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Comparison of Diagnostic Efficiency of Visual Inspection of Cervix with Acetic Acid and Histopathological Evaluation

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ABSTRACT
The most significant method for untimely diagnosis of cancer cervix is cytology screening, the development of low-cost technology e.g., visual inspection of the cervix after application of acetic acid is an alternative tool for diagnosis of cervical cancer. To compare the diagnostic accuracy of visual inspection with acetic acid (VIA) and histopathological evaluation in diagnosing cervical cancer in women. This was a prospective comparative study conducted on 265 women who fulfill selection criteria. The participant was subjected to detailed history, physical examination, VIA and Histopathological examination (HPE). The sensitivity and specificity of each test are determined and compared. A total of 9.1% of patients were detected positive on visual inspection of acetic acid (VIA) testing assessed by on site physician and 5.3% by off-site physician. 6.8% of study participants were detected positive for cervical cancer lesion in HPE testing, among that 47.62% were CIN II. Sensitivity of onsite physician was 100% for detection of cervical changes and 97.57% of specificity which is good. Onsite physicians test results had 75% PPV, 100% NPP and 97.74% accuracy. Sensitivity of onsite physician was 77.78% for detection of cervical changes and 100% of specificity. Offsite physicians test results had 100% PPV, 98.4% NPP and 98.49% accuracy. This study concluded that visual inspection with acetic acid (VIA) is more sensitive and accurate than Pap smear in diagnosing cervical cancer, but less sensitive than HPE.

INTRODUCTION

Visual inspection with acetic acid is naked-eye examination of the uterine cervix, after application of 5% acetic acid and interpreting the result after one minute. This is a simple and inexpensive test for the detection of cervical precancerous lesions a nd early invasive cancer in low middle income countries. Cervical cancer is an important women's reproductive health problem. It is a preventable disease of significant public health concern especially in developing countries. 83% of more than 493,000 new cases of cervical cancer and 85% of all cervical cancer deaths globally occur in developing countries[1]. Its impact on the lives of women worldwide is indisputable[2]. It is the third most common cancer worldwide and the second most common cancer and leading cause of death from cancer among women in developing countries[2]. Globally, cervical cancer remains an important cause of mortality among young women[2]. In 2005, almost 260,000 women died from cancer of the cervix globally[3]. Cervical screening programs are covering only 5% of the population in the developing countries whereas it is the cancer which is having a pre malignant condition and that can be easily screened by the screening tools[4-5]. CIN is characterized by abnormal cellular proliferation, abnormal epithelial maturation and cytological atypia. It is characterized into three types i.e. CIN I, CIN II and CIN III. Risk factors for cervical cancer are multiparity, age at first intercourse, oral contraceptive pills usage, smoking, socioeconomic status and Human Papillomavirus (HPV) infection[6]. HPV 16 and 18 are the most common high-risk types, a sexually transmitted infection accounting for 60% of HPV positive invasive cervical cancers. Although in majority of cases this virus is not activated due to body's immune response but poor immunity due to underlying risk factors or repeated infection may lead to cause changes in cervix. Hence, the diagnosis of the disease earlier can prevent fatal complications. The premalignant changes in the cervix can be detected by methods like Pap smear cytology and liquid-based cytology (LBC) along with HPV DNA testing[7]. Visualization of the cervix is also performed as one of the screening procedures where the cervix is examined for the acetowhite regions after the application of 3%-5% acetic acid with a further evaluation with the application of Lugol's iodine. This can be followed by colposcopic examination and directed biopsies. However, histopathology is considered the gold standard in the diagnosis of premalignant and malignant lesions of the cervix[8]. VIA involves naked eye examination of the 3% acetic acid swabbed uterine cervix without any magnification with illumination provided by a bright light source such as halogen lamp. A positive test is the detection of well defined, dull acetowhite lesions on the cervix. The objective of VIA is to detect acetowhite lesions leading to the early diagnosis of high grade cervical intraepithelial neoplasia and early preclinical, asymptomatic invasive cancer.

Aim of this Study: Objective of this study is comparison of diagnostic efficiency of visual inspection of cervix with acetic acid and histopathological evaluation in cervical carcinoma.

MATERIALS AND METHODS

This prospective comparative study was conducted in the Department of Obstetrics and Gynecology, Kamla Raja Hospital and J.A. Group of Hospitals, Gwalior (M.P.). Study duration was one and half years from January 2021 to June 2022. A total of 265 cases meet inclusion criteria were enrolled in the present study.

Inclusion Criteria

- Patients with gynaec complaints attending gynecology OPD during the study period.
- Patients ≥18 years of age.
- Patients who provide written informed consent for the study.

Exclusion Criteria:

- Patients <18 years of age.
- Pregnant women, Former conization and Total Hysterectomy patients.
- Refusal of consent for participation in study.

Per speculum examination was done. Vaginal discharge to be removed with a cotton swab than the first native picture of the cervix will be taken.

Application of 5% acetic acid and leave the cervix for 1 minute, then visual evaluation was performed under 100-watt illumination. The transformation zone was carefully checked for any dense non movable acetowhite areas in the mucosa and presence or absence of cervical cancer was noted.

After this, all patients were undergone biopsy from the cervix and histopathological examination was done.

The results of Pap smear and visual inspection with acetic acid (VIA) were compared with histopathology report. All this data (age, duration of symptoms, parity, marital status, menopausal status, cervical carcinoma on Pap smear, VIA and histopathology) was recorded on a specially designed proforma.

Statistical Analysis: Data will be collected compiled and analyzed through computer software SPSS 22. The different statistical tests as percentage proportions and chi square will be applied. P value <0.05 was considered as statistically significant.

RESULTS AND DISCUSSIONS

A total of 265 patients meeting inclusion criteria were enrolled and analysed in this study. 9.1% of study participants were detected positive on visual

inspection of acetic acid (VIA) testing assessed by on site physician. Only 5.3% of study participants were detected positive on VIA testing assessed by off-site physician while 2.6% cases were kept under suspicious category by off-site assessor.

Table 1: VIA Results of Study Subjects by Physician

VIA results		Frequency	Percentage
VIA results by onsite physician	Positive	24	9.1%
	Negative	241	90.9%
VIA results by off-site physician	Positive	14	5.3%
	Negative	244	92.1%
	Suspicious	7	2.6%

A total 6.8% of study participants were detected positive for cervical cancer lesion in HPE testing, among that 47.62% were CIN II and 19.05% patients were diagnosed as CIN I and CIN III category respectively.

Fig. 1: HPE report of positive and suspicious cases

A substantial agreement between onsite and offsite assessor was found. All 14 offsite positive cases were detected positive by on site physician. Onsite physician detected total 24 cases out of them 10 cases were detected as suspicious or negative by offsite physician.

Table 2: Agreement Analysis Between Onsite and Offsite Physician Test Results

		Off-site physician results Positive	Negative	p-value
On site physician results	Positive	14	10	<0.67
	Negative	0	241	

Kappa-0.845 (Substantial Agreement): Sensitivity and specificity of any test is independent to prevalence of any diseases and rest other variables are prevalence dependent. Sensitivity of onsite physician was 100% for detection of cervical changes and 97.57% of specificity which is good. Onsite physicians test results had 75% PPV, 100% NPP and 97.74% accuracy.

Table 3: Sensitivity and Specificity of Onsite Physician Against HPE Report

		HPE report Positive	Negative	p-value
On site physician results	Positive	18	6	<0.63
	Negative	0	241	

Statistic	Value	95% CI
Sensitivity	100%	81.47% -100%
Specificity	97.57%	94.79% - 99.10%
Positive Predictive Value (*)	75%	57.65%- 86.86%
Negative Predictive Value (*)	100%	
Disease prevalence (*)	6.79%	4.08%-10.52%
Accuracy (*)	97.74%	95.14%-99.16%

Sensitivity of onsite physician was 77.78% for detection of cervical changes and 100% of specificity. Offsite physicians test results had 100% PPV, 98.4% NPP and 98.49% accuracy.

Table 4: Sensitivity and Specificity of Onsite Physician Against HPE Report

		HPE report Positive	Negative	p-value
On site physician results	Positive	14	0	<0.69
	Negative	4	247	

Statistic	Value	95% CI
Sensitivity	77.78%	52.36%- 93.59%
Specificity	100%	98.52% - 100%
Positive Predictive Value (*)	100%	
Negative Predictive Value (*)	98.41%	96.30% - 99.32%
Disease prevalence (*)	6.79%	4.08% - 10.52%
Accuracy (*)	98.49%	96.18%- 99.59%

Cervical cancer (CC) is one of the most prevalent diseases in women and one of the main causes of cancer death in developing nations. It is one of those cancers which are easily preventable yet an ignored disease because of poor coverage of its screening in masses. Pap smear is a screening tool to detect its premalignant condition. It is now an urgent need of an hour for alternate ways of screening this deadly cancer for early diagnosis and treatment. Human papillomavirus (HPV) DNA testing and visual inspection of acetic acid are the alternate screening methods for cervical cancer[9-10].

Along with financial and technical difficulties, recent studies have shown a higher rate of up to 30% of false positive reports from Pap smear. To overcome these drawbacks visual inspection with acetic acid (VIA)" was proposed as an alternate screening test to diagnose cervical cancer. Some randomized control trials prove VIA as significantly efficient screening test having ability to reduce mortality rate in women having cervical cancer[11].

We have reported that 9.1% of study participants were detected positive on VIA testing assessed by on site physician and 5.3% were detected positive on VIA testing assessed by off-site physician, our results were comparable with the Goel[12] and Megevand[13] reported VIA positive rate were 12.5% and 4.2% respectively.

In our study, 6.8% of the patients were detected positive for cervical carcinoma in HPE testing, majority of them were diagnosed as CIN II category, similar finding were observed by David[14] and Concul[15].

Our study showed the sensitivity, specificity, PPV, NPP and accuracy of on-site physician for detection of cervical changes were 100%, 97.5%, 75%, 100% 97.7% respectively, in agreement with the Adnan[16] and Pragya Shree[17].

Sensitivity, specificity, PPV, NPP and accuracy for detection of cervical changes of off-site physician in

current study were 77.78%, 100%, 100%, 98.4% and 98.49% respectively, according to the findings of a study by Ricard-Gauthier[18].

In this trial, 2 off-site physicians correctly recognized 6 of 7 lesions, compared to 2 on-site physicians who correctly identified just 2 lesions (sensitivity of 28.6%., p=.13), concordance with the Haroon[19].

The diagnostic accuracy of VIA for CIN 2+ was published in a comprehensive review and meta-analysis done by Allanson[20], with a sensitivity of 74.6% and specificity of 61.7%.

A study done by Bhattacharya[21], VIA showed higher sensitivity (96.15%) but low specificity (62.50%). The reason behind the high sensitivity and/or low specificity of VIA in our study could be due to: presence of infection and inflammation that take up acetowhite stain; some faint acetowhite areas might have been interpreted as being positive; and scoring those areas with distinct acetowhite uptake on cervix as positive.

The diagnosis of cervical cancer at CIN or early stage may help in effective treatment and encouraging results. VIA may be the best alternate screening tool where Pap smear could not provide adequate coverage for large population due to lack of infrastructure and resources for cytological screening.

CONCLUSION

We have concluded that the diagnostic accuracy of cervical screening for visual inspection after acetic acid (S-VIA) for the detection of CIN 2+. In addition, S-VIA appears practical and applicable. The prevention of cervical cancer in LMICs remains a critical global health priority and the use and scale up of S-VIA may allow for the accurate detection of CIN 2+ alongside support and training of the health care providers delivering screening in LMICs.

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