First- versus second-generation endometrial ablation devices for treatment of menorrhagia: a systematic review, meta-analysis and appraisal of economic evaluations

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CRD summary
This review concluded that second-generation endometrial ablation devices seemed to be as effective as first-generation devices, and were likely to reduce operating time, could be used more often with local anaesthesia, and had fewer complications. Considering the high or unclear risk of bias in most of the trials, the authors' conclusions are overly optimistic.

Authors' objectives
To evaluate the efficacy of second-generation endometrial ablation devices, compared with first-generation devices, for treating menorrhagia in pre-menopausal women.

Searching
MEDLINE and EMBASE were searched in October 2012, for studies in English. The conference proceedings from 2009 to 2012 of the American Association of Gynecologic Laparoscopists were searched. Reference lists of relevant articles were checked, and manufacturers' websites were searched for relevant unpublished studies. A search strategy was reported in an online appendix.

Study selection
Randomised controlled trials (RCTs) of women who were before the menopause, had menorrhagia, and were undergoing endometrial ablation were eligible. Trials had to assess at least one second-generation device, which had to be bipolar radiofrequency, thermal balloon, hydrotherm ablation, or cryoablation. Any first-generation comparison device was eligible, except laser.

In the included trials, all women had a normal uterine cavity. Their mean or median age ranged from 40 to 46 years. In most trials women had a menstrual bleeding score of more than 150. The interventions and types of anaesthesia used varied.

The authors did not state how many reviewers selected trials.

Assessment of study quality
Trial quality was evaluated using the Cochrane risk of bias tool; the authors did not state how many reviewers performed the assessments.

Data extraction
The data were extracted to calculate risk ratios or mean differences, with 95% confidence intervals. The results were extracted for the one-year time point. The authors did not state how many reviewers extracted the data.

Methods of synthesis
Meta-analyses were performed to calculate pooled risk ratios or mean differences, using a random-effects model. Heterogeneity was assessed using $I^2$. Subgroup analyses were planned to look at the effects of the presence of fibroids, and the type of device.

Results of the review
Eleven RCTs were included (1,679 participants). Allocation concealment methods were adequate in one trial, inadequate in five trials, and not reported in five trials. Four trials reported adequate blinding (for patients, outcome assessors, or both), one had inadequate blinding, the methods were not reported in the other six trials. Two trials lost enough patients at follow-up for this to be judged likely to have biased the results.

First- versus second-generation: There were no differences between the groups for the incidence of further surgery (six
trials; Ι²=0), the number of patients with menstrual bleeding scores less than 75 at one year (four trials; Ι²=20%), and
the rate of amenorrhoea (five trials; Ι²=68%). Second-generation devices had fewer complications (RR 0.52, 95% CI
0.35 to 0.76; seven trials; Ι²=0), shortened the operating time (MD 16.6 minutes, 95% CI 12.1 to 21.2; three trials;
Ι²=89%), and could more commonly be used with local anaesthesia (RR 1.87, 95% CI 1.04 to 3.37; three trials;
Ι²=74%).

Second- versus second-generation: There was a significantly higher rate of amenorrhoea in patients treated with
Novasure than with other second-generation devices (RR 2.60, 95% CI 1.63 to 4.14; four trials; Ι²=24%). There were
no differences between these groups for the incidence of further surgery and complications.

Cost information
Three European studies were included in the synthesis of economic data. Second-generation devices were more cost-
effective than first-generation devices (two UK studies).

Authors’ conclusions
Second-generation endometrial ablation devices seemed to be as effective as first-generation devices, and were likely to
reduce operating time, could be used more often with local anaesthesia, and had fewer complications.

CRD commentary
The review addressed a clear question, which was supported by reproducible eligibility criteria. Two relevant electronic
databases were searched, but the restriction to trials published in English means that some relevant trials may have been
missed. The authors did not report any methods to minimise the risk of reviewer error and bias, such as two people
independently selecting studies.

The risk of bias assessments revealed that most of the trials were at a high risk of at least one type of bias. Appropriate
methods were used to pool the data and to assess heterogeneity. The authors stated that the reasons for the heterogeneity
could not be explored due to insufficient data, but the possible effects of bias were not examined.

Considering the high or unclear risk of bias in most of the trials, the authors' conclusions are overly optimistic.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that large studies of the cost-utility and effectiveness of first- and second-generation
ablation devices, in both in-patient and out-patient settings, in Canada, were needed. They stated a need for high-quality
trials comparing different second-generation devices, with standardised assessment of those outcomes that were
important to patients, such as quality of life, satisfaction, amount of bleeding, and pain.

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