Systematic review of diagnostic tests for vaginal trichomoniasis
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Authors' objectives
To review critically, and to summarise the evidence of diagnostic tests and culture media for the diagnosis of Trichomonas vaginitis.

Searching
MEDLINE was searched from January 1976 to November 1998 for articles published in any language, which described diagnostic tests for vaginal trichomoniasis in humans. The keywords used were: explode (exp)'Trichomonas', (exp)'Trichomonas infections', 'Trichomonas vaginalis' and 'Trichomonas vaginitis'. Any terms under each subheading were also retrieved. The textword 'Trichomonas' and the wildcard word 'trichomon$' were also searched. The keywords to identify the diagnostic tests were: (exp)'sensitivity and specificity', (exp)'diagnostic errors', 'diagnostic tests routine', 'multiphasic screening', 'likelihood functions', 'diagnosis-differential', 'false-positive reactions', (exp)'false negative reactions', (exp)'diagnosis', 'receiver operating curve', 'sensitivity' (textword) and 'specificity' (textword). The references listed in these published studies and recent review articles were retrieved.

Study selection
Study designs of evaluations included in the review
Studies were included if they evaluated a diagnostic test against a reference standard.

Specific interventions included in the review
There were no specific inclusion criteria regarding the diagnostic tests. The tests included in the review were: polymerase chain reaction (PCR), enzyme-linked immunosorbent assay, direct fluorescence antibody assay, enzyme immunoassay, dot-immunobinding assay, indirect fluorescence antibody assay, and agglutination test. Studies of the wet mount on the Papanicolaou smear were excluded.

Reference standard test against which the new test was compared
Studies were included if the reference standard was trichomonas culture in one or more media, with or without the wet mount; i.e., trichomonas was said to be present when the organism was identified in one or more culture media, or when the motile organism was seen in the wet mount. Only studies in which samples were taken from the vagina were included.

Participants included in the review
There were no specific inclusion criteria relating to the participants.

Outcomes assessed in the review
There were no specific inclusion criteria regarding the outcomes. The outcome measures used in the review were: prevalence, sensitivity, specificity, positive and negative predictive values, and likelihood ratios (LRs).

How were decisions on the relevance of primary studies made?
Two investigators independently reviewed each title and abstract for inclusion. The articles were reviewed entirely when agreement on eligibility could not be resolved by consensus among four investigators.

Assessment of study quality
Studies were classified as 'Level I' when they explicitly fulfilled at least two of the three validity criteria: (1) consecutive patients were evaluated prospectively; (2) the test result did not influence the decision to perform the reference standard; and (3) the test of interest and reference standard were blinded and independently examined. Studies were categorised as 'Level II' if any one of these criteria were fulfilled, or as 'Level III' if no criteria were fulfilled. Two raters independently abstracted the validity criteria. Any disagreements were resolved by consensus.
among four raters who examined the full article.

**Data extraction**
The data extracted were: reference details, year, which quality criteria satisfied, setting, disease prevalence, sample size, and reference standard. Two raters independently abstracted the data from 2x2 contingency tables. Any disagreements were resolved by consensus among four raters who examined the full article.

**Methods of synthesis**
How were the studies combined?
The estimates of sensitivity and specificity were pooled using a random-effects model, then used to calculate an overall positive LR (LR+ equals the sensitivity divided by, one minus the specificity).

How were differences between studies investigated?
Homogeneity of sensitivity and specificity between the studies was explored using the chi-squared test.

**Results of the review**
A total of 36 studies (n=9,882) were included in the review. Of these, 13 (n=5,047) were classified as 'Level I', 15 (n=3,970) as 'Level II' and 8 (n=865) as 'Level III'.

The sensitivity of PCR was 95% (95% confidence interval, CI: 91, 99), the specificity was 98% (95% CI: 96, 100), and the LR+ was 48. The sensitivity of the enzyme-linked immunosorbent assay was 82% (95% CI: 74, 90), the specificity was 73% (95% CI: 35, 100), and the LR+ was 3. The sensitivity of the direct fluorescence antibody assay was 85% (95% CI: 79, 90), the specificity was 99% (95% CI: 98, 100), and the LR+ was 85. The sensitivities of culture media were 95% for Diamond’s, 96% for Hollander, and 95% for CPLM.

**Authors’ conclusions**
There was wide variation in the sensitivity and specificity of tests to diagnose trichomoniasis.

**CRD commentary**
Relevant details of the included studies were presented in the text and in tabular format, and these studies were appropriately summarised. The inclusion criteria were only explicitly stated for the study design and the reference standard used. However, these criteria appear to have been adequate for the purposes of this review. The literature search was well reported, but only a single electronic database (MEDLINE) was searched. Similar searches of other databases may have uncovered further articles. The papers were graded according to whether they met three validity criteria. Whilst this approach gave a broad indication of the overall validity of the included studies, it did not provide a great deal of information about the methodological rigour of the individual studies.

The authors’ conclusions appeared to follow from the evidence presented.

**Implications of the review for practice and research**
Practice: The authors state ‘In the meantime, it seems prudent to use only the culture media with the highest sensitivity as a reference standard (Diamond, Hollander, or CPLM)’.

Research: The authors state ‘PCR is a promising technique with sensitivity equal to or better than that of culture. However, more Level I studies are needed. The CDC (Center of Disease Control and Prevention) should make a uniform recommendation with the appropriate reference standard for the diagnosis of trichomoniasis’.

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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.