

Validity of Self-Obtained Vaginal Specimens for Diagnosis of Trichomoniasis

JANE R. SCHWEBKE,^{1,2*} SHELLIE C. MORGAN,¹ AND GLORIA B. PINSON^{1,2}

*Division of Infectious Diseases, University of Alabama at Birmingham, Birmingham, Alabama 35294-0006,¹
and Jefferson County Department of Health, Birmingham, Alabama 35202²*

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A comparison of self- and clinician-collected vaginal specimens for the diagnosis of trichomoniasis was conducted. The sensitivities of culture methods using self- and clinician-collected specimens were 84.6 and 88.5%, respectively. There was no significant difference between the sensitivities of culture methods using self- and clinician-collected vaginal specimens for the diagnosis of trichomoniasis.

Trichomoniasis remains a common cause of vaginitis and has been linked to outcomes such as preterm birth and human immunodeficiency virus acquisition (7, 9, 11). Although the diagnosis of trichomoniasis is currently made in the physician's office, there has been increasing interest in home diagnosis and treatment of vaginal infections (4). Published data on the validity of self-collected vaginal specimens for the diagnosis of trichomoniasis is lacking. Therefore, we conducted a comparison study to determine the validity of self-collected versus clinician-collected vaginal specimens for the diagnosis of trichomoniasis.

Women who were patients at the Jefferson County Department of Health STD Clinic were eligible for the study. Patients were enrolled and examined by a single nurse after providing oral consent for participation. The study was approved by the institutional review boards of the University of Alabama at Birmingham and the Jefferson County Department of Health.

The patient was given a sterile cotton-tipped swab and instructed to insert the swab into the vagina and to swab the vaginal wall. The patient then returned the swab to the clinician, who inoculated culture medium for *Trichomonas vaginalis* (In Pouch TV test; BioMed Diagnostics Inc., Santa Clara, Calif.) (2). The clinician then performed a pelvic examination and obtained vaginal specimens for pH determination (ColorpHast indicator strips; EM Science, Gibbstown, N.J.), "whiff" test, wet-preparation microscopy, and culture of *T. vaginalis*. Endocervical specimens were obtained for tests for gonorrhea and were plated directly onto modified Thayer-Martin media and incubated in 3 to 5% CO₂. Endocervical specimens for chlamydia culture were placed into transport media, refrigerated, and transported to the laboratory within 24 h.

Cultures for *T. vaginalis* were incubated at 35°C and examined daily by light microscopy (magnification, ×100) for 5 days. Cultures were considered positive based upon the identification of motile trichomonads within the pouch. The presence of bacterial vaginosis (BV) was determined by use of the Amsel criteria (1). Cultures for gonorrhea and chlamydia (microtiter plates) were processed according to standard methods (10, 12). Trichomoniasis was defined as the presence of motile trichomonads as determined either by direct wet-mount examination of the vaginal fluid or by a positive culture.

Statistical comparisons were made by the EpiInfo software

program, version 6 (3). Fisher's exact test or the chi-square test was used to compare categorical variables, and Wilcoxon's test was used to compare continuous variables. Ninety-five percent confidence intervals were calculated to evaluate statistically significant differences between collection methods (5).

One hundred women were enrolled in the study between February and May of 1996. None of the women who were asked to participate refused. The overall prevalence of trichomoniasis was 26%. There were no significant differences between women with and without *T. vaginalis* with regard to age, race, or mean number of sexual partners. Of the women with trichomoniasis, 6 of 26 (23.1%) had gonorrhea, 2 of 26 (7.7%) had chlamydia, and 22 of 26 (84.6%) had BV. Of those without trichomoniasis, 7 of 74 (9.5%) had gonorrhea, 10 of 74 (13.5%) had chlamydia, and 35 of 74 (47.3%) had BV. These differences in coinfection rates were not statistically significant, with the exception of BV ($P = 0.002$). Among those women with positive cultures for *T. vaginalis*, 20 of 25 (80%) tested positive with both the self- and clinician-collected samples. For these concordant pairs, 19 of 20 (95%) had cultures that became positive on the same day, while for the remaining pair there was a 1-day difference.

The sensitivities and predictive values of culture methods using self- and clinician-collected samples are presented in Table 1. There was no significant difference between the sensitivities of the culture techniques with self- and clinician-collected specimens.

On examination, vaginal discharge was found to be present in 25 of 26 (96%) of the women with trichomoniasis, although only 16 of 26 (61%) women complained of this symptom. Moderate to high numbers of leukocytes were present in the vaginal fluid in 19 of 26 (73%) of the patients. There was no correlation between the presence or absence of leukocytes and the sensitivity of the direct wet-preparation examination of the vaginal fluid. Of interest, three of four (75%) of the women with *T. vaginalis* but without BV had a vaginal pH of <4.5.

Due to a lack of resources, control of *T. vaginalis* has not been considered a priority in terms of control of sexually transmitted diseases. Increased ease of screening with a sensitive diagnostic test, either in a health care setting or at home, could result in an increase in diagnosis and treatment. Vaginal self-sampling combined with low-cost diagnostics could make possible specific diagnosis and treatment in situations where women have limited access to pelvic examination due to either economic or cultural barriers. Wawer et al. used self-collected vaginal specimens obtained during home visits to women in rural Uganda. Swabs were inoculated into trichomonas culture

* Corresponding author. Mailing address: 1900 University Blvd., 229 Tinsley Harrison Tower, Birmingham, AL 35294-0006. Phone: (205) 934-5191. Fax: (205) 934-5155. E-mail: jschwebke@uabid.dom.uab.edu.

TABLE 1. Comparison of diagnostic methods for *T. vaginalis*^a

Diagnostic method	No. positive	No. false negative	Sensitivity (%)	95% CI ^b	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Culture							
Self-collected specimens	22	4	84.6	64.3–95.0	100	100	94.9
Clinician-collected specimens	23	3	88.5	68.7–97.0	100	100	96.1
Wet-preparation examination of clinician-collected specimens	18	8	69.2	48.1–84.9	100	100	90.2

^a *n* = 100.^b Confidence interval for sensitivity.

media on site. Although no comparisons to results obtained with clinician-collected samples were made, 47% of the women sampled had positive cultures (13). Gwyther et al. examined the validity of self-collected versus clinician-collected vaginal specimens among a group of 21 symptomatic patients. They found good correlation between the two different types of specimens for several different cellular elements; however, only one patient had trichomoniasis (6).

The sensitivity of wet-preparation examination in our study was 68%, similar to that found in previous studies (8, 14). With regard to clinical and epidemiological characteristics, our study did not show an association between trichomonas and gonorrhea, an association which has been shown by some investigators (14). There was a significant association between the presence of trichomonads and BV, which has also been previously shown (1, 14).

In summary, we have demonstrated the validity of self-collected vaginal specimens for the diagnosis of trichomoniasis. This technique has applicability for studies involving the epidemiology of *T. vaginalis* as well as for home diagnostic testing.

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REFERENCES

- Amsel, R., P. A. Totten, C. A. Speigel, K. C. S. Chen, D. Eschenbach, and K. K. Holmes. 1983. Non-specific vaginitis: diagnostic criteria and microbial and epidemiological associations. *Am. J. Med.* **74**:14–22.
- Borchardt, K. A., and R. F. Smith. 1991. An evaluation of an InPouch™ TV culture method for diagnosing *Trichomonas vaginalis* infection. *Genitourin. Med.* **67**:149–152.
- Dean, A. G., J. A. Dean, and D. Columbeer. 1994. EpiInfo, version 6: a word processing database and statistics program for epidemiology on microcomputers. Centers for Disease Control and Prevention, Atlanta, Ga.
- Ferris, D. G., C. Dekle, and M. S. Litaker. 1996. Women's use of over-the-counter antifungal medications for gynecologic symptoms. *J. Fam. Pract.* **42**:595–600.
- Fleiss, J. L. 1981. *Statistical methods for rates and proportions*. John Wiley and Sons, Inc., New York, N.Y.
- Gwyther, R. E., L. A. Addison, S. Spottswood, E. J. Bentz, S. Evens, and A. Abrantes. 1986. An innovative method for specimen autocollection in the diagnosis of vaginitis. *J. Fam. Pract.* **23**:487–488.
- Krieger, J. N. 1981. Urologic aspects of trichomoniasis. *Investig. Urol.* **18**:411–417.
- Krieger, J. N., M. R. Tam, C. E. Stevens, I. O. Nielsen, J. Hale, N. B. Kiviat, and K. K. Holmes. 1988. Diagnosis of trichomoniasis. *JAMA* **259**:1223–1227.
- Laga, M., A. Manoka, M. Kivuvu, B. Malele, M. Tuliza, N. Nzila, J. Goeman, F. Behets, V. Batter, M. Alary, W. L. Heyward, R. W. Rupler, and P. Piot. 1993. Non-ulcerative sexually transmitted diseases as risk factors for HIV-1 transmission in women from a cohort study. *AIDS* **7**:95–102.
- Mårdh, P. A., and D. Danielsson. 1990. *Neisseria gonorrhoeae*, p. 903–916. In K. K. Holmes, P. A. Mårdh, P. F. Sparling, and P. J. Wiesner (ed.), *Sexually transmitted diseases*. McGraw-Hill, Inc., New York, N.Y.
- Minkoff, H., A. N. Grunebaum, R. H. Schwarz, J. Feldman, M. Cummings, W. Crombleholme, L. Clark, G. Pringle, and W. M. McCormack. 1984. Risk factors for prematurity and premature rupture of membranes: a prospective study of the vaginal flora in pregnancy. *Am. J. Obstet. Gynecol.* **150**:965–972.
- Stamm, W. E., and P. A. Mårdh. 1990. *Chlamydia trachomatis*, p. 917–925. In K. K. Holmes, P. A. Mårdh, P. F. Sparling, and P. J. Wiesner (ed.), *Sexually transmitted diseases*. McGraw-Hill, Inc., New York, N.Y.
- Wawer, M. J., D. McNairn, F. Wabwire-Mangen, L. Paxton, R. H. Gray, and N. Kiwanuka. 1995. Self-administered vaginal swabs for population-based assessment of *Trichomonas vaginalis* prevalence. *Lancet* **345**:131–132.
- Wölner-Hanssen, P., J. N. Krieger, C. E. Stevens, N. B. Kiviat, L. Koutsky, C. Critchlow, T. De Roven, S. Hillier, and K. K. Holmes. 1989. Clinical manifestations of vaginal trichomoniasis. *JAMA* **261**:571–576.