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Should Side Lab Tests for Diagnosis of Vaginitis Be Resumed

Nidhi Sharma*, Sonal Gupta, Alka Sehgal and Bharti Goel

Department of Obstetrics and Gynecology, Chandigarh Government Medical College and Hospital, India

1. Abstract

Background: Vaginal discharge is one of the most common complaint of patients presenting in Gynecology OPD and clinical diagnosis remains subjective, hence the present study was conducted to compare clinical diagnosis with simple side lab tests with swabs sent to microbiology laboratory for further evaluation and results compared to evaluate whether diagnosis can be improved.

Material and methods: Vaginal swabs were collected from 100 sexually active patients presenting with vaginal discharge for Wet mount (direct microscopy and KOH mount), pH test and Whiff test (labeled as side lab test for presumptive diagnosis) and for relevant cultures in laboratory of microbiology Department.

Results: The study revealed poor correlation (19%) between clinical diagnosis and final laboratory diagnosis (kappa coefficient 0.1982). This may effect treatment provided only on the basis of clinical (visual) examination. However, very encouraging correlation (71%) was observed between presumptive and final lab diagnosis (kappa coefficient= 0.7149) The diagnostic accuracy of these side lab tests for physiological discharge, bacterial vaginosis, candidiasis, mixed vaginitis, trichomoniasis was 84%, 88%, 95.1%, 89% and 98%, respectively, in reference to final lab tests.

Conclusion: Simple side lab tests improve diagnosis of vaginitis and should be incorporated in all teaching and tertiary care centers for better management of vaginitis.

2. Keywords: Vaginal discharge; Side lab tests; Presumptive lab diagnosis; Final lab diagnosis

3. Introduction

Vaginal discharge is the most common complaint in the reproductive age group [1]. Inflammation of the vaginal mucosa causes symptomatic vaginal discharge that occurs in 1%-14% of all women in the reproductive age group. Prevalence of vaginal discharge in India has been quoted to be 30% [1]. If left untreated, partially or wrongly treated, it may predispose to ascending infections and resultant complications like pelvic inflammatory diseases (PID), in-fertility, endometriosis, urethral syndrome, pregnancy loss, preterm labour etc. In OPD's, by and large, clinical diagnosis is based on the nature of the discharge, which is subjective appreciation and associated with possibility of incorrect pathology and hence, treatment. To address the same, the World Health Organization (WHO) in 2003 developed the syndromic management approach keeping in view the most common causative organisms, identification of relatively constant combination of symptoms and signs (syndrome) and their antimicrobial

***Corresponding author:** Nidhi Sharma, Department of Obstetrics and Gynecology, Chandigarh Government Medical College and Hospital, Chandigarh, India, E-mail: drnidhi.sharma16@gmail.com

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susceptibility. The main disadvantage of this management is the cost of over diagnosis and over treatment when multiple antibiotics are given to a patient where infection is caused by none or only one microorganism. Also, there is risk of adverse drug reactions, alteration of normal vaginal flora and the potential for developing antibiotic resistance in the community with this approach [2].

However, addition of simple side laboratory tests (KOH mount, Wet smear, pH strip test, whiff test) can be used as a noncultural diagnostic technique for diagnosing the cause of vaginitis and helping in proper treatment. The present study was conducted to find out to what extent these side laboratory tests were accurate in diagnosing the cause of vaginitis over clinical diagnosis if culture-based results (final laboratory tests) were taken as gold standard.

4. Material and Methods

The present study was conducted in the Department of Obstetrics and Gynecology, Government Medical College Hospital, Chandigarh, in collaboration with Department of Microbiology over a period of one year (from 1st may 2014 to 30th April 2015). Hundred patients coming to the OPD with the primary complaint of vaginal discharge were evaluated with following inclusion and exclusion criteria. This study was conducted on ethical guidelines for biomedical research on human subject as given in the "Declaration of Helsinki" and by Central Ethics Committee on Human Research (CEHER) of ICMR, New Delhi. The study was conducted only after approval of study by the Institutional Ethics Committee of Government medical college and hospital, Chandigarh. A written and informed consent was taken from all the patients. The patients were given the right to opt out of the study at any time they wanted without any impact on the treatment to be given. Inclusion criteria was pregnant or non-pregnant female presenting in OPD aged between 18 to 45 years, sexually active with symptoms of vaginal discharge or vaginal itching. And exclusion criteria were patient presenting with bleeding per vaginum or upper genital tract infection like frank endometritis, puerperal or post- abortal sepsis and septic induced abortions. Patient underwent a per speculum examination during which vaginal swabs were collected and the following side laboratory tests were done for presumptive diagnosis:

1) Wet mount: Wet mount was prepared for direct microscopy for Trichomonas vaginalis, clue cells for bacterial vaginosis and fungal elements for Candida albicans.

2) Whiff Test: conducted by mixing vaginal discharge with 10% KOH preparation. Detection of fishy amine odour is considered positive for bacterial vaginosis.

For final laboratory diagnosis

Cultures: A swab each sent for anaerobic and aerobic culture, SDA culture for fungal growth and for last 25 patient cultures for Trichomoniasis was attempted at Department of Parasitology, PGIMER, Chandigarh for our inability to observe any motile trichomonas on the wet mount. Statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows). To see relationship between clinical and laboratory test kappa test of agreement was applied. All statistical tests were two-sided and performed at a significance level of $p<0.05$.

5. Results

All the 100 patients coming to the OPD were selected randomly from the reproductive age group including antenatal patients. (Table 1) The most frequent clinical diagnosis made was Mixed vaginitis without specifying suspected causative organisms (28%), followed closely by candidiasis (25%) (Table 2). The commonest presumptive diagnosis (based on side lab tests) was physiological discharge (41%), followed by bacterial vaginosis (32%) and candidiasis (17%) (Table 2). The aerobic and anaerobic organisms grown on culture revealed bacterial vaginosis as the most frequent infection (25%). On correlating clinical diagnosis with the final laboratory diagnosis

candidiasis and mixed vaginitis were detected to be over diagnosed while Bacterial Vaginosis and physiological discharge were underdiagnosed on clinical basis. Only 25% cases of vaginal discharge were correctly diagnosed clinically (Table 3). Presumptive diagnosis based on pH, whiff test, wet mount had results closely matching final laboratory diagnosis (Table 4) and complete matching was seen in 71 % cases. These side lab tests had diagnostic accuracy in cases of candidiasis, mixed vaginitis, bacterial vaginosis and physiological discharge as 95.18%, 89%,88% and 84% respectively (Table 5) which is better than clinical diagnosis done alone (mixed vaginitis-68%, bacterial vaginosis-74%, physiological discharge-75%, candidiasis-76%).

Table 1: Baseline characteristics of patients and their chief complaints.

Characteristic	No. of patients	Percentage
Age(years)		
18-30	54	54%
31-40	35	35%
>40	11	11%
Nature of discharge		
Asymptomatic	1	1%
Curdy white	5	5%
Dirty white	73	73%
Thin watery	17	17%
Yellowish green	4	4%
Foul discharge		
Yes	47	47%
No	53	53%
Pregnant		
Yes	25	25%
No	75	75%
Other associated complaints		
Backache	5	5%
Itching	10	10%
Infertility	3	3%
Previous history of treatment	27	27%
Abdominal pain	19	19%
Urinary complaints	9	9%
Associated diabetes mellitus		
Yes	10	10%
No	90	90%

Table 2: Distribution of various infections on the basis of three diagnostic approaches.

Diagnosis	Clinical diagnosis (n=100)	Presumptive lab diagnosis (n=100)	Final lab diagnosis (n=100)
Bacterial vaginosis	7	32	25
Candidiasis	25	17	19
Mixed vaginitis	28	9	20
Physiological discharge	8	41	25
Trichomoniasis	1	1	1
Cervicitis	7	0	0
PID	24	0	0
Aerobic vaginitis	0	0	10

Data represented by number of patients (n).

Table 3: Co-relating clinical diagnosis with final laboratory diagnosis.

		Final laboratory diagnosis						Total
		AV	BV	C	MV	Py	T	
Cinical Diagnosis	BV	0 (0%)	3 (42.9%)	2 (28.6%)	2 (28.6%)	0 (0%)	0 (0%)	7[a]
	C	1 (4%)	5 (20%)	10 (40%)	3 (12%)	6 (24%)	0 (0%)	25[a]
	Cy	1 (14.3%)	3 (42.9)	0 (0%)	1 (14.3%)	2 (28.6%)	0 (0%)	7[a]

	MV	3 (10.7%)	8 (28.6%)	4 (14.3%)	8 (28.6%)	4 (14.3%)	1 (3.6%)	28[a]
	PID	4 (16.7%)	4 (16.7%)	2 (8.3%)	5 (20.8%)	9 (37.5%)	0 (0%)	24[a]
	Py	1 (12.5%)	2 (25%)	1 (12.5%)	0 (0%)	4 (50%)	0 (0%)	8[a]
	T	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	1[a]
Total		10[*]	25[*]	19[*]	20[*]	25[*]	1[*]	100

Data represented by number of patients (% within clinical diagnosis).

[a] Shows the number of patients and their clinical diagnosis reached by the treating physician.

[*] number of patients and their final laboratory diagnosis.

Abbreviations: AV-Aerobic vaginitis, BV- bacterial vaginosis, C-Candidiasis, Cy-Cervicitis, Py-Physiological discharge, MV-mixed vaginitis, PID-pelvic inflammatory disease, T-Trichomoniasis.

Table 4: Co-relating presumptive laboratory diagnosis with final laboratory diagnosis.

		Final laboratory diagnosis						**Total**
		AV	**BV**	**C**	**MV**	**Py**	**T**	
Presumptive lab diagnosis	BV	0 (0%)	22 (68.8%)	1 (3.1%)	8 (25%)	0 (0%)	1 (3.1%)	32[a]
	C	0 (0%)	0 (0%)	15 (88.2%)	2 (11.8%)	0 (0%)	0 (0%)	17[a]
	MV	0 (0%)	0 (0%)	0 (0%)	9 (100%)	0 (0%)	0 (0%)	9[a]
	Py	9 (22%)	3 (7.3%)	3 (7.3%)	1 (2.4%)	25 (61%)	0 (0%)	41[a]
	T	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1[a]
Total		10[*]	25[*]	19[*]	20[*]	25[*]	1[*]	100

Data represented by number of patients (% within presumptive lab diagnosis).

[a] Represents number of patients and their presumptive diagnosis.

[*] Represents number of patients and their final lab diagnosis.

Abbreviations: AV-Aerobic vaginitis, BV- bacterial vaginosis, C-Candidiasis, Py-Physiological discharge, MV-mixed vaginitis, T-Trichomoniasis.

Table 5: Comparison of Sensitivity and specificity of clinical and presumptive diagnosis in reference to final laboratory diagnosis.

	Sensitivity	**Specificity**	**PPV**	**NPV**	**Diagnostic accuracy**
Clinical diagnosis					
BV	12 %	94.67 %	42.85 %	76.34 %	74 %
Candidiasis	52.63 %	81.48 %	4 %	88 %	76 %
Mixed vaginitis	40 %	100%	100%	83.33 %	68 %
Trichomoniasis	0%	98.99%	0%	98.99%	98%
Physiological	4 %	94.87 %	20 %	77.89 %	75 %
Presumptive diagnosis					
BV	88 %	86.63%	68.72%	95.59%	88%
Candidiasis	78.95%	97.51%	88.23%	95.18%	95.18%
Mixed vaginitis	45%	100%	100%	87.91%	89%
Trichomoniasis	0%	98.99%	0%	98.99%	98%
Physiological	100%	78.67%	60.97%	100%	84%

Abbreviations: BV, Bacterial Vaginosis; PPV, Positive predictive value; NPV, Negative predictive value.

6. Discussion

In this study, as discussed earlier, we tried to find out whether the addition of simple side lab tests to the clinical examination helps in more (better) specific diagnosis and thereby, treatment in patients with vaginal discharge. Maximum number of patients with this complaint were in the age group of 18 to 30 years (54%) and most common chief complaint was dirty white discharge per vaginum (73%, Table 2). Mixed vaginitis was the most frequent clinical diagnosis made by the clinician (28%) in contrast to other studies where bacterial vaginosis was commonest [3-6]. We cannot quote the prevalence of various infections as our study had small sample size. We assume that these patients coming to the OPD with the complaint of dirty white discharge are labelled as mixed vaginitis and broadly treated as per WHO guidelines [2] without even an attempt to diagnose physiological discharge or co-relating it with the menstrual phase. Attempting laboratory diagnosis for vaginal discharge is a little time-consuming process and requires a microscope or a side laboratory and hence usually not even attempted. Patients in whom diagnosis of cervicitis and PID was made, it was purely subjective diagnosis of the physician. No laboratory tests were conducted to collaborate these findings except vaginal swab culture as a result of which, no comments can be made on diagnosis of cervicitis and PID. Similarly, only one patient was clinically suspected to have trichomoniasis and we could detect a flagellate, that too a dead one, in one wet smear. The time lapse between sample collection and transport to the laboratory might had been the limiting criteria for non-detection of motile Trichomonas. Twenty-five culture were sent to the department of microbiology, PGIMER in later part of the study, irrespective of the clinical diagnosis and Trichomonads grew only in one culture. This is possible because the vaginal swabs were sent for all discharges & not specifically for those suspected to be trichomoniasis or since it is difficult to grow these flagellates. Combining wet mount with Papanicolaou smear, the sensitivity increased to 92.6% in one study [7]. Unfortunately, we had not attempted Papanicolaou smear in our patients, hence this comparison is not possible. Thus, the results of culture for trichomoniasis cannot be extrapolated to the whole study. In our study it was found that only clinical evaluation led to overdiagnosis of candidiasis and mixed vaginitis and under diagnosis of Bacterial vaginosis and physiological discharge in reference to final lab tests (Table 3). Other studies too had similar findings except that bacterial vaginosis was over diagnosed and trichomoniasis, underdiagnosed [4-9]. But these studies took presumptive diagnosis as the reference and culture studies were not done.

References

1. Thulkar J, Kriplani A, Agarwal N, Vishnubhatla S. Aetiology & risk factors of recurrent vaginitis & its association with various contraceptive methods. Indian J Med Res. 2010; 131: 83-87.
2. Zemouri C, Wi TE, Kiarie J, Seuc A, Mogasale V, Latif A, et al. The Performance of the Vaginal Discharge Syndromic Management in Treating Vaginal and Cervical Infection: A Systematic Review and Meta-Analysis. PLoS ONE. 2016; 11: e0163365.
3. Rekha S, Jyothi S. Comparison of visual, clinical and microbiological diagnosis of symptomatic vaginal discharge in the reproductive age group. Int J Pharm Biomed Res. 2010; 1: 144-148.
4. Sowjanya R, Prathyusha V, Sai Sree Sudha R. Comparative study of visual, clinical and microbiological diagnosis of white discharge. IOSR J Dent Med Sci. 2015; 14: 24-27.
5. Vijaya D, Patil Sunil S, Sambarey Pradip W. Clinical and Microscopic Correlation of Vaginal Discharge. Int J Contemp Med Res. 2016; 3: 1328-1331.
6. Farhan AM, Eldesouky EA, Gaballah EA, Soltan ME. Comparison of visual, clinical and microbiological diagnosis of symptomatic vaginal

discharge in the reproductive age group. Benha Med J. 2017; 34: 43-48.

7. Stoner KA, Rabe LK, Meyn LA, Hillier SL. Survival of Trichomonas vaginalis in wet preparation and on wet mount. Sex Transm Infect. 2013; 89: 485-488.

8. Government of India, Ministry of Health and Family Welfare. Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections: National AIDS Control Organization; 2014.

9. Esim Buyukbayrak E, Kars B, Karsidag AY, Karadeniz BI, Kaymaz O, Gencer S, et al. Diagnosis of vulvovaginitis: comparison of clinical and microbiological diagnosis. Arch Gynecol Obstet. 2010; 282: 515-519.

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