Diagnosis of Trichomonas Vaginalis Infection in Women of Childbearing Age at a University Setting Using OSOM A New Diagnostic Technique

Mona M. Aboulghar, MD *, Omaima M Aboushady MD ^, Jomana A Ahmed MD ^, Nihal A Hanafy MD ^
*Cairo University, Department of Obstetrics & Gynecology
^Cairo University, Department of Parasitology

ABSTRACT:

Objectives: To investigate the use of OSOM a new diagnostic method in detection of trichomonas vaginalis in women of child bearing age. Methods: Patients in their child bearing age, from the Obstetric and Gynecology out patient clinics at Cairo university hospital, were included. They were complaining of vaginal discharge, itching or both. In addition a control group of asymptomatic patients was included. Vaginal swabs were obtained from all patients and studied using direct wet mount examination, Giemsa staining method and In Pouch TV culture. The OSOM test was done to 100 randomly selected patients only. Results: The mean age of symptomatic patients was 30.6 years, comparable to 31.7 in the asymptomatic patients (p>0.05). Vaginal discharge and itching were the most prevalent symptoms, found in eighty six patients (43%), while 44 patients (22%) had only itching and 70 (35%) had only vaginal discharge. In the studied population the prevalence of infection was 36%. The In Pouch culture was found to have the highest sensitivity and specificity (100%), followed by the OSOM test (87.5%) Wet mount had sensitivity of (56%), while Giemsa stain was the least sensitive (49%). Conclusion: Trichomonas infection is a highly prevalent infection especially in Patients complaining of vaginal discharge and itching. The new OSOM rapid test has a good sensitivity and specificity and is rapid giving immediate results.

Key words: Trichomonis vaginalis, OSOM

INTRODUCTION

Trichomonas is among the most common sexually transmitted non viral infectious diseases worldwide1). The World Health Organization estimated that over 340 million cases of curable STI occurred in 1999 alone. Sexually transmitted infections are responsible for significant morbidity and mortality world wide because of their adverse effects on reproductive health and their ability to increase the risk of sexual and vertical transmission and acquisition of human immune-deficiency virus type I (HIV-I) 2,3).

While T. vaginalis has been found responsible for significant and costly adverse health outcomes, such as pelvic inflammatory disease, vaginitis, cervicitis, preterm labor, urethritis and prostatitis4,5). It can also cause ectopic pregnancy, tubal factor infertility and adverse pregnancy outcomes6,7).

The prevalence of T. vaginalis is likely to be underestimated because there are no guidelines for T. vaginalis screening of women, and clinicians often rely upon insensitive diagnostic methods. Screening for trichomonas infection has been performed using direct microscopy or culture of the organism. However, many programs do not include Trichomonas infection screening.

Laga et al.5 demonstrated a nearly twofold increase in the odds of HIV infection in women infected with T. vaginalis in an African cohort. The research group subsequently demonstrated a 1.7-fold increase in relative risk for HIV infection for women infected with T. vaginalis, suggesting that trichomonas infection may increase women's susceptibility to HIV6,8).

Incorporating trichomonas infection control into (STDs) control programs may be useful to reduce upper reproductive tract infections and adverse outcomes of pregnancy. It may also act as a preventive measure to reduce the spread of HIV7,9).

It is known that about 50% of patients positive for trichomonas are asymptomatic9, however in the group of low socioeconomic standard studied only symptomatic patients seek medical help.

The aim of this work was to study the diagnosis of Trichomonas vaginalis infection in women in the child bearing age including
infertile and pregnant, using OSOM, a new diagnostic technique, compared to older techniques.

MATERIAL & METHODS

The study was carried out from June 2005 to June 2007. Patients included were in the child bearing age; 20-45 years, presenting to Cairo University obstetric and gynecology outpatient clinic, with vaginal discharge, itching or both. A group of females of matching age and socioeconomic status were selected as controls, free of vaginal symptoms.

Exclusion criteria:

Patients already under treatment for infection either by local or systemic treatment.

Pregnant patients with history of rupture of membranes or in active labour.

Approval of local IRB was obtained before starting the study. Full history taking was performed to all patients, including; obstetric history, contraceptive history, infertility investigations including; semen analysis, hysterosalpingography, laparoscopy and hormonal profile were performed when found necessary in infertile patients. In addition history of any systemic disease; diabetes, hypertension was recorded.

All patients underwent thorough gynecological exam including comment on vaginal discharge, skin signs, any tenderness; vaginal or cervical, uterine size & mobility & state of adnexa.

All patients were sampled from the vaginal discharge and the sample taken was used for examination by the following techniques in the following order;

Wet mount preparation; to visualize motile trichomonas vaginalis. Giemsa staining, and Culture of swab using the In pouch culture system (BioMed Diagnostics, Santa Clara, Calif.). The kit allows specimens to be inoculated into the medium contained within the In Pouch TV culture system, this was used for direct examination of the specimen and culture (of T. vaginalis species only) in one self-contained system. The lower chamber of the pouch was examined for trichomonads every 24 hours up to 3 days using the viewing slide in the wet mount examination. The culture was considered negative if no trichomonads were observed after 3 days.

Lastly the OSOM® *Trichomonas* Rapid Test was performed. This is based on color immunochromatographic, capillary flow, “dipstick” technology. It is a test resulting in rapid qualitative detection of *Trichomonas vaginalis* antigens when making wet mounts from vaginal swab. Within 10 minutes the appearance of a visible blue test line along the red control line indicated a positive result. The test was performed on 100 randomly chosen patients; out of which 75 were symptomatic & 25 asymptomatic. Randomization was done using sealed envelopes that were opened by an attending nurse.

Statistical analysis;

Statistical analysis was performed with SPSS (statistical package for social science) software package (Version 9.0 for Windows). For comparison of the groups independent samples Chi-square test was used. A probability value of p<0.05 indicated a statistically significant difference. The results are presented by calculating; Sensitivity, Specificity, Positive predictive value (PPV) and negative predictive value (NPV).

RESULTS

Two hundred Symptomatic patients were included of which; 40 were pregnant, 76 were infertile & 84 patients were using contraception.

A Control group of 100 asymptomatic fertile and pregnant females was also studied (40 pregnant & 60 fertile non pregnant).

The mean age of symptomatic patients was 30.6 years (range 20-45), comparable to 31.7 in the asymptomatic patients (p>0.05).

Vaginal discharge and itching were the most prevalent symptoms, found in eighty six patients (43%), while 44 patients (22%) had only itching, and 70 (35%) had only vaginal discharge.

Seventy two (36%) of symptomatic female patients were found positive for *Trichomonas vaginalis* infection by all the methods done collectively (positive by all tests used), while 6 (6%) of asymptomatic female patients were found positive by the same methods (being only positive using culture). Only 44 (22%), 38 (19%) were detected positive by wet mount and Giemsa stain respectively in symptomatic female patients and none were positive in asymptomatic female patients by either of the two methods, while the In Pouch TV culture detected 72 cases (36%) in symptomatic and 6 (6%) in asymptomatic females. Using the Ozom test on 100 randomly chosen patients, (75
symptomatic and 25 asymptomatic) showed a detection rate of 21%.

The distribution of trichomonas infection according to age group is shown in Table 1.

The distribution of infection in the various groups; pregnant, infertile & using contraceptives is seen in Table 2.

The highest positivity for trichomonas detection by all methods of detection was in patients complaining of itching and vaginal discharge; 72.7% for wet mount, 78.9% for Giemsa staining, 66.7% for IN pouch culture and 71.4% using the OSOM technique.

Detection according to type of investigation in each of the studied groups is seen in Table 3.

Sensitivity, specificity, PPV & NPV of diagnostic techniques in comparison to culture as the gold standard was; 56%, 100%, 100 & 87 for wet mount technique. Forty nine%, 100%, 100 & 85 for Geimsa staining and 87.5%, 100%, 100 & 96 for the OSOM test.

Table 1: Distribution of positivity of T. vaginalis infection and age groups in all 300 patients

<table>
<thead>
<tr>
<th>Test</th>
<th>Wet mount</th>
<th>Giemsa</th>
<th>In pouch</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Group</td>
<td>Number (%)</td>
<td>Number (%)</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>20-25 N=82</td>
<td>10(22.7%)</td>
<td>8(21.1%)</td>
<td>18(23.1%)</td>
<td>18(23.1%)</td>
</tr>
<tr>
<td>26-30 N=76</td>
<td>8(18.3%)</td>
<td>6(15.8%)</td>
<td>16(20.5%)</td>
<td>16(20.5%)</td>
</tr>
<tr>
<td>31-35 N=62</td>
<td>6(13.6%)</td>
<td>6(15.8%)</td>
<td>16(20.5%)</td>
<td>20(25.6%)</td>
</tr>
<tr>
<td>36-40 N=24</td>
<td>14(31.8%)</td>
<td>14(36.8%)</td>
<td>20(25.6%)</td>
<td>20(25.6%)</td>
</tr>
<tr>
<td>41-45 N=24</td>
<td>6(13.6%)</td>
<td>4(10.5%)</td>
<td>8(10.3%)</td>
<td>8(10.3%)</td>
</tr>
</tbody>
</table>

Table 2: The number of trichomonas infection cases in the study groups

<table>
<thead>
<tr>
<th>Number of positive Group name</th>
<th>+ve</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant females Group I</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>Infertile females Group II</td>
<td>20</td>
<td>26.3%</td>
</tr>
<tr>
<td>Females using contraceptive methods Group III</td>
<td>44</td>
<td>52.4%</td>
</tr>
</tbody>
</table>

Table 3: Results of investigations done for 200 symptomatic and 100 asymptomatic females

<table>
<thead>
<tr>
<th>Group Test done</th>
<th>Symptomatic Positive cases N=200</th>
<th>Asymptomatic N=100</th>
<th>Total N=300</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wet mount</td>
<td>N=44 (22%)</td>
<td>0 0%</td>
<td>44 14.7%</td>
</tr>
<tr>
<td>Giemsa stain</td>
<td>N=38(19%)</td>
<td>0 0%</td>
<td>38 12.7%</td>
</tr>
<tr>
<td>In Pouch</td>
<td>N=72(36%)</td>
<td>6 6%</td>
<td>78 26%</td>
</tr>
</tbody>
</table>
DISCUSSION

Trichomoniiasis is an important public health disease that is associated with vaginitis, cervicitis, urethritis, pelvic inflammatory disease (PID) and in some cases infertility. It plays a role in the acquisition and transmission of the human immunodeficiency virus (HIV). In pregnant women trichomonads may be associated with the premature rupture of membranes, premature delivery, and delivery of low-birth weight infants.

The prevalence of trichomonas is reported to be varying, in our study group it was 36% which is high, most likely due to socioeconomic group of patients studied. Others have reported a much less incidence; ranging from 1.3% to 13.3%. The study done in the USA, included patients of varying ethnic origin, and showed factors related to its increase; a greater number of lifetime sex partners, increasing age, lower educational level, poverty, and douching.

Other studies have showed a high prevalence similar to our study using similar diagnostic techniques; 23.4%, 37.4%.

The highest positivity was found in groups complaining of discharge and itching (43%) which makes this an important group to be screened. This is comparable to other studies. El-Gayar and Rashwan, reported vaginal discharge and itching in their symptomatic female patients to be (100%) and (54.4%) respectively.

The highest positivity was found in the age group 36-40 years which represent the group of high sexual activity. Previous reports gave similar results, they recorded median age of women with Trichomonas vaginalis infection 31-39 years in samples obtained from women visiting a general practitioner.

The low sensitivity of wet mount diagnosis of trichomonas in our study (56%) is very similar to other studies, reported sensitivity of wet mount was; 58.5%, 61.9%, 56% and 55% respectively. The reason for this is probably due to deterioration which leads the trichomonads to lose motility, retracted flagella, change morphology by becoming rounder and thereafter become difficult to distinguish from similar structures, such as leucocytes. In addition the examination should be done immediately after collection of specimen and needs experience and access to microscopy.

Similarly Geimsa staining has a low sensitivity of 49% which agrees with previous studies having a low sensitivity of 52.4% and may be explained by the fact that during the microscopic examination of Giemsa staining preparations, it is possible to overlook or not recognize trophozoites, because the organism can be damaged or lost during the process of staining. In addition, the Giemsa staining method is considered subjective.

In the present study, In Pouch culture detected all the positive cases found in all studied groups and was taken as the standard method in diagnosing Trichomonas vaginalis infection, with a sensitivity and specificity of 100%.

The sensitivity of the OSOM test was 87.5% and specificity 100%, the highest sensitivity as compared to wet mount and Giemsa staining. This relatively new technique OSOM, based on color immunochromatographic, capillary flow, “dipstick” technology carries the advantage of being a rapid test done immediately on the specimen. The only disadvantage is cost which was the reason for limiting the test on 100 of our patients.

Similar results have been reported, where the sensitivity and specificity of OSOM vaginal-swab specimens were 83.3 and 98.8%, respectively. And later reported sensitivity and specificity of OSOM at 89.6% & 100% respectively, where OSOM was compared to transcription mediated amplification testing, wet mount and culture for diagnosing trichomoniiasis. In this study transcription mediated amplification testing and rapid antigen tests proved highly sensitive and specific, and both are superior to wet mount. Rapid antigen testing was equivalent to culture.

In the present study, the OSOM test was able to detect T. vaginalis in samples that have a lower organism load missed by wet mount and Giemsa staining and that require longer incubation time in culture before being classified as positive. The OSOM test is 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. In addition, in this study it was reported that, the OSOM test is more sensitive than wet mount for detecting T. vaginalis culture. Therefore, the OSOM rapid test would enhance contact tracing in a difficult-
to reach population. However with a remaining problem of the expense.

More recent literature PCR study using transcription mediated amplification testing gave very good sensitivity and specificity as compared to culture; 100% & 99.6% compared to 69% & 100%.\textsuperscript{23,24} This technique was not used in our study and should be evaluated in future studies compared to the OSOM test.

Conclusion:

Trichomonas infection is a highly prevalent infection in our female population especially in those using contraceptives and in the sexually active age of 36-40. Patients complaining of vaginal discharge and itching should be screened. The new OSOM rapid test has a high sensitivity and specificity and is rapid giving immediate results, with one disadvantage of being an expensive technique. Further studies comparing the OSOM rapid test to PCR testing for detection of trichomonas vaginalis should be conducted.

REFERENCES


