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Original Research Article

Molecular Detection of HPV in Cervical Lesions: Correlation with Cytological and Histopathological Findings at a Tertiary Care Hospital in Uttar Pradesh

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Abstract

Background: Human papillomavirus (HPV) is established as the principal etiological agent in cervical cancer. Molecular techniques for HPV detection are enhancing the diagnostic precision for cervical lesions, enabling improved patient management. This study aimed to evaluate the prevalence of high-risk HPV (HR-HPV) in cervical lesions and to correlate molecular detection with cytological and histopathological findings at a tertiary care hospital in Uttar Pradesh, India.

Methods: A cross-sectional study was conducted among women undergoing routine cervical screening. Cervical samples were analyzed using Pap Cytology, Histopathology and multiplex real-time Polymerase chain reaction (PCR) for HPV genotyping. The correlation between HPV presence, cytological findings (Bethesda system), and histopathological diagnosis was statistically evaluated.

Results: Out of total 250 women screened, 58 (23.2%) had abnormal cytology and HPV DNA was detected in 81.0% of these cases. HR-HPV genotypes, predominantly HPV-16 (60.4%), were identified across a spectrum of lesions, increasingly prevalent from low-grade squamous intra-epithelial lesions (LSIL) to high-grade (HSIL) and malignancy. Concordance between molecular HPV detection and histopathology findings was strong, with all squamous cell carcinoma (SCC) cases positive for HPV-16 or a combination of HR-HPV types.

Conclusion: Findings suggested that Molecular detection of HR-HPV is strongly correlates with both cytological and histopathological evidence of cervical lesions and provides an additional sensitive tool for early identification of women at risk. Integrating molecular HPV testing in routine cervical screening programs in tertiary care settings could markedly improve early detection and prevention strategies for cervical cancer.

Keywords: Human Papilloma Virus (HPV), Cervical Lesions, Pap smear, Hisptopathology, Cytology.

Introduction

Cervical cancer represents a major public health challenge in women in world including India. The World Health Organization (WHO) reports that cervical cancer is the fourth most common cancer among women worldwide, with 604,000 new cases and 342,000 deaths reported in 2020. Over 85% of these deaths occurred in low- and middle-income countries (LMICs). [1, 2]

Human papillomavirus (HPV) is established as the principal etiological agent in cervical cancer. High-risk genotypes such as HPV-16 and HPV-18 account for the majority of cases. Early identification of HPV infection, especially HR-HPV, is vital for effective prevention and intervention but LMICs often rely opportunistic screening or symptomatic diagnosis due to limited access, inadequate infrastructure, and shortage of trained personnel. As a result, many are diagnosed at advanced stages, leading to high morbidity and preventable mortality. Economic, educational, systemic, and cultural barriers further hinder early detection and consistent treatment.[3,4]

Although cervical cancer is preventable and curable in early stages, yet remains a leading cause of cancer-related mortality worldwide due to this situation. Unequal access to HPV vaccination, screening, and treatment highlights broader disparities within health systems. Low health literacy, stigma surrounding gynecological care, fragmented services, and insufficient public awareness campaigns reduce the effectiveness of existing interventions, especially in LMICs.[5]

While conventional cytology (Pap smears) and histopathology remain standard diagnostic modalities, molecular testing significantly increases sensitivity for detecting pre-malignant changes and provides direct risk stratification. In addition, molecular techniques for HPV detection are enhancing the diagnostic precision for cervical lesions, enabling improved patient management. [6]

This study aimed to evaluate the prevalence of high-risk HPV (HR-HPV) in cervical lesions and to correlate molecular detection with cytological and histopathological findings at a tertiary care hospital in Uttar Pradesh, India.

Materials and Methods

Study Setting: Prospective cross-sectional study at Department of Obstetrics & Gynaecology, Tertiary Care Hospital, and Uttar Pradesh.

Study Participants: Women aged 20–65 years attending with Gynaecology problems in OPD and undergoing cervical screening;

Inclusion Criteria

- Women of age 20-65 years undergoing cervical screening.
- Married and sexually active, were included
- Provided informed consent for participation and sample collection.

Exclusion Criteria

- Women with previously biopsy-confirmed precancerous or cancerous cervical lesions.
- Women with frank visible cervical lesions on examination.
- Women with treatment for cervical lesion or neoplasia.
- Those with a history of hysterectomy were excluded.
- Pregnant women and those unwilling for vaginal examination.

Methodology

This study was conducted among 240 women, who undergoing cervical screening for gynecological problems. Ethics approval and informed consent obtained in compliance with standard protocols. Demographic and clinical variables such as like Age, residence, education, sexual history, contraception, substance use, and symptoms (especially abnormal vaginal discharge) were recorded. Clinical examination was done Speculum and gross pelvic examination. Cervical swabs obtained for cytology and molecular testing; biopsies taken when indicated.

Cytology: Cytological Examination Cervical samples were collected using an Ayre' s spatula and cytobrush, immediately fixed in 95% ethanol, and stained using the Papanicolaou method. Smears were reported according to the Bethesda System (2014).

HPV Detection: Multiplex real-time PCR targeted the L1 region, differentiating HR-HPV genotypes (notably HPV-16, HPV-18 and others).

Histopathology: Tissue processing and reporting was followed according to WHO criteria for intraepithelial and invasive lesions. HPV DNA Testing was done among 125 cervical samples by PCR-based HPV DNA testing. The results were categorized as HPV-positive or HPV negative.

Statistical Analysis: Associations between cytological findings, demographic/clinical variables, and HPV status were analyzed using appropriate statistical tests. A p value <0.05 was considered statistically significant. Concordance and correlation was assessed by using chi-square test and kappa statistics.

Results

Demographics and Clinical Profile: Out of 250 women screened, mean age was 39.2±9.8 years. Most participants (66%) were multigravid and from rural backgrounds.

Cytological Findings: Normal cytology in 192 (76.8%); 26 (10.4%) LSIL, 16 (6.4%) HSIL, 4 (1.6%) ASC-US, 2 (0.8%) ASC-H, 10 (4.0%) carcinoma smear.

Table 1: Cytological findings of Study Population

Cytological findings	Frequency	Percent
Normal	192	76.8%
LSIL	26	10.4%
HSIL	16	6.4%
ASC-US	4	1.6%
ASC-H	2	0.8%
carcinoma smear	10	4.0%

Molecular HPV findings: Out of total 47 (18.8%) participants were positive for HR-HPV and most frequent genotype was HPV-16 (60.4%), followed by mixed HPV infections (20.8%), HPV-18 (6.25%), and others (12.5%).

Table 2: HPV DNA findings among Abnormal Cytological Cases

HPV DNA findings	Frequency	Percent
HPV-16	28	59.6
HPV-18	3	6.4
Mixed HPV	10	21.3
Others	6	12.8

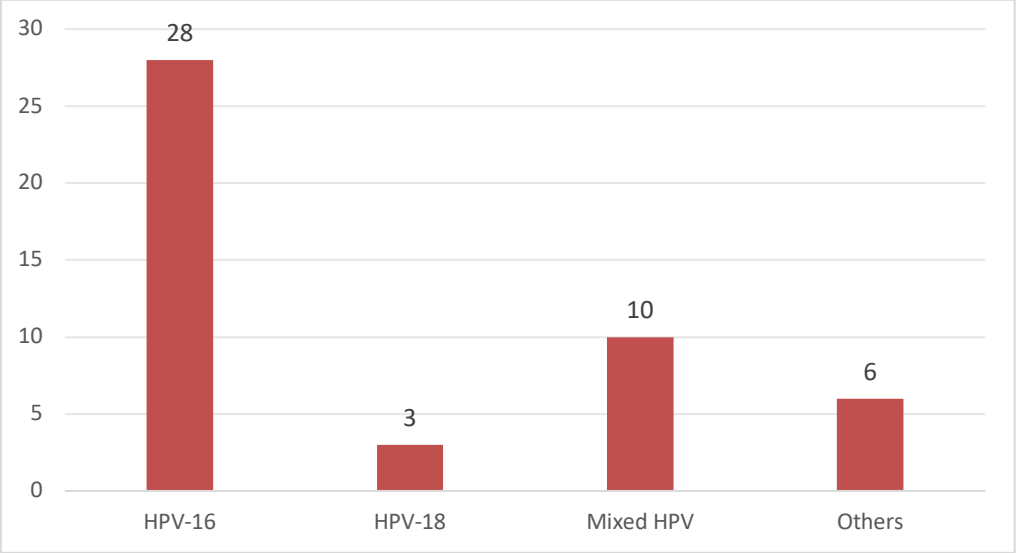

Figure 1: Overall Distribution of HPV Genotypes in Study Population

In abnormal cytology cases, HPV positivity was seen in 81% (47/58). HPV DNA positivity increased with cytological severity and found 65.7% in LSIL, 84.6% in HSIL, and 94% in cancer cases.

Histopathological Correlation: On histopathological examination the Squamous cell carcinoma was confirmed in 44 (17.6%) cases and adenocarcinoma in only 1 (2.2%) case. All histologically malignant cases were HR-HPV positive, mainly genotype-16.

Significant association found between HR-HPV and increasing severity of cytological/histopathological lesions ($p<0.001$).

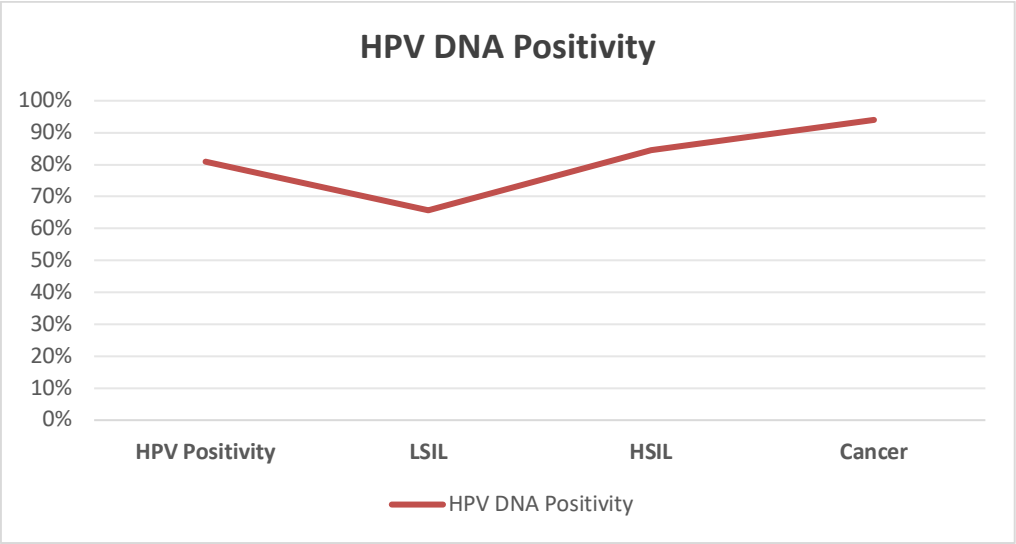

Figure 2: Frequency of Cytological Abnormalities with HPV-DNA Positivity

Discussion

Cervical cancer remains a major public health concern globally, amounting to 6,04,127 new cases and the 3,41,831 deaths in year 2020. [8]

This study affirms the high prevalence and type distribution of HR-HPV, particularly HPV-16, in cervical lesions in northern India. There is strong concordance between molecular HPV detection and

cytological/ histopathological abnormalities, underscoring the clinical value of incorporating HPV DNA testing as a complementary modality to cytology. Detection of HPV, even in normal cytology, supports a 'screen and follow' approach for early intervention. In May 2018, the World Health Organization issued a 'Call for Action' for cervical cancer elimination by 2030. As a part of the strategy for achieving this goal, at least 70 per cent of the eligible women should be screened using a high-performance test twice in their life (at 35 yr and 45 yr). [9]

Among the available modalities for cervical cancer screening, HPV DNA-based tests have shown higher sensitivity for detecting CIN2+ lesions. However, the majority of the commercially available US-FDA-approved HPV detection tests are costly with the requirement of an elaborate laboratory set up and trained workforce. These limitations have hampered the widespread utility of HPV-based cervical cancer screening in resource-constrained countries. Hence, various researchers have been attempting to develop a cost-effective, easy-to-use, rapid and efficient POC test for HPV-based cervical cancer screening. Camara et al. reported a high level of acceptability of self-collection of cervical samples for POC HPV testing by GeneXpert™ and the screen-and treat approach in the Pacific Islands paving the way for further research on POC HPV-based tests for resource constrained countries. [10]

Xpert® HPV: GeneXpert® HPV is a cartridge-based test that employs nucleic acid amplification test (NAAT) for a qualitative result for 14 HR-HPV types with partial genotyping for HPV16 and HPV18/45 and can be performed on analyzers that are used for diagnosis of diseases such as tuberculosis and HIV by the same method. This assay can be performed as POC or near-POC using benchtop equipment and minimum hands-on sample preparation requirement and provides results within one hour. [11]

Truenat® HPV-HR: Truenat® HPV-HR assay has been developed by MolBio Diagnostics, India, entailing a real-time PCR-based detection of four HR-HPV types: 16, 18, 31 and 45 and providing results within one hour. A recent study compared this assay with the US FDA approved HC2 method. The sensitivity and specificity of Truenat® HPV-HR were reported as 97.7 per cent and 98.9 per cent, respectively, for the detection of HR-HPV (gold standard being HC2). However, further studies are mandated to validate these results as well as evaluate the performance characteristics of this assay for CIN2+ or CIN3+ detection. [12]

These findings are in keeping with national meta-analyses and corroborate the need for molecular HPV testing in primary screening, particularly in high-burden settings with resource constraints.

Conclusion

Findings suggested that Molecular detection of HR-HPV is strongly correlates with both cytological and histopathological evidence of cervical lesions and provides an additional sensitive tool for early identification of women at risk. Integrating molecular HPV testing in routine cervical screening programs in tertiary care settings could markedly improve early detection and prevention strategies for cervical cancer.

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