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Accuracy of Naked Eye Visual Inspection in Early Detection of Cervical Intraepithelial Neoplasia at Zagazig University Hospitals

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ABSTRACT

Background: Cervical cancer is a major contributor to mortality and morbidity among women in low- and middle-income countries. Unlike other cancers, cervical cancer is preceded by a spectrum of cytomorphological changes called cervical intraepithelial neoplasia (CIN) for many years before developing into a frank malignancy.

Objective: We aimed to detect the accuracy of naked eye (NE) visual inspection in early detection of cervical intraepithelial neoplasia.

Patients and Methods: This **c**ross sectional study was conducted at Obstetrics and Gynecology Outpatients Clinic and Pathology Department, Zagazig University Hospitals on 206 patients during the period from January 2021 to June 2021.

Results: About 81% of patients had normal appearance cervix on NE examination. Visual naked eye inspection with acetic acid staining was negative in 41.3%, low threshold positive in 36.4% and high threshold positive occurred in 22.3%. There was significant association between presence or intensity of visual inspection with acetic acid (VIA) and nature of lesion. Within normal/benign lesion, 49.1%, 39.3% and 11.7% had negative, low threshold positive and high threshold positive respectively. Within CIN-1, 42.9%, 14.3% and 42.9% had negative, low threshold positive and high threshold positive respectively. Within CIN-2, 50% and 50% had low threshold positive and high threshold positive respectively. Within CIN -3, 35.7% and 64.3% had low threshold positive and high threshold positive respectively.

Conclusion: Visual inspection with acetic acid (VIA) can be used as cervical cancer screening test especially in low-resource settings.

Keywords: Cervical Intraepithelial Neoplasia, Naked Eye Visual Inspection, Screening Test.

INTRODUCTION

Cervical cancer is the second commonest cancer among women, worldwide, with only breast cancer occurring more commonly [(1)]. While cervical intraepithelial neoplasia (CIN) is a pre-malignant condition of the cervix. It is usually asymptomatic and detected by routine cytological screening [(2)].

The concept of CIN was introduced first in 1968, when Ralf Richart indicated that all dysplasia has the potential for progression. The term CIN is equivalent to the term dysplasia [(3)], which means disordered growth and development of the epithelial lining of the cervix [(4)].

Consequently, squamous metaplasia should not be diagnosed as dysplasia or CIN because it does not progress to invasive cancer [(5)]. Approximately 10% of women with CIN have concomitant pre invasive neoplasia of the vulva, vagina or anus. Conversely 40-60% of patient with vulvar intraepithelial neoplasia (VIN) or vaginal intraepithelial neoplasia (VAIN) have synchronous CIN [(6)]. World-wide, cervical cancer comprises 12% of all cancers in women [(6)].

The presence of effective screening programs and the administration of prophylactic vaccine against human papillomavirus (HPV) make the cervical cancer a preventable condition [(7)].

At present the most recent technique of cervical cytology is the liquid based cytology. The collected cell sample is rinsed in a vial containing a liquid preservative, the sample then processed under the control of the cytology laboratory to provide a thin layer of cervical cells without debris on a glass slide. Thin layer cytology has proven to be more sensitive than conventional glass slide Pap smears because the cells doesn't clump on top of each other in the liquid based medium and there is less debris on the resulting slide. More intraepithelial lesions are identified [(8)].

An alternative test is visual inspection of the cervix with acetic acid (VIA). It has been advocated as an alternative screening method to Pap smears in developing countries**.** The attractive features of VIA include low cost, simple administration, real-time screening of results and accuracy comparable to good quality Pap smears[(9)].

The purpose of this study was to detect the accuracy of naked eye visual inspection in early detection of cervical intraepithelial neoplasia.

PATIENTS AND METHODS

This **c**ross sectional study was conducted at Obstetrics and Gynecology Outpatients Clinic and Pathology Department, Zagazig University Hospitals on 206 patients during the period from January 2021 to June 2021.

Inclusion criteria:

Women of age group between 25 and 50 years attending the Obstetrics and Gynecology Outpatients Clinic in Zagazig University Hospital, and women who approved the written consent.

Exclusion criteria:

Virgin, pregnant woman, previous history of cervical cancer or CIN, prior total hysterectomy,

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women with severe cervicitis until they had completed treatment, and vaginal bleeding.

Methods:

1. The patients included in the study were given information about the study.
2. Full history taking: including: Age of patient, age of marriage, menstrual history, vaginal bleeding pattern especially post coitus bleeding, contraceptive method, parity, level of education of woman and her husband with occupation of both, history of smoking, and family history of cervical cancer.
3. All patients were subjected to general and local examination.

Visual Inspection with Acetic Acid (VIA):

Procedure requirements:

The procedure and the reason for it were carefully explained to the woman beforehand.

This starts off with: Assembling equipment. Vaginal speculum (Cusco's speculum). Sterile rubber gloves. Adequate light source about 100 watts (halogen or flash light). Cotton swabs, and freshly prepared 5% acetic acid solution (5 ml of glacial acetic acid with 95 ml of distilled water) **[10].**

Steps of the procedure:

(1) The woman was asked to lie in a modified lithotomy position onto the examination table after she had emptied her bladder. (2) Inspection of external genitalia was done to rule out presence of lesions, warts, papules, ulceration, discharge, redness, swelling and excoriation. (3) A sterile Cusco's speculum was carefully inserted in the vagina, and use of antiseptic solution for sterilization of genitalia was avoided. Inspection of the cervix was done for cervicitis, ectropion, nabothian cyst, cervical ulcer or ectopy, polyp, outgrowth, and bleeding. The four vaginal fornices then were examined to make sure they are free from any growth or abnormal visual finding. The gross appearance of the cervix was classified into: (Normal, abnormal, and suspicious of malignancy).

Normal cervix: A normal cervix appears smooth, round, pink, lubricated with clear mucoid secretion and has a central hole (the external os).

Abnormal cervix: This category includes all benign looking lesions, such as: Hypertrophy, redness or congestion, irregular surface, distortion, simple ectopys (that do not bleed on touch), cervical polyps (with smooth surface), and abnormal discharge (foul smelling, dirty/greenish, white/cheesy, blood stained).

Suspicious of malignancy

Malignancy was suspected when there was ectopy that bleeds on touch, a growth with an irregular surface.

- The woman should have this test when she is not menstruating; the best time is between day 10 and 20 after the first day of the last menstrual period. Those with vaginal bleeding on the day of the test, they were postponed until the bleeding stops. The patient should avoid douching or using vaginal medicines, spermicidal foams, creams, or gels and sexual intercourse.
- First the cervix was washed with normal saline.
- VIA was done and it involved gentle application of 5% acetic acid using cotton swab to avoid bleeding. The woman was informed that she might feel a slight stinging sensation.
- After 1-2 minutes a naked eye evaluation was performed under 100-watt illumination. The transformation zone was carefully checked for any dense non-movable acetowhite areas in the mucosa with examination of vasculature. If acetowhite areas were identified on the cervix after 1-2 minute, the test was positive. Criteria for categorization VIA test result can be shown in the following table (1).

Table (1): Criteria for categorization VIA test result **[11]**

Negative (-)	No acetowhite lesions. Acetowhitening on endocervical polyps, nabothian cysts.
Single positive (+) (low threshold)	Prominent white line like acetowhitening of the squamocolumnar junction.
Double positive (++) (high threshold)	Faint, translucent, ill defined, irregular acetowhite lesions on the cervix. Definite, angular, geographic acetowhite lesions far away from the squamocolumnar junction. Opaque, dense, dull, definite, well-defined acetowhite lesions touching the squamocolumnar junction or close to the external os. Large, circumferential, well-defined, thick, dense acetowhite lesions. Growth on the cervix turns acetowhite.

The rapid acetowhiteness of high-grade lesions can be explained by large number of dysplastic cells having more nucleoproteins in superficial layers of the epithelium **[11]**.

Acetowhiteness may also occur in various conditions such as: Immature squamous metaplasia, congenital transformation zone, leukoplakia, condyloma, and inflamed, regenerating cervical epithelium**[11]**.

Acetowhiteness of these conditions is thin, less pale, translucent, and without well-defined margins and takes longer time to appear and disappears more rapidly than CIN**[11]**.

Ethical consent:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for the Social Sciences) version 22 for Windows® (IBM SPSS Inc, Chicago, IL, USA). Qualitative data were represented as frequencies and relative percentages and were compared by Chi square test (χ^2). Quantitative data were expressed as mean ± SD (Standard deviation) and range. P value < 0.05 was considered significant.

RESULTS

Table (2) shows that mean of age was (40.05 ± 8.07), mean of age of marriage was (21.57 ± 4.29). Regarding education, 37.4% were illiterate, 23.3% for both read and write and basic education, regarding occupation, 66.5% were housewives and 14.1% were clerk. Regarding parity, 69.4% were (1 – 3). 88.3% were smokers. 93.2% had irrelevant family history of cancer cervix. 64.1% complained of vaginal discharge.

Table (2): Demographic data of the studied patients

	N=206	%
Age (years):		
Mean ± SD	40.05 ± 8.07	
Range	25 – 50	
Age of marriage (year):		
Mean ± SD	21.57 ± 4.29	
Range	16 – 35	
Education:		
Illiterate	77	37.4%
Read and write	48	23.3%
Basic	48	23.3%
Secondary	22	10.7%
University	11	5.3%
Occupation:		
Housewife	137	66.5%
Unskilled	16	7.8%
Skilled	13	6.3%
Clerk	29	14.1%
Professional	11	5.3%
Parity:		
1 – 3	143	69.4%
4 – 7	63	30.6%
Smoking:		
No	182	88.3%
Yes	24	11.7%
Family history of cancer cervix:		
Irrelevant	192	93.2%
Relevant	14	6.8%
Complaint		
Vaginal discharge	132	64.1%
Dyspareunia	25	12.1%
Postcoital bleeding	6	2.9%

Table (3) shows that about 81% of patients had normal appearance of the cervix on NE examination.

Table (3): Distribution of the studied patients according to naked eye examination

	N=206	%
Naked eye appearance		
Looks normal	166	80.6%
Bleed on touch	3	1.5%
Cervical ectopy	6	2.9%
Hypertrophied cervix	17	8.3%
Suspicious cervix	14	6%

Table (4) shows that 79.1% of the patients had benign nature.

Table (4): Distribution of the studied patients according to HPE

	N=206	%
Pathology:		
Benign nature	163	79.1%
Abnormal pathological nature	43	20.9%

Table (5) shows that according to VIA, 41.3% of the studied cases were negative.

Table (5): Distribution of the studied patients according to VIA

	N=206	%
VIA:		
Negative	85	41.3%
Low threshold positive	75	36.4%
High threshold positive	46	22.3%

Table 6 shows the diagnostic indices of both low and high threshold positive VIA to predict malignant nature of lesion with sensitivity of 68.8% and 84.8% respectively.

Table (6): Validity of VIA in diagnosis of abnormal pathology

VIA		**Benign/normal**		**Abnormal pathology**	
Negative		80 (49.1%)		5 (11.6%)	
Low threshold		64 (39.3%)		11 (25.6%)	
High threshold		19 (11.7%)		27 (62.8%)	
Positive VIA	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Accuracy**
Low threshold	68.8%	55.6%	14.7%	94.1%	56.9%
High threshold	84.8%	80.8%	58.7%	94.1%	81.7%

Table 7 shows the diagnostic indices of both low and high threshold positive VIA to predict CIN-1 with sensitivity of 25% and 50% respectively.

Table (7): Validity of VIA in diagnosis of CIN-1 of lesion

VIA		**Benign/normal**		**Abnormal pathology**	
Negative		80 (49.1%)		3 (42.9%)	
Low threshold		64 (39.3%)		1 (14.3%)	
High threshold		19 (11.7%)		3 (42.9%)	
Positive VIA	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Accuracy**
Low threshold	25%	55.6%	1.5%	96.4%	57.1 %
High threshold	50%	80.8%	13.6%	96.4%	79.1%

Table 8 shows the diagnostic indices of both low and high threshold positive VIA to predict CIN-2 with sensitivity of 100% for each of them.

Table (8): Validity of VIA in diagnosis of CIN-2 of lesion

VIA		**Benign/normal**		**Malignant**	
Negative		80 (49.1%)		0 (0%)	
Low threshold		64 (39.3%)		4 (50%)	
High threshold		19 (11.7%)		4 (50%)	
Positive VIA	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Accuracy**
Low threshold	100%	55.6%	5.9%	100%	56.8%
High threshold	100%	80.8%	17.4%	100%	81.6%

Table 9 shows the diagnostic indices of both low and high threshold positive VIA to predict CIN-3 with sensitivity of 100% for each of them.

Table (9) Validity of VIA in diagnosis of CIN-3 of tumor

VIA		Benign/normal		Malignant	
Negative		80 (49.1%)		0 (0%)	
Low threshold		64 (39.3%)		5 (35.7%)	
High threshold		19 (11.7%)		9 (64.3%)	
Positive VIA	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Accuracy**
Low threshold	100%	55.6%	7.3%	100%	57.1%
High threshold	100%	80.8%	32.1%	100%	82.4%

Table 10 shows the diagnostic indices of both low and high threshold positive VIA to predict cancer cervix with sensitivity of 33.3% and 84.6% respectively.

Table (10): Validity of VIA in diagnosis of presence of invasive cancer

VIA		Benign/normal		Cancer	
Negative		80 (49.1%)		2 (14.3%)	
Low threshold		64 (39.3%)		1 (7.1%)	
High threshold		19 (11.7%)		11 (78.6%)	
Positive VIA	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Accuracy**
Low threshold	33.3%	55.6%	1.6%	97.6%	55.1%
High threshold	84.6%	80.8%	36.7%	97.6%	81.3%

DISCUSSION

In the current study, the main complaint was in 132 (64.1%) vaginal discharge, 25 (12.1%) dyspareunia and 6 (2.9%) postcoital bleeding. This comes in agreement with the study of, **Zahan *et al.*** [12] who reported that patient who attended the outpatient clinic were with common complaints of vaginal discharge as foul smell, blood stain discharge, discharge with itching, post coital bleeding, and post-menopausal bleeding. All the women were married and were sexually active. Maximum participants were housewives and of middle to lower economic class.

In the current study, distribution of the studied patients according naked eye examinations showed that 166 (80.6%) looked normal, 3 (1.5%) bled on touch, 6 (2.9%) had cervical ectopy, 17 (8.3%) had hypertrophied cervix, and 14 (6%) had suspicious cervix. On histopathological examination we found that, 79.1% of the patients had benign in nature cervix and 20.9% had malignant in nature cervix. In agreement with our study, **Rahatgaonkar *et al.*** [13] found that maximum; number of women, (300/509:58.9%), were reported to have normal cytology followed by 169 (33.2%) with inflammatory smears. They also demonstrated that on NE test, 141 were screen-positive (27.7%), and 367 were screen-negative (72.1%), which is also in agreement with our results.

In the current study, visual naked eye inspection with acetic acid staining was negative in 85 (41.3%), low threshold positive in 75 (36.4%), and high threshold positive occurred in 46 (22.3%). In agreement with our study, **Zahan *et al.*** [12] demonstrated that out of all patients 53 (30.3%) had VIA positive and 122 (69.7%) had VIA negative findings. While in **Belinson *et al.*** [14] study, they demonstrated that visual inspection was done on all 1997 women in the study. The visual inspection results were normal in 1445 women (72%) that was higher than our results, low-grade in 525 (26%), high-grade in 21 (1%), and cancer in six (0.3%).

In the present study, visual naked eye inspection with Lugol's iodine staining was negative in 27.7%, and positive staining occurred in 72.3%. **Sarian *et al.*** [15] reported that overall test positivity was 11.6% for VIA.

This discrepancy may be due to our University Hospital is a referral hospital so it might be acceptable if consider our subjects as a high risk population and there would be more abnormal screening test results compared to general population.

In the current study, regarding distribution of pathological features based on screening test, there was significant association between presence or intensity of VIA and nature of lesion. Within normal/benign lesion, 49.1%, 39.3% and 11.7% had negative, low threshold positive and high threshold positive respectively. Within CIN-1, 42.9%, 14.3% and 42.9% had negative, low threshold positive and high threshold positive respectively. Within CIN-2, 50% and 50% had low threshold positive and high threshold positive respectively. Within CIN-3, 35.7% and 64.3% had low threshold positive and high threshold positive respectively. Within cancer cervix, 14.3%, 7.1% and 78.6% had negative, low threshold positive and high threshold positive respectively. In contrast with our study, **Sarian *et al.*** [15] found that VIA was positive in 61.8% of the women with CIN 1, 57.0% of those with CIN 2, 35.0% of those with CIN 3 and in 21 of 28 (75%) women with cancer. Approximately10% of women with no detectable disease had an abnormal VIA.

Regarding validity of VIA in diagnosis of malignancy, low threshold positive VIA can predict

malignant nature of lesion with 68.8% sensitivity, 55.6% specificity, 14.7% positive predictive value, 94.1% negative predictive value, and 56.9% accuracy. High threshold positive VIA can predict malignant nature of lesion with 84.8% sensitivity, 80.8% specificity, 58.7% positive predictive value, 94.1% negative predictive value, and 81.7% accuracy. In agreement with our study, **Zahan *et al.*** [(12)] demonstrated that among the validity test the sensitivity, specificity, PPV, NPV and accuracy of VIA report was 90.20%, 88.10%, 69.80%, 96.70%, 88.6% respectively.

Honarvar *et al.* [(16)] demonstrated that sensitivity, specificity, positive predictive value and negative predictive value of VIA in comparison with those in biopsy were, respectively, 67.7%, 91.3%, 70% and 90.4%. **Basu *et al.*** [(17)] reported that PPV, sensitivity, specificity, and NPV of VIA report was 6.2% 55.7%, 82.1%, 98.9% respectively. **Hegde *et al.*** [(18)] reported that sensitivity, specificity, PPV and NPV of VIA report was 70.8%, 95%, 62.9% and 96.5% respectively. **Rana *et al.*** [(19)] reported that sensitivity, specificity, PPV and NPV of VlA report was 93%, 90%, 62.5% and 98% respectively. **Bhatla *et al.*** [(20)] reported that sensitivity, specificity, PPV and NPV of VlA report was 100%, 53.3%, 15.7% and 100% respectively.

Regarding validity of VIA in diagnosis of CIN-1 of tumor, low threshold positive VIA can predict CIN-1 with 25% sensitivity, 55.6% specificity, 1.5% positive predictive value, 96.4% negative predictive value, and 57.1% accuracy. High threshold positive VIA can predict CIN-1 of lesion with 50% sensitivity, 80.8% specificity, 13.6% positive predictive value, 96.4% negative predictive value, and 79.1% accuracy. Regarding validity of VIA in diagnosis of CIN-2 of tumor, low threshold positive VIA can predict CIN-2 with 100% sensitivity, 55.6% specificity, 5.9% positive predictive value, 100% negative predictive value, and 56.8% accuracy. High threshold positive VIA can predict CIN-2 of lesion with 100% sensitivity, 80.8% specificity, 17.4% positive predictive value, 100% negative predictive value, and 81.6% accuracy. Regarding validity of VIA in diagnosis of CIN-3 of tumor, low threshold positive VIA can predict CIN-3 with 100% sensitivity, 55.6% specificity, 7.3% positive predictive value, 100% negative predictive value, and 57.1% accuracy. High threshold positive VIA can predict CIN-3 of lesion with 100% sensitivity, 80.8% specificity, 32.1% positive predictive value, 100% negative predictive value, and 82.4% accuracy.

In agreement with our study, **Qiao *et al.*** [(21)] showed that sensitivity and specificity of VIA for CIN II+ varies between 66.5–80.0% and 82.9–90.4%, respectively. Also, **Fakour *et al.*'s** [(22)] showed that VIA works effectively in identifying lesions and high-level dysplasias.

Belinson *et al.* [(14)] demonstrated that with abnormal visual inspection defined as low-grade or worse, the sensitivity for at least CIN II was 71% (61of 86, 95% CI 60%, 80%). The specificity was 74% (1420 of 1911, 95% CI 72%, 76%). The positive predictive value was 11% (61 of 552, 95% CI 9%, 14%). The negative predictive value was 98% (1420 of 1445, 95% CI 97.6%, 98.9%). The sensitivity for at least CIN III was 79% (34 of 43, 95% CI 64%, 90%), and it was 67% (8 of 12, 95% CI 35%, 90%) for cancer.

CONCLUSION

VIA can be used as cervical cancer screening test especially in low-resource settings. Effort should be geared toward training health care providers in the use of VIA in this environment.

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