Original Research Paper

Volume-7 | Issue-10 | October-2017 | ISSN - 2249-555X | IF : 4.894 | IC Value : 79.96

Microbiology

EVALUATION OF RAPID OSOM TRICHOMONAS TEST FOR DIAGNOSIS OF TRICHOMONIASIS IN FEMALES OF REPRODUCTIVE AGE GROUP

Razia Khatoon MD., Associate Professor, Department of Microbiology, J.N.M.C.H, AMU,Aligarh, INDIA

***Richa Gupta** MD., Senior Resident, Department of Microbiology, J.N.M.C.H, AMU,Aligarh, INDIA
*Corresponding Author

Haris M Khan MD., Professor, Department of Microbiology, J.N.M.C.H, AMU, Aligarh, INDIA

ABSTRACT

Introduction: *Trichonomas vaginalis* is a parasitic protozoan, sexually transmitted worldwide.Diagnosis is usually done by observing motile parasite from vaginal or cervical swab specimens by direct wet mount examination,geimsa staining, fluorescent staining and culture. OSOM rapid test is newer method available for diagnosis of this sexually transmitted disease.

Methods: Study was carried out on 405 patients attending gynecological OPD with complaint of vaginal discharge.Four high vaginal swabs from posterior fornix of vagina were taken from each patient; each for wet mount,giemsa and acridine orange staining and other for OSOM *trichomonas* rapid test.Culture was done on kupferberg culture medium.

Results: Wet mount and giemsa staining showed *T.vaginalis* in 7(1.7%) cases each.Acridine orange staining was positive in 12 cases (3.0%), while OSOM rapid test detected *T.vaginalis* infection in 15 cases. Culture on kupferberg medium was positive in 18(4.4%) patients and was taken as gold standard.Sensitivity,specificity of wet mount examination was found to be 38.9%(CI 18.2-63.8),100%(CI 98.7-100), positive and negative predictive values,100% and 97.2%. Giemsa and acridine orange staining showed sensitivity of 38.9%(CI 18.2-63.8) and 66.67%(CI 41.4-85.6) and specificity 100 %(CI 98.7-100) each. OSOM rapid test was found to be most sensitive(83.3%,CI 57.7-95.5) when compared to wet mount examination and staining techniques taking while staining methods and OSOM test were found to be equally specific(100%,CI 98.7-100).

Conclusion: OSOM rapid test is simple to perform,objective and can provide results in 10 min.It will be an important addition to the repertoire of techniques available for *T.vaginalis* detection,especially for facilities without access to a microscope or incubator and in settings where difficult patient follow-up makes point-of-care testing attractive.

KEYWORDS : *trichomonas*, OSOM test, rapid, diagnosis

INTRODUCTION

Trichomoniasis is caused by *Trichomonas vaginalis* which was first observed by Donne (1836). Trichomoniasis is the most common non viral sexually transmitted disease (STD) worldwide,an annual incidence of more than 170 million cases worldwide. Data are limited for women with a low prevalence of infection (1). Vaginitis due to *Trichomonas vaginalis* clinically manifests with symptoms of vaginal itching, dysuria, foul smelling, and copious purulent discharge. Recent studies also show that *T. vaginalis* is an important cause of the premature rupture of membranes, premature delivery, pelvic inflammatory disease, and cytological changes in cervical cell morphology (2,3,4).*T vaginalis* has also been associated with epididymitis, prostatitis and balanitis (5).The organism has now been associated with a significantly higher risk of HIV transmission(6), and it is suggested that this parasite may increase maternal-to-infant transmission in HIV. This increased transmission in females is believed to be due to the denution of the cervicovaginal epithelium along with the accumulation of CD4 lymphocytes and macrophages at the site of infection, which could provide pools of HIV-susceptible or HIV-infected cells (7).It is difficult to diagnose trichomoniasis due to its heterogeneous presentation and problems with diagnostic testing. Diagnosis is usually done by observing motile parasite from vaginal or cervical swab specimens by direct wet mount examination. Other diagnostic test includes giemsa staining, fluorescent staining and culture. All diagnostic tests are fraught with imperfections. OSOM rapid test (Genzyme Diagnostics Cambridge Massachusettes) based on immunochromatographic capillary flow dipstick is newer method available for diagnosis, of this sexually transmitted disease. This study aims at comparing wet mount examination, giemsa staining and acridine orange staining, culture as diagnostic test for *Trichomonas vaginalis*. To evaluate sensitivity, specificity of OSOM *trichomonas* rapid test with culture and different staining techniques.

MATERIAL AND METHODS

The study group comprised of all the females of reproductive age group (15-45 years) attending Gynaecological and Antenatal Out-Patient Department of J. N. Medical College Hospital, A.M.U., Aligarh, India, with complaints of foul smelling vaginal discharge, pruritis, dysuria, dyspareunia, pain in lower abdomen etc. Four vaginal swabs from posterior fornix of vagina were taken from each patient. One swab was used for preparing wet mount, one for making smears (giemsa and acridine orange staining) and others for OSOM *Trichomonas* Rapid test and culture was done on Kupferberg culture medium. This study was approved by Institutional Ethics Committee of the Faculty of Medicine, A.M.U., Aligarh. The purpose and procedures of this investigation were explained to all participants, and informed consent was obtained from all the women studied.

RESULTS

Table 1 shows distribution of patients suffering from *Trichomonas vaginalis* infection according to their pregnant and non-pregnant status. All the 18 cases positive for *T. vaginalis* infection were those suffering from some gynaecological disorders and none of the pregnant females were positive for *T. vaginalis*. Table 2 shows distribution of patients suffering from *Trichomonas vaginalis* infection according to their clinical signs. Out of 18 (4.4%) patients having trichomoniasis 18 (4.4%) had vaginal inflammation, 3 (0.7%) had curdy discharge, 9 (2.2%) had serous discharge and 6 (1.5%) had mucinous discharge. Foul smelling discharge and cervical inflammation was present in 18 (4.4%) patients each and cervical erosion in 15 (3.7%) patients. Table 3 shows distribution of patients in our study according to results observed on wet mount examination and by different staining techniques. Out of 405 patients, 7 (1.7%) were positive for *Trichomonas vaginalis* by Wet mount examination, 7 (1.7 %) were positive by Giemsa staining and 12 (3.0%) were positive by Acridine Orange staining,18 (4.4%) were positive for *Trichomonas vaginalis* by culture in Kupferberg medium and 15 (3.7 %) patients in the study group were positive for *Trichomonas vaginalis* by OSOM *Trichomonas* Rapid Test. Table 3 also shows sensitivity and specificity of different technique used for the diagnosis of *Trichomonas vaginalis* infection taking culture in Kupferberg Medium as gold standard. Sensitivity, specificity of wet mount examination was found to be 38.9% (CI 18.2-63.8), 100% (CI 98.7-100), positive and negative predictive values, 100% and 97.2%. Giemsa and acridine orange staining showed sensitivity of 38.9% (CI 18.2-63.8) and 66.67% (CI 41.4-85.6) and specificity 100 % (CI 98.7-100) each. OSOM rapid test was found to be most sensitive (sensitivity 83.3% CI 57.7-95.5) when compared to wet mount examination and staining techniques taking while staining methods and OSOM test were found to be equally specific (specificity 100%,CI 98.7-100).

DISCUSSION

Our study evaluates that OSOM Trich had improved sensitivity (83.3%) as compared to that of WP (38.9%), giemsa staining (38.9%) and acridine orange staining (66.7%), in this context. OSOM Trich also had the excellent specificity required for screening patients with a low prevalence of infection. Huppert et al. (8) recently evaluated OSOM Trich in two separate studies in female populations with a high prevalence of *T. vaginalis* infection. The initial evaluation used OSOM Trich to rapidly detect *T. vaginalis* in vaginal specimens collected from sexually active women ≥ 18 years of age (*n*≥ 449) presenting with symptoms of vaginitis, exposure to *T.vaginalis*, or multiple sexual partners (5). Their study population had a high prevalence of *T. vaginalis* at 23.4%. OSOM Trich detected more *T. vaginalis* cases, with a sensitivity of 83.3%; that for WP was 71.4%. In a more recent study, sexually active adolescent women aged 14 to 21 years (*n* ≥330) were recruited from a teen health center and the emergency department (9). Vaginal swabs were tested for *T. vaginalis* using WP, culture (In Pouch *T. vaginalis*; BioMed Diagnostics), OSOM Trich. Their study group also had a high prevalence of trichomoniasis at 18.5%. WP had the lowest sensitivity (56%), while that of OSOM Trich was 83%. Although OSOM Trich (83%) had lower sensitivity than that of culture (90%), test results were available the same day, whereas it takes a several days' delay for culture.

Females detected positive for *T. vaginalis* infection along with their partners were treated with oral dose of metronidazole.Treatment was based on positivity in culture after 7 days.

Since the OSOM rapid test is a point-of-care test, it would enhance contact tracing in a difficult-to-reach population. As a result, the test could have an important impact on individual, as well as societal, consequences of untreated STDs. In addition, this rapid test is projected to cost significantly less than culture and nucleic acid amplification methods and approximately the same as wet mount when cost estimates are based on a technician's time.

The limitations of this study are that the OSOM test was performed on frozen samples in batches in a research setting. However, the manufacturer's data demonstrated that freezing and transport of specimens did not appreciably alter the test characteristics [8].

OSOM test could also be used for screening purposes as described in a study conducted by Jones et al [10]. A total of 925 women performed rapid point-of-care tests for *Trichomonas vaginalis* on self-collected vaginal swabs. Using PCR as the gold standard, rapid self-testing achieved high specificity (99.1%; 95% confidence interval [CI], 98.2 to 99.6%) and moderate sensitivity (76.7%; 95% CI, 61.4 to 88.2%).

The new OSOM rapid test, an immunochromatographic capillary flow (dipstick) assay, is simple to perform, objective and can provide results in 10 min, so it may be applied as a point-of-care test. Thus, it will be an important addition to the repertoire of techniques available for *T. vaginalis* detection, especially for facilities without access to a microscope or incubator and in settings where difficult patient follow-up makes point-of-care testing attractive. Its high sensitivity and specificity advocates its use in settings when the culture is not possible as direct microscopic examination and different staining techniques fails to detect infection in large number of cases.

Table 1 Distribution of patients having *Trichomonas vaginalis* infection according to their pregnant and non-pregnant status

Status	*Trichomonas vaginalis* infection (**Culture in Kupferberg Medium**)		Total number of patients
	Absent	**Present**	
Pregnant	114	0	114
Non-pregnant	273	18	291
Total number of patients	387	18	405

Table 2 Distribution of patients suffering from *Trichomonas vaginalis* infection according to their clinical signs

Clinical signs	*Trichomonas vaginalis* infection (**Culture in Kupferberg Medium**)			Total number of patients n = 405
	No	**Absent n = 387**	**Present n = 18**	
Vaginal inflammation		156	0	156
	Yes	231	18	249
Foul smelling discharge	**No**	138	0	138
	Yes	249	18	267
Vaginal discharge type	**Curdy**	96	3	99
	Mucinous	222	6	228
	Serous	69	9	78
Cervical inflammation	**No**	156	0	156
	Yes	231	18	249
Cervical erosion	**No**	309	3	312
	Yes	78	15	93

Table 3 Sensitivity and Specificity of Different Technique Used for the diagnosis of *Trichomonas vaginalis* infection taking Culture in Kupferberg Medium as gold standard

S. No.	Technique Used	Number of patients (%)		Sensitivity (CI)	Specifity (CI)
		Positive	**Negative**		
1.	**Wet mount Examination**	7 (1.7)	398 (98.3)	38.9% (18.2-63.8)	100% (98.7-100)
2.	**Giemsa Staining**	7 (1.7)	398 (98.3)	38.9% (18.2-63.8)	100% (98.7-100)
3.	**Acridine Orange Staining**	12 (3.0)	393 (97.0)	66.7% (41.4-85.6)	100% (98.7-100)
4.	**OSOM Trichomonas Rapid Test**	15 (3.7)	390 (96.3)	83.3% (57.7-95.5)	100% (98.7-100)

REFERENCES

1. World Health Organization. An overview of selected curable sexually transmitted diseases. In: Global program on AIDS. World Health Organization, Switzerland, 1995:2-27.
2. Hardy PH, Hardy JB, Nell EE, Graham DA, Spence MR, Rosenbaum RC. Prevalence of six sexually transmitted disease agents among pregnant inner-city adolescents and pregnancy outcome. Lancet 1984;2:333-7.
3. Minkoff H, Grunebaum AN, Schwarz RH, et al. Risk factors for prematurity and premature rupture of membranes: A prospective study of the vaginal flora in pregnancy. Am J Obstet Gynecol 1984;150:965-72.
4. Gram IT, Macaluso M, Churchill J, Stalsberg H. Trichomonasvaginalis (TV) and human papillomavirus (HPV) infection and the incidence of cervical intraepithelial neoplasia (CIN) grade III. Cancer Causes Control 1992;3:231-6.
5. Krieger JN. Prostatitis syndromes: Pathophysiology, differential diagnosis, and treatment. Sex Transm Dis 1984;11:100-12.
6. Royce RA, Seva A, Gates W, Cohen MS. Sexual transmission of HIV. N Engl J Med, 1997, 336: 1072-8.
7. Laga M, Manoka A, Kivuvu M, et al. Non-ulcerative sexually transmitted diseases as risk factors for HIV-1 transmission in women: Results from a cohort study. AIDS 1993;7:95-102.
8. Huppert JS, Batteiger BE, Braslins P, Feldman JA, Hobbs MM, Sankey HZ, Sena AC, Wendel KA. Use of an Immunochromatographic Assay for Rapid Detection of Trichomonas vaginalis in Vaginal Specimens.J ClinMicrobiol, 2005, 43 (2): 684-687.
9. Huppert JS, Mortensen JE, Reed JL, Kahn JA, Rich KD, Miller WC, Hobbs MM. Rapid antigen testing compares favorably with transcription-mediated amplification assay for the detection of Trichomonas vaginalis in young women. Clin Infect Dis, 2007, 45: 194-198.
10. Jones HE, Lippman SA, Caiaffa-Filho HH, Young T.Performance of a Rapid Self-Test for Detection of Trichomonas vaginalis in South Africa and Brazil. J. Clin. Microbiol. 2013, 51(3):1037-1039.