ORIGINAL ARTICLE

EFFICACY OF OSOM TRICHOMONAS RAPID TEST FOR THE DIAGNOSIS OF TRICHOMONIASIS IN FEMALES OF NORTH INDIA
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HOW TO CITE THIS ARTICLE:

ABSTRACT: BACKGROUND: Trichomonas vaginalis causes trichomoniasis, a common sexually transmitted disease, which may lead to adverse sequelae and increased risk of transmission of human immunodeficiency virus infection. Although wet mount examination is the most common test to diagnose it, but culture is considered as gold standard. Newer methods for diagnosis have recently been introduced like OSOM Trichomomas Rapid test which is based on Immunochromatographic assay of trichomonal protein antigens. Hence, the present study was done to evaluate the efficacy of OSOM Trichomonas Rapid test in comparison with conventional methods like Wet mount examination and Culture. MATERIALS AND METHODS: Vaginal swabs were taken from 615 female patients and Wet mount examination, Culture in Kupferberg medium and OSOM Trichomonas Rapid test were performed. RESULTS: Out of 615 patients included in our study, 46 (7.5%) positive cases of trichomoniasis were detected by culture. OSOM Trichomonas Rapid test detected 41 (6.5%) cases, whereas, wet mount examination could detect only 25 (4.1%) cases of Trichomonas vaginalis infection. Sensitivity and specificity of OSOM Trichomonas Rapid test was found to be 84.8% and 99.6% respectively, when compared to Wet mount examination which had sensitivity of 43.5% and specificity of 99.1%. CONCLUSION: As OSOM Trichomonas Rapid test gave results better than Wet mount examination & almost comparable to Culture, it should be recommended for use as a point of care test in peripheral areas lacking laboratory facilities. Since it is a rapid test, it will help in prompt diagnosis and early treatment of patients, thereby, preventing development of adverse sequelae. KEYWORDS: Culture in Kupferberg medium, OSOM Trichomonas Rapid test, Trichomonas vaginalis, Wet mount examination.

INTRODUCTION: Trichomoniiasis is one of the most common sexually transmitted diseases, caused by Trichomonas vaginalis, a parasitic protozoan. Its annual incidence is found to exceed 180 million cases per year.¹ The spectrum of disease ranges from asymptomatic infection to chronic inflammation of the reproductive tract of females and urethritis in males.²,³ Multiple studies have found association of T. vaginalis infection with significant adverse health outcomes, such as, pelvic inflammatory diseases, Human Immunodeficiency Virus infection and Cervical Carcinoma.⁴-⁹ Thus, early diagnosis & prompt management of Trichomaniiasis, will be helpful in preventing associated morbidity in women. The clinical symptoms are non-specific and cannot be relied upon for an accurate diagnosis. Therefore, the diagnosis has to be based on laboratory procedures.

Several methods have been developed for the detection of T. vaginalis. The conventional methods for diagnosis of T. vaginalis involve direct microscopic examination of wet mount and culture. Although, wet mount examination of clinical specimens is the most common and least expensive technique for identifying T. vaginalis, but it requires expertise and access to a
microscope.[10] Even in the hands of trained observers, the wet mount examination is only 36 to 75% sensitive compared to culture.[11]

The present “gold standard” for the diagnosis of *T. vaginalis* is Culture and various culture media have been described like Diamond’s, Trichosel, Kupferberg and InPouch TV.[1,12,13] However, the unavailability of culture facilities make it a difficult procedure for routine diagnostic laboratories with little or no expertise.

Newer diagnostic methods for Trichomoniasis have recently become commercially available that do not require the presence of viable flagellate. OSOM Trichomonas Rapid test (Genzyme Diagnostics, United Kingdom) is a new point of care immunochromatographic monoclonal-antibody based detection system which is highly sensitive and specific. It has been approved by US Food and Drug Administration (FDA) for use on a direct vaginal swab or on used wet mount saline.[14]

Hence, the present study was done to evaluate the efficacy of OSOM Trichomonas Rapid test in diagnosing vaginal trichomoniasis and to compare it with conventional diagnostic methods like wet mount and culture.

**MATERIALS AND METHODS:** The study was a hospital based prospective study done over a 1 year period from April 2009 to March 2010.

**Study Group:** The study group comprised of 615 females of reproductive age group (15-45 years) attending gynecological out-patient department with complaints of foul smelling vaginal discharge, pruritis, dysuria, dyspareunia and pain in lower abdomen.

**Exclusion Criteria:** Females, who had recently douched, used spermicidal agents within 72 hours prior to testing and those who were menstruating at the time of examination were excluded from the study.

The study was approved by the Institutional Ethics Committee. An oral informed consent was taken from all the patients, followed by history and physical examination. The patients were then asked to lie in lithotomy position and examined with a vaginal speculum lubricated with water only (no antiseptic used). Vaginal fluid was collected from posterior fornix of the vagina by using sterile swabs. Three swabs were collected from each patient for performing wet mount examination, culture and OSOM Trichomonas Rapid test respectively.

**Wet Mount Examination:** Vaginal swab was placed in a tube containing 0.5ml of saline and mixed vigorously. It was then removed and depressed onto a clean and dry glass slide to express a small amount of liquid. A coverslip was placed and the slide was examined under light microscope at 40X.[14] Motile protozoa with characteristic jerky movements were noted.

**Culture in Kupferberg Medium:**

**Medium Preparation:** Kupferberg Trichomonas medium was prepared by dissolving 23.5 g of the Kupferberg Trichomonas base (Hi Media Laboratories, India) in 950 ml of distilled water and sterilized by autoclaving at 121°C for 15 minutes. It was then cooled to 50-55°C in a water bath and 50 ml of sterile bovine serum was added aseptically. The medium was supplemented with rehydrated contents of Trichomonas selective supplement I (Hi Media Laboratories, India) containing...
Streptomycin 500 mg and Penicillin G 1,25,000 Units. The culture medium was mixed well and dispensed in a glass screw-capped bottle and stored at 4°C.

**Cultivation:** Before the inoculation of the medium, culture bottles were warmed to 37°C for 15 minutes. The vaginal swabs were placed into the culture medium and incubated at 37°C. The cultures were examined microscopically on 3rd, 5th and 7th day respectively.[1] A positive result was defined as the presence of motile *T. vaginalis* at any time of examination and negative result was defined as the absence of motile trichomonads after 7 days of incubation.

**OSOM Trichomonas Rapid Test:**

**Principle of Test:** The OSOM Trichomonas Rapid test (Genzyme Diagnostics, United Kingdom) uses immunochromatographic, capillary flow and dipstick technology. The test procedure requires the solubilization of trichomonas proteins from a vaginal swab by mixing the swab in sample buffer. Trichomonas present in the sample will form a complex with the primary anti-trichomonas antibody conjugated to colored particles. The complex will then bind to second anti-trichomonas antibody coated on the nitrocellulose membrane. The appearance of a visible blue test line along with the red control line indicates a positive result.

**PROCEDURE:** The test was performed according to manufacturer’s instructions (Genzyme Diagnostics, United Kingdom). Vaginal swab was placed in a tube containing 0.5ml of sample buffer with 0.01% sodium azide, and mixed vigorously. This tube was then allowed to stand for 1 minute after which OSOM Trichomonas Rapid Test stick was placed in it and result was read at 10 minutes. A positive result was indicated by the presence of a blue test line along with a red control line, whereas negative result was indicated by the appearance of only a red control line (Figure 1).

**Statistical Analysis:** The collected data were analyzed by using SPSS Data Editor Software, version 16 (SPSS Inc, United States). Pearson's Chi-square test was performed and P values <0.05 were considered statistically significant.

**RESULTS:** A total of 615 female patients of reproductive age group (15-45 years) were included in the study. The mean age of the patients was 30.56±0.3 years. Out of 615 patients, maximum cases of trichomoniasis (7.5%) were detected by culture in Kupferberg medium, followed by OSOM Trichomonas Rapid Test (6.7%), whereas, least number of cases (4.1%) was detected by wet mount examination (Figure 2).

Out of the 46 positive cases detected by culture, 39 (84.8%) were positive by OSOM Trichomonas Rapid test and only 20 (43.5%) were positive by wet mount examination. A correlation was done between all the diagnostic tests performed and it was found that out of 46 positive cases of trichomoniasis, 20 cases were detected by all the three tests, whereas, 2 cases detected by OSOM Trichomonas Rapid test and 5 cases detected by wet mount examination were negative in culture (Figure 3).

A comparison of the efficacy of the test procedures was done by taking culture as the gold standard and calculating the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of wet mount examination and OSOM Trichomonas Rapid test (Table 1). By
putting Pearson’s Chi-square test it was found that the difference between the sensitivity of OSOM Trichomonas Rapid test and wet mount examination was statistically significant (P<0.001).

**DISCUSSION:** In our study, out of the 615 patients tested, 25 (4.1%) were positive for *T. vaginalis* infection by wet mount examination. When compared with culture, the sensitivity of wet mount examination was found to be 43.5%. This is comparable to another study which reported the sensitivity of wet mount as 35.69% with respect to culture.[15] Although, a positive wet mount is diagnostic because of its high specificity, a negative test cannot exclude trichomoniasis because of low sensitivity.[16] Sluggish motility or low number of trichomonas can be easily missed. And also, douching prior to physical examination can lower the detection of motile trichomonas.[17]

Culture is the most accurate method for detecting the presence of *T. vaginalis* as it has high sensitivity. In our study, 46 (7.5%) out of 615 patients were positive for trichomoniasis as diagnosed by culture in Kupferberg medium. A previously done study also showed good growth of *T. vaginalis* in this medium.[1] However, laboratory facilities for culture are not widely available to physician, and it takes 2 to 7 days to give positive results. This often results in loss of patients in follow-up. This problem of delayed diagnosis and difficult patient follow-up can be overcome by the use of rapid tests.

OSOM Trichomonas Rapid test gave positive results in 41 out of 615 patients (6.7%) included in our study, which is comparable to that of culture. It performed well and showed high sensitivity and specificity of 84.8% and 99.6% respectively, whereas, the sensitivity and specificity of wet mount examination was found to be 43.5% and 99.1% respectively. Our findings are supported by studies done by different workers who have also shown good performance of this rapid test with high sensitivity and specificity in comparison to wet mount examination.[14,18,19]

**CONCLUSION:** Although wet mount examination is used as a primary method for diagnosis of *T. vaginalis* infection, it is less sensitive, time consuming, needs technical expertise and a microscope for diagnosis. In remote areas, the non-availability of microscope and trained personnel makes its diagnosis difficult.

The OSOM Trichomonas Rapid Test had a good sensitivity (84.8%) and gave almost comparable results with culture. It is a point of care test useful in set up lacking microscopic and culture facilities. It is more sensitive than wet mount and requires less technical expertise and time than *T. vaginalis* culture. It is simple to perform and provides result in ten minutes. In the present study, the rapid test detected several culture positive samples that were wet mount negative and thus, it may be a useful adjunct test for wet mount negative subjects where culture is not available. Our findings support and expand upon the recommendation by Centre for Disease Control (CDC) to provide additional *T. vaginalis* testing for wet mount negative women.

**REFERENCES:**


Table 1: Comparison of efficacy of OSOM Trichomonas Rapid test and Wet mount examination taking culture as gold standard

<table>
<thead>
<tr>
<th>Diagnostic tests</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
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<td>80.0</td>
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<td>99.6</td>
<td>95.1</td>
<td>98.8</td>
</tr>
</tbody>
</table>

**Figure 1**: Results of OSOM Trichomonas Rapid Test. Positive result has blue line along with red control line.

**Figure 2**: Bar graph showing the number of patients tested for Trichomonas vaginalis presence and absence.

- **Wet mount examination**: 25 patients with Trichomonas vaginalis present, 41 patients with Trichomonas vaginalis absent.
- **OSOM Trichomonas Rapid test**: 590 patients tested.
- **Culture in Kupferberg medium**: 569 patients tested.
Figure 2: Distribution of patients suffering from *Trichomonas vaginalis* infection detected by different diagnostic tests.

Figure 3: Correlation of different diagnostic tests in positive cases of trichomoniasis.

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