

ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF PATHOLOGY

Correlation of Pap Smear Cytology with Histopathology in the Detection of High-Grade Cervical Lesions: A Multicenter Retrospective Study in Addis Ababa, Ethiopia

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The thesis submitted to the Department of Pathology, College of Health Science, Addis Ababa University, in partial fulfillment of the requirements for the Specialty Diploma in Pathology.

February, 2026

Addis Ababa, Ethiopia

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Declaration

I, Dr. Isa Salo Abdo, hereby declare that the research thesis entitled **"Correlation of Pap Smear Cytology with Histopathology in the Detection of High-Grade Cervical Lesions: A Multicenter Retrospective Study in Addis Ababa, Ethiopia"** is my original work and has been prepared in accordance with the academic and ethical guidelines of Tikur Anbessa Specialized Hospital (TASH). I undertook this work under the guidance of my advisors, Dr. Nejat Ahmed, Dr. Yonas Girma, and Dr. Wajana Lako. To the best of my knowledge, this thesis has not been submitted in whole or in part to any other institution for any other academic qualification.

I further affirm that all sources of information, data, and ideas used in the preparation of this thesis have been duly acknowledged and referenced. I also confirm that ethical approval was obtained prior to the commencement of the study and that all necessary ethical standards, including patient confidentiality and, where applicable, informed consent, were strictly observed.

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Acronyms and abbreviations

AAU: Addis Ababa University
CHS: College of Health Sciences

TASH: Tikur Anbessa Specialized Hospital

ZMH: Zewditu Memorial Hospital

FGAE: Family Guidance Association of Ethiopia

WHO: World Health Organization

Pap: Papanicolaou test

HPV: Human papillomavirus

HIV: Human Immune Deficiency Virus

CIN: Cervical intraepithelial neoplasia

MRN: Medical Record Number

Dx: Diagnosis

SCJ: Squamocolumnar junction

Abstract

Background: Cervical cancer is a major global health problems, particularly in low- and middle-income countries due to suboptimal screening programs. The Papanicolaou test is a widely used screening test for the early detection of premalignant and malignant cervical lesions; however, histopathology remains the gold standard for diagnosis. The correlation between Pap smear cytology and histology reflects the effectiveness and reliability of screening programs.

Objective: To assess the diagnostic correlation between abnormal Pap smear cytology and biopsy for the detection of high-grade cervical lesions among women who underwent both Pap smear and biopsy.

Methods: A retrospective cross-sectional study was performed among 144 women who underwent both Pap smear and cervical biopsy at three study sites. The Pap smear results were categorized according to the Bethesda System for Cervical Cytology,whereas histopathological findings were categorized according to the WHO CIN grading system. The concordance rates of Pap smears with histologic findings were calculated for each cytologic category. The diagnostic performance of the Pap smear was evaluated by calculating its sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), chi-square test, and receiver operating characteristic (ROC) curve.

Results: The mean age of the study participants was 51.4 years. ASCUS (36.8%) was the most common cytological finding, followed by HSIL (36.1%) and ASC-H (15.3%). On the other hand, histopathologic examination revealed that 50 (34.7%) patients had high-grade lesions (≥CIN II) and 94 (65.3%) had benign or low-grade findings (<CIN II). Squamous cell carcinoma was the most frequent biopsy diagnosis (25%) among high-grade lesions. Age was significantly associated with biopsy results ($p = 0.041$), with the prevalence of high-grade lesions increasing with advancing age. The overall cytohistological concordance rate was 55.6%; however, the diagnostic accuracy varied significantly among the classifications, highlighted by a 67.3% concordance for HSILs. The Pap smear demonstrated a sensitivity of 80%, specificity of 63.8%, positive predictive value of 54.1%, and negative predictive value of 85.7% when biopsy was used as the gold standard. The ROC curve showed that the Pap smear test had an area under the curve (AUC) of 0.819 (95% CI, 0.632 to 0.906; $P < 0.001$), indicating that the test had good diagnostic accuracy.

Conclusion: The current study revealed that Pap smear have high sensitivity for detecting high-grade cervical lesions. Although the Pap smear is not an alternative to histopathological examination, its high sensitivity and discriminative ability, as shown by an AUC of 0.819, make it a strong screening method in our clinical setting.

Keywords: Pap smear, Cervical intraepithelial lesion, Sensitivity and Specificity, Ethiopia

1. Introduction

1 .1 Background

Cervical cancer is a major global public health problem. Despite being largely preventable, it remains the fourth most commonly diagnosed cancer among women (1,2). According to the WHO, over 600,000 new cases and 340,000 deaths were reported in 2020. The burden of cervical cancer is unevenly distributed, with approximately 90% of deaths occurring in low- and middle-income countries (LMICs). This is mainly due to the region's limited screening and vaccination coverage.

Sub-Saharan Africa has the highest burden, with 19 of the 20 countries with the highest-incidence in this region (3). The main reason is the interplay between HPVinfection and other risk factors, such as HIV, which contributes significantly to the high incidence in Africa (4,5).

In Ethiopia, cervical cancer is the second leading cause of cancer-related deathamong reproductive-aged women, next to breast cancer. In 2020, 7,445 new cases and 5,338 deaths were reported (6,7). Despite the introduction of HPV vaccination in 2018 and efforts to expand screening, uptake remains far below the WHO elimination targets (8). Public awareness about cervical cancer, its risk factors, and available preventive services also remains limited. These factors further delay early detection.

The Papanicolaou (Pap) smear is a highly effective and cost-effective screening tool for identifying premalignant and malignant cervical lesions. It remains the most successful cancer prevention program to date. While the cytological approach plays a crucial role in initial screenings, its accuracy can be influenced by various factors. Therefore, histopathology (biopsy) remains the definitive method for accurately diagnosing cervical lesions.

Understanding the correlation between this screening method (Pap smear) and biopsy is essential for determining how reliably Pap smears can be used as screening tools to avoid the risk of under- or overdiagnosis. This research investigated the correlation between Pap smear cytology and biopsy for detecting cervical lesions at Tikur Anbessa Specialized Hospital (TASH), Zewditu Memorial Hospital (ZMH), and the Ethiopian Family Guidance Association (FGAE),where both services are available.

1.2 Statement of the Problem

Cervical cancer ispreventable through vaccination and early detection. Accurate, reliable screening and diagnostic pathways are essential for detecting cervical precancer and early invasive disease and preventing needless morbidity and death. The remarkable success of cervical cancer control in high-income nations is attributable mainly to organized screening programs (9).

However, cervical cancer remains a significant public health challenge in Ethiopia, which leads to high incidence and mortality rates annually. One of the main reasons is that the percentage of cervical cancer screenings among eligible women was much lower than the WHO recommendations (9). Furthermore, factors such as a poor referral system and diagnostic delays in health facilities often result in late-stage diagnosis and treatment initiation.

The Pap smear remains one of the most widely used screening tests worldwide. It allows for the identification of precancerous lesions before they progress to invasive cancer. However, cytological screening has certain limitations. These include the dependence on sampling adequacy and interobserver variability in interpretation (10,11). Histopathological examination of biopsy samples remains the gold standard for definitive diagnosis. However, a biopsy is more invasive, costly, and not always feasible in low-resource settings.

In Ethiopia, the Pap smear screening program is still developing, and its correlation with biopsy results has not been well studied.

1. 3 Significance of the Study

This study provides critical, locally derived evidence on the diagnostic accuracy of cervical Pap smears compared with histopathology in the Ethiopian context. Through an examination of the data from three key institutions in Addis Ababa, Tikur Anbesa Specialized Hospital, Zewditu Memorial Hospital, and the Family Guidance Association of Ethiopia, this study can provide clinicians with useful information on the general correlation of results from a Pap smear and histopathological examination in a resource-limited setting. In addition, it will identify the cytological categories that show higher concordance with biopsy findings as well as those with lower concordance. This allows clinicians to interpret screening results more effectively, reducing the risks of both overcalling and missed diagnoses. Furthermore, establishing the

reliability of the Pap smear will provide evidence supporting its role as a frontline screening method that is less invasive and more cost-effective for large-scale cervical cancer screening programs. Finally, the information revealed by this study could also help future researchers investigate the factors that contribute to the discordance between Pap smear and biopsy results.

2. Literature review

Cervical cancer continues to pose a significant global health challenge, especially in developing countries such as Ethiopia, where screening programs have yet to reach their full potential (12). Pap smear cytology is considered one of the most effective screening techniques for detecting cervical lesions. This is due to its ability to detect premalignant and malignant cervical lesions by detecting abnormal epithelial cellular changes long before the onset of invasive carcinoma. Biopsy serves as the diagnostic gold standard for confirming abnormal cytological findings. The correlation between Pap smear cytology and biopsy reflects the reliability of cytology as a screening tool (13) for detecting these lesions. Theoretically, perfect correlation is expected when cytology accurately captures the true disease status. However, numerous factors, ranging from sample collection and processing to human interpretation, may introduce discordance between these two methods.

The interpretation of Pap smears is standardized via the Bethesda System, which categorizes findings into negative for intraepithelial lesion or malignancy (NILM), atypical squamous cells of undetermined significance (ASC-US), low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), and squamous cell carcinoma (SCC) (13). Moreover, biopsy results are classified via the WHO cervical intraepithelial neoplasia (CIN) grading system (14).

Researchers have predominantly assessed correlations via using cross-sectional or retrospective studies, compared paired Pap and biopsy results, and analyzing sensitivity, specificity, positive predictive value (PPV), and negative Predictive Value (NPV)tests to determine significance (15,16).

Although the Pap smear is a screening tool proven to be useful for reducing incidence and mortality of cervical cancer, it is not a definitive diagnostic test. It has well-documented limitations, including susceptibility to sampling errors (missing the lesion), preparation artifacts,

and interpretative variability (17). Therefore, histopathological examination of a cervicalbiopsy, obtained under colposcopy guidance, is considered thegold standard for the definitive diagnosis of cervical intraepithelial neoplasia (CIN) and invasive carcinoma (18). The central methodological problem lies in the concordance between the initial cytological screening (Pap smear) and the final histological diagnosis (biopsy). A high degree of correlation validates the screening program's effectiveness, whereas a significant discordance may indicate issues with sensitivity, specificity, or the clinical management pathway.

Globally, several studies across diverse geographical and healthcare settings have established variable concordance rates between Pap smear cytology and biopsy findings.

A study from India on 120 patients in 2025 reported that the overall concordance rate between cytology and histology was 81%. The sensitivity and specificity of Pap smears for detecting high-grade lesions (CIN II or higher) were 88.2% and 76.4%, respectively. The positive predictive value was 84.3%, and the negative predictive value was 80.5% (12). A study from Nigeria (2020) involving 100 patients reported that the sensitivity of cytology was 34.6%, and the specificity was 94.7%. The accuracy of cytology was 46%, whereas that of colposcopy was 93% (19). A study from Korea (2018) comparing abnormal cytology and histology revealed that the pooled sensitivity and specificity were 93.9% (95% confidence interval [CI], 93.7%–94.1%) and 77.6% (95% CI, 77.4–77.8%), respectively (15).A similar study performed in Nepal (2016) revealed that, compared with those of biopsy, the sensitivity, specificity, positive predictive value (PPV), and negative predictive value of Pap smears were 77.80%, 100%, 100%, and 97%, respectively(20). Another study in Turkey (2015) reported that the sensitivity, specificity, PPD, and NDP of smears were 57%, 76%, 26%, and 92%,respectively (17). The correlation between abnormal cytology and histopathology results was statistically significant (r=0.273, p=0.000) (6). One study from Iraq (2015) reported that the overall accuracy was 86.36%. Sensitivity: 89.39%, specificity: 84.12%, PPV: 80.79%, NPV: 91.37% (21). Another study (2014) in Serbia reported a significant association between cytology and biopsy, with a sensitivity of 87.3%, specificity of 96.86%, PPV of 63.95%, NPV of 99.17%, and overall accuracy of 96.28% (6). A systematic review and meta-analysis published in 2023, which compared the performance of screening tools for cervical neoplasia, revealed a pooled estimate for Pap smear sensitivity of 60.2% and specificity of 97.4% (22).

Although the concordance rates of these two diagnostic methods are welldocumented in high-resource settings worldwide, the generalizability of these findings is severely limited in low- and middle-income countries such as Ethiopia. A comprehensive review ofthe current literature reveals that no published studieshave specifically investigated the concordance between Pap smear cytology and subsequent histological biopsy in Ethiopia.

While general trends are consistent, the exact concordance rates, sensitivity, and specificity of Pap smears vary considerably between studies from different countries as described above. The reasons for this variability are not fully standardized and require localized audit and quality control.

The integration of liquid-based Cytology (LBC) and HPV DNA testing has been shown to improve screening accuracy (1). However, their cost-effectiveness, optimal implementation algorithms, and impact on cytology-histology concordance in low-resource settings, such as Ethiopia, are not yet fully established and require further context-specific research.

In conclusion, the literature confirms a substantiated but variable correlation between Pap smear cytology and cervical biopsy. This highlights the necessity of histopathological confirmation for abnormal screening results and highlights the need for continuous quality assurance and context-specific evaluation of screening programs, especially in resource-limited settings.

3. Objective of the study

3.1. General objective of the study

To assess the diagnostic correlation between abnormal Pap smear cytology and biopsy for the detection of high-gradecervical lesions among women who underwent both Pap smear andbiopsy at Tikur Anbessa Specialized Hospital, Ethiopian Family Guidance Association,andZewditu Memorial Hospital, Addis Ababa, Ethiopia.

3.2. Specific objective of the study

Classify the Pap smear result based on the Bethesda category and the biopsy result based on CIN classification.

Assess concordance rates within each cytologic category (ASC-US, LSIL, HSIL) by comparing Pap smear results to the corresponding biopsy diagnoses (CIN).

To describe patterns of discordance (e.g., cytology undercalls or overcalls) and related clinical/demographic predictors (age, HIV status).

4. Materials and Methods

4.1 Study area

This study was conducted at the Addis Ababa UniversityDepartment of Pathology Tikure Anbesa Specialized Hospital, Family Guidance Association of Ethiopia and Zewditu Memorial Hospital, Addis Ababa, Ethiopia.

4.2 Study design and period

This was a hospital-basedretrospectivecross-sectional study. The study period was from September 2024 to December 2025.

4.3. Source population

All women who underwent screening for Pap cytology in the selected study areas served asthe source population for this study.

4.4. Study population

All womenwho had a Pap smear and subsequently underwentbiopsy during the study periodfulfilled the inclusion criteria.

4.5. Inclusion criteria

All women who had both a Pap smear cytology and subsequently underwent biopsy at the selected study sites during the study period.All women whose medical/hospital recordswere complete for the required data were included in this study

4.6. Exclusion criteria

All women who undergo only Pap smear,not a biopsy.

All women who had a history of cervical cancer and had undergone a hysterectomy.

4.7. Sample size determination

All patients who underwent both Pap smear cytology and biopsy were included in the study.

4.8. Sampling technique

Initially, the medical records of patients who underwent Pap smear cytology were reviewed. Patients meeting the predefined inclusion criteria were subsequently selected, and their records were organized for data extraction.

4.9. Data collection and tools

Data were collected via a structured checklist (see Annex I). A checklist was used to systematically extract information from eligible women's medical records (I Care system and the pathology department reporting app). A checklist was used to gather information in the following three key areas:

Sociodemographic and Clinical Characteristics**:** This section contains variables such as patient ageand relevant medical history (e.g., HIV status), which may influence cervical pathology.

Pap smear cytology results**:** Data regarding the Pap smear findings were extracted from the original cytology reports. All cytological diagnoses recorded and classified according to the Bethesda System (2014) for reporting cervical cytology (2). These categories include the following:negative for intraepithelial lesion or malignancy (NILM), atypical squamous cells of undetermined significance (ASC-US), atypical squamous cellscannot exclude HSIL (ASC-H), low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), squamous cell carcinoma (SCC), atypical glandular cells (AGC), and other relevant diagnoses.

Histopathological results: Data from the histopathology reports of the biopsies were extracted. The biopsy results were recorded and classified on basis of the World Health Organization (WHO) classification of cervical intraepithelial neoplasia (3). The categories includedchronic cervicitis, cervical intraepithelial neoplasia grade 1 (CIN 1), cervical intraepithelial neoplasia grade 2 (CIN 2), cervical intraepithelial neoplasia grade 3 (CIN 3), squamous cell carcinoma in situ, squamous cell carcinoma, adenocarcinoma in situ (AIS), and other relevant diagnoses.

Table 1: Bethesda System for reporting cervical cytology and WHO classification of CIN

category

Bethesda System for reporting cervical cytology Categories		WHO classification of cervical intraepithelial neoplasia (CIN's)
Negative for Intraepithelial Lesion or Malignancy (NILM)		Chronic cervicitis
Atypical Squamous Cells of Undetermined Significance (ASC-US), Atypical Squamous Cells, cannot exclude HSIL (ASC-H)		Cervical Intraepithelial Neoplasia Grade 1 (CIN 1)
Low-grade Squamous Intraepithelial Lesion (LSIL)		Cervical Intraepithelial Neoplasia Grade 2 (CIN 2)
High-grade Squamous Intraepithelial Lesion (HSIL)		Cervical Intraepithelial Neoplasia Grade 3 (CIN 3)
Squamous Cell Carcinoma (SCC)		Squamous Cell Carcinoma
		Squamous cell carcinoma in situ
Atypical Glandular Cells (AGC) and other relevant diagnoses.		Adenocarcinoma in situ (AIS) and other relevant diagnoses.

4.10. Study variables

4.10.1. Dependent variable

The dependent variable in this study is the histopathological diagnosis obtained from cervical biopsy, which serves as the gold standard against which the Pap smear results are compared. The histopathological diagnostic categories included chronic cervicitis, CIN1,CIN2, CIN3, SCC, and adenocarcinoma in situ.

4.10.2. Independent variables

The Pap smear cytology result was the primary independent variable. The categories include NILM, ASC-US, ASC-H, LSIL, HSIL, carcinoma in situ, and SCC. Other independent variables include age and HIV status.

4.11. Operational definition

Correlation: If the Pap smear result based on the Bethesda system matches the complementary biopsy result based on WHO cervical intraepithelial lesion grading for the same case, the two systems are said to be correlated for that patient.

To calculate the diagnostic performance of Pap smears for high-grade lesions, we used the following cutoff value: a positive Pap smear was defined as ASC-H or HSIL, similarly for biopsy results a high-grade lesion (positive for lesion) was defined as CIN II or worse.

To evaluate the diagnostic performance of cervical cytology for high-grade cervical lesions specific thresholds were established. A positive Pap smear is operationally defined as a finding of ASC-H or HSIL. Correspondingly, a positive histopathology (biopsy) resultswere defined asCIN II or worse.

Table 2: Pap smearcategories and their corresponding biopsycategories

Pap Smear Findings	Histopathology Diagnosis Considered as Concordant
ASC-US	CIN I / CIN II / CIN III
ASC-H	CIN II / CIN III
LSIL	CIN I/LSIL
HSIL	CIN II / CIN III (HSIL, SCC in situ, SCC)
Abbreviations: ASCUS=atypical squamous cells of undetermined significance, CIN=cervical intraepithelial neoplasia, HSIL=high-grade squamous intraepithelial lesion, LSIL=low-grade squamous intraepithelial lesion, SCC=squamous cell carcinoma	

4.12. Data Processing and Analysis

After data collection, all the information was entered into the Kobo Toolboxto ensure accuracy. Descriptive statistics, such as percentages and frequencies, were used to summarize the data. The relationship between the biopsy results and the Pap smear results was evaluated. To do this, a contingency table was created, with histopathological diagnoses in the columns and Pap smear diagnoses in the rows.

Additionally, the area under the receiver operating characteristic (ROC) curve (AUC) was used to assess diagnostic accuracy of the Pap smears. Biopsy was used as the gold standard in our setup to calculate sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). The outcome is deemed statistically significant if the p-value is less than 0.05. SPSS software was used for all the statistical analyses.

4.13. Ethical considerations

Ethical clearance was approved by the Institutional Review Board of the College of Health Science, Addis Ababa University, and the Pathology Department at TASH. Confidentiality was maintained by keeping information anonymous and ensuring that it was not available to anyone other than the researcher.

4.14. Result dissemination plan

The results of this study will be presented to the Department of Pathology, Addis Ababa University. A copy of the study publication will be distributed to the Addis Ababa University central campus library archive. It will also be submitted for medical journals in the future for possible publication.

5. Results

5.1 Demographic characteristics of patients who underwent both Pap smear and punch biopsy

A total of 144 patients who underwent both Pap smear and punch biopsy were included in the analysis. Nearly half of the patients, 69 (47.9%), were from Tikur Anbessa Specialized Hospital (TASH), 43 (29.9%) were from Zewditu Memorial Hospital (ZMH) and 32 (22.2%) were from the Family Guidance Association of Ethiopia (FGAE). The mean age of the patients was 51.4 years (SD = 10.78). The largest proportion of patients (32.6%) were in the 50–59 years age group, followed by 26.4% in the 40–49 years age group and 24.3% in the 60 years or older age group. With respect to HIV status, 58.3% of the patients were HIV negative, 32.6% were HIV positive, and 9.0% had not been tested (Table 3).

Table 3. Demographic characteristics ofpatients who underwent both Pap smear and punch biopsy

Variable	frequency	Percent
Institution		
TASH	69	47.9
Family guidance	32	22.2
ZMH	43	29.9
Age in years		
20-29	2	1.4
30-39	22	15.3
40-49	38	26.4
50-59	47	32.6
>=60	35	24.3
HIV status		
negative	84	58.4
Positive	47	32.6
Not tested	13	9

5.2 Pap smear results of the study participants

Regarding Pap smear results, the majority of patients had findings reported as atypical or intraepithelial lesions. Among the144 patients, 132 (91.7%) had results categorized as ASCUS or higher, whereas 12 (8.3%) were categorized as NILM.

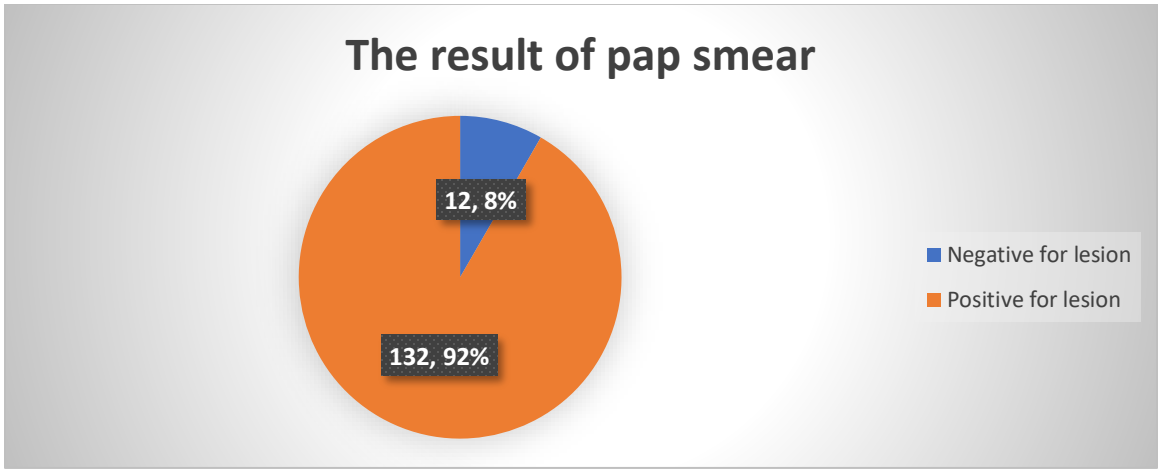


Figure 1. Pap smear results of the cervical lesion.

5.3 List of Pap smear impressions

The distribution of Pap smear results revealed that ASCUS was the most common finding, accounting for 53 cases (36.8%), followed by HSIL, which was identified in 52 patients (36.1%). ASC-H was reported in 22 patients (15.3%). A smaller proportion of patients had NILM and LSIL.

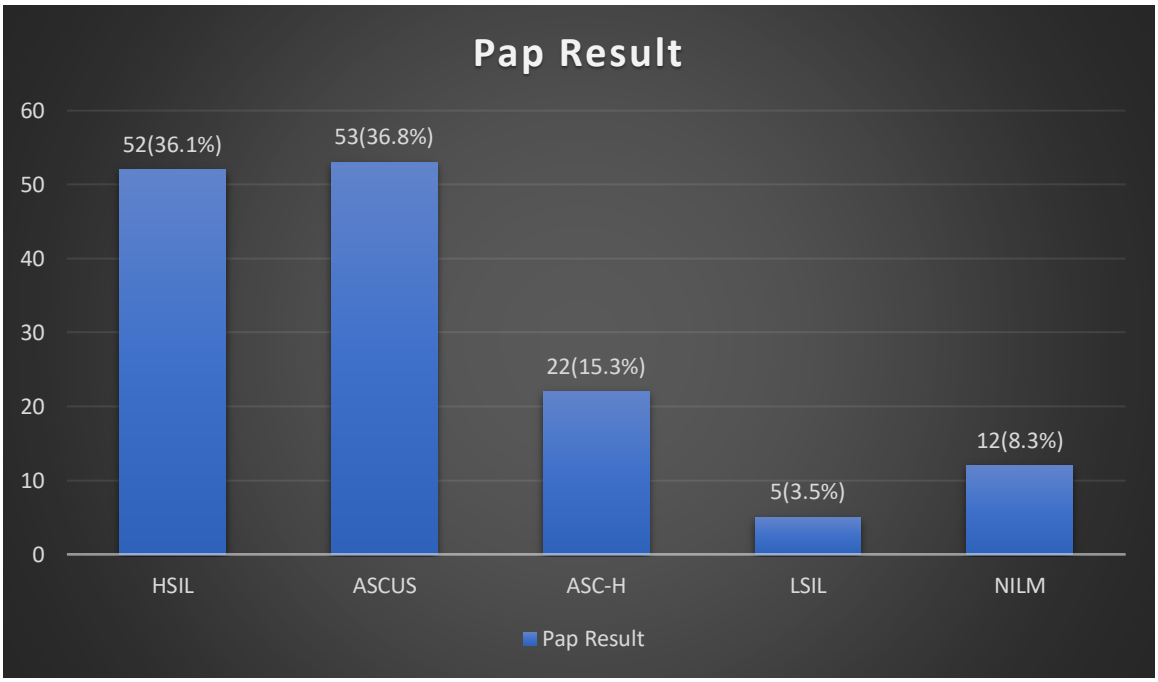


Figure 2. List of the Pap smear impressions

5.4 The general result of biopsy

Histopathological analysis revealed that 35% of patients had high-grade lesions (defined as ≥ CIN II), whereas 65% were diagnosed with benign or low-grade findings (< CIN II).

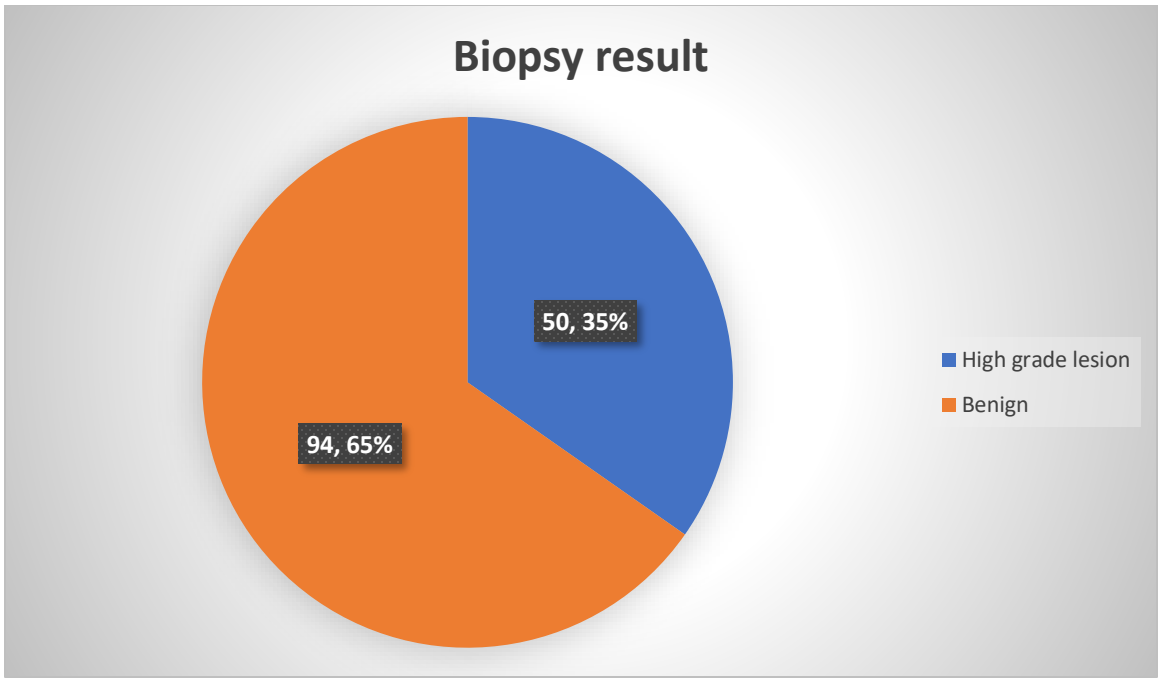


Figure 3. The biopsy result of the cervical lesion

5.5 The list of specific biopsy results

The distribution of biopsy results revealed that squamous cell carcinoma was the most common finding, accounting for 36 cases (25%), followed closelyby LSIL, which was identified in 27patients (18.8%). Chronic cervicitis was reported in 21 patients (14.6%).

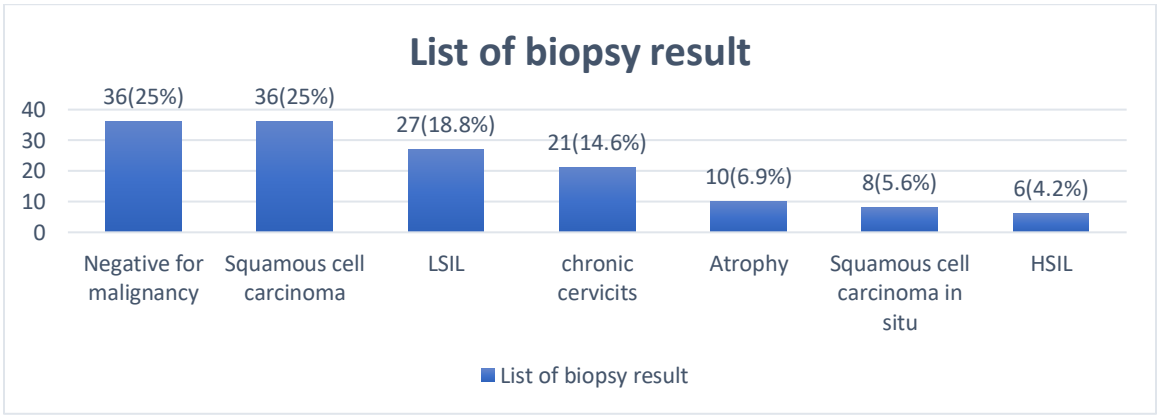


Figure 4. The list of biopsy results among cervical lesions

5.6 Biopsy finding results by type

Among the 94patients with benign biopsy results, 38.3% were reported as negative for malignancy. Chronic cervicitis accounted for 22.3%, of the cases, whereas 10.6% showed atrophic changes. Among the 50 patients with high-gradelesionbiopsy findings, squamous cell

carcinoma was the most common diagnosis, accounting for 72% of the cases. Squamous cell carcinoma in situ accounted for 16%, while HSIL accounted for 12% of high-grade cases.

Table 4. The biopsy findings by type

Category	Finding	Frequency	Percent
Benign (n=94) (< CIN II)	Negative For Malignancy	36	38.3
	LSIL	27	28.7
	Chronic cervicitis	21	22.3
	Atrophy	10	10.6
Highgrade lesion(n=50) (≥ CIN II))	Squamous cell carcinoma	36	72
	Squamous cell carcinoma in situ	8	16
	HSIL	6	12

5.7 Relations between patient characteristics and biopsy results

The associations between the selected variables and biopsy results revealed that age was significantly associated with histopathological outcome ($\chi^2 = 9.42$, $p = 0.041$). High-grade lesionsincrease with advancing age. The patientsaged 20–29 years (only 2 patients)both had benign biopsy results. In the 30–39 year age group, 90.9% had benign findings 9.1% had high-grade lesions. Conversely, the prevalence of high-grade lesions increased significantly with age, accounting for 42.1% of patients aged 40–49, 61.7% of those aged 50–59, and 60.0% of those aged 60 and older.

In contrast, HIV status was not significantly associated with biopsy results ($\chi^2 = 0.194$, $p = 0.907$). Among the HIV-negative patients, 66.7% had benign findings, and 33.3% had high-grade lesion findings. Among the HIV-positive patients, 63.8% had high-grade lesions and 36.2% had benign results (Table 5).

Table 5. Relationships between patient characteristics andbiopsy results

Variable	Biopsy result		Chi square (p-value
	benign	High grade lesion	
Age in years			
20-29	2(100)	0	9.42(0.041)
30-39	20(90.9)	2(9.1)	
40-49	22(57.9)	16(42.1)	
50-59	30(63.8)	29(61.7)	
>=60	14(40)	17(36.2)	
HIV status			
negative	56(66.7)	28(33.3)	0.195(0.907)

Positive	30(63.8)	17(36.2)	
Not tested	8(61.5)	5(38.5)	

5.8 Relationships between biopsy results and Pap smear results

Among the five patients with LSILs on Pap smears, 3 (60%) were confirmed to have LSILs on biopsy, while 1 (20%) was diagnosed with squamous cell carcinoma and 1 (20%) had chronic cervicitis (Table 6).

Among the 52 patients reported to have HSILs on Pap smears, 50.0% (26) were confirmed to have squamous cell carcinoma on biopsy, and 11.5% (6) were diagnosed with carcinoma in situ. Smaller proportions were found to have NILM (11.5%), LSIL (5.8%), HSIL (5.8%), chronic cervicitis (13.5%), and atrophy (1.9%). Among the 53 patients with ASCUS, the most frequent biopsy finding was LSIL (30.2%), followed by NILM (24.5%) and atrophy (17.0%). Squamous cell carcinoma accounted for 11.3%, whereas HSIL and chronic cervicitis each represented 5.7%. For the 22 patients with ASC-H, biopsy most commonly revealed NILM (40.9%), followed by LSIL (22.7%). Squamous cell carcinoma and chronic cervicitis each accounted for 13.6%, whereascarcinoma in situ represented 9.1%. Among the 12 patients reported as NILM on Pap smears, two-thirds (66.7%) were confirmed as NILM on biopsy, whereas 33.3% were diagnosed with chronic cervicitis.

Table 6. Relationship between results of the biopsy and the pap smear

Pap result * Biopsy result									
		Biopsy result							Total
		SCC in situ	SCC	NILM	LSIL	HSIL	Chronic cervicitis	Atrophy	
Pap result	LSIL	0	1	0	3	0	1	0	5
	HSIL	6	26	6	3	3	7	1	52
	ASCUS	0	6	13	16	3	6	9	53
	ASC-H	2	3	9	5	0	3	0	22
	NILM	0	0	8	0	0	4	0	12
Total		8	36	36	27	6	21	10	144

5.9.1 Cytohistological Concordance Rates

A total of 144 cases with paired cytological and histological results were analyzed to assess the cytohistological diagnostic concordance. The level of diagnostic concordance varied significantly across the different cytological classifications. For the HSIL results, the

concordance rate for predicting a histological diagnosis of a high-grade lesion was 67.3% (35/52). In contrast, the ASC-H category demonstrated a 22.7% (5/22) concordance rate for cases confirmed as high-grade lesions (CIN II+) on biopsy. LSIL cytology accurately predicted histological CIN I in 60.0% (15/25) of the patients. For the ASC-US results, the concordance rate with a histological diagnosis of CIN I or worse was 47.2% (25/53). Finally, the NILM category demonstrated a 100% (12/12) concordance rate. Across all diagnostic categories, the overall cytohistological concordance rate was 55.6% (80/144).

5.9.2 The Diagnostic performance of Pap smears

The diagnostic performance of Pap smears for detecting high-grade lesions was evaluated with biopsy as the gold standard. For this analysis, a positive Pap result was defined as ASC-H or HSIL. Moreover, a high-grade lesion in a biopsy sample is defined as CIN II or worse. All results falling below these thresholds were categorized as negative for high-grade lesions.

Among the 144 participants, 74 (51.4%) were positive for lesions on Pap smears, whereas 70 (48.6%) were negative for lesions. The biopsy results revealed that 50 (34.7%) participants had high-grade lesions, and 94 (65.3%) had benign lesions. Among the participants with positive Pap smear results, 40 (54.1%) had high-grade lesions confirmed by biopsy, whereas 34 (45.9%) had benign lesions. These results reveled that the sensitivity of Pap smears was 80%, the specificity was 63.8%, the positive predictive value was 54.1%, and the negative predictive value was 85.7%.

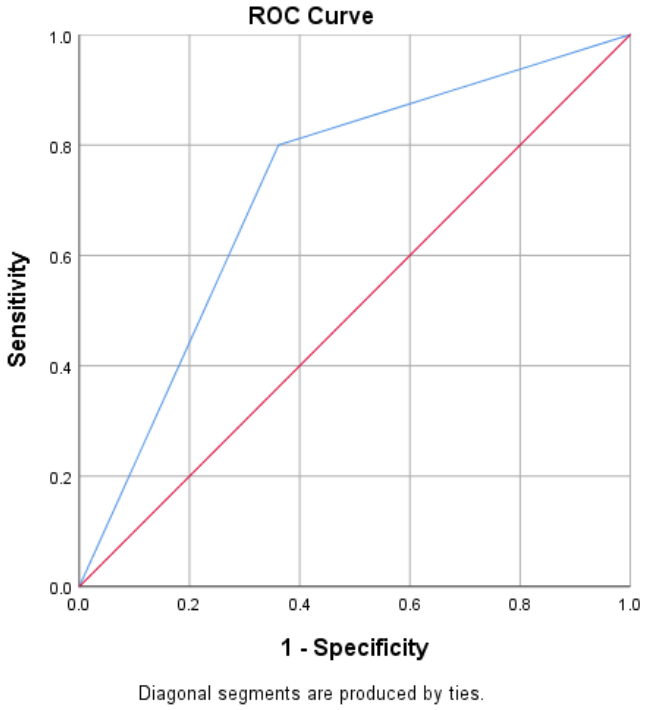
Table 7.1Sensitivity and specificity of pap smears

Papstatus * biopsyresult					
			Biopsy result		Total
			benign lesion	high grade lesion	
Pap status	negative for lesion (<ASC-H)	Count	60	10	70
		% within pap status	85.7%	14.3%	100.0%
		% within biopsy result	63.8%	20%	48.6%
	positive for lesion (ASC-H +)	Count	34	40	74
		% within pap status	45.9%	54.1%	100.0%
		% within biopsy result	36.2%	80%	51.4%
Total		Count	94	50	144
		% within pap status	65.3%	34.7%	100.0%
		% within biopsy result	100.0%	100.0%	100.0%

Receiver operating characteristic (ROC) curve analysis was performed to evaluate the diagnostic performance of Pap smears in detecting high-grade cervical lesions using biopsy as the reference standard. The area under the curve (AUC) was 0.819, with a standard error of 0.044, indicating

statistically significance (p < 0.001). The 95% confidence interval for the AUC ranged from 0.632- 0.906. Since the AUC is substantially greater than 0.5, the Pap smear has good diagnostic ability for distinguishing between benign lesions and high-grade lesions.

The coordinates of the ROC curve indicate that at the selected cutoff value of 1.5, the sensitivity was 80% and the false-positive rate (1 − specificity) was 0.362, corresponding to a specificity of 63.8%.This finding indicates the best balance between sensitivity and specificity for the identification of high-grade lesions. The analysis also demonstrated that there were ties between the positive and negative groups in the Pap smear test results, which may introduce slight statistical bias in the ROC estimates. Overall, the ROC analysis demonstrated that the Pap smearshave acceptable diagnostic accuracy for identifying high-grade cervical lesions.



Area Under the Curve				
Test Result Variable(s): pap status				
Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.819	.044	.000	.632	.906
The test result variable(s): pap_status has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.				
a. Under the nonparametric assumption				

b. Null hypothesis: true area = 0.5

Coordinates of the Curve		
Test Result Variable(s): pap status		
Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
.0000	1.000	1.000
1.5000	.800	.362
3.0000	.000	.000
The test result variable(s): pap_status has at least one tie between the positive actual state group and the negative actual state group.		

6. Discussion

In the present study, 51% of the participants had positive cytological findings for cervical lesions, whereas 49% had negative results. Among the cytological categories, ASCUS was the most common finding (36.8%), followed by HSIL (36.1%), whereas ASC-H accounted for 15.3% of the cases. A smaller proportion of participants had NILM or LSIL. The relatively high proportion of abnormal cytological findings in this study may be attributed to the fact that many participants were referred for evaluation due to suspected cervical pathology. Similar patterns of abnormal cytological distribution have been reported in clinical-based studies where screening populations include symptomatic or high-risk individuals (15).

The data from histopathological analysis revealed that 35% of patients had high-grade lesions (≥CIN II), whereas 65% had benign or low-grade findings (<CIN II). Overall, among the biopsy diagnoses, squamous cell carcinoma was the most common lesion (25%), followed by LSIL (18.8%) and chronic cervicitis (14.6%). Among the high-grade lesions, squamous cell carcinoma accounts for 72% of cases, followed by carcinoma in situ, which accounts for 16% and HSIL which account for 12%. These results demonstrate the high prevalence of advanced cervical pathology among the study participants. Similar observations have been reported in studies conducted in other developing countries where limited access to routine screening results in late presentation and a greater proportion of invasive lesions at diagnosis (12).

This study revealed a statistically significant association between age and histopathological findings (p = 0.041). The study also revealedthat the prevalence of high-grade lesions increased with increasing age, particularly among women aged 40 years and above. Among women aged 20–29 years all had benign biopsy results, while the prevalence of high-grade lesions increased to 42.1% in those aged 40–49 years and more than 60% among women aged 50 years and above. This trend is consistent with the natural history of cervical neoplasia, where persistent infection with oncogenic human papillomavirus leads to progressive epithelial changes over time and leads to carcinoma. Similar age-related increases in high-grade lesions have been reported in several epidemiological studies of cervical cancer (15).

In contrast, HIV status was not significantly associated with biopsy results in our study (p = 0.907). Although studies have shown a greater prevalence of cervical intraepithelial neoplasia among HIV-positive women due to immunosuppression, the findings of this study did not demonstrate a significant association. This difference may be due to the specific population characteristics of our study. The study was conducted in centers with established ART programs, where high treatment adherence may have preserved immune function among HIV-positive patients. Additionally, the high degree of integrated care at these study sites might have encouraged HIV-positive women to seek medical attention more frequently, which could have obscured the higher risk that is usually associated with groups with less access to healthcare.

When comparing Pap smear cytology with biopsy findings, the level of agreement varied depending on the cytological category. In patients whose Pap smears yielded LSIL results, biopsy confirmed the same diagnosis in 60% of patients, although a smaller number of patients received more serious diagnoses, such as squamous cell carcinoma, while other patients had only chronic cervicitis on histology. Among those patients with HSIL cytology, half were confirmed to have squamous cell carcinoma on biopsy, while the others were diagnosed with carcinoma in situ or benign lesions. Similar cyto-histology discrepancies have been reported in previous studies, reflecting the inherent limitations of cytological screening methods (17). Factors such as sampling error, preparation artifacts, and interobserver variability in cytological interpretation may contribute to these differences (17).

Our study demonstrated an overall cytohistological concordance rate of 55.6%, reflecting practical diagnostic challenges such as cytological preparation artifacts and the high prevalence

of severe background inflammation common in our setting. Despite this, the Pap smear remains a highly reliable screening tool at the diagnostic extremes: the NILM category showed a perfect 100% concordance with benign histopathology, and definitive HSIL demonstratedstrong 67.3% concordance with CIN II or worse. The lower-tier categories performed as biologically anticipated, with LSIL and ASC-US showing 60.0% and 47.2% concordance, respectively, reflecting the transient nature of HPV infections and the inherently heterogeneous, equivocal nature of the ASC-US classification.

Conversely, in this study, a critically the low concordance rate was observed for the ASC-H category (22.7%). This pronounced discordance suggests a significant tendency toward cytological overcalling in our demographic data. Chronic cervicitis, endemic genitourinary infections, and atrophic changes frequently cause reactive nuclear atypia that morphologically mimics high-grade dysplasia, leading to false-positive ASC-H interpretations. Consequently, these findings highlight the absolute necessity of colposcopy-guided biopsy as the definitive diagnostic gold standard for equivocal cases. Furthermore, they emphasize the urgent need for targeted cytomorphological training and quality improvement initiatives within the pathology department to better differentiate severe reactive atypia from true dysplasia, thereby reducing the ASC-H overcall rate.

A comparison of the diagnostic accuracy of our study with that of international data revealed significant differences in cytohistological concordance. The overall cytohistological concordance rate in this Ethiopian cohort was 55.6%. The overall agreement was low compared with similar studies from India (84.15%) (24), Nepal (62.5%) and Mongolia (62.5%). The overall concordance differences across these regions are likely multifactorial. These differences are often associated with variability in institutional cytology screening protocols, case volumes, and the subjectivity inherent in the interpretation of equivocal categories (ASC-US and ASC-H), which greatly affects overall agreement rates.

However, for high-grade lesions, there is a very encouraging finding in our setting. The specific agreement rate for HSIL in the present study was 67.3%. This percentage is lower than that reported Indian cohort (82.35%) but much higher than the HSIL concordance rates reported in Nepal (40.0%) and Mongolia (37.8%). This suggests diagnostic challenges for relating low-grade or atypical reactive changes, but high diagnostic competence exists in this setting for the

identification of definite, high-grade cervical lesions. However, overall concordance may vary depending on low-grade discrepancies, and maintaining high accuracy for high grade lesions remains the most critical metric for effective cervical cancer prevention.

The diagnostic performance of the Pap smear is highly dependent on the selected clinical threshold. In this study, we adopt ASC-H and HSIL as thresholds for a positive result. On this basis, the Pap smear showed a sensitivity of 80% and a specificity of 63.8%. Additionally, the positive predictive value was 54.1%, and the negative predictive value was 85.7%. These results indicate that Pap smears have a relatively good ability to detect high-grade cervical lesions and are particularly reliable in ruling out disease. However, the moderate specificity and positive predictive value imply that a certain number of false-positive cases exist. This underlines the need to conduct a biopsy to confirm abnormal cytological results.

The diagnostic performance of the Pap smear in our study is comparable to that reported in several international studies. For example, a study conducted in India reported a sensitivity of 88.2% and specificity of 76.4% for detecting high-grade lesions (12). Similarly, a study conducted in Korea reported sensitivity and specificity values of 93.9% and 77.6%, respectively (15). However, some studies have reported lower sensitivity. A study performed in Nigeria reported a sensitivity of 34.6% but a higher specificity of 94.7% (19). Studies from Nepal and Turkey also reported sensitivity values ranging from 57% to 77.8% and specificity values between 76% and 100% (17,20). These variations may reflect differences in study populations, laboratory quality, screening protocols, and cytological interpretation.

The result of receiver operating curve analysis in this study further demonstrated the diagnostic accuracy of Pap smear cytology. The AUC was 0.819, which indicates good diagnostic accuracy for distinguishing between benign and high-grade cervical lesions. This finding is consistent with previous studies reporting acceptable diagnostic accuracy for Pap smear screening (21). An AUC greater than 0.8 generally reflects the good discriminative ability of a diagnostic test.

7. Strengths and limitations of the study

Ourstudy has several key strengths. Notably, this study is the first of its kind to assess the correlation between Pap cytology and biopsy in Ethiopia. Additionally, the use of histopathological diagnosis as a reference ensures the validity and accuracy of the correlation results. Finally, this study includes three major health institutions in Addis Ababa (TASH, ZMH, and FGAE), enhancing the sample's representativeness and improving the generalizability of the findings.

On the other hand, this study has certain limitations. First, this study is multicenter, across different clinical sites, which may have led to interobserver variability in interpreting the results and influenced the correlation. Second, HPV DNA co-testing data were unavailable for this study. Given that high-risk HPV is the primary etiological factor for cervical neoplasia, the absence of these data limits the ability to further triage equivocal cytological results such as ASC-US and ASC-H. Finally, althoughHIV status was recorded, the study lacked a detailed clinical history, such as CD4 counts and the duration of antiretroviral therapy (ART), which are known to influence the progression and recurrence of cervical lesions.

8. Conclusion

This study evaluated the correlation between Pap smear cytology and cervical biopsy findings in 144 patients who underwent both tests. More than half of the participants (51%) had positive Pap smear results, of which HSIL (36.1%) was the most common cytological abnormality. Histopathological examination revealed that 34.7% of patients had high-grade cervical lesions (≥CIN II), while 65.3% had benign or low-grade findings, with squamous cell carcinoma representing the majority of high-grade diagnoses. Age was significantly associated with biopsy outcomes, as the proportion of high-grade lesions increased markedly among women aged 40 years and above, whereas HIV status was not significantly associated with histopathological results. When biopsy was used as the gold standard, the Pap smear demonstrated a sensitivity of 80%, specificity of 63.8%, positive predictive value of 54.1%, and negative predictive value of 85.7%, indicating good ability to detect high-grade lesions and a strong capacity to rule out disease when the test result was negative. Additionally, the ROC curve analysis revealed an area under the curve (AUC) of 0.819, confirming good overall diagnostic accuracy.

9. Recommendations

On the basis of the findings of this study, the following key recommendations are proposed.

The markedly high proportion of ASC-US and ASC-H diagnoses observed in this study, which exceeds internationally accepted reporting benchmarks, suggests possible overutilization of equivocal cytological categories and highlights the need for strengthening cervical cytology diagnostic practices in the study setting. Therefore, it is recommended that the responsible institutions implement regular quality assurance and quality control measures, including periodic cytology–histology correlation audits, standardized use of the Bethesda reporting criteria, and continuous refresher training for cytotechnologists and pathologists to minimize interobserver variability and improve diagnostic precision. The introduction of adjunctive screening methods, such as HPV DNA testing and liquid-based cytology.These diagnostic tests can significantly improve diagnostic sensitivity and reduce the risk of underdiagnosis, particularly in equivocal or borderline cases such as ASCUS and ASC-H.

Furthermore, larger multicenter studies across Ethiopia are necessary to validate concordance rates and evaluate the cost-effectiveness of combined screening strategies. Such research is essential for optimizing local cervical cancer prevention programs and ensuring that screening protocols are effectively adapted to the Ethiopian healthcare context.

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Annex

Data collection table (check list)

Ser No.	MRN	Pap smear No.	Biopsy No.	Age	Marital Status	parity	History Of any STI	HIV status	SCJ status	Pap dx	Biopsy dx
1											
2											
3											
4											
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