CRD summary
This review assessed the role of clinical and laboratory examination for the diagnosis of candidiasis, bacterial vaginosis and vaginal trichomoniasis. The authors concluded that the poor performance of individual signs, symptoms and office tests made it difficult to identify the cause of vaginal complaints. Given the limitations in the review methodology and the evidence available, the reliability of the results is uncertain.

Authors’ objectives
To evaluate the role of clinical examination, and to determine the positive and negative likelihood ratios (LRs) for the diagnosis of vaginal candidiasis, bacterial vaginosis and vaginal trichomoniasis.

Searching
MEDLINE was searched for studies published from 1966 to April 2003; the search terms were reported. The 1996 Technical Bulletin (number 226) of the American College of Obstetricians and Gynaecologists, and the reference lists of included studies and reviews were also checked. The authors of the included studies were contacted, where possible, to identify further studies.

Study selection
Study designs of evaluations included in the review
Studies comparing a diagnostic test with a recognised criterion standard were eligible for inclusion. No specific details on the designs of the included studies were reported.

Specific interventions included in the review
Studies of tests that provided diagnostic information during an office visit were eligible for inclusion. The included studies evaluated the use of signs, symptoms and laboratory tests for diagnosis.

Reference standard test against which the new test was compared
Studies that used a recognised criterion standard were eligible for inclusion. For vaginal candidiasis, the criterion standards were culture and/or microscopy. For bacterial vaginosis, the criterion standard was the Amsel criteria. The included studies also used the Nugent criteria, Spiegel criteria, clinical criteria, culture and exclusion of other causes. For trichomoniasis, the criterion standards were culture, microscopy and immunofluorescence.

Participants included in the review
Studies of symptomatic premenopausal women who were evaluated in a primary care setting (including sexual health clinics) were eligible for inclusion. Studies of women evaluated in a speciality or referral setting, women with recurrent or treatment-refractory vaginitis or those who were asymptomatic, were excluded. The presenting symptoms varied across the included studies (further details were reported).

Outcomes assessed in the review
Studies that provided data which allowed the sensitivity and/or specificity to be calculated, thus enabling an assessment of the accuracy of symptoms, signs and office laboratory tests, were eligible for inclusion. In the included studies, the symptoms evaluated were characteristics of the discharge as reported by the patients, itching, irritative symptoms, odour, patients self-diagnosis, urinary tract symptoms, bleeding and dyspareunia. The signs evaluated were characteristics of the discharge on examination, inflammation and odour. The office laboratory tests evaluated were microscopy, pH measurement and the whiff test.

How were decisions on the relevance of primary studies made?
Each retrieved article was assessed for eligibility by at least one author. Three reviewers assessed eligibility in cases of
uncertainty.

**Assessment of study quality**
The authors assigned a quality grade, ranging from level 1 (highest) to level 3 (lowest), to each study on the basis of the following: explicit inclusion and exclusion criteria; the percentage of patients who received a diagnostic work-up; more than two persons performed the diagnostic test and a measure of inter-observer variability was reported; a definition of a sensible normal range for continuous variables was given and criterion standards were used. The authors did not state how many reviewers performed the quality assessment.

**Data extraction**
Three reviewers independently extracted data and computed the sensitivity and specificity values from each individual study. Any disagreements were resolved by consensus. Data on the sensitivity, specificity and LRs were abstracted as reported, or calculated from the data given. To prevent division by zero when calculating LRs, 0.5 was added to each cell in the 2x2 table.

**Methods of synthesis**

*How were the studies combined?*
The studies were combined in a narrative, grouped according to diagnostic test.

*How were differences between studies investigated?*
Differences between the studies were assessed through tabulation of the results, grouped by diagnostic test and condition and then ordered by outcome.

**Results of the review**
Eighteen studies (n=3,901) were included in the review.

There were no level 1 studies. There were 15 level 2 studies, and three level 3 studies.

**Accuracy of symptoms.**

Discharge described by the patient (6 studies): only 2 studies reported that the patient description of discharge was diagnostically useful. One reported that the presence of a ‘cheesy’ discharge increased the likelihood of candidiasis, and the other that a watery discharge decreased the likelihood of candidiasis.

Itching (7 studies): the presence of itching was found to be highly associated with candidiasis, with the absence of itching decreasing the likelihood of candidiasis. Itching was not found to be a symptom useful for the diagnosis of bacterial vaginosisis or trichomoniasis.

Irritative symptoms (3 studies): one study found that erythema slightly increased the likelihood of candidiasis, while the absence of erythema decreased the likelihood.

Odour or malodour (6 studies): 3 studies reported that odour was diagnostically useful, one that the presence of odour perceived by the patient decreased the likelihood of candidiasis and the absence of odour increased the likelihood. Another study found that malodour increased the likelihood of bacterial vaginosis, while the absence of malodour ruled out the condition. A further study found that the presence of a ‘fishy’ odour was not suggestive of trichomoniasis.

Self-diagnosis (4 studies): one study found that women who had another yeast infection were more likely to have a diagnosis of candidiasis; one study found that the presence of a urinary tract infection was not suggestive of candidiasis, bacterial vaginosis or trichomoniasis; and another study found that external dysuria was associated with a diagnosis of candidiasis. Bleeding (2 studies): postcoital bleeding and abnormal bleeding were not suggestive of trichomoniasis and bacterial vaginosis, respectively.
Dyspareunia (1 study): dyspareunia was not suggestive of a diagnosis of trichomoniasis in this study.

Accuracy of signs.

Discharge on examination (8 studies): the finding of a discharge on examination could not be used to make a distinction between candidiasis, bacterial vaginosis and trichomoniasis. Four studies found that the presence of a thick, curdy or flocculent white discharge was highly predictive of candidiasis, and the absence of these signs reduced the likelihood of candidiasis. One study reported that a discharge of a normal or mild nature was less likely to be associated with a diagnosis of bacterial vaginosis than moderate to profuse discharge. Two studies found that the presence of a white discharge reduced the likelihood of a diagnosis of bacterial vaginosis; one study found that blood-stained, green, or clear discharges were not associated with bacterial vaginosis; another study found that purulent and frothy discharges were also not associated with bacterial vaginosis. The presence of a yellow discharge (noted in 4 studies) increased the likelihood of bacterial vaginosis in one study and trichomoniasis in another. One study reported that all women with trichomoniasis had a homogeneous discharge.

Inflammation (8 studies): 5 studies found that the presence of vulvar and/or vaginal oedema, erythema, fissures or excoriations increased the likelihood of a diagnosis of candidiasis. One study found that these signs could be suggestive of a diagnosis of trichomoniasis. However, the absence of these signs did not exclude a diagnosis of either candidiasis or trichomoniasis.

Odour (3 studies): one study found that the presence of a 'fishy' odour reduced the likelihood of a diagnosis of candidiasis, while the absence of the odour increased the likelihood; another study found that the presence of a 'high cheese' odour increased the likelihood of a diagnosis of bacterial vaginosis. Limited data were available for trichomoniasis.

Office laboratory tests. Microscopy (13 studies): microscopic evidence suggested that the absence of yeast cells rules against a diagnosis of candidiasis, but candidiasis cannot be excluded on this basis. One study found that the presence of bacilli with corkscrew motility is highly associated with bacterial vaginosis. One study found that the presence of few or no lactobacilli is common in bacterial vaginosis, whereas normal levels suggest that bacterial vaginosis is highly unlikely. Two studies found that the presence of clue cells suggests that candidiasis unlikely, and one study found that they are not associated with a diagnosis of trichomoniasis. One study reported that the presence of trichomonads in wet mounts diagnosed trichomoniasis, but their absence did not eliminate the diagnosis.

Microscopic evidence of inflammation (4 studies): the presence of many leukocytes is unlikely in the diagnosis of candidiasis and bacterial vaginosis, but may be suggestive of a diagnosis of trichomoniasis.

pH (5 studies): 4 studies found that candidiasis is associated with a normal pH range, while the remaining study found an association with higher pH. Most patients with trichomoniasis were found to have an elevated pH. Elevated pH forms part of the diagnostic criteria associated with bacterial vaginosis.

Whiff test (3 studies): one study found that a positive whiff suggests the absence of candidiasis, while another study found it is positively associated with trichomoniasis. A positive whiff test forms part of the diagnostic criteria for bacterial vaginosis.

Authors' conclusions
The cause of vaginal complaints could be easily diagnosed using microscopy when typical findings were present. However, the poor performance of individual symptoms, signs and office laboratory tests often made it difficult to identify the cause of vaginal complaints.

CRD commentary
The inclusion criteria were clear for the participants, intervention and outcomes. The search was limited to one electronic database, therefore publication bias cannot be ruled out. The authors did not state whether any language restrictions were imposed, thus the potential for language bias could not be assessed. The methods used to select the studies for inclusion were prone to selection bias as a single author will have selected some of the studies. The quality
of the included studies was assessed systematically; however, details of the methods used were not reported. Methods were used to reduce reviewer bias and error in the data abstraction.

The decision not to statistically combine the studies was appropriate given the apparent differences across the included studies. The narrative synthesis concentrated on the evidence provided by LRs. Since specificity was not reported for many of the included studies, indicating that 2x2 data were not available and LRs could not be calculated, such studies do not appear to have been included in the narrative synthesis. The authors appropriately discussed the limitations of the evidence presented in the review, including the use of multiple criterion standards and the lack of standardised definitions for symptoms and conditions. Given these limitations in the reporting of the review and the evidence presented, caution should be exercised when interpreting the results of the review.

Implications of the review for practice and research
The authors did not state any implications for practice or further research.

Bibliographic details

PubMedID
15026404

DOI
10.1001/jama.291.11.1368

Original Paper URL
http://jama.ama-assn.org/

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Candidiasis, Vulvovaginal /diagnosis; Clinical Laboratory Techniques; Female; Humans; Physical Examination; Trichomonas Vaginitis /diagnosis; Vaginal Discharge /microbiology; Vaginosis, Bacterial /diagnosis

AccessionNumber
12004000573

Date bibliographic record published
31/08/2005

Date abstract record published
31/08/2005

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.