and depression scores were similar and improved by both procedures, and in terms of patient satisfaction: 90% in the ELA group and 91% in the TCRE group were satisfied with their treatment.

**Clinical conclusions**
At 12 months, no clear differences were detected between ELA and TCRE in terms of clinical and psychological outcomes.

**Measure of benefits used in the economic analysis**
Since the effectiveness analysis showed no difference in effectiveness/clinical benefit between the groups, the economic analysis was based on costs only.

**Direct costs**
Limited direct costs were considered and no attempt was made to estimate costs which were common to both techniques (such as preoperative treatment, or ward costs). The cost per ELA procedure was estimated by combining the hourly gynaecology theatre charge (for the significantly longer theatre time) with the costs of the technical equipment (laser machine and laser fibre). The theatre charge which includes a proportion of capital costs, staff equipment, supplies and consumables, was taken from the Grampian Health Board Finance Statement 1991 and deflated to 1994 levels. The costs of the laser machine and laser fibre were taken from a detailed evaluation performed in an earlier phase of the study.

**Statistical analysis of costs**
Not performed.

**Indirect Costs**
Not measured.

**Currency**
UK pounds sterling (£).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The significantly longer theatre time of ELA was estimated to cost an extra 122 per procedure and the costs of the laser machine and laser fibre were estimated to cost an extra 45. As no differences in patient costs were found between the two randomised groups, this led to an estimated total extra cost of 167 per ELA.

**Synthesis of costs and benefits**
Not undertaken.

**Authors' conclusions**
At one year, very similar outcomes were achieved with ELA and TCRE. But as a procedure, TCRE cost less, was significantly quicker, caused less fluid absorption and proved to be more useful than ELA in the presence of large or irregular uterine cavities. The authors recognised that in the longer term, the re-treatment rate should be taken into account, especially as more TCRE cases are treated by hysterectomy (a costlier procedure). However in their view, the choice of re-treatment is influenced by practitioner and patient preference, rather than a genuine need for a more definitive procedure.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparators is clear and they appear to represent variations of usual practice.

**Validity of estimate of measure of benefit**
The validity of the outcome measures is likely to be high as the trial was powered appropriately and statistically tested. The randomisation process adopted is likely to eliminate the effects of confounders.

**Validity of estimate of costs**
Although the authors provided adequate details of the sources of the estimates, prices and the price dates, the nature of the costing was rather crude.

**Other issues**
The cost data are unlikely to be generalisable to other settings. If there are any significant differences between procedures in the length of time before patients can return to work, then productivity losses should be considered.

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