

## SCREENING FOR EPITHELIAL CELL ABNORMALITY IN CERVIX - A HOSPITAL BASED STUDY

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### Abstract

**Background:** In developing countries, cervical cancer remains a significant health challenge, particularly in India where there's a lack of comprehensive data, especially among low-income and underserved populations. This issue is acutely pronounced in the North Coastal region of Andhra Pradesh, an area that has seen limited research, particularly concerning cervical epithelial cell abnormalities. The primary aim of this study is to ascertain the prevalence of various types of epithelial cell abnormalities in the cervix. Additionally, the study focuses on the follow-up and treatment of patients who exhibit these abnormalities. **Material and Methods:** The study involved the examination of 10,400 conventional Pap smears to identify cervical lesions. Histopathological evaluations were conducted as necessary. Patients diagnosed with epithelial cell abnormalities were given appropriate treatment and followed up. **Results:** From the 10,400 Pap smears analyzed, 6.42% exhibited epithelial cell abnormalities, while 91.04% were negative for intraepithelial lesions or malignancy (NILM). Unsatisfactory results were observed in 2.52% of the smears. The most common symptom reported was vaginal discharge. The prevalence of epithelial cell abnormalities was notably higher in the age group of 31-40 years. Atypical squamous cells of undetermined significance (ASC-US) were detected in 3.04% of cases. Furthermore, reparative changes were observed in 52.44% of the screened population. Among the cases with abnormalities, 27.24% received treatment, and 61.22% were followed up. The study recorded a loss to follow-up rate of 11.52%, and there were 2 deaths reported. **Conclusion:** This study highlights the vital role of conventional Pap smears in identifying the burden of cervical lesions, particularly in specific regions. The challenge lies in distinguishing between reparative changes and ASC-US, highlighting the necessity of biopsies for more accurate diagnoses.

## INTRODUCTION

Cervical cancer remains a critical health concern in India, where the National Institute of Cancer Prevention and Research reports the alarming statistic of one woman succumbing to the disease every eight minutes, making it the most prevalent cancer among women. A notable study from

Ananthapur district revealed that a significant portion of the population, more than one-fourth, had never heard of cervical cancer. Despite over half of the women being aware of the symptoms, risk factors, and preventive measures, there persists a considerable lack of awareness, especially in rural areas. The primary sources of information for these women are media, friends, and family. While most women exhibit a positive attitude towards cervical

cancer screening, a disconnect remains between perception and practice.<sup>[1]</sup>

Barriers to effective screening utilization include fears of a positive cervical cancer diagnosis, cervical screening, and vaginal examination, as highlighted in some research studies.<sup>[2]</sup> Implementing continuous awareness programs about cervical cancer is crucial to alter women's attitudes and perceptions towards screening.

An epidemiological survey in Andhra Pradesh, utilizing data from medical colleges between 2009 and 2012, found that out of 6971 surveyed cancer cases, 29.5% (2058 cases) were cervical cancer. Notably, 28.1% of these were in stages I and II, while a significant 71.8% were in advanced stages (III and IV).<sup>[3]</sup> Few studies have been conducted in North Coastal Andhra Pradesh focusing on the screening of various cervical lesions via Pap smears. This study aims to investigate the range of cervical lesions in underserved communities, particularly focusing on the prevalence of epithelial cell abnormalities across different age groups. It seeks to detect early pre-malignant and malignant cervical lesions, providing subsequent follow-up and treatment where necessary.

The goal of this study is to estimate the prevalence of various cervical lesions in women from North Coastal Andhra Pradesh, particularly those of low socioeconomic status. It aims to correlate pre-malignant and malignant lesions of the cervix with histopathological findings and ensure follow-up as required.<sup>[4]</sup>

## MATERIALS AND METHODS

The study, conducted at the Department of Pathology, Andhra Medical College, Visakhapatnam, was a hospital-based observational study spanning from December 2016 to November 2021. It aimed to assess cervical epithelial cell abnormalities in women of low socioeconomic status.

### Inclusion Criteria

Socioeconomic Status: Women classified as upper lower class/IV (semi-skilled) and lower class/V (unskilled) according to the modified Kuppuswamy scale.

### Age and Symptoms

Symptomatic women over 30 years old attending the Gynaecology outpatient department.

Asymptomatic women over 30 years old volunteering for Pap smear screening.

### Exclusion Criteria

Pregnant women.

Cases with an obvious growth upon clinical examination.

Previously treated cases of epithelial cell abnormalities or carcinoma cervix.

Recurrent cases.

## Study Design and Data Collection

The Institutional Ethics Committee granted prior permission for the study, which began on December 2nd, 2016. Two trained cytopathologists were assigned full-time to examine the conventional Pap smears. A coordinator, recruited in December 2016, contacted the patients as per protocol and followed up on cases.

### Pap Smear Procedure

Women attending with symptoms such as leucorrhoea, abnormal uterine bleeding, dysfunctional uterine bleeding, post-coital bleeding, and post-menopausal bleeding were included. After thorough counseling and obtaining informed consent, detailed clinical data were recorded in a structured proforma. Pap smears were collected using a disposable Pap smear kit, which included an Ayres spatula, endocervical brush, speculum, and gloves. Samples from the transformation zone and endocervix were obtained, placed on labeled glass slides, fixed in 95% Isopropyl alcohol, and stained with Pap stain.

### Reporting and Follow-Up

Pap smears were reported according to The Bethesda Classification System - TBS (2014). Women with identified epithelial cell abnormalities underwent biopsy. Appropriate therapy and periodic follow-up were conducted.

### Data Analysis

Data were tabulated using Microsoft Excel and analyzed with SPSS version 24. Sensitivity, specificity, positive predictive value, and negative predictive value of intraepithelial lesions on Pap smear were calculated, using histopathology as the gold standard.

### Ethical Considerations

The study adhered to ethical standards and obtained necessary approvals: Approval from the Institutional Ethics Committee at AMC (Andhra Medical College), Visakhapatnam. Written informed consent was obtained from each participant, indicating that they voluntarily agreed to participate in the study. p value less than 0.05 was considered as significant.

## RESULTS

In this study, a comprehensive analysis of 10,400 Pap smears yielded significant insights into cervical epithelial cell abnormalities. The results are presented in various categories for clarity:

General Overview: Of the total Pap smears analyzed, 668 cases (6.42%) displayed epithelial cell abnormalities. A significant majority, 9469 smears (91.04%), were classified as negative for Intraepithelial Lesion or Malignancy (NILM). There were also 263 unsatisfactory smears, accounting for 2.52% of the total. The most commonly reported symptom among the participants was white discharge.

Age Group Distribution: The findings indicated a variation in the prevalence of abnormalities across

different age groups. Women in the 31-40 years age group predominantly showed Atypical Squamous Cells of Uncertain Significance (ASCUS), Low-Grade Squamous Intraepithelial Lesion (LSIL), and Atypical Glandular Cells, Not Otherwise Specified (AGC-NOS). In contrast, the 41-50 years age bracket exhibited a higher prevalence of High-Grade Squamous Intraepithelial Lesion (HSIL) and Squamous Cell Carcinoma (SCC).

**Breakdown of Specific Abnormalities:** The detailed breakdown of abnormalities (as outlined in Table 1) revealed the following:

NILM normal, reactive changes, and atrophy were observed in 8588 cases (82.57%).

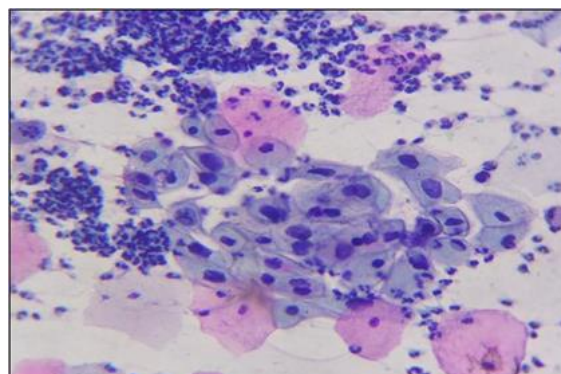
NILM with nonspecific inflammation was found in 34 cases (0.32%).

Infections such as *Trichomonas vaginalis*, *Candida*, and Bacterial vaginosis were noted in 296 (2.84%), 411 (3.95%), and 140 (1.34%) cases, respectively.

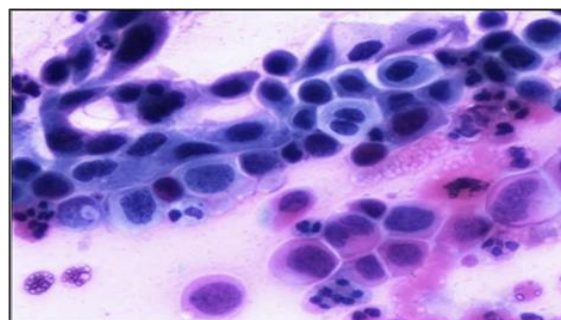
Specific epithelial cell abnormalities included ASCUS (284 cases, 2.73%), ASC-H (33 cases, 0.31%), LSIL (108 cases, 1.03%), HSIL (85 cases, 0.81%), HSIL suspicious of invasion (21 cases, 0.20%), Squamous Cell Carcinoma (38 cases, 0.36%), and Glandular abnormalities (99 cases, 0.95%).

**Biopsy Correlation and Diagnostic Metrics:** Among the 371 cases with epithelial cell abnormalities where biopsies were conducted (as reported in Table 2), the correlation with histopathology varied. It was 51.80% for ASCUS, 68.18% for ASC-H, 92.70% for LSIL, 96.05% for HSIL, 100% for HSIL suspicious of invasion, 100% for Squamous Cell Carcinoma, and 28.2% for AGC-NOS. The diagnostic metrics for malignant lesions of the Pap smear (Table 3) showed a sensitivity of 75%, specificity of 99%, positive predictive value of 90%, negative predictive value of 97.1%, and diagnostic accuracy of 96.5%.

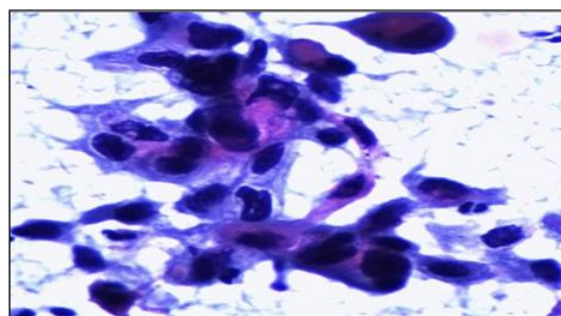
**Follow-up and Treatment Outcomes:** Follow-up was successfully conducted in 409 cases, which is 61.22% of those identified with abnormalities. Treatment was administered in 182 cases (27.24%). There were, however, 77 patients (11.52%) lost to follow-up, and two deaths attributed to the disease were recorded. Among the 108 LSIL cases, 49 underwent hysterectomy due to associated conditions like fibroids or adenomyosis. For HSIL cases, cryotherapy and conization were the primary treatment modalities. All 38 cases of Squamous Cell Carcinoma received radiotherapy, as detailed in Table 4.



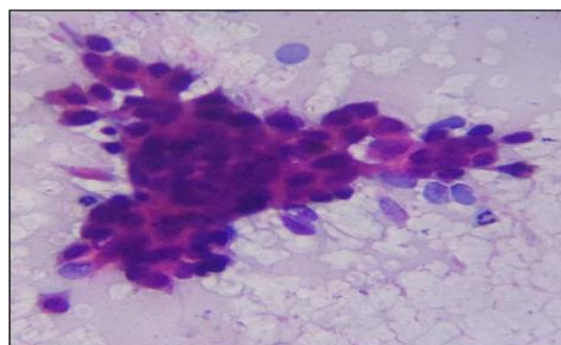
**Figure 1: Low Grade Squamous Intra epithelial Lesion(LSIL) ,400X, Pap stain**



**Figure 2: High Grade Squamous Intra epithelial Lesion (HSIL) ,400X, Pap stain**



**Figure 3: Clusters of pleomorphic cells of Squamous Cell Carcinoma,400X, Pap stain**



**Figure 4: Atypical Glandular cells, NOS, 400X, Pap stain**

**Table 1: Distribution of Cases on Pap Smears Dec. 2016 to November 2021- 10,400 Cases**

PAP SMEARS	NO. OF CASES	PERCENTAGE
NILM-NORMAL	2772	26.65
NILM-NONSPECIFIC INFLAMMATION	34	0.32
NILM – REACTIVECHANGES WITH (INCLUDING REPAIR)	5454	52.44
NILM -ATROPHY	362	3.48

NILM –TRICHOMONAS VAGINALIS	296	2.84
NILM – CANDIDIASIS	411	3.95
NILM- BACTERIAL VAGINOSIS	140	1.34
ASC-US	284	2.73
ASC-H	33	0.31
LSIL	108	1.03
HSIL	85	0.81
HSIL WITH SUSPICIOUS OF INVASION	21	0.20
SQUAMOUS CELL CARCINOMA	38	0.36
AGC-NOS	85	0.81
AEC-NOS	14	0.13
UNSATISFACTORY SMEAR	263	2.52
TOTAL	10,400	

**Table 2: Distribution of epithelial cell abnormality on pap smears Dec. 2016 to November 2021- 668 cases**

EPITHELIAL CELL ABNORMALITIES(ECA) ON PAP SMEARS	NO. OF CASES	PERCENTAGE % of 668 cases of ECA
ASC-US	284	42.51
ASC-H	33	4.94
LSIL	108	16.16
HSIL	85	12.72
HSIL WITH SUSPICIOUS OF INVASION	21	3.14
SQUAMOUS CELL CARCINOMA	38	5.68
AGC-NOS	85	12.71
AEC-NOS	14	2.09
TOTAL	668 (6.42%)	

**Table 3: Epithelial cell abnormality sent for histopathology -371**

Pap smear	CIN 1	CIN 2	CIN 3	SCC	Adenocarcinoma	Non specific inflammation/Benign lesions	Overall correlation % as Epithelial cell abnormality
ASC-US (83)	34	6	2	1	0	40	51.80
ASC-H(22)	7	4	4	0	0	7	68.18
LSIL(96)	78	11	0	0	0	7	92.70
HSIL(76)	2	7	46	18	0	3	96.05
HSIL with suspicious of invasion(20)	0	0	2	17	1	0	100
SCC(35)	0	0	1	33	1	0	100
AGC-NOS(39)	6	4	1	0	0	12 – chronic non specific cervicitis 7-Papillary endocervicitis 9 cases of Endocervical polyp	28.2

**Table 4: Follow up of cases and therapy given in 668 cases**

EPITHELIAL CELL ABNORMALITIES(ECA) ON PAP SMEARS	NUMBER OF CASES	FOLLOW UP AND THERAPY GIVEN
ASC-US	284	Follow up -261 Lost to follow up -56
ASC-H	33	
LSIL	108	49-Hysterectomy (Adenomyosis or Fibroids) 48-Follow up 11- Lost to follow up
HSIL	85	42-Cryotherapy 16-Conization 27-Follow up
HSIL WITH SUSPICIOUS OF INVASION	21	21-Hysterectomy
SQUAMOUS CELL CARCINOMA	38	38-Radiotherapy
AGC-NOS	69	73-Follow up 10- Lost to follow up
AEC-NOS	14	

## DISCUSSION

This study provides significant insights into cervical epithelial cell abnormalities and their prevalence in

India, emphasizing the importance of Pap smear screening in detecting these conditions.

HPV Infection and Cervical Neoplasia: Despite the high exposure to HPV infection among Indian



women, the progression to cervical neoplasia is relatively uncommon. Most HPV infections do not advance to high-grade Cervical Intraepithelial Neoplasia (CIN) or cervical cancer and often regress spontaneously. The long duration from initial infection to overt disease suggests the involvement of several cofactors in disease progression, although spontaneous regression is common.<sup>[5]</sup>

**Risk of Disease Progression:** Holowaty et al. calculated the Relative Risk (RR) of progression and regression of moderate and severe dysplasia over a 2-year follow-up, using mild dysplasia as a baseline. The progression to carcinoma in situ was 8.1 for moderate dysplasia and 22.7 for severe dysplasia, while the progression to invasive cancer was 4.5 and 20.7, respectively. The World Health Organization predicts that cervical cancer could be eliminated by 2120 with widespread HPV vaccination coverage and increased screening, especially in lower-middle-income countries.<sup>[5]</sup>

**Pap Smear Screening:** The primary purpose of Pap smear screening is to detect malignant or pre-malignant conditions. Absence of these features is considered normal, even if associated with specific infections or reactive changes, and categorized under NILM (Negative for Intraepithelial Lesion or Malignancy). In this study, the percentage of NILM was 82.90%, aligning with findings by Sarma U et al,<sup>[6]</sup> and Bamanikar SA et al,<sup>[7]</sup> who reported 88.05% and 88.02% respectively. Comparatively, Omna Sakhi et al,<sup>[8]</sup> and Mishra P et al,<sup>[9]</sup> reported lower percentages of NILM at 52.8% and 52.5%, respectively.

**Specific Infections as Cofactors:** Specific infections like Candida, Trichomonas vaginalis, Chlamydia trachomatis, HIV, and Herpes simplex can act as cofactors influencing the progression of high-grade lesions and cervical cancer. This study found NILM with nonspecific inflammation (0.32%), NILM with Trichomonas vaginalis infection (2.84%), and NILM with Candida infection (3.95%). These findings are in line with those reported by Malpani G et al,<sup>[11]</sup> and Vaddatti Tejeswini et al,<sup>[12]</sup> though the latter's incidence rates slightly differ.

**Bacterial Vaginosis and Cervical Cancer:** Bacterial vaginosis, often unnoticed in the clinical course of cervical cancer, can influence the progression due to its impact on the vaginal ecosystem. The present study observed NILM with Bacterial vaginosis at 1.34%, a rate lower than that reported by Malpani G et al,<sup>[11]</sup> who found a significantly higher incidence.

**Epithelial Cell Abnormality:** The prevalence of epithelial cell abnormality in this study was 6.42%, higher than reported in several other studies including those by Sarma U et al,<sup>[6]</sup> Shekhar H et al,<sup>[15]</sup> and Chaitanya K et al,<sup>[16]</sup> The most common epithelial cell abnormality was ASCUS, comprising 3.04% of all cases, a finding similar to Bamanikar SA et al,<sup>[7]</sup> and Vaddatti Tejeswini et al,<sup>[12]</sup>

**Prevalence of Specific Lesions:** The present study showed LSIL at 1.0%, in agreement with studies by Bamanikar SA et al,<sup>[7]</sup> and Patel PCB et al,<sup>[17]</sup>

However, Patel MM,<sup>[18]</sup> Mehnez Nasreen et al,<sup>[21]</sup> and Wasim M Khatib,<sup>[22]</sup> reported contrasting findings, with LSIL as the most common abnormality. For HSIL, this study's prevalence of 1.01% was comparable to Vaddatti Tejeswini et al,<sup>[12]</sup> but higher than other studies such as Patel PCB et al,<sup>[17]</sup> and Tailor HJ et al,<sup>[23]</sup>

**Squamous Cell Carcinoma:** The prevalence of Squamous Cell Carcinoma (SCC) in this study was 0.36%, aligning with findings from various other studies, including Patel PCB et al,<sup>[17]</sup> Bamanikar SA et al,<sup>[7]</sup> and Vaddatti Tejeswini et al.<sup>[12]</sup>

**ASCUS/SIL Ratio:** The ASCUS/SIL ratio in this study was 1.45, similar to Bamanikar SA et al,<sup>[7]</sup> but varied in other studies like Patel MM et al,<sup>[18]</sup> and Gajeshri et al,<sup>[20]</sup> Regular monitoring of the ASCUS/SIL ratio is recommended as a quality improvement measure for laboratories.

**Glandular Lesions:** Glandular cell abnormalities, though uncommon, are crucial to detect due to the higher likelihood of underlying high-grade lesions. Suresh P.K et al,<sup>[27]</sup> reported a lower prevalence of glandular cell abnormalities, while D Ajit et al,<sup>[28]</sup> recorded a slightly higher incidence. The present study found AGC-NOS in 0.81% of cases, underscoring the importance of distinguishing between neoplastic and non-neoplastic lesions.

**Diagnostic Metrics:** The specificity for diagnosing malignant lesions on Pap smears in this study was 99%, with a sensitivity of 75%, closely matching the findings of Malpani G et al,<sup>[11]</sup> The positive and negative predictive values were 90% and 97.1%, respectively, paralleling the results of Kalyani R et al,<sup>[25]</sup> and Omna Sakhi et al,<sup>[8]</sup> The overall sensitivity for detecting LSIL and HSIL was 91.7% and 94.82%, respectively, highlighting the efficacy of Pap smear screening in this context.

## CONCLUSION

In developing countries, the conventional Pap smear remains a valuable tool for assessing the prevalence of cervical lesions, particularly in underserved and low socioeconomic groups. The diagnosis of ASCUS and glandular cell abnormalities has posed challenges and controversies, with interpretations ranging from reparative changes to epithelial cell abnormalities. To ensure early detection of epithelial cell abnormalities, it is crucial that all cases of ASCUS and glandular cell abnormalities undergo histopathological examination. This approach can significantly contribute to the timely identification and management of cervical abnormalities, ultimately improving women's health in these regions.

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