



# Vaginal pH Estimation, an Additional Tool for RTI/STI Community Screening

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## Abstract

**Objective** To study laboratory evidence of infection in STI/RTI cases managed by syndromic approach. To evaluate vaginal pH estimation as an additional supplementary tool for community screening of STI/RTI cases.

**Material and Methods** Study was conducted in department of Gynecology and Obstetrics, Mahila Chikitsalaya Sangneri gate Jaipur in collaboration with Department of Microbiology, SMS Medical College Jaipur, Rajasthan. STI cases screened by syndromic approach attending the STI clinic were included in study. Vaginal pH of these cases was measured with help of Jaipur pink V strip. Cases with vaginal pH more than five and less than 5 were grouped separately. Evidence of infection was assessed in both groups by performing predefined battery of tests. Results of both the groups were analyzed.

**Results** Laboratory evidence of infection was seen in 78% of syndromically screened RTIs/STI cases while screening by combined approach, i.e., syndromic approach and Vaginal pH estimation both, showed positive predictability of 92% with 75% sensitivity and 79% specificity.

**Conclusion** Laboratory evidence of infection was found in 92% of RTI/STI cases when screened by combined approach as compared to 78% in syndromic approach alone. Vaginal strips being user friendly can be used as additional tool for community screening of RTI/STI.

**Keywords** RTI/STI · Syndromic approach · Combined approach (syndromic approach with vaginal pH estimation both) · Screening · Jaipur pink V strip (Jaipur pink vaginal strip)

## Introduction

RTI/STI have been a serious community health issue since ages. With changing socioeconomic and cultural scenario of society, vulnerability to these diseases have increased [1]. As per new CDC guidelines [2] rate of STD in adolescent, young and HRG group is on increase. WHO estimates (2019) [3] also show that worldwide approximately 357 million new cases of STI occur every year, adding to

increased morbidity and mortality in reproductive age group. Community-based RTI/STI Prevalence study conducted by ICMR 2002–2003 shows 6% of adult population in India has one or more RTI/STI. Rapid assessment survey in 2005 indicated that 12% adult female clients and 6% of male clients attending OPDs have complaints related to STI while awareness and treatment seeking behavior as shown in BSS 2006 is very low in India. STI/RTI cases if diagnosed timely are not only fully manageable but permanent and long-term effects caused by them can also be prevented.

Currently community screening of RTI/STI is done through syndromic approach [4]. Cases are screened on the basis of complaints and findings on per speculum examination. They are managed as per their defined syndrome by pre decided combinations of drugs. Many times due to non-availability of facilities of clinical examination or competent staff screening protocols are not strictly followed and cases are screened on the basis of complaints only. Also, there are few of the clinical criteria under this approach like vaginal discharge and abdominal pain which are generic in nature.

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Hence, there is possibility of over identification and treatment, irrational treatment and even leading to drug resistance [5, 6]

Healthy vaginal pH is 3.5–4.5. It protects vagina from infection. Acid loving symbiotic relationship of *Lactobacillus* and corny bacterium regulate the vaginal milieu and prevents the growth of other organisms. While alkaline pH of vagina makes it susceptible to infections [7]. Current study is an attempt to assess can vaginal pH estimation of syndromically identified cases be used as additional screening aid so as to minimize number of false identification of cases of STI/RTI.

## Objective

- To study laboratory evidence of infection in STI/RTI cases managed by syndromic approach.
- To evaluate vaginal pH estimation as a supplementary tool for community screening of STI/RTI cases

## Material and Method

Study was conducted in department of Gynecology and Obstetrics in collaboration with Department of Microbiology, SMS Medical College Jaipur, Rajasthan. Routinely RTI/STI cases are screened by syndromic approach in OPD and are sent to STI clinic for further management. All cases attending the STI clinic during study period were included in study.

Complete personal details, complaints, clinical findings and treatment history of clients were documented as per proforma. Cases were classified according to syndrome and medicine Kit was given according to their defined syndrome.

All cases were simultaneously subjected to battery of tests as per NACO Guideline, [4] i.e., HIV, VDRL and hepatitis, KOH mount, wet mount and bacterial culture and sensitivity. Additionally, vaginal pH of all these cases was also measured with help of Jaipur pink V strip. Cases with vaginal pH more than five and less than 5 were grouped separately. Evidence of infection was assessed in both groups, i.e., in solely syndromically screened cases and cases screened by combined approach (syndromic and vaginal pH). Data thus obtained were analyzed and compared.

## Target Group

Syndromically screened RTI/STI cases attending STI clinic for syndromic management.

## Sample Size—100 Cases

### Jaipur Pink V Strip

Red litmus paper turns blue in alkaline media. In Jaipur Pink, V strip was made by pasting red litmus paper on soft strip of cardboard 3" × 1/4" size. This pH paper strip was held against the wall of vagina for a few seconds and then color of tip of pH paper was compared to the color of strip which was outside vagina. Full conversion from pink to blue was noted.

## Observation

Among the total 100 syndromic management cases Laboratory evidence of infection was present in 78% cases. In rest of the cases, no evidence of infection could be detected with set of investigation used in this study (Tables 1, 2, 3, 4, 5, 6).

Data showed that laboratory evidence of infection was significantly higher, i.e., 92.2% in cases screened by combined approach and false identification of 7.8% was observed in combined approach. Although 17% of cases with confirmed infection were missed by combined approach.

Assessment of efficiency and accuracy of combined screening approach shows a very high positive predictive value with significant sensitivity and specificity. F1 value which is suggestive of precision and sensitivity is 83%. This indicates that combined method can be a good community screening tool.

## Discussion

Screening tests are not diagnostic but they identify the individual more likely to have particular disease. Detection of disease in pre-clinical phase permits prevention and early management resulting in decreased morbidity and mortality. [8]

**Table 1** Demographic profile (total Cases100)

Age			Urban / Rural		Marital status		Obstetric history	
< 15	15–45	> 45	Urban	Rural	Married	Unmarried	Nulliparous	Multipara
1	95	4	95	5	81	19	19	81

**Table 2** RTI/STI syndromes v/s evidence of infection

	Vaginal / cervical discharge	Genital Ulcer herpatic	Genital Ulcer non herpatic	Genital ulcer non herpatic	lower abdominal pain	Urethral Discharge	Anorectal discharge	inguinal bubo	wart	Pain abdomen with Vaginal discharge	Total
Number of cases per syndrome	48	0	0	0	10	0	0	0	0	42	100
Evidence of Infection	35	.	.	.	8	.	.	.	.	35	78
% infection detected	72.9%	.	.	.	80%	.	.	.	.	83%	78%

A good screening method should show positive outcome when disease is present and negative when no disease is there. Ideal Screening test has to be specific and extremely sensitive, inexpensive, easy to administer, should cause minimal discomfort to client, accessible and non-dangerous. It should be able to place fewer demand of diagnostic test on health system too. They need to be bench marked against the agreed gold standard test (5) But in practice screening tests fall short for these ideals and exhibit false negative and false positive results.

In RTI/STI cases, syndromic screening and management have been presented as a simplified and affordable approach for sexually transmitted infection management in limited resource settings. Laboratory etiological diagnosis is considered the gold standard for diagnosis sexually transmitted infections. But in current field scenario, many times due to non-availability of facilities of clinical examination or competent staff and due to generic nature of few complaints in syndromic approach there is possibility of misidentification of cases.

Evaluation of syndromic management of sexually transmitted infections within the Kisumu Incidence Cohort Study [9] suggested that syndromic management of sexually transmitted infections is not a sufficient tool for sexually transmitted infection diagnosis. Development and improvement of sexually transmitted infection diagnostic capabilities through laboratory confirmation are needed in resource-limited settings. Similarly in study conducted at Baroda Medical College, on assessment of efficiency of syndromic approach in RTI/STI [10] showed that Syndromic management is effective in relieving the symptoms in 64% cases. Lack of identification of actual infection, chances of over treatment, increased financial burden and drug resistance are known major limitations of this approach.

So current study was an attempt to minimise false positive cases. Considering the fact that Lactobacillus keeps vaginal pH acidic, thereby prevents overgrowth of pathogens, rise in vaginal pH was tried as an additional indicator to screen the infection cases.

W. Frobenius and C. Bogdan in their study on diagnostic value of vaginal discharge, Wet mount and vaginal pH—An update on the basics of gynecologic infectiology [11] also showed that the majority of uncomplicated vulvovaginal complaints (e.g., bacterial vaginosis, vulvovaginal candidiasis, trichomoniasis) can be detected with uncomplicated basic infectiological Tests including measurement of vaginal pH.

Hence, in the current study, total hundred RTI/STI cases which were screened through syndromic approach, vaginal pH was measured as an additional indicator for RTI/STI. Cases with vaginal pH more than 5 were grouped separately as screened by combined approach. Lab investigations were considered as gold standard for infection in current study.

**Table 3** Comparative laboratory results of both approaches (Lab results (1))

Approaches	Total STI/RTI cases identified	Infection confirmed	No evidence of infection
Syndromic	100	78 (78%)	22 (22%)
Combined(synd + vag pH)	64	59 (92.1%)	5 (7.8%)

On estimation of vaginal pH in these syndromically identified 100 cases only 64 cases showed vaginal pH more than 5. Evidence of infection in these 64 cases was compared with syndromic screening

**Table 4** Etiological details (Lab results (2))

	Infection confirmed	Type of infection					
		Candida	Trichomonas	Bacterial	VDRL	HIV	Mixed (Bacterial + candida)
Cases screened by syndromic approach	78	11	4	31	1	1	30
Cases screened by combined approach	59	4	4	27	1	1	22
Cases missed by combined approach	-	7	0	4	0	0	6
% case missed by combined approach	-	63.6%	0	12.9%	0%	0%	27%

Among the missed cases by combined approach candida infection constituted major chunk

**Table 5** Statistical analysis of combined approach (1)

Syndromically screened	Vaginal pH	Evidence of infection				Inference
100	> 5	64	Present	59	Correctly identified	True Positive (TP)
			Absent	5	Incorrectly identified (Type 1 error)	False positive (FP)
	< 5	36	Present	19	False rejection (type 2 error)	False Negative (FN)
			Absent	17	True Rejection	True Negative (TN)

$P$  = number of real positive in data = total number of cases with infection = 59 + 19 = 78

$N$  = number of real negative in data = total number of cases without infection = 5 + 17 = 22

**Table 6** Statistical analysis of combined approach (2)

	True positive rate	True negative Rate	Positive predictive value	Negative predictive value	Accuracy	F1 Value
Formula	$TP/TP + FN$	$TN /TN + FP$	$TP/TP + FP$	$TN/TN + FN$	$TP + TN/P + N$	$2TP/2TP + FP + FN$
Value	$59/78 = 0.75$	$17/22 = 0.77$	$59/64 = 92$	$17/36 = 0.47$	$59 + 17/78 + 22 = .76$	$118/118 + 5 + 19 = 83\%$
Inference	Sensitivity 75%	Specificity 77%	Precision 92%	Not good negative predictor 47%	Accuracy 76%	Precision & sensitivity 83%

Evidence of infection on lab investigation in syndromic screening and combined screening group was compared.

Out of total 100 syndromically screened cases, 64 cases showed vaginal pH more than 5. They were termed as screened by combined approach. Laboratory investigation of these cases showed.

- Confirmed infection in 59 cases, i.e., in 92% cases.
- No evidence of infection was detected in 7.8% cases. They were incorrectly identified as infected and showed type I error.
- Out of total Thirty six cases identified infection free on combined screening. Among them 17 cases were true rejection, i.e., they showed vaginal pH < 5 and no evidence of infection was seen on lab investigation.
- In rest of the 19 cases although were screened free of infection by combined approach but on laboratory testing presence of infection was confirmed. These 19 cases were false rejection cases suggestive of type II error.

Combined approach showed 75% sensitivity and 79% specificity and 92% positive predictive value. On comparing both the approaches, evidence of infection was 92% in combined approach as compared to 78% in syndromic approach.

Similar findings were observed in **Clinical Review Vaginal discharge by Des Spence, [12]**. Their results showed that vaginal pH testing is quick cheap and simple test and stated that except in vulvo vaginal candidiasis pH testing alone had sensitivity of 73% and in combination with clinical symptoms it raised to 80%. Study conducted in **All India Institute of Medical Sciences, New Delhi, India, 2010, [13]** to evaluate sensitivity and specificity of pH test and Whiff test in diagnosis of abnormal vaginal discharge, suggested that Simple tools like pH test and Whiff test can be done without high expertise, microscope and even speculum. This can improve diagnostic value of syndromic approach of abnormal vaginal discharge.

As per their results Candidiasis (83.72%) was the commonest infection with pH less than 4.5. Similar findings were seen in our study as well. More than 60% of candida infection case showed vaginal pH less than five. Candidiasis was mainly responsible for high negative predictive value of 47% by Combined approach Otherwise 100% of trichomonas, VDRL and HIV positive cases and nearing 80% bacterial cases were correctly screened by combined approach. In false positive cases, need was to reconfirm contamination with menstrual blood, cervical mucus or semen but this couldn't be done due to non-availability of client

at the time of analysis. Mean of precision and sensitivity, i.e., F1 score in current study was 82% and accuracy turned out 76%. Study indicates that combined approach of screening will help in relatively accurate identification of RTI/STI as compared to Syndromic approach alone. This will also minimize irrational use of drugs in clients presenting with generic complaints as pain abdomen and vaginal discharge.

## Conclusion

Ninety two percent of positive predictability of combined approach in screening of RTI/STI cases suggests that addition of vaginal pH estimation with syndromic approach can be an added tool for effective screening of RTI /STI cases in field.

As Jaipur Pink V Strip is user friendly It Can be used by client herself and field staff as ASHA, Saheli etc. for screening purpose.

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## Declarations

**Conflict of interest** All of the author declare that they have no conflict of interest or financial conflict.

**Informed Consent** Informed consent was obtained from all the individual participant.

**Ethical Approval** All procedures performed in study involving human participant were in accordance with the ethical standards of institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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