

**Whiff Test and Vaginal pH >4.5 as Rapid and Accurate Bed-side Screening Test
for Vaginal Infection**

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Abstract

Bacterial vaginosis and Trichomonas vaginalis infection have been associated with adverse pregnancy and health outcomes.

Aims of the study :

To evaluate the diagnostic yield of determination of vaginal pH considering pH>4.5 as diagnostic for vaginal infection and positive Whiff test as rapid bed-side diagnostic tests and their applicability as screening tests for vaginal infection in women apparently free of symptoms

Materials & method:

The current study included 120 women; 60 women were complaining of vaginal discharge (Patient group) and another 60 women have no complaint of vaginal discharge (Screening group). An unlubricated Cusco's vaginal speculum was inserted into the vagina and characteristics of the discharge with respect to amount, odor and type of discharge were evaluated. Two samples of the vaginal discharge

collected on dry sterile cotton wool tipped swabs. Secretions from the second swab were placed on pH indicator strips with a pH range of 3.5 to 6 to determine vaginal pH. Two drops of 10% KOH solution were added to the second and release of fishy amine odor signified a positive whiff test.

Results:

Thirty-three patients (55%) complained of vaginal discharge, 5 patients (8.3%) had itching and 14 patients (23.3%) had history of recurrent discharge and past history of treatment. Thirty-nine patients 39 (65%) had positive whiff test and 43 swabs (71.7%) had pH>4.5. Twenty-seven patients were missed on reliance on clinical data only, while 21 patients were missed in case of whiff test and only 17 patients in case of pH>4.5. Thus, both tests improved the diagnosis of vaginal infection with sensitivity rate of 85% and accuracy rate of 65% compared to

sensitivity rate of 58.9% and accuracy rate of 46.7% for clinical alone.

Conclusion:

Determination of vaginal pH >4.5 and positive Whiff test are rapid, simple and easy to perform as bed-side diagnostic tests and could be used as screening tests for vaginal infection in women apparently free of symptoms.

Introduction

Bacterial vaginosis and *Trichomonas vaginalis* infection have been associated with adverse pregnancy and health outcomes. Being the most common vaginal infections among women. BV and TV increase risk for acquisition of other sexually transmitted infections. In obstetrics, BV has been implicated in causing higher rates of late miscarriage, preterm premature rupture of membrane, chorio-amnionitis, spontaneous preterm labor, preterm birth, and postpartum endometritis ^(1, 2, 3). The high prevalence of BV and TV and the large burden of associated disease, there is a compelling public health need for simple and inexpensive point-of-care diagnostic tests for expanded screening of women especially in poor settings ⁽⁴⁾. In many parts of the developing world, laboratory diagnosis of vaginal infections is not available outside urban areas. Even simple and inexpensive methods such as Gram stain of vaginal

smears or microscopic examination for motile trichomonads are generally beyond the reach of most primary healthcare settings

⁽⁵⁾Healthcare workers typically manage

vaginal infections using a syndromic approach which bases treatment on symptoms and signs. Unfortunately, studies have shown low sensitivity and low predictive values for diagnoses of reproductive tract infections (RTI) using a syndromic approach among women. Such an approach not only misses asymptomatic infections but also results in substantial under-diagnosis and over-treatment of BV and TV ⁽⁶⁻⁹⁾. The present study aimed to evaluate the diagnostic yield of determination of vaginal pH considering pH>4.5 as diagnostic for vaginal infection and positive Whiff test as rapid bed-side diagnostic tests and their applicability as screening tests for vaginal infection in women apparently free of symptom

Materials & Method

Research design:

The research was prospective study

Setting:

The study was conducted at the outpatient clinic of Department of Obstetrics & Gynecology, South Valley University Hospital at Kena

Subject:

The subject was composed of 120 women were enrolled in the study. Sixty women were collected from those attending the gynecology outpatient clinic complaining from vaginal discharge (Patient group) -Another 60 women collected from those attending Family Planning Clinic requesting for appropriate contraceptive modality and have no complaint of vaginal discharge (Screening group).

Tools of data collection

Tool I: Structure questioner sheet was developed by the researcher to collect the necessary data which includes the following:

Part I: Socio demographic data: which includes as age, marital status, educational level, occupation, and parity were recorded

Part II: Participants were asked about their symptoms, the nature of their complaints concerning presence and amount of discharge, presence of itching, past illness, and history of treatment before enrollment. Pregnant and menstruating women or those who had used antibiotics and/or topical vaginal creams within seven days prior to

the date of examination were excluded from the study.

Tool II

An un-lubricated Cusco's vaginal speculum was inserted into the vagina and characteristics of the discharge with respect to amount, odor and type of discharge were evaluated. Two samples of the vaginal discharge collected on dry sterile cotton wool tipped swabs. Secretions from the second swab were placed on pH indicator strips with a pH range of 3.5 to 6 to determine vaginal pH. Two drops of 10% KOH solution were added to the second and release of fishy amine odor signified a positive whiff test.

Results

As regarding sociodemographic data, the study included 120 women with mean age of 34.9 ± 3.4 ; ranged from 23-41 years. The majority of studies sample were age group of 30-40 years. Eighty-nine women were currently married while 9 women were single while 11 were widow and 11 were divorced. Twenty-three women were university graduate, As regarding

educational level , it was noticed that 41 women were high school graduate while 35 %of them were not graduated and 21% of them were illiterate. Only 11 women were nullipara, 21 women were primipara, 40 women were para-two, 32 women were para-three and 16 women were para-four. There was non-significant difference between both groups as regards enrollment data, (Table 1).

Thirty-three patients (55%) complained of vaginal discharge which was profuse in 11 patients (18.3%), minimal in 15 patients (25%) and scanty in 7 patients (11.7%). Five patients (8.3%) had itching and 14 patients (23.3%) had history of recurrent discharge and past history of treatment.

Among studied patients 39 women (65%) had positive whiff test and 43 swabs (71.7%) had pH>4.5, while both tests were positive in 22 patients. Only 10 patients had discharge gave positive pH test, 11 patients had discharge gave positive whiff test and 12 patients had discharge gave positive both tests, (Table 2, Fig. 1). Considering presence of vaginal discharge as the frequent clinical symptom and the main complaint, 27

patients will be missed on reliance on clinical data only. On contrary 21 patients will be missed on reliance on whiff test and only 17 patients in case of pH>4.5. Thus, both tests improved the diagnosis of vaginal infection with sensitivity rate of 85% and accuracy rate of 65% compared to sensitivity rate of 58.9% and accuracy rate of 46.7% for clinical alone. Application of both tests to screen the apparently healthy group allowed detection of 28 cases with vaginal infection despite the absence of complaints or clinical findings. Fifteen women (25%) had vaginal pH>4.5, while 13 women gave a swab giving positive Whiff test and 5 of these women gave both tests positive (Table 3, Fig. 3).

Table (1): Percentage distribution of the Study participants as regarding socio demographic data enrollment data

			Total	Patients group	Screening group	Statistical difference
Age (years)	Strata	20-25	2 (1.7%)	1 (1.7%)	1 (1.7%)	p>0.05
		>25-30	11 (9.2%)	6 (10%)	5 (8.3%)	
		>30-35	51 (42.5%)	26 (43.3%)	25 (41.7%)	
		>35-40	52 (43.3%)	23 (38.3%)	29 (48.3%)	
		>40	4 (3.3%)	4 (7.7%)	0	
	Total		34.9±3.4 (23-41)	34.8±3.7 (23-41)	35±3.2 (25-40)	p>0.05
Marital status	Single		9 (7.5%)	5 (8.3%)	4 (6.7%)	p>0.05
	Currently married		89 (74.1%)	42 (70%)	47 (78.3%)	
	Divorced		11 (9.2%)	6 (10%)	5 (8.3%)	
	Widow		11 (9.2%)	7 (11.7%)	4 (6.7%)	
Educational status	Illiterate		21 (17.4%)	11 (18.2%)	10 (16.7%)	p>0.05
	Educated but not graduated		35 (29.2%)	18 (30%)	17 (28.4%)	
	High school		41 (34.2%)	19 (31.8%)	22 (36.7%)	
	University graduate		23 (19.2%)	12 (20%)	11 (18.3%)	
Parity	0		11 (9.2%)	6 (10%)	5 (8.3%)	p>0.05
	1		21 (17.5%)	10 (16.7%)	11 (18.3%)	
	2		40 (33.3%)	22 (36.7%)	18 (30%)	
	3		32 (26.7%)	15 (25%)	17 (28.4%)	
	4		16 (13.3%)	7 (11.6%)	9 (15%)	

Data are presented as means & numbers; ranges & percentages are in parenthesis

Table (2): Percentage distribution of Patients groups regarding Clinical and swab examination

			Data	Number	Percentage
Clinical data	Discharge	Profuse		11	18.3
		Minimal		15	25%
		Scanty		7	11.7
		Total		33	55
	Itching			5	8.3
	Recurrent complaint			14	23.3
Swab examination	pH>4.5	Positive		43	71.7
		Negative		17	28.3
	Whiff test	Positive		39	65
		Negative		21	35
	Both	Positive		22	36.7
		Negative		38	63.3

Table (3): Percentage distribution of screening groups regarding Clinical and swab examination

Test	Result	Number	Percentage
pH>4.5	Positive	15	25
	Negative	45	75
Whiff test	Positive	13	21.7
	Negative	47	78.3
Both	Positive	5	6.3
	Negative	55	93.7

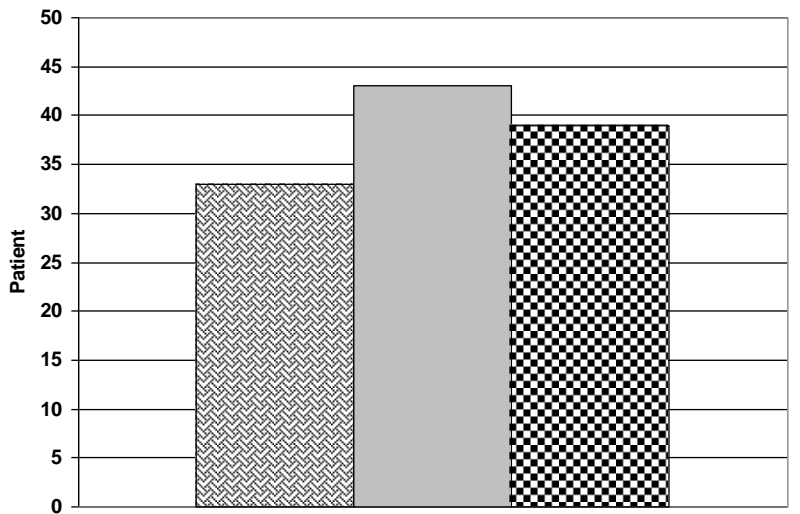


Fig. (1): Frequency of clinical data and swab findings in patients group

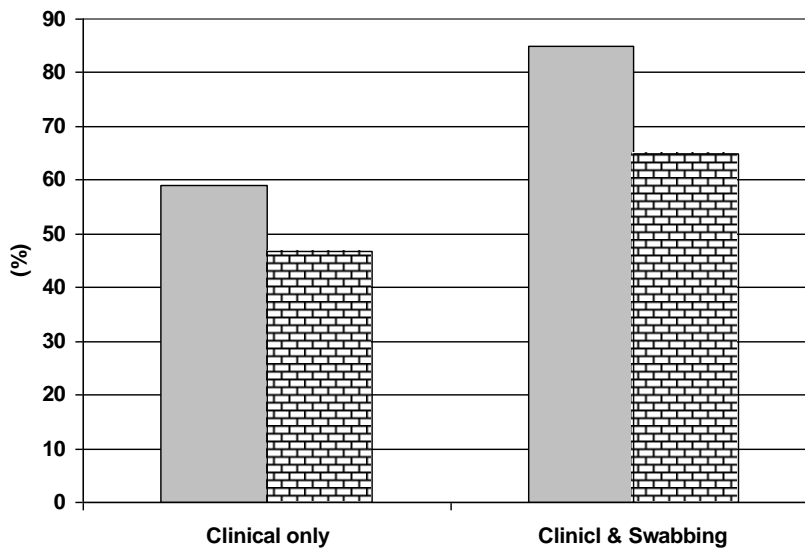


Fig. (2): Test validity rates of clinical and/or swabbing for diagnosis of vaginal infection

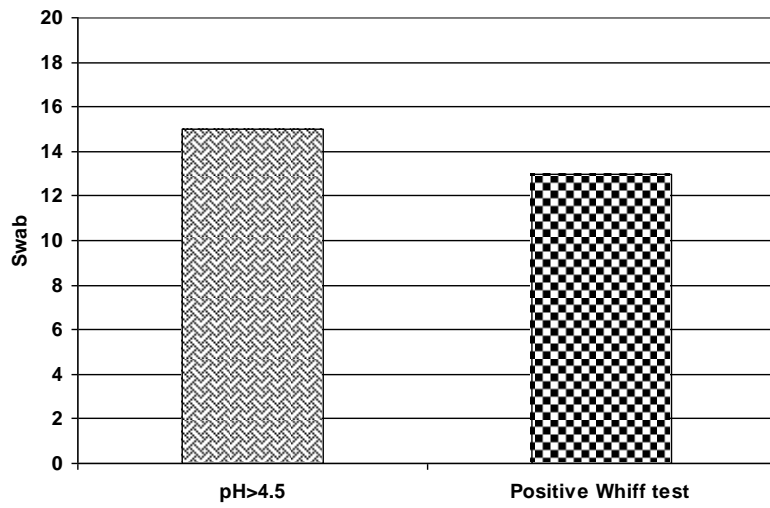


Fig. (3): Frequency of positive swab result among women screened for infection

Discussion

The frequency of vaginal discharge varied between various populations and among certain population; in developing countries the frequency of vaginal infection varied between 20 to 50% of non-pregnant women and bacterial vaginosis was found to affect about 70% of women ^(10,11).

Proper diagnosis of bacterial vaginosis is challenging. In addition to scientific considerations, choosing a method for laboratory diagnosis requires consideration of complexity, cost, and the frequency of uninterpretable specimens. Nevertheless, some alternative diagnostic methods have been developed, such as the polymerase chain reaction, rapid nucleic acid hybridization test, proline amino peptidase activity. More recently, several point-of-care tests based on various combinations of microbial products, presence of RNA, or more complex laboratory instrumentation such as sensor arrays, have also been introduced for the diagnosis of bacterial vaginosis. However, most of these are expensive and their sensitivities and specificities do not offer a huge advantage over the classical methods

^(12, 13). Through the current study, the dependence on clinical manifestations allowed identification of 33 patients with vaginal infection, while reliance on positive Whiff test allowed detection of 39 patients and vaginal pH>4.5 allowed detection of 43 patients. Thus, reliance on these rapid bedside tests raised sensitivity for presence of vaginal infection to 89% and accuracy of diagnosis to 65%. The diagnostic bedside tests were applied to non-symptomizing women considering themselves free of vaginal infection and could identify 28 cases of vaginal infection, so both tests could be used for screening of vaginal infection among apparently healthy women. In line with the reliance on these both tests in conjunction with clinical manifestations if present; **Madhivanan et al.** ⁽¹⁴⁾ who compare the performance of simple inexpensive point-of-care tests; vaginal pH; and Whiff test to laboratory diagnosis including serology for HSV-2; cultures for TV, Candida sp., and Neisseria gonorrhoea; Gram stains and found that in the absence of laboratory diagnostics, vaginal pH; and

Whiff test is not only inexpensive and practical, but also significantly more sensitive than the syndrome management approach, resulting in less over-treatment.

Quan ⁽¹⁵⁾ who documented that vaginitis is one of the most common ambulatory problems to occur in women, the medical history and examination are an important source of clues to the underlying diagnosis; however, making a definitive diagnosis requires skillful performance of office laboratory procedures, including the vaginal pool wet mount examination, determination of the vaginal pH, and the whiff test and vaginal and cervical cultures, nucleic acid tests, and point-of-care tests are available and may be required in selected patients.

Thulkar et al. ⁽¹⁶⁾ evaluated sensitivity and specificity of pH test and Whiff test in diagnosis of abnormal vaginal discharge, considering microscopic diagnosis as gold standard and found pH ≥ 4.5 and positive Whiff test had sensitivity of 94.1% and specificity 87.5% in diagnosing vaginal infection and concluded that pH test and Whiff test can improve diagnostic value of

speculum examination where microscope facilities are not available.

Hainer & Gibson ⁽¹⁷⁾ who stated that bacterial vaginosis, trichomoniasis, and vulvovaginal candidiasis are the most common infectious causes of vaginitis and diagnosis is commonly made using the Amsel criteria, which include vaginal pH greater than 4.5, positive whiff test, milky discharge, and the presence of clue cells on microscopic examination of vaginal fluid.

The procedure as a whole was applied by the author, a gynecologically qualified staff nurse without the attendance of physician, and owing to simplicity and good yield could be applied as training course for nurses working in healthcare units for widespread screening program. In hand with this assumption, multiple studies tried self-obtained swabs for diagnosis of vaginitis and reported applicability. **Huppert et al.** ⁽¹⁸⁾ compared the accuracy of self-performed point-of-care tests with clinician-performed tests for trichomoniasis in adolescent women and found that young women performing a self-point-of-care test

detected as many trichomoniasis infections as clinician- point-of-care tests or culture, twice as many as wet mount and slightly fewer than an amplified test. Incorporating self-obtained or self-performed point-of-care tests into routine practice could effectively increase the identification and treatment of trichomoniasis in this vulnerable population. It could be concluded that determination of vaginal pH >4.5 and positive Whiff test are rapid, simple and easy to perform as bed-side diagnostic tests and could be used as screening tests for vaginal infection in women apparently free of symptoms.

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