

## **EVALUATION AND COMPARISON OF CLINICAL AND PATHOLOGICAL METHODS FOR THE DIAGNOSIS OF CERVICAL-VAGINAL INFECTION**

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### **ABSTRACT**

One of the important problems in the public health and clinical Medicine is cervical-vaginal infections. Pap smear is one of the most widely accepted screening procedures for cervical cancer, and can prevent pre- invasive disease, cervical dysplasia, and invasive cervical cancer. This study aims to compare the clinical and pathological methods in the diagnosis of vaginal infections and determine whether clinical observation is sufficient in the absence of pathological methods. **Method:** This cross-sectional study was performed on 1448 non-pregnant women attended to 12 health centers in the Dasht-e-Azadegan city during 2007-2011. After taking the informed consent from participants and explaining the aim of study, questionnaires regarding demographic characteristics, and contraceptive methods used

were completed by researcher. Then, the women were examined by a trained obstetrician and Pap smear tests were taken. Also, Pap smear samples were sent to the pathology laboratory. All data were analyzed using SPSS/ver 19. As well as descriptive and analytical statistics (chi-square test) were applied. **Results:** The results showed that most participant had primary

education, Majority of the women were in the age group 20-30 years. 55.9% and 44.1% of individuals were respectively in urban and rural areas. Most of the women were using LD as a contraceptive method (34.2%). Based on Pap smear results the prevalence of cervical-vaginal infections was 9% while in pathological method this rate was almost 32%. There were significant differences between clinical and pathological methods ( $p < 0.001$ ). **Conclusion:** The current study has emphasized the simultaneous use of both clinical observations and pathological methods in the diagnosis of vaginal infections because applying only the clinical method causes unnecessary interventions such as prescribing inappropriate drugs.

**Keywords:** Cervical-vaginal, Infection, Clinic, Pathologic, Diagnosis, Pap-smear, women.

## INTRODUCTION

One of the important problems in the public health and clinical Medicine is cervical-vaginal infections [1]. Such infections can lead to costly treatments and even death [2-4]. The long term complications of infections can include infertility, preterm delivery, and low birth weight [1, 5]. Many studies have shown that cervical-vaginal infections play an important role in developing of cervical cancer [5-6]. Cervical cancer is the second most common cancer worldwide [7]. Also, the organisms responsible for these infections facilitate HIV transmission [8-11]. About 95% of cervical-vaginal infections are caused by Gardnerellavaginalis, Candidiasis and Trichomoniasis[1].

Pap smear is one of the most widely accepted screening procedures for cervical cancer[7]. Pap smear, by identification either of the organism or of characteristic cytological cellular changes, can easily detect Gardnerellavaginalis, Trichomonasvaginalis, Candida albicans, and STD pathogens[12-13]. Since cervical cancer is a slow progressive disease, Pap smear can prevent pre- invasive disease, cervical dysplasia, and invasive cervical cancer[2, 7]. Thus, this technique can become an important tool especially in developing countries[14].

Considering genital infections constitute a significant percentage of outpatient visits in the obstetrics and gynecology clinic[15], this study aims to compare the clinical and pathological methods in the diagnosis of vaginal infections and determine whether clinical observations is sufficient in the absence of pathological methods.

## METHOD

This cross-sectional study was conducted to evaluate and compare the results obtained from pap-smear test and clinical observations about cervical-vaginal infections in women in the Dasht-e-Azadegan city during 2007-2011. All non-pregnant women attended to 12 health centers (including 8 rural health centers and 4 urban health centers) were enrolled, and overall 1448 women were considered as the study population. After taking the informed consent from participants and explaining the aim of study, questionnaires regarding demographic characteristics, and contraceptive methods used were completed by researcher. Then the women were examined by a trained obstetrician and Pap smear tests were taken.

### The Pap smear sampling method

The woman was in litotomia position for examination and taking discharges from the vaginal wall and posterior fornix using the speculum and sterile cotton swabs on glass slides by a trained obstetrician. Then these samples were sent to check for cervical-vaginal infections (like Chlamydia, Candida, Gardnerella, and Trichomonas) in the pathology laboratory.

### Data analysis

All data were analysed using SPSS v.19. To analyze, descriptive statistics such as mean, and standard deviation were used. As well as the chi-square test was applied to find the differences between two variables. The Significance level of 0.05 was considered for statistical analysis.

## RESULTS

The results showed that most participants had primary education and only about 4% of them had a university education. Majority of the women were in the age group 20-30 years. Also, 55.9% and 44.1% of participants were respectively in urban and rural areas (Table 1). About the use of contraceptive methods, most of the women were using LD as the contraceptive method (34.2%).

### The results of pap-smear test

Almost 9% of samples were infected with one of microorganisms such as Chlamydia, Coccobacillus, Candida, Gardnerella, and Trichomonas. The highest rate of cervical-vaginal infections was related to the candida, which included 6% of infections.

The most prevalence of cervical-vaginal infections was in the age group of 20-30 years and the lowest rate was seen in the age group above 50 years (Table 2). But there was not a significant association between age groups and cervical-vaginal infections ( $p=0.31$ ).

Regarding the use of contraceptive methods, the lowest cervical-vaginal infection rate was observed in those who were using DMPI and the highest rate was related to LD. Also a significant association was between contraceptive methods and cervical-vaginal infections ( $p < 0.001$ ).

Maximum prevalence of cervical-vaginal infections was seen respectively in illiterate women and women with the primary education. A significant association was between education levels and cervical-vaginal infections ( $p = 0.018$ ). The prevalence of cervical-vaginal infections was more in rural women than urban women and there was a significant association between residence and cervical-vaginal infections ( $p < 0.001$ ).

### The results of clinical observations

Overall, around 32% of infections were caused by Chlamydia, Gonorrhea, Candida, Gardnerella, and Trichomonas. The candida was responsible for 18.7% of cervical-vaginal infections. As can be seen in Table 3, the highest prevalence of cervical-vaginal infections was in women with the primary education. A significant association was between education levels and cervical-vaginal infections ( $p = 0.035$ ).

**Table 1-General characteristics of study participants (n=1448)**

Variable		Number	Percent
Education	Illiterate	417	28.8
	Elementary	443	30.6
	Guidance	253	17.5
	diploma	272	18.8
	University degree	63	4.4
Age	<20	147	10.2
	20-30	631	43.6
	31-40	466	32.2
	41-50	163	11.3
	>50	41	2.8
Residence	Urban	809	55.9
	rural	839	44.1

**Table2-The prevalence of cervical-vaginal infections obtained from pap-smear test by demographic characteristics and contraceptive methods used**

Variable		The type of cervical-vaginal infection N(%)								P-value
		Chlamydia	Coco Bacillus	Condida	Gardnerella	Normal	Trichomonasis	Other*	Total	
Education	Illiterate	1(2%)	4(1%)	35(8.4%)	3(0.7%)	187(44.8%)	6(1.4%)	181(41.7%)	417	0.018
	Elementary	1(0.2%)	4(0.9%)	30(6.8%)	4(0.9%)	192(43.3%)	4(0.9%)	208(47%)	443	
	Guidance	0(0%)	1(0.4%)	16(6.3%)	3(1.2%)	85(33.6%)	2(0.8%)	146(57.7%)	253	
	diploma	1(0.4%)	0(0%)	8(2.9%)	1(0.4%)	100(36.8%)	2(0.7%)	160(58.8%)	272	
	University degree	0(0%)	0(0%)	2(3.2%)	0(0%)	21(33.3%)	0(0%)	40(63.5%)	63	
Age	<20	0(0%)	1(0.7%)	14(9.5%)	1(0.7%)	57(38.8%)	2(1.4%)	72(48.9%)	147	0.31
	20-30	0(0%)	6(1%)	40(6.3%)	7(1.1%)	257(40.7%)	4(0.6%)	317(50.3%)	631	
	31-40	2(0.4%)	0(0%)	24(5.2%)	2(0.4%)	187(40.1%)	4(0.9%)	247(53%)	466	
	41-50	1(0.6%)	2(1.2%)	10(6.1%)	1(0.6%)	65(39.9%)	4(2.5%)	80(49.1%)	163	
	>50	0(0%)	0(0%)	3(7.3%)	0(0%)	19(46.3%)	0(0%)	19(46.4%)	41	
Residence	Urban	2(0.2%)	2(0.2%)	34(4.2%)	8(1%)	271(33.5%)	11(1.4%)	481(59.5%)	809	<0.00
	rural	1(0.2%)	7(1.1%)	57(8.9%)	3(0.5%)	314(49.1%)	3(0.5%)	254(39.7%)	639	1
The methods of	LD	2(0.4%)	4(0.8%)	40(8.1%)	7(1.4%)	212(42.8%)	7(1.4%)	235(46.5%)	495	<0.00
	TP	0(0%)	0(0%)	7(6.9%)	1(1%)	45(44.1%)	3(2.9%)	46(45.1%)	102	1
	DMPI	0(0%)	1(1.6%)	1(1.6%)	0(0%)	34(54%)	0(0%)	27(42.8%)	63	

contraception	IUD	0(0%)	0(0%)	2(4.3%)	2(4.3%)	10(21.3)	0(0%)	33(70.1%)	47
	CONDOM	0(0%)	0(0%)	11(4.9%)	0(0%)	89(39.7%)	2(0.9%)	122(54.5%)	224
	TL	0(0%)	0(0%)	8(7.3%)	0(0%)	42(38.2%)	2(1.8%)	58(52.7%)	110
	Natural	0(0%)	0(0%)	8(6.3%)	1(0.8%)	50(39.1%)	0(0%)	69(53.8%)	128
	Un met need	1(0.6%)	4(2.4%)	11(6.5%)	0(0%)	58(34.3%)	0(0%)	95(56.2%)	169
	Menopause	0(0%)	0(0%)	0(0%)	0(0%)	4(30.8%)	0(0%)	9(69.2%)	13
	Other	0(0%)	0(0%)	3(3.3%)	0(0%)	36(40%)	0(0%)	53(56.7%)	92

\*Other including: atrophy, inflammation, reactive, and etc.

**Table3-The prevalence of cervical-vaginal infections obtained from clinical observations by demographic characteristics and contraceptive methods used**

Variable		The type of cervical-vaginal infection N(%)								P-value
		Chlamydia	Gonorrheal	Condidia	Gardnerella	Normal	Trichomonas	Other*	Total	
Education	Illiterate	24(5.8%)	0(0%)	80(19.2%)	2(0.5%)	155(37.2%)	32(7.7%)	116(27.6%)	417	0.035
	Elementary	44(9.9%)	0(0%)	79(17.8%)	1(0.2%)	160(36.1%)	16(3.6%)	143(32.4%)	443	
	Guidance	17(6.7%)	1(0.4%)	59(23.3%)	2(0.8%)	60(23.7%)	17(6.7%)	97(38.4%)	253	
	diploma	20(7.4%)	0(0%)	40(14.7%)	0(0%)	84(30.9%)	11(4%)	117(43%)	272	
	University degree	5(7.9%)	0(0%)	13(20.6%)	0(0%)	19(30.2%)	1(1.6%)	25(39.7%)	63	
Age	<20	9(6.1%)	1(0.7%)	23(15.6%)	0(0%)	52(35.84%)	7(4.8%)	55(36.96%)	147	<0.001
	20-30	44(7%)	0(0%)	115(18.2%)	2(0.3%)	207(32.8%)	34(5.4%)	229(36.3%)	631	

	31-40	42(9%)	0(0%)	104(22.3%)	0(0%)	144(30.9%)	21(4.5%)	155(33.3%)	466	
	41-50	13(8%)	0(0%)	25(15.3%)	2(1.2%)	59(36.2%)	14(8.6%)	50(30.7%)	163	
	>50	2(4.9%)	0(0%)	4(9.8%)	1(2.4%)	16(39%)	1(2.4%)	17(41.5%)	41	
Residence	Urban	61(7.5%)	0(0%)	203(25.1%)	3(0.4%)	209(25.8%)	65(8%)	268(33.2%)	809	<0.00
	Rural	49(7.7%)	1(0.2%)	68(10.6%)	2(0.3%)	269(42.1%)	12(1.9%)	238(37.2%)	639	1
Work Experience (year)	2	29(24.4%)	1(0.8%)	23(19.3%)	0(0%)	36(30.31%)	1(0.8%)	29(24.39%)	119	<0.00
	4	23(3.9%)	0(0%)	121(20.6%)	0(0%)	161(27.4%)	32(5.5%)	250(42.6%)	587	1
	5	41(7.5%)	0(0%)	90(16.4%)	2(0.4%)	223(40.5%)	25(4.5%)	169(30.7%)	550	
	7	17(8.9%)	0(0%)	37(19.3%)	3(1.6%)	58(30.2%)	19(9.9%)	58(30.1%)	192	
The methods of contraception	LD	38(7.7%)	0(0%)	118(23.8%)	0(0%)	157(31.7%)	30(6.1%)	152(30.7%)	495	<0.00
	TP	6(5.9%)	0(0%)	10(9.8%)	2(2%)	38(37.7%)	5(4.9%)	41(39.7%)	102	1
	DMPI	3(4.8%)	0(0%)	8(12.7%)	0(0%)	29(46%)	1(1.6%)	22(34.9%)	63	
	IUD	2(4.3%)	12(25.5%)	2(4.3%)	0(0%)	7(14.9)	1(2.1%)	23(48.9%)	47	
	CONDOM	23(10.3%)	1(0.4%)	47(21%)	0(0%)	70(31.3%)	12(5.4%)	71(31.6%)	224	
	TL	13(11.6%)	0(0%)	20(18.2%)	0(0%)	35(31.8%)	6(5.5%)	36(32.9%)	110	
	Natural	7(5.5%)	0(0%)	27(21.1%)	0(0%)	48(37.5%)	6(4.7%)	40(31.2%)	128	
	Un met need	13(7.7%)	4(2.4%)	16(9.5%)	2(1.2%)	51(30.2%)	11(6.5%)	72(42.5%)	169	
	Menopause	0(0%)	0(0%)	1(7.7%)	0(0%)	3(23.1%)	0(0%)	9(69.2%)	13	
	Other	5(5.6%)	0(0%)	12(13.3%)	0(0%)	35(38.9%)	0(0%)	40(42.2%)	92	

\*Other including: atrophy, inflammation, ulcer, and etc.

**Table4- The prevalence of cervical-vaginal infections based on clinical diagnosis and Pap smear (n=1448)**

Diagnostic methods	The type of cervical-vaginal infection				
	Chlamydia	Candida	Gardnerella	Trichomonasis	Normal
Clinical diagnosis	110(7.6%)	271(18.7%)	5(0.3%)	77(5.3%)	478(33%)
Pap-smear	3(0.2%)	91(6.3%)	11(0.8%)	14(1%)	585(40.4%)

The most prevalence of cervical-vaginal infections was in the age group of 20-30 years and the lowest rate was seen in the age group above 50 years. There was a significant association between age groups and cervical-vaginal infections ( $p < 0.001$ ). The prevalence of cervical-vaginal infections was more in urban women than rural women and a significant association observed between residence and cervical-vaginal infections ( $p < 0.001$ ). About the use of contraceptive methods, the highest rate of cervical-vaginal infections was related to LD and CONDOM so that there was a significant association between contraceptive methods and cervical-vaginal infections ( $p < 0.001$ ). Our findings indicated a significant association between clinical observations and the work experience of obstetricians ( $p < 0.001$ ).

Table4 shows the prevalence of vaginal infections according to the diagnostic methods applied. There are significant differences between clinical and pathological methods ( $p < 0.001$ ). Also, the percentage of agreement (coordination) was low between these methods (43.4%).

## DISCUSSION

Our findings indicated that the mean age of women was  $28 \pm 8.075$ . The most prevalence of cervical-vaginal infections was observed in the age group of 20-30 years so that with increasing age the prevalence of infections rises and then decreases, which is consistent with results from other studies [16-18]. The results showed that in both methods there was an association between contraceptive methods and cervical-vaginal infections, and the highest prevalence of cervical-vaginal infections was related to LD. Some of studies reported similar results [15, 17] because combined oral contraceptive play an important role in the incidence of vaginal yeast infections [19].



In this study according to the clinical examinations, the prevalence of Chlamydia, Candida, Gardnerella, Trichomonas infections was respectively 7.6%, 18.7%, 0.3%, and 5.3% while in the pathological method these rates were respectively 0.2%, 6.3%, 0.8%, and 14%. Also, in the clinical observations 33% of subjects were normal, but based on Pap smear test about 40% of participants had normal result. Kheirkhah et al. also showed that based on clinical examination the prevalence of Candida, Trichomonas, Gardnerella, and normal was respectively 10.3%, 4.3%, 13.4%, and 28.6%, but laboratory results respectively indicated prevalence of 9.6%, 2.9%, 14.1% and 27.6% [15]. In other study, the prevalence of Trichomonas in the clinical examinations was 19/04%, but this rate in the microscopic observation was 42.9% [17].

Comparing the results of the two methods, we found that percentage of false positive for Chlamydia infections and Candidiasis was respectively 7.2% and 12.4%, and regarding Gardnerella, Trichomonas percentage of false negative was respectively 0.5% and 8.7%. Also, about detecting normal individuals this rate was 7.4%. In another study, Clinical diagnosis than Pap smear had 25.7% false-positive in the diagnosis of Trichomonas [16]. These findings demonstrated that the clinical method alone is not enough and reliable.

Unlike our study, some studies reported that there was no significant association between clinical and pathological methods [15, 17]. This difference could be due to different population studied. Also Kheirkhah et al. indicated that the coordination rate between the obstetrician and Pathologist was 57% whereas in our research this rate was lower (43.4%) [15].

## CONCLUSION

Many studies [16]- as current study- have emphasized the simultaneous use of both clinical observations and pathological methods in the diagnosis of vaginal infections because applying only the clinical method causes unnecessary interventions such as prescribing inappropriate drugs.

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