A meta-analysis of the Papanicolaou smear and wet mount for the diagnosis of vaginal trichomoniasis

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Authors' objectives
To obtain reliable estimates of the sensitivity and specificity of the cervical Papanicolaou (Pap) smear and wet mount to diagnose vaginal trichomoniasis.

Searching
MIDLINE was searched from January 1976 to February 1998. The keywords used to identify trichomoniasis were (explode)'Trichomonas', (explode)'trichomonas infections', 'trichomonas vaginalis' and 'trichomonas vaginitis'. Terms under each sub-heading were also retrieved. The textword 'trichomonas' and the wild card 'trachodon$' were also searched. The keywords used to identify the diagnostic tests were explode (exp)'sensitivity and specificity', (exp)'diagnostic errors', 'diagnostic test routine', 'multi phasic screening', 'likelihood functions', 'diagnosis differential', 'false positive reactions', (exp)'false negative reactions', (exp)'diagnosis', 'receiver operator curve', 'sensitivity' (textword), and 'specificity' (textword). Publications in any language were considered. The references listed in the articles and in recent review articles were also retrieved.

Study selection
Study designs of evaluations included in the review
No a priori inclusion criteria relating to the study design appear to have been used. Twelve studies were excluded because they could not be translated.

Specific interventions included in the review
Studies of Pap smear or wet mount smears were eligible for inclusion.

Reference standard test against which the new test was compared
Only studies that used culture as the reference standard were eligible for inclusion. The type of reference standard used by the included studies were Diamond, multiple cultures, agar, Ovoid, In Pouch TV, CALM II, Schneider's, Hollander, AC medium and Feiner Whittington.

Participants included in the review
No a priori criteria relating to the participants were specified. Studies of women suspected of having vaginal trichomoniasis infection were included. The settings used for the included studies were specialty clinics, sexually-transmitted disease clinics and general clinics. The prevalence of trichomoniasis ranged from 7 to 73%.

Outcomes assessed in the review
No a priori inclusion criteria relating to the outcome measures appear to have been used. The outcome measures used in the review included prevalence, sensitivity, specificity and likelihood ratios (calculated from contingency tables).

How were decisions on the relevance of primary studies made?
Two reviewers independently reviewed each title and abstract for relevancy, and any disagreements were resolved by discussion; if any doubt existed the full paper was retrieved. Two reviewers independently reviewed the retrieved articles for inclusion or exclusion. There were no disagreements on the inclusion of papers.

Assessment of study quality
Studies were assessed according to three criteria: consecutive patients were evaluated prospectively; the test results did not influence the decision to perform the reference standard test; and the test of interest and the reference standard test were blinded and independently examined. The selected studies were defined as level I if they fulfilled at least two of the criteria, level II if they fulfilled one of the criteria, and level III otherwise. Level I studies represented the best
evidence. The articles were randomly distributed between reviewers who were general internists with expertise in evidence-based medicine. All reviewers reviewed the first ten articles simultaneously to standardise the definitions. Two reviewers independently assessed the quality of each study. There was moderate agreement for the first quality criterion, fair agreement on the second, and almost perfect agreement on the third. Any disagreements were resolved by the consensus of four reviewers.

**Data extraction**
The articles were randomly distributed between reviewers, who were general internists with expertise in evidence-based medicine, for independent data extraction. All reviewers reviewed the first ten articles simultaneously to standardise the definitions. Two reviewers independently extracted the following data for each study: study setting, validity of the study design, and 2x2 contingency tables. Any disagreements were resolved by consensus.

**Methods of synthesis**
How were the studies combined?
Summary values for sensitivity and specificity were pooled for each test and level of evidence, using a random-effects model. The 95% confidence intervals (CIs) were also presented. An overall likelihood ratio for a positive test was calculated, based on the pooled estimates of the sensitivity and specificity.

How were differences between studies investigated?
Homogeneity was tested using the chi-squared test and graphical methods.

**Results of the review**
Thirti-one studies (published in 30 articles) with 9,501 patients were included. There were 12 level I (4,792 patients) studies, 15 level II (4,107 patients) studies and 4 level III (602 patients) studies.

Pap smear to diagnose trichomonas vaginitis (7 studies, 2,958 patients).

For level I studies (n=3), the prevalence of trichomoniasis ranged from 15 to 50%. The pooled sensitivity was 57% (95% CI: 51, 63) and the pooled specificity was 97% (95% CI: 93, 100). The sensitivity values were homogeneous and the specificity values were heterogeneous (P<0.05). The likelihood ratio for a positive Pap smear was 19.

Overall, the prevalence of trichomoniasis ranged from 6 to 73%. The pooled sensitivity was 58% (95% CI: 43, 73) and the pooled specificity was 97% (95% CI: 95, 100).

Wet mount smear to diagnose trichomonas vaginitis (30 studies, 9,501 patients).

For level I studies (n=13) the prevalence of trichomoniasis ranged from 7 to 50%. The pooled sensitivity was 58% (95% CI: 51, 66) and the pooled specificity was 99.8% (95% CI: 99.53, 100). The sensitivity and specificity values were heterogeneous (P<0.05). The likelihood ratio for a positive wet mount was 290.

Overall, the prevalence of trichomoniasis ranged from 6 to 73%. The pooled sensitivity was 68% (95% CI: 62, 74) and the pooled specificity was 99.9% (95% CI: 99.8, 100).

**Authors’ conclusions**
A positive Pap smear for trichomonads in settings in which trichomoniasis is common (prevalence of greater than or equal to 20%) requires treatment. A positive Pap smear is indeterminate when the prevalence of trichomoniasis is approximately 10%; thus, clinicians should either confirm the diagnosis by culture or treat all such patients, recognising that some patients will be treated unnecessarily. A culture should be obtained in women with a positive Pap smear who are unlikely to have trichomoniasis (prevalence less than or equal to 1%). While a positive wet mount is diagnostic, a negative wet mount does not exclude trichomoniasis.
Elements of this diagnostic review were well conducted. The objectives were clearly stated, and the limited inclusion and exclusion criteria were defined. The literature search was not very comprehensive, as only one electronic database was searched and no attempt was made to find unpublished data. This means that some important information may have been missed and publication bias cannot be ruled out. Information about the methodology of the review process was provided. A systematic process involving more than one reviewer was used to select the studies for inclusion and to extract the data. The validity of the included studies was assessed, and based on this assessment, the studies were graded as one of three levels of evidence. Two reviewers assessed each study independently, and any discrepancies were resolved by the consensus of four reviewers.

Relevant details of the primary studies (including results) were tabulated clearly. Not all estimates of the sensitivity and specificity were homogeneous and, therefore, a random-effects model was used to pool the data. The source of heterogeneity was not explored in detail, e.g. different settings were used and therefore patient populations may have differed. It may not, therefore, have been appropriate to pool the results since the studies may have been too clinically diverse.

The authors’ conclusions appear to follow from the results.

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

**Practice:** The authors state that a positive Pap smear is indeterminate when the prevalence of trichomoniasis is about 10%; thus, clinicians should either confirm the diagnosis by culture or treat all such patients, recognising that some patients will be treated unnecessarily. A culture should be obtained in women with a positive Pap smear who are unlikely to have trichomoniasis (prevalence less than or equal to 1%).

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

**Bibliographic details**


**PubMedID**

11014723

**Other publications of related interest**

This additional published commentary may also be of interest. Harper D. Review: papanicolaou and wet mount smears have low sensitivity but high specificity for detecting vaginal trichomoniasis. Evid Based Med 2000;5:186.

**Indexing Status**

Subject indexing assigned by NLM

**MeSH**

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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.