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Study of Diagnostic Efficacy of Visual Inspection with Acetic Acid (VIA) in Comparison with PAP Smear in Cervical Cancer Screening

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ABSTRACT

Well established screening programmes for early detection of carcinoma cervix are present in developed countries which are contrary to scenario in developing countries like India. Present study was aimed to study diagnostic efficacy of visual inspection with acetic acid (VIA) in comparison with PAP smear in cervical cancer screening. Present study was single-center, prospective, comparative, observational study, conducted female over 19 years of age, married and gave valid consent for examination All subjects were screened simultaneously by Pap smear and VIA. Among 500 patients, 99 patients had ace to white lesions and 401 patients did not have ace to white lesions. Among 500 patients who underwent pap smear testing, 455 patients were negative for intra epithelial lesion, 7 patients had ASCUS, 2 patients had ASC-H, 17 patients had LSIL, 17 patients had HSIL and 2 patients had squamous cell carcinoma. Out of 500 patients, 99 of them had ace to white lesions on VIA, 45 were reported to have lesions on pap smear, 19 were lesions on both pap smear and VIA. Hence biopsy was done. Rest 375 patients did not have ace to white lesions on VIA and Pap smear also was negative was intra epithelial lesion. So, biopsy was done. Out of 500 patients, biopsy was done in 125 patients where 67 patients were negative for dysplasia, 36 patients had CIN 1, 6 patients had CIN 2, 14 patients had CIN 3 and 2 patients had squamous cell carcinoma. In this study VIA had sensitivity 89.65%, specificity 89.36%, PPV 52.5% and NPV 98.5% while Pap smear had sensitivity 41%, specificity 95.7%, PPV 53.33% and NPV 90.96%. VIA should be considered as a screening modality especially in a low resource setting and be implemented as a large-scale screening method.

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Key Words

VIA, PAP smear, screening modality, carcinoma cervix, diagnostic efficacy

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INTRODUCTION

Cervical cancer is the third most common cancer in women worldwide[1]. 86% of cervical cancer is from developing world. In India, it's the most common cancer in women, accounting nearly 126000 new cases and 70500 deaths every year[2]. Thus cervical cancer is an important public health problem that deserves urgent attention. In India, an estimated 1.5 lakh women develop cervical cancer annually, about 16% of world annual incidence. thus cervical cancer is an important public health problem that deserves urgent attention. Cervical cancer progresses slowly from preinvasive cervical intra epithelial neoplasia to invasive cancer and screening asymptomatic women allows diagnosis of readily treatable preinvasive phase[3,4]. Hence appropriate screening programmes are an important public health issue. Well established screening programmes for early detection of carcinoma cervix are present in developed countries which are contrary to scenario in developing countries like India where there is lack of infrastructure, trained health personnel and financial constraints. Present study was aimed to study diagnostic efficacy of visual inspection with acetic acid (VIA) in comparison with PAP smear in cervical cancer screening.

MATERIALS AND METHODS

Present study was single-center, prospective, comparative, observational study, conducted in department of obstetrics and Gynecology, at JSS Medical Hospital, Mysore., India. Study duration was of 2 years (October 2011 to September 2013). Study was approved by institutional ethical committee.

Inclusion Criteria:

- Subjects will be eligible for inclusion if they over 19 years of age, married and gave valid consent for examination.

Exclusion Criteria:

- Pregnant women.
- Known case of carcinoma cervix.
- Frank growth on cervix.
- Previously treated for CIN or carcinoma cervix.
- History of pelvic irradiation.

Study was explained to participants in local language and written informed consent was taken. After taking informed consent, history was taken followed by general systemic examination and per speculum examination. All subjects were screened simultaneously by Pap smear and VIA. Positive cases by one or both screening methods were subjected to biopsy. Histology of biopsy was taken as gold standard to evaluate performance of test. Data was collected and compiled using Microsoft Excel, analysed through SPSS for windows (v 16.0). Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

RESULTS AND DISCUSSIONS

Among 500 patients, 38 patients were within 25 years, 183 patients between 26-35 years, 165 patients between 36-45 years, 80 patients between 46-55 years and 34 patients were aged beyond 55 years. 214 patients were married at age less than 19 years, 278 patients were married at age between 19-25 years and 8 patients were married at age between 25-30 years. Among 500 patients, 9 patients were nulliparous, 33 patients were Para one, 289 patients were Para two, 118 patients were Para three, 33 patients were Para four and 18 patients were grand multiport (Table 1).

Table 1: General Characteristics

Characteristics	No. of subjects	Percentage
Age group (in years)		
<25	38	7.6
26-35	183	36.6
36-45	165	33.0
46-55	80	16.0
55+	34	6.8
Age at marriage		
<19	214	42.8
19-25	278	55.6
25-30	8	1.6
PARITY		
Nulli	9	1.8
Primi	33	6.6
Para 2	289	57.8
Para 3	118	23.6
para 4	33	6.6
para 4+	18	3.6

Among 500 patients, 141 of them had no complaints, 205 patients complained of white discharge per vagina, 24 patients had blood-stained discharge/ intermenstrual bleeding/post coital bleeding, 13 patients had post-menopausal bleeding, 22 complained of excessive bleeding, 55 patients had pain abdomen, 23 patients had mass per vagina, 11 had irregular menses, 5 patients had low backache and 1 patient had dyspareunia (Table 2).

Table 2: Distribution of Complaints

Complaints	No. of subjects	Percentage
Nil	141	28.2
White discharge	205	41.0
Blood stain discharge, intermenstrual bleeding, post coital bleeding	24	4.8
Postmenopausal bleeding	13	2.6
Menorrhagia	22	4.4
Pain abdomen	55	11.0
Mass per vagina	23	4.6
Irregular menses	11	2.2
low backache	5	1.0
Dyspareunia	1	.2

Among 500 patients, 147 patients had normal per speculum findings, 24 patients had atrophied cervix, 41

patients had cervicitis, 212 patients had erosion of cervix, 28 patients had erosion bleeds on touch, 21 patients had hypertrophied cervix, 20 patients had UV prolapse, 4 patients had Nabothian cyst and in 3 patients cervix was flushed with vagina (Table 3).

Table 3.:Cervical Findings on Per Speculum Examination

Per Speculum Findings	No. of subjects	Percentage
Normal	147	29.4
Atrophic.	24	4.8
Cervicitis	41	8.2
Erosion	212	42.4
Erosion bleeds on touch	28	5.6
Hypertrophied	21	4.2
UV prolapse	20	4.0
Nabothian cyst	4	.8
cervix flushed with vagina	3	.6

Among 500 patients, 99 patients had acetowhite lesions and 401 patients did not have ace to white lesions (Table 4).

Table 4: Screening Results of VIA

VIA results	frequency	PErcent
Negative	401	80.2
Positive	99	19.8
Total	500	100

Among 500 patients who underwent pap smear testing, 455 patients were negative for intraepithelial lesion, 7 patients had ASCUS, 2 patients had ASC-H, 17 patients had LSIL, 17 patients had HSIL and 2 patients had squamous cell carcinoma (Table 5).

Table 5: Screening Results of PAP Smear

	Frequency	Percent
NIL	455	91.0
ASCUS	7	1.4
ASC-H	2	.4
LSIL	17	3.4
HSIL	17	3.4
squamous cell carcinoma	2	.4
Total	500	100.0

Out of 500 patients, 99 of them had acetowhite lesions on VIA, 45 were reported to have lesions on pap smear, 19 were lesions on both pap smear and VIA. Hence biopsy was done. Rest 375 patients did not have acetowhite lesions on VIA and Pap smear also was negative was intraepithelial lesion. So, biopsy was done (Table 6).

Table 6: Correlation of PAP smear, VIA and Biopsy

Biopsy done	VIA positive	99	125 (99+45-19)
	Pap positive	45	
	Both positive(VIA and Pap)	19	
Biopsy not done	VIA/Pap negative	375	375

Out of 500 patients, biopsy was done in 125 patients where 67 patients were negative for dysplasia, 36 patients had CIN 1, 6 patients had CIN 2, 14 patients had CIN 3 and 2 patients had squamous cell carcinoma (Table 7).

Table 7: Results of biopsy

Results of Biopsy	Frequency	Percent
Not done	375	74.8
Negative for malignancy	67	13.6
CIN 1	36	7.2
CIN 2	6	1.2
CIN 3	14	2.8
Squamous cell carcinoma	2	.4

Among 99 patients who were positive for VIA, on biopsy 47 patients were negative for dysplastic lesions, 33 had CIN 1, 5 had CIN 2, 12 had CIN 3 and 2 had squamous cell carcinoma. VIA was negative in 3 patients with CIN 1, one patient with CIN 2 and 2 patients with CIN 3 (Table 8). Among 7 patients with ASCUS on pap smear, 2 were negative for dysplasia, 5 patients had CIN 1. Two patients where pap smear showed ACH, biopsy was negative for dysplasia. Out of 17 patients with LSIL on pap smear, 12 did not have lesions, 2 had CIN 1, 2 had CIN 2 and 1 had CIN 3. out of 19 patients with HSIL on pap smear, 5 were negative for dysplasia, 1 had CIN 2, 11 had CIN 3 and 2 had squamous cell carcinoma (Table 9). 375 patients did not have ace to white lesions on VIA and Pap smear was negative for intra epithelial lesion. So, biopsy was not done. 26 patients had lesion on pap smear but on VIA there was no ace to white lesions. Among them 6 patients had lesions and 20 patients did not have lesions on biopsy. Out of 80 patients who showed ace to white lesions on VIA and pap smear was negative for intra epithelial lesion, 34 patients had lesion on biopsy. Rest 46 patients did not lesion on biopsy. 19 patients had lesions both on pap smear and VIA out of which 18 of them had lesion and one patient did not have lesion on biopsy (Table 10). In this study VIA had sensitivity 89.65%, specificity 89.36%, PPV 52.5% and NPV 98.5% while Pap smear had sensitivity 41%, specificity 95.7%, PPV 53.33% and NPV 90.96% (Table 11). While the incidence and mortality rates of cervical cancer have declined over 80% in developed countries since the advent of successful screening programs, there has been no such trend in developing countries. (Miller, Int Journal of Cancer 2000). Screening programs were implemented in developing countries since the early 1980's, yet have failed to reduce the mortality rates. The WHO in 2002 estimated that only 5% of women in developing countries are screened appropriately. Likely reasons for failure in screening programs include lack of funding, insufficient access in rural areas where most of the population in developing countries reside, lack of awareness/education as to need for screening and poor follow-up[5]. In light of the poor results from Pap-based screening programs, alternative methods for cervical cancer screening have been sought. One method, direct visualization with acetic acid has gained popularity and proven itself in many clinical trials as an adequate alternative to Pap smears in developing countries[6-8]. In our study white discharge per vagina

Table 8: Correlation Between VIA and Biopsy

		BIOPSY					
		Chronic cervicitis	CIN 1	CIN 2	CIN 3	Squamous cell carcinoma	Total
VIA	Positive	47	33	5	12	2	99
	Negative	20	3	1	2	0	26
	Total	67	36	6	14	2	125

Table 9. Correlation Between PAP Smear and Biopsy

		BIOPSY					
		Chronic cervicitis	CIN 1	CIN 2	CIN 3	Squamous cell carcinoma	Total
PAPSMEAR	Nil	46	29	3	2	0	80
	ASCUS	2	5	0	0	0	7
	ACH	2	0	0	0	0	2
	LSIL	1	2	2	2	1	0
	HSIL	5	0	1	11	2	17
Total	67	36	6	14	2	125	19

Table 10: Cross-Tabulation of VIA, PAP Smear and Biopsy

		VIA			
		Negative PAP		Positive PAP	
		Negative	Positive	Negative	Positive
BIOPSY	Not Done	375	0	0	0
	Negative	0	20	46	1
	Positive	0	6	34	18

Table 11. Diagnostic Efficacy of VIA and PAP Smear

	Sensitivity	Specificity	PPV	NPV
VIA	89.65%	89.36%	52.33%	98.5%
Pap smear	41%	95.7%	53.33%	90.96%

was most common complaint in the study group. But blood-stained discharge, intermenstrual bleeding and postcoital bleeding was significantly associated with preinvasive lesions. Another retrospective study of 142 women with postmortal bleeding reported a total of 27 (19%) had cervical intra epithelial neoplasia (CIN) out of which there were 15 (10.6%) cases of high-grade disease (CIN2 and CIN3)[7]. On comparing the diagnostic value of VIA with other studies we found that the findings of the present study correlate with the findings of Methasinee Pothisuwan[9] Juneja[10] and Gaffikin[5] cytology of present study correlated with Hendrick s Cronje[11] Doh[12] and Goel[13]. VIA has higher sensitivity than cytology. Disadvantage of VIA in the present study compared to cytology was low specificity which leads to higher rates of referral for colposcopy and high rates of treatment. Ace to white areas due to immature squamous metaplasia and inflammatory lesions are responsible for a larger number of false positive findings. This also has been pointed out in many studies Juneja[10] found VIA had sensitivity of 76.9%, specificity of 85.5% and cytology with sensitivity 52% and specificity 92% which was comparable to our study. Doh[12] screened 4,813 women. Sensitivity of VIA was 70.4 % vs. 47.7% for PAP. VIA specificity was 77.6% vs. 94.2% Pap. PPV of VIA was 44% and NPV 91.3%. Doh concluded that, although Pap has slightly better testing qualities, VIA has acceptable test qualities. Gaffkin[5] in 2003 published a mini- meta-analysis reviewing the data of what had been published about direct visualization with acetic acid from 1982-2002. After finding numerous cites on Pub Med, she chose 15 studies from which to review. The 15 studies encompassed over 34,000 women from across the world and the specialists performing the tests ranged from nurses to physicians. The range of estimated VIA sensitivity values from these studies was 66-96% and specificity rates from 64-98%. Sritipsukho[14] did a meta-analysis by using random effect method measured the pooled estimates of sensitivity, specificity, positive predictive value and negative predictive value of VIA-VIAM were 71.8%, 79.4%, 16.7% and 99.0% respectively. When comparing with conventional cytology, VIA have favorably characteristics especially sensitivity and negative predictive value. VIA confers a very high negative predictive value, which means that when a test is negative, the women can go home reassured that she is not likely to have a neoplastic cervical lesion., eliminating the need for follow-up visits. However, the low positive predictive value of VIA does present the problem of many false positives, discouraging the see-and-treat method. This could conceivably lead to over treatment, but in low-resource areas where large numbers of women are still dying of cervical cancer., VIA confirmed with cervical biopsy has a major role in preventing cervical cancer. Pap smear screening has moderate sensitivity and high specificity. It requires a spatula, cytobrush, fixative and transport of slides to a laboratory for staining. Cytologists must read the slide and send a report to clinic. The patient must return if there is any abnormality for a diagnostic test/ treatment. This is very expensive, labor intensive and inconvenient for the woman.

CONCLUSION

VIA has comparable sensitivity and specificity to Pap smear. It is much less expensive, less labor intensive and requires only one visit where patient can be treated during same visit. Hence VIA should be considered as a screening modality especially in a low resource setting and be implemented as a large-scale screening method.

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