

Original Article

## A comparative study of Pap test and colposcopy in the evaluation of unhealthy cervix in a tertiary care hospital serving a rural population of West Bengal

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### Abstract

**Background:** Cervical cancer remains a leading cause of cancer-related mortality among women in developing countries. Early detection through effective screening is crucial for reducing morbidity and mortality. This study aimed to compare the diagnostic performance of Pap smear and colposcopy as screening tools for detecting cervical premalignant and malignant lesions among symptomatic women at a tertiary care centre serving the Sundarban region of West Bengal.

**Methodology:** A hospital-based prospective study was conducted among 110 sexually active women aged 21-50 years presenting with symptoms suggestive of an unhealthy cervix. Participants underwent Pap smear examination followed by colposcopy and colposcopy-guided biopsy. Histopathological examination served as the gold standard for diagnosis. Sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were calculated for both screening modalities, and agreement was assessed using Cohen's kappa.

**Results:** The mean age of participants was 33.2±4.1 years, with 41.8% aged 31-40 years. White vaginal discharge was the most common presenting complaint (50.9%), followed by intermenstrual bleeding (33.6%). Histopathological examination revealed premalignant and malignant conditions in 13.6% of participants. Cervical pathology was significantly associated with lower socioeconomic status ( $p<0.001$ ), early pregnancy ( $p=0.004$ ), multiple sexual partners ( $p=0.002$ ), history of STI ( $p<0.001$ ), and prolonged OCP use ( $p<0.001$ ). Pap test demonstrated 33.3% sensitivity and 97.9% specificity, while colposcopy showed superior performance with 86.7% sensitivity and 80.0% specificity. Agreement between Pap and colposcopy was weak ( $\kappa = 0.284$ ).

**Conclusion:** Colposcopy demonstrates significantly higher sensitivity than Pap smear for detecting cervical lesions among symptomatic women, although the two tests demonstrated only weak concordance. While both methods provide useful information where HPV-based screening is not widely available, combined use should be considered cautiously, given resource constraints.

**Keywords:** Cervical cancer screening, Pap smear, colposcopy, cervical intraepithelial neoplasia, diagnostic accuracy, premalignant lesions

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## Introduction

Cervical cancer remains the fourth most common malignancy among women globally, with 660,000 new cases reported in 2022 [1]. The burden disproportionately affects low and middle-income countries (LMICs), where approximately 94% of the 350,000 cervical cancer deaths occur annually [1]. India has a disproportionately high burden of cervical cancer. According to the GLOBOCAN 2020 reports, cervical cancer accounts for 9.4% of all cancers and 18.3% of new cancer cases (123,907 cases) among women in 2020 [2], making it the second leading cause of cancer deaths in 12 Indian states [3].

The prevalence is particularly pronounced among rural women of low socioeconomic status, who constitute over 70% of India's population [4]. These women face multiple risk factors, including early marriage, multiparity, poor nutritional status, limited contraceptive awareness, and inadequate access to screening programs. The challenge is compounded by limited health literacy, with only 66% of rural women having exposure to health information through media [5].

Cervical cancer is unique among malignancies due to its preventable nature through early detection and screening. The disease typically progresses through a spectrum of precancerous lesions, including cervical intraepithelial neoplasia (CIN), before developing into invasive carcinoma. This prolonged pre-invasive phase provides an opportunity for effective screening and intervention [6].

The Papanicolaou test (Pap test) has been the cornerstone of cervical cancer screening for decades. While it offers high specificity and is cost-effective, non-invasive, and easily implementable, its sensitivity for detecting CIN 2-3 lesions remains suboptimal, with high false-negative rates particularly in inflammatory conditions [7]. Although liquid-based cytology and HPV DNA co-testing can improve sensitivity, cost constraints limit their widespread adoption in resource-limited settings [8].

Colposcopy, an optical visualization technique of the lower genital tract, serves as a selective screening tool following abnormal cytology or clinical findings. Colposcopy-guided biopsy provides definitive histopathological diagnosis and has demonstrated superior accuracy in detecting precancerous lesions in single-visit protocols [9]. However, reported diagnostic precision varies widely, with sensitivity ranging from 29-100% and specificity from 12-88% across different studies [10].

Given the limited and inconclusive evidence from Eastern India, particularly in resource-constrained rural settings, there is a critical need to evaluate the comparative effectiveness of these screening modalities. In this backdrop, the present study aimed to compare the diagnostic utility of Pap smear and colposcopy in evaluating an unhealthy cervix in a tertiary care centre serving the Sundarban region of West Bengal. We hypothesize that colposcopy has higher diagnostic sensitivity than the Pap smear in detecting premalignant cervical lesions.

## Material and Methods

**Study design and population.** This was a hospital-based prospective observational study conducted over a period of 12 months from January 2023 to December 2023 in the Department of Gynaecology and Obstetrics, Diamond Harbour Government Medical College and Hospital, West Bengal. The study included women aged 21-50 years presenting with complaints indicative of an unhealthy cervix, such as vaginal discharge, menstrual disorders, something coming out of the vagina, post-coital bleeding, post-menopausal bleeding, and intermenstrual bleeding. Women not providing informed written consent, those with active vaginal bleeding at the time of examination, pregnant women, and those with frank invasive cervical cancer were excluded from the study.

**Operational definition.** "Unhealthy cervix" refers to the presence of abnormal features on clinical assessment, such as unusual growth patterns, ulceration, visible cervical inflammation or erosion, etc. [11].

**Sample size and sampling technique.** The sample size was calculated with reference to a prior study by Dasgupta et al. [11], which reported a 45.5% prevalence of unhealthy cervix among reproductive age women in West Bengal. Considering a 95% confidence level ( $Z = 1.96$ ) and 10% absolute error margin, the calculated minimum sample size was 96. Accounting for a 15% non-response rate, a total of 110 patients were included in the study. Consecutive sampling was employed to recruit eligible participants.

**Data collection tool and method.** Data were collected using a predesigned, pretested proforma encompassing:

1. **Demographic and clinical data:** Maternal age, socioeconomic status, religion, parity, age at first pregnancy, number of sexual partners, past history of sexually transmitted infections, long-term oral contraceptive use, and presenting complaints.
2. **Clinical examination procedures:** All participants underwent a comprehensive per speculum examination to assess cervical and vaginal conditions, including evaluation of inguinal and general lymphadenopathy, vulval infections, vaginal inflammation, discharge characteristics (color, odor, amount, type), cervical inflammation, and any growth or bleeding.
3. **Screening and diagnostic procedures:**
  - *Pap test:* Following speculum examination, cervical samples were obtained using Ayre's spatula (360° rotation) and endocervical brush (180° rotation). Specimens were immediately smeared on glass slides, fixed in 95% ethanol, and processed using standard cytological techniques. Results were reported according to the Bethesda system, with positive results defined as Low-grade Squamous Intraepithelial Lesion (LSIL), High-grade Squamous Intraepithelial Lesion (HSIL), carcinoma in situ, or invasive cancer.
  - *Colposcopy:* Colposcopic examination was performed using Divine Digital Video Colposcope (Model: Colpro222D) with initial visualization at 7.5x-10x magnification. Normal saline application with green filter assessment of vasculature was followed by 3-5% acetic acid application to identify acetowhite areas. Abnormal colposcopy was defined as the presence of acetowhite areas with abnormal vasculature or unsatisfactory examination in the presence of a positive Pap smear.
  - *Histopathological examination:* Colposcopy-guided biopsies were obtained from suspicious areas within the transformation zone and processed, followed by interpretation by two senior pathologists for definitive histopathological diagnosis. Cases with disagreement between observations underwent joint re-evaluation with discussion to reach consensus.

**Data entry and statistical analysis.** Data were organized in Microsoft Excel 2016 and analyzed using Statistical Package for Social Sciences (SPSS) version 23.0. Continuous variables were expressed as mean  $\pm$  standard deviation, while categorical variables were presented as frequencies and percentages. Independent sample T-test and Mann Whitney U test were used for continuous variables, while Chi-square test and Fisher's Exact test were employed for categorical variables. Considering histopathological biopsy results as the gold standard, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated for both Pap test and colposcopy. Agreement between Pap test and colposcopic impression was evaluated using Cohen's kappa statistic. Statistical significance was set at  $p < 0.05$ .

**Ethical considerations.** The study protocol was approved by the Ethics Committee of Diamond Harbour Government Medical College and Hospital (*videreference no.* DHGMC/2022/1640A dated 21.12.2022) prior to initiation of data collection. All participants were provided detailed information about the study purpose, and written informed consent was obtained in local languages (Bengali/Hindi). For illiterate participants, the consent form was read aloud, and thumb impressions were obtained in the presence of witnesses. The principles of confidentiality, autonomy, beneficence, non-maleficence, and

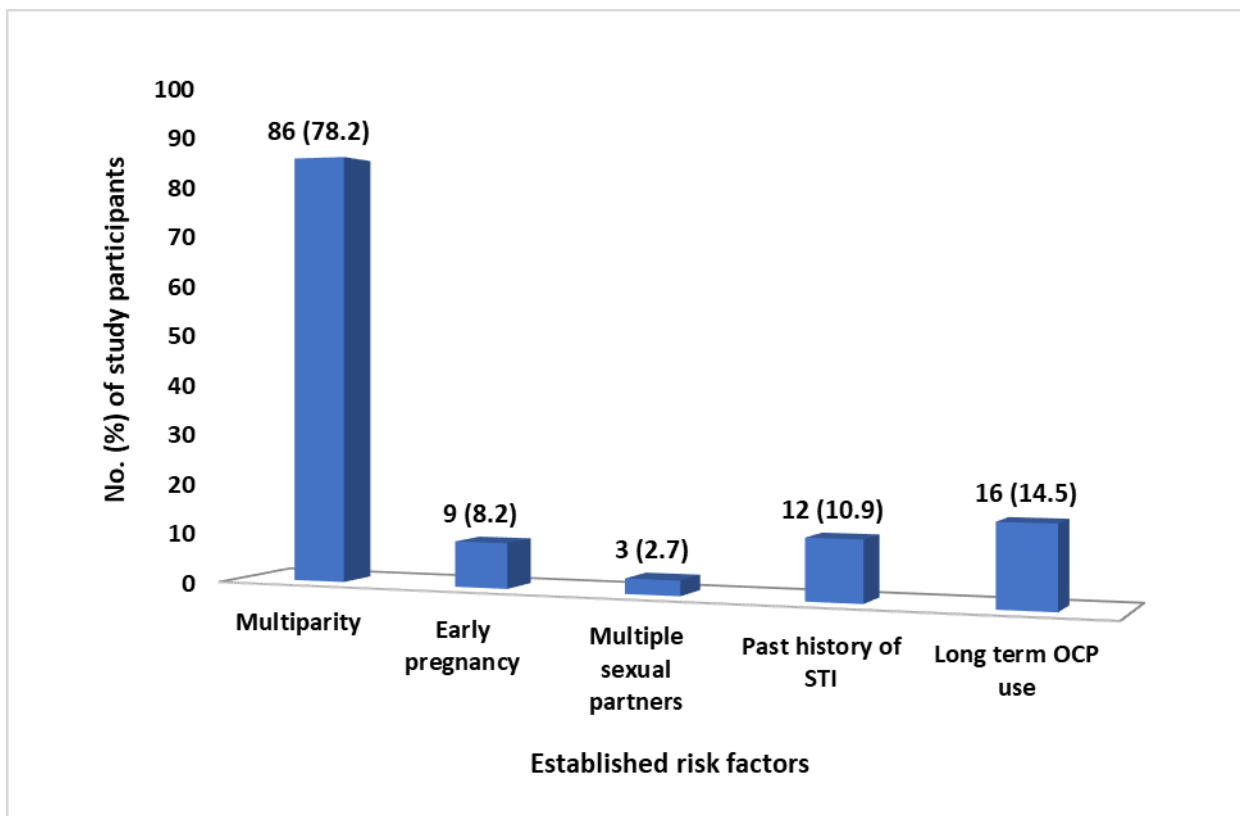
justice were strictly adhered to throughout the study. Participants received appropriate counselling regarding treatment and prevention, and any detected morbidities were managed according to standard protocols with referrals as necessary.

## Results

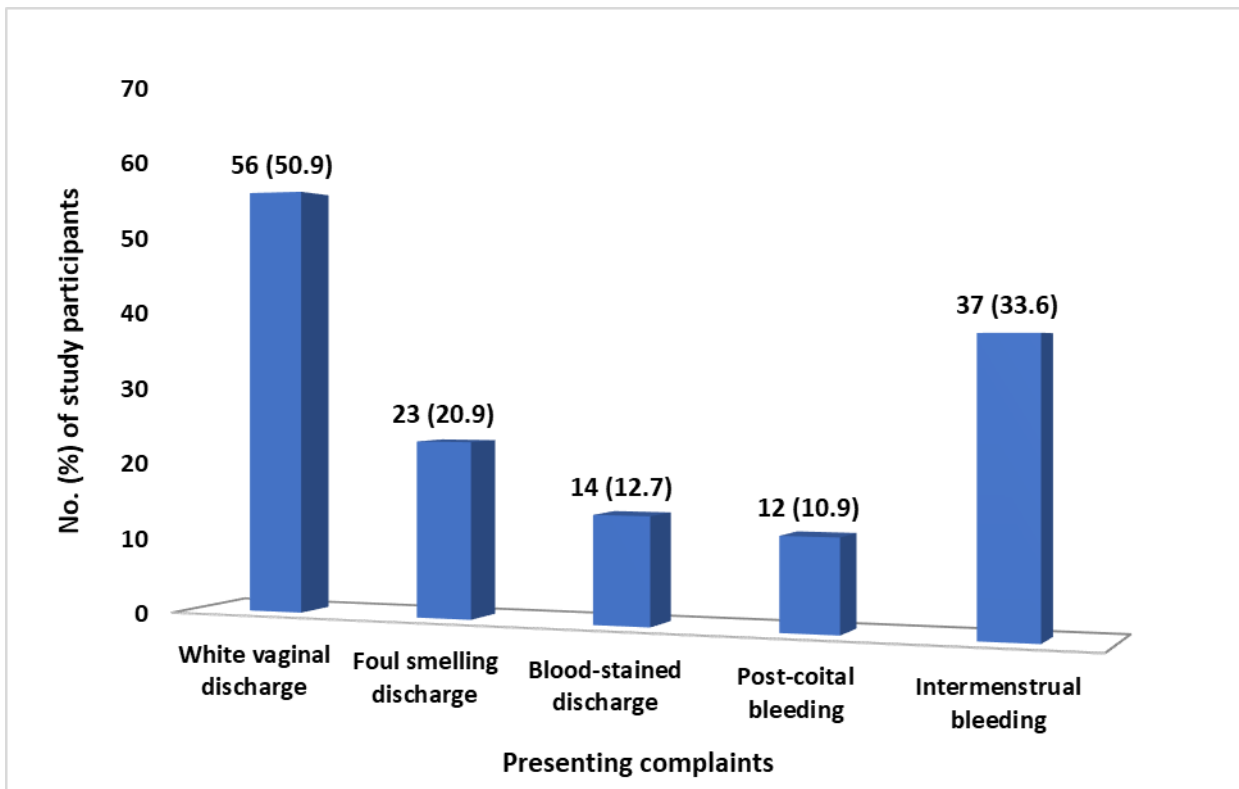
Final analysis was done on 110 patients who met the eligibility criteria. Out of them, the majority (41.8%) were aged between 31-40 years, followed by women in the age range of 21-30 years (36.4%). The mean ( $\pm$ SD) age of the study participants was 33.2 ( $\pm$  4.1) years, where the minimum age was 21 years, and the maximum age was 49 years. Most of the participants were from the middle class (54.5%) or lower middle class (27.3%). The proportion of Hindu patients was 44.5% and the remaining 55.5% were Muslim by religion.

The proportion of participants with some of the important established risk factors of an unhealthy cervix was evaluated. These were multiparity (78.2%), early pregnancy (8.2%), history of having multiple sexual partners (2.7%), past history of STI (10.9%) and OCP use for  $\geq$ 5 years (14.5%) (Figure 1).

**Figure 1: Established risk factors of an unhealthy cervix among the study participants (N=110)**



The most common presenting complaint was white vaginal discharge reported by 50.9% of the study participants. While 20.9% participants had foul-smelling discharge, 12.7% reported blood-stained vaginal discharge. The second most common presentation was intermenstrual bleeding (33.6%). Post-coital bleeding was reported by 12.7% of the study participants (Figure 2).

**Figure 2: Distribution of study participants according to presenting complaints (N=110)**

The result of the Pap test was considered positive if it revealed LSIL, HSIL, carcinoma in situ or invasive cancer. A total of 7 participants (6.4%) were found to have abnormal results on Pap smear examination. These included 3 cases with ASCUS (2.7%) and 2 cases each of L-SIL (1.8%) and H-SIL (1.8%) (Table 1).

**Table 1: Distribution of study participants according to Pap test findings (N=110)**

Pap test findings	Frequency	Percentage
Normal	28	25.4
Benign inflammation	75	68.2
ASCUS	3	2.7
L-SIL	2	1.8
H-SIL	2	1.8

The result of colposcopic examination was considered abnormal if it revealed acetowhite areas with abnormal vasculature or was reported as unsatisfactory in the presence of a positive Pap test. A total of 32 participants (29.1%) were found to have abnormal colposcopic features. These included 12 cases with unsatisfactory report (10.9%), 17 cases with hazy/ faint acetowhite lesions (15.5%), 2 cases of dense acetowhite areas (1.8%) and one case with an intense acetowhite area (0.9%) (Table 2).

**Table 2: Distribution of study participants according to colposcopy examination findings (N=110)**

Colposcopy findings	Frequency	Percentage
Normal	23	20.9
Inflammation/ erosion	53	48.2
Polyp	2	1.8
Unsatisfactory	12	10.9
Hazy/faint acetowhite areas	17	15.5
Dense acetowhite areas	2	1.8
Intense acetowhite lesion	1	0.9

Confirmation of premalignancy or malignancy was carried out by means of cervical biopsy, and there were 15 cases (13.6%) who were reported to have positive biopsy results. These included 7 cases with atypia (6.4%), 5 cases of CIN 1 (4.5%) and 1 case each of CIN 2 (0.9%), CIN 3 (0.9%) and invasive carcinoma (0.9%).

Among our study participants, the more frequently occurring non-malignant etiologies of vaginal discharge were cervical erosion (23.6%), physiological leucorrhoea (20%) and candidal vaginitis (15.5%). Invasive cervical carcinoma was diagnosed in 1 participant (0.9%), and premalignant conditions were noted in 14 cases (12.7%) (Table 3).

**Table 3: Final diagnosis based on clinical and biopsy results (N=110)**

Diagnosis	Frequency	Percentage
Physiological leucorrhoea	22	20.0
Non-specific vaginitis	7	6.4
Bacterial vaginosis	13	11.8
Candidal vaginitis	17	15.5
Cervical erosion	26	23.6
Chronic PID	8	7.3
Cervical polyp	2	1.8
Pre-malignant condition	14	12.7
Cervical carcinoma	1	0.9

Table 4 identifies the various factors associated with cervical premalignant and malignant conditions. As compared to those with biopsy negative for malignancy, a significantly higher proportion of patients with cervical premalignant and malignant conditions belonged to lower socioeconomic classes (73.3% vs 21.1%;  $p < 0.001$ ), had early pregnancy (26.7% vs 5.3%;  $p = 0.004$ ), reporting having multiple sexual partners (20% vs 0%;  $p = 0.002$ ), had a past history of STI (46.7% vs 5.3%;  $p < 0.001$ ) and reported long term OCP use (60% vs 7.4%;  $p < 0.001$ ). However, the mean age and proportion of multiparous women were statistically comparable between participants with biopsy-positive and biopsy-negative results.

**Table 4: Factors associated with cervical premalignant and malignant conditions (N=110)**

Characteristics	Total	Biopsy positive (N=15)	Biopsy negative (N=95)	p-value <sup>#</sup>
Age (years)	--	32.9 ± 3.9	33.1 ± 4.4	0.741
SES				
Class I, II, III	79	4 (26.7)	75 (78.9)	<0.001*
Class IV, V	31	11 (73.3)	20 (21.1)	
Multiparity				
Yes	86	12 (80.0)	74 (77.9)	0.854
No	24	3 (20.0)	21 (22.1)	
Early pregnancy				
Yes	9	4 (26.7)	5 (5.3)	0.004*
No	101	11 (73.3)	90 (94.7)	
Multiple sexual partners				
Yes	3	3 (20.0)	0 (0.0)	0.002*
No	107	12 (80.0)	95 (100.0)	
Past history of STI				
Yes	12	7 (46.7)	5 (5.3)	<0.001*
No	98	8 (53.3)	90 (94.7)	
Long-term OCP use				
Yes	16	9 (60.0)	7 (7.4)	<0.001*
No	85	6 (40.0)	88 (92.6)	

Values are presented as n (%) or mean ± SD; # Based on Chi-square test for categorical variables and Mann-Whitney U test for age; \*  $p < 0.05$  is considered statistically significant.

Among the study participants, for the diagnosis of cervical premalignant and malignant conditions, the Pap test showed a sensitivity of 33.3% (95% confidence interval [CI]: 11.8%–61.6%) and a specificity of 97.9% (95% CI: 92.6%–99.7%). The PPV was 71.4% (95% CI: 34.7%–92.2%) and the NPV was 90.3% (95% CI: 86.7%–93.0%). The overall diagnostic accuracy was 89.1% (95% CI 81.7%–94.2%). On the contrary, colposcopy had a sensitivity of 86.7% (95% CI 59.5%–98.3%) and a specificity of 80.0% (95%

CI 70.5%–87.5%). Its PPV was 40.6% (95% CI 30.4%–51.7%) and its NPV was 97.4% (95% CI 91.2%–99.3%). The diagnostic accuracy was 80.9% (95% CI 72.3%–87.8%) (Table 5).

**Table 5: Association of Pap test impression and colposcopy impression with biopsy results (N=110)**

Test	Impression	Total patients	Biopsy impression		p-value <sup>#</sup>
			Positive (n=15)	Negative (n=95)	
Pap test	<b>Positive</b>	7	5 (33.3)	2 (2.1)	<0.001*
	<b>Negative</b>	103	10 (66.7)	93 (97.9)	
Colposcopy	<b>Abnormal</b>	32	13 (86.7)	19 (20.0)	<0.001*
	<b>Normal</b>	78	2 (13.3)	76 (80.0)	

Values are presented as n (%); # Based on Chi-square test for categorical variables \* p<0.05 is considered statistically significant.

It was observed that although there was a significant association between colposcopy and PAP smear, the agreement was weak (Cohen's kappa = 0.284) (Table 6).

**Table 6: Agreement between PAP smear and colposcopy (N=110)**

Colposcopy impression	Total patients	PAP smear impression		Cohen's kappa	p-value <sup>#</sup>
		Positive	Negative		
Abnormal	32	7	25	0.284	<0.001*
Normal	78	0	78		
Total patients	60	7	103		

Values are presented as n (%); # Based on Kappa statistics for measure of agreement; \* p<0.05 is considered statistically significant.

## Discussion

The demographic profile of our study participants revealed that the majority (41.8%) were aged between 31-40 years, with a mean age of 33.2 ( $\pm$ 4.1) years. This pattern resembles findings from Venkatesh et al. [12] and Subramanyam et al. [13], who also noted the highest burden of cervical abnormalities in women in their thirties. This age distribution reflects the peak reproductive years when women are more likely to present with cervical pathology, possibly due to cumulative exposure to risk factors, including HPV infection and hormonal influences. The socioeconomic distribution showed predominance of middle class (54.5%) and lower middle class (27.3%) participants, which is representative of the patient population typically attending government tertiary care centres. The religious composition with 55.5% Muslim participants reflects the local demographic characteristics of the study area.

Among established risk factors, multiparity was highly prevalent (78.2%), consistent with literature associating multiple pregnancies and cervical trauma with increased risk of dysplasia [14]. Other high-risk behaviors, including multiple sexual partners (2.7%) and prior STIs (10.9%), were uncommon, possibly due to social stigma surrounding disclosure of these factors.

White vaginal discharge was the most common presenting complaint (50.9%), followed by intermenstrual bleeding (33.6%). These findings align with previous studies that consistently report vaginal discharge as the leading symptom among women with cervical pathology [12,13,15,16]. The high rate of discharge-related symptoms may reflect underlying inflammation or coexisting infections. Post-coital bleeding, reported by 12.7% of women, is clinically important because it may indicate advanced lesions or malignancy.

A central finding of this study concerns the diagnostic performance of Pap testing and colposcopy. The Pap test demonstrated low sensitivity (33.3%) despite high specificity (97.9%). Similar low sensitivities were previously reported by Subramanyam et al. [13] (29.4%) and Savitha et al. [17] (50%). Factors contributing to poor sensitivity include inflammatory smears obscuring atypical cells, sampling limitations, fixation problems, and interpretive subjectivity. These challenges are particularly relevant in resource-limited settings where high workloads and limited training may further affect reliability.

Colposcopy showed substantially higher sensitivity (86.7%) with moderate specificity (80%). These results align with studies by Prasad et al. [18] (83.3% sensitivity, 72.2% specificity) and Oğlak et al. [19] (85.7% sensitivity, 76.2% specificity). The higher sensitivity supports its value in settings where identifying true positives is a priority. However, colposcopy is known to be operator dependent, and performance varies with training and experience. Prior research has noted that agreement between colposcopic impressions and histopathology ranges from 52% to 66% [22], underscoring the need for ongoing skill development [23].

Biopsy, the diagnostic gold standard, confirmed premalignant and malignant lesions in 13.6% of study participants, including one case of invasive carcinoma (0.9%). Most abnormalities were low grade, with atypia (6.4%) and CIN 1 (4.5%) more common than CIN 2 or CIN 3 (each 0.9%). This distribution is typical of screening populations where mild lesions predominate and often regress spontaneously.

Several risk factors demonstrated significant associations with cervical premalignant and malignant conditions. Lower socioeconomic status had the strongest association (73.3% vs 21.1%;  $p < 0.001$ ), consistent with evidence that economic disadvantage is linked to poor hygiene practices, delayed health-seeking behavior, and higher infection burdens [20]. Early pregnancy (26.7% vs 5.3%;  $p = 0.004$ ) reflects longer duration of sexual activity and sustained HPV exposure. The associations with multiple sexual partners (20% vs 0%;  $p = 0.002$ ) and prior STI (46.7% vs 5.3%;  $p < 0.001$ ) reinforce the established role of sexually transmitted HPV in cervical carcinogenesis. Long-term oral contraceptive use ( $\geq 5$  years) was also strongly associated (60% vs 7.4%,  $p < 0.001$ ), and recent reviews indicate increased risk of cervical cancer with prolonged OCP use, particularly for adenocarcinoma [21].

A key addition to this study is the evaluation of test concordance. Although Pap testing and colposcopy were significantly associated, their agreement was weak (Cohen's kappa = 0.284). This indicates that the tests often classify women differently and detect only partially overlapping subsets of abnormalities. The weak concordance underscores that the two methods serve complementary roles rather than interchangeable ones. In symptomatic populations, this finding helps explain why relying on Pap testing alone may miss clinically important disease.

Placing these findings in the global context is important. WHO 2021 global screening guidance recommends HPV-based testing as the preferred primary strategy because of its high sensitivity and longer rescreening intervals. Many low-resource settings, however, continue to rely on cytology or colposcopy for symptomatic evaluation because HPV testing is either unavailable or limited to pilot programs. The current study adds evidence relevant to these settings by comparing two commonly available diagnostic tools and highlighting their respective strengths and limitations when used in symptomatic women. The low sensitivity of Pap testing in this context raises concern about relying on cytology alone for symptomatic patients. Higher sensitivity of colposcopy supports its use as a primary evaluation tool in this group. While the results suggest that using Pap testing and colposcopy together

may enhance case detection, such recommendations must be made cautiously. Colposcopy requires trained providers, functional equipment and time for detailed evaluation, all of which may limit scalability [22,23]. In many facilities, colposcopy is more feasible as a triage tool rather than part of universal dual-test strategies. Any combined approach should therefore be tailored to capacity and implemented only where resources and staffing allow.

Overall, this study provides insight into how Pap testing and colposcopy perform in a real-world symptomatic, hospital-based population. The findings highlight the importance of improving diagnostic pathways and ensuring appropriate use of available tools while also acknowledging the longer-term need to expand access to HPV-based screening consistent with WHO guidance.

### **Limitations of the study**

The present study has some important limitations that warrant consideration when interpreting the results. Because the work was carried out in a single government tertiary hospital, the results may not apply to other settings, particularly private healthcare facilities or primary care centres where patient demographics and disease patterns may differ significantly. The sample was drawn from women who were already symptomatic and seeking care, which means the group does not reflect the broader population targeted in routine screening programs. This hospital-based approach potentially overestimates the prevalence of cervical abnormalities compared with what would be seen in community or primary care settings. The sample size of 110 participants, although reasonable for the study period, also restricts the ability to detect smaller differences in test performance or to examine less common risk factors. Additionally, our research focused on PAP smear and colposcopy; the prospect of other potentially viable population-based screening alternatives such as visual inspection with acetic acid (VIA) or HPV-based testing, which might be more feasible and cost-effective in resource-limited settings, were not explored.

### **Conclusion**

This study shows that colposcopy performs better than Pap testing in identifying cervical premalignant and malignant lesions in symptomatic women, with higher sensitivity. Despite higher specificity of Pap test, its poor sensitivity limits its effectiveness as a standalone screening tool in this population. Cervical pathology was strongly associated with lower socioeconomic status, early pregnancy, multiple sexual partners, STI history, and prolonged OCP use. While using both tests in the same visit may improve detection, this approach should be considered carefully in resource-constrained settings where colposcopy availability is limited. Strengthening pathways for symptom-based evaluation, including appropriate use of colposcopy and the gradual integration of HPV-based testing in line with WHO 2021 guidelines, may offer a more feasible long-term strategy.

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