

# Comparison of clinical diagnosis and microbiological test results in vaginal infections

**M. Karaca<sup>1</sup>, M.D., Assist. Prof.; A. Bayram<sup>2</sup>, M.D., Assist. Prof.; M.E. Kocoglu<sup>3</sup>, M.D., Ph.D.; A. Gocmen<sup>4</sup>, M.D., Prof.; F. Eksi<sup>5</sup>, M.D., Ph.D.**

<sup>1,4</sup>Department of Obstetrics and Gynaecology, <sup>2,5</sup>Department of Microbiology and Clinical Microbiology, School of Medicine, Gaziantep University; <sup>3</sup>Department of Microbiology and Clinical Microbiology, Izzet Baysal Medical Faculty, Abant Izzet Baysal University, Bolu (Turkey)

## Summary

Lower genital tract infections continue to be a problem due to the fact that the clinical diagnosis is usually inadequate, and subsequent care is suboptimal. This study aimed at evaluating the accuracy of clinical diagnosis by comparing it with microbiologic test results, and to determine the causative agents of vaginal infections.

Sixty-seven nonpregnant women (18-45 years of age) with the clinical diagnosis of lower genital tract infection were enrolled in the study. Patients were not included if they had a history of vaginal infection during the previous three-month period or intrauterine device. The clinical diagnosis was based on the combinations of symptoms, direct observation of wet mount, homogeneous discharge, vaginal pH > 4.5, and detection of the amine odor after exposure of vaginal secretions to 10% KOH. Vaginal samples were taken with two cotton swabs, one was used for pH determination, and the second was utilized for microbiological tests. Gram staining and cultures with Sabouraud agar and chocolate agar were performed for microbiological diagnosis, and the results were compared.

The clinical diagnoses included 26 (38.8%) candidiasis, 18 (26.8 %) bacterial vaginosis, three (4.5%) trichomoniasis, and 20 (29.9%) mixed vaginal infections. Of the 26 patients with clinical diagnoses of candidiasis, 12 (46.1%) revealed *Candida albicans*, nine (34.6) patients revealed microorganisms other than candida species, and five (19.2%) patients had no growth. Five (27.8%) bacterial vaginosis patients revealed *Gardnarella vaginalis* and 12 patients (66.6%) did not grow any microorganism. The overall rate of accurate clinical diagnoses confirmed by microbiological test results was 43.2%. Seventeen (43.6) of the 39 microbiological test results correlated with clinical diagnosis, and no growth was observed in 28 (41.8%) cultures.

We conclude that the clinical diagnosis of vaginal infection is inadequate and should be confirmed with microbiological testing if the resources are available.

**Key words:** Vaginal infection; Clinical diagnosis; Microbiological diagnosis.

## Introduction

Vaginal infections are the most commonly encountered vaginal diseases in reproductive age and are associated with important complications [1, 2]. Vaginal infections occur as an overgrowth of normal or common colonizers, or as a frank infection [3]. The most common causes are yeast, bacteria, protozoa, viruses, and parasites [3]. Vaginal discharge is the most common complaint in these patients, and bacterial vaginosis is the most common cause of abnormal vaginal discharge in adult women [3, 4]. The diagnosis of vaginal infections are based primarily on the clinical findings, and Amsel criteria [milky discharge, pH greater than 4.5, positive whiff test, clue cells in wet-mount preparation) are mostly used for this purpose [5-7]. Evaluating gram-stained vaginal smears also aids in the identification of vaginal infections [8]. The gram stain is usually scored by using the Nugent system which uses a scoring system between 0 and 10 [9]. However, the diagnosis of vaginal infections using the combinations of clinical signs and symptoms with office-based tests and microscopy is mostly inadequate [10]. In addition, the evaluation and care provided to women presenting with vulvovaginal symptoms have

been reported to be suboptimal [11]. Therefore, the diagnosis and the subsequent treatment modality for women with lower genital tract infections continue to be a major problem for women's healthcare clinics [10]. The aim of this study was to evaluate the correlation between clinical and laboratory diagnosis, and to determine the causative agents of vaginal infections.

## Materials and Methods

The study was approved by the Local Ethical Committee of the Faculty of Medicine, University of Gaziantep, and written and verbal informed consent was obtained from all patients. Sixty seven nonpregnant women aged between 18-45 years who had had at least one untreated genital complaint, and had the clinical diagnosis of lower genital infection were enrolled in the study. Inclusion criteria consisted of history of vaginal discharge, change in the character of vaginal discharge, abnormal vaginal odor, vaginal itching, and lower genital tract burning. Patients were not included if they had a history of vaginal infection during the last three-month period or intrauterine device.

Each woman underwent a speculum examination that included direct observation and evaluation of vaginal secretions for color, viscosity, and homogeneity. Vaginal samplings with two cotton swabs were performed, one of which was used for pH determination. The second swab was utilized for microbiological tests.

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Clinical diagnoses were based on the combinations of symptoms and office-based testing that included direct observation of wet mount, homogeneous discharge, vaginal pH > 4.5, and detection of the amine odor after exposure of vaginal secretions to 10% potassium hydroxide. The following methods were used for microbiological diagnosis: Gram stain for bacterial vaginosis, Sabouraud agar for yeasts, and chocolate agar for *Neisseriae spp.* The correlation between the clinical diagnosis and the microbiological diagnosis was investigated together with the causative agents of vaginal infections.

Statistical analysis was performed with the SPSS statistical software (SPSS Inc., Chicago, IL) program. Results are presented as mean  $\pm$  standard deviation or %. The chi square test was used to compare occurrences between the two groups; a p value of less than 0.05 was considered significant.

## Results

Demographic data of the patients are shown in Table 1. The mean age of 67 enrolled women was  $33.5 \pm 11$  and the majority were married. Most of the patients had a

Table 1. — Demographic data of patients ( $n = 67$ ) (number  $\pm$  SD or %).

Age	33.5 $\pm$ 11
Weight	65 $\pm$ 17
Marital status (married/unmarried)	66/1
History of previous lower genital tract infection	46/21

history of previous genital tract infections. The most common complaint was abnormal vaginal discharge, and the most frequently encountered clinical diagnosis was vaginal candidiasis (38.8%). Eighteen patients (26.8%) had a clinical diagnosis of bacterial vaginosis, three patients (4.5%) were diagnosed with trichomoniasis, and 20 (29.9%) patients were diagnosed as having mixed vaginal infections. Of the 26 patients who had a clinical diagnosis of candidiasis, 12 (46.1%) revealed *Candida albicans*, nine (34.6%) revealed microorganisms other than candida species, and no growth was observed in five (19.2%) cultures. Five patients (27.8%) with a clinical diagnosis of bacterial vaginosis revealed *Gardnerella vaginalis*, one revealed *Candida Albicans*, and 12 patients (66.6%) did not grow any microorganisms in the culture. The overall rate of the accurate clinical diagnosis confirmed by the microbiological test results was 43.2%. Twenty-eight (41.8%) patients did not grow any microorganisms in the culture although they had a clinical diagnosis of vaginal infection, and ten (14.9%) patients revealed different microorganisms than that of the clinical diagnosis. Of the 39 microbiological test results, 17 (43.6%) results correlated with clinical diagnosis (Table 2).

## Discussion

The diagnosis of lower genital tract infections continues to be a problem since most of the diagnoses are based on clinical findings. It has been reported previously that presumptive diagnoses of lower genital infections in

Table 2. — Results of clinical and microbiological diagnoses (number, %).

	Clinical Diagnosis (n, % of total)	Confirmed clinical diagnosis (n, % of clinical diagnosis)	Microbiological diagnosis (n, % of total)
Vaginal Candidiasis	26 (38.8%)	12 (46.1%)	22 (32.8%)
Bacterial vaginosis	18 (26.8%)	5 (27.8%)	15 (22.3%)
Trichomoniasis	3 (4.5%)	0	2 (2.9%)
Mixed	20 (29.9)	12 (60.0%)	0
No growth	—	—	28 (41.8%)
Total	67 (100%)	29 (43.2%)	67 (100%)

women with genital tract complaints invariably lead to significant numbers of women being misdiagnosed or under diagnosed. Even under the best circumstances, there will be missed diagnoses and consequently erroneous treatment [10]. Wiesenfeld *et al.* [11] reported that treatment without adequate evaluation of the etiology of the symptoms occurred in 54% of visits in which medication was prescribed. Contradictory to these reports Hellberg *et al.* [12] reported that when there is a clinical suspicion of bacterial vaginosis, the sniff test is positive and differential diagnoses are excluded, one can safely treat a woman for bacterial vaginosis. In our study the clinical diagnosis was confirmed in only 43.2% of patients meaning that the treatment in 56.8% of patients was not correct. These results indicate that symptoms alone should not be used to direct treatment in instances in which resources permit more complete evaluation.

There are different reports in the literature about the causes of lower genital tract infections. Bacterial agents (*Neisseria*, *Streptococcus* and *Staphylococcus* species) were predominantly (51.2%) isolated from vaginal fluid culture, followed by fungi (43.2%) in the study of Otuonye *et al.* [13]. Similarly, bacterial vaginosis among women complaining of vaginal discharge was more prevalent than vaginitis caused by *Trichomonas vaginalis* or yeasts [14]. On the other hand, Rivera *et al.* [15] reported that the most frequent diagnosis was candidiasis (26%), followed by bacterial vaginosis (16%), and trichomoniasis (16.5%). *Candida* genus (26%) and *Gardnerella vaginalis* (13.8%) were the two most common pathogens reported in a study performed by retrospective microbiologic evaluations of vaginal cultures [16]. Similar to the reports of Rivera *et al.* [15] and Acikgöz *et al.* [16], the most frequently encountered microorganisms in our study were *Candida* genus (32.8%) and *Gardnerella vaginalis* (22.3%).

The most frequently encountered symptoms of vaginal infections include abnormal vaginal discharge, odor, and wetness [3]. Posner *et al.* [17] reported that using the WHO syndromic diagnosis for bacterial vaginosis, 99% of women had abnormal vaginal discharge. However, Klebanoff *et al.* [18] reported that 58% of women with bacterial vaginosis had noted odor, discharge, and/or wetness in the previous six months compared with 57% of women without bacterial vaginosis, and there was no significant difference between the two groups. There was

no correlation reported in a study between the symptoms of vaginal discharge and the diagnosis of bacterial vaginosis, but the presence of discharge noted by the clinician was associated with bacterial vaginosis [19]. All vaginal discharge does not mean bacterial vaginosis, however most of the patients with bacterial vaginosis had vaginal discharge. Gram stain provides a simple and inexpensive method for laboratory confirmation of bacterial vaginosis [19]. Hiller *et al.* [20] claimed that vaginal gram stains are more useful than cultures for laboratory confirmation of bacterial vaginosis. Gratacos *et al.* [21] reported that the sensitivity and specificity of Amsel criteria compared with gram stain in the diagnosis of bacterial vaginosis in 492 pregnant women were 35% and 99%, respectively. The best correlation was reported to be between clinically diagnosed bacterial vaginosis and gram stain results in which 92% of women with gram stain evidence of bacterial vaginosis were diagnosed by Amsel's clinical criteria [5]. However, the clinical diagnosis in our study did not correlate well with the microbiological test results.

### Conclusion

Our results indicate an inaccurate diagnosis of lower genital tract infections that was based on clinical symptoms. We conclude that the diagnosis of vaginal infections should be based on microbiological testing if the resources are available.

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Address reprint requests to:  
M.E. KOCOGLU, M.D.  
Aibü İzzet Baysal Tıp Fakültesi  
Mikrobiyoloji ve Klinik  
Mikrobiyoloji Anabilim dalı  
14280 Bolu (Turkey)

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