

Efficacy of rapid diagnostic tests for trichomoniasis and bacterial vaginitis

Original
Article

Waleed M Tawfik¹, Heba M Aboelela², Hasnaa S Abdelhamid³, Abdelbar M Sharaf⁴

Departments of Obstetrics and Gynecology¹, Faculties of Medicine, Benha¹ and Menoufia⁴ Universities, Parasitology², and Medical Microbiology and Immunology³ Faculty of Medicine, Benha University, Benha, Egypt

ABSTRACT

Background: Mixed *Trichomonas* vaginitis (TV) and bacterial vaginosis (BV) seriously affect females' reproductive and sexual health. Misdiagnosis may predispose to continued symptoms and inappropriate treatment. This necessitated trials to evaluate the diagnostic performance of simple tests to rapidly and accurately diagnose vulvovaginitis (VV).

Objective: To evaluate the efficacy of OSOM[®] *Trichomonas* rapid test and the comprehensive 4-parameter (C-4-P) test for TV and BV, respectively in women with VV.

Patients and Methods: Vaginal swabs of 85 non-pregnant women with VV were collected. Diagnosis of TV was achieved by anaerobic broth culturing of swabs, the capillary-flow dipstick OSOM[®] rapid test for detection of antigen, the colorimetric detection of the sialidase enzyme activity (SNA) and leukocyte esterase (LE), and determination of vaginal pH and H₂O₂ levels by the C-4-P test. Diagnosis of BV was by the Nugent scoring system for Gram-stained vaginal smear.

Results: The culture detected 8 positive specimens for trichomoniasis (9.4%). The OSOM[®] test detected positive cases with 100% specificity and positive predictive value (PPV), with 87.5% sensitivity and 98.72% negative predictive value (NPV), and 98.82% accuracy rate. The Nugent scoring system defined 25 negative, 39 intermediate, and 21 positive smears for BV. The C-4-P test differentiated the intermediate smears as 27 positives and 12 negatives and showed sensitivity and specificity rates of 95.24% and 92%, respectively with PPV and NPV of 90.91 and 93.48 and 93.48% accuracy rate for BV diagnosis.

Conclusion: The OSOM[®] and the C-4-P rapid tests provided high diagnostic performance for TV and BV with accuracy rates of 98.82% and 93.48%, respectively, and thus might spare the need for culture and molecular methods to save time and resources.

Keywords: bacterial vaginosis; C-4-P test; nugent scoring system; OSOM[®] rapid test; trichomoniasis.

Received: 24 January, 2025; **Accepted:** 17 April, 2025.

Corresponding Author: Heba M. Aboelela; **Tel.:** +20 1273438995; **Email:** heba.mahmoud@fmed.bu.edu.eg

Print ISSN: 1687-7942, **Online ISSN:** 2090-2646, **Vol. 18, No. 1, April, 2025.**

INTRODUCTION

Trichomonas vaginalis is a protozoan parasite that possesses an uncommon and complex cytoskeleton formed of several fibers and proteinaceous structures associated with basal bodies^[1]. Adherence of extracellular trophozoite to vaginal wall cells is required for infection to develop. During attachment, it changes its ovoid shape to a flat ameboid form to expand its contact surface and colonize mucosal epithelial surfaces or migrate through tissues^[2]. A common vaginal bacterial infection that causes BV is characterized by low levels of *Lactobacillus* spp. which is the dominant flora in the healthy vagina, leading to increased levels of nonoptimal anaerobes^[3]. Vaginal anaerobic dysbiosis is responsible for the unpleasant vaginal discharge and odor that characterizes BV^[4].

Mixed infectious vaginitis poses a serious threat to females' general health with special regard to their reproductive and sexual health. This high risk is secondary to the complex pathogenic factors, long

course of infection that may be asymptomatic or unnoticeable, easy recurrence, antibiotic resistance, and secondary dysbiosis^[5]. Inaccurate or delayed diagnosis leads to continued symptoms, repeat visits, inappropriate treatment, and unnecessary costs^[6].

Diagnosing the causative agent for vaginitis typically depends on a combination of presenting symptoms, medical history, physical examination, and laboratory-based testing which demonstrates varying sensitivity and specificity^[7]. Alternatively, the use of molecular-based assays increases sensitivity for the detection of vaginitis causes^[6]. However, the expensive molecular-based assays and their unavailability especially in low-income countries, necessitated trials to evaluate the diagnostic performance of simple office-based tests for the diagnosis of VV^[8]. Accordingly, the present study is a trial for evaluation of the performance of OSOM[®] *Trichomonas* rapid test and C-4-P test for the diagnosis of TV and BV, respectively in non-pregnant women presenting with clinical manifestations of VV.

PATIENTS AND METHODS

This prospective multicenter observational study was conducted at the Departments of Obstetrics and Gynecology, Faculty of Medicine, Benha and Menoufia Universities in conjunction with Medical Parasitology and Medical Microbiology, Faculty of Medicine, Benha University. The study was performed during the period from October, 2024 to December, 2024.

Study design: Non pregnant women younger than 40 y and complaining of vulvovaginitis were enrolled from the Gynecology outpatient clinics at Benha and Menoufia Universities in a clinical study to evaluate the performance of OSOM® *Trichomonas* rapid test and C-4-P test for the diagnosis of TV and BV, respectively.

Patients: Non-pregnant women attending the Gynecology outpatient clinics at the shared hospitals were subjected to evaluation to ensure the inclusion criteria. Patients (no.=100) were subjected to a questionnaire to determine patients' demographic data including age, marital status, menstrual history, history of previous pregnancies, number of deliveries, and living offspring. Patients were inquired about the manifestation of VV including the presence of vaginal discharge and its characteristics, associated symptoms especially vaginal or vulvovaginal itching, burning during micturition, and sexual manifestations including dyspareunia, bleeding on vaginal touch, decreased libido. Inclusion criteria included non-pregnant women younger than 40 years and complaining of VV manifestations. The exclusion criteria stressed on the presence of acute or chronic diseases, especially inflammatory, autoimmune, and immune disturbing diseases, and refusal to participate in the study.

Clinical examination: According to Tchoudomirova *et al.*^[9], patients complaining of vaginal itching, thin discolored vaginal discharge, foul-smelling, "fishy" vaginal odor, and burning during urination were provisionally diagnosed as having BV, and TV was suspected if patients complained of the presence of homogeneous, thin discharge with a milk-like consistency. Patients were inspected for itching marks, and the presence of outflowing discharge and its possible characteristics were recorded. With the patient in lithotomy position, a bivalve vaginal speculum was inserted to allow inspection of the vaginal walls for signs of inflammation. The presence of 'strawberry cervix' was highly suggestive^[10].

Sampling: Two high vaginal swab samples saturated with vaginal fluid, were obtained from the lateral vaginal wall or the posterior fornix of each patient. The samples were labelled and inserted in sterile perfectly closed tubes and sent to the lab.

Parasitological examination: One swab was subjected to conventional parasitological examination including a

saline wet mount, and Giemsa stained smear to identify the sharply outlined dark blue trophozoites with a red nucleus, flagella and the undulating membrane, under 100x magnification^[11]. The second swab was introduced into Diamond's TYI medium broth tube and incubated anaerobically at 37°C; within 48 h^[12].

The OSOM® *Trichomonas* rapid test^[13]: The test (Genzyme Diagnostics, UK) is a qualitative immunochromatographic assay for rapid detection of *T. vaginalis* antigen from genital swabs. It utilizes capillary flow dipstick technology. The procedure is based on solubilized *Trichomonas* proteins in the swabs' mixing buffer. Introduction of a sample test dipstick allows migration of the sample along its membrane surface. Trichomoniasis antigen forms a complex with the primary anti-*Trichomonas* antibody conjugated to blue-colored particles. The complex bound by a second anti-*Trichomonas* antibody coated on the nitrocellulose membrane forms a visible blue test line along with a red control line (internal control) indicating a positive result^[14].

Bacteriological examination: The conventional bacteriological examination included the Whiff test^[15] and microscopic examination of Gram stained vaginal smears. The stained smears were scored according to the enumeration of Gram-positive *Lactobacillus* versus Gram-negative bacteria using the Nugent scoring system that scored negative BV samples by 0-3, altered samples or indeterminate samples as 4-6, while positives were scored as 7-10^[14].

The C-4-P test: The test (Ray Biotech, UK) is based on detection of chemicals produced secondary to vaginal infection leading to raised pH levels. By bacterial expression of SNA an inflammatory response with leukocytic infiltration is induced leading to elevated levels of LE. Finally, the hydrogen peroxide (H₂O₂)-producing *Lactobacilli* spp. decrease or disappear with subsequent decreased H₂O₂ concentrations in the vaginal tract^[16].

Statistical analysis: Statistical analyses were conveyed by IBM®SPSS®Statistics software (Ver. 26, 2019; IBM Corporation; Armonk, USA). Data normality was assessed using the Kolmogorov-Smirnov test of normality and the normal Q-Q plots. The data were presented as numbers and percentages, and the significance of the differences was assessed using the Chi-square test. The significance of the analysis was evaluated at the cutoff point of $P > 0.05$. For test performance characteristics; the sensitivity and specificity rates, the positive predictive value (PPV) and the negative predictive value (NPV), and the accuracy rate of the used tests against the TV culture and the Gram-stained Nugent score, respectively.

Ethical considerations: The study protocol was approved by the Local Ethics Committee, Faculty of

Medicine, Benha University by number:14/11/2024. All patients signed a written consent to participate in the study. They were informed with the study results and subjected to the appropriate care and treatment.

RESULTS

In the present study, 100 non-pregnant women presented manifestations of vulvovaginitis: 15 were excluded of which 6 were diabetics, 4 had inflammatory disorders, 2 had autoimmune disorders, and 3 patients refused to attend the study. However, 85 women

fulfilled the inclusion criteria and were included in the survey (Fig. 1). The inclusion data of the surveyed women are shown in table (1).

The anaerobic broth culture and saline wet mount for the obtained swabs detected 8 (9.4%) positive specimens for trichomoniasis. Only 6 (7.06%) of the positive mounts were also positive by culture. The Giemsa staining confirmed the 6 cases positive by smears and culture, but missed diagnosing a proven case of trichomoniasis by culture, and falsely diagnosed 2 (2.35%) smears as positive, while culture assured the absence of the growth. The OSMO® test gave

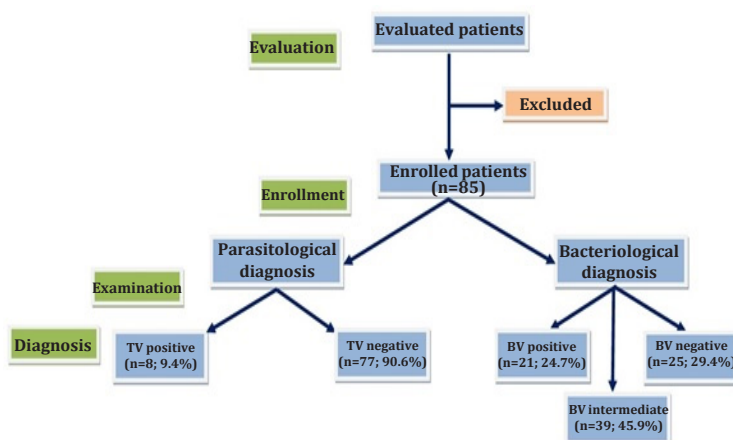


Fig. 1. The study flowchart.

Table 1. Patients' demographic and obstetric data.

Data		Findings
Age (years)	25-29	45 (53%)
	30-35	28 (32.9%)
	>35	12 (14.1%)
Menstrual history	Regular	68 (80%)
	Irregular	17 (20%)
Current marital status	Married	64 (75.3%)
	Divorced	17 (20%)
	Widow	4 (4.7%)
Gravidity (G)	G1:G2:G3:G4	23:52:8:2
Parity (P)	P1:P2:P3	34: 50: 1
Living offspring	1:2:3	41: 43:1

Data are presented as numbers, percentages, mean±SD, and ratios.

Table 2. Results of the studied tests versus culture for diagnosis of trichomoniasis.

Standard test Evaluated test results		The anaerobic broth culture for <i>T. vaginalis</i>		
		Positive	Negative	Total
Saline wet mount test	Positive	6 (7.06%)	2 (2.35%)	8 (9.41%)
	Negative	2 (2.35%)	75 (88.24%)	77 (90.59%)
	Total	8 (9.41%)	77 (90.59%)	85 (100%)
Giemsa staining	Positive	6 (7.06%)	2 (2.35%)	8 (9.41%)
	Negative	1 (1.18%)	76 (89.41%)	77 (90.59%)
	Total	7 (8.24%)	78 (91.76%)	85 (100%)
OSMO® test	Positive	7 (8.24%)	0	7 (8.24%)
	Negative	1 (1.18%)	77 (90.59%)	78 (91.76%)
	Total	8 (9.41%)	77 (90.59%)	85 (100%)

Data are presented as numbers, and percentages.

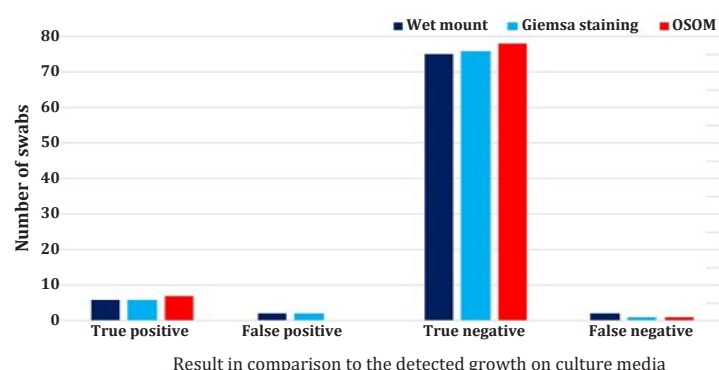


Fig. 2. Diagnostic yield of studied methods relative to results of swabs culture for diagnosis of TV.

superior results by detecting 7 positive tests that were confirmed by culture as positive and 78 negative tests that were also confirmed by culture as negative for trichomoniasis in 77 swabs, and one OSOM® test was false negative (Table 2, Fig. 2).

The diagnostic performance of the studied tests for diagnosing trichomoniasis versus culture, defined a sensitivity rate and PPV of 75%, specificity rate and NPV of 97.4%, and 95.29% accuracy rate for diagnosis of trichomoniasis by the saline wet mount test. Giemsa staining had sensitivity and specificity rates of 85.71% and 97.44%, respectively, and PPV and NPV of 75% and 98.7% respectively, with an accuracy of diagnosis of 96.47%. In contrast, the OSMO® test showed 100% specificity and PPV, with 87.5% sensitivity, 98.72% NPV, and an accuracy of trichomoniasis diagnosis of 98.82% (Table 3, Fig. 3).

The Nugent scoring system for BV recorded 25 negative (29.4%), 39 intermediate (45.9%), and 21 positive smears (24.7%). The Whiff test detected 11 positive smears out of the 21 positives for Nugent scoring system with a positive coincidence rate of 52.4%, and the 17 negative tests assured negativity of 17 smears

by the scoring with a negative coincidence rate of 68%. The Whiff test differentiated the intermediate smears as 10 (25.6%) positives and 29 (74.4%) negatives. According to the Whiff test, the collective

positive diagnosis of BV was 29 smears (34.1%), while the remaining 56 smears (65.9%) were diagnosed as negative for BV.

Table 3. Diagnostic performance characteristics of the studied tests for trichomoniasis relative to culture as gold standard.

Test performance character	Saline wet mount		Giemsa staining		OSOM® test	
	Value	95% CI	Value	95% CI	Value	95% CI
Sensitivity	75%	34.91-96.81%	85.71%	42.13-99.64%	87.5%	47.35-99.68%
Specificity	97.4%	90.93-99.68%	97.44%	91.04-99.69%	100%	95.32-100%
Disease prevalence	9.41%	4.15-17.71%	8.24%	3.38-16.23%	9.41%	4.15-17.71%
PPV	75%	41.91-92.58%	75%	42.5-92.41%	100%	59.04-100%
NPV	97.4%	91.86-99.2%	98.7%	92.52-99.79%	98.72%	92.49-99.79%
Accuracy	95.29%	88.39-98.7%	96.47%	90.03-99.27%	98.82%	93.62-99.97%

PPV: Positive predictive value; NPV: Negative predictive value; CI: Confidence interval.

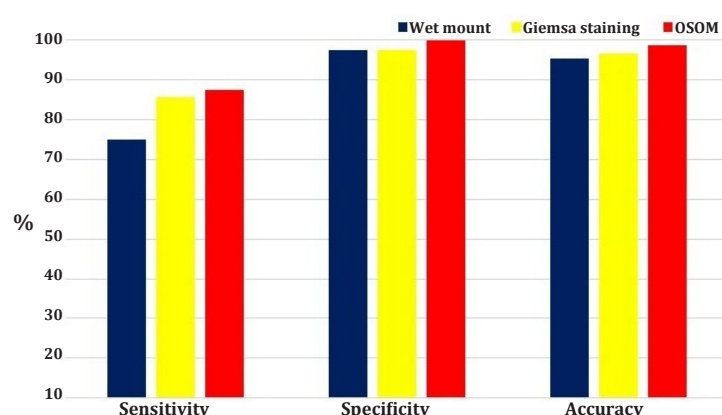


Fig. 3. Diagnostic performance characteristics of the studied tests for trichomoniasis relative to swabs culture.

Concerning the pH testing, 15 from the 21 positive smears showed a pH >4.5 and were considered positive at a coincidence rate of 71.4%. At the same time, among the 25 negative samples, 12 gave a pH of <4.5 with a negative coincidence rate of 48%. Among the intermediate samples, 15 samples showed a pH of >4.5 and were considered positive, while 24 samples gave a pH of <4.5 and were diagnosed as negative. Collectively, the pH testing defined 43 positives (50.6%) and 42 samples (49.4%) as negatives for BV. The C-4-P test assured the positivity of 20 of the positive 21 smears with a positive coincidence rate of 95.2%. Also, the C-4-P test detected 23 samples of the 25 negatives with a negative coincidence rate of 92%. Regarding the intermediate smears, the C-4-P test defined 27 positive and 12 negative samples. Collectively, the C-4-P test defined 47 positive samples (55.3%) and 38 negative (44.7%) samples for BV (Table 4).

The assurance of positive results on the Nugent scoring system using the C-4-P test was significantly higher in comparison to that of the Whiff test ($P=0.0016$) and pH testing ($P=0.038$) with an insignificantly higher rate with pH testing compared to the Whiff test. Similarly, the ensuring rate for the negative results by the Nugent scoring system was significantly higher using the C-4-P test than the Whiff test ($P=0.038$) and pH test ($P=0.0007$), while the difference between the pH testing and the Whiff test was insignificant in favor

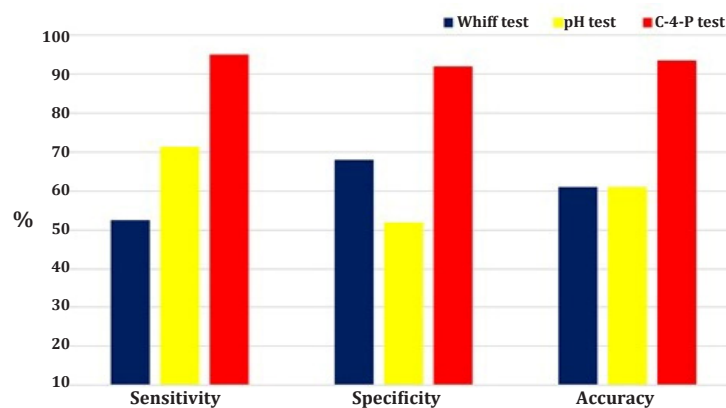
of the Whiff test. For differentiation of the intermediate smears, the rate of detecting positivity by the use of the C-4-P test was significantly higher than the detection rate depending on the Whiff test ($P=0.0001$) or the pH test ($P=0.0064$) while the identification of positives among intermediate smears was insignificantly higher with the pH testing versus the Whiff test (Table 4). Collectively, the ensuring positivity for a BV smear using the C-4-P test was significantly ($P=0.0021$) higher in comparison to the Whiff test, while it was insignificantly higher in comparison to pH testing. Furthermore, the detection rate of smears positive for BV using pH testing was significantly ($P=0.030$) higher than that of the Whiff test (Table 4, Fig. 4).

The diagnostic performance characteristics of the C-4-P test outweighed that of the pH test and Whiff test for the detection of BV and showed sensitivity and specificity rates of 95.24% and 92% respectively, with PPV and NPV of 90.91 and 93.48 and accuracy rates for diagnosis of BV of 93.48%. On the contrary, the pH test showed sensitivity and specificity rates of 71.43% and 52% respectively, and PPV and NPV of 55.56% and 68.42% with an accuracy rate of 60.87%. The Whiff test had the lowermost sensitivity of 52.38% and NPV of 62.96%, despite the specificity rate and PPV that were 68% and 57.89% and the accuracy diagnostic rate of 60.87% (Table 5, Fig. 4).

Table 4. Results of Whiff, pH, and C-4-P tests in comparison to the Nugent scoring system results.

Nugent scoring system tests		Positive (n=21:24.7%)	Intermediate (n=39:45.9%)	Negative (n=25:29.4%)	Total (n=85:100%)
Whiff test	Positive	11 (52.4%)	10 (25.6%)	8 (32%)	29 (34.1%)
	Negative	10 (47.6%)	29 (74.4%)	17 (68%)	56 (65.9%)
pH test	Positive	15 (71.4%)	15 (38.5%)	13 (52%)	43 (50.6%)
	Negative	6 (28.6%)	24 (61.5%)	12 (48%)	42 (49.4%)
Significance vs. Whiff test		0.204	0.225	0.152	0.030*
C-4-P test	Positive	20 (95.2%)	27 (69.2%)	2 (8%)	49 (57.6%)
	Negative	1 (4.8%)	12 (30.8%)	23 (92%)	36 (42.4%)
Significance vs.	Whiff test	0.0016*	0.0001*	0.033*	0.0021*
	pH test	0.038*	0.0064*	0.0007*	0.335

Data are presented as numbers and percentages, and the significance of differences was determined using the Chi-square test. *: Significant (P<0.05).

**Fig. 4.** Sensitivity, specificity, and accuracy rates of tests for diagnosis of BV relative Gram-stained Nugent scoring system.**Table 5.** Diagnostic performance characteristics of tests for diagnosis of BV relative to results of Gram-stained Nugent scoring system

Test performance character	Whiff test		pH staining		C-4-P test	
	Value	95% CI	Value	95% CI	Value	95% CI
Sensitivity	52.38%	29.78-74.29	71.43%	47.82-88.72	95.24%	76.18-99.88
Specificity	68.00%	46.5-85.05	52.00%	31.31-72.2	92.00%	73.97-99.02
Disease prevalence	45.65%	30.9-60.99	45.65%	30.9-60.99	45.65%	30.9-60.99
PPV	57.89%	40.53-73.51	55.56%	43.38-67.1	90.91%	72.51-97.43
NPV	62.96%	50.19-74.15	68.42%	49.98-82.45	95.83%	77.19-99.36
Accuracy	60.87%	45.37-74.91	60.87%	45.37-74.91	93.48%	82.1-98.63

PPV: Positive predictive value; NPV: Negative predictive value; CI: Confidence interval.

DISCUSSION

The current study depended on culture for diagnosis of trichomoniasis as a gold standard diagnostic test^[17], that detected 8 infected specimens with an infection rate of 9.4%. This rate coincided with the previously reported rates of 11.3%^[18], 9.3%^[19], and 10%^[20], but was lower than those of 16.3%, 26.9%^[21] and ~20%^[22], and higher than 4.86%^[23] and 5.9%^[24]. Discrepancy between rates may be attributed to the differences in patients' environment, customs, and religion; nevertheless, these figures ensured the competence of culture as a diagnostic modality for trichomoniasis.

The qualitative OSOM[®] test provided an accurate positive diagnosis of trichomoniasis of 8.24%, which coincides with the recorded culture rate, and is significantly better than the saline wet mount

examination and Giemsa staining rates of 7.06%. Moreover, the OSOM[®] test showed 100% specificity and PPV, with a 87.5% sensitivity rate, 98.72% NPV, and 98.82% accuracy rate. The reported performance characteristics of the OSOM[®] test supports the previously documented reports on its being a simple, rapid, and objective test with high sensitivity, excellent specificity, PPV and NPV compared to the wet mount test; and can improve screening and diagnosis of the infection especially where microscopy and culture are unavailable^[22]. Additionally, Keating and Nyirjesy^[25] reported that among newly diagnosed trichomoniasis cases, 41.7% were diagnosed by OSOM[®] test, 35% by saline microscopy, and 23.3% by Aptima TV kit. Furthermore, Nathan *et al.*^[26] detected a 92% sensitivity rate for the OSOM[®] and Aptima tests, and 38% by wet mount microscopy among patients who were positive for TV by real-time PCR and culture. Khatoon *et al.*^[27]

also documented sensitivity and specificity rates of 88.2% and 99.6% for the OSOM® test with a higher detection rate (7.5%) than for acridine orange staining (6.3%) and the wet mount examination (5.4%). One year later, Territo *et al.*^[28] documented a comparable detection rate of trichomoniasis (13.6% versus 15.5%) using the OSOM® and *Trichomonas* nucleic acid amplification tests.

Moreover, using the self-administered OSOM® test, Hsieh *et al.*^[29] reported sensitivity and specificity of 96.0% and 100%, respectively and Hawash *et al.*^[30] recorded 83.3% sensitivity and 98.4% specificity versus 88.8% sensitivity and 100% specificity of the clinician-collected specimen, and concluded that *Trichomonas* screening based on OSOM® self-testing might be implemented in the routine evaluation of vulvovaginitis patients. Thereafter, Hawash *et al.*^[22] recorded sensitivity, specificity, NPV, and PPV of 86.9%, 100%, 97.7%, and 100% respectively for the detection of trichomoniasis using the OSOM® test versus nested PCR.

The Gram stain-based Nugent score for BV detected 25 (29.4%) negative and 21 (24.7%) positive smears, while 39 (45.9%) smears were diagnosed as intermediate. Despite being still used for the differentiation of cases of vulvovaginitis, it is criticized for the need for a prepared lab and efficient operator, and its wide gap of intermediate diagnoses. Similarly, Watanabe *et al.*^[31] documented that the Nugent score is a standard method for diagnosing BV, however, it is based on the manual interpretation of Gram-stained vaginal smears that relies on the skill and experience of trained professionals, leading to variability in results. Elvy *et al.*^[32] also found Gram stain for BV to be error-prone, with 20% of results being discordant on repeat examination.

The C-4-P test is a multi-purpose test for detection of vaginal pH and H₂O₂ concentrations and activity levels of SNA and LE enzymes improved the diagnostic yield for BV. In our study, it allowed differentiation of the Nugent intermediate smears with sensitivity and specificity, PPV, NPV of 95.24%, 92%, 90.91%, 93.48% respectively, and accuracy rate for diagnosis of BV of 93.48%. Moreover, the ensuring positivity and negativity of a smear for BV using the C-4-P test was significantly higher in comparison to the Whiff test and pH testing.

Wang *et al.*^[33] examined the relation between the levels of functional indicators of infection as pH, H₂O₂, β -glucuronidase (GUS), coagulase, SNA, and LE in women with low-grade cervical intraepithelial neoplasia versus women with normal cervix. Their results showed that the highest sensitivity and specificity was for pH value and SNA and the area under ROC curve for detection of vaginal infection was highest for the combination of pH, SNA, and LE than

other combinations. Dun *et al.*^[34] also investigated functional indicators of vaginal infection in women who had intrauterine adhesions and documented the presence of a higher incidence of abnormal indicators in women with adhesions than in control women. Later, Feng *et al.*^[35] investigated the diagnostic value of a six-index functional test for the diagnosis of BV and found that pH, SNA, H₂O₂, and LE showed satisfactory sensitivity, while GUS and acetylglucosidase showed excellent specificity in identifying vaginal inflammatory diseases.

In support of the efficacy of evaluating the functional indicators of BV, Shen *et al.*^[36] detected a LE positivity rate of 92.44% among women with BV who were infected by SNA-producing pathogens. Also, multiple recent studies assured the importance of detection of the activity of SNA for not only the diagnosis of BV but also for arousing the possibility of infection by certain anaerobes, especially *Prevotella timonensis* which is a critical source of SNA in the vaginal microbiome^[36-39].

In conclusion, diagnosis of the causative agents for vulvovaginitis is still a dilemma and the diagnostic performance of the conventional tests is limited. The OSOM® and the C-4-P rapid tests provided high diagnostic performance for TV and BV with accuracy rates of 98.82% and 93.48%, respectively. The implementation of these rapid tests for TV and BV might spare the need for culture and molecular methods to save time and resources. It is worth mentioning that the small sample size and absence of molecular diagnosis are the study limitations.

Author contribution: Tawfik, WM contributed to the data analysis and manuscript drafting. Aboelela, HM contributed to the data collection and interpretation. Abdelhamid, HS contributed to the study design and literature review. Sharaf, AM contributed to the study supervision and provided critical revisions. All authors have approved the manuscript for submission, and accept it before publication.

Conflicts of interests: None.

Funding statement: None.

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