Vaginoscopic approach to outpatient hysteroscopy: a systematic review of the effect on pain

Cooper NA, Smith P, Khan KS, Clark TJ

CRD summary
The review found the vaginoscopic approach to outpatient hysteroscopy significantly reduced the pain experienced by patients during the procedure compared to the traditional technique using a vaginal speculum and with no significant difference for visualising the uterine cavity. The review was generally well-performed. Limitations to the evidence presented imply that the authors' conclusions should be treated with caution.

Authors' objectives
To evaluate the efficacy of a vaginoscopic approach to outpatient hysteroscopy compared to the traditional approach using a vaginal speculum on the patient's experience of pain.

Searching
MEDLINE (from 1950), EMBASE (from 1980), CINAHL (from 1981) and The Cochrane Library were searched to February 2009 for publications in any language; search terms were reported. Bibliographies of selected articles were handsearched.

Study selection
Randomised controlled trials (RCTs) that compared vaginoscopic (no-touch) technique versus traditional hysteroscopy using a vaginal speculum of women who underwent diagnostic or operative hysteroscopy (without general anaesthesia) were eligible for inclusion. Trials needed to be in the outpatient setting and assess pain. The primary outcome was assessment of pain associated with the procedure. The secondary outcome was the feasibility of the vaginoscopic approach (failure to visualise the uterine cavity).

For the intervention groups (vaginoscopic technique), vaginas were distended with normal saline before hysteroscope introduction in all studies. Three studies reported initial vagina cleaning. Two studies reported positioning patients in lithotomy. Two studies reported that the labia minora was held together. Rigid hysteroscopes were used, mostly 3.5mm or 3.7mm; one study used 3.5mm and 5mm hysteroscopes. Two studies were reported that they used 2.7mm hysteroscopes with either 3.5mm or 3.7mm sheaths. Details of the interventions in the comparative groups that used traditional hysteroscopy were provided for most studies; the same types of hysteroscopes were used as for groups that used the vaginoscopic technique. All the traditional study arms used a tenaculum. The authors reported that there were minor procedural differences between studies. All the included studies used a visual analogue scale to assess the level of pain. All studies were of premenopausal and postmenopausal women who underwent diagnostic outpatient hysteroscopy; one study excluded patients aged under 18 years; three studies excluded patients for reasons such as pregnancy or suspected pregnancy, heavy or active uterine bleeding, recent uterine perforation (within last 30 days), pelvic inflammatory disease, current genital infection, cervical cancer, severe cardiovascular disease and use of hormonal vaginal cream.

Two independent researchers performed the selection. Disagreements were resolved by consensus.

Assessment of study quality
Methodological quality was assessed by two reviewers independently. The criteria assessed included randomisation sequence, allocation concealment and follow-up (%). The criteria were assessed as adequate, inadequate or not reported. Maximum score was 3 (all three criteria assessed as adequate).

Data extraction
Two independent reviewers performed data extraction in duplicate using data extraction forms.

Studies varied in how pain was assessed. Overall pain scores were extracted for the meta-analysis, where reported. For studies that reported scores for each step separately and no overall pain score, the score for inspection of the uterine cavity was extracted for use in the meta-analysis. When scores were given after the procedure, the most immediate
score was used for the meta-analysis.

Standardised mean differences (SMDs) and 95% confidence intervals (CI) were calculated. Where median pain scores were reported, they could not be used to calculate standardised mean differences. For data reported categorically, the mid-point of each category and the number of patients selecting that category were used to calculate the mean and standard deviation.

Feasibility data were extracted as the number of failed procedures for each technique and used to calculate odds ratios (OR) with 95% CI.

**Methods of synthesis**

Weighted standardised mean differences were pooled using a random-effects model. Odds ratios for feasibility were pooled using a fixed-effects model (Peto). Between-study heterogeneity was determined using the $I^2$ statistic and visually using forest plots; $I^2 \geq 75\%$ suggested considerable heterogeneity. Inter-rater agreement for study selection was determined using the kappa statistic.

**Results of the review**

Six RCTs were identified (n=1,321, range 120 to 400). Four RCTs scored 2 out of 3 for quality, one trial scored 3 and one scored 1. Allocation concealment was generally inadequate. Follow-up was 100% for all six studies. The authors considered the quality of the studies to be generally high. Suitable data for the meta-analysis for pain was provided by only four RCTs. Inter-rater agreement for study selection was good (K=0.81).

The vaginoscopic approach was significantly less painful than the traditional technique (SMD -0.44, 95% CI -0.65 to -0.22, $I^2$=58%; four studies, random-effects model). This result remained significant after the exclusion of the poorest quality study (SMD -0.52, 95% CI -0.71 to -0.33, $I^2$=30%; three studies, random-effects model).

There was no significant difference in the feasibility of the procedure between the vaginoscopic approach and the traditional approach (OR 1.28, 95% CI 0.74 to 2.24, $I^2$=16%; five studies, fixed-effect model).

**Authors' conclusions**

The vaginoscopic approach to outpatient hysteroscopy was successful and significantly reduced the pain experienced by patients during the procedure compared to the traditional technique with a vaginal speculum.

**CRD commentary**

The review addressed a well-defined question in terms of participants, interventions, study design and relevant outcomes. Relevant databases were searched. There were no apparent language restrictions. Unpublished studies were not considered and some relevant studies may have been missed. Publication bias was not assessed, but any assessment would probably not have been meaningful due to the small number of included studies. Study quality was assessed using suitable criteria. Efforts were made to reduce error and bias in all aspects of the review process. Relevant study details were reported, but precise differences between the traditional and vaginoscopic approaches of individual studies were not always clear. The overall number of participants reported in the text was much higher than the total numbers given in the tables; this was corrected in a corrigendum (see Other Publications of Related Interest). Statistical heterogeneity was assessed and there was evidence for heterogeneity with some outcomes. The statistical method used for the meta-analysis of the RCTs seemed appropriate. A sensitivity analysis excluded the poorest-quality study.

The review was generally well conducted and the authors' conclusions were supported by the results presented, but should be interpreted with a degree of caution due to the possibility of publication bias and the small number of included trials.

**Implications of the review for practice and research**

**Practice:** The authors stated that vaginoscopy should become standard practice for endoscopic instrumentation of the uterine cavity in the outpatient setting.
Research: The authors identified a need for large trials that compared vaginoscopy against traditional hysteroscopy using both flexible and rigid hysteroscopes. Trials needed to explicitly define and standardise procedures and assess outcomes such as acceptability and quality of life, risk of ascending infection and vasovagal episodes in addition to pain. The authors suggested assessment of the clinical significance of pain. Also, they suggested that trials should identify patient subgroups where the vaginoscopic approach was less likely to succeed (such as parity, menopausal status, previous cervical biopsy, caesarean section and body mass index) and evaluate use of the vaginoscopic technique in operative outpatient hysteroscopic surgery.

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