Prevalence of Premalignant and Malignant Cervical Lesions among Patients by Visual Inspection with Acetic Acid (VIA) in a Tertiary Care Hospital in Bangalore- An Observational Study

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ABSTRACT

BACKGROUND

Cervical cancer continues to be a major public health problem in India in the absence of widespread organized cervical screening programs. Visual inspection of the cervix with acetic acid (VIA) is an effective, inexpensive screening test that can be combined with simple treatment procedures for early cervical lesions, provided by trained health workers. We report 2 years' experience in early detection of cervical cancer and pre-cancers using the VIA test in a tertiary care hospital in Bengaluru, India. We wanted to study the prevalence of malignant and premalignant cervical lesions by VIA with acetic acid in Bangalore Baptist Hospital, Bangalore and study the demographic factors associated with malignant and premalignant lesions of cervix among the same population.

METHODS

This is a cross-sectional study. Eligible women aged between 20 years (sexually active) and 60 years were screened using the VIA test for 2 years. Women who tested positive were further evaluated by taking punch biopsy.

RESULTS

A total of 516 women were screened by a single round of VIA testing with a positive rate of 11.2% and 3.5% were biopsy positive. Out of 516 women, VIA was positive in 58 cases (11.2%). Biopsy done in 57 cases and biopsy was positive in 18 cases (3.5%). Biopsy reports showed 9 women with squamous cell carcinoma, 1 with adenocarcinoma, 1 with CIN1, 3 with CIN3, 4 with koilocytic atypia. Positive predictive value for VIA is 30%. Prevalence of premalignant and malignant lesions of cervix is 3.5%.

CONCLUSIONS

Our study reports experience of implementing VIA based cervical screening method in patients attending gynaecology OPD in a tertiary care hospital. VIA is a simple and affordable screening test with acceptable sensitivity and specificity in the range of 50-88.6% and 66.7-89.7% respectively. These results have important implications for efficient service delivery in cervical screening programs in low resource settings.

KEY WORDS

Cervical Cancer Screening, Cervical Screening in Low Resource Settings, Early Detection of Cervical Cancer, Malignant and Premalignant Lesions, Visual Inspection with Acetic Acid (VIA)

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BACKGROUND

Cancer cervix is the fourth most common cancer in women, and the seventh overall, with an estimated 528,000 new cases in the world and 123,000 new cases in India.^[1] In developing countries, there is a lack of effective screening programs for cervical cancer. In these countries no clinically significant reduction in the incidence of cervical cancer has occurred during the past three decades. In developed countries, in contrast, there has been a major decline in cervical cancer mortality after the introduction of large-scale cytological screening. The limited success of such screening in developing countries has stimulated evaluation of testing for Human Papilloma virus (HPV) and Visual inspection with acetic acid (VIA). The association between certain oncogenic (high risk) strains of HPV and cervical cancer is well established. HPV has been implicated in 99.7% of cervical squamous cell carcinoma cases worldwide.^[2] HPV infection has prolonged latent phase. Hence screening methods are necessary for early detection of premalignant lesions of cancer cervix. Screening for cancerous and precancerous changes of cervix has traditionally been performed by pap test. Factors which reduce the efficacy of screening programs in developing countries are lack of funds, expertise, knowledge among people regarding disease screening programs and compliance to treatment.

After analysing the above factors, various studies are being done to see that VIA can be included in screening trial, in developing countries because it is simple, easy to learn approach, minimal infrastructure, low start up and sustaining costs, test results are available immediately, requires only one visit, can be performed at any time during the menstrual cycle, including during menses (Provided flow is not heavy), during pregnancy, at a postpartum examination, or during a post abortion check-ups. It can also be done when a woman comes for care related to STIs, HIV screening or follow up care.^[3] VIA has emerged as a promising, cost-effective, non-cytology based, "see and treat" alternative for economically underprivileged geographical regions.^[4] Limitations of VIA are false positive rates and resources being spent on unnecessary treatment of women who are free of precancerous lesions in a single visit approach.^[5]

We wanted to determine the prevalence and the associated demographic factors for premalignant and malignant lesions of cervix by VIA among patients visiting gynaecology OPD in a tertiary care hospital. If VIA has a proven approach in screening cervical cancers it can be used further to screen patients as a replacement for pap smear or in addition to pap smear in a simple cost-effective manner.

METHODS

Study Setting

This is a cross sectional study which includes women attending the outpatient department of Bangalore Baptist Hospital, Bangalore for 2 years.

Sample Size

According to Globocan 2012 statistics, there are 123 per 1000 new cases of cancer cervix in India. The sample size is calculated based on this data and the sample size is 685.

$$\text{Sample size } n = [\text{DEFF} * Np(1-p)] / [(d^2 / Z^2_{1-\alpha/2} * (N-1) + p * (1-p))]$$

Population size (for finite population correction factor or fpc) (N):	1000000
Hypothesized % frequency of outcome factor in the population (p):	12.3%+/-2.46
Confidence limits as % of 100(absolute +/- %)(d):	2.46%
Design effect (for cluster surveys-DEFF):	1

Sample Size Calculation

Confidence Level (%)	Sample Size
95%	685
80%	293
90%	483
97%	839
99%	1182
99.9%	1927
99.99%	2692

Sample Size (n) for Various Confidence Levels

Inclusion Criteria

Women of age group 20 years (Sexually active) to 60 years including pregnant women.

Exclusion Criteria

1. Patients with active vaginal infection.
2. Patients with menstrual bleeding.
3. Patients with macroscopic cervical lesions.

Study Principle

VIA is based on principle that acetic acid coagulates the proteins of nucleus and cytoplasm and makes the proteins opaque and white.

Methodology

Questionnaire which includes age, socioeconomic status, symptoms, menstrual history, age of menarche, age of marriage, age of first coitus, age of first pregnancy, no. of sexual partners, age of menopause(if attained), any previous pap smear reports if available.

Visual Inspection after Acetic Acid Test

The procedure and the reason for it will be carefully explained to the woman to be examined and she will be made as comfortable as possible taking into consideration the privacy of the patient. Patient will be put in lithotomy position (If possible) or dorsal position. The light source will be directed to the genital area. Any abnormal findings in the external genitalia will be observed and recorded. The speculum will be lubricated with warm water and inserted into the vagina with the speculum closed. The speculum will be opened, and the light source adjusted so as to get a clear view of the cervix. If there is excess mucus or discharge, it will be cleared with a cotton swab soaked in boiled water or normal saline solution. Findings will be observed and recorded. The cervix will be wiped with a cotton swab dipped in normal saline followed by application of 3-5% acetic acid dipped in another cotton swab to the cervix and will be waited for approximately 2 minutes. The cervix is inspected for acetowhite areas. The squamocolumnar junction is located.

Criteria for Positive VIA

Appearance of well-defined densely opaque acetowhite lesions in the transformation zone close to squamocolumnar junction or external os. Anything that doesn't meet the criteria for a positive test including. Absence of acetowhite lesion. Faint or ill-defined translucent acetowhite areas. Faint acetowhitening of endocervical polyps. Nabothian cysts. Dot like acetowhite appearance. Will be categorised negative. Since VIA has high Negative predictive value and Specificity, all VIA negative cases are considered biopsy negative in our study.

Statistical Analysis

The statistical software namely SPSS 16.0 were used for the analysis of the data and Microsoft word and excel have been used to generate graphs, tables etc.

Ethics

The study procedure will be explained to all women and written informed consent will be taken from them. The patients will not be charged any additional amount for the study. Patient's medical information (Personal details, results of physical examinations, investigations and medical history) will be maintained confidentially. Patient's decision not to participate in this research study will not affect medical care or relationship with the investigator or the institution.

RESULTS

Age	Frequency	Percent
20-30	76	14.7
31-40	164	31.8
41-50	193	37.4
51-60	83	16.1

Table 1. Age Distribution Frequency Table

Most of the patients are in the age group of 41-50 years (37.4%) and 31-40 years is 31.8%.

SES	Frequency	Percent
Low	108	20.9
Middle	365	70.8
Upper	43	8.3
Total	516	100.0

Table 2. Socio Economic Status Frequency Table

Most of the study population belong to middle socioeconomic population that is 363 (70.8%) out of 516.

AOM	Frequency	Percent
10-20	268	51.9
21-30	245	47.5
>30	3	0.6
Total	516	100.0

Table 3. Age of Marriage

268 (51.9%) women are married between 10 years and 20 years. 245 (47.5%) are married between 21 and 30 years. 3 (0.6%) women are married after 30 years

Symptoms	Frequency	Percent
Backache	13	2.5
Dysmenorrhea	6	1.2
Dyspareunia	4	0.8
health plan	104	20.2
HMB	45	8.7
Intermenstrual bleeding	5	1.0
Mass per vaginum	4	0.8
Menstrual irregularities	42	8.1
Pain abdomen	36	7.0

PMB	23	4.5
postcoital bleeding	7	1.4
Routine check up	52	10.1
RV positive routine pap smear	56	10.9
Urinary complaints	14	2.7
WDPV	105	20.3
Total	516	100.0

Table 4. Symptoms

Patients presented with varied symptoms. Majority of population were screened in health plan (20.2%). majority of population presented with white discharge per vaginum (20.2%).

Previous Pap Smear	Frequency	Percent
Done- Abnormal	8	1.6
Done - Normal	57	11
Not done	451	87.4
Total	516	100.0

Table 5. Previous Pap Smear

Pap smears were not done in majority of population (87.4%). It was done in 12.6% of women. 11% of pap smears were normal reports and 1.6% were abnormal reports

Cervix (Per Speculum)	Frequency	Percent
Abnormal	24	5
Erosion	61	12
Hypertrophied cervix	19	4
Infection+	31	6
Normal	381	73
Total	516	100.0

Table 6. Cervix (Per speculum)

Majority had normal appearing cervix on per speculum examination. Abnormal cervix seen in 5% of population.

SES	Biopsy Negative	Biopsy Positive	Total	Chi-Square Value	p-Value
L	97(19.4)	11(61)	108	18.248	.000
M	359(72)	6(33)	365		
U	42(8.6)	1(6)	43		
Total	498	18	516		

Table 7. SES * Biopsy

Majority of biopsy positive cases seen in low socioeconomic population.

Age Group	Biopsy Negative	Biopsy Positive	Total	Chi-Square Value	p-Value
20-30	76(15)	0(0)	76	5.660	0.129
31-40	160(32)	4(22)	164		
41-50	184(37)	9(50)	193		
51-60	78(16)	5(28)	83		
Total	498	18	516		

Table 8. Age Group * Biopsy

Majority of biopsy positive cases were in between 41-50 years (50%), and between 31-40 years (28%).

DISCUSSION

This is a cross sectional study done in Bangalore Baptist hospital during 2016 to 2018. The current study was designed to know the effectiveness of alternatives to cytologic screening for detecting high grade SIL and invasive carcinoma in a resource poor setting. Visual screening methods recently received considerable attention as alternatives to cytologic screening in resource-poor settings. They are perceived as requiring a lower level of infrastructure and as being less expensive than cytologic screening because they do not require cytology laboratories with their attendant training and quality control costs. Visual methods provide an immediate result that is preferable in settings in which transportation facilities are minimal, in which it is difficult to track women with abnormal test results, or in which women must travel for long distances to health care facilities.

Authors	Study Period	Location	Population Screened	Age Range (Years)	VIA Positive
Denny L., Kuhn L., Pollack A., Wainwright H., Wright T. ^[6]	January 1996 to September 1997, 19 months.	Khayelitsha, South Africa (squatter settlement outside Cape Town)	2,944	35-65	537 (18.1)
University of Zimbabwe/ JHPIEGO Cervical Cancer Project ^[7]	Phase I initiated in October 1995, Phase II in August 1997. Number of months not stated	Zimbabwe 15 primary care clinics	8,731 2,203	25-55 25-55	1762 (20.2) 868 (39.8)
Sankaranarayanan R., Shyamalakumary B., Wesley R., Sreedevi Amma N., Parkin D.M., Krishnan Nair M. ^[8]	1995-1997, approx. 24 months.	Ernakulam, Kerala, India Early Cancer Detection Center	1,351	22-70	509 (37.7)
Sankaranarayanan R., Wesley R., Somanathan N., Dhakad N., Shyamalakumary B., Amma N.S., Parkin D.M., Nair M.K. ^[9]	1996-1997, approx. 12 months	Southern Kerala, India Cancer detection clinics of Trivandrum	3,000	20-70+	298 (9.9)
Megevand E., Denny L., Dehaeck K., Soeters R., Bloch B. ^[10]	February to September 1994, 7 months.	Cape Town, South Africa (squatter area)	2,426	20-83	76 (3.1)
Cecchini S., Bonardi R., Mazzotta A., Grazzini G., Iossa A., Clatto S. ^[11]	May 1991 to January 1992, 8 months.	Florence, Italy Centro per lo Studio e la Prevenzione Oncologica	2,105	17-83	341 (25.4)
Slawson D., Bennett J., Herman J. ^[12]	August 1989 to April 1990, 8 months	Pennsylvania, USA Harrisburg Area Research Network (HARNET)	2,827	15-45	113 (4.2)
Our study	2016-2018	Outpatients attending tertiary care centre	516	20-60	58 (11.2)

Table 9. Discussion of Related Studies

In our study among the screened population of 518 women, 58 are screened positive by VIA. Biopsy done in 57 women, among them 18 are positive for premalignant and malignant lesions of cervix. The biopsy reports show 9 women with Squamous cell carcinoma, 1 with adenocarcinoma, 1 with CIN-1, 3 with CIN-3, 4 with koilocytic atypia. Hence the positive predictive value is 3.5% which is comparable with other studies. According to Sankaranarayanan et al^[8] a single good quality VIA screen has a sensitivity around 40-50%, specificity around 80-90% and a positive predictive value around 5-10% for detecting high grade CIN. A negative VIA has a high negative predictive value. A single round of VIA screening has been shown to reduce cervical carcinoma incidence by 25% and mortality by 35% in a randomized controlled trial in India. In another randomized trial in South Africa VIA screen and treat strategy led to a 35% reduction in cervical precancerous lesions. World Health Organization recommends VIA screening as one of the best buys for cancer control.

CONCLUSIONS

Our study reports experience of implementing VIA based cervical screening method in patients attending OPD in a

tertiary care hospital. VIA is a simple and affordable screening test with acceptable sensitivity and specificity in the range of 50-88.6% and 66.7-89.7% respectively. Our study results show that the screen positivity is 11.2% and the detection rate of premalignant and malignant lesions of cervix is 3.5%. This is comparable with other research studies on VIA where positivity ranged from 6.6% to 27.4%. Early age of marriage (10-20 years), low socioeconomic status, abnormal cervix in per speculum examination, the cervix which bleeds on touch and hard consistency are significant risk factors in history and examination for malignant and premalignant lesions of cervix as described by other studies as well. The prevalence of malignant and premalignant lesions of carcinoma cervix is 3.5% in our study as we have screened the symptomatic patients attending OPD in a tertiary care hospital unlike community-based screening programs. Hence VIA can be taken as effective screening method in countries with limited resources or in situations when such screening is not available as it is an inexpensive and easy alternative that can be performed by non-medical health workers with considerable sensitivity and specificity which is similar to cytology.

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