Original Research Article

Comparative study between Pap smear and VIA in screening of cancer cervix in rural population

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Abstract

Background: Carcinoma cervix is the second most common cancer among women in India. There is a significant reduction in carcinoma cervix incidence and mortality with implementation of intensive screening programs. **Aims and Objectives:** The objective of the study was to screen patients between 18 and 60 years by Pap smear and VIA for cervical cancer and to detect sensitivity and specificity of each test and compare the VIA positive cases with colposcopic study. **Materials and Methods:** This was a prospective cross sectional study conducted in 210 women of age group of 18 to 60 years who attended department of Obstetrics and Gynecology over a period of one year from October 2016 to October 2017. The pap smear and VIA were done in these cases. **Results:** In our study, majority of positive cases on Pap smear were in the age groups of 41 to 50 years and 51 to 60 years of age (n = 4 in each age group; 4.88 and 8.7% respectively).There were 11 cases with abnormal Pap smear and 9 patients with ASCUS and 41 cases with positive VIA results. When LSIL/HSIL was evaluated, surprisingly a greater proportion was observed in women with 10 to 20 years of marriage. Majority of Pap smear findings were benign with negative for intraepithelial lesion or malignancy (NILM) accounting for 37.6% of patients followed by inflammatory changes (cervicitis) in 37.2% of patients and lastly atrophic smear in 33 patients (15.7%). **Conclusion:** From the study we conclude that if we compare VIA with Pap smear, VIA is easy-to-perform, results are obtained almost instantly and the patients with abnormal findings can be subjected for biopsy in single setting and low cost make it an ideal test in rural set up.

Key Words: Screening, pap smear, VIA, Carcinoma cervix.

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INTRODUCTION

Carcinoma cervix is the second most common cancer among women in India with an estimated incidence rate of about 22.9%. It is also a common cause of cancer-related mortality among women in India accounting to >20% of all cancer-related death[1] Globally, the highest burden of carcinoma cervix is in India[2]. There is a significant reduction in carcinoma cervix incidence and mortality with implementation of intensive screening programmes[3]. Although guidelines regarding screening for carcinoma cervix have been in force in India since 2006, it is yet to be implemented aggressively[3].There is a reduction in incidence of carcinoma cervix over the years in India however it still remains the second leading cancer among women. Moreover the risk of cervical cancer is high among rural population as recorded in many cancer registeries[3,4] Various causes for failure of implementation of cervical screening system range from inadequate infrastructure, limited resources and a large population**Error! Bookmark not defined.**.Visual

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inspection with acetic acid (VIA) is considered as a promising method for cervical cancer screening. It is particularly useful in low resource setting. It is also simple to perform and therefore can be used as an alternative to cytology[2]. VIA is also a real time screening test as the results are known immediately following the test[1]. Therefore we wish to determine if VIA has a diagnostic performance comparable to cytology and can replace Papanicolaou(Pap) smear in cervical cancer screening.

AIMS AND OBJECTIVES

The objective of the study was to screen patients between 18 to 60 years by Pap smear and VIA for cervical cancer and to detect sensitivity and specificity of each test and compare the VIA positive cases with colposcopic study.

MATERIALS AND METHODS

This was a prospective cross sectional study conducted in 210 women of age group of 18 to 60 years who attended department of Obstetrics and Gynecology over a period of one year from October 2016 to October 2017. Patients were included in the study if the fulfilled the inclusion and exclusion criteria. An informed consent was obtained from the patient for their willingness to participate in the study. The study was approved by the institutional ethics committee. Inclusion criteria were high-risk women aged between 18 to 60 years, which included early marriage, early pregnancy, sexual activity at early age, multiparity, multiple sexual partners, presence of sexually transmitted disease, leucorrhoea, and abnormal uterine bleeding. The exclusion criteria were unmarried status, per vaginal bleed, active infection at the time of examination and frank invasive carcinoma cervix. Complete history of the patient was obtained, which included history of white discharge per vagina, post coital bleeding, menstrual history and contraception. Per speculum examination of cervix and vagina was performed. The squamocolumnar junction was visualized, with hooked end of Ayers spatula. Squamocolumnar junction was scraped gently throughout its circumference and material was transferred to glass slides. Two smears were taken for evaluation. They were fixed with 95%alcohol immediately and stained by Pap stain. The Bethesda system (2014) for cytological reporting was used in this study. Normal smears where there was no dyskaryosis were considered as negative for squamous intraepithelial lesion (SIL), whereas abnormal smears showing dyskaryosis were designated as SIL. Furthermore they were classified into two subclassifications, low-grade squamous intraepithelial lesion (LSIL) and high-grade squamous intraepithelial lesion (HSIL). LSIL included lesions that were previously classified as koilocyticatypia (following human papilloma virus (HPV) infection) and low-grade cervical intraepithelial neoplasia (CIN1). HSIL encompassed moderate and severe dysplasia, carcinoma in situ (CIS), CIN 2 and CIN 3[2]. Undefined cases underwent repeat pap smears 6 months later. In case of equivocal findings compared with previous study they were designated as atypical squamous cell of undetermined significance (ASCUS). Cases of chronic cervicitis were designated as negative with inflammation. Following Pap smear VIA was performed. In this procedure 3 to 5 % of acetic acid was applied to the cervix with a cotton swab and left for 60 seconds, after which the cervix was visually examined with naked eye and lamp. Acetic acid (5%) causes swelling of cervical epithelial tissue with precipitation or reversible coagulation of cellular proteins. Therefore when applied to cells with high nuclear protein content such as neoplastic cells, coagulation results in acetowhite areas in cervix, whereas normal cervix appears pink due to lesser coagulation[2,3]. In our study VIA test was considered positive for precancerous lesions when there were acetowhite lesions close to or touching the squamocolumnar junction on application of 3-5% acetic acid, while absence of acetowhite was considered negative study. Additionally features suggestive of cervicitis were also excluded from the study. The thick acetowhite lesions were immediately examined under digital video colposcope (Techmann Sony Digital CCD HD Q11) and a biopsy was taken if indicated, which was sent for histopathological examination. Colposcopy was used as the confirmatory test in this study based on the findings. The VIA findings were classified as normal, CIN, previnvasive carcinoma and inflammatory lesions (Table). Indicated in abnormal PAP smear, visible or palpable abnormality of cervix, persistent leucorrhoea not responding to treatment, contact bleeding, postmenopausal bleeding. 3 to 5% of acetic acid is applied. Acetic acid is mucolytic and coagulates proteins. Areas of high nuclear density appear acetowhite. Areas of columnar epithelium will stand out as typical grapelike structures. examination through green filter is used to visualize the vascular pattern of cervix. The details of blood vessels are enhanced against light green background.

RESULTS AND OBSERVATIONS

Table 1: Results of VIA Study

Result	Findings
Normal colposcopy	Normal squamous epithelium appears pink, smooth, and translucent. Columnar epithelium identified by grape like appearance. On application of acetic acid, columnar epithelium swells and appears acetowhite
CIN	CIN lesions are usually localized and appear acetowhite. Margins are usually well demarcated. Surface of the contour may be irregular or nodular. Abnormal vascular patterns such as punctuation and/or mosaics on acetowhite areas suggest high grade lesion.
Preinvasive carcinoma	Dense acetowhite lesions with atypical vessels pattern and may take the form of hairpins commas or appear as bizarre branching patterns. Large acetowhite lesions, involving both anterior and posterior lips of the cervixwith raised and rolled out margins suggestive of invasive cancer.
Inflammatory lesions	Colposcopic changes are not confine to the transformation zone and tend to be diffuse. Diffuse acetowhitening and inflammatory punctuations are features of inflammation.

In the present study majority of the patients were in the age group of 41 to 50 years (n = 82) followed by age group of 31 to 40 years (n = 74) and 51 to 60 years (n = 46) and least patients were in the age group of 20 to 30 years (n = 8) (Table). It could be discerned from the data that majority of positive cases on Pap smear were in the age groups of 41 to 50 years and 51 to 60 years of age (n = 4 in each age group; 4.88 and 8.7% respectively). There were three cases with abnormal Pap smear in age group of 31 to 40 years (4.05%) and no abnormal Pap smear in patients in age group of 20 to 30 years. This shows the increasing tendency of abnormal Pap smears with advancing study in our study. In contrast there was an increase in the percentage of cases with VIA with advanced age groups with the exception of abnormal VIA in four patients in 20 to 30 year age group. Importantly, there were 11 cases with abnormal Pap smear and 9 patients with ASCUS and 41 cases with positive VIA results.

Table 2: Distribution of Patients Based on Age, VIA, LSIL/HSIL/ASCUS and Carcinoma Cervix.

Age group (in years)	No screened	VIA n (%)	ASCUS n (%)	LSIL/HSIL/n (%)	Carcinoma Cervix n (%)
20-30	8	4 (50)	0 (0)	0 (0)	0 (0)
31-40	74	3 (4.05)	0 (0)	3 (4.05)	0 (0)
41-50	82	21 (25.60)	2 (2.4%)	3 (3.66)	1 (1.22)
51-60	46	13 (28.26)	7 (15.2%)	2 (4.35)	2 (4.35)
Total	**210**	**41 (19.52)**	**9 (4.28%)**	**8 (3.8)**	**3 (1.43)**

ASCUS = atypical squamous cell of undetermined significance; HSIL = high-grade squamous intraepithelial lesion; LSIL = low-grade squamous intraepithelial lesion; n = number of patients; VIA = visual inspection with acetic acid

In our study majority of women had parity of ≤ 2 (n = 195) followed by multiparous women (>2). It is interesting to observe that although the percentage of cases with VIA are greater in patients with parity >2 as compared with parity of ≤2 (18.46% and 33.3% respectively), the difference was not considered statistically significant (*P* = .09). Similarly there was an increasing trend in cases of LSIL/HSIL and carcinoma cervix in multiparous women compared with parity ≤2 and ASCUS was more common in patients with parity ≤ 2 (Table). As the number of cases in in ASCUS and LSIL/HSIL and carcinoma cervix were less in multiparous women a definite statistical analysis could not be arrived at.

Table 3: Relationship between Parity, Pap Smear and VIA

Parity	No screened	VIA n (%)*	ASCUS n (%)	LSIL/HSIL/n (%)	Carcinoma Cervix n (%)
≤2	195	36 (18.46)	9 (4.28)	6 (3.07)	2 (1.02)
>2	15	5 (33.3)	0 (0)	2 (13.3)	1 (6.67)
Total	**210**	**41 (19.52)**	**9 (4.28%)**	**8 (3.8)**	**3 (1.43)**

ASCUS = atypical squamous cell of undetermined significance; HSIL = high-grade squamous intraepithelial lesion; LSIL = low-grade squamous intraepithelial lesion; n = number of patients; Pap = Papanicolaou; VIA = visual inspection with acetic acid;
*P = .09; Mid-P exact

In our study a majority of patients were married for >20 years (n = 150; 71.4%) followed by 10 to 20 years of marriage (n = 40; 19.04%) and lastly <10 years of age (n = 20; 9.5%). It can be observed from that duration of marriage has a

direct correlation between findings of abnormal VIA and abnormal Pap test. It is interesting to note that all cases of carcinoma cervix were reported in patients with >20 years of marriage. When LSIL/HSIL was evaluated, surprisingly a greater proportion was observed in women with 10 to 20 years of marriage. When abnormal Pap smear findings were considered 16 abnormal Pap smears were seen in patients with marriage >20 years (7.6%) followed by women with marriage age 10 to 20 years (7.5%) and least abnormal Pap smears were reported from patients with <10 years of marriage (5%). The incidence of abnormal VIA were similarly greater in patients with marriage >20 years (19.33%) followed by 10 to 20 years of marriage (17.5%) and lastly in patients with <10 years of marriage (15%). There were only three patients with duration of marriage <10 years with abnormal VIA (Table).

Table 4: Relationship between duration of Marriage, Pap Smear and VIA

Duration of marriage (in years)	No screened	VIA n (%)	ASCUS n (%)	LSIL/HSIL/n (%)	Carcinoma Cervix n (%)
>20	150	29 (19.33)	7 (5.83)	6 (2.86)	3 (1.43)
10-20	40	7 (17.5)	1 (2.5)	2 (5)	0 (0)
<10	20	3 (15)	1 (5)	0 (0)	0 (0)
Total	**210**	**29 (13.8)**	**9 (4.28%)**	**8 (3.8)**	**3 (1.43)**

ASCUS = atypical squamous cell of undetermined significance; HSIL = high-grade squamous intraepithelial lesion; LSIL = low-grade squamous intraepithelial lesion; n = number of patients; Pap = Papanicolaou;VIA = visual inspection with acetic acid

Majority of Pap smear findings were benign with negative for intraepithelial lesion or malignancy (NILM) accounting for 37.6% of patients followed by inflammatory changes (cervicitis) in 37.2% of patients and lastly atrophic smear in 33 patients (15.7%)(Table). The benign findings accounted for 180 of 210 patients (85.71% patients). Among the remaining patients eight patients (3.8%) presented with ASCUS, five patients with HSIL (2.4%), LSIL in four patients (1.9%) and lastly carcinoma cervix in three patients (1.4%).

Table 5: Pap smear findings

Pap smear finding	No of Patients	%
Inflammatory changes (cervicitis)	78	37.2
Atrophic smear	33	15.7
NILM	79	37.6
AUSCUS	8	3.8
LSIL	4	1.9
HSIL	5	2.4
Carcinoma cervix	3	1.4
Total	**210**	**100%**

ASCUS = atypical squamous cell of undetermined significance; HSIL = high-grade squamous intraepithelial lesion; LSIL = low-grade squamous intraepithelial lesion; n = number of patients; NILM = negative for intraepithelial lesion or malignancy; Pap = Papanicolaou.

Pap Smear Results: There were 20 patients with abnormal Pap smear in our study. Of these patients, 10 patients were positive for carcinoma cervix and carcinoma was absent in remaining 10 patients. Among the positive cases two cases were of LSIL (50%), four cases of HSIL (80%) and three cases of carcinoma cervix (100%) and one case of ASCUS (12.5%). Among the 10 false positive cases four patients were normal and six patients had chronic cervicitis. Following colposcopy true negative results were obtained in 175 patients. There were 15 false negative findings on Pap screening. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV)of Pap smear in detecting precancerous lesions of cervix was 40%, 94.59%, 50% and 92.11% respectively with an overall accuracy of 88.10% (Table 6)

Table 6: Sensitivity, Specificity, PPV and NPV of Pap Smear with Final Diagnosis

Pap Screening results*	Disease present	Disease absent	Total
Positive	10	10	20
Negative	15	175	190
Total	**25**	**185**	**210**

*Based on the values the values are presented as value% (95% CI), Sensitivity 40.00 (21.13 to 61.33). Specificity 94.59 (90.28 to 97.38%), Positive predictive value 50.00 (31.63 to 68.37), Negative predictive value 92.11 (89.42 to 94.15), Accuracy 88.10 (82.93 to 92.15), NPV = negative predictive value; Pap = Papanicolaou; PPV = positive predictive value

VIA Results: In our study VIA showed abnormal results in 41 patients and was normal in 169 patients. Following final diagnosis there were 23 women with true positive results and 18 patients had false positive findings (colposcopy showed

normal findings in six patients and chronic cervicitis in remaining 12 patients). False negative was again seen in three patients and true negative was seen in 166 patients. The sensitivity, specificity, PPV and NPV for VIA were 88.46%, 90.22%, 56.10% and 98.22% respectively with an overall accuracy of 90%.

Table 7: Sensitivity, Specificity, PPV and NPV of VIA with Final Diagnosis

VIA Screening results*	Disease present	Disease absent	Total
Positive	23	18	41
Negative	03	166	169
Total	**26**	**184**	**210**

*Based on the values the values are presented as value% (95% CI), Sensitivity 88.46 (69.85to 97.55), Specificity 90.22 (84.98 to 91.40), Positive predictive value 56.10 (44.64 to 66.94), Negative predictive value 98.22 (95.02 to 99.38), Accuracy 90 (85.12 to 93.70), NPV = negative predictive value; PPV = positive predictive value; VIA = visual inspection with acetic acid

DISCUSSION

Globally, Pap smear cytology is the accepted screening technique for evaluation of cervical cancer. There are certain limitations for adopting Pap smear aggressively for cervical screening in India. The healthcare infrastructure and organizational manpower needed for such a screening program is not yet feasible in India. This coupled with the high burden of cervical cancer and cervical-cancer related deaths necessitate developing alternate strategies, which can help in cervical screening**Error! Bookmark not defined.**. In our study we found increasing risk of cervical cancer with increasing age and increasing married age. A similar increasing trend was also observed in patients with increased parity (>2). Similar findings were reported by Bhattacharyya et al, who reported cervical cancer in older women (>40 years). They reported CIN incidence of 54% in patients with parity >2 and carcinoma cervix in women with parity >2. Similarly, they reported highest incidence of CIN and carcinoma cervix and in women with >20 years of duration of marriage. In our study Pap smear showed a lower sensitivity of 40% as compared with VIA, which had a higher sensitivity of 88.46%. Pap smear showed a better specificity as compared with VIA (94.59% and 90.22% respectively). Similarly the positive predictive value of VIA was better as compared with Pap smear (56.10% versus 50.00% respectively). Similarly, the NPV with VIA was better compared with Pap smear (98.22% versus 92.11% respectively). The overall accuracy of VIA was marginally better as compared with Pap smear (90% versus 88.10% respectively)[2]. Egede et al in their study of 200 patients sensitivity of Pap smear and VIA at 80% and 73% respectively with greater specificity with VIA as compared with Pap smear (96.5% and 91.8% respectively). The PPV with VIA was better when compared with Pap smear (78.6% versus 63.2% respectively). Similarly NPV with VIA was comparable with Pap smear (95.3% versus 96.3% respectively). VIA also showed higher accuracy as compared with Pap smear (93% versus 90% respectively). Our findings are also similar to study by Bhattarcharyya et al, who demonstrated higher sensitivity with VIA as compared with Pap for diagnosis of CIN (89% versus 52% respectively). Similarly Pap smear showed better specificity as compared with VIA in their study (95% versus 87% respectively). However, they reported a better PPV with Pap smear as compared with VIA (45% and 32% respectively). In our study the PPV with Pap smear was 50%, which is comparable to their findings, whereas we observed a better PPV with VIA (56.10%). NPV was better with VIA in their study, which was similar to our finding**Error! Bookmark not defined.**. Sokkary HH reported better sensitivity with Pap smear as compared to VIA (83.3% versus 66.67% respectively). They also did not report any significant difference in specificity between Pap smear and VIA (90.7% and 91% respectively). Although the PPV reported by Sokkary HH for Pap smear (50.8%) was comparable to our study PPV for VIA was lower. There was no significant difference in accuracy between Pap smear and VIA in their study as well[2]. These differences may be expected as various studies have shown different results'[2] VIA offers many advantages over Pap smear. The primary health care workers can be easily trained in the technique of VIA. The results are obtained almost instantly and there is no need to wait for results as in Pap smear, which requires skilled staff. In our experience this reduces the number of patients who would otherwise be lost to follow-up. A single visit examination is considered ideal in rural set up, where patients may not turn for further follow-up. VIA fits the bill perfectly in these situations as a positive VIA will help to take biopsy in the same setting without having to wait for results. VIA has propensity for high false positive results as acetowhite appearance is not unique to cervical cancer and may be seen in other conditions such as chronic cervicitis, leukoplakia and condyloma as was reflected in our study. However, high specificity and high NPV suggests that in patients in whom VIA is negative can be assured with confidence about absence of cancer. It is for these many advantages that the cervical screening programs are also advocating the use of alternative methods such as VIA for cervical

screening programs. Considering the low cost of the test, easy training of healthcare workers, single-setting results and high NPV, VIA should be part of every cervical screening program in our county. Our study has certain limitations. In our study we evaluated patients who came for cervical screening camps. This population may not be representative of the given population and the disease burden may not be indicative of the actual prevalence of disease. Secondly, the results were performed by hospital staff, who have experience in performing the tests. It would have been ideal if the healthcare workers were trained for this study and they would have performed the procedures.

CONCLUSION

We conclude that women with risk factors such as advancing age (>40 years), multiparity, longer duration of marriage should undergo cervical screening. VIA and Pap smear are equally effective in screening for cervical cancer. VIA is easy-to-perform, results are obtained almost instantly and the patients with abnormal findings can be subjected for biopsy in single setting and low cost make it an ideal test in rural set up. The high NPV of VIA suggests that one can rule out cervical cancer confidently in case of a negative study.

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