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Comparison of visual, clinical and microbiological diagnosis of symptomatic vaginal discharge in the reproductive age group

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ABSTRACT

In the present study, the inaccuracies of visual or presumptive clinical diagnosis of the causative agent of vaginal discharge were investigated. Further it was examined whether the addition of simple microscopic techniques such as wet smear and Gram stain can aid accurate diagnosis of this common condition. Also the accuracy of the WHO syndromic approach and the blanket therapy advocated by this approach was evaluated. This is a prospective study done over a period of one year. 203 women with symptomatic vaginal discharge were evaluated by the visual, clinical and microbiological diagnostic methods and compared. Etiological diagnosis was obtained in 146 patients (72%) included and in the remaining 57 (28%) of the patients etiological cause could not found. Visual approach diagnosed and treated 38.5% of the cases as bacterial vaginosis and 9% as candidiasis with no microbiological evidence of infection whereas 6% of cases with confirmed microbiological diagnosis of trichomoniasis were missed out on visual diagnosis and were not treated. If blanket therapy is given to all women complaining of abnormal vaginal discharge then, 44% of the women would receive antibiotics and 84% antifungal treatment unnecessarily. For the etiological diagnosis of symptomatic vaginal discharge, the most ideal approach is the microbiological approach. Blanket therapy based on the WHO algorithm in patients with symptomatic vaginal discharge has limited advantage. In a resource constrained setting, at least a clinical diagnosis based on simple microscopy, pH and amine test and the WHO algorithm has to be made prior to treatment, to avoid diagnostic and treatment mismanagement.

Key words: Symptomatic vaginal discharge, Syndromic management, Blanket therapy

1. INTRODUCTION

Vaginal discharge in the reproductive age group is the most common complaint encountered everyday both by gynecologists and general practitioners. Symptomatic vaginal discharge is caused by inflammation due to infection of the vaginal mucosa. It occurs in 1-14% of all women in the reproductive age group [1] and is responsible for 5-10 million OPD visits per year throughout the world. The prevalence of vaginal discharge in India is estimated to be 30% [1]. Abnormal vaginal discharge also predisposes to significant morbidity in the form of pelvic inflammatory diseases, infertility, endometriosis, cuff cellulitis, urethral syndrome, pregnancy loss, preterm labour, to enumerate a few. Most

common cause of symptomatic vaginal discharge is bacterial vaginosis (33-47%) [2], followed by candidiasis (20-40%) and trichomoniasis (8-10%) [3,4]. These three conditions account for 90% of all etiologies of abnormal vaginal discharge. Multiple infections can also coexist [3].

Successful management of symptomatic vaginal discharge lies in the diagnostic approach. The traditional approach to diagnosis is through laboratory diagnosis of the aetiological agent(s). This approach is expensive and not available at all health centres or dispensaries. Most of the time a presumptive diagnosis is made based on the nature of the discharge (Visual diagnosis), which is often inaccurate and incomplete. This eliminates the laboratory component (Microbiological diagnosis) leading to treatment mismanagement [5,6].

To address the limitations of both aetiological and visual diagnosis, the World Health Organisation (WHO) developed and advocated the Syndromic management approach [5,6].

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This approach is based on the identification of a relatively constant combination of symptoms and signs (syndrome) and on the knowledge of the most common causative organisms of these syndromes and their antimicrobial susceptibility. Antimicrobial regimens are chosen to cover the major pathogens responsible for the syndromes. The main disadvantage of this management is the cost of over diagnosis and over treatment when multiple antimicrobials are given to patient where infection is caused by none or only one organism. Also to be considered are the risks of adverse drug reactions, alteration of normal vaginal flora and also the potential for developing antibiotic resistance in the community [5,6].

The addition of a simple microscopic evaluation by Gram's stain of the vaginal smear has evolved as a sensitive noncultural diagnostic technique for bacterial vaginosis [1,2] and candidiasis [2]. Direct microscopy (wet smear) of the vaginal discharge to visualize the motile *Trichomonas vaginalis* has been determined to be as accurate as culture for the diagnosis of Trichomoniasis [2]. The present study was conducted to determine the inaccuracies of visual/presumptive diagnosis of symptomatic vaginal discharge and to evaluate if addition of simple microscopic techniques such as wet smear & Gram's stain can aid in the accurate diagnosis of this common condition. This study also tries to evaluate the accuracy of the blanket therapy advocated by WHO in the syndromic management of vaginal discharge.

The aim of this study is to compare the visual diagnosis (as made on per speculum examination and on clinician's presumptive diagnosis); Clinical diagnosis (as per WHO syndromic approach) and the microbiological diagnosis (Gram's stain of vaginal smear for bacterial vaginosis and candida; wet smear for trichomoniasis) in the etiology of symptomatic vaginal discharge and to determine if blanket treatment (antimicrobial with antifungal) is more effective as compared to treatment after establishing the microbiological diagnosis.

2. MATERIALS AND METHODS

This was a prospective study conducted at a teaching tertiary care hospital in Bangalore. 203 women in the age group of 15 to 45 years with symptomatic vaginal discharge attending the gynaecological outpatient department were studied over a period of one year. The patients with vaginal discharge constituted the cases and those without the disease

the controls. Informed consent was taken from all patients. Patients in whom per speculum and pelvic examination was not possible, menstruating, those who have received antimicrobials/antifungals (topical/oral) in the previous one month, pregnancy, postmenopausal patients, posthysterectomy status and patients who have delivered or aborted six weeks prior were excluded from the study.

The patients were given a Visual diagnosis based on the clinician's judgement of the symptoms and signs; this was followed by a Clinical diagnosis according to the WHO syndromic management algorithm for vaginal discharge [4] and a microbiological diagnosis based on Gram's stain for bacterial vaginosis and candidiasis; wet mount for trichomoniasis.

Vaginal discharge was classified as *abnormal* if women referred to it as the main reason for attending the clinic. The Visual diagnosis was made based on the characteristics depicted in Table 1 by the treating gynecologist [3]. The discharge from the vagina was collected using the vaginal speculum into a sterile container and tested for bacterial vaginosis, candidiasis and trichomoniasis by standard microbiological procedures [7].

The diagnostic criteria used for microbiological diagnosis were:

- 1) Bacterial vaginosis – A Gram's stain score of seven or more based on the scoring system by Nugent *et al.* [8]
- 2) Candidiasis – if gram positive budding yeasts and pseudohyphae were seen on gram's stain.
- 3) Trichomoniasis – if wet smear microscopy was positive for motile *Trichomonas vaginalis*.

All the findings were recorded and comparisons drawn between visual, clinical and microbiological diagnostic approaches. The data was analysed using SPSS version 11 and categorical tables, Chi-square values, probability coefficients, sensitivities, specificities, positive predictive value and negative predictive values of the three diagnostic approaches was derived and compared. Conclusions were drawn from the tabulated results.

3. RESULTS

In this study, 203 women presented with vaginal discharge. A diagnosis was obtained for 146 (72%) of them and in 57 (28%) the etiological diagnosis could not be found. 40% were in the age group of 26-30 years, 35% in the age group of 31-40 years and 25% between 20-25 years. Bacterial vaginosis (BV) and trichomoniasis (TV) infections was

Table 1

Characteristic clinical manifestations of common infections associated with abnormal vaginal discharge

Sl. No.	Characteristics	Physiological	Bacterial vaginosis	Trichomoniasis	Candidiasis
1	Symptoms	none	profuse, malodorous, ±irritation	profuse, malodorous, ±irritation, ±pruritis	pruritis, thick white discharge
2	Vulva	normal	normal	±edema	erythema, ±fissure, pustules
3	Discharge at os	white	gray	gray yellow to green	white
4	Consistency	curdy	homogenous	homogenous	curdy
5	Viscosity	high	low	low	high
6	Vaginal distribution	dependant	adherent	adherent	adherent

common in women between the age groups of 26-30 years accounting for 60% of the cases but, candidiasis was commoner in women between age groups 31-40 years (40%). The association of age with the vaginal infections was not statistically significant (p value >0.5).

Majority of the women (42%) complained of symptoms for more than one year while (30%) between 1 to 6 months. The commonest symptom noted was pruritis (20%) seen in 23% of the patients diagnosed with candidiasis. Majority of the women presented with homogenous discharge. The discharge associated with candidiasis was curdy white. 79% of BV and all TV cases had grey yellow discharge, while 50% of candidiasis patients had homogenous white discharge, and this trend was statistically significant ($p=0.001$). Majority (37%) of the cases with vaginal discharge had pH ranging from 5.6 to 6. BV and TV had pH ranging from 5.6 to 6, whereas candidiasis cases had $pH < 4.5$. These findings were statistically significant ($p < 0.001$). The commonest diagnosis was bacterial vaginosis.

Table 2 depicts the prevalence of the various infections as per the three diagnostic approaches. Fig.1 depicts the prevalence of the vaginal infections as per each of the diagnostic approaches. The prevalence of BV and Candida by the visual & clinical diagnostic approaches was more than the microbiological approach, while TV was under diagnosed by the visual approach. Fig.2 shows the difference in the prevalence of vaginal infections by visual and clinical diagnostic methods from the microbiological diagnosis (+sign indicates an excess above the microbiological diagnosis; - sign indicates a deficit below the microbiological diagnosis). Table 3 compares the Sensitivity, Specificity, Positive predictive value (PPV) and Negative predictive values (NPV) of the visual and clinical diagnostic methods against the microbiological diagnosis. Clinical diagnosis had a higher sensitivity for diagnosing BV, with moderate sensitivities of both visual and clinical diagnosis for candidiasis. On comparison of the visual diagnosis with the clinical diagnosis, it was noted that visual diagnosis has high sensitivity (88%) for BV, moderate sensitivity (60%) for Candida and very low sensitivity for TV (21%).

4. DISCUSSION

This prospective study included 203 patients with symptomatic vaginal discharge. The etiological diagnosis was reached in 146 (72%) of the patients included. In the remaining 28% of the patients, diagnosis could not be made with the microbiological diagnostic approach. This is in concurrence with other studies [3,4,8,9] which show that in 10 to 58% of the patients complaining of vaginal discharge, diagnosis could not be reached using any of the diagnostic approaches under consideration. This group of patients probably may have normal physiological discharge or less frequently viral vaginitis, aerobic vaginitis [10] or vaginal lactobacillosis which are not routinely detected.

Table 2

Prevalence of various infections based on the three diagnostic approaches

Sl. No.	Diagnosis	Visual diagnosis n = 203 (%)	Clinical diagnosis n = 203 (%)	Microbiological diagnosis n = 203 (%)
1	TV only	5 (3%)	7 (3%)	7 (3%)
2	BV only	118 (58%)	96 (47%)	48 (24%)
3	Candida only	38 (19%)	20 (10%)	22 (11%)
4	TV and BV	10 (5%)	22 (11%)	11 (5%)
5	BV and Candida	12 (6%)	24 (12%)	8 (4%)
6	TV and Candida	0	2 (1%)	1 (0.5%)
7	TV, BV and Candida	0	3 (2%)	1 (0.5%)
8	Etiology not found	20 (10%)	29 (14%)	57 (28%)
9	Intermediate Flora	0	0	48 (24%)

Table 3

Validation of the three diagnostic approaches with microbiological diagnosis as the gold standard (100%)

Diagnostic approach	Bacterial vaginosis (%)	Trichomoniasis (%)	Candidiasis (%)
1) Visual diagnosis			
Sensitivity	78.5	33.3	52.8
Specificity	35.8	96.6	81.4
Positive predictive value	38.6	60.0	38.0
Negative predictive value	76.2	90.4	88.9
2) Clinical diagnosis			
Sensitivity	97.1	99.9	58.3
Specificity	36.8	99.9	82.0
Positive predictive value	44.7	99.9	41.2
Negative predictive value	96.1	99.9	90.1

Vaginal infections commonly occur in women of reproductive age i.e between 25-30 years as noted in several other studies [1,2,4,11,12]. In this study only 6 (3%) of the patients were < 20 years old. Hence the population studied was a low risk one attending the gynaecologic clinic. Studies by some authors show that the probability coefficients for all vaginal infections depend on the type of population studied and the prevalence in the population studied [4,8,9,13]. Most of the patients in this study sought medical help atleast 1-6 months after the onset of symptoms. This shows a tendency towards increased sequelae or complications associated with the infections.

Abnormal vaginal discharge was the chief complaint with BV in certain studies [2,11,14,15]. In this study, pruritis was the commonest symptom while abnormal vaginal discharge as a chief complaint was noted in only 4% of the patients with BV. Similar findings were noted by other authors [2,3,14,16,17]. The nature of the vaginal discharge may be helpful as one of the criterion in differentiating the types of vaginal infections as noted by other authors [2,3,11]. Vaginal pH has been regarded to be a sensitive but not a specific criterion for diagnosing vaginal infections. The number of pus cells would also give a correlation to the severity of infection. These findings probably aid in the syndromic management of abnormal vaginal discharge [2,3,5,9].

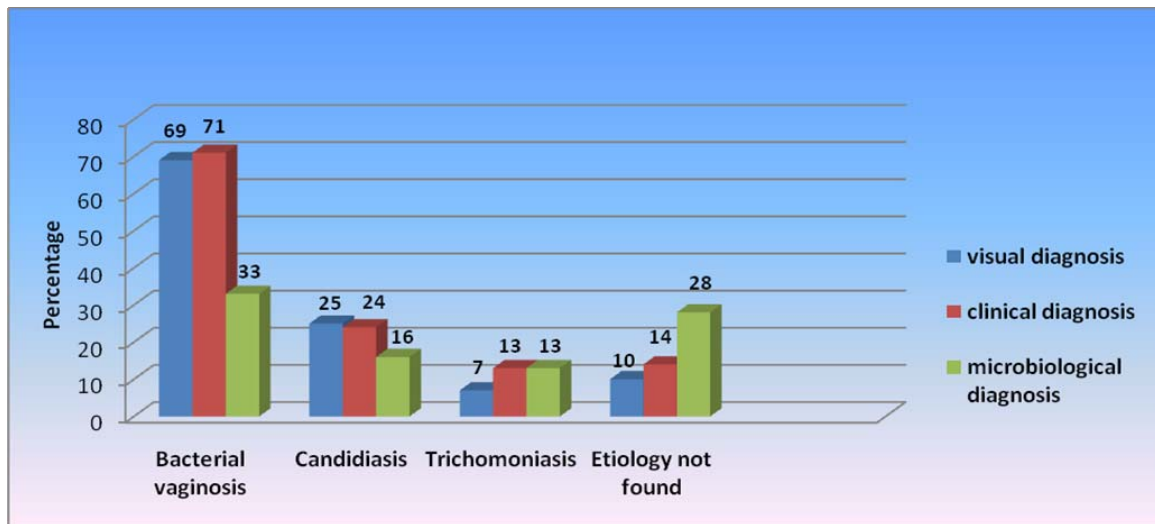


Fig.1. Overall prevalence of various infections based on the three diagnostic approaches

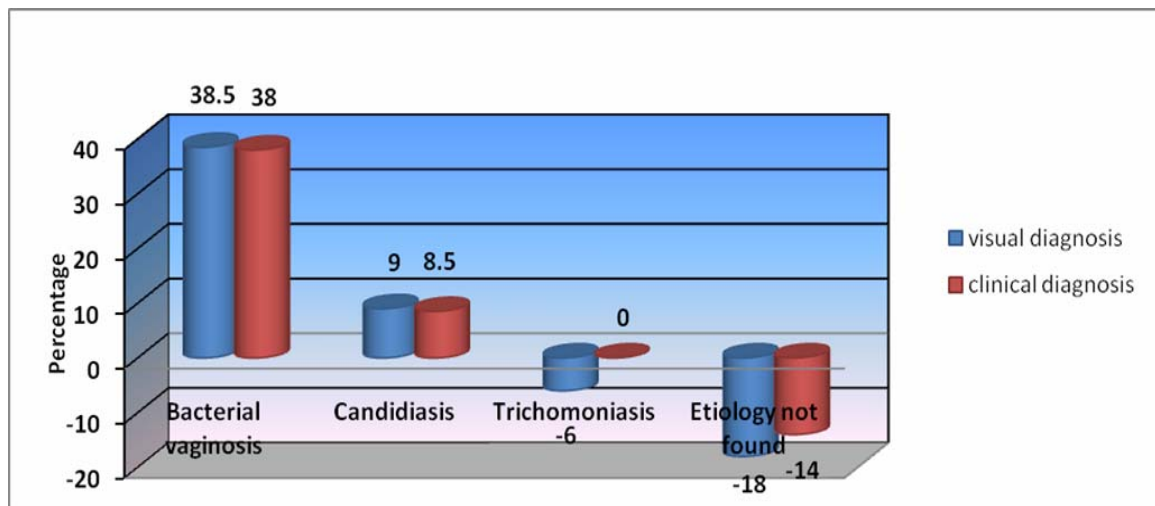


Fig.2. Differences in the prevalence of vaginal infections by the visual and clinical approaches from the microbiological diagnostic approach

BV was the commonest diagnosis by the Visual and the Clinical approaches in this study. When the Visual and Clinical diagnostic approaches were compared with the microbiological diagnosis, visual diagnosis was noted to have moderate sensitivity for BV and Candida, moderate specificity for TV; lower sensitivity for TV and lower specificity for BV. This implies that if the visual or the clinical approaches were used to diagnose the infections, BV and Candida would be over treated while TV would be under treated. Also the positive predictive value was low for BV and Candida but high for TV with moderate negative predictive values for all infections implying, that the Visual diagnosis was not suited for diagnosis of TV and Candida but has a moderate reliability for BV. Our analysis of these two diagnostic approaches show that neither deal adequately with the management of abnormal vaginal discharge. By adding

simple tests as recommended by WHO, the sensitivity of Clinical diagnosis for all the vaginal infections improved, but only minimal change was noted in the specificity. These findings are similar to studies done by some authors which show that addition of simple Gram staining of the vaginal smears to the clinical diagnosis has a very good sensitivity (89-93%) but a low specificity of only 70% [2,3].

WHO recommends that all women complaining of abnormal vaginal discharge be treated empirically with metronidazole and when candida noted, to treat for candidiasis as well. This study showed that 28% of patients had no TV, BV or candidiasis by the microbiological diagnostic approach while the visual approach diagnosed 19% of the cases with candidiasis only. If blanket treatment was advocated to all the women complaining of abnormal vaginal discharge then 44% of the women would receive

metronidazole and 84% would receive antifungal therapy unnecessarily. Not only does over diagnosis have financial consequences for the health system, but also carries the risk of possible social consequences in the community [15].

Oral metronidazole is associated with anorexia, nausea, vomiting and skin rashes. It crosses the blood brain barrier and may cause dizziness, convulsions and peripheral neuropathy. Transient leucopenia and disulfiram like action has been seen with metronidazole. 10 to 30% of patients treated with the drug had Candidiasis three weeks later. Hence metronidazole should not be used unless definitely indicated. Antifungal therapy is associated with renal and hepatic complications, hypersensitivity reactions, nausea and vomiting, flatulence and rarely angioedema. FDA condemns blanket therapy and combination therapy for treatment of vaginal infections without proof of infections [5].

5. CONCLUSIONS

Treatment based on Visual diagnosis over treats 38.5% of BV and 9% of Candidiasis whereas it under treats 6% of TV and hence is discouraged. The most ideal approach is the microbiological diagnostic approach for the etiological diagnosis of symptomatic vaginal discharge. In a resource constrained setting, at least a clinical diagnosis based on simple microscopy, pH and amine test with WHO algorithm has to be made prior to treatment. Blanket therapy of symptomatic vaginal discharge with antimicrobials and antifungal has limited role in view of the trends noted in this study. Further studies are needed to know the utility of the various diagnostic approaches and the best approach that

could be implemented in the rapid and accurate diagnosis of symptomatic vaginal discharge.

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