RESEARCH COMMUNICATION

Cervical Cancer Screening by Visual Inspection with Acetic Acid- Interobserver Variability between Nurse and Physician

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Abstract

Objectives: The objective of the study was to evaluate and compare the test performance of visual inspection with acetic acid (VIA) by a physician and nurse so as to evaluate the feasibility and efficacy of training a nurse in interpreting VIA. Methods: It was a cross sectional study conducted in the colposcopy clinic at the University teaching hospital. 406 women who fulfilled the selection criteria underwent VIA done by both physician and nurse and the findings were interpreted independently. This was followed by colposcopy done by a gynecologist blinded to the results of VIA and directed biopsy was taken if indicated. The diagnostic efficacy was calculated separately for physician and nurse using threshold of cervical intraepithelial neoplasia (CIN) 2 and above and concordance of results between the physician and nurse was determined by kappa statistics. Results: VIA by physician had a higher sensitivity (88.89% versus 80%) and a higher specificity (69.81% versus 54.85%) with disease threshold of CIN 2 and above. The concordance of results showed moderate agreement (kappa=0.366). Conclusion: Trained nurses can be an effective alternative human resource for cervical cancer screening using VIA as a preliminary screening method. Intensive training and periodic reinforcement sessions are needed so as to reduce the false positive results.

Keywords: Cervical cancer - visual inspection with acetic acid - screening - colposcopy - paramedical worker

Asian Pacific J Cancer Prev, **11**, 619-622

Introduction

Cervical cancer is a global health problem and is the leading cause of death due to cancer among women in developing countries. According to World Health Organization projections in 2005 there were over 500,000 new cases of cervical cancer, of which over 90% were in developing countries. Almost 260,000 women died of the disease, nearly 95% of them in developing countries. Cervical cancer has a long latent phase and can be prevented easily by early detection using various screening procedures like Pap smear, HPV DNA testing, visual inspection with acetic acid and visual inspection with lugol's iodine (Kathy et al., 2006). Screening techniques vary in regard to feasibility, test characteristics, effectiveness, and economic considerations.

Pap smear requires several prerequisites without which there is a little benefit in detection of disease incidence. In the low resource settings technical, logistic and other barriers affect the provision of pap screening and follow-up of cases are seriously hampered (Bharti et al., 2005). Visual inspection of cervix neither requires a second person for interpretation of result nor second visit by the patient to collect the report and it allows the use of "screen & treat" methodology (Alliance for cervical cancer prevention, 2009).

Resource and medical manpower constraints have led to inadequate or no screening in developing countries. Trained paramedical workers may prove to be an effective alternative human resource for cervical cancer screening in developing countries. Keeping in mind the potential benefits of VIA, this study was conducted to find out the variability of VIA between a nurse and a physician and to assess the feasibility of implementing VIA by a paramedical worker by assessing the correlation and concordance of results between physician and nurse.

Materials and Methods

Our study was a cross sectional interventional study conducted in the colposcopy clinic at University teaching hospital from April 2008 to October 2009. Prior to the commencement of the clinical trial the study nurse and the physician received training for two weeks which comprised of brief overview on the anatomy and pathophysiology of the cervix and hands on clinical examination. They were also taught to categorize the VIA results as positive and negative based on the IARC criteria.

A total of 406 women referred to the colposcopy clinic with complaints of persistent vaginal discharge, suspicious looking cervix, post coital bleeding, post menopausal bleeding, inter menstrual bleeding or with positive cervical

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cancer screening test results were included in the study. Exclusion criteria were frank growth on the cervix & prior total hysterectomy. Women with active vaginal bleeding were asked to come back after cessation of bleeding. Informed written consent was taken from all women referred to the colposcopy clinic.

Screening intervention procedures

Visual inspection with acetic acid (VIA). All women enrolled for the study underwent VIA by both nurse and physician independently. VIA was performed by applying 5% freshly prepared acetic acid to the cervix with a cotton swab. The findings were interpreted after one minute by visualizing the cervix under the illumination of a lamp with 100 watt bulb. A proforma was filled which contained general information of the participant and observations of VIA were recorded independently by the physician and nurse by a schematic representation as positive or negative.

Colposcopy and directed biopsy. Colposcopy was performed in all participants by a gynecologist trained in colposcopy. A cervical biopsy was obtained in cases where colposcopy revealed a precancerous lesion using cervical punch biopsy forceps by the study gynecologist.

Other treatment/ surgical procedures

Women with histologically confirmed lesion of CIN 2 and above were counseled to undergo either loop electrosurgical excision procedure (LEEP) or cold knife conization or hysterectomy following appropriate evaluation.

Categorization of results

VIA test results were categorized according to criteria laid down by the International Agency for Research on Cancer (IARC) (Sankarnarayanan et al., 2003). Colopscopic diagnosis was made based on Reid's coloposcopic index (Sellors et al., 2003). Biopsy results were categorized as benign, CIN 1, CIN 2, CIN 3 and invasive cervical cancer.

Statistical analysis

The sensitivity, specificity, predictive values and diagnostic accuracy of VIA was calculated for physician and nurse with the disease threshold of CIN 2. Concordance of results of VIA between physician and nurse was determined by kappa statistics.

Results

We evaluated 406 women who fulfilled the eligibility criteria and provided informed consent. Maximum number of women were in the age group of 30 -39 years (42.6%) with mean age of 35 years. In terms of parity majority of the women were para 2 (50%), 26.8% of women were para 3 & 9.8% were para 4 and above. The common presenting complaint was persistent white discharge per vaginum seen in 64.2% followed by suspicious looking cervix in 21.4%, post menopausal bleeding in 6.6% & postcoital bleeding in 5.6%. VIA was positive in 149 cases (36.7%) by physician & in 199 cases (49.01%) by nurse (Table 1). Of the study population 110 cases (27%) were VIA positive & 168 cases (41.37%) were VIA negative by both physician & nurse resulting in a moderate agreement between the two (k=0.366).

Abnormal colposcopy findings were observed in 130 cases & directed biopsy was obtained for histopathological confirmation. Biopsy revealed benign lesions in 16 cases, CIN 1 in 69 cases, CIN 2 in 12 cases, CIN 3 in 19 cases & squamous cell carcinoma in 14 cases (Algorithm 1). Of the 69 biopsy confirmed CIN 1 lesions 52 were reported VIA positive by physician & 48 by nurse. Of the 31 high grade lesions (CIN 2 & CIN 3) 5 cases were missed by the physician & 9 cases by the nurse. All cases of early invasive carcinoma were picked by both the physician & nurse.

With disease threshold of CIN 2 VIA by physician had better sensitivity & specificity than VIA by nurse. The diagnostic efficacy of VIA by physician & nurse are presented in Table 2.

Table 1. Agreement of VIA test results between physician and Nurse

Nurse	Physician		Total
	Negative	Positive	
Negative	168	39	207
Positive	89	110	199
Total	257	149	406

Kappa co- efficient= 0.366 (moderate agreement)

Figure 1. Flow Chart of Women Screened by VIA by Doctor & Nurse

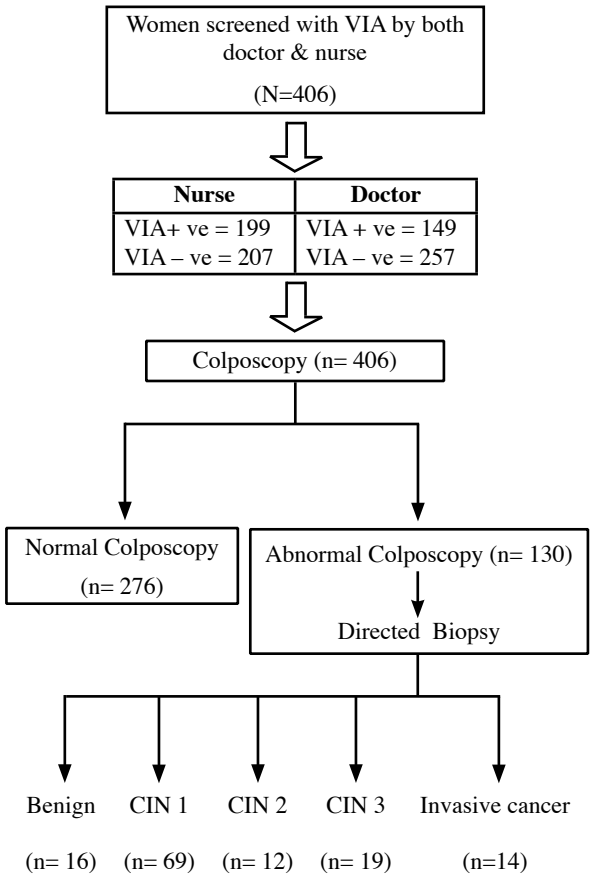

Table 2. Diagnostic Efficacy of VIA by Physician & Nurse with CIN 2 as Disease Threshold

Diagnostic efficacy	Physician (CI)	Nurse (CI)
Sensitivity	88.9% (79.7- 98.1)	80.0% (68.3- 97.7)
Specificity	69.8% (65.1- 74.5)	54.9% (49.7- 60.0)
Positive predictive value	26.9% (19.7- 34.0)	18.1% (12.7- 23.4)
Negative predictive value	98.1% (96.4- 99.7)	95.7% (92.9- 98.4)
False positive rate	30.2%	45.1%
False negative rate	11.1%	20.0%
Diagnostic accuracy	71.9%	57.6%

Discussion

Visual inspection with acetic acid as a screening test in the prevention of cervical cancer has been extensively evaluated for its accuracy for more than a decade. The Government of India and World Health Organization have recommended VIA as primary screening test to be performed by trained nurses and health workers at the primary health care level (Government of India & World Health Organization, 2006). However limited information is available regarding the difference in the test performance between paramedical workers and physicians.

Our study was performed on a select population who were referred to preventive gynaec oncology unit. An important aspect of our study was that both the physician and the nurse underwent similar training before the commencement of the study. Colposcopic evaluation was also performed at the same sitting and directed biopsy was taken when indicated.

Though the test characteristics of VIA done by both physician and nurse were in the same range as mentioned in various studies (Arbyn et al., 2006) our study revealed a better sensitivity and specificity by physician as compared to that of the nurse. The characteristics of the study population & the criteria used to categorize VIA test results of the present study were similar to a study done in India in 2003 (Bhatla et al., 2004). However the sensitivity of VIA by nurse (100%) was found to be better than that by physician (88%) but the specificity by physician (63%) was superior to that by nurse (53%) in their study. Findings similar to our study were observed in a study done in a primary health care setting in Africa where the sensitivity by physician & nurse were 71% & 55% & specificity was 71% & 65% respectively, but the sensitivity by nurse & physician were significantly lower than our study probably due to the fact that biopsy was performed in a small percentage of colposcopy negative cases which revealed high grade lesions in few cases (Ghislain et al., 2006).

Another important feature in our study which warrants special mention is the high negative predictive value (NPV) by both physician & nurse (98.1% & 95.7%). This implies that women assessed as test negative can be safely assured that they are not likely to have a high grade disease. The NPV in our study by physician & nurse was similar to that reported in other studies (Bhatla et al., 2004), (Ghislain et al., 2006).

One of the limitations of VIA screening technique is its high false positive rate owing to the subjective nature of the test. In the present study as well, the false positivity by nurse was significantly higher as compared to that by the physician (45.1% versus 30.2%). In women with false positive results the acetowhite areas appeared like dots or were less dense. Although this would be categorized as test negative the nurse who was aware that colposcopy would be performed the same day has reported it as positive in order to ensure that she missed as few cases as possible.

Several variables have been identified which affect the performance of VIA like the light source used, presence of inflammation and standardized training. Though these variables were present in both the groups, it was observed that the physician with a better clinical skill level who was familiar with gynecological examination and various pathological conditions of cervix comprehended the proceedings of the training session better than the nurse. This was reflected as better test performance by the physician. This study emphasizes the fact that VIA is provider dependent. As standardization of the test is difficult we feel that intensive training with periodic reinforcement is essential for providers who have limited knowledge regarding cervical pathology.

In our study the concordance of results between physician and nurse showed moderate agreement (k=0.366) which was comparable to a study done at New Delhi, India (k=0.56) (Bhatla et al., 2004). In a study done for inter rater variability for VIA between experts moderate to substantial agreement was observed, however the study noted the test performance of experts on static images (Sellors et al., 2002).

In the Osmanabad trial they concluded that a single HPV testing resulted in 50% reduction in incidence & mortality for cervical cancer while VIA & cytology had no effect whereas a contradictory outcome was noted in a randomized control trial in Dindigul district in South India where it was found that there was a reduction in cervical cancer incidence & mortality by 25% & 35 % respectively with a single visit VIA followed by cryotherapy done by mid level providers (Sankarnarayanan et al., 2009), (Sankarnarayanan et al., 2007). Inspite of the above observations Alliance for cervical cancer prevention (ACCP) & Global guidance for cervical cancer prevention by FIGO still recommend that VIA plus cryotherapy programs using local physicians, nurses, midwives & paramedical personnel could result in significant program impact until affordable HPV DNA tests become available (Alliance for cervical cancer prevention, 2009), (International Federation of Gynecology & Obstetrics, 2009).

In conclusion VIA has shown moderate agreement between physician and nurse and has acceptable test characteristics by both. Hence trained nurse can be an effective alternative human resource for cervical cancer screening using VIA as a primary screening method. However keeping in mind the high number of false positive results intensive training and periodic reinforcement sessions are needed so as to reduce the cost

to the patient and the health care system.

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