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ORIGINAL ARTICLE

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Can trichomonas immunochromatographic test increase the validity and reliability of WHO syndromic algorithm for vaginal discharge as a screening tool for trichomoniasis?

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Abstract

Background: Trichomoniasis is a sexually transmitted parasitic infection. The World Health Organization (WHO) advocated flow charts for curable sexually transmitted infections (STIs) to improve the care. In this study, an attempt was made to evaluate the validity and reliability of WHO syndromic algorithm for vaginal discharge against trichomonas immunochromatographic test (ICT). Trichomonas ICT is a test with high validity, reliability, and feasibility. **Objectives:** The objective was to evaluate the validity and reliability of "WHO syndromic algorithm for vaginal discharge" against "trichomonas ICT" as a screening tool for trichomonas infection among women of reproductive age in the Western Province, Sri Lanka. **Materials and Methods:** This cross-sectional study was conducted in sexually transmitted disease clinics, well woman clinics, gynecology clinics, and institutional health clinics in the Western Province, Sri Lanka. We enrolled 100 women in the age group of 15-45 years using the stratified random sampling method. They were interviewed and examined and the specimens were collected to identify trichomoniasis by culture and ICT. Two-stage analyses were done to evaluate the performance of the WHO algorithm against Trichomonas ICT. **Results:** In a two-stage analysis, the specificity of syndromic algorithm improved from 80.9% to 94.4% while false positive rate reduced from 19.1% to 5.6%. The net effect of specificity was 98.7% while the false positive rate was 1.3%. **Conclusion:** The validity and reliability of WHO syndromic algorithm as a diagnostic tool for trichomoniasis can be improved by adding trichomonas ICT.

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Introduction

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Trichomoniasis is a sexually transmitted parasitic infection and considered as an orphan in the field of medicine as it is underdiagnosed and undertreated by the medical community. The World Health Organization (WHO) estimated that it accounts for a prevalence of 153 million cases and 248 million new cases among adults in the age group of 15-49 years in the world. The prevalence among women accounts for over 17 million. [1] Vaginal trichomoniasis has been linked to complications such as preterm birth, premature rupture of membranes, low birth weight, postabortion or posthysterectomy infection, and acquisition and transmission of human immunodeficiency syndrome (HIV). [2][3][4] *Trichomonas vaginalis* (*T. vaginalis*) is a predictor for cervical neoplasia. [5] *T. vaginalis* can also reduce the chances of conception for both females and males. [6]

About 10-50% of trichomoniasis-infected women are asymptomatic. Symptomatic females present with a vaginal discharge (50-70%), dyspareunia (50%), and pruritus (25-50%). [7] The common method of detecting trichomoniasis is wet mount microscopy. However, this becomes a setback in resource-poor settings where diagnostic facilities or resource persons are not available. Coexistence of trichomoniasis with other sexually transmitted infections (STIs) such as bacterial vaginosis, candidiasis, and gonorrhea complicates the proper identification of the condition [4] that depends on the experience of the care provider.

The user-friendly syndromic case management of curable STIs is advocated and recommended by the WHO as being ideal for primary care settings. One of the main concerns regarding STIs is the high possibility of acquiring HIV by STI-infected individuals. Syndromic approach has grouped together infections that cause similar symptoms and signs, and flow charts assist the health care worker to work out a diagnosis. The objective of the process is to deliver effective treatment quickly during the health worker's first encounter. In addition, health education with condom promotion and partner tracing are also targeted as part of the management. However, the cost and side effects of overtreatment remains a major disadvantage of this method.

Trichomonas immunochromatographic test (ICT) has emerged as a test with high validity, reliability, and feasibility. It uses color chromatography, capillary flow, and dipstick technology. If the trichomonas antigen is present in the sample, it forms a complex with the primary antitrichomonas antibodies conjugated to colored particles. This antigen-antibody complex is captured by a second antitrichomonas antibody coated on the nitrocellulose strip. The appearance of a visible blue test line, along with the red control line, will indicate a positive result.

The objective of this study was to evaluate the validity and reliability of "WHO syndromic algorithm for vaginal discharge" against "trichomonas ICT" as a screening tool for trichomonas infection among women of reproductive age in the Western Province, Sri Lanka.

Materials and Methods

This cross-sectional study was conducted in STI clinics, well woman clinics, gynecology clinics, and institutional health clinics in various private and government institutions in the Western Province, Sri Lanka. We enrolled 100 women in the age group of 15-45 years using stratified random sampling method.

Exclusion criteria

Females who were taking antibiotics at the time of data collection or during the previous 2 weeks and those who had no history of sexual contact/virgins, refused vaginal examination, refused participation in the study, and were pregnant were excluded from the study.

Data collection

Details of vaginal discharge and other associated symptoms were collected using an interviewer-administered questionnaire. All the participants underwent clinical and speculum examinations by a medical doctor and relevant clinical signs from the external and internal genitalia were recorded. Two high vaginal swabs from each patient were collected for etiological identification of *T. vaginalis* by culture using a modified cysteine-peptone-liver infusion-maltose (CPLM) culture medium (HIMEDIA[®] Ref M 460, Mumbai, India) and trichomonas ICT (OSOM[®] trichomonas rapid test, Genzyme Diagnostics, Cambridge, MA, USA). Trichomonas ICT is a qualitative assay for the detection of *T. vaginalis* antigens by an immunochromatographic dipstick technology using the saline solution prepared from a vaginal swab.

Data analysis

Data were analyzed using SPSS for Windows, Version 16.0. (SPSS Inc., Chicago). Validation of WHO syndromic algorithm for vaginal discharge against trichomonas ICT was carried out. Then, two-stage analyses were done to evaluate the performance of the WHO algorithm against trichomonas ICT. The WHO syndromic algorithm flow chart 1 for vaginal discharge was summarized for the analysis as those women with vaginal discharge and vulval itching/burning or dysuria at presentation were having trichomoniasis. In addition, they may have symptoms of lower abdominal pain, history of STIs, and may have erythema in the vaginal mucosa on examination (optional features for diagnosis). The true positives (etiological diagnosis of *T. vaginalis*) were determined by culture that is the gold standard laboratory test. The sensitivity, specificity, positive predictive value, negative predictive value, and false positive rate were calculated at each step of the analysis. Finally, the net effect on WHO syndromic algorithm for vaginal discharge with the addition of trichomonas ICT was calculated.

Ethical clearance

The study was approved by the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jaywardenepura and the Ethical Review Committee of Colombo South Teaching Hospital.

Results

There were 100 females who participated in the study. They were in age group of 15-45 years and 64% were married at the time when the study was conducted or had been married in the past. Out of the total, 57% of the females were in the symptomatic category.

Summary of the validation data of WHO syndromic algorithm for vaginal discharge against the trichomonas ICT is shown in [Table 1] and [Figure 1]. The WHO syndromic algorithm for vaginal discharge was unable to detect any of the positives by ICT. Instead, it erroneously detected 18 ICT negative females as positives.

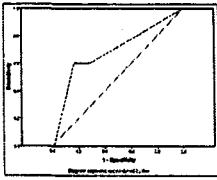


Figure 1: Receiver operating characteristic (ROC) curve Area under the curve is 0.688

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WHO syndromic algorithm for vaginal discharge (n)	Trichomonas ICT (n)		Total
	Positive	Negative	
Positive	0/0	18/180	18/180
Negative	18/180	72/810	90/900
Total	18/180	90/900	108/1080

Table 1: Validation of WHO syndromic algorithm for vaginal discharge against trichomonas ICT

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The two-stage analyses to evaluate the performance of the WHO algorithm against trichomonas ICT are shown in [Table 2] and [Table 3]. Gradual increase of specificity with declining false positive rate was the most significant finding.

Stage 1

WHO syndromic algorithm for vaginal discharge (n)	Trichomonas culture (n)		Total
	Positive	Negative	
Positive	0/0	18/180	18/180
Negative	6/72	76/828	82/900
Total	6/72	94/908	100/1000

Sensitivity	0.0%
Specificity	92.9%
Positive predictive value (PPV)	0.0%
Negative predictive value (NPV)	92.9%
False positive	8.1%

Table 2:

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Stage 2

Trichomonas ICT (n)	Trichomonas culture (n)		Total
	Positive	Negative	
Positive	0/0	1/100	1/100
Negative	0/0	17/170	17/170
Total	0/0	18/180	18/180

Sensitivity	0.0%
Specificity	94.4%
Positive predictive value (PPV)	0.0%
Negative predictive value (NPV)	100%
False positive	5.6%

Table 3:

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The net effect on WHO syndromic algorithm for vaginal discharge with the addition of trichomonas ICT is shown in [Table 4].

Net effect

WHO syndromic algorithm for vaginal discharge (n)	Trichomonas culture (n)		Total
	Positive	Negative	
Positive	0/0	1/100	1/100
Negative	0/0	76/828	76/828
Total	0/0	77/828	77/828

Sensitivity	0.0%
Specificity	98.7%
Positive predictive value (PPV)	0.0%
Negative predictive value (NPV)	92.2%
False positive	1.3%

Table 4:

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Discussion

In trichomoniasis, about 10-50% of infected women are asymptomatic. Since the WHO syndromic algorithm is applied only to those who present with vaginal discharge or vulval itching/burning, it will exclude all those infected "asymptomatic" patients at the outset and make it unsuitable for community screening on its own.

Syndromic case management is defined as identifying a consistent group of symptoms and easily recognized signs for treatment. However, trichomoniasis being devoid of consistent or pathognomonic clinical features to aid this concept, the WHO syndromic algorithm becomes debatable.

Sensitivity indicates the power of a screening tool to identify individuals suffering from the infection. According to the findings of the study, using the WHO syndromic algorithm the health care worker is unable to detect any true positives, thereby making it an unsuitable tool for community screening.

Meanwhile, it erroneously detected 18 uninfected females. Apart from receiving unnecessary treatment, these women may subject to the stigma of having a STI. It may prevent them from seeking treatment for the true incidence of STIs and may also lead to conflicts with the spouse and psychological problems. Inadvertent treatment with metronidazole can also enhance the existing metronidazole resistance against *T. vaginalis*. [8]

In the two-stage analysis, the specificity of syndromic algorithm improved from 80.9% to 94.4% while false positive rate dropped sharply from 19.1% to 5.6%. The net effect of specificity of the combined effect of WHO syndromic algorithm and trichomonas ICT was 98.7% while the false positive rate was 1.3%. This denotes that the specificity of

the WHO syndromic algorithm for vaginal discharge can be improved to nearly 99% by adding trichomonas ICT to the screening process. Specificity signifies the ability of a test to correctly identify individuals without the infection. Specificity is a must-have tool for conditions such as STIs that are associated with stigma, especially in Asian culture.

The OSOM trichomonas rapid test is easy to perform, gives results within 10 min, and can be stored at room temperature with a shelf life of 16 months, thereby making it an ideal point-of-care technique. The reported sensitivity is of 83.3-97.98% range and specificity is of 97.5-99.37% range against a composite reference standard of wet mount microscopy and culture. [9][10] When trichomonas ICT was validated against wet mount, 100% sensitivity and 97.5% specificity were reported [11] while the same against culture was 90% and 92.5%, [12] correspondingly. These research findings are much higher than the performance indicators stated by the manufacturer. Thus, it can completely replace or supplement the WHO syndromic algorithm tool. Yet, further analysis may be required to address aspects of its affordability and advantages in the settings of developing countries.

Conclusion

According to the findings of this study, WHO syndromic algorithm for vaginal discharge is a poor screening tool to be used in the community for the diagnosis of trichomoniasis infection. The validity and reliability of WHO syndromic algorithm as a diagnostic tool for trichomoniasis can be improved immensely by adding trichomonas ICT.

Recommendations

Complete replacement or supplementation of syndromic algorithm tool with a point-of-care diagnostic tool such as trichomonas ICT can be recommended based on the findings of this study. However, replication of the study is recommended to verify the results in a larger sample.

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Conflicts of interest

There are no conflicts of interest.

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