Levonorgestrel-releasing intrauterine system and endometrial ablation in heavy menstrual bleeding: a systematic review and meta-analysis

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CRD summary
This meta-analysis assessed the efficacy and safety of levonorgestrel intrauterine system compared with endometrial ablation for treating heavy menstrual bleeding in terms of menstrual blood loss, failure rate, quality of life and adverse events. The authors concluded that levonorgestrel intrauterine system was safe and had similar therapeutic effects to endometrial ablation. These conclusions appear to be reliable.

Authors' objectives
To compare the effects of the levonorgestrel intrauterine system and endometrial ablation on reducing heavy menstrual bleeding.

Searching
MEDLINE and EMBASE were searched from inception to January 2009. Search terms were reported. Reference lists of retrieved papers were handsearched. There were no apparent attempts to contact experts for unpublished trials.

Two reviewers performed the search and resolved disagreements by discussion.

Study selection
Randomised controlled trials (RCTs) comparing the efficacy of levonorgestrel intrauterine system and endometrial ablation in the treatment of heavy menstrual bleeding were eligible for inclusion in the systematic review. Eligible trials had to report baseline and post-treatment menstrual blood loss. Review articles and non-randomised trials were excluded. The reason for excluding each trial was reported.

The primary outcome was menstrual blood loss, estimated using validated a pictorial bleeding assessment chart. Details of the validated chart were reported. The secondary outcome measures were failure rate, quality of life and adverse events. Failure rate was clearly defined. Three scales were used for assessing quality of life: Short Form 36 (SF-36); Hospital Anxiety and Depression Scale; and EuroQol-visual analogue scale.

The age of women included in the trials ranged from 25 to 50 years. The included trials reported effect of treatment at six months (two trials), 12 months (five trials) and 24 months (two trials).

Two reviewers independently applied the inclusion criteria and selected the studies

Assessment of study quality
Quality of the included trials was assessed using the Jadad criteria. The details of how the individual components were assessed were not reported. The number of participants lost to follow-up in each trial was reported. Some authors were contacted for clarification or additional information.

Two reviewers independently assessed validity.

Data extraction
Dichotomous outcomes were extracted as risk ratios (RR). Continuous data were extracted as weighted mean differences (WMD). Both outcomes were extracted with 95% confidence intervals (CI).

Two reviewers independently extracted the data.
Methods of synthesis
The effects of levonorgestrel-releasing intrauterine system and endometrial ablation were combined as weighted mean differences using random-effects model. Relative risks were combined using fixed-effects model when no heterogeneity was detected. Homogeneity tests were conducted using Breslow-Day method. Publication bias was assessed by funnel plot. Sensitivity analysis was performed to determine the robust of the analysis.

Results of the review
Six trials met the inclusion criteria for the meta-analysis (n=390 participants). The range of quality scores were 2 to 3 points out of a possible maximum of 5 on the Jadad criteria. Follow-up assessment of effect of treatment ranged from six to 36 months.

No statistically significant difference was observed between levonorgestrel-releasing intrauterine system and endometrial ablation in reducing menstrual blood loss: at six months (WMD -31.96, 95% CI -65.96 to 2.04), 12 months (WMD 7.45, 95% CI -12.37 to 27.26), and 24 months (WMD -26.70, 95% CI -78.54 to 25.15).

There was no significant difference in treatment failure between patients who received levonorgestrel-releasing intrauterine system and patients who received endometrial ablation (RR 1.40, 95% CI 0.89 to 2.20; six RCTs; n=390 participants).

There was no difference between treatment groups in overall quality of life scores at one year, although marked improvements were found between baseline and post-intervention quality of life scores. Also, there was no difference in the eight dimensions of the SF-36 scale evaluated between levonorgestrel-releasing intrauterine system and endometrial ablation.

No serious adverse events were reported (two RCTs).

These findings did not change in any of the planned sensitivity analyses.

Authors' conclusions
The efficacy of levonorgestrel intrauterine system appeared to be similar to endometrial ablation in the management of heavy menstrual bleeding up to two years after treatment.

CRD commentary
The review addressed a well-defined question in terms of participants, interventions, outcomes and study design. The search included appropriate electronic databases. However, given that no apparent attempts were made to search the Cochrane CENTRAL database or experts contacted for unpublished trials, there may be the concern over whether all relevant data were included. All stages were conducted in duplicate to minimise bias and errors during the review process.

Trial validity was assessed using the Jadad score, but the details of the individual components and how each domain was assessed were not reported. The characteristics of the individual trials were presented. Potential sources of heterogeneity were explored and reported. Sensitivity analysis demonstrated that the results were robust to changes in the factors considered.

Although the small number of participants included in the trials limited statistical confidence, the authors' conclusions were consistent with the evidence shown and are likely to be reliable.

Three of the authors disclosed financial links with Bayer Schering Pharma AG (manufacturers of the levonorgestrel-releasing intrauterine system).

Implications of the review for practice and research
Practice: The authors stated that levonorgestrel intrauterine system appeared to be safe and effective for the treatment of heavy menstrual bleeding. This treatment is also appropriate for women who may consider future pregnancies.
Research: The authors stated that there is a need for bigger randomised controlled trials to raise the statistical power.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.