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Comparison of Visual Inspection Methods Using Either Acetic Acid Solution or Lugol's Iodine Solution with Colposcopy in Screening of Cervical Cancer: A Cross Sectional Study

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ABSTRACT

Background and Objective: We compared two different methods of visual inspection of the cervix, including Visual inspection of the cervix with acetic acid (VIA) and Visual inspection of the cervix with Lugol's iodine (VILI) in terms of sensitivity and specificity in diagnosis of pre-malignant cervical lesions in comparison to colposcopy guided biopsy.

Methods: In this cross-sectional study, a total number of 200 women who were referred to the colposcopy clinic of Arash women's hospital (Tehran, Iran) for cervical cancer screening, underwent VIA, VILI, and colposcopy guided biopsy during 2018-2019.

Results: The calculated sensitivity and specificity of VIA and VILI in this population were (100% and 69.5%) and (100% and 60%), respectively, whereas the sensitivity and specificity of both VIA and VILI tests in combination were 100% and 77.2%. The positive and negative predictive values were 32.7% and 100%, respectively, when combined form of VIA and VILI was applied in this population.

Conclusion: VIA and VILI alone or in combination could be used as screening tests to evaluate the presence of cervical cancer and in case of positive results, supplementary tests such as colposcopy guided biopsy could be performed for definite diagnosis.

Keywords Cervical cancer; Screening; Colposcopy

Introduction

Cervical cancer has the fourth place between the most common cancers of women in the world and the second place in low- and middle-income countries (LMICS). Cervical cancer as a life-threatening disease poses a considerable economical and mental pressure to the involved patients and their families, and increases medical financing costs nationally. **(1-3)**. Fortunately, it's a preventable disease and usually has a long pre-invasive course **(4)**. So using screening program can help to find this cancer and pre-courser the cancer in this period **(5, 6)**.

Nowadays several screening programs are available. Using Pap smear and HPV testing in cervical cancer screening, help to recognize pre-invasive and invasive disease and appropriate treatment can decrease the burden of the disease. But in less developed regions, due to shortage of health care service and treatment and lack of health information among people, the scenario is quite different **(7)**. It seems that alternative methods for cervical cancer screening that are based on direct cervix visualization after application of 3% to 5% acetic acid (VIA) or iodine solution (VILI) can be promising in this context **(8, 9)**. These methods are inexpensive, don`t require laboratory infra- structure, are easy to apply and could be done even by ordinary paramedics, and have immediate results which allow faster treatment and use of "screen and treat protocol" **(10, 11)**.

Due to cultural and socio-economical characteristics of our country, it is essential to use low-cost, feasible and short-term screening methods that their results are immediately available and do not need to visit the cases frequently. So, the present research focused at comparing the results of these 3 visual inspection procedures in screening the cervical cancer using acetic acid, Lugol's iodine, and colposcopy-guided biopsy.

Materials and Methods

The present cross-sectional study was performed at colposcopy clinic of Arash Women's Hospital, Tehran, Iran during 2018-2019. The study protocol was approved by the Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran with an approval code of IR.TUMS.MEDICINE.REC.1396.4636, and all participants signed a written informed consent.

According to our eligibility criteria we just included women aged 25-70 who were candidate for cervical colposcopy due to abnormal Pap smear, high risk HPV infection, abnormal cervical appearance, recurrent or refractory vaginal discharge, or post-coital bleeding. The exclusion criteria were history of total hysterectomy, cervical intraepithelial neoplasia, pregnancy and history of any cervical surgery or therapy for cervical lesions including cryotherapy, cautery or laser, allergy to acetic acid or iodine, and severe physical or mental disorders.

All women underwent visual inspection with acetic acid and Lugol's iodine, separately. Following the insertion of a non-lubricated speculum and visual examination of cervix, acetic acid 3-5% was applied to the surface of the cervix and after an interval of one minute the visual inspection was made followed by the performance of colposcopy after VIA. Later, lugol's iodine, regardless of the VIA and colposcopy results, was employed and visual inspection was repeated followed by the performance of second colposcopy after VILI. Cervical punch biopsy was taken from the women with positive result for colposcopy, VIA or VILI tests. All Colposcopies were done by an expert colposcopist.

Statistical analyses were performed by STAT software version 11 (StataCorp, Texas, USA).

Results and Discussion

The basic characteristics of participants are shown in Table 1 and result of each screening test is presented in Table 2. The sensitivity of both VIA and VILI for detection of CIN lesions were 100%, and their specificity were 69.5% and 60%, respectively. The sensitivity of either method (VIA or VILI) was 100% with a specificity of 52.7%. The sensitivity of combined methods (VIA or VILI) was 100% with a specificity of 77.2%. More details about PPV, NPV and accuracy of test are provided in Table 3.

Table 1. Socio demographic characteristics of all screened women

Age*		**41.19 ± 9.45**
Job†	Employed	62 (31)
	housewife	138 (69)
Marital status†	Married	195 (75.5)
	Single	5 (2.5)
Parity†	Nulliparous	25 (12.5)
	multiparous	175 (87.5)
Contraception †	Yes	82 (41)
	No	118 (59)
Smoking†	Yes	5 (2.5)
	No	195 (97.5)
Education†	Illiterate	3 (1.5)
	Primary	8 (4)
	Intermediate	37 (18.5)
	High school	92 (46)
	Academic	60 (30)

* data presented as Mean±SD; † data presented as Number (%)

Table 2. Result of Screening tests

HPV Test *	High Risk	3 (1.5%)
	Low Risk	28 (14%)
	Negative	169 (84.5%)
Pap Smear *	CINI	18 (9%)
	CINII	1 (0.5%)
	CINIII	1 (0.5%)
VIA*	Positive	75 (37.5%)
	Negative	125 (62.5%)
VILI*	Positive	92 (46%)
	Negative	108 (54%)
Colposcopy guided Biopsy*	Positive	20 (10%)
	Negative	180 (90%)

***** data presented as Number (%); HPV: Human papillomavirus; VIA: Visual inspection with acetic acid; VILI: Lugol's iodine solution

Table 3. Number of true and false positive and negative results; test accuracy of VIA and VILI in accordance to biopsy result as a gold standard

Screening test	TP	FN	FP	TN	Se %	Sp %	PPV %	NPV %	Accuracy %
VIA	20	0	55	125	100	69.5	26.7	100	72.5
VILI	20	0	72	108	100	60	21.7	100	64
VIA or VILI	20	0	85	95	100	52.8	19	100	57.5
VIA and VILI	20	0	41	139	100	77.2	32.7	100	79.5

TP: True positive. FN: False negative. FP: False positive, TN: True negative. SE: Sensitivity. SP: Specificity. PPV: Positive predictive value, NPV: Negative predictive value.

Result of Kappa statistics indicate a moderate inconsistency between to screening test (Kappa=0.54, P=0.0001). The chi-squared test result showed a significant relationship between biopsy tests as a gold standard and VIA (Chi^2= 37.03, Fisher exact test p-value=0.0001) and VILI (Chi^2= 26.08, Fisher exact test p-value=0.0001) as other accurate screening tests.

The accuracy of VIA and VILI in cervical cancer screening has been compared in several studies. In a study in India VIA ad VILI were more sensitive and had low cost compared to pap smear **(12)**. Another cross-sectional study in harmony with our results showed a sensitivity and specificity of 87.5% and 97.7% for Pap smear, 50% and 96.7% for VIA, and 50% and 95.7% for VILI, in detection of CIN-2+ lesions respectively **(13)**. There are several studies that their findings are consistent with the results of the present study. One of these studies showed that the sensitivity and specificity of VIA and VILI for CIN-2 were 73.2% and 86.7% and 88.1% and 85.9%, respectively and the performance of combined form of VIA and VILI could be regarded as a reliable test in cervical cancer screening **(14)**. In the other meta-analysis, the sensitivity and specificity of VIA and VILA were 77% and 87% for VIA and 91% and 85% for VILI, respectively and VILI was suggested as an ideal technique in diagnosis of pre-invasive cervical lesions in developing countries **(15)**.

Also, according to a meta-analysis the sensitivity of VILI in screening of CIN lesions was higher than VIA (95.1% versus 82.4%) and VILI could be used as a simple and cheap method with higher sensitivity (compared to VIA) and also as a primary replacement for cytological exam in cervical cancer screening in low-income countries **(16)**.

Investigating VIA accuracy in cervical cancer screening was the focus of another meta-analysis that reported a sensitivity of around 80%, a specificity of 92%, and a positive predictive value of 10% for this method **(17)**; an outcome comparable to the present study.

VIA and VILI were also recognized as acceptable methods in cervical cancer screening and detection of high-grade pre-cancerous lesions **(18)**. Finally, in a multi-center clinical trial in India and Africa, VILI showed an obviously higher sensitivity, compared to VIA, in detecting HSIL but with similar specificity value **(19)**.

In our study, VIA revealed a specificity value of 69.5% and that of VILI was 60% in detecting the CIN lesions and when the combined form of both VIA and VILI was used it produced a sensitivity of 100% and a specificity of 77.2% in detecting the CIN lesions. The sensitivity obtained in our study was higher, compared to similar trials, with specificity somehow lower than other comparable studies.

Conclusion

It could be concluded that all cases of CIN might possibly be properly screened without missing even one case if the observer is skillfull and well-experienced. Both VIA and VILI could be used alone or in combination as cervical cancer screening tests and in case of a positive test, the results should be verified by confirmatory or supplementary tests such as biopsy for making a final diagnosis. Also, it is recommended that increasing the number of study population in future studies could reveal higher sensitivity and specificity for evaluating these screening tests.

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Conflict of Interest

The authors declare no conflict of interest.
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