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Accuracy of the Clinical Diagnosis of Vaginitis Compared to a DNA Probe Laboratory Standard

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Abstract

Objective—To estimate the accuracy of the clinical diagnosis of the three most common causes of acute vulvovaginal symptoms (bacterial vaginosis, candidiasis vaginitis, and trichomoniasis vaginalis) using a traditional, standardized clinical diagnostic protocol compared to a DNA probe laboratory standard.

Methods—This prospective clinical comparative study had a sample of 535 active duty United States military women presenting with vulvovaginal symptoms. Clinical diagnoses were made by research staff using a standardized protocol of history, physical examination including pelvic examination, determination of vaginal pH, vaginal fluid amines test, and wet-prep microscopy. Vaginal fluid samples were obtained for DNA analysis. The research clinicians were blinded to the DNA results.

Results—The participants described a presenting symptom of abnormal discharge (50%), itching/irritation (33%), malodor (10%), burning (4%), or others such as vulvar pain and vaginal discomfort. According to laboratory standard, there were 225 cases (42%) of bacterial vaginosis 76 cases (14%) of candidiasis vaginitis, 8 cases (1.5%) of trichomoniasis vaginalis, 87 cases of mixed infections (16%), and 139 negative cases (26%). For each single infection, the clinical diagnosis had a sensitivity and specificity of 80.8% and 70.0% for bacterial vaginosis; 83.8% and 84.8% for candidiasis vaginitis; and 84.6% and 99.6% for trichomoniasis vaginalis when compared to the DNA probe standard.

Conclusion—Compared to a DNA probe standard, clinical diagnosis is 81-85% sensitive and 70-99% specific for bacterial vaginosis, candida vaginitis, and trichomoniasis. Even under research conditions that provided clinicians with sufficient time and materials to conduct a thorough and standardized clinical evaluation, the diagnosis and therefore, subsequent treatment of these common vaginal problems remains difficult.

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Précis: Compared to a DNA probe standard, clinical diagnosis is 81-85% sensitive and 70-99% specific for bacterial vaginosis, candida vaginitis, and trichomoniasis.

Symptoms of acute vulvovaginitis are one of the most common reasons for women's healthcare visits with annual estimates of 6 to 10 million visits in the United States.¹⁻² Despite technological advances in point-of-care testing options, expert recommendations continue to describe a standard of clinical diagnosis via history and physical examination, pH determination, amine (whiff) test, and wet prep microscopy for these common women's health complaints partially due to concerns about increased costs associated with newer options.^{1,3} In a review of studies published between 1966 and 2003, the diagnosis of bacterial vaginosis (BV) was made in 22 to 50% of symptomatic women, candidiasis vaginitis (CV) in 17 to 39%, and trichomoniasis vaginalis (TV) in 4 to 35%. Approximately 30% of symptomatic women remained undiagnosed after clinical evaluation.⁴

Several investigators have highlighted inaccuracies in the clinical diagnosis of these common clinical problems when compared to traditional gold standards for both symptomatic and asymptomatic women.⁵⁻⁷ In addition, concerns have been raised about the infrequency with which the recommended clinical diagnostic tools of microscopic assessment of vaginal fluid, pH determination and amine testing is actually performed in routine clinical practice.⁸⁻⁹ Whether declines in use of the traditional diagnostic tools are due to training failure resulting in poor skills, the imposition of Clinical Laboratory Improvement Amendment (CLIA) regulations causing abandonment of previously performed microscopic examinations,¹⁰ a decrease in time available per patient to maintain productivity, or other factors is unclear.

The gold standards to which symptoms and clinical diagnoses primarily have been compared are culture in Diamond's media for TV, Gram stain using Nugent's criteria for BV, and agar culture for CV. These methods are not immediately available in many clinical settings, are individually time-consuming, and do not provide timely results. A DNA probe analysis of vaginal fluid for *Gardnerella vaginalis*, *Candida* species and *Trichomonas vaginalis* (Affirm™ VPIII¹¹) provides a point-of-care testing option for these 3 common causes of acute vulvovaginal symptoms. The purpose of this study was to estimate the accuracy of clinicians' diagnoses for military women experiencing symptoms suggestive of vulvovaginitis compared to the DNA probe standard.

Materials and Methods

This was a prospective, clinical comparative study in which clinicians conducted standardized clinical examinations for women presenting with vulvovaginal symptoms. Active duty military women who presented for healthcare with vulvovaginal or urinary symptoms at one of 4 troop medical clinics in the U.S. Army or Navy between November 2002 and July 2006 were invited to participate in the parent study. The total sample was 715 women, 547 of whom were experiencing vulvovaginal symptoms and are the focus of this report (see Figure 1). Sample size was calculated for the primary aim of the parent study using the approach of the prevalence of the condition (a population proportion) and the desired levels of accuracy of the diagnostic test.¹² Using criteria of 95% positive predictive values (PPV), 95% negative predictive values (NPV), and precision of plus or minus 3% with a 38% prevalence of BV/TV and 45% CV from our previous clinical study of civilian women,¹³ we needed at least 534 participants with vaginal symptoms. The study protocol was approved by The Ohio State University, Oregon Health & Science University, the U.S. Army, and the U.S. Navy. institutional review boards for human subject research.

The clinicians in this study were nurse practitioner (NP) research staff for the parent project with the primary aim of testing the accuracy of women's self-diagnosis of vulvovaginal symptoms compared to the DNA probe analysis of vaginal secretions for BV, TV, or CV. One component of the research protocol was a clinical diagnosis and treatment plan by the research staff. The 4 research clinicians were masters prepared nationally certified women's health nurse

practitioners with 6 to 11 years of experience in the role. Two of the NPs were also certified as family or adult nurse practitioners. Three of the NPs had served from 4 to 21 active duty years in the U.S. Air Force, or Navy with one of these a current reservist.

After informed consent and completion of the self-diagnosis portion of the parent study, participants were interviewed and examined by the research NPs according to a standard clinical protocol for the diagnosis and management of vulvovaginal symptoms. Women were excluded from participation if they were menstruating or had coitus within the last 24 hours. The NPs were blinded to the participants' self-diagnoses throughout the data collection procedures.

The research interview protocol included behavioral risk factors, and prior occurrence of and treatment for genitourinary infection, as well as a standard clinical history including chief complaint, current symptoms, and self-care for symptoms. The clinical examination included a speculum exam for observation of mucopurulent cervicitis and evaluation of secretions for color, viscosity, and homogeneity. Vaginal specimens were collected for wet prep microscopy (normal saline and 10% potassium hydroxide [KOH] slides), whiff (amines) test using 10% KOH added to the vaginal secretions, and determination of vaginal secretion pH (Phenazine™ Paper, Decon Laboratories, Inc.). Vaginal fluid samples were collected for DNA probe analysis (Affirm™ VPIII) for *G. vaginalis*, *T. vaginalis*, and *Candida* species, and from the endocervix for DNA probe analysis (GenProbe®) for *Chlamydia trachomatis* and *Neisseria gonorrhea*.

The DNA probe uses nucleic acid hybridization (two distinct single-stranded probes for each organism and a color development probe) to detect and identify *G. vaginalis*, *T. vaginalis*, and *Candida* fungal species. Although *G. vaginalis* is not the only bacteria associated with the polymicrobial disruption of BV, it is the sentinel organism.¹⁴ A test swab used to obtain a sample of vaginal fluid can be held at room temperature for up to one hour or up to 4 hours at 2-8°C. Study swabs were tested by trained military laboratory technicians in each clinical laboratory according to the manufacturer's directions for the BD MicroProbe Processor. The DNA probe test readers were blind to the clinical findings including the clinicians' diagnoses. Test results are not adversely affected by variables that make visual identification of microbial agents difficult, such as vaginal lubricants, douches, menses, or spermicides.¹⁵

Reported respective sensitivities and specificities of the DNA probe compared to conventional gold standards of Gram stain/Nugent's criteria and/or culture for identifying *G. vaginalis* (BV) are 88-98% and 81-97%¹⁴⁻¹⁶; for *Trichomonas* (TV) 83-100% and 98-100%¹⁴; and for *Candida* (CV) 82% and 94%.¹⁷ In two other studies, the identification of organisms associated with BV, TV and CV was consistently greater using the DNA probe than by Amsel criteria or by wet mount alone.¹⁸⁻¹⁹

The NPs made their clinical diagnoses and treatment decisions on the basis of the clinical data without knowledge of the DNA probe results. Because of the protocol of the parent study, the NPs remained blinded to the DNA probe results for *G. vaginalis*, *T. vaginalis*, and *Candida* fungal species throughout the study but treated *C. trachomatis* and/or *N. gonorrhea* as indicated on the basis of the laboratory results for these organisms. The study protocol also included an in-person or telephone follow up visit from 2 to 5 days after the initial enrollment visit. During this follow-up, data were systematically collected about the resolution of clinical symptoms, the timing of symptom resolution, satisfaction with the treatment prescribed, occurrence of treatment side effects, and other self-treatment approaches used.

For all analyses, laboratory diagnosis by DNA probe was considered the diagnostic standard for comparison. The data were analyzed with SPSS (version 16.0, SPSS Inc., Chicago, IL). Descriptive statistics, cross tabulations, and 2×2 contingency tables were used to calculate sensitivity, specificity, positive predictive value, and negative predictive value with a 95%

confidence interval. Absolute clinical diagnostic accuracy was mathematically defined as the number of matches between the clinical diagnoses (CD) and the DNA probe results, divided by the total number of DNA probe diagnoses in each category. Kappa coefficients (κ) were calculated as a measure of agreement that corrects for chance agreement between two raters, ²⁰ or in this case between the clinician and the DNA probe result.

Results

The sample was 547 active duty U.S. military women (43% Army, 54% Navy, and 3% other branches) who presented for healthcare with vulvovaginal symptoms. The presenting symptom was abnormal discharge of a wide range of descriptions (278, 50.8%), itching/irritation (182, 33.3%), malodor (57, 10.4%), vulvar burning (23, 4.2%), and miscellaneous others (7, 1.3%) including vulvar pain and vaginal discomfort. Of this sample, 535 participants had complete data sets for the relevant clinical and DNA probe laboratory standard tests and were the sample for this report. As summarized in Table 1, these participants had a mean age of 25.7 years and were predominantly Black or White, enlisted personnel, with a high school or some college education.

The CDs and the DNA probe laboratory standard diagnoses by vaginal organism type are summarized descriptively and cross-tabulated by all categories of diagnosis including mixed vaginal infections in Table 2. Overall, there was no evidence of TV, BV or CV in 17% of the women by CD and more than 25% by laboratory standard. The CD for these 3 most common causes of vaginitis had a 64.5% overall absolute accuracy with the highest level of accuracy for the diagnosis of BV or CV alone (77.3% and 76.3% respectively). The lowest levels of absolute CD accuracy for these symptomatic women were for the absence of vaginitis (i.e. normal or non-infectious vaginitis), TV alone, or mixed infections.

To understand the pattern of diagnostic accuracy and inaccuracy, the CD for each single vaginal infection (TV, BV, or CV) was determined (Table 3). In this analysis, mixed infections were assigned to their individual diagnostic categories so that a CD of BV/TV was counted as 1 BV diagnosis and 1 TV diagnosis. Therefore each row in Table 3 is an independent diagnostic accuracy evaluation for the presence or absence of that specific diagnosis. CD accuracy was highest for TV (98.9%) and lowest for BV (76.3%). Sensitivities ranged from 80.8% (BV) to 84.6% (TV); specificities from 70.0% (BV) to 99.6% (TV); positive predictive values (PPV) from 76.8% (CV) to 91.7% (TV); and negative predictive values (NPV) from 72.4% (BV) to 99.2% (TV). The κ coefficients indicated excellent agreement between clinician and the DNA probe for TV, good agreement for CV, and fair agreement for BV.

All except 9 of the participants had DNA probe results for *C. trachomatis* and *N. gonorrhoeae* from samples taken at the time of data collection. Only 14 (2.6%) were positive for *C. trachomatis* alone, 2 (0.4%) for *N. gonorrhoeae* alone, and 14 (2.6%) for both organisms. Of the 30 participants positive for *C. trachomatis* and/or *N. gonorrhoeae*, 26 (86.7%) were also positive for BV alone or in combination with TV and/or CV. Only one woman who was DNA probe negative for BV, TV, or CV was positive for *C. trachomatis* and/or *N. gonorrhoeae*, and she was positive for both organisms.

The protocol for the parent study called for a follow up interview with the study participants preferably in person or by telephone. Follow up interviews were conducted with 474 (88.6%) of the participants at a mean of 7 and median of 5 days after the enrollment clinical visit. Ninety-three percent of these interviews occurred within 2 weeks and 75.9% were conducted in person. Prolonged delays in follow up and those lost to follow up primarily occurred due to military responsibilities including deployments. Among the 446 (94.1%) women whose symptoms had

been relieved, 60% of the CDs, including the presence of mixed infections, were accurate when compared to the DNA probe.

Only 28 (5.9%) of the participants reported that their symptoms had not been relieved after their clinic visit. Of these 28 women, 57% (16) had identical diagnoses by CD and DNA probe (10 no infection, 5 BV only, and 1 CV) and there were no cases of TV. Of the remaining 12 women, 7 had BV by DNA probe that was not identified by CD; 4 had no infection by DNA probe, of which 2 were given a CD of BV and 2 CV; and 1 had BV/CV by DNA probe and CV only by CD. Because the research staff was blinded to the DNA probe results, clinical re-evaluation was offered to those women who remained symptomatic.

As presented in Table 2, 139 (25.9%) of 535 women with both CD and laboratory results had no identifiable DNA for TV, BV, or CV. Of these 139 women, 3 had no *C. trachomatis* or *N. gonorrhoeae* results recorded and 1 was positive for both organisms. Therefore, the remaining 135 symptomatic women were DNA probe laboratory negative for these five most common causes of vulvovaginal symptoms. Forty of these women (29.6%) were identified clinically as normal, 23 (17.0%) were diagnosed with other vulvovaginal problems, 44 (32.6%) with BV, 24 (17.8%) with CV, and 4 (3.0%) with a mixed BV/CV infection. The 23 “other” diagnoses were contact dermatitis (6), yeast vulvitis (6), traumatic injury including abrasions and minor lacerations (4), herpes genitalis (2), condylomata (1), presumptive Chlamydia (1), lichen sclerosis (1), atrophic vaginitis (1), and possible vestibulitis (1).

Discussion

The distribution of vaginitis type detected by DNA probe or GC/Chlamydia DNA probe among these predominantly young-adult symptomatic military women was similar to that reported by Landers and colleagues⁷ in a similarly aged and ethnic/racially distributed sample of symptomatic women using traditional laboratory standards. Notably, in our data and that of Landers, more than 26% and 21% respectively of the women were found to be free of any laboratory identifiable BV or infections despite the presence of clinical symptoms. These findings are also consistent with those of others who have reported normal flora by laboratory standard²¹ and the absence of a diagnosis for a significant percentage (30-35%) of symptomatic women.⁴ Laboratory findings in both the current study and that by Landers et al.⁷ showed the highest incidences for BV (58.2% vs. 46%), followed by CV (27.6% vs. 29%), TV (4.8% vs. 12%), and GC/Chlamydia (5.7% vs. 11%). The incidence of sexually transmitted infections (TV, GC, or Chlamydia) was approximately 50% lower in our population of military women, although the numbers of these infections in both samples was small.

Since the CD of TV relies on the microscopic visualization of the trichomonads (present or absent) and the CD of BV relies on the multiple indicators of Amsel's criteria, it is not surprising that these 2 diagnoses were at opposite ends of the accuracy range for the CD of vaginitis in symptomatic women. However, our accuracy estimates for the CD of the 3 most common causes of vulvovaginal symptoms compare favorably with those of Landers et al.⁷ despite differences in the laboratory standard used for comparison. For CV alone, the CD of CV was made in 83.8% of women in our study who were positive for *Candida* by DNA probe similar to 87.1% of 364 culture positive women reported by Linhares et al.²² These similar findings support the conclusion that, regardless of the laboratory standard used, the CD of these common vaginal problems remains challenging even under conditions wherein the clinicians conducted a systematic clinical and microscopic evaluation as dictated by the research protocols. Because of reports suggesting that this systematic evaluation may be relatively uncommon in day to day clinical practice,⁸⁻⁹ it is highly likely that most women experience a diagnostic accuracy that is significantly below these research findings. Perhaps as suggested by Fowler,²³ part of the apparently common CD inaccuracy is that our current vaginitis diagnostic classification

system requires revision and expansion to accurately reflect the full spectrum of altered vaginal microflora.

Clinically, the practical issues are the avoidance of inappropriate treatment that can be categorized as errors of commission (prescribing a drug in the absence of disease) or errors of omission (not prescribing a drug in the presence of disease), the resolution of symptoms, and patient satisfaction. Overall, of the symptomatic women in our study, 23.4% were prescribed a medication on the basis of CD not supported by the laboratory standard representing commission prescriptive errors. The CD led to 16.1% omission prescriptive errors in which women were not prescribed a medication indicated by the laboratory result. Despite these errors the participants who were contacted for follow up reported a high level of symptom resolution (> 94%). It is unknown whether this apparent success of clinical management regardless of both commission and omission treatment errors would have been as high if information from those lost to follow up (about 13%) was available. Further, it is unknown how many of the participants experienced recurrent symptoms and returned for additional evaluation outside of their research involvement or experienced symptom decline due to spontaneous remission of infections and microflora disruptions.

Limitations of our study include its observational nature, small subgroup size for TV, and the laboratory standard for BV limited to a DNA probe for *G. vaginalis* that ignores the polymicrobial nature of this disruption of the vaginal microflora. Despite these limitations, we found that under research conditions during which clinicians had sufficient time and materials to conduct a standardized clinical evaluation including physical examination, determination of vaginal pH, an amines test, and wet prep microscopy, the diagnosis and subsequent treatment of common vaginal infections remains problematic when compared to a laboratory standard provided by the DNA probe. However, despite the diagnostic and treatment inaccuracies, women in our study generally reported significant symptomatic relief on follow-up. The question remains whether the accumulation of data documenting the relative inaccuracy of clinical diagnosis for common causes of lower genital tract complaints even under the best of circumstances points to an unacceptably poor quality of women's health care. The availability of the DNA probe analysis for BV, TV, and CV, as well as other newer specific point-of-care testing options, may provide the opportunity to significantly improve the accuracy of diagnosis and treatment for these common ambulatory problems.

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Figure 1.
Number of Participants at Each Stage of the Study.

Table 1
Demographic characteristics of sample (n = 535).

Age		
Range 18 - 50 years, Mean = 25.7 years, Standard deviation = 5.8 years		
Ethnicity/Race		
Black	230	43.0%
Hispanic/Latina	97	18.1%
White	168	31.4%
Other or not reported	40	7.5%
Education		
High School Graduate or GED	123	23.0%
Some College	305	57.0%
Associate Degree	40	7.5%
College Degree	47	8.8%
Post Graduate	17	3.2%
Not reported	3	0.6%
Marital Status		
Single	212	39.6%
Married/Living with Significant Other	213	39.8%
Divorced/Widowed/Separated	104	19.4%
Other/not reported	6	1.1%
Branch of Military Service		
Army	232	43.4%
Navy	288	53.8%
Air Force/Marines/CoastGuard	14	2.6%
Not reported	1	0.2%
Military Rank		
Enlisted (E1 - E3)	142	26.5%
NCO * (E4 - E9)	350	65.4%
Junior Officer (O1 - O3)	37	6.9%
Senior Officer (O4 - O6)	3	0.6%
Not reported	3	0.6%

* Non-commissioned officer.

Table 2
Crosstabulation of vaginitis clinical diagnosis (CD) and DNA probe laboratory standard (n = 535).

CD	DNA probe laboratory standard							
	Negative	TV ¹ only	BV ² only	CV ³ only	BV/TV mixed	BV/CV mixed	BV/TV/CV mixed	Row Total
Normal or Other CD *	64	0	21	4	0	3	0	92 (17.2%)
TV only	0	4	0	0	7	0	1	12 (2.2%)
BV only	46	0	174	5	1	9	1	236 (44.1%)
CV only	25	1	9	58	0	18	1	112 (20.9%)
BV/TV	0	3	1	0	7	1	0	12 (2.2%)
BV/CV	4	0	20	9	0	38	0	71 (13.2%)
BV/TV/CV	0	0	0	0	0	0	0	0
Column Total	139 (26.0%)	8 (1.5%)	225 (42.1%)	76 (14.2%)	15 (2.8%)	69 (12.9%)	3 (0.6%)	535
Accuracy	46.0	50.0	77.3	76.3	46.7	55.1	0	64.5

¹Trichomoniasis vaginalis

²Bacterial vaginosis

³Candida vaginitis

* This category also includes miscellaneous non-infectious clinical diagnoses such as contact dermatitis, herpes genitalis, condylomata, presumptive Chlamydia or gonorrhea, traumatic injury, etc.

Accuracy of single vaginitis clinical diagnosis (CD) and treatment implication for each infection compared to DNA probe laboratory standard (n=535).

		Accuracy Indices									
		Accurate		Inaccurate		Percent Accuracy ³	Kappa statistic ⁴	Sensitivity	Specificity	PPV ⁵	NPV ⁶
CD		+/+	-/-	+/- ¹	-/+ ²						
TV		22	507	2	4	98.9%	.87	84.6% (64.3-95.0) ⁷	99.6% (98.4-99.9)	91.7% (71.5-98.5)	99.2% (97.9-99.7)
BV		252	156	67	60	76.3%	.51	80.8% (75.9 - 84.9)	70.0% (73.4 - 75.8)	79.0% (74.0 - 83.3)	72.2% (65.7 - 78.0)
CV		124	328	59	24	84.5%	.64	83.8% (76.6 - 89.1)	84.8% (80.7 - 88.1)	67.8% (60.4 - 74.4)	93.2% (89.9 - 95.5)

¹ This inaccurate diagnosis would cause a commission treatment error, i.e. prescribing a medication that is not indicated.

² This inaccurate diagnosis would cause an omission treatment error, i.e. not prescribing a medication that is indicated.

³ Number of accurate CD divided by the total number of CD (accurate and inaccurate).

⁴ Measure of agreement corrected for chance.

⁵ Positive predictive value.

⁶ Negative predictive value.

⁷ 95% confidence interval.