Section: Obstetrics and Gynaecology

Original Research Article

COMPARATIVE EVALUATION OF HPV DNA TESTING AND PAP SMEAR IN CERVICAL CANCER SCREENING: A STUDY FROM A TERTIARY CARE CENTRE IN NORTH-EAST INDIA

Manash Jyoti Konch[1], Bishnu Prasad Das[2], Bipul Deka[3], Mandeep Bayan[4], Lahari Saikia[5]

[1]*Post Graduate Trainee, Obstetrics and Gynaecology, Gauhati Medical College and Hospital, India.*
[2]*Professor, Department of Obstetrics and Gynaecology, Gauhati Medical College and Hospital, India.*
[3]*Assistant Professor, Department of Obstetrics and Gynaecology, Gauhati Medical College and Hospital, India.*
[4]*Assistant Professor, Department of Obstetrics and Gynaecology, Gauhati Medical College and Hospital, India.*
[5]*Professor, Department of Microbiology, Nagaon Medical College and Hospital, India.*

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Corresponding Author:
Dr. Manash Jyoti Konch,
Post Graduate Trainee, Obstetrics and Gynaecology, Gauhati Medical College and Hospital, India.
Email: manashjyotikonch153@gmail.com

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ABSTRACT

Background: Cervical cancer remains a significant public health challenge, especially in low- and middle-income countries like India, where effective screening is often limited. This study aimed to evaluate and compare the diagnostic accuracy of Pap smear and HPV DNA testing in detecting cervical neoplasia.

Materials and Methods: A prospective comparative study was conducted at the Department of Obstetrics and Gynaecology, Gauhati Medical College and Hospital, from 2024 to 2025. A total of 100 sexually active women aged 30–65 years underwent both Pap smear testing and HPV DNA typing using the PaxView® HPV16/18/Others MPCR-ULFA Kit. Abnormal cases were further evaluated by colposcopy and cervical biopsy. Data were analyzed using SPSS version 26.

Results: Pap smear showed a sensitivity of 44.44% and specificity of 95.60%, while HPV DNA testing had a sensitivity of 100% and specificity of 92.31%. High-risk HPV types, especially HPV-16, showed a strong correlation with histologically confirmed high-grade lesions. Co-testing improved diagnostic yield, and a significant correlation was observed between abnormal cytology/HPV results and biopsy-proven pathology ($p = 0.001$).

Conclusion: HPV DNA testing demonstrates superior sensitivity compared to Pap smear and should be integrated into routine cervical cancer screening, especially for women aged 30–65. A co-testing approach significantly enhances diagnostic accuracy and enables early detection, thus reducing cervical cancer-related morbidity and mortality.

Keywords: Pap smear, HPV DNA, cervical cancer, screening, cytology, biopsy, colposcopy, CIN, HSIL.

INTRODUCTION

Cervical cancer remains a leading cause of cancer-related deaths among women globally, with a particularly high incidence in low- and middle-income countries.[1,2] Persistent infection with high-risk human papillomavirus (HPV) types, primarily HPV-16 and HPV-18, is the established etiological factor.[8,9] Screening strategies are crucial in reducing the incidence and mortality associated with cervical cancer. Among these, the Pap smear has historically been the cornerstone (4), while HPV DNA testing is emerging as a powerful tool due to its higher sensitivity.[10,12] This study explores the comparative effectiveness of these screening modalities in a tertiary care hospital setting.

MATERIALS AND METHODS

This **prospective comparative study** was conducted over a period of one year, from 2024 to 2025, in the **Department of Obstetrics and Gynaecology** at **Gauhati Medical College and Hospital (GMCH), Guwahati**, a tertiary care center in Northeast India.

Study Population

A total of **100 sexually active women**, aged **30 to 65 years**, attending the gynecology outpatient department were recruited for the study. The participants were selected based on defined **inclusion and exclusion criteria**.

Inclusion Criteria

- Sexually active women between the ages of 30 and 65 years.
- Willingness to provide informed written consent.
- No prior history of cervical intraepithelial neoplasia or cervical cancer.

Exclusion Criteria

- Women with active vaginal bleeding.
- History of hysterectomy.
- Pregnancy or postpartum state.
- Prior treatment for cervical lesions or malignancy.
- Use of vaginal medications within the previous 48 hours.

Ethical Considerations

Approval for the study was obtained from the **Institutional Ethics Committee**. All participants were informed about the nature of the study, and **written informed consent** was obtained before enrolment.

Study Procedure

Each participant underwent a structured interview for **demographic and clinical data collection**, followed by a **per speculum examination** to assess the cervix and vagina for any visible abnormalities.

Sample Collection

Two samples were collected from each participant:

1. **Pap Smear (Cytology):**
   - Performed using Ayre's spatula and endocervical brush.
   - Samples were smeared on a glass slide, fixed immediately with 95% ethanol, and stained using the **Papanicolaou staining technique**.
   - Cytological interpretation was carried out according to **The Bethesda System 2014**.
2. **HPV DNA Testing:**
   - Collected using the **PaxView® HPV16/18/Others MPCR-ULFA Kit**.
   - The sample was stored in a transport medium and sent to the microbiology laboratory for analysis.
   - The kit detects high-risk HPV types, including HPV-16, HPV-18, and other carcinogenic strains.

Further Evaluation

Participants with **abnormal cytology or positive HPV DNA results** were referred for **colposcopic examination** using a standard colposcope (magnification 10x–16x) to visualize aceto-white changes, mosaicism, punctuation, and abnormal vascular patterns.

If colposcopy findings were suspicious or diagnostic, **directed cervical biopsies** were taken and sent for **histopathological examination**.

Statistical Analysis

The data collected were tabulated and statistically analyzed using **IBM SPSS software version 26**. Descriptive statistics were used for demographic profiling. **Chi-square test** was applied to determine associations between test results and histopathology. The **diagnostic performance** of Pap smear and HPV DNA testing was compared in terms of:

- Sensitivity
- Specificity
- Positive Predictive Value (PPV)
- Negative Predictive Value (NPV)
- Diagnostic accuracy
- A **p-value < 0.05** was considered statistically significant.

RESULTS

Demographic Profile

Table 1: Age of the participants

Age Category	Frequency	Percent
30-39	52	52.0
40-49	33	33.0
50-59	6	6.0
60-69	9	9.0
Total	**100**	**100.0**

The age distribution of participants (Table 1) showed that the majority (52%) were in the 30–39 years age group, followed by 33% in the 40–49 age group. Women aged 50–59 accounted for 6%, and those aged 60–69 made up 9% of the study population

Reproductive History

Table 2: Parity of the participants

Parity	Frequency	Percent
0	9	9.0

1	15	15.0
2	43	43.0
3	21	21.0
4	5	5.0
5	5	5.0
6	2	2.0
Total	100	100.0

Parity data (Table 2) revealed that 43% of the women had two children, making this the most common parity level. 21% had three children, 15% had one child, and 9% had no children. Participants with parity of four or more comprised 12% of the total group.

Pap Smear Findings

Table 3: Pap smear results among the participants

Pap Smear Results	Frequency	Percent
ASCUS	5	5.0
HSIL	3	3.0
NILM	83	83.0
Unsatisfactory	9	9.0
Total	100	100.0

As shown in Table 3, Pap smear analysis indicated that 83% of participants had results classified as NILM (Negative for Intraepithelial Lesion or Malignancy). ASCUS (Atypical Squamous Cells of Undetermined Significance) was detected in 5% of participants, and HSIL (High-Grade Squamous Intraepithelial Lesion) in 3%. About 9% of the smears were unsatisfactory for evaluation. These findings are visually represented in Figure 1-4.

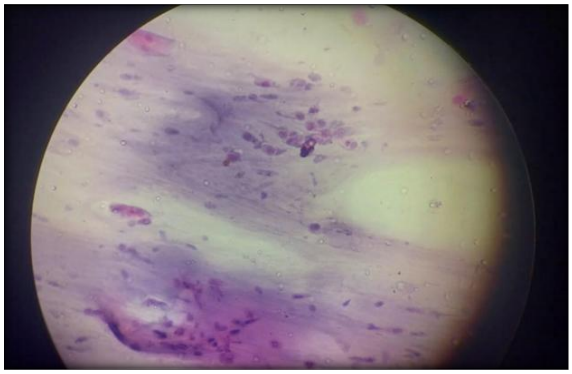

FIGURE 1: PAP SMEAR SHOWING ASCUS

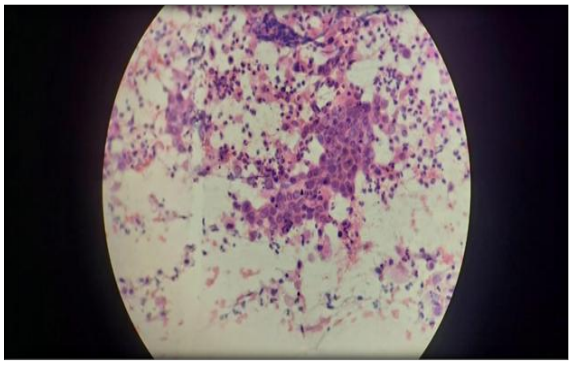

FIGURE 2: PAP SMEAR SHOWING ASC-H

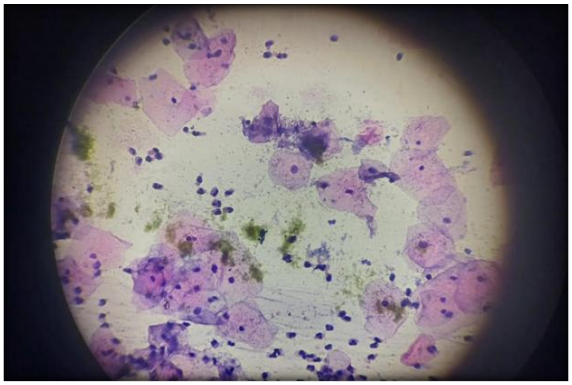

FIGURE 3: PAP SMEAR SHOWING NILM WITH INFLAMMATION

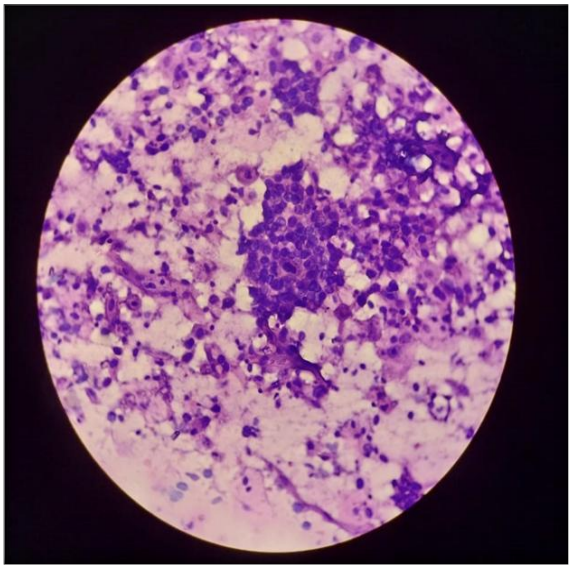

FIGURE 4: PAP SMEAR SHOWING HSIL

Pap Smear Sample Adequacy

Table 4. Pap smear cellularity among the participants

Pap Smear Cellularity	Frequency	Percent
Adequate	91	91.0
Inadequate	2	2.0

Pauci cellular	1	1.0
Unsatisfactory	6	6.0
Total	100	100.0

According to Table 4, most Pap smears (91%) were of adequate cellularity. Inadequate samples were found in 2%, pauci-cellular in 1%, and unsatisfactory in 6% of the participants.

HPV DNA Typing Results

Table 5: HPV DNA typing among the participants

HPV DNA Typing	Frequency	Percent
HPV Others	14	14.0
HPV-16	13	13.0
HPV-18	3	3.0
Not Detected	70	70.0
Total	100	100.0

Table 5 presents that 70% of women tested negative for HPV DNA. Among those with detectable infection, 14% had types categorized as 'HPV Others,' 13% had HPV-16, and 3% had HPV-18. The breakdown of HPV types is illustrated in Figure 12, showing HPV-16 as the most prevalent high-risk type.

Colposcopic Examination

Colposcopy was performed on individuals with abnormal cytological or HPV findings. Table 6 shows that 10% had abnormal colposcopic findings, 7% had normal findings, and 83% did not require the procedure.

Table 6: Colposcopy among the participants

Colposcopy Findings	Frequency	Percent
Abnormal	10	10.0
Normal	7	7.0
Not Done	83	83.0
Total	100	100.0

Histopathological Confirmation via Biopsy

Table 7: Cervical biopsy among the participants

Cervical Biopsy Findings	Frequency	Percent
CIN-2	4	4.0
CIN-3	2	2.0
Moderately Differentiated Adenocarcinoma	1	1.0
Moderately Differentiated Squamous Cell Carcinoma	1	1.0
Normal	1	1.0
Not Done	90	90.0
Poorly Differentiated Carcinoma	1	1.0
Total	100	100.0

Table 7 demonstrate that histological confirmation via cervical biopsy revealed CIN-2 in 4% of participants and CIN-3 in 2%. Additionally, 1% each had moderately differentiated adenocarcinoma, moderately differentiated squamous cell carcinoma, and poorly differentiated carcinoma. Only 1% of biopsied participants had normal histology.

Correlation Between Pap Smear and HPV DNA Testing

Table 8: Comparison of Diagnostic Performance Between Pap Smear and HPV DNA Testing

Parameter (with 95% CI)	Pap smear	HPV DNA testing
Sensitivity	44.44% (13.7-78.8%)	100% (66.3-100%)
Specificity	95.60% (89.1-98.7%)	92.31% (84.7-96.8%)
PPV	50.00% (23.0-76.9%)	56.25% (38.6-72.3%)
NPV	94.57% (90.6-96.9%)	100.00% (95.7-100%)
Diagnostic accuracy	91.00% (83.6-95.8%)	93.00% (86.1-97.1%)

Table 8 confirms a significant association ($p = 0.001$) between HPV DNA typing results and biopsy outcomes. HPV-16 showed the strongest correlation with biopsy-confirmed high-grade lesions, including CIN-2, CIN-3, and cervical carcinoma. HPV Others also displayed relevant associations.

DISCUSSION

This study sought to compare the effectiveness of Pap smear and HPV DNA testing in the screening of cervical neoplasia among sexually active women aged 30–65 years. The findings highlight the superior sensitivity of HPV DNA testing, particularly for detecting high-grade cervical lesions, while also

underscoring the complementary value of the Pap smear in a co-testing strategy.

In our study, Pap smear sensitivity was 44.44%, consistent with prior research demonstrating its moderate sensitivity but high specificity. For instance, Mayrand et al. reported that Pap smear had a sensitivity of around 55.4%, while HPV DNA testing showed 94.6% sensitivity in detecting high-grade cervical intraepithelial neoplasia (CIN 2 or worse).[12] Similarly, in a meta-analysis by Koliopoulos et al., cytology showed lower sensitivity than HPV-based screening but higher specificity.[10]

In contrast, the HPV DNA test in our study showed 100% sensitivity and a specificity of 92.31%, aligning with the findings of Ronco et al., who demonstrated that HPV-based screening not only improves early detection but also provides longer protection from invasive cervical cancer due to its high negative predictive value (6). Our results showed a 100% NPV for HPV DNA testing, confirming its reliability in ruling out high-grade lesions in screen-negative women.

The strong association between HPV-16 positivity and biopsy-confirmed CIN-2, CIN-3, or carcinoma observed in this study echoes the findings of Walboomers et al. and Bosch et al., who identified HPV-16 as the most oncogenic type and a necessary cause of cervical cancer in the majority of global cases.[8,9] Our data revealed that 13% of women had HPV-16, and this subgroup showed a high correlation with histopathologically confirmed high-grade lesions, reinforcing HPV-16's predictive role in disease progression.

Although Pap smear continues to be a widely accessible and cost-effective tool, its limitations in sensitivity pose challenges in identifying early high-grade lesions. Schiffman and Castle highlighted this issue, suggesting that cytology alone may miss a significant proportion of at-risk women, especially when the quality of sample collection or interpretation is suboptimal.[3] In our study, although 91% of smears were deemed adequate, 9% were either inadequate or unsatisfactory, indicating the inherent variability of cytology-based screening.

Interestingly, despite 83% of participants showing NILM results on Pap smear, some of these cases tested positive for high-risk HPV types. This discrepancy supports the rationale for co-testing, which has been advocated by the US Preventive Services Task Force as a more effective strategy in reducing cervical cancer incidence through earlier detection.[5]

Furthermore, our study underscores the importance of triage strategies: only 17% of participants underwent colposcopy, and even fewer required biopsy. This efficiency in resource utilization mirrors global screening recommendations for HPV-based triage, especially valuable in low- and middle-income countries (LMICs) like India, where healthcare resources are limited.[1,2]

Finally, our findings support the growing consensus for shifting toward primary HPV screening or co-testing models, as noted by Kang et al. in cases of adenocarcinoma, where Pap smear sensitivity is especially poor.[11]

CONCLUSION

The combination of Pap smear and HPV DNA testing enhances the accuracy and reliability of cervical cancer screening, particularly in detecting pre-cancerous and cancerous lesions. HPV DNA testing, due to its higher sensitivity, should be considered an integral part of routine screening protocols for women aged 30 to 65 years. Implementation of a co-testing strategy can significantly reduce cervical cancer burden through early intervention.

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