

A Study of Quality Control in Pap Smear Cytology in a Tertiary Care Centre Using ASC:SIL Ratio

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ABSTRACT

Introduction: Internal quality indicators used in gynecological cytopathology include determining the rate of atypical squamous cells (ASC), calculation of ASC: SIL ratio, cytology-histology correlation, and high-risk HPV-positivity rates in ASC-US. These indicators help in quality control measures. Bethesda suggests that the ASC: SIL ratio should be less than 3:1. this study aims to determine the ASC: SIL ratio as an internal quality control indicator in gynecological cytological smears.

Material and Methods: The present study was conducted in the Department of Pathology SRMS Institute of Medical Sciences, Bareilly, UP. Archived cases of the preceding 2 years, from January 1, 2023, to December 31, 2024, were taken. The clinical details were retrieved from records. The study included conventional pap-stained smears of ASC-US, ASC-H, LSIL, HSIL, and SCC. ASC: SIL ratio was calculated by dividing the Sum of all ASC cases by the Sum of all SIL cases.

Results: About 5231 cervical Pap smears were received during the study period, of which 5061 (97%) were satisfactory. There were 39 cases with squamous cell abnormality, of which 13 were ASCUS, 9 were ASC-H, 8 were HSIL, 3 were LSIL, 6 were SCC cases, and the ratio ASC: SIL was 1.28, which was below the upper benchmark of 3:1.

Conclusion: The ASC: SIL ratio is a simple method for calculating internal quality indicators in cervical cytopathology. Keeping it below 3:1 reduces diagnostic uncertainty and supports WHO's goal to eliminate cervical cancer. Regular feedback and periodic training programs can help reduce the ASC: SIL ratio, which exceeds the benchmark of 3:1.

Keywords: Pap Smear, Cancer Cervix, Cytology, HPV

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INTRODUCTION

Cervical cancer is a rapidly rising entity, being the fourth most common cancer in women, with around Six hundred thousand new cases presenting globally. Approximately 92% of these cases occur in lower and middle-income countries, with African countries, Central America, and South-East Asia having the highest rates of incidence and mortality.¹ As far as India is concerned, cervical cancer ranks as the second most common cancer among women, with about 1,27,526 new cases reported every year. The estimates of the GLOBOCAN 2020 showed the incidence of cervical cancer in India rounding up to 123907.²

The pap test, also known as a pap smear, is a screening procedure used to detect abnormal cells in the uterine cervix, the lower part of the uterus. It is an essential tool for early detection and prevention of cervical cancer. Screening has significantly reduced cervical cancer incidence in high-income countries, but the burden remains high in low-resource settings. The test involves collecting a small sample of cells from the cervix using a swab or brush and examining them under a microscope for abnormalities. It detects premalignant and malignant changes, infections, and reactive changes caused by inflammation or other factors that can lead to cervical cancer.³

There are two acceptable techniques for collecting the pap smear— liquid-based and conventional. In both methods, a clinician inserts a speculum into the woman's vagina and identifies the cervix. The LBC involves collecting cells from the transformation zone of the cervix using a brush and transferring the cells to a vial of liquid preservative. The conventional technique involves collecting cells from the transformation zone of the cervix using a brush and spatula, transferring the cells to a slide and fixing the slide with a preservative. The main advantage of LBC is a reduction in inadequate smears, as it eliminates background blood and inflammation. Additionally, it allows for reflex testing for HPV using the same sample.³

The Bethesda System provides standardized terminology for the reporting of cervicovaginal cytology specimens. It was introduced in 1988, and the latest revision was done in 2014. Although it is a systematic way

of reporting cervical cytology, interpretation is subjective by cytopathologists due to morphologic overlap between reactive changes and epithelial cell abnormalities. Good-quality cytopathology reports are crucial, as they guide the management strategy of the treating clinician. Several methods of quality assurance have been developed to evaluate performance and provide feedback to cytotechnologists and cytopathologists. The various internal quality indicators used in gynecological cytopathology include determining the rate of atypical squamous cells, calculation of ASC:SIL ratio, cytology-histology correlation and high-risk HPV-positivity rates in ASC-US.⁴

This study aimed to determine the ASC:SIL ratio as an internal quality control indicator in gynecological cytological smears.

MATERIAL AND METHODS

The present study was conducted in the Department of Pathology, SRMS-IMS, Bareilly. The study included conventional pap-stained smears and LBC smears received from January 1, 2023, to December 31, 2024. The data was retrieved from the hospital-based electronic medical records.

The cytopathologists classified the smears as ASC-US, ASC-H, LSIL, HSIL, and SCC according to the Bethesda System for Reporting Cervical Cytology.

ASC: SIL ratio was calculated by dividing the sum of all ASC cases by the sum of all SIL cases.

ASC components included ASC-US and ASC-H. SIL included all LSIL, HSIL, and SCC cases.

RESULTS

Over 35,231 cervical pap smears were received during the study period, out of which 170 (3.2%) were unsatisfactory.

The common causes of unsatisfactory smears were low squamous cell cellularity and obscuring of cell morphology by inflammatory cells or blood.

Excluding the unsatisfactory smears, a total of 5061 satisfactory smears were considered for statistical analysis in this study.

Squamous cell abnormality was seen in 39/5061 (0.8%) cases. The age of these patients ranged from 32 to 74 years, and the mean age was 52 ± 11.57 years.

Lower abdominal pain seen in 48.7% (19/39) patients with squamous cell abnormality was the most common clinical presentation, followed by postmenopausal bleeding seen in 28.2% (11/39) patients (Table 1).

Table 2 shows the number and distribution of ASC and SIL cases. The percentage of squamous cell abnormalities when considering all satisfactory smears ($n = 5061$) were as follows: ASCUS-0.26%, ASC- H- 0.18%, LSIL- 0.06%,

Table 1: Chief complaints in the study population

Chief complaints	Cases (%)
Lower abdominal pain	19 (48.7%)
Postmenopausal bleeding	11 (28.2%)
Vaginal discharge	05 (12.8%)
Vaginal itching	02 (5.1%)
Menorrhagia	02 (5.1%)

Table 2: Distribution of ASC and SIL cases

Pap smear finding	Cases
ASCUS	13
ASC-H	09
HSIL	08
LSIL	03
SCC	06
Total	39

HSIL- 0.15%, and SCC- 0.12%. The ASC:SIL ratio was found to be $22 / 17 = 1.28$.

DISCUSSION

Cervical cancer is one of the leading causes of cancer death among females worldwide. The WHO has set three targets to be achieved by the year 2030 for cervical cancer elimination: (1) 90% of girls vaccinated with the HPV vaccine by age 15, (2) Screening of 70% of women with a high-quality test by ages 35 and 45, and (3) 90% of women with cervical disease receiving treatment.⁵

The pap smear is a major screening tool that helps to diagnose precancerous and cancerous conditions of the cervix. Several internal quality control indicators have been developed for pap smear reporting, of which ASC:SIL ratio is easy to calculate and widely practiced.

The ASC:SIL ratio is the number/percentage of atypical squamous cells of uncertain significance (ASCUS) and atypical squamous cells- cannot exclude high-grade dysplasia (ASC-H) diagnosed cases divided by the number/Percentage of low (LSIL) and high (HSIL) grade squamous intraepithelial lesions and malignant cases. It is a surrogate quality control tool to ensure that ASC interpretation is not overused by cytopathologists.⁶

The Bethesda system suggests that the ASC:SIL ratio should be less than 3:1, and lower ratios are more desirable, as a low ratio decreases the uncertainty produced by the laboratory and may help reduce the percentage of women with negative biopsy results.⁴

In the present study ASC:SIL ratio was $22/17 = 1.28$, which is well below the benchmark of less than 3:1.

ASC:SIL ratio as a quality control indicator calculated by various other authors are shown in Table 3. Our study showed concordant results with Davey DD *et al.*,⁶ who obtained a ratio of 1.3.

Table 3: ASC:SIL ratio in various studies:

Study	ASC:SIL ratio
Davey DD <i>et al.</i> ⁶	1.3
Renshaw AA <i>et al.</i> ⁷	2.5
Nascimento A F <i>et al.</i> ⁸	1.9
Rajagopal P <i>et al.</i> ⁹	1.5
Hemlatha P <i>et al.</i> ¹⁰	1.1
Present study	1.28

The limitations of this study are that cytology-histopathology correlation was not done, and hence, the number of false positives and false negatives is not known. Additionally, the ASC:SIL ratio was calculated for the laboratory as a whole rather than for individual cytopathologists. Providing confidential feedback to individual cytopathologists about their ASC:SIL ratio would be a more useful quality control measure.

CONCLUSION

ASC:SIL ratio serves as a simple measure to calculate quality control markers for pap smear reports. As a diagnosis of ASCUS conveys uncertainty, a low ratio decreases the uncertainty in pap smear reports produced by the laboratory. Effective feedback to cytopathologists and periodic training programs can help reduce the ASC:SIL ratio if it exceeds the benchmark of 3:1. This will contribute to more reliable cervical screening and aid in achieving the WHO's cervical cancer elimination target.

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