

## Cyto-Histological Correlation: A Tool to Assess, Improve and Assure the Quality of Cytology Laboratory

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### Abstract

**Background:** Documentation of cyto-histological correlation and discrepancies is an important tool for assessing quality of cytological diagnosis. Regular monitoring of discrepancies provides a window of opportunity to improve the performance of cytology laboratory.

**Aims:** To report cyto-histological discrepancies and factors associated with discrepancies.

**Settings and Design:** This retrospective record based study was done at the cyto-histology laboratory in a tertiary care hospital in Gujarat.

**Materials and Methods:** The samples in which both Fine needle aspiration cytology (FNAC) and histology examination was done during 2015-2017 were included in the study. Diagnoses of these examinations were compared and discrepancies noted. Discrepancies were classified based on organ involved, size and nature of the lesion. The results were reported as proportions.

**Results:** The cyto-histological discrepancies were observed in 36 out of 150 samples (24%). Maximum discrepancies were observed in lymphnodes followed by thyroid and breast lesions. There was no significant difference between rate of discrepancies and size of the lesions. Cyto-histological discrepancies were found more in benign/reactive lesions as compared with malignant lesions (91% vs 9% respectively). Out of 36 discrepancies, 32 samples were benign and 2 samples were malignant, on both the cytology and histology examination with different subtype.

**Conclusion:** Out of total 150 samples, agreement between cytology and histology reports was found in 114 samples; and discrepancy was noted in 36 samples. Documentation of cyto-histological correlation is a useful tool to report discrepancies and factors associated with it. This can be monitored on regular basis as a measure to improve quality.

**Keywords:** Discordance; Discrepancies; Error; Quality Assurance; Quality Control; Quality Improvement.

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**Introduction**

Fine needle aspiration cytology (FNAC) is widely advised as one of the first line investigations for palpable lesions. The results of FNAC further decide the line of investigation and management. It is, therefore, important to assess the quality of the cytology results routinely. One of the powerful and underused quality assurance tools for cytology test is cyto-histological correlation (CHC). CHC is the comparison of cytological diagnosis with histological diagnosis of the same lesion from the same site. The procedure of cyto-histological correlation is valuable not only for FNAC, but also for tissue biopsy (histology) [1]. CHC must be done and documented in order to assess the cyto-histological discrepancies. These discrepancies can further be evaluated to assess the factors associated with their occurrence. This can be monitored on a regular basis for quality improvement.

Many studies have reported cyto-histological correlation and discrepancies in specific organs like salivary glands, thyroid and breast, to know the accuracy of cytology examination [2-4]. However, we found only one study from India focusing on correlating results from all the systems. [5] The overall cyto-histological discrepancies and its associated factors are not well reported in Indian literature. While, the study of specific organ system provides usefulness and limitations of FNAC in a particular system, general cyto-histological correlation provides the overall performance of cytology laboratory. It can highlight the system or some specific condition associated with more number of discrepancies. This can provide a window of opportunity for quality improvement. Hence, the present study was conducted to report cyto-histological discrepancy rate in the cytology laboratory and its associated factors, in a tertiary care hospital of Central Gujarat, India.

**Materials and Methods**

Ethical clearance and waiver of consent was obtained from the Institutional Human Ethics Committee. The study was conducted in cyto-

histology laboratory of the Department of Pathology, a tertiary care hospital in Central Gujarat. This is a retrospective review of the records of samples having documented reports of both cytological (FNAC) and histological examinations carried out from January 2015 to December 2017. All documented reports of samples with both cytology and histology examinations carried out over a period of three years between January 2015 and December 2017 were included in this study. The Principal Investigator reviewed the records of all samples in which both cytology and histology examinations were done to find the cyto-histological discrepancies. From the records, basic demographic details like age and gender of the patients, site/organ involved, size of the lesion and nature of disease were extracted.

The size of the lesion was assessed clinically while taking FNAC, and categorised as small (<1.5cm), medium (1.5-4cm) or large (>4cm) in dimension. The nature of the disease was classified as benign/reactive and malignant. Histological diagnosis was considered to be the standard while defining discrepancies.

Data of all samples having both cytological and histological diagnosis were extracted as per the pre-designed datasheet. Data were entered in the pre-validated Microsoft Excel Worksheet by applying appropriate checks to ensure data quality. Unique identity code was given to each sample to ensure confidentiality. This data sheet was exported and the data were analysed using Epi Data analysis V2.2.183.

Proportion of discrepancy rate was calculated using the following formula below:

Discrepancy rate = Number of samples having cyto-histo discrepancies

Total number of cyto-histological samples

The primary outcome (cytohistological discrepancy) was summarized as proportion (%). In order to find the factors associated with cyto-histological discrepancies, the discrepancies were classified based on organ/system, size of the lesion and nature of the diagnosis.

## Results

During the study period, 2824 cytology and 6097 histology tests were performed in the cyto-histology laboratory of the Pathology department (Table 1). Out of these, 150 samples had both cytological and histological examinations carried out and reported. There were 43 males and 107 females, with a ratio of 1:2.5. Majority of the patients were in the age group of 21 to 50 years.

**Table 1:** Total number of tests performed in Cytology and Histology sections from 2015 to 2017

Year	Cytology	Histology
2015	791	1857
2016	967	2090
2017	1066	2150
Total	3713	8349

The proportion of cyto-histological discrepancies was 24%. On further organ-system wise segregation, highest discrepancies were found in lymphnodes (43%), followed by thyroid (28%) and breast (21%). When discrepancies were divided based on the size of the lesion, the rate of discrepancies was almost similar in small (25%), medium (23%) and large lesions (26%). However, when the nature of the disease was considered, more discrepancies were found in benign/reactive lesions (91%) as compared to malignant lesions (9%).

**Table 2:** Cytohistological discrepancies among patient attending cytology OPD from 2015 to 2017

Variables	Cyto-histological discrepancies n (%)	Cyto-histological non discrepancies n (%)
Total	36 (24)	114 (76)
Thyroid	5 (28)	13 (72)
Breast lesion	13(21)	49 (79)
Lymphnode	9 (43)	12 (57)
Salivary gland	1 (8)	11 (92)
Soft tissue	3 (15)	17 (85)
Nasal mass	0 (0)	3 (100)
Oral lesion	0 (0)	4 (100)
Others	5 (50)	5 (50)
Size*		
Small	7 (25)	21 (75)
Medium	18 (23)	62 (77)
Large	11 (26)	31 (74)
Nature		
Benign / Reactive	33 (28)	83 (72)
Malignant	3 (9)	31 (91)

% is row percentage,

\*size of the lesion assessed clinically while taking FNAC. Small < 1.5cm, medium-3.5-4cm, large > 4cm in greater dimension.

Out of total 36 discrepancies, 32 were diagnosed as benign and 2 as malignant lesions in both cytology and histology examination. However, one sample diagnosed as benign in cytology turned out to be malignant in histology and the other sample diagnosed as malignant in cytology turned out to be benign in histology examination.

## Discussion

Since the inception of this institution (2012), this is our first attempt to report cyto-histological discrepancies from the Pathology Department. The number of tests performed in the cytology and histology sections has increased over the period of time from hundreds to thousands (Table 1). We have started documenting cyto-histological correlation, as it is an important tool for quality assessment.

Nowadays External Quality Assurance System (EQAS) is being widely used in laboratories to assure the quality of tests. But in case of FNAC, each sample being unique, the overall quality of the laboratory work is not reflected in EQAS performance. However, a simple cyto-histological correlation can provide an opportunity to know the limitations in cyto-histological examinations and ways to improve them. In absence of proper documentation, we would never know the actual magnitude of the discrepancies in the cyto-histological diagnosis.

The overall discrepancy rate in this study was 24%. We could find only one study conducted by Taylor et al in India which reports the overall discrepancy rate of 7%. In various cyto-histological correlation studies of specific organs, discrepancy rate was ranging from 5% to 31% [2,6,7]. Variation in the rate of cyto-histological discrepancies may be due to different criteria for defining discrepancy. Moreover, reporting practices also shows inter-laboratory and inter-person (subjective) variability. There is no standard performa for cyto-histological correlation and defining discrepancies and its practice widely varies from one laboratory to another [8]. These lead to variation while reporting and comparing discrepancies. Standardisation of the reporting system as well as documenting system can improve the correlation practice.

We had maximum discrepancies in lymphnodes (43%) which was similar with a study done by Saha et al reporting 30% discrepancies [9]. Contrary to this, some studies have reported less discrepancies in lymph node around 7% and 18% [10,11].

In our study, we reported 28% discrepancies in thyroid samples, with one false negative report. Many other studies conducted by Pandey et al, Gupta et al and Hamdani et al have reported discrepancies in thyroid samples around 20%, 16% and 14% respectively [12-14]. Few studies done by Gamit et al. and Disha et al. have reported lesser discrepancies in thyroid samples like 5% to 10% [3,6].

In case of breast lesions, 21% discrepancy rate was observed in this study. However, some studies by Mehra et al, Hassan et al and Tiwari et al reported a lower discrepancy rate [4,7,15]. In our study, 8% (one out of 12) discrepancy was reported in salivary gland with one false positive. Other studies have reported discrepancies ranging from 20% to 31% [2,16,17].

Our study reported discrepancy rates among various organ-systems. Maximum discrepancies were observed in lymphnodes (43%) followed by thyroid (28%) and breast (21%) samples. This knowledge regarding the discrepancies in specific organ systems during cyto-histology will help to improvise the current practices in cytology laboratory. Thus, these examinations may be reported with extra caution. The record review showed no significant difference between the size of lesion and discrepancy rate. As a practice, it may be thought that it is easier to perform FNAC on larger lesions. However, practically, the amount of diagnostic material and therefore diagnosis does not depend on size of the lesion but the characteristic of lesion. If the lesions have degenerative changes like inflammation, haemorrhage, necrosis or cystic changes, it may affect the diagnosis.

In this study, more discrepancies were observed in benign lesions (91%) as compared to malignant lesions (9%). Out of total 36 samples with discrepancies, 33 were diagnosed benign and 3 as malignant in cytology examination. Out of 33 benign lesions, 32 were diagnosed as benign only by histological examination, but with different sub-diagnosis. One sample diagnosed as benign on cytological examination turned out to be malignant on histological examination. Out of the three malignant lesions, two were confirmed as malignant lesions on histological examination, with different subtype. One cytologically malignant lesion turned out to be benign on histological examination.

In case of FNAC, there is a lack of architecture in the sample as well as the availability of diagnostic material is limited. Thus, it would be difficult to correctly diagnose the subcategories of benign/reactive and malignant conditions in some of the samples. The reason for missing the malignancy

could be sampling error (aspirated material is not representative of the lesion), or interpretational error (missing the malignant foci). Presence of hemorrhage, severe acute inflammation can mask the cellular details and lead to erroneous diagnosis. Sometimes, regenerative atypia in the cells can be mistaken to be malignant, leading to diagnosis of benign lesion as malignant. Sometimes, especially in epidermal cysts, cytological examination proves to be more helpful than histological. In our study, two epithelial cysts were diagnosed by cytological examination and were reported as 'non-specific' or 'descriptive' in histological examination.

There are some limitations in this study. Being a retrospective record review study, it was not possible to know whether the discrepancies were due to technical error or interpretative error. In majority of the records, clinical impression and radiological findings were not available so we were unable to include them for analysis.

## Conclusion

In this study, out of 150 samples, 114 show total agreement in cytology and histology diagnosis. Discrepancies were reported in 36 cases. Rate of discrepancies were different in different organ system and was more in benign lesions. Difference in size of lesion was not associated with significant variation in rate of discrepancy. Such documentation of cyto-histo correlation and evaluation of the discrepancies would provide us a good opportunity to learn and improve the practices in future in our own set up.

Routinely, cyto-histological correlation is done retrospectively after the reports are already dispatched. However, real time cyto-histological correlation can be more helpful to find the responsible factors associated with discrepancies.

*Prior publication:* Nil

*Support:* Nil

*Conflicts of interest:* Nil

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