

The Diagnostic Accuracy of Visual Inspection with Acetic Acid (VIA) in Screening of Women for Cervical Intraepithelial Neoplasia (CIN) Taking Colposcopy as Gold Standard

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Received: August 2020

Accepted: August 2020

ABSTRACT

Background: Cervical cancer is the second most common cancer among women in developing countries and accounts for approximately 16% of the annual cancer incidence in the world. Objectives: The aim of the study is to govern the diagnostic accuracy of VIA in the screening of women for cervical intraepithelial neoplasm (CIN) by taking colposcopy as gold standard. **Methods:** The cross sectional study was held in department of Gynecology unit 2, Lahore General Hospital in six months after approval of synopsis. The calculated sample size was 225 with 95% confidence level 7% for margin of sensitivity i.e. 91% and 9% margin of error for specificity i.e. 39% VIA in the diagnosis of CIN with an expected percentage of CIN i.e. 20% taking colposcopy as gold standard. All the women of age 20-45 years presenting in gynecology OPD for screening of CIN were included in the study. The demographic data and detailed history was taken. **Results:** 225 females were enrolled in the study. Mean age found was 29.22 with standard Deviation 6.96. When cases were screened with VIA, 45 (20%) were found positive while 180 (80%) were negative. Colposcopy was considered as gold standard for CIN. During colposcopy 50 (22.2%) cases were screened positive and 175 (77.8%) were screened as negative. Post stratification for age was done and age is categorized into different categories, 40 cases were in age from category 19-25, 69 cases were from 26-30 years, 71 cases from 31-35 years, 22 years from 36-40 years and 23 cases from 41-45 years. **Conclusion:** Visual inspection with acetic acid has expressively greater sensitivity and thus can be used as a precursor for CIN before going for colposcopy (the gold standard). The test combined with advanced predictive accuracy can be used for opportunistic screening.

Keywords: Visual, Cervical, Colposcopy, Cancer.

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INTRODUCTION

Cervical cancer was found to be the second most common malignancy among females in under developed countries and accounts for about 16% of the annual cancer incidence worldwide. In Pakistan, surveyed evidence indicates that 3.6% of total female cancer is of cervical origin, mainly affecting females in their 5th and 6th decades of life. In industrialized countries, the cervical cancer incidence has reduced due to early detection, screening and management. Though, in under developed, 80% of cervical cancer cases cannot be cured when detection because of their advanced stages. For women suspected of cervical cancer, colposcopy is recommended in the screening recommendation.

Colposcopy is a standard screening test used in many countries. However, they have some limitations. This method of screening requires a cytopathologist and trained technicians. So, there

was a need to explore other methods of screening. The visual inspection of the cervix with acetic acid (VIA) is the alternative method of screening. It is particularly suitable for a country like us because of the low cost and minimum technology requirements. Mahmud G et al. The previous study included 519 people. In their studies, the VIA sensitivity was 78.5% and its specificity was 99.3% (taking colposcopy as the gold standard). Neha G et al. In another study by, VIA sensitivity was 91% and its specificity was 39% (colposcopy was the gold standard).

Colposcopy is not viable option in many low resource countries and given resource and logistics, it is impossible at present to introduce the colposcopy smear to all parts of the world and low-resource setting where cervical cancer is very common, we need a practical approach to screening and early detection. Given the dilemma, we should look for a more economical but reliable detection method that, as emphasized by WHO, ensures that it covers at least 70% of the target population so that positive impact must ensured. In the previous studies, VIA has been found a useful screening tool, but it has shown variable results in different studies. In study by Mahmud G, et al, the sensitivity was low (78.5%) but specificity was high (99.3%), while

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in other study by Neha G, et al, the sensitivity was high (91%) but specificity was very low (39%). the authors have also recommended to run more studies to run more studies. So, I want to conduct this study to know the diagnostics accuracy of VIA (taking colposcopy as gold standard) in order to know whether this can be a useful screening tool and can replace colposcopy in low resource countries like Pakistan.

Aim

The aim of the study is to determine the diagnostic accuracy of VIA in the screening of women for cervical intraepithelial neoplasm (CIN) by taking colposcopy as gold standard.

MATERIALS & METHODS

This cross sectional study was held in department of Gynecology unit 2, Lahore General Hospital, during 5th June, 2015 to 5th December, 2016. Sample size of 225 cases is calculated with 95% confidence level 7% for margin of sensitivity i.e. 91% and 9% margin of error for specificity i.e. 39% VIA in the diagnosis of CIN with an expected percentage of CIN i.e. 20% taking colposcopy as gold standard.

Inclusion Criteria:

- All the women of age 20-45 years presenting in gynecology OPD for screening of CIN.
- Consenting for screening

Exclusion Criteria

- Pregnant Females
- Post-menopausal patients
- Patients with previous history of atypical cytology
- Previous treatment for cervical intra-epithelial neoplasia (CIN) or oblivious invasive cancer at the time of clinical evaluation or with severe cervicitis.

Data collection

225 women achieving the criteria of inclusion were enrolled from outpatient department of gynecology, Lahore General Hospital, Lahore. The demographic data and detailed history was taken. From every patient; an informed consent was taken. The study was approved by ethical committee of hospital. All the patients had VIA followed by colposcopy. All VIA and colposcopy was done by fellow of Gynecology who have at least 5 years' experience in conducting these examination. The biopsy reports were sent to department of pathology, where histopathology was performed by fellow of pathology who have experience of 5 years of performing histopathology for detection of malignancy (positive or negative). Specificity, sensitivity, NPV, PPV and accuracy of VIA will be calculated by taking histopathology of surgically obtained tissue findings as gold standard. The data was collected on specially designed Performa.

Data analysis

Data was entered in SPSS version 20.0. Numerical variables like age will be described as standard deviation and mean. The quantitative variables like CIN on VIA and colposcopy will be described as frequency and percentage.

RESULTS

225 females were enrolled in the study. Mean age found was 29.44 with standard Deviation 6.96. When cases were screened with VIA, 45 (20%) were found positive while 180 (80%) were negative. Colposcopy was considered as gold standard for CIN. During colposcopy 50 (22.2%) cases were screened positive and 175 (77.8%) were screened as negative. Post stratification for age was done and age is categorized into different categories, 40 cases were in age from category 19-25, 69 cases were from 26-30 years, 71 cases from 31-35 years, 22 years from 36-40 years and 23 cases from 41-45 years. When data was evaluated for diagnostic accuracy, the sensitivity of VIA was 80%, specificity was 97.14%, Positive Predictive value was evaluated was 0.888, Negative Predictive Value was 0.974. Stratification for age is also done to deal with effect modifiers.

Table 1: 2x2 Table for Accuracy

Visual Inspection with Acetic Acid * Colposcopy Cross tabulation				
		Colposcopy		Total
		Yes	No	
Visual Inspection with Acetic Acid	Yes	40	5	45
	No	10	170	180
Total		50	175	225

Sensitivity	=	80%
Specificity	=	97.14%
PPV	=	0.888
NPV	=	0.974

DISCUSSION

Cervical cancer is the second most common cancer among women in developing countries and accounts for about 16% of the annual cancer incidence in the world. Globally; cervical cancer is the most usual malignancy among females. This is a significant reproductive health issue, particularly for women in developing countries. Every year, 500,000 new cases are diagnosed worldwide, 80% of which occurs in low-income countries. Our study is based on patients admitted to third-level hospitals in Lahore. 225 women enrolled in the study were presented for CIA and colposcopy. Mean age found was 29.22 with standard Deviation 6.96. When cases were screened with VIA, 45 (20%) were found positive while 180 (80%) were negative. Colposcopy was considered as gold standard for CIN. During colposcopy 50

(22.2%) cases were screened positive and 175 (77.8%) were screened as negative. Post stratification for age was done and age is categorized into different categories, 40 cases were in age from category 19-25, 69 cases were from 26-30 years, 71 cases from 31-35 years, 22 years from 36-40 years and 23 cases from 41-45 years. One study reported 3.6% of cervical cancer cases each year in Pakistan, which affect women in their fifth and sixth year of life. Due to the speed and simplicity of the test, VIA has become a promising alternative to Pap tests in developing countries. Some previous reports have suggested that the test may achieve similar or better results than the Pap test in CIN detection.^[16] When we evaluated data for diagnostic accuracy, the sensitivity of VIA was 80%, specificity was 97.14%, Positive Predictive value was evaluated as 0.888, Negative Predictive Value was 0.974. Mehmud et al, 2013,^[16] reported the sensitivity of visual inspection was 78.5% vs 61.1% for Pap smear ($p < 0.001$). The specificity of visual control was 99.4% compared to 99.3% for cytology ($p < 0.1$). The combined test found significantly higher sensitivity and specificity than both; 93.1% and 99.1%, respectively ($p < 0.001$). Positive predictive value of Pap smear was 78.5% vs. 84.6% ($p < 0.001$), and a negative predictive value of 98.6% vs. 96.5%. Some other studies also show the same results and recommend visual inspection of acetic acid before colposcopy.^[17] As colposcopy is not a cost effective option in cervical cancer in developing and third world countries. Very few studies didn't agree and vote in favors of Colposcopy but these studies were done in developed countries.

In another study (Allan B, et al.) the VIA positivity, as well as the sensitivity and specificity estimates, were within the range of similar studies of HIV-infected women, adding to the existing body of literature and providing support for the performance of these tests by clinical officers and nurses.^[18,19] In our cohort, test specificity increased with increasing age, without a significant drop in sensitivity. This differs from prior studies, perhaps because we had an overall younger cohort and used 35 as the age cut-off for stratification. This finding of improved sensitivity of VIA among women with a healthier immune status supports previous data.¹⁹ (Sankaranarayanan R. et al) and (Mugo NR. Et al) Evaluated that One of the main strengths of VIA is the immediate availability of results, which allows it to be coupled directly with treatment, either the same day or at a referral site. There is some concern that skipping histologic confirmation leads to overtreatment of women, resulting in increased costs, referral burden and potential for short- and long-term complications. If treatment decisions were based solely on VIA results in our cohort, 25% of women attending screening would have been treated unnecessarily. However, in the sensitivity analysis broadening the outcome to include CIN1, which may

reflect transient infection with HPV, the positive predictive value of VIA was 67%. Although we are aware of the lack of precision introduced by the combined visual and histologic diagnosis of CIN, including it as a final outcome reduces the proportion of women with completely normal cervical exams to 11%. Further, in most low-resource settings, VIA has been coupled with cry therapy, which also has extremely low rates of short- and long-term side effects.^[20,21]

We limited our sample to women with satisfactory VIA, in order to have a dichotomous result for our calculations. This potentially would inflate the value of VIA, however in our setting, less than 1% of women had unsatisfactory VIA.

CONCLUSION

It is concluded that visual inspection with acetic acid has considerably advanced sensitivity and thus can be used as a precursor for CIN before going for colposcopy (the gold standard). For opportunistic screening, combined test with greater predictive accuracy can be used.

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How to cite this article: Iqbal S, Ajum S, Ashraf M. The Diagnostic Accuracy of Visual Inspection with Acetic Acid (VIA) in Screening of Women for Cervical Inter-Epithelial Neoplasia (CIN) Taking Colposcopy as Gold Standard. *Ann. Int. Med. Den. Res.* 2020; 6(5):OG11-OG14.

Source of Support: Nil, **Conflict of Interest:** None declared