Original Article

A Study on Internal Quality Control Indicators in Cervical Cytology in a Tertiary Care Centre

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Abstract

Background: Cervical cancer is the fourth most common cancer in women worldwide. Hence early screening and evaluation can reduce the mortality. Pap smear is a cost-effective screening test. QC (Quality Control) forms the integral part of any laboratory system and ensures accuracy of interpretation and reporting of pap smears. Quality Indicators are the tools to monitor the QC system in the laboratory. This study was conducted to evaluate the various internal QC indicators of cervical smears with an intent to know our performance and to improve for further quality of reports. **Material and Methods:** This was a retrospective cross-sectional study conducted in the department of Pathology, BGSGIMS, Kengeri, Bengaluru, where pap smear reported from January 2023 to January 2025 were retrieved and rescreened and various Internal quality indicators were calculated by descriptive analysis. **Results:** We have analyzed 1467 pap smear cases received over a period of 2 years comprising of patients ranging in age from 20yrs -80yrs.Majority of the patient came for routine cervical screening (56.7%). Total abnormal cases were 10, out of which 6 cases were ASC and 4 cases were SIL. Using the formulas various quality indicators percentage were calculated and the results are as follows: ASC % among the satisfactory tests-0.41%, Percentage of tests compatible with LSIL-0.20%, Percentage of tests compatible with HSIL-0.06%. The ASC/SIL and ASCUS/SIL were found to be 1.5% each respectively. The positivity rate was 0.69%. False negative case was 0.09%. **Conclusion:** We have analyzed that the few of our Internal QC indicators are still low compared to the standard values suggested by Bethesda. Regular monitoring the Internal quality indicators and participating in proficiency testing programmes helps us to identify the scope for improvement but also improves the performance outcomes, thus achieving the WHO's cervical cancer elimination target.

Keywords: Quality Control, Quality Indicators, Cervical cytology.

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INTRODUCTION

Cervical cancer is the fourth most common cancer in women worldwide.[1] In India it's one of the leading cause of death among women between the age of 30-69yrs.WHO has recommended a "Call for elimination of cervical cancer by 2030" with its major goal of achieving 90% vaccination coverage for girls under 15yrs, 70% screening of women by the age of 35yrs, with high performance tests by the age of 45 yrs and providing treatment to 90% of women with cervical cancer.[2] Cervical cancer shows progression of disease from dysplasia to malignancy over a period of 10-12 yrs approximately. Hence early screening and evaluation can reduce the mortality.

Cervical Pap smear introduced in 1945 still remains as the major screening tool for identifying the preinvasive cervical lesions at the earliest.[3] TBS (The Bethesda system) of reporting cervical cytology provide uniform system with clear guidelines for classifying the cervical lesions which helps the clinicians in management of disease process.[4] Pap smear is a cost effective screening test and it contributes for reduced mortality. Discrepancies in results are encountered and around 20% of these errors are attributed to inter and intraobserver variabilities hence the need for Quality Control (QC) and Quality Assurance (QA) measures, which play an important role in

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evaluating cervical cancer.

Cervical cytology is subjected to strict regulations with QA enforced by the clinical Laboratory Improvement Amendments of 1988(CLIA '88).[1] QA in pap smears aims at improving the test performance reducing the false positive and false negative cases. The various internal quality indicators used in cervical cytopathology include positive rate, percentage of tests compatible with Atypical squamous cell(ASC) among satisfactory tests, percentage of tests compatible with ASC among abnormal tests, Atypical squamous cell/Squamous Intraepithelial lesion(ASC/SIL ratio), Atypical squamous cell of undetermined significance/ Squamous Intraepithelial lesion (ASCUS/SIL ratio), percentage of tests compatible with Low grade squamous intraepithelial lesion (LSIL), percentage of tests compatible with High grade squamous intraepithelial lesion(HSIL), percentage of false negative tests and percentage of unsatisfactory smears.[5] These quality indicators helps in improving the reporting quality and accuracy in detection of early preinvasive cervical lesions and reducing the false positive and false negative cases, hence all the cytopathology laboratory should carry out regular checks on quality indicators to attain bench marks for providing best quality services to the patient.

MATERIALS AND METHODS

This was a retrospective cross-sectional study conducted in the department of Pathology, BGSGIMS, Kengeri, Bengaluru, where pap smear reported from January 2023 to January 2025 were retrieved and rescreened. Ethical Clearance was obtained.

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Study procedure: Our study documented the cytological findings with relevant clinical details, and the following Internal Quality Indicators were calculated as mentioned below:

- **Positivity rate:**

Number of abnormal tests in a particular location and year×100

Total number of satisfactory tests

- **Percentage of tests compatible with ASC among satisfactory tests**

Number of tests with ASC-US and ASC-H×100

Total number of satisfactory tests

- **Percentage of tests compatible with ASC among abnormal tests**

Number of tests with ASC-US and ASC-H×100

Total number of abnormal tests*

*Abnormal tests include ASC-US, ASC-H, LSIL, HSIL, carcinoma

- **ASC/SIL ratio**

Number of tests compatible with ASC-US & ASC-H

No number of tests with LSIL and HSIL

- **ASCUS/SIL ratio**

Number of tests compatible with ASCUS

No number of tests with LSIL and HSIL

- **Percentage of tests compatible with LSIL**

Number of tests with LSIL×100

Total number of satisfactory tests

- **Percentage of tests compatible with HSIL**

Number of tests with HSIL×100

Total number of satisfactory tests

- **Percentage of false negative tests**

False negative are the smears which were classified as negative while routine screening, but found to be abnormal by the cytopathology quality team in random review of at least 10% of cases.

- **Percentage of unsatisfactory smears**

Number of unsatisfactory smears×100

Total Number of pap tests

Statistical Analysis: Data were entered on an excel sheet and descriptive statistical analysis was calculated for the quality indicators.

RESULTS

We have analysed 1467 pap smear cases received over a period of 2 years comprising of patients ranging in age from 20yrs - 80yrs.Majority of the patient came for routine cervical screening (56.7%). Rest of the patient had varied symptoms which are tabulated in [Table 1]

Table 1: Various reasons for Hospital visit in cases of pap smears (LBC) received in this study

Sl No.	Reason for Hospital Visit	Total Number of cases(N=1467)	Percentage of cases(%)
1	Routine Cervical Screening	833	56.7%
2	Vaginal Discharge	170	11.7%
3	Post-Menopausal Bleeding	06	0.41%
4	Dysmenorrhea	170	11.7%
5	Itching in private part	37	2.55%
6	Heavy Menstrual bleeding	212	14.6%
7.	Abnormal menstrual bleeding	35	2.42%
8	Family History of cervical Ca	04	0.27%

Out of the total 1467 cases that was screened, 21 cases were found to be unsatisfactory with rate of 1.43%. The data collected during the study is tabulated in [Table 2]

Table 2: Various Data collected during the study

Sl. No.	Number of cases	For 2 yrs together
1	Total number of cases	1467

2	Total number of satisfactory cases	1446
3	Total Number of unsatisfactory cases	21
4	Total number of abnormal tests	10
5	Total number of ASC cases	6
6	Total Number of ASCUS cases	6
7	Total number of ASC-H cases	0
8	Total number of SIL cases	04
9	Total number of LSIL cases	03
10	Total number of HSIL cases	01
11	Positivity rate	0.69%
12	ASC % among the satisfactory tests	0.41%
13	% of tests compatible with LSIL	0.20%
14	% of tests compatible with HSIL	0.06%
15	ASC/SIL	1.5
16	ASCUS/SIL	1.5
17	Percentage of false negatives	0.09%

Total abnormal cases were 10, out of which 6 cases were ASC and 4 cases were SIL.Using the formulas various quality indicators percentage were calculated and the results are as follows: ASC % among the satisfactory tests-0.41%, Percentage of tests compatible with LSIL-0.20%, Percentage of tests compatible with HSIL-0.06%. The ASC/SIL and ASCUS/SIL were found to be 1.5% each respectively. The positivity rate was 0.69%.

Random slide review of previously negative cases revealed one abnormal case which was missed during initial reporting, hence false negative rate in the present study was found to be 0.09% and the case were informed to concerned cytopathologist for further action.

DISCUSSION

Cervical Cancer is the fourth most common cancer seen worldwide and it's the leading cause of death in India among women between the age group of 30-69yrs.Due to increased awareness nowadays many women are subjecting themselves for Pap Smear screening. Pathologist play a crucial role in providing good quality cervical cytology reports with good accuracy. TBS provides us standardized reporting in cervical cytology and clinical relevance. Over a period of time with the evolution of scientific knowledge, technical advances, respective changes in clinical management of cervical cancer and its precursor lesions have undergone revisions over a period. New Insights into adjunctive HPV testing methods and Immunocytochemistry methods are also added.[3]

The quality of cytopathology report is based on attaining the proposed benchmarks. To assess our standard, the Internal Quality Control Indicators were compared with the standard benchmark provided by CAP/Bethesda and other studies done. [Table 3]. Percentage of false negatives in various studies is shown in [Table 4].

Table 3: Comparison of Internal Quality control indicators of our study with standard benchmarks and with other studies

Sl. No	Parameters	Present study	Bethesda	Poongodi Rajagopal et al,[5]	Tan KB et al,[6]	Crasta JA et al,[7]	Davey DD et al,[8]
1	Year of study	2025	1994	2021	2004	2009	1996
2	Place of study	India	India	India	Singapore	India	America
3	Unsatisfactory rate	1.43	0.5%	3.34%	1.3%	1.36%	0.5%
4	Positivity rate	0.69%	3-10%	1.26%	-	-	-
5	ASCUS	0.42%	-	0.42%	0.9%	0.9%	4%
6	LSIL	0.20%	-	0.08%	0.8%	0.8%	2.5%
7	HSIL%	0.06%	>=0.4%	0.25%	0.4%	0.4%	0.6%
8	ASC/Satisfactory%	0.41%	5%	0.51%	-	-	-
9	ASC/SIL	1.5	2 -3	1.50	-	-	0.4-5.1
10	ASCUS/SIL	1.5	-	1.25	0.4	0.4	1.8

Table 4: Comparison between the percentage of false negatives in various studies

Studies	Place/Year of study	Percentage of false negatives
Present Study	India,2025	0.09%
Davey DD et al,[8]	Brazil,2015	2.10%
Bonilha JL et al,[9]	Brazil,2006	2.80%
Currens HS et al,[10]	America,2012	0.18%
Poongodi Rajagopal et al,[4]	India/2021	0.16%

In Our study the positivity rate, ASCUS, LSIL, HSIL, ASC among the satisfactory cases were below the benchmark recommended by CAP, Bethesda and other studies. On analysis the reason attributed for the difference was that 56.7% of the Hospital visited patients came for routine screening and with normal per speculum examination.

Lesser LSIL rate of 0.20% was attributed to low risk urban population and routine Health checkups.

Bethesda system suggests that ASC/SIL ratio should be less than 3:1, the lower ratio decreases the unpredictability produced by the laboratory and decreases the percentage with negative biopsy results. A higher ASC/SIL ratio suggests overuse and over interpretation of both ASC and SIL which can keep the ratio within accepted guidelines. This ratio should be used for

detecting pattern related to interpretation threshold.

HSIL is considered as the precursor lesion for cervical cancer. Hence detection of HSIL is the main objective of cervical cytopathology. In one of the study conducted by Tobias Ah et al,[11] which included multiple laboratories, the study results showed that 80% of laboratories have HSIL/satisfactory tests below the recommended level, indicating that precancerous lesions are not detected efficiently, thus highlighting the importance of rescreening of slides to detect false negative cases.

Rescreening of slides can be done in various methods, like random screening of 10% negative cases, rapid screening of 100%negative cases and rapid screening of all smears. These methods depend on the sample load and the number of working cytopathologists. In our study it was practically not possible to screen all the negative cases, only 10% of the negative cases were rescreened with a false negative case of 0.09%, which is compared with the other studies[Table4& Figure 1]. Lower detection of precancerous lesions can be attributed t eople in screening.

Fig a

Unsatisfactory smears of 1.43% is slightly higher to the benchmark of Bethesda, which could be attributed to sample error. This emphasis the proper pathologist and clinician communication.

In our study we had only one case with cyto-histo correlation which is shown in [Figure 2]

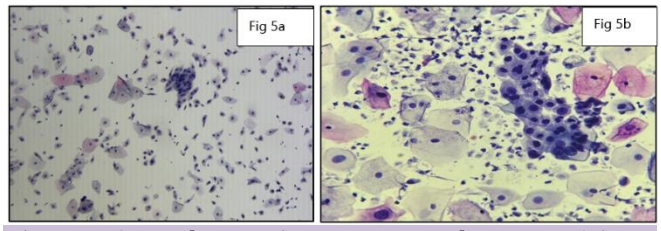


Figure 1: One False negative case; reported as NILM (Figure a), rescreening showed ASCUS (Figure b)

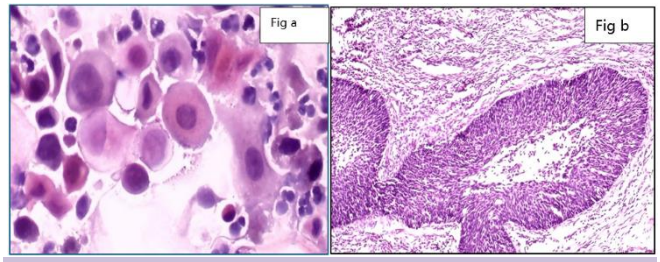


Figure 2: Cyto-Histo Correlation of a case of HSIL: Pap smear showing clusters cells with high N:C ratio, nuclear irregularity (Fig a: Pap 400x), On Histopathology, Cervical epithelium showing Full thickness high grade dysplasia of the lining epithelium extending into endocervical glands (Figure 6b:H&E;400x)

With reference to maintaining the accepting range in internal quality indicators in various laboratories all over the following areas can be focused

- Proper intercommunication with the clinician regarding unsatisfactory cases and resampling
- Rescreening of slides of doubtful cases by senior pathologist
- Cyto-Histo correlation discussion with the clinicians.

CONCLUSION

We have analysed that the few of our Internal QC indicators are still low compared to the standard values suggested by Bethesda. Regular monitoring the Internal quality indicators and participating in proficiency testing programmes helps us to identify the scope for improvement but also improves the performance outcomes, thus achieving the WHO's cervical cancer elimination target.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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