An analysis of internal quality indicators in department of cytopathology of a tertiary care hospital

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Abstract

Introduction: Various QC and QA including the pre analytical, analytical and post analytical variables were taken into consideration for the internal quality indicators in department of cytopathology of a tertiary care hospital.

Aims: To evaluate the importance of quality control (QC) and quality assurance (QA) parameters in the routine work of cytology pathology laboratory in a tertiary care hospital.

Materials and Methods: This is a retrospective and quantitative study in a tertiary care hospital for a period of one year for the analysis of the internal quality indicators for Cytopathology laboratory for gynaecological and non- gynaecological cases with selected variables.

Results: Data was analyzed using various mentioned formulas and excel sheet along with review of literature in the cytopathology laboratory.

Conclusion: It is very important to set the standards and review the procedures of QA and QC as per the requirement for the laboratory to ensure the quality for the cytopathology laboratory.

Keyword: Cytopathology, Quality assurance, Quality indicators.

Introduction

Cytopathology is a branch of pathology that deals with study of individual cells or clusters of cells and also as a preliminary assessment tool, in both gynecologic and nongynecologic pathology. Quality control (QC) is a system for verifying and maintaining a desired level of quality in a test or process. A quality control practice includes the entire testing process from collection of sample to the time the patient receives the report.

Quality assurance (QA) is defined by College of American Pathologists (CAP) as systematic monitoring of QC results and quality practice parameters to assure that all systems are functioning appropriately. QA is the coordinated effort to bring together the various activities in the labs that are designed to detect, control and prevent the occurrence of errors.[1]

Cytological tests are performed as preliminary diagnostic procedures with advantages in the turnaround time, cost, invasiveness and diagnostic accuracy. The Papanicolaou smear (PAP Smear) test is performed worldwide in order to detect cervical cancer at its earliest stages when treatment is most effective.

However, to ensure that these tests are effective, the sample as to be handled with utmost care, the smears are to be prepared and processed correctly, analyzed and reported by the laboratory with a higher degree of accuracy. In 1999 Institute of Medicine report entitled "To Err Is Human: Building A Safer Health System"[2] and through subsequent publications, in 2015 Institute of Medicine report entitled "Improving Diagnosis in Health Care",[3] which specifically indicated pathology as a target for patient safety.

Material and Methods

A retrospective and quantitative study was carried out in a tertiary care hospital for a period of one year from January 2018 to December 2018 to analyze the internal quality control protocol for cytopathology laboratory, for gynaecological and non- gynaecological cases. All samples received during this period were included in the study. Clearance from ethical committee of the institution was obtained. Patient's consent was taken before Fine needle aspiration (FNAC) procedure. The gynaecological samples of PAP smears were stained by rapid PAP stain (BIOLAB). FNAC smears, fluid cytology and Bronchioalveolar lavage (BAL) smears were stained with Leishman stain, Geimsa stain and PAP stain. All slides were independently examined and reported by two cytopathologists. The Bethesda system was used for reporting of PAP smears and thyroid cytopathology. Selected variables as described below with their respective formula were studied:

1. No of unsatisfactory cases = No of unsatisfactory test/ smears X 100 / Total no of cytology tests
2. Daily review of technical quality of cytological preparations smears and stains used in cytology laboratory.
3. Turnaround time (TAT) – No of tests exceeding more than 2 working days.
4. Cytology histology correlation = Total no of test correlating with cytology/ Total no of tests referred to Histopathology.
5. Positivity Rate for PAP Tests = No of abnormal tests X 100 / Total no of satisfactory tests.
6. Percentage of tests compatible with ASC among satisfactory PAP tests = No of tests with ASC-US and ASC- H X 100 / Total no of satisfactory tests.

7. Percentage of tests compatible with ASC among abnormal PAP tests = No of tests with ASC-US and ASC- H X 100 / Total no of abnormal tests.
8. ASC/SIL ratio = No of tests compatible with ASC-US / No of tests with LSIL and HSIL
9. Percentage of tests compatible with HSIL = No of test with HSIL X 100 / Total no of satisfactory tests.

Data was entered in a spreadsheet and analyzed by translating it into percentage and proportions.

Results

1873 cytology cases were studied from a period of January to December 2018, of which 46 cases were found to be unsatisfactory. Hence 1827 cases were included in this study. Fig. 1 show a total of 46 cases were unsatisfactory of which 16 cases were of Cervicovaginal PAP smears, 28 cases were of FNAC and 02 others which included BAL, nasal smears etc. Thus 2.45% of cases were found to be unsatisfactory for the study period.
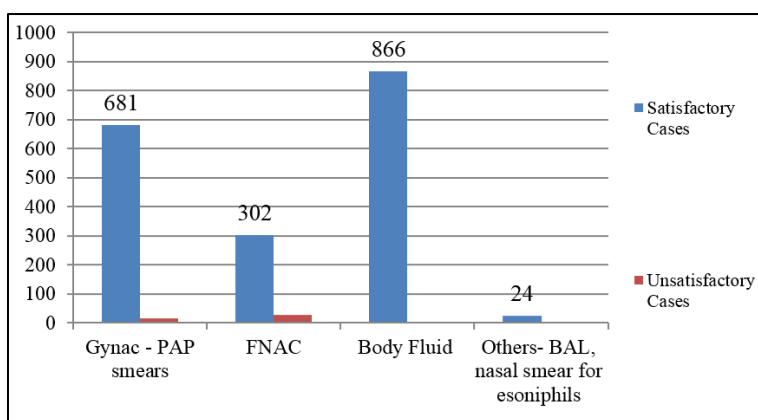

Fig. 1: Diagrammatic representation of total number of satisfactory and unsatisfactory cases

Fig. 2 shows the daily review of technical quality of a good cytological slide preparation along with staining quality for Giemsa stain, Leishman stain and PAP stain which was found to be an average of 97.5% from the study period.
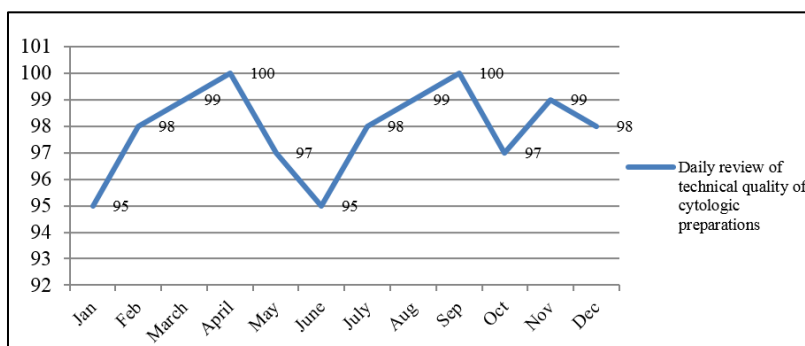

Fig. 2: Diagrammatic representation of technical quality of cytology preparations.

Fig. 3: An average of 8.8% of the cases was found to have an increase turnaround time (TAT) of more than 2 days during the study period. The PAP smears were not received on the day of entry in the software was the main reason for increase in TAT.
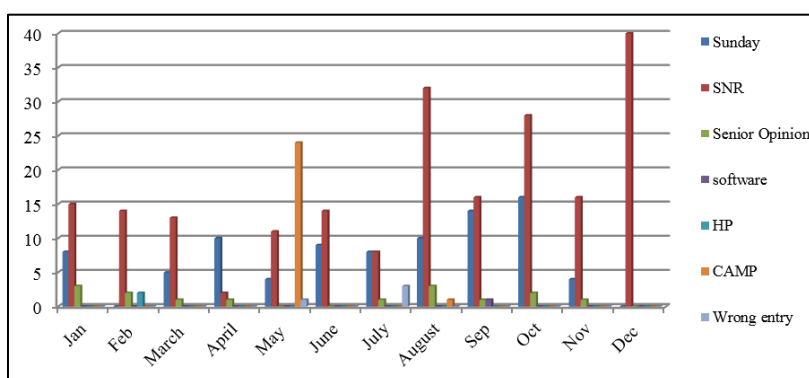

Fig. 3: Diagrammatic representation of turnaround time

The cytology histology correlation was possible in 105 of 1873 cases. In 93 of 105 cases, histopathology correlated with cytological findings. The non-correlation was mainly due to the limitations in cytology techniques in the FNAC smears aspiration smears (10 cases) of which 04 cases needed corrective actions which were due to the difference in diagnostic criteria and limitation in the clinical history.
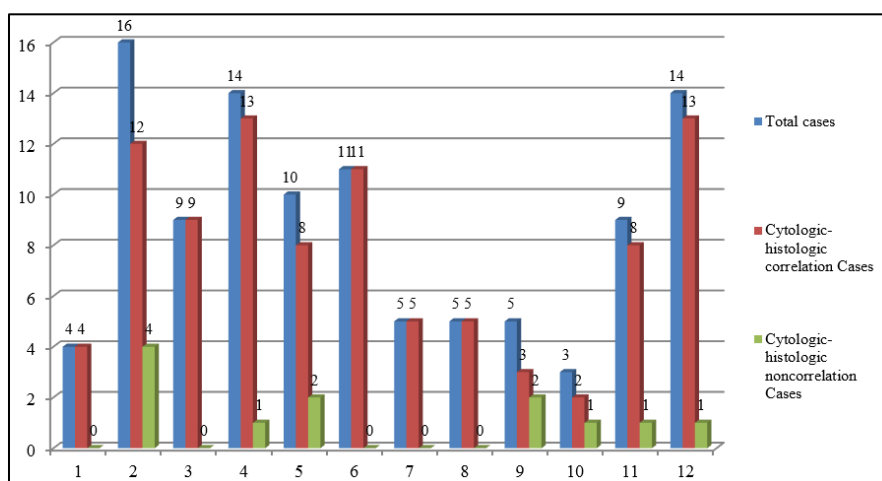

Fig. 4: Diagrammatic representation of cytology histology correlation and non-correlation

For a total of 631 Cervicovaginal PAP smears the various quality parameters used along with their results are shown in table 1.

Table 1: Results of various quality parameters in Cervicovaginal PAP smears

Parameters	Result
Positivity Rate for PAP Tests	4.4
Percentage of tests compatible with ASC among satisfactory PAP tests	2.3
Percentage of tests compatible with ASC among abnormal PAP tests	53.3
ASC/SIL ratio	Jan to June – 0.4 July to Dec – 1.4
Percentage of tests compatible with HSIL	0.7

The above table no 01 it shows the percentage of various quality indicators in PAP smears. The positivity rate is 4.4%, the ASC percentage among the abnormal tests is 53.3%, the ASC percentage among the satisfactory tests is 2.3%, and the ASC/SIL ratio remained between 0.4 to 1.4 and the percentage of tests compatible with HSIL 0.7% during the study period.

Discussion

The cytology has long been at the leading forefront of quality assurance (QA), internal and external quality control (QC) in pathology. Historically, cytology was a pioneer in QA/QC compliance as early as 1967, with federal regulative legislation like the Clinical Laboratory Improvement Act (CLIA, revised in 1988) via the various centers for healthcare and medicinal Services[4] and continued on by accreditation bodies like the Joint Commission and the College of American Pathologists (CAP).[5]

The most outstanding theorist of Quality Assurance within the field of healthcare is Avedis Donabedian who in 1988 has projected the QA into three parts - the Structure, methods and Outcome which can be similarly applied to a cytology laboratory also.[6]

The various divisions into which quality assurance can be divided into are -
a. Resources (staff and qualification, equipment)
b. Organization (availability of a mission and vision, job descriptions, policies to develop and update standard operative procedures (SOP) and to observe and monitor their implementation)
c. Workload and productivity (e.g. range of slides processed annually by the laboratory)
d. Quality of information taken (i.e. responsibilities, accuracy, completeness of data) of reporting and recording.
e. Implementation of internal and external quality control.
f. Diagnostic accuracy and reliability.

Sample adequacy is the most important keystone hallmark for quality in cytology which directly affects the sensitivity. Sample preparation is a very critical and crucial step for the optimal performance for interpretation, so as to avoid errors. Conventional smears have more chances to be inadequate than the LBC preparations, and hence is an important to maintain a thin-layer of distribution of the cells, especially in Pap staining.[7]

The factors adopted in our laboratory for gynecological and non-gynecological smears / FNAC considered "unsatisfactory for evaluation" or inadequate for reporting are, when the following criteria were met:

1. Lack of patient identification.
2. Scant squamous epithelial component especially for PAP smears i.e. less than 10% of squamous cells.
3. Obscuring cells in form of RBC's, inflammatory infiltrate, excess of cytolysis, thick areas, poor fixation, air-drying and contamination.
4. A smear containing abnormal cells is never being categorized as inadequate.
5. The cause for inadequate FNA is also because of lack of technical experience in performing FNA.

The average percentage of unsatisfactory smears was found to be 2.45%. This rate of inadequacy of smears depended on the various causes mentioned above. The rate for unsatisfactory smears also varies depending on the source of the smears and the laboratory to advise to those who collect smears and to discuss and improve the techniques used so that the quality of the material received can be improved.

Automation can reduce errors of staining and coverslip mounting. Cost could be a limitation to introducing equipment for preparing, staining and mounting coverslips automatically. However, the benefits in terms of quality are recognized.[8]

The interpretation of slides should always be with caution to avoid false-negative and false-positive reports.[9-12] Interpretation of screening are very closely associated to the skills of the quality of basic theoretical and practical training and also the continued education. Classification of microscopic findings must follow rigorous criteria for classifying the cellular abnormalities in order to avoid errors in interpretation and the laboratory performance.[12,13]

The quality control requires two major approaches:

1. Internal quality control: this is applied within a laboratory and demands a definite approach under the control of a senior staff member.
2. External quality assurance: this is usually done at an interlaboratory level and run by a professional peer group, such as an institute or college of pathology so as to obtain a fair assessment of the practice in each laboratory from its individual members of staff.

The various continuous quality assurance and internal quality control procedures laid down in our laboratory are -

1. Systematic assessment of smear adequacy.
2. Supervisory review of borderline and abnormal smears.
3. Supervisory review of random cases.
4. Quality control and management of negative or inadequate smears is performed by random screening or rapid review.
5. Peer review and discussion of abnormal smears or as interesting cases.
6. Histopathology and cytology comparison.
7. Storage of slides.
8. Handling of complaints.
9. Monitoring of turnaround time.
10. Preparation of Annual report.

The external quality control procedures laid down are -
1. EQAS (External quality assurance system)
2. Proficiency Testing

The other measure to assurance quality assurances are training, certification and continuing professional education of all the staff.

The turnaround time for any laboratory test is a vital quality component.[14] The clinical impact of quick reporting is quite variable, depending on the nature of the test and clinical circumstances. Gynecologic cytology is designed as a screening test, which for few diminishes the urgency of the results. Some take gynecologic cytology turnaround time to be "unrelated to quality of patient care."[15] The CAP and ISO 15189 believe that a goal of two working days TAT for cytology specimens is reasonable. Cytopathology, like histopathology, is a very subjective discipline. In the final analysis all cytological reports are of the opinion of one person and are in turn monitored by the opinion of a colleague reporting in histological sections from the same patient. The TAT was well maintained for 94.2% of the cases.

The cytology and histology microscopy method allows a precise correlation with the report. Whenever discrepancies occur, both cytological and histological smears are reviewed and an error is identified.

The reasons for numerous diagnostic variability and their frequency as the root cause might be divided into -[16]

1. Pathologist related
 i. Difference of opinion.
 ii. Not noting focal diagnostic findings.
 iii. Different diagnosis criteria.
2. Specimen related
 i. Poor slide quality/artifacts
 ii. Limited diagnostic material.
 iii. Required further additional stains for diagnosis and identification.

In this study, the positivity rate is observed to be 4.4% which is very well maintained within the appropriate standards. The literature suggests that countries like the United States[17] Norway[18] and the United Kingdom [19] show the positivity rate of 6.8%, 4.9% e 6.4%, respectively.

The mean percentage of tests compatible with ASC among the satisfactory smears in the study period accounts to 2.3%. The atypical cells of undetermined significance were considered as suspicious cases wherever the presence of cellular changes is inadequate for the diagnosis of squamous intraepithelial lesions. The mean of ASC percentage among abnormal smears within the period is 53.3%. This indicator includes an indirect assessment of quality, however does not permit an independent analysis of the quality for the process. The rise in this index is harmful for women and the health care network as it results in rise in the repetition of the tests or requires a biopsy for confirmation.[20]

The Recommended ASC/SIL ratio should not exceed 3.0.[20,21] The 0.4 and 1.4% for every six monthly ASC/SIL

ratio is comparable to 1.4% in the study of Renshaw,[23] 1.5%, of Chebib[24] and 1.9% of Catteau.[25]

An acceptable profile for a laboratory involved in a screening programme is shown below:[26] HSIL (CIN 2 and CIN 3) 1.6% ± 0.4

1. LSIL (HPV and CIN 1), ASCUS and AGUS 5.5% ± 1.5
2. Inadequate 7.0% ± 2.0

Thus, there are several strategies of review, to observe and monitor the quality of cytology smears, to the discretion of every laboratory to select the method that meets its profile. The data could be either be fetched through LIS or hand written log.[27] The review strategies recommended are: analysis of cytohistological correlation, retrospective review of the tests, random review of 10% smears, review of smears based on clinical criteria for risk, quick and fast review of 100% of negative smears, fast prescreening of all smears.[20] Few others also could be rejected specimen/ slides, processing problems, cytology follow-up correlation and amendment or revised test reports etc.[28]

Conclusion

Thus in the cytopathology laboratory, quality is directly linked to the microscopy and to avoid false results this should be in activity of various internal and external quality controls programmes. Caution should be monitored mainly in 2 areas: first is in sampling and preparation and second in the screening and interpretation. It is also important to systematically monitor the quality of all these procedures and set standards for the laboratory. Internal quality procedures should be a priority and an external audit on the QC and QA measures of the laboratory is also required.[15,16] Training of personnel is the fundamental to maintain the standard quality skills and also along with continuous education programmes. With this the results of such studies can significantly improve the cytological process in sampling and interpretation and overall reduce the errors in reporting.

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References

1. Branca M, Longatto-Filho. A. Recommendations on quality control and quality assurance in cervical cytology. *Acta Cytologica* 2015;59(5):361-9.
2. Kohn LT, Corrigan J, Donaldson MS Ed. To Err Is Human: Building A Safer Health System. Washington, DC: National Academy Press; 2000:1.
3. Balogh E, Miller BT, Ball J Ed. Improving Diagnosis in Health Care. Washington, DC: National Academy Press; 2015:1
4. United States Department of Health and Human Services. Clinical Laboratory Improvement Amendments of 1988, Final Rule. Washington, DC: United States Government Printing Office; 1992:7001-88.
5. College of American Pathologists. Cytopathology checklist. http://www.CAP.org. Accessed October 1, 2016.
6. Margherita Branca, Dulcie V. Coleman. Ed. Quality assurance and continuous quality improvements laboratories which undertake cervical cytology, Italy: PHARM IT Srl; 2000:7
7. Longatto-Filho A, Schmitt FC: Cytology education in the 21st century: living in the past or crossing the Rubicon. *Acta Cytol* 2010;54:654-6.
8. Stein MD, Fregnani JH, Scapulatempo C, Mafra A, Campacci N, Longatto-Filho A. RODEO Study Team from Barretos Cancer Hospital: Performance and reproducibility of gynecologic cytology interpretation using the Focal Point system: results of the RODEO Study Team. *Am J Clin Pathol* 2013;140:567-71.
9. Koss LG: The Papanicolaou test for cervical cancer detection. A triumph and a tragedy. *J Am Med Assoc* 1989;261:737-43.
10. Frable WJ: Error reduction and risk management in cytopathology. *Semin Diagn Pathol* 2007;24:77-88.
11. Coleman DV, Poznansky JJ. Review of cervical smears from 76 women with invasive cervical cancer: cytological findings and medico legal implications. *Cytopathol* 2006;17:127-136.
12. Bethesda Terminology. The 1988 Bethesda system for reporting cervical/ vaginal cytologic diagnoses. *Acta Cytol* 1989;33:567–74.
13. Nayar R, Wilbur DC: The Pap test and Bethesda 2014. *Cancer Cytopathol* 2015;123: 271-281.
14. Valestine P. Laboratory turnaround time. *Am J Clin Pathol* 1996;105:676-88.
15. Allen K.A. Strife in the fast lane. *Diagn Cytopthaol* 1997;17:406-7.
16. Kimberly H Alison, Lisa M Reisch. Understanding diagnostic variability in breast pathology: lessons learned from an expert consensus review panel. *Histopathol* 2014;62(2):240-51.
17. Davey DD, Neal MH, Wilbur DC, Colgan TJ, Stver PE, Mody DR. Bethesda 2001 implementation and reporting rates: 2003 practices of participants in the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal Cytology. *Arch Pathol Lab Med* 2004;128(11):1224-9.
18. Nygård JF, Skare GB, Thoresen SØ. The cervical cancer screening programme in Norway, 1992-2000: changes in Pap smear coverage and incidence of cervical cancer. *J Med Screen, London* 2002;9(2):86-91.
19. NHS Cancer Screening Programmes. NHS Cervical Screening Programme Statistical Bulletin. England, Nov 11.
20. Ministério da Saúde. Brasil. National Cancer Institute Jose Alencar Gomes Da. General Coordination of Prevention and Surveillance. Estimate. Manual for quality management in cytopathology. *Rio de Janeiro: Inca;* 2012.58.
21. Kurman RJ, Solomon D. The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses. New York, NY: Springer-Verlag; 1994:34.
22. Tabbara SO, Faser C, Frost AR et al. Toward establishing a target value for the ASCUS:SIL ratio [abstract]. *Acta Cytol* 1995;39:989.
23. Renshaw AA, Auger M, Birdsong G, et al. ASC/SIL ratio for cytotechnologists: a survey of its utility in clinical practice. *Diagn Cytopathol* 2009;38(3):180-3.
24. Chebib I, Rao RA, Wilbur DC, Tambouret RH. Using the ASC/SIL ratio, human papillomavirus, and interobserver variability to assess and monitor cytopathology fellow training performance. *Cancer Cytopahol* 2013;121(11):638-43.
25. Catteau X, Simon P, Noël JC. Evaluation of the oncogenic human papillomavirus DNA test with liquid-based cytology in primary cervical cancer screening and the importance of the ASC/SIL ratio: a Belgian study. *ISRN Obstetr Gynecol* 2014;18;2014.
26. Branca M, Morosini PL, Duca PG. Reliability and accuracy in reporting CIN in 14 laboratories. Developing new indices of diagnostic variability in an Interlaboratory study. *Acta Cytol* 1998;42:1370-6.

27. Heher Y, Chen Y, Vander Laan P. Measuring and assuring quality performance in cytology: a toolkit. *Cancer Cytopathol* 2017;125 (56):502-7.
28. Andrew A, George G Birdsong. Freeing the data from cytology databases in order to improve the quality of cytology. *Diagn Cytopathologist* 2019:48-52.
29. Branca M, Morosini P, Severi P, Erzen M, Di Benedetto C, Syrjänen K: New statistical software for inter laboratory and inter laboratory quality control in clinical cytology. Validation in a simulation study on clinical samples. *Acta Cytol* 2005;49:398-404.

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