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CORRELATION OF CYTOLOGY WITH COLPOSCOPIC FINDINGS IN VISUAL INSPECTION OF ACETIC ACID POSITIVE PATIENTS

Obstetrics & Gynaecology

Dr. Gayatri Mathuriya Associate Professor,Department of obstretics and Gynaecology MGM &MY Hospital Indore M.P

Dr. Pallavi Pathak Resident , Department of obstretics and Gynaecology MGM &MY Hospital Indore M.P.

Dr. P. Rohini Resident , Department of obstretics and Gynaecology MGM &MY Hospital Indore M.P

Dr. Rini Bachotiya Senior Resident , Department of obstretics and Gynaecology MGM &MY Hospital Indore M.P

Dr. Akansha Parihar* M.G.M.M.C &M.Y. HOSPITAL,INDORE(M.P.) Resident (Deptt. of obstretics and gynaecology)*Corresponding Author

ABSTRACT

Background: Adopting VIA (visual inspection of acetic acid) as a primary screening modality in low resource settings, we undertook the present study to find the correlation of cytology with colposcopic findings in Visual Inspection of Acetic Acid positive patients for early detection of carcinoma of cervix and to study the role of colposcopy in evaluation of unhealthy cervix. This study has been carried out to compare the efficacy of cytology with colposcopy in detecting precancerous lesion in patient with clinically unhealthy cervix. **Methods:** A total of 200 VIA positive female patients screened positive who qualified the inclusion criteria during the period of study were enrolled for the study after taking pre-informed written consent. **Results:** A statistically significant association ($P<0.05$) was observed between colposcopic diagnosis outcome and Pap Smear outcome and higher proportion of similar outcome was observed. The high sensitivity 95.9% and moderate specificity 73.0% for overall positive cases shows that colposcopy is more accurate in predicting positive outcomes as compared to negative outcomes against pap smear method. **Conclusion:** From the results of this study, it is evident that colposcopy is definitely more sensitive and accurate than pap smear. Colposcopy, which gives immediate results, can be considered as a secondary testing tool to triage women found positive on VIA in settings where cytology and histopathology services are logistically and technically not feasible.

KEYWORDS

Colposcopy, visual inspection of acetic acid, unhealthy cervix, cytology

INTRODUCTION

Globally, Cervical cancer is recognized as the second common female malignant cancer and one of the leading causes of cancer death among women.[1,2] Over the past 30 years, the increasing proportion of young women affected by cervical cancer has ranged from 10% to 40%.[3]

However, approximately 85% of the worldwide deaths from cervical cancer occur in underdeveloped or developing countries, and the death rate is 18 times higher in low-income and middle-income countries compared with wealthier countries.[4] Cervical cancer ranks second in incidence and mortality behind breast cancer in lower Human Development Index (HDI) settings.India contributes to 25.4% and 26.5% of the global burden of cervical cancer cases and mortality, respectively.

The incidence of cervical cancer is 1.5 to 2 times higher in rural area women than urban area.[5] A number of risk factors for cervical cancer are linked to exposure to the HPV.[6,7] Invasive cancer development process could prolong up to 20 years from the precursor lesion caused by sexually transmitted HPV.[8] However, there are also other numerous risk factors such as reproductive and sexual factors, behavioral factors, etc for cervical cancers which include sexual intercourse at a young age (<16 years old), multiple sexual partners, smoking, high parity and low socio-economic level.[9,10]

Though cervical cancer can be detected in the earlier treatable stages, the morbidity and mortality due to cervical cancer is not reducing because of the failure of the cervical cancer screening programs especially in the developing world. Cervical cancer is preventable in preinvasive state when effective screening, diagnostic and therapeutic procedures are implemented to detect and treat its precursor lesions.[5]

Studies have shown that HPV is responsible for more than 99.7% of the cases of invasive cervical cancer worldwide, and it is related to 80% of precancerous changes in the cervix.[11]

The high mortality of cervical cancer can be explained by high prevalence of human papillomavirus (HPV), lack of or infrequent screening leading to advanced disease at diagnosis, and underuse of recommended treatment. The risk of late reporting is usually found increased among the women with lack of education.

The screening procedures for cervical cancer are mainly as following: VIA (Visual inspection of cervix with acetic acid), VILI (Visual inspection of cervix with lugol's iodine), Pap's smear, liquid-based cytology (LBC) and HPV DNA test. Colposcopy is the triage in screening, taking colposcopy directed biopsy as well as treatment of CIN such as cold coagulation, cryotherapy, and LEEP (Loop electro-surgical excision procedure).[12]

In developed countries, Pap smear screening has been successful in reducing the incidence and mortality due to invasive cervical cancer. Organized and frequently repeated cytology screening has resulted in a substantial reduction of cervical cancer burden in developed countries. But in low-resource countries where organized cytology-based cervical cancer screening programs cannot be implemented due to financial, technical, and logistic barriers, low-cost technologies, such as the VIA-based approaches have been successfully tested and proposed to address the need to effectively improve and extend screening services in the country.[13-17]The incidence of cervical cancer can be reduced by as much as 80% if the quality, coverage and follow-up of screening methods are of high standard.[13]

In a developing country like India Conventional cytology based screening programmes currently are not feasible as the infrastructures and quality assurance requirements are not readily met. VIA (visual inspection with acetic acid) meets the criteria of good screening test as its sensitivity ranging from 70% to 85% in detecting high grade cervical intraepithelial neoplasia and invasive cancer and specificity ranges from 67% to $_{85\%.}$[13-17]

With the added advantage of the immediate availability of VIA test result, VIA- positive women can be subjected to further investigative procedures to ensure diagnostic and treatment compliance with a "Single Visit" approach.

Diagnostic triage of VIA-positive women by cytology or colposcopy directed biopsy are still not very feasible in low-resource country settings like ours where adequate expertise, facility, and infrastructure are still not available for cytology and histopathology confirmation,

outside of the city limits. Also, poor patient compliance for further diagnosticor treatment visits and inadequate patient tracking system creates further barriers in the successful implementation of screening programs.

Hence a "Single Visit" screen and treat strategy that uses VIA and colposcopy alone that eliminates the need for repeated visits due to delays in diagnostic results, will be highly attractive in terms of cost effectiveness and compliance to treatment, which is crucial to bring down the incidence and mortality due to cervical cancer. Colposcopy and biopsy is the gold standard but is expensive and needs skilled manpower.

METHODS.

Study Design: The design of the study was Prospective Observational Study.

Study Center: The study was conducted in Department of Obstetrics & Gynaecology, M.G.M.
Medical College and M.Y. and MTH Hospital, Indore

Study Duration: Study was undertaken for a period of 12 months after approval from ethical committee (December 2021 to November 2022)

Sample Size: A total of 200 VIA positive female patients screened positive after examining 3500 females visiting the Gynaecology OPD of MYH and MTH Hospital, Indore (M.P) who qualified the inclusion criteria during the period of study were enrolled for the study after taking pre-informed written consent.

INCLUSION CRITERIA

Women of age group of 30 to 65 years with following symptoms: Abnormal vaginal discharge, lower abdominal pain, irregular menstrual bleeding, postmenopausal bleeding, postcoital bleeding, prolapse and burning micturition, Women with unhealthy looking cervix. Women between 30 to 65 years of age willing for screening of cervical cancer. 39

EXCLUSION CRITERIA

Women with frank cancer cervix /already diagnosed cases of cancer cervix, Patient with bleeding p/v, active infection at the time of examination, Pregnant women. Post total hysterectomy patients, Patient not willing for the procedure.

METHODOLOGY

Each patient visiting the gynaecology OPD and falling under inclusion criteria was evaluated. Written and informed consent was taken from all the patients after a brief explanation of the procedure.

A careful history, obstetric and Gynaecological history, General and systemic examination was done and all the data was recorded on a pre written proforma.

Naked eye examination was done after exposing the cervix with bivalved cusco's speculum. PAP smear slides were taken using Ayre's spatula and cytobrush fixed in 95% ethyl alcohol and ether, followed by visual inspection of cervix after applying 5% freshly prepared acetic acid.

In cases where VIA is positive, patient was enlisted for colposcopy. Colposcopic assessment will follow the technique of assessing abnormal areas after application of acetic acid followed by lugol's iodine and calculating modified Reid's index.

If colposcopy suggests then biopsy was done and sent in 10% formalin fixative.

STATISTICALANALYSIS

The data was collected and entered in Microsoft Excel 2010 (Microsoft corp.) and analyzed using the SPSS version 20.0 operating on Windows 10.A P value of <0.05 was considered statistically significant.

ETHICALAPPROVAL

Ethical approval was given by ethics and scientific review committee, MGM Medical college and MY hospital Indore, Madhya Pradesh in November 2021.

For the present study, we used modified Reid's index grades for colposcopy as defined: Score 0: Inflammatory lesion
Score 1-2: CIN 1
Score 3-5: CIN 2
Score 6-8: CIN 3

OBSERVATIONS:

TABLE 1: DISTRIBUTION ON THE BASIS OF COLPOSCOPIC DIAGNOSIS.

The distribution shows the higher proportion 47.0% for Inflammatory diagnosis, 32.5% for CIN 1 diagnosis and the lower proportion 17.5% for CIN 2 diagnosis, 3.0% for CIN 3 diagnosis respectively.

Colposcopic Diagnosis	Frequency	Percent
INFLAMMATORY	94	47.0
CIN 1	65	32.5
CIN 2	35	17.5
CIN 3	6	3.0
Total	200	100.0

TABLE 2: DISTRIBUTION ON THE BASIS OF PAP SMEAR.

The distribution shows the higher proportion 63.0% for NILM, 24.5% for LSIL and the lower proportion 5.5% for HSIL, 0.5% for SCC respectively.

Pap Smear	Frequency	Percent
NILM	126	63.0
LSIL	49	24.5
HSIL	11	5.5
Atypical Squamous Cells – US	13	6.5
SCC	1	0.5
Total	200	100.0

TABLE 3: Association between Colposcopic Diagnosis and Pap Smear Outcome (Inflammatory-NILM)

Chi square test for association between two variables was applied, which shows that the association between colposcopic outcome and Pap smear outcome was statistically significant and higher proportion of similar outcome was observed. (P<0.05)In Negative outcome of Pap Smear have 97.3% of Negative outcome of colposcopic but only 2.7% for positive outcome.

Similarly, in positive outcome of pap smear have 73.0% of positive outcome ofcolposcopic also but only 27.0% of negative outcome

INFLAMMATORY Colposcopic diagnosis		NILM Pap Smear		Total
		Negative	Positive	
Negative	Count	72	34	106
	%	97.3%	27.0%	53.0%
Positive	Count	2	92	94
	%	2.7%	73.0%	47.0%
	Count	74	126	200
	%	100.0%	100.0%	100.0%
Pearson ChiSquare	Value	Df	P Value	Result
	92.528a	1	0.000	0

TABLE 4: Association between Colposcopic Diagnosis and Pap Smear Outcome (CIN 1- LSIL)

Chi square test for association between two variables was applied, which shows that the association between colposcopic outcome and Pap smear outcome was statistically significant and higher proportion of similar outcome was observed. (P<0.05)

In Negative outcome of Pap Smear have 78.8% of Negative outcome of colposcopic but only 21.2% for positive outcome.

Similarly, in positive outcome of pap smear have 67.3% of positive outcome of colposcopic also but only 32.7% of negative outcome.

CIN 1 Colposcopic diagnosis		LSIL Pap Smear		Total
		Negative	Positive	
Negative	Count	119	16	135
	%	78.8%	32.7%	67.5%
Positive	Count	32	33	65
	%	21.2%	67.3%	32.5%
	Count	151	49	200
	%	100.0%	100.0%	100.0%

Pearson ChiSquare	Value	Df	P Value	Result
	35.925a	1	0.000	Sig

TABLE 5: Association Between Colposcopic Diagnosis and Pap Smear Outcome (CIN 2- HSIL)

Chi square test for association between two variables was applied, which shows that the association between colposcopic outcome and Pap smear outcome was statistically significant and higher proportion of similar outcome was observed. (P<0.05)

In Negative outcome of Pap Smear have 85.7% of Negative outcome of colposcopic but only 14.3% for positive outcome.

Similarly, in positive outcome of pap smear have 72.7% of positive outcome of colposcopic also but only 27.3% of negative outcome

CIN 2 Colposcopic diagnosis		HSIL Pap Smear		Total
		Negative	Positive	
Negative	Count	162	3	165
	%	85.7%	27.3%	82.5%
Positive	Count	27	8	35
	%	14.3%	72.7%	17.5%
	Count	189	11	200
	%	100.0%	100.0%	100.0%
Pearson ChiSquare	Value	Df	P Value	Result
	24.591a	1	0.000	0

TABLE 6: Association between colposcopic diagnosis and pap smear outcome (CIN3- HSIL)

Chi square test for association between two variables was applied, which shows that the association between colposcopic outcome and Pap smear outcome was statistically significant and higher proportion of similar outcome was observed. (P<0.05)

In Negative outcome of Pap Smear have 98.4% of Negative outcome of colposcopic but only 1.6% for positive outcome.

Similarly, in positive outcome of pap smear have 72.7% of negative outcome of colposcopic also but only 27.3% of positive outcome.

CIN 3 Colposcopic diagnosis		HSIL Pap Smear		Total
		Negative	Positive	
Negative	Count	186	8	194
	%	98.4%	72.7%	97.0%
Positive	Count	3	3	6
	%	1.6%	27.3%	3.0%
	Count	189	11	200
	%	100.0%	100.0%	100.0%
Pearson Chi-	Value	Df	P Value	Result
Square	23.567a	1	0.000	0

TABLE 7:Association between Colposcopic Diagnosis and Pap Smear Outcome (CIN 2+CIN 3-HSIL)

Chi square test for association between two variables was applied, which shows that the association between colposcopic outcome and Pap smear outcome was statistically significant and higher proportion of similar outcome was observed. (P<0.05)

In Negative outcome of Pap Smear have 84.1% of Negative outcome of colposcopic also but only 15.9% for positive outcome.

Similarly, in positive outcome of pap smear have 100.0% of positive outcome of colposcopic also but 0.0% of negative outcome.

CIN2+CIN3_ Colposcopy diagnosis		HSIL Pap Smear		Total
		Negative	Positive	
Negative	Count	159	0	159
	%	84.1%	0.0%	79.5%
Positive	Count	30	11	41
	%	15.9%	100.0%	20.5%
	Count	189	11	200
	%	100.0%	100.0%	100.0%
Pearson ChiSquare	Value	Df	P Value	Result
	45.141a	1	0.000	0

TABLE 8:Association Between Colposcopic Diagnosis and Pap Smear Outcome.

Chi square test for association between two variables was applied, which shows that the association between colposcopic outcome and Pap smear outcome was statistically significant and higher proportion of similar outcome was observed. (P<0.05)

In Negative outcome of Pap Smear have 73.0% of Negative outcome of colposcopic but only 27.0% for positive outcome.

Similarly, in positive outcome of pap smear have 95.9% of positive outcome of colposcopic also but only 4.1% of negative outcome.

Colposcopic diagnosis		Pap Smear		Total
		Negative	Positive	
Negative	Count	92	3	95
	%	73.0%	4.1%	47.5%
Positive	Count	34	71	105
	%	27.0%	95.9%	52.5%
	Count	126	74	200
	%	100.0%	100.0%	100.0%
Pearson ChiSquare	Value	Df	P Value	Result
	88.907a	1	0.000	Sig

TABLE 9: Sensitivity, Specificity values for Colposcopy against Pap Smear .

The Moderate degree of sensitivity 73% for inflammatory, 67.3% for CIN 1, 72.7% for CIN2 and 27.3% for CIN3, but lower degree of PPV 50.8% for CIN 1, 22.9% for CIN2 and 50% for CIN3 shows that colposcopy can't be used for predicting positive cases of these outcomes against pap smear method.

100% sensitivity of CIN2+CIN3 shows that colposcopy can be used for predicting positive cases of these outcomes against pap smear.

Whereas the high value of Specificity for 97.3% for Inflammatory, 78.8% for CIN1, 85.7% for CIN 2, 98.4% for CIN 3 and 84.1% for CIN2+CIN3 along with moderate degree of NPV 67.9% for Inflammatory, but high degree of 84.8% for CIN1, 98.2% for CIN 2, 95.9% for CIN 3 and 100% for CIN2+CIN3 shows that colposcopy can be used for predicting negative cases of these outcomes against pap smear method.

The high sensitivity 95.9% and moderate specificity 73.0% for overall positive cases shows that colposcopy is more accurate in predicting positive outcomes as compared to negative outcomes against pap smear method.

Colposcopic Diagnosis V/s Pap Smear					
Colposcopic Diagnosis	Sensitivity	Specificity	PPV	NPV	Accuracy
Inflammatory	73.0%	97.3%	97.9%	67.9%	82.0%
CIN 1	67.3%	78.8%	50.8%	88.1%	76.0%
CIN2	72.7%	85.7%	22.9%	98.2%	85.0%
CIN3	27.3%	98.4%	50.0%	95.9%	94.5%
CIN2+CIN3	100.0%	84.1%	26.8%	100.0%	85.0%
Positive	95.9%	73.0%	67.6%	96.8%	81.5%

DISCUSSION

In the present study colposcopy revealed that out of 200 VIA positive females maximum 46.5% scored 0 followed by 20% females who scored 1, 12.5% who scored 2, 7% who scored 3 and 4, 3% who scored 5,6 and lastly lowest proportion 1.0% scored 7 respectively.

Evidence of CIN and invasive lesions in colposcopy-directed cervical biopsy among the VIA-positive patients strongly suggested the need of VIA as an essential screening test.Similar results were obtained in study done by Kasem SB et al[18] who stated that, out of 97 cases, all had VIA-positive acetowhite areas. But colposcopy revealed that 76.29% had CIN and invasive lesions, while 23.71% had either normal or inflammatory lesions. Colposcopy- directed punch biopsy revealed that 59.79% cases had positive lesions like CIN or invasive carcinoma and 40.21% had neither CIN nor invasive lesions

Similarly, study done by Arora RS et al[19] where they evaluated the performance of colposcopy vs conventional cytology in estimating the presence and grade of cervical disease against the reference standard of histopathology as a secondary test modality to triage women found positive on primary screening by visual inspection with 5% acetic acid (VIA) and found that diagnostic accuracy of Colposcopy was 87%.

In the present study colposcopic diagnosis shows that out of 200 VIA positive females 47.0% (94) had Inflammatory diagnosis followed by 32.5% (65/200) who had CIN 1 diagnosis, 17.5% (35/200) for CIN 2 diagnosis and lastly only 3.0% (6/200) for CIN 3 diagnosis respectively. The results were in concurrence with studies done by Kasem SB et al and Arora RS et al. Arora RS et al[18,19] reported that out of 50 VIA positive patients.10% had normal colposcopic findings, 6% had infection, 20% had CIN I, 30% had CIN II, 18% had CIN III and 16% patients had invasion. It suggest that Colposcopic examination does serve as an accurate diagnostic tool for early diagnosis of cervical cancer in adjunction to VIA.

In present study, the distribution on basis of Pap smear showed that out of 200 VIA positive females 37% women showed positive PAP smear findings. The results of the study were comparable with study done by done Z. Vahedpoor et al[20] where patients with positive VIA, 27.5% had positive Pap smear and 72.5% were Pap smear negative. For patients with VIA negative, 14.2% had positive Pap smear and in 85.8% of patients, Pap smear was reported negative.

This data suggested that with colposcopy as a screening tool, the rate of false negative cytology could be significantly reduced. Colposcopy enhanced cervical screening particularly in women with otherwise negative smears.

A statistically significant and higher proportion of similar outcome was observed between Colposcopic Diagnosis and Pap Smear Outcome. In Negative outcome of Pap Smear have 73.0% of Negative outcome of colposcopic also but only 27.0% for positive outcome. Similarly, in positive outcome of pap smear have 95.9% of positive outcome of colposcopic also but only 4.1% of negative outcome.

Sensitivity, Specificity values for Colposcopy against Pap Smear was also evaluated in the present study.

The Moderate degree of sensitivity 73% for inflammatory, 67.3% for CIN 1, 72.7% for CIN2 and 27.3% for CIN3, but lower degree of PPV 50.8% for CIN 1, 22.9% for CIN2 and 50% for CIN3 shows that colposcopy can't be used for predicting positive cases of these outcomes against pap smear method.

100% sensitivity of CIN2+CIN3 shows that colposcopy can be used for predicting positive cases of these outcomes against pap smear.

Whereas the high value of Specificity for 97.3% for Inflammatory, 78.8% for CIN1, 85.7% for CIN 2, 98.4% for CIN 3 and 84.1% for CIN2+CIN3 along with moderate degree of NPV 67.9% for Inflammatory, but high degree of 84.8% for CIN1, 98.2% for CIN 2, 95.9% for CIN 3 and 100% for CIN2+CIN3 shows that colposcopy can be used for predicting negative cases of these outcomes against pap smear method.

The high sensitivity 95.9% and moderate specificity 73.0% for overall positive cases shows that colposcopy is more accurate in predicting positive outcomes as compared to negative outcomes against pap smear method. VIA is a suitable primaryscreening procedure alternative to Pap smear as it has high sensitivity and negative predictive value. Women with positive VIA result should be subjected to colposcopy to avoid unnecessary treatment in disease free, as VIA has high false positive rate.

CONCLUSION

From the results of this study, it is evident that colposcopy is definitely more sensitive and accurate than pap smear. Colposcopy was found to be useful in understanding the morphology of the cervical lesions, both of the neoplastic and the non-neoplastic ones and this was very helpful in planning their management. Colposcopy is a good sensitive test for the detection of CIN and can be considered as a secondary testing tool to triage women found positive on VIA.

Thus colposcopy, which gives immediate results, can be considered as a secondary testing tool to triage women found positive on VIA in settings where cytology and histopathology services are logistically and technically not feasible.

Limitations of the study

The present study, however, suffers from the limitation of colposcopy being performed by multiple colposcopists at various levels of expertise, many of them recently trained, presumably in their learning curves during the entire phase of the study. Thus, in spite of the above limitations, our findings suggest that colposcopy shows acceptable sensitivity for a histologic outcome.

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ETHICAL APPROVAL: THE STUDY WAS APPROVED BY THE INSTITUITONAL ETHICS COMMITTEE.

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