

Comparing some screening values of Pap test and visual inspection with acetic acid in the diagnosis of precancerous cervical lesions (2016-2017)

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Article Info	Abstract
* Corresponding authors: Fatemeh Amiri, E-mail: amiri.f.986@gmail.com	Background: Visual inspection with acetic acid (VIA) is one of the several methods that can serve as an alternative to the Pap test for diagnosis of precancerous lesions in the cervix. This study aimed to compare the screening value of VIA and Pap test in such diagnosis.
Article history Received: Apr, 2018 Accepted: Jul, 2018	Materials and Methods: The population of this descriptive study was 304 women who attended Afzalipour Hospital in Kerman, Iran, from March 2016 to March 2017 that enrolled in the study by the convenience sampling method. Pap test and VIA were performed and followed by colposcopy. Data were analyzed using SPSS software, chi-square and Fisher's exact tests, logistic regression.
doi 10.29252/johe.7.3.132	Results: The result of Pap test in 136 (44.74%), VIA in 200 (65.79%), and colposcopy in 98 (32.24%) patients was positive. The sensitivity and specificity of VIA was 100% and 34.7%, respectively. The sensitivity and specificity of Pap test was 50.0% and 55.3%,
Print ISSN: 2251-8096 Online ISSN: 2252-0902	respectively. In 93.5% of cervical intraepithelial neoplasia 1 (CIN 1) cases and 100% of CIN 2 and CIN 3 cases, VIA results were true positive (P > 0.999), whereas in 44.2% of CIN 1 cases, 50% of CIN 2 cases, and 42.9% of CIN 3 cases, Pap test results were true positive (P = 0.923).
Peer review under responsibility of Journal of Occupational Health and	Conclusions: The sensitivity of VIA and Pap test was reflected VIA ability to identify all cases of the disease, but the specificity of VIA was found to be only 34.7%, which means that it will cause additional costs by imposing supplementary tests on healthy individuals (false-positives).
Epidemiology	Keywords: Cervical Cancer, Colposcopy, Screening, Pap Test, Iran.

Introduction

Cervical cancer is one of the most common types of cancer in Iranian women after breast, esophageal, gastric, and colorectal cancers (1). This disease is known to be one of the most common causes of death from cancer in developing countries (2).

In Iran, cervical cancer has an annual incidence rate of 400-500 cases, and it is the cause of more than 240 death each year (3). Most often, pre-invasive lesions of this cancer can be diagnosed approximately 10-15 years before the invasion (4). Invasive cervical cancer can be considered a preventable disease; because, firstly, it has a long premalignant period, and secondly, the pre-invasive lesions can be effectively treated (5).

The advanced screening methods are able to identify most cases of cervical cancer even at early stages. More than half of the cases of uterine cancer have been identified by new screening methods in the first phase, when the tumor is limited to the cervix and there is up to 90% chance of survival after surgical treatment or radiation therapy (6). Cervical cancer screening is an important means of preventing this cancer which aims at detecting

preventing this cancer, which aims at detecting lesions in the premalignant stage and reducing the risk of mortality from the disease (7).

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For many years, the primary method of cervical cancer screening around the world has been the cytological evaluation method commonly known as Pap smear or Pap test (8). The main objective of this test is to monitor and address the abnormal changes in cervical cells, which, if left unchecked, may progress toward cervical cancer (9). Considering the limitations of Pap test such as low sensitivity, the need for laboratory facilities, trained staff and special equipment, and the problem in tracking the patients great interest has been shown in the prospects of using alternative methods for screening (10).

One of these alternative methods is visual inspection with acetic acid (VIA). In this method, the cervix must be washed with 3-5 percent acetic acid and then visually inspected in search for intraepithelial lesions appearing as white spots, which if found, will indicate that the result is positive. This test is inexpensive, can be performed during the examination, and does not require special equipment or a second person to interpret the results (8).

Some studies have shown that VIA is as sensitive as or even more sensitive than Pap test in the diagnosis of premalignant or malignant lesions in the cervix (8, 11, 12). In less developed regions of Iran, the shortage of medical facilities and trained pathologists limits the effectiveness of cervical cancer screening through Pap test. An evaluation of VIA's effectiveness in diagnosing cervical cancer may significantly contribute to the planning of such efforts, adoption of proper therapeutic strategies, and improvement of health care in these regions and thus in Iran as a whole. In view of these potentials, the present study aimed to compare the sensitivity, specificity, and positive predictive value of VIA and Pap test in screening for cervical cancer. Still, Pap test is approved by the World Health Organization (WHO) as the preferred method of screening for cervical cancer. Therefore, in lowresource settings, it is necessary to seek low-cost, high-efficiency alternatives for the diagnosis of cervical cancer.

Materials and Methods

The population of this descriptive study consisted of non-virgin and non-pregnant women who attended the gynecologic clinic of Afzalipour Hospital in Kerman, Iran, from March 2016 to March 2017. The inclusion criterion was the consent to participate in the study and the exclusion criteria were virginity, menstruation, and history of cone biopsy, total hysterectomy, or cervical cancer. The sample size was equal to the population (n = 304). A checklist was prepared for collecting and organizing demographic data (age, parity, type of delivery, contraceptive methods, smoking) and the results of clinical and laboratory examinations. All participants were first briefed about the study and asked to fill the form of informed consent, and then underwent gynecologic examination for Pap test and VIA. The VIA examiner was kept blind to the result of Pap test.

At VIA, the cervix was stained with 3-5 percent acetic acid for 30 to 60 seconds, and was then observed under sufficient light. The patients with clearly observable acetowhite lesions were considered VIA-positive. Patients with atypical squamous cells of undetermined significance (ASCUS) or more severe lesions were considered Pap test positive (13). Both tests were performed by the same examiner.

Patients with a positive result in any of these tests were sent to the obstetrics and gynecology clinic of the Afzalipour Hospital for colposcopy. If the result of colposcopy was normal, the patient was considered negative; otherwise, biopsy or endocervical curettage (ECC) was performed. Cytology, biopsy, and ECC samples were sent to the pathology department of the same hospital for examination by a pathologist. If the histological report indicated cervical intraepithelial neoplasia 1 (CIN 1) and more severe lesions, the patient was considered positive. The time between screening tests and colposcopy was 1 to 50 days. Finally, SPSS software (version 23, IBM Corporation, Armonk, NY, USA) was used to analyze the data with the help of descriptive statistical methods, chisquare test and Fisher's exact test. The sensitivity, specificity, and predictive value of each test were calculated [95% confidence interval (CI)]. The significance level of all tests was considered to be 0.05.

Results

A total of 304 patients with mean age of 38.14 ± 9.34 years were examined (age range: 22-75 years).

From 304 women, 31 (10.20%) ones did not have a parity, 58 (19.08%) had one, 107 (35.20%) had two, 54 (17.76%) had three, 26 (8.55%) had four, 18 (5.92%) had five, 1 (0.33%) had six, 3 (0.99%) had seven, 4 (1.31%) had eight, and 2 (0.66%) had ten parities prior to the examination.

The most frequent delivery type was vaginal with 218 cases (71.7%). The most frequent contraception methods, excluding the postmenopausal subjects, were the tubectomy (25.0%) and use of barrier (22.0%). 4.3% of patients were smokers.

There was no significant difference in terms of delivery type between the patients with positive and negative VIA test (P = 0.274). However, a significant difference was found between these patients in terms of contraception method (P = 0.001). In the cases with positive Pap test, the postmenopausal patients were the most frequent group, and the

women who were using barrier and those who had no contraception had the second and third highest frequency, respectively (P = 0.017). No significant difference was found between the VIA results (P = 0.553) or the Pap test results (P = 0.500) of smoking and non-smoking patients (Table 1).

Table 1: The relationship between diagnostic tests with type of delivery, contraceptive method, and smoking in women
referred to Afzalipour Hospital of Kerman, Iran (2016-2017)

				VIA*					Pap te	st	
Variable		Positive Negativ		jative	Р	Positive		Negative			
	Ν	%	Ν	%	- P	Ν	%	Ν	%	P	
	Without	25	12.5	7	6.7		18	13.2	14	8.3	0.387
Type of delivery	Vaginal	139	69.5	79	76.0	0.274	94	69.1	124	73.8	
	Cesarean	36	18.0	18	17.3	-	24	17.6	30	17.9	-
	None of them	6	3.0	70	67.3	0.001	22	16.2	54	32.1	- 0.017
Contraceptive	After menstruation	101	50.5	0	0		54	39.7	47	28.0	
	Others	4	2.0	0	0		3	2.2	1	0.6	
	Oral tablet	19	9.5	0	0		6	4.4	13	7.7	
	IUD**	4	2.0	8	7.7		7	5.1	5	3.0	
	Barrier	48	24.0	19	18.3	-	32	23.5	35	20.8	•
	Tubectomy	18	9.0	7	6.7	-	12	8.8	13	7.7	-
Smoking	Yes	10	5.0	3	2.9	0 550	7	5.1	6	3.6	- 0.500
Smoking	No	190	95.0	101	97.1	0.553	129	94.9	162	96.4	

* VIA: Visual inspection with acetic acid;

** IUD: Intrauterine device

The results showed that there was no correlation between number of parities with VIA test (P = 0.163) and Pap test (P = 0.176).

In total, 77 cases of CIN 1, 10 cases of CIN 2, and 7 cases of CIN 3 were observed. VIA was positive in 93.5% of CIN 1 cases and 100% of CIN 2 and CIN 3 cases. In comparison, Pap test revealed only 42.2% of CIN 1 cases, 50% of CIN 2 cases, and 42.9% of CIN 3 cases.

The results of VIA and Pap test with colposcopy are compared in table 2. Of 98 patients who were

ultimately diagnosed positive, 93 cases were successfully identified by VIA (true positive) and 5 were not identified by this method (false negative). This test also incorrectly identified 107 healthy people as positive (false positive). Of 98 patients who were ultimately diagnosed positive, only 54 cases were successfully identified by Pap test (true positive), and 44 cases remained unidentified by this method (false negative). Pap test falsely identified 82 healthy people as positive (false positive).

Table 2: The sensitivity and specificity of the visual inspection with acetic acid (VIA) and Pap test with the golden test
(standard) of colposcopy of women referred to Afzalipour Hospital of Kerman, Iran (2016-2017)

		Colposcopy				
		+	-	Total		
VIA*	+	93	107	200		
	-	5	99	104		
Pap test —	+	54	82	136		
	-	44	124	168		
Total		98	206	304		

* VIA: Visual inspection with acetic acid

The VIA managed to correctly identify 95% of positive cases, which reflects its high sensitivity in the diagnosis of precancerous cervix lesions. However, the specificity of this test (i.e., the ratio of healthy patients who have been correctly identified

as being healthy) was calculated to be 48.06%, which is very low. The positive predictive value (PPV) of VIA was found to be 46.5%. The PPV is the probability that the subjects who tested positive indeed have the disease. Mathematically, this

parameter is the ratio of the number of true positives to the number of positive calls, i.e., the number of all patients who have been identified, truly or falsely, as positive. According to the positive likelihood ratio calculated for VIA, this method makes the diagnosis 1.83 times more accurate. It can be seen that only about half of the patients who were ultimately diagnosed positive also tested positive using Pap smear. Accordingly, the sensitivity of Pap test in the diagnosis of precancerous cervical lesions was calculated to be 55.1%. The specificity of this test was found to be 61.19%. The PPV of Pap test was calculated to be 39.71%, and the positive likelihood index calculated for this test indicates that it makes the diagnosis 1.38 times more accurate (Table 3).

Table 3: The results of diagnosis of cervical cancer by the visual inspection with acetic acid (VIA) and Pap test methods in women referred to Afzalipour Hospital of Kerman, Iran (2016-2017)

Indiaatar		VIA*	Pap test		
Indicator —	Value	95% CI**	Value	95% CI	
Sensitivity	94.90%	88.49% to 98.32%	55.10%	44.72% to 65.17%	
Specificity	48.06%	41.06% to 55.11%	60.19%	53.16% to 66.93%	
Positive likelihood ratios	1.83	1.59 to 2.10	1.38	1.08 to 1.77	
Negative likelihood ratios	0.11	0.04 to 0.25	0.75	0.58 to 0.95	
Positive predictive value	46.50%	43.06% to 49.97%	39.71%	34.01% to 45.70%	
Negative predictive value	95.19%	89.28% to 97.92%	73.81%	68.79% to 78.28%	

* VIA: Visual inspection with acetic acid;

** CI: Confidence interval

Table 4 presents the results of logistic regression analysis of the relationship between the variables that affect VIA results. Most of the studied variables were not significantly correlated with the outcome of VIA. The only exclusion in this regard was the contraception method, in the sense that women who were not using any contraception method were 86 times less likely to be VIA positive than postmenopausal patients, and were 14 times less likely to be VIA positive than patients who were using barrier contraception.

Table 4: Results of logistic regression analysis: Investigating the relationship between effective variables on the outcome
of the visual inspection with acetic acid (VIA) of women referred to Afzalipour Hospital of Kerman, Iran (2016-2017)

Variable	в	Р	Exp(B)	95% CI * fo	Hosmer and Lemeshow	
				Lower	Upper	Р
Age	-0.048	0.259	0.954	0.878	1.036	
Parity	-0.387	0.194	0.679	0.379	1.218	-
No delivery						-
Vaginal delivery	1.528	0.222	4.610	0.396	53.618	-
Cesarean	0.305	0.617	1.357	0.410	4.496	-
No contraceptive						-
After menstruation	-5.051	< 0.001	0.006	0.001	0.056	0.895
Other	20.021	0.996	495703179.6	0.000	•	-
Oral tab	17.621	0.999	44933302.4	0.000	•	-
IUD **	18.547	0.999	113468637.5	0.000		-
Barrier	-3.527	0.002	0.029	0.003	0.288	-
Tubectomy	-1.580	0.074	0.206	0.036	1.165	-
Smoking	-1.867	0.336	0.155	0.003	6.908	-

* **CI:** Confidence interval

** IUD: Intrauterine device

The results of logistic regression analysis of the relationship between the variables that affect Pap test results are presented in Table 5. None of the

variables had a significant relationship with the results of Pap test.

Variable	в	Р	Exp(B)	95% CI* f	Hosmer and Lemeshow	
				Lower	Upper	Р
Age	0.031	0.150	1.032	0.989	1.076	
Parity	0.049	0.684	1.050	0.830	1.327	_
No delivery						_
Vaginal delivery	0.735	0.224	2.085	0.638	6.811	_
Cesarean	-0.189	0.630	0.827	0.383	1.788	_
No contraceptive						—
After menstruation	-0.555	0.333	0.574	0.187	1.766	0.718
Other	0.477	0.379	1.611	0.557	4.663	_
Oral tab	21.088	0.999	1439946913.0	0.000		—
IUD **	-0.244	0.766	0.784	0.158	3.891	—
Barrier	0.128	0.879	1.137	0.218	5.926	_
Tubectomy	0.064	0.913	1.066	0.337	3.370	—
Smoking	-0.079	0.908	0.924	0.242	3.529	_

Table 5: Results of logistic regression analysis: Investigating the relationship between effective variables on the outcome of the Pap test of women referred to Afzalipour Hospital of Kerman, Iran (2016-2017)

* CI: Confidence interval

** IUD: Intrauterine device

Finally, the results of VIA and Pap test were compared using the receiver operating characteristic (ROC) curve. As can be seen, the area under the curve (AUC) obtained for VIA was 0.715 (95% CI: 0.658-0.772), that is greater than the one obtained for Pap test that was 0.576 (95% CI: 0.508-0.645), which suggests that VIA is of higher diagnostic value than Pap smear (Figure 1).

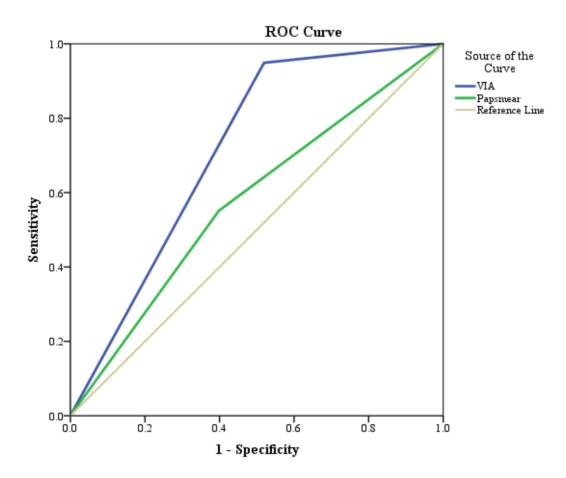


Figure 1: The comparison of visual inspection with acetic acid (VIA) and Pap test of women referred to Afzalipour Hospital of Kerman, Iran (2016-2017) in receiver operating characteristic (ROC) curve (The gold test is colposcopy)

Discussion

One of the most important goals of Pap test is the cervical cancer screening as a prerequisite for control and prevention measures. This method has a proven efficacy in confirming cervical cancer (14), but colposcopy, which is a semi-invasive diagnostic biopsy, still plays the primary role in this regard (15, 16). Pap test has long been the most common method of screening for cervical malignancies in developed countries. However, because of its need for sampling and laboratory equipment, such screening is difficult to be performed in underdeveloped and developing countries (17). As a result, researchers have long searched for alternative methods of cervix screening. Many researchers have suggested that VIA has the potential to serve this purpose. VIA has been already approved in various studies as a valid method of cervical cancer screening (8, 11, 18, 19). This method has been shown to facilitate such screening in underdeveloped regions (12). In a study by Bhattacharyya et al they compared the diagnostic value of VIA and Pap test in screening for cervical cancer in 300 women aged 18 to 60 years. The sensitivity of VIA test and Pap test was 87% and 93%, respectively, which showed that VIA test can be used as an effective method for early diagnosis of cervical cancer (19).

In the present study, VIA test was successful in identifying 93.5% of CIN 1 cases and 100% of CIN 2 and CIN 3 cases, whereas Pap test was successful in identifying only 42.2% of CIN 1 cases, 50% of CIN 2 cases, and 42.9% of CIN 3 cases. Therefore, VIA was found to be considerably more effective than Pap test in identifying premalignant cases. The results reported by Fakour (8), Bhattacharyya (19), and Consul (20) confirm this finding.

In the present study, VIA showed 100% sensitivity and 34.7% specificity, while Pap test showed 50.0% sensitivity and 55.3% specificity. These results are consistent with the findings of other studies in this field (8, 11). In our study, the false positive rate of VIA was 2.0%, which is considerably lower than the rates reported in similar studies (21, 22). Perhaps the reason for the conflict of results is the young research community, because in young people, ectropion and metaplasia are more common (23). The study of Ardahan et al. in Turkey reported 82.14% sensitivity and 50% specificity for VIA, and suggested that VIA can serve as the method of choice for cervical malignancy screening (11). The study carried out by Consul in India reported that the sensitivity and specificity of VIA was 84.2% and 55.2% and sensitivity and specificity of Pap test was 84.2% and 62.1%, respectively. Like the previous

work, these researchers recommended the use of VIA for screening because of its cost-effectiveness. ease of implementation, and high sensitivity (20). Goel applied another method of these tests on 400 women. He used large loop excision of the transformation zone (LLETZ) as the gold standard of diagnosis. The LLETZ method was applied if the result of VIA, Pap test, and colposcopy of the patients was positive. The sensitivity and specificity of VIA was 96.7% and 36.4% and Pap test was 50% and 90%, respectively. They suggested that VIA methods be combined with methods such as colposcopy or Pap test (24). Longatto-Filho showed that Pap test seems a realistic option to improve the detection of high-grade lesions in population-based screening programs (25).

The specificity of VIA in the present study was 34.7%, which signifies the relatively low ability of the method to successfully identify healthy patients. The PPV of VIA, that is the probability that the subjects who tested positive using VIA truly have the disease, was 2%. According to the positive likelihood index calculated for VIA, this diagnostic test is able to make the diagnosis 1.5 times more accurate. The specificity of Pap test was found to be 53.3%, which means that this test correctly identified about half of the healthy patients. The PPV of Pap test was 1.5%, and according to the positive likelihood index, this test is able to make the diagnosis 1.1 times more accurate. From limitations of this study was the discontent of some people with colposcopy. This reduced the positive cases of malignancy. Moreover, the multi-partnership and genital tract infections have not been investigated. It is suggested that in the future studies attention should be paid to the multi-partnership and the history of infections as the causes of malignancy.

Conclusion

This study aimed to compare the performance of VIA and Pap test in the diagnosis of precancerous cervical lesions in terms of sensitivity, specificity, PPV, and positive likelihood ratio. The differences suggest that VIA is more successful than Pap test in improving the diagnosis of precancerous lesions in the cervix. Based on this finding, screening at community settings in Kerman should include a combination of VIA, followed by confirmatory colposcopy to increase the efficiency of screening.

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Conflict of interest: None declared.

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