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EVALUATION OF PRE ANALYTICAL ERRORS IN CYTOLOGY LABORATORY – A ONE YEAR STUDY AT A TERTIARY CARE HOSPITAL.

Pathology

Dr. R. Muthukrishnan Associate Professor of Pathology, A. C. S. Medical college, Chennai

Dr. S. Harshavardini Post graduate in Pathology, SRIHER, Chennai

Dr. T. M. Karthikeshwaran Post graduate in Paediatrics, Vijaya hospital, Chennai.

Dr. M. Indumathy* Deputy Director, King Institue, Chennai. *Corresponding Author

ABSTRACT

Objective: Cytological examination is a very important modality in diagnosing, staging and treating of numerous diseases. Due to the varied techniques available in sampling, a wide variety of pre-analytical errors become possible. The present study was therefore conducted between January and December 2019 using 4168 samples to analyse the prevalence of pre analytical errors and their distribution among rejected samples

Methods: This study was conducted for a 1 year period at a tertiary care hospital in Chennai. All the samples received in cytopathology were considered.

Results: Among the 4168 samples, 464 samples were asked to be repeated and 66 samples were rejected. Most of the rejections were attributed to insufficient samples (62.1%) followed by discrepancy in registration (18.2%) and soiled TRF (9.1%) respectively

Conclusions: Pre-analytical errors are a significant cause of rejection or repeat of samples in cytology. Regular training and repeated reinforcement are crucial in reducing these errors to ensure correct results and faster turnaround times.

KEYWORDS

Cytology laboratory, Pre analytical errors, sample rejection, Re do's, TRF (Test request forms), Turnaround time (TAT).

INTRODUCTION:

Results generated by laboratories are important to categorise and classify disease entities, to understand their clinical outcomes and to formulate treatment protocols. Total quality management is key to any laboratory in order to maintain quality, reduce or eliminate the errors, and improve patient safety. It basically involves all three of the phases of laboratory operation, which include pre-analytical, analytical, and post analytical stages.

Diagnostic accuracy is critical in helping a treating physician to significantly reduce the mortality and morbidity of the patient. The quality management in the cytopathology laboratory is comparatively more difficult than other laboratory branches, mostly due to descriptive reports, subjective variability, and lack of numerical data. In addition, except for few uniform reporting systems, such as cervico vaginal pap smears, urine, thyroid, etc., which are followed worldwide, the literature lacks any such uniform system for other cytological lesions. This also adds to the different terminologies which are followed in cytology, making the concept of quality management difficult.

In this era of lab automation, pre analytical test processes still contributes to major preventable irrelevant and clinically non-contributory test results[1]. The pre-analytical phase of total quality management includes all the steps which are involved in the lab until the analysis or reporting of the required investigation, along with patient and professional satisfaction. The pre analytical phase is recognized as one of the most vulnerable phase in the diagnostic testing process and accounts for 49% to 68% of errors in a medical laboratory.

This study analyses the incidence of pre analytical errors resulting in rejection of samples during the study period of one year from January 2019 to December 2019 in a tertiary care hospital.

MATERIAL AND METHODS:

Test samples for cytology evaluation from a 600 bedded tertiary care hospital were included in this study. These samples were collected from OP, IP and from facilities provided by community health outreach programmes, particularly PAP smears and transported to central lab by adhering to hospital transport guidelines. These samples were analysed using automated cell counters and strainers.

Exclusion criteria: Samples for bio-chemistry and microbiology were excluded from the study.

Inclusion criteria: Samples exclusively for cytological examination were included in this study.

The samples were selected by A total number of 4168 were analysed during this period.

RESULTS:

During the study period, 4168 samples were analysed in the cytopathology lab. Majority of the samples were of vaginal cytology - PAP smear (22.6%) followed by fluid cytology (19.3%) and FNAC thyroid (17.8%). Of these samples, 464 samples were asked to be repeated and 66 samples were rejected. (TABLE 1)

Table 1: Distribution Of Samples

S.NO	Type Of Sample	Number Of Samples			No. Of Repeat Samples			No. Of Samples Rejected	% Of Samples – Rejected / Re-do
		IP	OP	TOTAL	IP	OP	TOTAL		
1	Fnac Thyroid	22	719	741	1	158	159	8	22.5
2	Fnac Breast	6	574	580	2	18	20	2	3.8
3	Fnac Lymph Node	13	277	290	2	54	56	4	20.7
4	Fnac Soft Tissue	1	256	257	0	40	40	28	26.5
5	Fnacs Alivary Gland	8	349	357	1	75	76	6	23
6	Fluid Cytology (ascitic, Pleural, Etc)	790	15	805	46	4	50	5	6.8
7	Exfoliative Cytology (sputum, Skin, Etc)	2	191	193	0	7	7	1	4.1
8	USG Guided Fnac	3	0	3	0	0	0	0	0
9	Vaginal Cytology – Pap Smear	47	895	942	5	51	56	12	7.2

The cause of rejection was attributed to the following pre analytical errors:
1. Inadequate sample
2. Discrepancy in registration
3. Spilled sample
4. Wrong containers
5. Clot in sample
6. Broken slides
7. Soiled test request forms. (TABLE 2).

Majority of rejections were attributed to inadequate sample (62.1%), followed by discrepancy in registration (18.2%) and soiled TRF (9.1%)

Table 2: Distribution of Rejected Samples

S.NO	Reason For Rejection	IP	OP	Total	Percentage
1	Inadequate Sample	1	40	41	62.1
2	Discrepancy In Registration	0	12	12	18.2
3	Sample Spillage	0	3	3	4.5
4	Wrong Container	0	1	1	1.5
5	Clot In Sample	1	0	1	1.5
6	Broken Slides	1	1	2	3
7	Soiled TRF	2	4	6	9.1

DISCUSSION:

Cytological analysis is an important diagnostic tool for physicians to initiate treatment and classify diseases, for example, a critical cytological reports like unsuspected malignancy can help the treating clinician to initiate appropriate treatment options[2]. More over samples for cytology tests, except guided FNAC[3] can be collected in all clinics, and hospitals with limited resources, as the test requires less space and less costly equipment.

But a clinically significant cytological test report is dependent on three important variables viz: 1, pre analytical, 2. Analytical, & 3. Post analytical variables. In this era of lab automation, analytical and post analytical phase errors have largely been minimised, yet the pre analytical errors continue to be major issue.[1]

The pre-analytical phase of the total laboratory testing process is where the majority of laboratory errors occur. Studies have shown that pre-analytical errors predominated in the laboratory ranging from 31.6% to 75%. The pre-analytical phase can be classified into two namely the "Pre"-pre-analytical constituting (46-68%) and the "true" or "conventional" preanalytical phase (3-5%).[4]

Cytological analysis requires a certain number of follicular epithelial cells in thyroid FNAC, adequate number of ductal epithelial cells in mammary and salivary gland for a clinically relevant test report. This present study identifies inadequate sample (inadequate number of cells in FNAC) as the single most important cause of re do and rejection (63.1%).

An ideal needle biopsy yields an adequate sample for the intended diagnostic assessment. More comprehensively, an ideal adequate biopsy provides a sample containing the most reliable diagnostic information representative of the lesion in the timeliest fashion, with the least burden to the patient, the biopsy operator, and health system costs. Conceptually, needle biopsies can be classified as inadequate, somewhat adequate, or fully adequate for the intended diagnostic purpose. The characteristics for an ideal needle biopsy sample are:

(i) reflects lesion localization
(ii) contains cells and cell component content for intended assessment
(iii) contains cells and cell content representative of the lesion
(iv) where possible, sample contains predominantly lesional tissue[5]

Presence of peripheral blood in cytology sample can obscure the cell morphology and thus makes the sample unsuitable for evaluation and warrants a repeat test, or can be an indication for rejection[6]. In our study, it accounts for 1.5% of the samples rejected.

FNAC from soft tissue lesions usually yield less cellularity, usually requires an invasive biopsy. Formulation of sample collection manuals, training on sample collection techniques like non aspiration methods for FNAC of thyroid, co –ordination between clinicians collecting samples as an outpatient procedure and the reporting pathologists, and periodic audits can bring down the need for re do's and sample rejection, and optimal turnaround time (TAT) can be achieved in the lab, as per the requirement of the hospital concerned.[7]

The next important cause of sample rejection & prolonged TAT is sample spillage causing soiled Test Request Forms (TRF) containing vital clinical information (LMP, site of primary collection etc.,) for cytological analysis.[8] In the present study this is found to contribute to 13.6% of the rejected samples. Training for proper capping the sample containers containing body fluids and usage of leak-proof sealing by appropriate materials followed by periodic audit of the corrective and preventive actions will significantly reduce the rejection of ascetic, peritoneal fluid cytology analysis.

Next significant rejection criteria noticed in the study is the broken vaginal cytology slides collected as a part of clinical outreach programmes[8] The present study noted 3% of the rejections to be due to broken slides. Training, provision of suitable packing materials can significantly reduce this pre analytical error.

Inappropriate sample containers shall make precious samples like synovial fluid[9], and excess of peripheral blood shall make sample not suitable for processing due to sample clot.[10] 1.5% of the rejections in our study were caused by use of wrong containers. Adequate training and audit shall significantly reduce these errors in the laboratory.

CONCLUSION:

Reliability and accuracy of cytological test results depends on three important variables namely pre analytical, analytical and post analytical processes. Critical alerts like presence of malignancy are generated and accuracy of these results are of paramount importance. Good lab practices, external & internal audits shall bring down the occurrences of preventable cause of errors in a cytology laboratory to ensure better accuracy and faster results.

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