



A PROSPECTIVE OBSERVATIONAL STUDY ON THE CORRELATION OF VISUAL INSPECTION OF CERVIX WITH ACETIC ACID (VIA), PAP SMEAR AND COLPOSCOPY IN DETECTION OF PREMALIGNANT LESION OF CERVIX

Obstetrics & Gynaecology

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ABSTRACT

Background: Carcinoma Cervix is one of the common malignant pathology causing considerable morbidity and mortality in women. One of the important aspects of management of carcinoma cervix is its early detection and appropriate management since delay in the diagnosis can have catastrophic consequences. Unfortunately in developing countries in many cases, diagnosis is delayed due to non-availability of facilities at rural areas. To overcome this screening methods such as Visual Inspection with Acetic Acid (VIA) and PAP smear can be done in high-risk patients and in selected cases cervical biopsy can be done. **Aims and Objectives:** (1) To compare VIA and PAP smear in relation to colposcopy as a screening method for premalignant lesions of cervix. (2) To study the efficacy of VIA as a primary screening test for detection of premalignant lesions of cervical cancer. **Materials and Methods:** This was a prospective analytical study in which 100 women with unhealthy cervix attending obstetrics and gynecology outpatient department who were willing to participate and gave written informed consent were enrolled in the study on the basis of a predefined inclusion and exclusion criteria. VIA was done. Pap smear was taken and slides were stained with modified Papanicolaou staining method and examined under light microscope. we compared the efficacy of VIA and PAP smear as a screening method for diagnosis of premalignant lesions of cervix in high-risk patient, and the results were confirmed with the help of colposcopy examination and its histopathological correlation with guided biopsy. **Results:** Mean age of the study population was found to be 40.94 years. When VIA, PAP Smear, and colposcopy were compared highest sensitivity was seen in VIA whereas colposcopy showed highest accuracy (82%). PAP was found to have a higher specificity (84.62%) as compared to VIA or colposcopy. Highest positive predictive value and negative predictive value was seen in PAP smear (78.95%) and colposcopy (86.96%). **Conclusion:** VIA is an easy to perform and highly sensitive test for diagnosis of carcinoma cervix however it has got a poor specificity. Colposcopy was found to be a better diagnostic test as it was both more sensitive as well as specific to diagnose premalignant lesions.

KEYWORDS

Carcinoma cervix; Colposcopy; PAP smear; VIA

INTRODUCTION

Cancer is one of the leading causes of adult deaths worldwide. Every year about 14 million new cancer cases are detected and 8 million people die of cancer.¹ Cervical cancer is the fourth most frequent cancer in women with an estimated incidence of 0.5 million new cases every year representing 6.6% of all female cancers.² Carcinoma Cervix is the most common cause of malignancy-related deaths among women in developing countries.³ Mortality due to cervical cancer is also an indicator of health inequalities, as 86% of all deaths due to cervical cancer are in developing, low- and middle-income countries.⁴ In contrast to the developed countries, cervical cancer is a public health problem in developing countries like India, so much so that India alone accounts for one-quarter of the worldwide burden of cervical cancers cases.

Women with invasive cervical cancer often present with one or more of the following symptoms: excessive white discharge, foul smelling vaginal discharge, burning micturition, urinary frequency and urgency, lower abdominal pain, backache, heavy menstrual bleeding, intermenstrual bleeding, and postcoital bleeding.⁵ Hence, these high-risk patients should be screened for premalignant lesions of cervix.

Visual Inspection with acetic acid (VIA) is a visual examination of the uterine cervix after application of 3–5% acetic acid. If the cervical epithelium contains an abnormal load of cellular proteins, the acetic acid coagulates the proteins conferring an opaque and white aspect to the concerned area. A precancerous lesion has higher protein content when compared to the normal epithelium. As a consequence, it becomes white (acetowhite) and is considered to be “VIA positive.”⁶

Cervical cytology is a method developed by Dr. George Papanicolaou for screening for cancerous or precancerous changes of the cervix. It is performed by scraping cells from the cervix and fixing them on a glass slide. It is also known as conventional cytology. It is a simple outpatient procedure and is routinely available.⁷

Colposcopy is the examination of vagina and cervix using a lighted magnifying instrument called a colposcope. Here, with application of 3–5% acetic acid and Lugol's iodine. Abnormal lesions are identified, diagnosis can be made for premalignant lesions and direct guided biopsy can be taken as well. Ultimately, the diagnosis of pre-invasive and invasive cancer is made by histopathological examination.⁸

All these techniques have their own merits and demerits. The Pap test is the only test in our practice settings that has been used in widespread screening programs and has been conclusively shown to reduce the incidence and mortality from the cervical cancer.⁹

The absence of trained personnel, including the failure to obtain an adequate smear by the clinician, and the incorrect interpretation of the smear by inexperienced person are the potential reasons for failure in cervical cancer screening. Their limited availability makes cytology-based screening programme difficult to be implemented on large scale basis.¹⁰

Whereas, VIA is easy to perform and can be interpreted even by paramedical staff, after providing sufficient training. The “see and treat” approach combines VIA with cryotherapy which helps to prevent losses due to follow-up and has been proved to reduce the incidence and mortality due to carcinoma cervix significantly.

In our study, we compared the efficacy of VIA and PAP smear as a screening method for diagnosis of premalignant lesions of cervix in high-risk patient, and the results are confirmed with the help of colposcopy examination and its histopathological correlation with guided biopsy.

Aims and objectives

To do a comparative analysis of VIA and Pap smear in relation to colposcopy for diagnosis of premalignant lesions of cervix.

MATERIALS AND METHODS

This was a prospective analytical study in which 100 women with unhealthy cervix attending obstetrics and gynecology outpatient department, Darbhanga Medical College and Hospital, Laheriasarai, Bihar who were willing to participate and gave written informed consent were enrolled in the study on the basis of a predefined inclusion and exclusion criteria. The study was carried out over a period of 18 months from June 2019 to December 2020.

Cases mentioned in the age group specified as above, who attended gynecology outpatient department with complaints such as white discharge, pain in abdomen, backache, menstrual irregularities, postcoital bleeding, and postmenopausal bleeding were selected for the purpose of the study. Written and informed consent was taken from all the cases after detailed explanation of the procedure. A thorough history, including demographic data such as age, residential address, socioeconomic status, parity, age at marriage of the patient, was taken. Detailed history of the patient chief complaints, number of pregnancies, menstrual history with last menstrual period, significant medical history and previous cytology reports if any was obtained. General, systemic and gynecological examination was done and information was filled in pretested pro forma.

Pap smear was taken and prepared Pap smear slides were fixed in 95% ethyl alcohol and ether and sent for staining and cytological examination by expert cytopathologist. Slides were stained with modified Papanicolaou staining method and examined under light microscope. Cytological interpretation of the smears was made according to the Bethesda system 2014.

Then patients were subjected for visual inspection of cervix with 5% acetic acid followed by examination with colposcopy. All patients enrolled in the study were subjected to cervical biopsy as a gold standard procedure for comparison of all the three screening tests.

In colposcopy test positive patients, colposcopy directed biopsy was taken from significant lesion area. In colposcopy negative patients, four-quadrant cervical biopsy was taken from significant area. Biopsy specimen was received in 10% formalin fixative. Histopathological slides were prepared and stained with hematoxylin and eosin stain and examined under light microscope by senior pathologist. Biopsy results were categorized as chronic cervicitis, cervical intraepithelial neoplasia (CIN) I, CIN II, CIN III, carcinoma in situ and squamous cell carcinoma according to the WHO.

Patients were asked for follow-up after 10 days for Pap smear and histopathology report. All collected data was entered into Microsoft Excel. Results were compiled and analyzed. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated for VIA, Pap smear with colposcopy and also with histopathology as a gold standard. Chi-square test was applied to compare the diagnostic efficacy of the tests.

Inclusion criteria

1. Women in age group 21–65 years having postmenopausal bleeding, intermenstrual spotting, postcoital bleeding, early sexual exposure, women with clinically unhealthy cervix, persistent vaginal discharge, cervical erosion or ulceration, unexplained occasional foul-smelling discharge per vaginum, cervix bleed on touch, or hypertrophied cervix.

2. Patient who consented to be part of study.

Exclusion criteria

1. Those who refused consent.
2. Patient who had undergone recent endometrial curettage, hysterosalpingography, cervical biopsy or hysterectomy.
3. Pregnant or postpartum women
4. Patient having any history of treatment for either cervical dysplasia or vulvar warts.
5. Immunocompromised patients.
6. Women with frank invasive cancer.

RESULTS

The analysis of the cases on the basis of age groups showed that the Maximum number of cases were found in the age group 31–40 years forming 38% total study population. Second commonest age group was 41–50 years which constituted 35% of total study population. Mean age of the study population was found to be 40.94 years.

About 75% of the total study population was belonging to lower socioeconomic status of class IV and V of Kuppuswamy socioeconomic class. Maximum 42% of the cases were belonging to class V. A very few numbers of cases (0% in class I, 7% in class II) were from upper socioeconomic class. Maximum number of cases (42%) were married at the age between 18 and 25 years, followed by 34% cases married at the age of <18 years. Majority of the patients belonged to parity 3 or above (48%). Most common presenting symptom was white discharge per vaginum (38%) followed by intermenstrual bleeding in 18% of the study population. 7% of the patients presented with the complaint of post coital bleeding and least i.e., 3% of the cases presented with foul smelling vaginal discharge (Table 1).

Table 1 : Socioeconomic status, age at marriage, parity and presenting complaints in cases

	Number of cases	Percentage
Kuppuswamy's socioeconomic scale		
• I	0	0
• II	7	7
• III	18	18
• IV	33	33
• V	42	42
Total	100	100
Age at marriage (years)		
• 18 years	42	42
• 18-25 years	48	48
• >25 years	10	10
Total	100	100
Parity of the studied cases		
• P1	14	14
• P2	38	38
• >P3	48	48
Total	100	100
Presenting complaints		
• White discharge per vaginum	38	38
• Intermenstrual bleeding	18	18
• Pain in abdomen	14	14
• Post-menopausal bleeding	10	10
• Low back pain	10	10
• Post coital bleeding	7	7
• Foul smelling discharge per vaginum	3	3
Total	100	100

About 78% of the cases showed positive results on examination with VIA. 22% cases were negative on examination with VIA. 31% of the cases were normal on PAP smear evaluation and another 31% showed inflammatory smear. 38% cases were having abnormal PAP smear, of which 20% cases were having report suggestive of LSIL, and 18% of the cases were having reports suggestive of HSIL. 46% of the cases showed normal results on colposcopic examination. 28% cases had CIN I lesion. 15% of the cases were having CIN II lesion while 11% of the cases were having CIN III lesion on colposcopic examination. 48 (48%) cases were having abnormal reports on cervical biopsy.

About 28 (28%) cases were having report suggestive of CIN I; 12 (12%) cases were having CIN II lesion and 7 (7%) cases were positive with CIN III lesion. 1 (1%) case was having squamous cell carcinoma in situ whereas 3 (3%) cases were having biopsy proven squamous cell carcinoma (Table 2).

Table 2 : Results of VIA, Pap smear, Colposcopy and cervical biopsy findings in studied cases

	Number of cases	Percentage
Visual inspection by acetic acid		
• VIA Positive	78	78
• VIA Negative	22	22
Total	100	100
Pap smear		
• Normal	31	31
• Inflammatory	31	31
• ASCUS	0	0
• AGUS	0	0
• ASCUS-H	0	0
• LSIL	20	20
• HSIL	18	18
Total	100	100

Colposcopy Result		
• Normal	46	46
• CIN I	28	28
• CIN II	15	15
• CIN III	11	11
Total	100	100
Cervical Biopsy Findings		
• Normal	30	30
• Cervicitis	22	22
• CIN I	25	25
• CIN II	12	12
• CIN III	7	7
• CIS	1	1
• Squamous cell carcinoma	3	3
Total	100	100

Of the 78 VIA positive cases, 42 cases (53.84%) were also positive for premalignant lesions on cervical biopsy. Out of the 22 VIA negative cases, 6 cases (27.27%) cases were positive on examination with cervical biopsy. PAP smear was found normal in 31 cases out of which 7 (22.58%) cases were having premalignant lesion on cervical biopsy. Pap smear was showing inflammatory result in 31 cases out of which 11(35.48%) cases were having premalignant lesions of cervix in biopsy report smear results were abnormal (i.e., LSIL and HSIL) in 38 cases out of which 30(78.95%) cases were having positive findings on cervical biopsy. 8 (21.05%) abnormal pap reports were normal on cervical biopsy smear could diagnose only 30 cases (62.5%) which were true positive on cervical biopsy whereas Pap smear failed to diagnose 18 cases (37.5%) which were positive on cervical biopsy (Table 3).

Table 3 : Comparison of Biopsy, Pap smear, VIA and colposcopy

	Normal	Cervicitis	CIN I	CIN II	CIN III	CIS	SCC	Total
Biopsy vs. VIA								
• Positive (78%)	23	13	21	11	6	1	3	78
• Negative (22%)	7	9	4	1	1	0	0	22
Total	30	22	25	12	7	1	3	100
Biopsy vs. Pap smear								
• Normal (31)	20	4	5	2	0	0	0	31
• Inflammatory (31)	6	14	7	3	1	0	0	31
• ASCUS (0)	0	0	0	0	0	0	0	0
• AGUS (0)	0	0	0	0	0	0	0	0
• ASCUS-H (0)	0	0	0	0	0	0	0	0
• KSIL (20)	3	2	8	4	2	0	1	20
• HSIL (18)	1	2	5	3	4	1	2	18
Total	30	22	25	12	7	1	3	100
Biopsy vs. Colposcopy								
• Normal (46)	27	13	6	0	0	0	0	46
• CIN I (28)	2	5	11	8	2	0	0	28
• CIN II (15)	1	3	6	3	2	0	0	15
• CIN III (11)	0	1	2	1	3	1	3	11
Total	30	22	25	12	7	1	3	100

Colposcopy was normal in 46 cases, out of which 6 cases (13.04%) were having premalignant lesion on cervical biopsy. Colposcopy was abnormal in 54 cases out of which 42 cases (77.77%) were abnormal on cervical biopsy. Out of 54 abnormal cases on colposcopy, 12 cases (22.22%) were diagnosed normal on cervical biopsy.

VIA was positive in 78 cases out of which 51 (65.38%) cases were diagnosed premalignant lesions on colposcopy.

Colposcopy was abnormal in 54 cases out of which 51 (94.44%) cases were VIA positive whereas VIA failed to diagnose 3 (5.56%) cases which were premalignant on colposcopy. Pap smear was normal in 62 cases out of which 22 (35.48%) cases showed premalignant lesions on colposcopy. Out of 38 abnormal pap results, 32 cases (84.21%) were also abnormal on colposcopy and 6 (15.79%) cases were normal on colposcopy. Colposcopy was positive in 54 cases out of which 32 (59.26%) cases were diagnosed abnormal on Pap smear and 22 (40.74%) cases were normal on Pap smear (Table 4).

Table 4 : Colposcopy versus VIA and Colposcopy versus Pap Smear in cases

	Normal	CIN I	CIN II	CIN III	Total
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Colposcopy vs. VIA					
• Positive	27	27	14	10	78
• Negative	19	1	1	1	22
Total	46	28	15	11	100
Colposcopy vs. Pap smear					
• Normal (31)	20	9	2	0	31
• Inflammatory (31)	20	8	3	0	31
• ASCUS	0	0	0	0	0
• AGUS	0	0	0	0	0
• ASCUS-H	0	0	0	0	0
• LSIL (20)	4	9	3	4	20
• HSIL (18)	2	2	7	7	18
Total	46	28	15	11	100

Out of 78 positive cases on VIA, maximum cases, that is, 32 (41.02%) were in the age group 31–40 years. 38 cases were abnormal on Pap test out of which, maximum 17 (44.74%) cases were in the age group 41–50 years, followed by 15 (39.47%) cases in 31–40 years age group. Colposcopy was abnormal in 54 cases out of which 21 (38.88%) cases were in the age group 31–40 years. Cervical biopsy was abnormal in 48 cases out of which maximum 20 (41.67%) cases were belonging to age group 41–50 years. Overall, incidence of test positive cases was more in 31–50 years suggesting that incidence of premalignant lesion is more in 3rd and 4th decade.

Overall, incidence of positive cases in all tests was more in group of parity 3 and more. out of 78 positive cases on VIA, 40 (51.28%) cases were married at age between 18 and 25 years. 38 cases were abnormal on Pap test out of which maximum 19 (50%) cases were married at age <18 years. Colposcopy was abnormal in 54 cases out of which maximum 28 (51.85%) cases were married at the age 18–25 years. Cervical biopsy was abnormal in 48 cases out of which 30 (62.5%) cases were married at age group 18–25 years. Overall incidence of test positive cases was more when women were married up to 25 years of age.

Out of 78 VIA positive cases maximum 34 (43.59%) cases presented with complaint of white discharge per vaginum. In 38 cases with abnormal pap results, maximum cases 20 (52.63%) came with complaint of white discharge per vaginum. Out of 54 abnormal colposcopy results, maximum 27 (50%) cases came with complaint of white discharge per vaginum. Out of 48 abnormal cervical biopsy results, 26 (54.16%) had complaint of white discharge per vaginum. Overall, the most common presenting symptom of all test positive cases was white discharge per vaginum followed by postmenopausal and intermenstrual bleeding.

Sensitivity, specificity, PPV, NPV, and accuracy of colposcopy when compared with VIA was- 94.44%, 41.30%, 65.38%, 86.36%, and 70%, respectively. Sensitivity, specificity, PPV, NPV, and accuracy of Pap smear when compared with colposcopy was 57.41%, 84.78%, 81.78%, 62.90%, and 70%, respectively.

When compared with cervical biopsy as a gold standard test, VIA has high sensitivity, that is, 87.50% but low specificity, that is, 30.77%. PPV, NPV, and Accuracy were 53.85%, 72.73%, and 58%, respectively.

Sensitivity, specificity, PPV, NPV, and accuracy of Pap smear when compared with cervical biopsy as a gold standard was 62.5%, 84.62%, 78.95%, 70.97% and 74% respectively.

Sensitivity, specificity, PPV, NPV, and accuracy of colposcopy when compared with cervical biopsy was - 87.50%, 76.92%, 77.78%, 86.96%, and 82%, respectively.

When VIA, PAP Smear, and colposcopy were compared highest sensitivity was seen in VIA whereas colposcopy showed highest accuracy (82%). PAP was found to have a higher specificity (84.62%) as compared to VIA or colposcopy. Highest PPV and NPV was seen in PAP smear (78.95%) and Colposcopy (86.96%).

DISCUSSION

In our study, majority of the cases were belonging to the age group 31–40 years, that is, 38% followed by 35% cases in the age group 41–50 years. It was comparable with the studies done by Joshi et al., and by Basu et al. In study done by Joshi et al., majority of the age group was between 41 and 50 years. 11 In a study by Basu et al., 63.4% study population was in 30–39 years age group.¹²

All the women in the present study were married; hence, we considered age at marriage as the best surrogate marker of sexual debut. In the present study, maximum 48% study followed by 42% cases married at the age <18 years. In the study done by Gravitt et al., in Andhra Pradesh, India, mean age at marriage was 15.6 years.¹³ In the present study, 48% of the study population was of parity status >3. Mean parity of the subjects in a study done by Saleh was 2.61.¹⁴

In our study, most common symptom was white discharge per vaginam accounting for 38% of the total study population, followed by intermenstrual bleeding in 18% of the women and pain in abdomen in 14% of the women. 7% of the women presented with post coital bleeding and 3% women presented with foul smelling discharge per vaginam. Most common presenting symptom in a study done by Hend S. Saleh was vaginal discharge in 80% of the cases.¹⁴

In our study, when compared with cervical biopsy as a gold standard test, VIA has high sensitivity i.e., 87.50% but low specificity, that is, 30.77%. Its PPV, NPV, and Accuracy of were 53.85%, 72.73%, and 58%, respectively. In a similar study Bhatla et al., found the sensitivity, specificity, PPV, and NPV to be 100%, 53.3%, 15.7%, and 100%, respectively.¹⁵ Results of our study were also comparable with the studies done by Goel et al. As VIA has very high NPV, which means that when the test is negative, the woman can go home reassured that she is not likely to have a premalignant cervical lesion.¹⁶

Sensitivity, specificity, PPV, NPV, and accuracy of Pap smear when compared with colposcopy as a gold standard was 57.41%, 84.78%, 81.78%, 62.90%, and 70%, respectively. In a similar study Shastri et al., found the sensitivity, specificity, PPV, and NPV to be 57.4%, 98.6%, 37.8%, and 99.4%, respectively. Results of our study as well as other similar studies showed that Pap smear test has low sensitivity and moderate specificity for diagnosis of premalignant lesions of the cervix. Hence, it can be concluded that, VIA as compared to Pap smear can be better screening test due to its ease of use and low cost.¹⁷

Sensitivity, specificity, PPV, NPV, and accuracy of colposcopy when compared with cervical biopsy was - 87.50%, 76.92%, 77.78%, 86.96%, and 82%, respectively. When compared with other studies our study shows comparable results with the studies done by Agrawal et al.¹⁸ Colposcopy has more sensitivity, NPV and accuracy of all the screening tests which makes colposcopy as the best diagnostic tool for the disease. Colposcopy provides precise visual localization of micropathological changes and site for subsequent histopathological diagnosis of early cervical disease. Hence, colposcopic assessment is a critical stage in diagnosis as well as in management of early cervical neoplasia.¹⁹

In the present study, VIA has more comparable results in terms of sensitivity as well as NPV than Pap test, with colposcopy. It also shows that Pap has very limited sensitivity (57.41%) for diagnosis of early cervical neoplasia when compared to VIA. Although Pap test has more specificity (84.78%) as compared to VIA (41.30%), it has limited value for recommending its use as a screening tool for premalignant lesions.²⁰

CONCLUSION

VIA was found to be an excellent screening method for diagnosis of premalignant lesion of cervix, as it is easy to perform (even by paramedical staff) had a very high sensitivity; however, it was found to have poor specificity. Pap smear was inferior to VIA in identifying abnormal cases, as it had quite a moderate sensitivity; however, it has got a high specificity. As compared to VIA and PAP smear colposcopy was found to be a better diagnostic test as it was both more sensitive as well as specific to diagnose premalignant lesions.

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