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Quality Indicators in Cytopathology in a Tertiary Care Hospital

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ABSTRACT

The pre analytical, analytical and post analytical variables of quality control (QC) and quality assurance (QA) for the internal quality indicators are analyzed in order to enhance the quality of service. 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.(16) . Our aims were to evaluate QC/QA parameters in cytology This is a retrospective study of prospectively collected data in a single tertiary care hospital for a period of one year from 1/05/2019 to 30/04/2020 for the analysis of the quality indicators for Cytology with selected quality variables with standard formula.1883 cytology cases were studied, of which 60 (3.2%) cases were unsatisfactory. The daily review of technical quality of adequate cytological slide preparation and staining quality was 98.2%. An increase turnaround time (TAT) of more than 2 days was 6.2 %. The histology was done in 128/1883(6.7%) and 120/128 (93.7%) of cases, histopathology correlated with cytological findings Positivity rate for PAP smear was 35/1092(3.2%).Thus to review and analyze QA and QC for the laboratory to ensure the quality for the cytopathology laboratory was essential and overall reduce the errors in reporting.

Keywords: Cytopathology, Quality indicators, Test Process monitoring

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INTRODUCTION

Cytopathology is a branch of pathology that deals with study of individual cells or clusters of cells and as a preliminary assessment tool, in both gynecologic and nongynecological pathology. Quality assessment in Laboratory medicine is an essential requirement to ensure accuracy and precision of test results. Quality control (QC) programs with respect to Clinical Pathology and Hematology are being widely practiced world-wide. 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 (1). There are various factors attributing to its poor acceptance in cytopathology, which includes cumbersome processing, subjectivity in reporting and lack of numerical data for easy assessment.

Cytological tests are performed as preliminary diagnostic procedures with advantages in the turnaround time, cost, invasiveness and diagnostic accuracy. To Err Is Human: Building A Safer Health System" (2) The present study was therefore initiated with the aim to evaluate and assess quality parameters in the pre-analytical analytical and postanalytical phase .

EXPERIMENTAL SECTION

A retrospective and quantitative study was carried out in a tertiary care hospital for a period of one year May 2019 to April 2020 to analyze the internal quality control protocol for cytopathology laboratory, for gynecological and non- gynecological(NGYN) 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 gynecological (GYN) samples of PAP smears were stained by PAP stain. FNAC smears, fluid cytology and Bronchioalveolar lavage (BAL) smears were stained with May Grunwald Giemsa and PAP stain. All slides were independently examined and reported by two cytopathologist. The Bethesda system was used for reporting of PAP smears and thyroid cytopathology. We analyzed the quality indicators in cytology with selected variables. Registers, records and files were retrieved and checked; errors identified with respect quality variables using standard formulas.

Selected variables as described below with their respective formula were studied:

- No of unsatisfactory cases = No of unsatisfactory test/ smears X 100 / Total no of cytology tests
- Daily review of technical quality of cytological preparations smears and stains used in cytology laboratory.

- Turnaround time (TAT) – No of tests exceedingly more than 48 hours in NGYN and 72 hours in GYN cases.
- Cytology histology correlation = Total no of test correlating with cytology/ Total no of tests referred to Histopathology.

Positivity Rate for PAP Tests = No of abnormal tests X 100 / Total no of satisfactory test.

RESULTS:

1883 cytology cases were studied in study period. Total number of unsatisfactory cases were 60/1883 (3.2%), with unsatisfactory cases in cervicovaginal PAP smears [GYN] were 28/1092 (2.5%) and fine needle aspiration cytology (FNAC)[NGYN] were 32/791 (4%) [table no 1].

The daily review of technical quality of adequate cytological slide preparation and staining quality was 98.2%. [figure no 1]

An increase turnaround time (TAT) of more was seen in 116/1883 (6.2 %). In increase TAT in GYN cases were 45/1092(4.1%) and NGYN cases were 71/791(8.9%). [figure no 2].

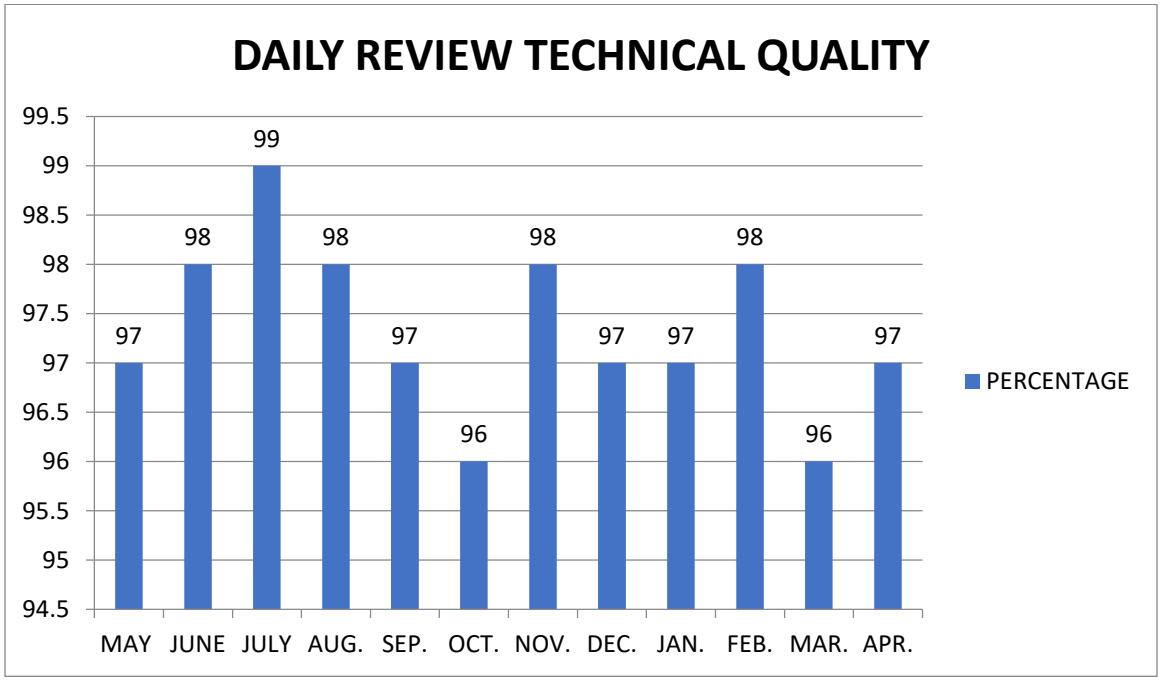
The histology was done in 128/1883(6.7%) Histopathology correlated with cytological findings in 120/128 (93.7%) Non correlation 8/128 (6.3%).Non correlation was in limitations in cytology interpretation/sampling in the 4/8 (50%) cases.

Positivity rate for PAP smear was 35/1092(3.2%).

Table 1- Reasons for unsatisfactory cases.

Reason	GYN Number (%)	FNAC Number(%)	Total (%)
Incomplete Test requisition forms (TRF)	6(21.4)	6(18.7)	12 (20)
Scant component	8(28.5)	4(12.5)	12(20)
Blood cells	2(7.1)	13(40.6)	15(25)
Inflammatory infiltrate	9(32.1)	4(12.5)	13(21.6)
Cytolysis	1(3.6)	3(9.3)	4(6.6)
Poor fixation	2(7.1)	2(6.2)	4(6.6)
Total	28	32	60

Figure 1- Daily review of slide technical quality



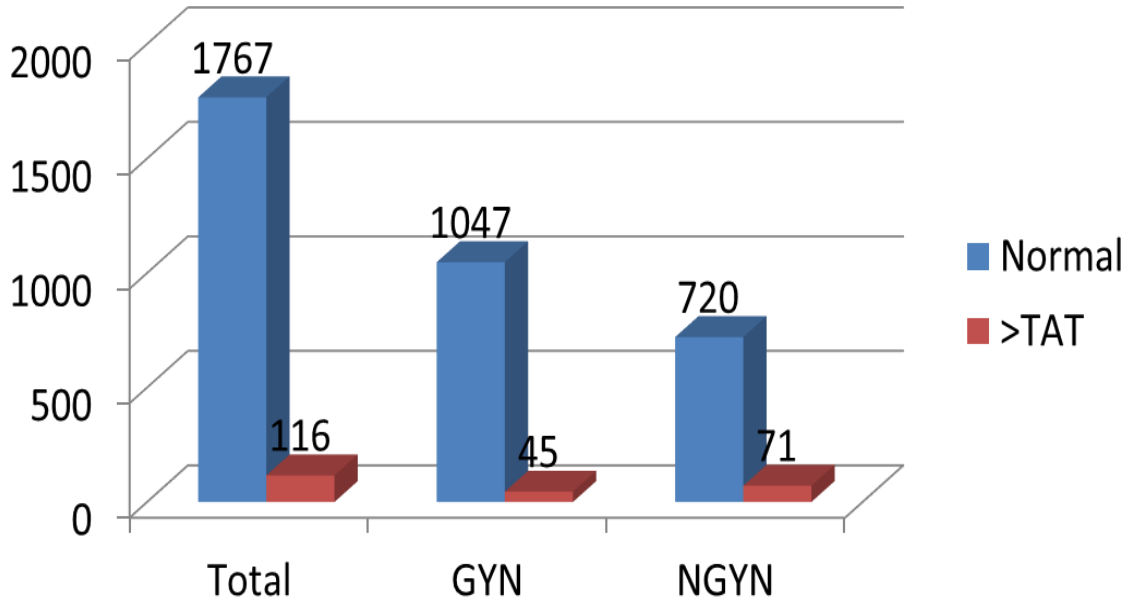


Figure 2- Turn around time (TAT) for gynecological (GYN) and non-gynecological (NGYN) samples

DISCUSSION

A well processed and good quality smear without any artifacts is the basic requirement for making an accurate cytopathological diagnosis. A study by Meier et al., showed that about 25% of all pathology errors occur due to diagnostic misinterpretation, while incidence of wrong identification and defective specimens ranges from 27% to 38% and 4% to 10% respectively (4).

Patient and specimen identification is the foremost essential step in this phase (5). Wrong labelling of specimens has resulted in unwarranted procedures (5). 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.(6) The factors adopted for gynecological and non-gynecological smears / FNAC considered "unsatisfactory for evaluation" or inadequate for reporting were scant squamous epithelial component especially for PAP smears i.e. less than 10% of squamous cells obscuring cells in form of RBC's, inflammatory infiltrate, excess of cytolysis, thick areas, poor fixation, air-drying and contamination.(7) The average percentage of unsatisfactory smears in our study was found to be 3.2%. This rate of inadequacy of smears depended on the various causes mentioned above.

Staining efficacy Papanicolaou staining procedure is commonly used for most cytologic samples, unless additional staining procedure is indicated. Staining solutions and chemicals used in the cytopathology laboratory should be labeled with the time of preparation, purchase, or both and standard preparation to review should be followed on day-to-day basis. (8) In our study we maintained adequate staining of 98.2%. This was maintained as the staff and technical support were adequately trained for slide preparation.

The CAP and ISO believe that a goal of two working days TAT for cytology specimens is standard. (9,10) Cytopathology is a very subjective discipline and delay in TAT may be due to senior opinion before making a final diagnosis. The TAT was well maintained for 93.8% of the cases.

The cytology and histology microscopy method allows a best possible correlation with the report. Both cytological and histological smears are reviewed, and an error is identified when there is variation and discrepancy. The reasons for numerous diagnostic variabilities may be pathologist related and difference of opinion based on clinical findings. (11,12) Other factors noted are that the slide

preparation, artifacts and different diagnostic criteria for histology and cytology (13) In our study non-correlation was noted in 6.3%.

The positivity rate is observed to be 3.2 % which was within the appropriate standards but less in this study . The literature suggests that developed countries like the United States (14) and the United Kingdom (15) show the positivity rate of 5.8% and 4.4%, respectively. The difference may be due to better screening programs in developed countries.

CONCLUSION

A satisfactory level of quality was being maintained in the cytopathology laboratory studied with respect to all phases, with a scope for further improvement. Thus, to review and analyze QA and QC for the laboratory to ensure the quality for the cytopathology laboratory was essential. It will help us in future to significantly improve the cytological process in sampling and interpretation and overall reduce the errors in reporting.

Support : Nil

Source of Interest: None

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