Saline contrast hysterosonography in abnormal uterine bleeding: a systematic review and meta-analysis

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CRD summary
The review concluded that saline contrast hysterosonography is an accurate diagnostic tool for evaluating uterine cavity abnormalities in pre- and postmenopausal women complaining of abnormal uterine bleeding. Few of the included studies used the 'gold' standard of hysterectomy to evaluate the diagnostic accuracy of the tool. The strength of the authors' conclusions is not supported by the evidence presented.

Authors' objectives
To assess the diagnostic accuracy of saline contrast hysterosonography in the evaluation of uterine cavity abnormalities in women with symptoms of abnormal uterine bleeding.

Searching
MEDLINE, EMBASE, Current Contents, the Science Citation Index, NLM Gateway, Bandolier, DARE and the Cochrane Library were searched from 1 January 1965 to 1 March 2003. There were no language restrictions. All known terms for saline contrast hysterosonography were combined with hysterectomy or hysteroscopy as keywords. The reference lists of the included studies were checked.

Study selection
Study designs of evaluations included in the review
Inclusion criteria relating to the study design were not specified. The included studies were of prospective and retrospective designs.

Specific interventions included in the review
Studies of saline contrast hysterosonography were eligible for inclusion.

Reference standard test against which the new test was compared
The studies had to compare saline contrast hysterosonography with hysteroscopy or hysterectomy to be included in the review. Some included studies reported both methods as the reference standard. In the included studies, hysteroscopy was used alone or in conjunction with biopsy. Hysterectomy was identified as the 'gold' standard.

Participants included in the review
Studies of pre- or postmenopausal women were eligible for inclusion provided no more than 5% of the participants used tamoxifen. In some of the included studies the menopausal status of the women was unknown. The women were being investigated or treated for a number of conditions including hysterectomy for benign pathology, abnormal uterine bleeding, postmenopausal bleeding with total endometrial thickness greater than 5 mm, and metorrhagia.

Outcomes assessed in the review
Inclusion criteria relating to the outcomes were not specified. The outcome measures used in the review were sensitivity, specificity, the likelihood ratio (LR) and post-test probability. The primary outcome was the diagnosis of abnormal uterine bleeding. The secondary outcomes were the diagnosis of endometrial polyps and intra-uterine fibroids.

How were decisions on the relevance of primary studies made?
Two reviewers independently assessed the identified articles for inclusion.

Assessment of study quality
Studies were assessed according to whether they fulfilled the following criteria: the reference standard (hysterectomy received the highest score, followed by hysteroscopy with biopsies then hysteroscopy alone); definition of abnormal polyps and fibroid; independent and blinded assessment of the reference test; avoidance of verification bias; study design (prospective or retrospective); handling of drop-outs; reason for referral; and the reporting of demographic information (age and menopausal state). The minimum possible score was one and the maximum was 13. Two reviewers independently assessed the quality of the included studies. Any disagreement was resolved by consensus.

**Data extraction**

Two reviewers independently extracted the data. The data were extracted to construct 2x2 tables for each of three abnormalities: uterine cavity abnormality, endometrial polyps and intra-uterine fibroids. Only cases with an abnormal saline contrast hysterosonography were included in the 2x2 tables for polyps and fibroids. None of the 2x2 tables included women with a failed saline contrast hysterosonography. Where necessary, authors were contacted for additional data. The sensitivity, specificity, disease prevalence, LR and post-test probability were calculated using data from the 2x2 tables.

**Methods of synthesis**

**How were the studies combined?**

The summary LRs and post-test probability were estimated for subgroups where the data were homogeneous.

**How were differences between studies investigated?**

Homogeneity was assessed using a chi-squared test, weighted for sample size (P=<0.05), and Spearman's correlation of sensitivities and specificities. A subgroup analysis was carried out based on items from the quality assessment scale, menopausal state, whether women had been scheduled for surgery, and whether or not they had been included because of failed medical treatment. Studies performing saline contrast hysterosonography in the first half of the menstrual cycle were also pooled separately.

**Results of the review**

Twenty-four diagnostic accuracy studies (2,278 procedures) were included in the review. Twenty were prospective and the others were retrospective.

The mean quality score of all the included studies was 7.4 (range: 3 to 11). The number of failed procedures ranged from 0 to 23%.

The 24 included studies were not pooled due to statistical heterogeneity. However, the data were pooled for the diagnosis of normal versus abnormal uterine cavity for the following subgroups of studies: where the 'gold' standard was hysterectomy (2 studies, 96 patients); where verification bias had been avoided (16 studies, 877 patients); where there had been independent interpretation of the reference test (8 studies, 562 patients); where a retrospective design had been used (4 studies, 151 patients); and where women had been included due to failed medical treatment (2 studies, 130 patients).

For studies where the 'gold' standard was hysterectomy, the positive LR was 16.8 (95% confidence interval, CI: 5.6, 50.7), the negative LR 0.05 (95% CI: 0.01, 0.19), the positive post-test probability 0.93 (95% CI: 0.86, 1.00), and the negative post-test probability 0.04 (95% CI: -0.01, 0.09).

For studies where verification bias had been avoided, the positive LR was 8.23 (95% CI: 6.22, 10.9), the negative LR 0.06 (95% CI: 0.04, 0.09), the positive post-test probability 0.91 (95% CI: 0.89, 0.94), and the negative post-test probability 0.07 (95% CI: 0.04, 0.10).

For the diagnosis of endometrial polyps (15 studies), the positive LR was 5.23 (95% CI: 3.98, 6.90) and the negative LR 0.12 (95% CI: -0.08, 0.17); the post-test probability was not reported.

For the diagnosis of intra-uterine fibroids (15 studies): the positive LR was 11.0 (95% CI: 6.86, 17.6) and the negative LR was 0.07 (95% CI: 0.03, 0.11); the post-test probability was not reported.
Authors' conclusions
Saline contrast hysterosonography is an accurate diagnostic tool for pre- and postmenopausal women complaining of abnormal uterine bleeding.

CRD commentary
There was a clearly defined review question in terms of the inclusion criteria. Several relevant electronic databases were searched and no language restrictions were applied, though only limited details of the search strategy were provided. Specific attempts to identify unpublished studies were not made, therefore it is possible that studies were missed. The study selection, data extraction and quality assessment processes were carried out in duplicate, which helps to reduce errors and any bias. Adequate details of the individual studies were reported, and a quality assessment was carried out and an overall score reported. However, the impact of study quality on the findings was given very limited consideration. Specific items from the quality scale were used only to identify a homogeneous group of studies for pooling. The statistical methods used for the synthesis appear to have been appropriate. Given that only two of the included studies used the 'gold' standard of hysterectomy, the authors' conclusions and recommendation for practice might have been overstated.

Implications of the review for practice and research
Practice: The authors stated that saline contrast hysterosonography, in combination with an endometrium aspiration if necessary, could become the standard diagnostic procedure in women with abnormal uterine bleeding.

Research: The authors did not state any implications for further research.

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Record Status
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.