

VIA (Visual inspection with acetic acid) and VILI (Visual inspection with lugol's iodine) as an initial approach with colposcopy as a next screening tool with its positive predictive value in low socioeconomic patients

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ABSTRACT

Background: Cervical Cancer is the second most common cancer in women worldwide and India alone contribute the 1/4th of the world's cases of cervical cancer. In view to this huge burden there was need to establish a feasible screening programme to detect cervical carcinoma at earliest in developing country.

Methods: This is a prospective study of 500 women who fulfil the selection criteria. 50 pregnant patients for VIA (Visual inspection with acetic acid), 50 pregnant patients for VILI (Visual inspection with lugol's iodine) and 400 non-pregnant women for VIA, VILI and colposcopy were enrolled. In positive cases, cervical biopsy with histopathological examination was done. The sensitivity, specificity and positive predictive value of each test were obtained and compared. Chi-square (X²) test was used to test the significance of difference between two proportions of a quantitative data.

Results: The sensitivity, specificity, positive predictive value and negative predictive value for VIA (85.1%, 84.1%, 41.7%, 97%), VILI (95.7%, 92.4%, 62.5%, 93.4%) and Colposcopy (83%, 86%, 51.3%, 96.6%) were statistically significant with its histopathological report.

Conclusions: In a poor developing country like India where pap smear and colposcopy is not available in low resource setting VIA and VILI can prove a very helpful tool in picking up abnormal looking cervix which can then be confirmed by pap or colposcopy. It will go a long way in reducing the incidence of cervical carcinoma.

Keywords: Colposcopy, Cervical Cancer, Lugol's Iodine, Low socioeconomic, VIA, VILI

INTRODUCTION

Cervical Cancer is the second most common cancer among women worldwide. More than 85% cases and 88% deaths from cervical cancer occur in developing country. India alone contribute 1/4th burden of cervical cancer globally. Carcinoma of the cervix is a great

challenge to gynaecologists, especially in the developing countries where poor socio-economic status, early marriage, multi parity, ignorance, illiteracy, poor hygiene and most importantly unavailability of cytology based screening programme are still prevalent. There is a great difference in the prognosis of the cases diagnosed early as compared to those diagnosed in advanced stages.

Advances in the diagnostic techniques have led not only to early recognition of cervical Cancer, but also the pre-cancerous lesion.¹ In view of high cost and unavailability of cytology based screening facility in developing country, early diagnosis on visual inspection is being evaluated. Visual inspection of cervix by 3% acetic acid (VIA) and Lugol's iodine (VILI), neither requires second person for interpretation of results nor second visit by the patients to collect the report, and has been recommended by WHO, which can be easily done in poor resource area.² In a low resource setting, screening on visual methods like VILI has excellent sensitivity(100%) and acceptable specificity (93.3%).³ The introduction of colposcopy by Hinselmann, involved the visualization of cervix with magnification and has a definite diagnostic importance in evaluating the severity and extent of the lesions.¹ Lack of trained doctor as well unavailability of colposcope in low economic status of rural population led this screening to be utilized in urban areas only. Hence, this study was carried out to evaluate the role of visual inspection methods (VIA and VILI) in poor resource setting in Indian scenario and to evaluate its positive predictive value as compared to more expensive and sophisticated colposcopy screening.

METHODS

This study was conducted in the obstetrics and Gynaecology outpatient Department (OPD) at Darbhanga Medical College and Hospital, Laheriasarai from March 2011 August 2012. This observational study was conducted in 500 women (18-65 years) who fulfil the selection criteria. The inclusion and exclusion criteria are summarised below. Patients who met the eligibility criteria at the initial examination were randomly assigned for study. The demographics details and socioeconomic status of the patients were recorded. Incidence of VIA and VILI positive was done in 100 pregnant and 400 non-pregnant women separately. In pregnant women, 50 patients for VIA and 50 patients for VILI were assigned. VIA, VILI and colposcopy all three screening tests were done in 400 non pregnant patients. Positive cases were planned for biopsy and histopathological examination. After taking consent about screening procedures, relevant obstetrics and gynaecology history was taken and recorded. Women were invited to lie down in a modified lithotomy position on a couch with leg rest. Results of Visual inspection (VIA) with (5%) acetic acid and VILI (Lugol's iodine) were reported. The opaque aceto white lesion and yellow iodine non-uptake area were considered as positive for VIA and VILI respectively. Patients undergone through colposcopy on next day, to see the finding of VIA and VILI under a 12/15 x magnification. The findings were observed and classified as normal (Pink squamous epithelium and reddish pink columnar epithelium) or abnormal (Atypical transformation zone and unsatisfactory) colposcopy. The findings on colposcopy like punctuation, mosaic, white epithelium, keratosis, abnormal blood vessels and suspected or frank invasive cancer were considered as

atypical transformation zone. Cases in which squamocolumnar junction was not visible included in unsatisfactory colposcopy. In all patients who presented with abnormal colposcopy findings, colposcopy guided biopsy was done. In case of unsatisfactory colposcopy endocervical curettages were done. HPE was obtained and evaluated with findings of VIA, VILI and colposcopy.

Inclusion criteria

- Frank growth of Cervix
- Active bleeding
- Past history of cervical neoplasia.
- Had previous positive pap smear
- Associated lesions on vulva and vagina
- Had absent cervix

Exclusion criteria

- Age less than 18 years and more than 65 years.
- Cervical cancer histologically proved.
- Frank invasive cervical carcinoma.
- Active bacterial or fungal infection with frank bleeding.

RESULTS

The results and observations of the present study are presented below. The incidence of VIA positive and VILI positive cases was 18% in both groups (Pregnant and Non-pregnant). Vaginal discharge was the most common symptom with 265 patients (53%). More than 95% women belonged to low socioeconomic group. It was observed that more than 75% of patients were from age group 21-30 years in group 1 (Pregnant group). Maximum number of patients in both groups was of 25 years of age (Table 1). This age distribution is because of early age of marriage and early child bearing in our society.

Table 1: Age distribution in two groups of women.

Age	Group 1	Group 2
≤20	12	14
21-25	50	34
26-30	28	22
31-35	8	8
36-40	2	2

Table 2: Distribution of VIA and VILI Positive women in different age group.

Age	VIA (%)	VILI (%)
<20	0	0
21-25	4	4
26-30	10	8
31-35	2	6
36-40	2	0

Table 2 shows VIA positive screening test were observed in 18% of women (9 patients) with the maximum of 10% (5 patients from age group 26-30). One patient of 40 years of age was observed to be VIA positive. VILI positive screening came also with 18%. None of the patients who were <20 years of age was screen positive.

Table 3: Number of patients on the basis of gravida distributed in two group.

Gravida	Group 1 (No. of patients)	Group 2 (No. of patients)
Primigravida	26	28
Second gravida	28	28
Third gravida	26	32
Fourth gravida	18	6
Fifth gravida and above	2	6

Mean age of both VIA and VILI positive test was 28 years. Table 3 shows 80% of women who participated in the study were under gravid <3. More patients enrolled with lower parity because women are more conscious in early pregnancy.

Table 4: Distribution of VIA and VILI positive patients according to obstetric status.

Gravida	Group 1 (%)	Group 2 (%)
Primigravida	0	2
Second gravida	4	2
Third gravida	2	4
Fourth gravida	10	4
Fifth gravida and above	2	6

Table 4 shows VIA test positive were maximum in fourth gravida with 5 cases and 3 patients with fifth gravida were positive with lugol's iodine. Women with age 26-30 years were maximum (30.5%) in which only 16.66% were VIA positive and 13.8% were VILI positive. As the age increases, risk of preinvasive lesions increases and thus the percentage of VIA and VILI positive patients in particular age group increases with age. Leucorrhoea or discharge per vaginum was the most common symptom (53%) followed by menstrual disturbance (12%) and pain abdomen (7.5%).

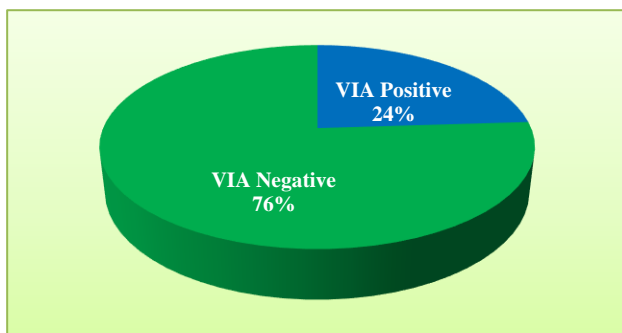


Figure 1: VIA Screening.

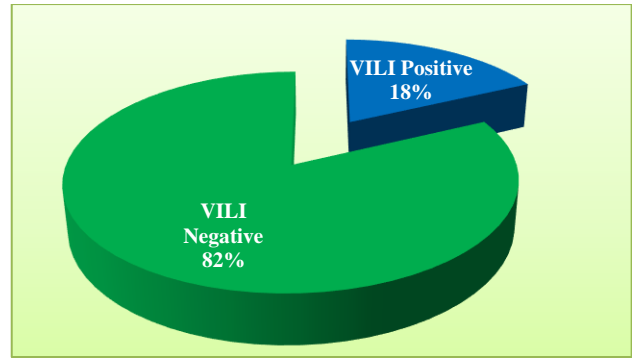


Figure 2: VILI Screening.

Figure 1 and 2 shows VIA and VILI were found to be positive in 96 patients (24%) and 72 patients (18%) and negative in 304 patients (76%) and 328 patients (82%) respectively. In present study out of 400 women, satisfactory colposcopy was observed in 316 patients (79%) and unsatisfactory in 84 patients (21%). Unsatisfactory results were common in menopausal women in which the endocervical curettage was done. On the basis of cytological report of curettage normal satisfactory colposcopy was observed in 237 patients (75%) and abnormal in 79 patients (25%).

Table 5: Distribution of VIA positive cases with Biopsy.

	Chronic cervicitis	LSIL	HSIL	Invasive cancer
Esosion	22	7	1	0
Cervicitis	30	9	1	0
Polyp	1	1	0	0
Bleeding on touch	1	5	2	0
Unhealthy cervix	2	2	4	2
Growth cervix	0	0	0	6

Table 6: Distribution of VIA negative patients on Biopsy.

Cervicitis	LSIL	HSIL	Invasive cancer
10	3	3	1

On biopsy of VIA positive and negative patient's chronic cervicitis was observed in 56 patients (58.3%) and 10 patients (3.4%) respectively (Table 5 and 6). The sensitivity of VIA to diagnose the invasive cancer was 85.1% and the percentage of false negative was 14.9%. The specificity of VIA was 84.1% with 15.1% of false positive rates. Positive predictive value and negative predictive value of this study for VIA were 41.7% and 97.7%.

One invasive cervical cancer, 3 Low Grade Squamous Intraepithelial lesions (LSIL) and 3 High Grade Squamous Intraepithelial lesions (HSIL) were missed by

VIA. VIA detected 27 mild dysplasia and 20 Cervical Intraepithelial Neoplasia (CIN). Present study was statistically significant with $p < 0.0001$.

Table 7: Distribution of VILI result with Biopsy.

VILI Status	Chronic cervicitis	LSIL	HSIL	INV. cancer
VILI positive	27	25	11	9
VILI Negative	3	2	0	0

Table 7 shows VILI positive were detected in 72 patients (18%) and negative in 328 patients (82%). The sensitivity was 95.7%, specificity 92.4%, positive predictive value 62.5% and negative predictive value 99.4. There were only 2 CIN II cases which were missed by VILI. VILI detected 27 LSIL, 11 HSIL and 1 invasive cancer. Present study was statistically significant with ($p < 0.0001$).

Table 8: Distribution of Abnormal colposcopy results with biopsy.

	LSIL	HSIL	Inv. cancer
White epithelium	10	4	1
Mosaic	4	2	0
Punctuation	1	1	0
Atypical vessels	2	1	-
Invasive cancer	1	2	7

In the present study Table 8 shows sensitivity of colposcopy with biopsy was 83%, specificity 86%, positive predictive value 51.3% and negative predictive value (96.6%), which was statistically significant with $P < 0.0001$. Colposcopy missed one invasive cancer and 1 HSIL and 6 LSIL.

DISCUSSION

One quarter of the world's cervical cancer burden is in India, where it is the most frequent genital malignancy in women accounting for 26% to 43.8% of all cancer in women. The number of deaths due to cervical cancer was 79,000 in year 2010 in India and makes the commonest cause of cancer death.⁴ Cervical Cancer kills 1 Indian women in every 7 minutes. Cervical cancer can be treated with 100 percent cure rate if detected earlier.⁵ In the developing country like India cytological screening test is not widespread because lack of trained personnel, unavailability of resources and health education.⁶ On the other hand initial screening with VIA, VILI and Colposcopy favour its simplicity and cost effective approach at wider level in low- resource settings.⁷ Rana et al suggested that VIA had a better negative predictive value than cytology screening test.⁸ In one study the sensitivity and specificity of VIA was 89% and 87%.⁹ In our study also sensitivity and specificity of VIA was 85.1% and 84.1%. In the present study more than 75% of patients were from age group 21-30 years and mean age was 25 years.

In one study the highest rate of dysplasia was in age group of 20-29 years and mean age was 36.5 years.^{10,11} More than 80% of women who participated in the study were under gravid ≤ 3 . VIA test positive was maximum in fourth gravida with 5 cases; however 3 patients with fifth gravida were positive with lugol's iodine. In contrary to the present study others studies shows no association of multiparity with cervical carcinoma.¹²⁻¹⁴ In the present study Leucorrhoea or discharge per vaginum was the most common symptom. These findings were consistent with those of Rose and Jean, Das and Bhargava, who also found discharge per vaginum, was the commonest symptom in lesions of the cervix. In our study more than 95% patients belonged to low socioeconomic status and favoured VIA, VILI and Colposcopy rather than cytological screening similar to observations of N Segnan.¹⁵ Shankaranarayanan R in his study also shared that VIA with good training is very useful screening method to prevent cervical cancer in developing countries.¹⁶ Many studies preferred VIA as primary screening approach.¹⁷⁻²² Some author preferred combined approach of VIA, VILI and Colposcopy similar to present study.^{23,24} Pothisuwan M et al emphasized the significance of VIA that it may reduce the necessity of colposcopy which was in concordance with our study.²⁵ Ghosh P found, all biopsy positive cases (CIN I or worse) were VILI positive.³ In Colposcopy, sensitivity was 83%, specificity 86%, PPV 51.3%, NPV 96.6%. All 3 tests were statistically significant with histopathological results with $p < 0.0001$. Since visual inspection method has a higher sensitivity; it can be used as a good screening method.

CONCLUSION

In a poor developing country like India where pap smear and colposcopy are not available in low resource setting VIA and VILI can prove a very helpful tool in picking up abnormal looking cervix which can then be confirmed by pap or colposcopy. It will go a long way in reducing the incidence of cervical carcinoma.

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