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Diagnosis of Vaginal *Candidiasis* and *Trichomonas vaginalis* Infection by Antibody Coated Latex Particles

Hossein Yousofi-Darani[1], Seyedeh Maryam Sharafi[2*], Maryam Heidari[3], Simin Taghi Poor[4], Rasool Jafari[1] and Seyed Mohsen Hosseini[5]

[1]Department of Parasitology and Mycology, Isfahan University of Medical Sciences, Isfahan, Iran.
[2]Student Research Committee, Isfahan University of Medical Sciences, Isfahan, Iran.
[3]Shahrekord University of Medical Sciences, Shahrekord, Iran.
[4]Jundishapur University of Medical Sciences, Ahvaz, Iran.
[5]Department of Statistics, School of Health, Isfahan University of Medical Sciences, Isfahan, Iran.

Authors' contributions

This work was carried out in collaboration between all authors. Author HYD designed the study and managed the literature searches and analyses of the work. Author SMS wrote the protocol and the first draft of the manuscript. Author MH collected the vaginal samples. Author STP performed lab works. Author RJ helped with preparing the first draft of the manuscript. Author SMH performed the statistical analysis. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: Candidiasis is a fungal infection caused by *Candida* spp. Trichomoniasis is also an infection with worldwide distribution. Recurrent vaginitis which may be associated with lack of proper diagnosis is now one of the problems of women visiting Gynecology clinics. Considering this fact that conventional laboratory methods do not possess enough sensitivity or may be time

**Corresponding author: E-mail: sharafi_maryam62@yahoo.com;*

consuming, using a rapid and easy method is important in the differential diagnosis of vaginal infections. The aim of this study was diagnosis of vaginal infections using latex agglutination method.

Methods: In this descriptive analytical investigation, vaginal swabs were collected from 186 women suspected to vaginal infection referred to the Gynecology clinics in Shahrekord, Iran. All samples were tested using wet smear, culture and latex agglutination methods. To estimate sensitivity and specificity of the latex agglutination method, culture method considered as gold standard.

Results: Sensitivity and specificity of the latex method for *Trichomonas vaginalis* infection was 70% and 96% and for *Candida* infection was 80% and 90% respectively. Also, the positive and negative predictive values for *Trichomonas vaginalis* were 50% and 98% and for *Candida* infection were 87% and 84%, respectively.

Conclusion: Latex agglutination method has an appropriate sensitivity and specificity for detection of *Trichomonas vaginalis* and *Candida* Spp. in human samples. So, with further modifications this method can be used for diagnosis of vaginal infections in medical laboratories.

Keywords: Sensitivity; specificity; latex agglutination kit; Trichomonas; Candida.

1. INTRODUCTION

Trichomonas vaginalis is a protozoan parasite with 4 flagella, an anterior nucleus, and an undulating membrane. Trichomoniasis is a sexually transmitted disease that causes infections in 2-3 million women annually [1]. The most common complaint is vaginal discharge with irritation and itching. Infection in men is often asymptomatic, but there are more severe signs when prostate or seminal sac and the upper part of the genitourinary tract are involved. Isolation of *Trichomonas vaginalis* from infants with respiratory diseases and conjunctivitis shows that infants can be infected during birth. Trichomoniasis diagnosis is based on detection of parasite in culture and wet smear. Immunological diagnostic tests for *Trichomonas Vaginalis* infection are including EIA (enzyme immunosorbent assays), DFA (direct fluorescent antibody) and LA (latex agglutination) [2].

Species of *Candida* can create wide range of opportunistic infections in humans and animals. *Candida albicans* is the main pathogenic species. *Candida* species cause surface and mucosal infections that lead to systematic and lethal infections [3]. Various PCR methods have been reported for differential diagnosis of *Candida* species [4].

Vaginal infection is one of the health problems of women in the primary health care system. Various methods such as wet smear, pap smear, culture, serological tests such as ELISA and recently molecular methods have been used for differential diagnosis of three main causes of vaginal infections (*Candida albicans*, bacterial vaginitis and *Trichomonas vaginalis*). Lack of an appropriate diagnosis test, is usually associated with using multi drug regime. Routine laboratory diagnostic methods such as microscopic examination don't have enough sensitivity and the culture methods are time consuming [5-9]. Therefore, it is important to use a rapid and easy method for differential diagnosis of vaginal infections. In this study, sensitivity and specificity of the latex agglutination method as a simple and rapid method for the diagnosis of vaginal infections have been investigated.

2. METHODS

In this descriptive study sensitivity and specificity of latex agglutionation kit developed by Darani et al. [10,11] for rapid diagnosis of vaginal infections have been evaluated. For this purpose vaginal samples from 186 women referred to Imam Ali Shahrekord clinic, in Shahrekord city, Iran were collected with informed consent. The women who were not satisfy to be enrolled in the study were excluded from the study. From each patient, three samples (one for wet smear, one for culture and one for latex agglutination test) were collected. For wet smear, one drop of normal saline was placed on slide and the vaginal swab sample mixed and examined under microscope. TYIS medium and Saboraud Dextrose agar mediums were used for culture of *Trichomonas vaginalis* and *Candida* spp. respectively. For this purpose following transferring vaginal swabs, the culture mediums kept in incubator at 37°C and inspected every 24 hours. For agglutination test each vaginal swab was mixed with normal saline and then latex particles coated with either anti *Trichomonas*

vaginalis antibodies or anti *Candida* antibodies were added. Latex particles were coated with purified antibodies as we published before [10]. With observation of agglutination, the test was considered as positive. With considering the culture method as gold standard, sensitivity, specificity, positive and negative predictive value of agglutination method were determined. Samples which were negative with gold standard but were positive with latex test considered as false positive. Also the samples which were positive with gold standard but negative with latex test considered as false negative.

3. RESULTS

In this study, from 186 vaginal samples, in 134 cases (72%) white blood cells (WBC) were observed. Approximately in 100% of cases epithelial cells were observed. In 4 cases, *Trichomonas vaginalis* and in 51 cases *Candida* spp. was observed in wet smear examination (Table 1). From 186 samples, 7 samples were positive for *Trichomonas vaginalis* by culture but base on latex method, 8 samples were positive for *Trichomonas vaginalis* infection.

From 186 samples, 80 samples by culture and 70 samples by latex method were positive for *Candida* spp. The result of two methods culture (Gold standard test) and latex agglutination test is summarized in Table 2.

Sensitivity and specificity of latex agglutination for *Trichomonas vaginalis* were 70% and 96% respectively and for *Candida* spp. were 80% and 90% respectively. Also, positive and negative predictive value for *Trichomonas vaginalis* were 50 and 98% and for *Candida* spp. were 87% and 84% respectively.

4. DISCUSSION

Results of this work showed that 3.7% and 4.3% of samples were positive for *Trichomonas vaginalis* infections using culture and latex agglutination methods respectively. Also 43% and 37.6% were positive for *Candida* spp. infections using culture and latex agglutination methods respectively. So latex agglutination method developed in our previous investigations [10,11] has sensitivity of more than 70% and 80% for diagnosis of *Trichomonas vaginalis* and *Candida* spp. Infections respectively. This method is able to differentiate vaginal infections agents (*Trichomonas vaginalis* and *Candida* spp.) in 5 minutes. In this regard, it has been shown that wet smear method is not enough sensitive, culture method is time consuming and molecular methods are expensive. So, advantages of latex agglutination method are high sensitivity, cost effectiveness and quickness.

In an investigation by Limi et al. it has been shown that latex agglutination method has sensitivity of 100% for *Candida* spp and 86.7% for *Trichomonas vaginalis* infection. The specificity of this test was also 93.3% and 95.1% for *Candida* spp. and *Trichomonas vaginalis* infections respectively. In another work also it has been shown that latex agglutination test was able to diagnosis vaginal infection agents in less than 3 minutes [12-14,9]. Rajakumar et al. also showed that in comparison with conventional methods latex agglutination method was more accurate and rapid for differential diagnosis of vaginal infections agents [15]. In another work sensitivity of latex agglutination method in comparison of culture method was investigated and showed that the sensitivity of this immunological test was 100% and 86.7% for *Candida* spp. and *Trichomonas vaginalis* respectively [12].

In another study, sensitivity and specificity latex agglutination test for presence of *Trichomonas vaginalis* in 3807 vaginal samples of women that referred to gynecology clinics were 98% and 92.1% respectively [16].

Table 1. Results of wet smear and culture methods for 186 vaginal swabs of patients referring to gynecology clinics

Observation or test	Number of patients	Percent
White blood cells	134	% 72
Epithelial cells	185	% 99.4
Trichomonas vaginalis by Wet smear	4	% 2.1
Trichomonas vaginalis by Culture	7	% 3.7
Candida spp. by wet smear	51	% 27.4
Candida spp. by culture	80	% 43

Table 2. Results of two methods of culture (Gold standard test) and latex agglutination test for diagnosis of vaginal infections in 186 swab samples of patients referring to gynecology clinics

	Trichomonas vaginalis		*Candida albicans*	
	Gold standard test	**Latex test**	**Gold standard test**	**Latex test**
Positive samples	7	8	80	70
Negative samples	179	178	106	116
total	186	186	186	186
False positives	7		11	
False negative	3		20	

5. CONCLUSION

In the present study, it has been shown that Latex Agglutination Kit used in this work has an appropriate sensitivity and specificity for the diagnosis of vaginal infections. This kit is able to differentiate *Trichomonas vaginalis* from *Candida* infections in about 5 minutes. In addition to rapid operation, this kit is more economical than culture and molecular method.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee. The ethical permission number is 192098, in Isfahan University of Medical Sciences, Isfahan, Iran.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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