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Original Research Article

Comparing the efficacy of visual inspection with acetic acid and lugol's iodine as a screening tool for detecting cervical lesions in asymptomatic women of reproductive age group with colposcopy and biopsy in a tertiary care hospital

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ABSTRACT

Background: A quarter of global burden of carcinoma cervix is experienced in India, where about 1, 26,000 new cases and 71,000 deaths attribute to cervical cancer are estimated to occur each year. Cervical cancer constitutes 15-55% of all female cancer and value of age standardized incidence ranges from 17.2 to 55 per 1 lakh women in different region in India with 5-year survival rate of less than 40% as most are detected at advanced stage. The objective of present study was to identify the incidence of cervical lesions in sexually active asymptomatic women.

Methods: This prospective study conducted in a tertiary care hospital for 1 year. This study comprises study subject of 734 women who were attending general and gynecology OPD. All 734 patients were subjected to visual inspection and magnification (VIA/VILI), colposcopy and biopsy was done in the positive patients.

Results: Of 734 cases studied, colposcopy was positive in 97 (13.1%). Among 97 cases who were colposcopy positive, VIA/VILI was positive in 90 cases. Colposcopy guided biopsy was positive in 97 cases. The sensitivity of VIA/VILI in detecting preinvasive lesions was 91.84% and specificity was 100% when compared with colposcopy which has sensitivity 98.98% and specificity 100%.

Conclusions: There is an enormous increase in the incidence of cancer cervix in geometric proportion. This can be controlled only with the introduction of mass screening programme by magnavision in a coordinated way in low resource settings.

Keywords: Biopsy, Cancer Cervix, Colposcopy, VIA, VILI

INTRODUCTION

Cancer cervix is the most common genital cancer in developing countries and second most common in developed countries. Carcinoma cervix has long pre-invasive stage of over 10-15 years. Availability of effective screening programmes and effective treatment along with long pre-invasive stage helps in reducing morbidity by early detection of pre-invasive lesions.¹

An estimated 4, 70,000 new cases of cervical cancer are diagnosed each year world wide and 80% of them occur in developing countries. A quarter of global burden is experienced in India, where about 1,26,000 new cases and 71,000 deaths attribute to cervical cancer are estimated to occur each year. Cervical cancer constitutes 15-55% of all female cancer and value of age standardized incidence ranges from 17.2 to 55 per 1 lakh women in different region in India with 5 year survival

rate of less than 40% as most are detected at advanced stage.

Every year in India, 122,844 women are diagnosed with cervical cancer and 67,477 die from the disease.² India has a population of 432.2 million women aged 15 years and older who are at risk of developing cancer. India also has the highest age standardized incidence of cervical cancer in South Asia at 22, compared to 19.2 in Bangladesh, 13 in Sri Lanka, and 2.8 in Iran. Therefore, it is vital to understand the epidemiology of cervical cancer in India. Opportunistic screening in various regions of India varied from 6.9% in Kerala 9 to 0.006% and 0.002% in the western state of Maharashtra and southern state of Tamil Nadu, respectively.

Most of the cases (85%) present in advanced and late stages, and more than half (63%-89%) have regional disease at the time of presentation. Cervical cancer diagnosis and treatment in the advanced stages makes it a costly exercise, with a poor prognosis resulting in poor compliance. Routine screening for cervical cancer with PAP smear for all women who are have been sexually active was done previously. In India, lack of experts in cytopathological studies and long period to get cytopathology report makes distinct need for alternate strategy. Now visual inspection of cervix with acetic acid and lugol's iodine is being recommended especially in low resource settings as a screening modality for cervical lesions.³ The primary goal of cervical screening is to prevent cervical cancer which is achieved by early detection; eradication and follow-up of pre-invasive cervical lesions.

Table 1: Approximate value of spontaneous regression or persistence and progression of CIN.

Course of CIN	CIN I	CIN II	CIN III
Regression to normal	60%	40%-50%	33%
Persistence	30%	40%	55%
Progression to cancer	1%	5%	>12%

Aim of study was to identify the incidence of cervical lesions in sexually active asymptomatic women using VIM, to compare the efficacy of VIM with colposcopy and to evaluate the feasibility of VIM as a mass screening for cervical lesions in low resource settings

METHODS

This prospective study conducted in a tertiary care hospital for 1 year from August 2008 to September 2009 at ISO-KGH-TRIPLICANE, Chennai. This study comprises study subject of 734 women who were attending general and gynecology OPD. All 734 patients were subjected to visual inspection and magnification (VIA/VILI), colposcopy and biopsy was done in the positive patients.

Inclusion criteria

Sexually active women between 18-40 years, Non-pregnant women, both nulliparous and multiparous, Women for screening on their own.

Exclusion criteria

Women with symptoms like vaginal discharge, pain etc., Pregnant women, Severe ill health, Postpartum until 12 weeks, Overt growth in cervix, Previous treatment for cancerous lesions, Allergy to acetic acid and iodine, those who had undergone hysterectomy, Women on hormonal therapy, Women below 18 years and above 40 years of age, Women with h/o surgery on cervix.

After getting informed consent for the procedure, Patient placed in lithotomy position and introduced bivalve self-retaining speculum, Characteristic of discharge was noted if present and inspection of unstained cervix, after application of acetic acid, after application of lugol's acid and inspection of fornices and vaginal wall, findings recorded and patient was advised to come after 2 to 3 weeks. Patients undergone VIA/VILI were subjected to colposcopy, cervix, vagina and vulva inspected for lesions, Colposcopic directed biopsy with punch biopsy forceps done in all positive patients, Specimen sent for histopathological examination and results obtained.

RESULTS

In this study, 91.8% of women belong to age group 21-35 years, age at marriage was less than 20 in 31.1%. Of them 67% belonging to second parity.

Table 2: Frequency of age group in this study (n=734).

Age (years)	Frequency	Percentage
18 - 20	12	1.6
21 - 25	258	35.2
26 - 30	251	34.1
31 - 35	165	22.5
36 - 40	48	6.5
Total	734	100

Age distribution in positive lesion was between 26-35 years (46% in 26-30 years, 53% in 31-35 years). Among positive lesions 13.1% belong to para 2 and above and no nulliparous women were positive. The lesions was significantly associated with low level of literacy and low socio economic status. Of 734 cases studied, colposcopy was positive in 97 (13.1%). Among 97 cases who were colposcopy positive, VIA/VILI was positive in 90 cases. Colposcopy guided biopsy was positive in 97 cases. The sensitivity of VIA/VILI in detecting pre-invasive lesions was 91.84% and specificity was 100% when compared with colposcopy which has sensitivity 98.98% and specificity 100%.

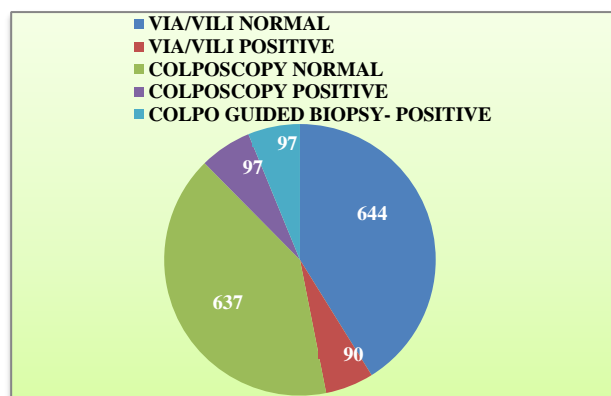


Figure 1: Number of positivity in VIA/VILI/colposcopy/biopsy (n=734).

DISCUSSION

Of 734 cases, 90 cases were found to be VIA/VILI positive and 644 cases were VIA/VILI negative, colposcopy was positive in 97 (13.1%). Among 97 cases who were colposcopy positive, VIA/VILI was positive in 90 cases. Among 97 cases who were positive for colposcopy also positive for Colpo guided biopsy. The sensitivity of VIA/VILI in detecting preinvasive lesions was 91.84% and specificity was 100%, colposcopy has sensitivity 98.98% and specificity 100%. The positive predictive value of VIA/VILI was 100% and its negative predictive value was 98.76%. The diagnostic accuracy of VIA is 98.91% and for colposcopy, it is 99.86%.

Table 3: Comparison of biopsy results and age group (n=97).

Age (years)	Biopsy positive
18-20	Not done
21-25	8 (1.1%)
26-30	46 (6.2%)
31-35	39 (5.3%)
36-40	4 (0.5%)
Total	97 (13.1%)

This prospective observational study analyse the efficacy of visual inspection methods (VIA/VILI) with colposcopy and cervical biopsy and to choose VIA and VILI as an easily interpretable low cost, non-invasive but effective method for detecting cervical lesions.

Table 4: Frequency of biopsy types (n=734).

Biopsy Positive	Frequency	Percentage
Normal	636	86.6
Chronic non-specific cervic citis	32	4.4
LSIL	57	7.8
HSIL	9	1.2
Total	734	100

In our study, age group taken was between 21-35 years which constitute about 91.8%. Similarly, study conducted in AIIMS, New Delhi in 2003 to evaluate and compare test performance of visual inspection of cervix by a doctor and paramedical worker, included study group of patients with 64% belonging to 30-39 years.⁴ In this study, age at marriage was less than 20 (31.1%) and which is similar to study conducted in obs and gyn department in AIIMS 2007 which showed 30.4% of the study group had their marriage at age less than 20 years.⁵

Table 5: Comparison of sensitivity and specificity.

Statistical values	VIA/VILI (%)	Colposcopy with biopsy (%)
Sensitivity	91.75	98.98
Specificity	99.84	100
PPV	98.89	100
NPV	98.76	99.84
Diagnostic accuracy	98.77	99.86

Similarly, study conducted in AIIMS, new Delhi in march 2003 for detecting cervical lesions on women with mean age at first sexual intercourse was 19±3.3years.⁴ In our study most of the women were para1 and para2 which is consistent with practice of our women for small family norm and para2 women undergo permanent method of sterilisation at an early age. Hence with the loss of fear of pregnancy their sexual activity also increases, putting them at higher risk for cervical lesions. Positive lesions are significantly associated with low level of literacy and low socio economic status, those who undergone graduations have nil lesions indicating that literacy have positive influence in reducing cervical lesions. Similarly, study on health literacy, cervical cancer risk factor and disease in low income africo-american women seeking colposcopy concluded that low level of health literacy is associated with increased level of disease among women at high risk for developing cervical cancer.⁶ This study showed that age distribution in positive lesion was between 26-35 years (475 in 26-30 years, 53% in 31-35 years). A study conducted at institute of medical sciences, lahore in 2007 showed that majority of women with CIN (60%) were between 35-45 years which also showed that there is higher incidence of positive biopsy when this women marry at early age and expose themselves to longer period of sexual activity.⁷

Among the positive lesions, 13.1% belong to para 2 and above and no nulliparous women was positive. In the study,conducted by IARC, a multicentric case control study on role of parity and HPV in cervical cancer, found that there was direct association between number of full term pregnancy and squamous cell carcinoma risk.⁸ The odds ratio for seven full term pregnancy or more was 3.8 (95% CI.2.7-5.5) compared with nulliparous women and 2.3 (CII.6-3.2) compared with women who had one or two full term pregnancy.

In present study, both in VIA/VILI and colposcopy, it was noted that all the positive women found to be positive when biopsy confirmation was sought. However, there were minor differences with both the methods missing on negative women. Hence both the methods were near complete in their negative predictive value was considered. Most of the positive biopsies were LSIL lesions and the women were treated accordingly. 1.2% of HSIL women counselled for further definitive management. Results of our study was comparable with study conducted in institute of medical science, Lahore showed LSIL IN 4.1% and HSIL in 1.8% and no invasive lesion. The sensitivity of VIA/VILI in detecting preinvasive lesions was 91.84% and specificity was 100% when compared with colposcopy which has sensitivity 98.98% and specificity 100%. The positive predictive value of VIA/VILI was 100% and its negative predictive value was 98.76%. Similarly the positive and negative predictive value in detecting cervical lesions with colposcopy in asymptomatic women was found to be 100% and 99.84% respectively. The diagnostic accuracy of VIA is 98.91% and for colposcopy, it is 99.86%.

CONCLUSION

There is an enormous increase in the incidence of cancer cervix in geometric proportion. This can be controlled only with the introduction of mass screening programme in a coordinated way. Hence the emphasis was shifted to visual inspection methods with acetic acid and lugol's iodine. This method could sustain due to its simplicity and ease of performing in mass programmes and the results are available immediately. Moreover, the specificity and sensitivity of these visual inspection based tests were also equally good 91.84% and 98.98% respectively. Hence for resource restricted settings, VIA/VILI is a real boon for mass screening. This study further emphasizes the need for programmed screening of all women who are sexually active whatever may be their literacy and socioeconomic status.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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