Section: Pathology

Original Research Article

ANALYSIS OF INCONCLUSIVE OR INADEQUATE CYTOLOGY REPORTS ON FINE NEEDLE ASPIRATION SAMPLES: A SIX-MONTH STUDY AT GAIMS, BHUJ, KACHCHH

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ABSTRACT

Background: To determine the frequency and pattern of inconclusive or inadequate FNAC reports over a six-month period from the month of May, 2025 to October 2025 at Gujarat Adani Institute of Medical Sciences (GAIMS), Bhuj, Kachchh, with assessment of their anatomical distribution and repeat/guided aspiration status. **Materials and Methods:** A retrospective observational study was conducted in the Department of Pathology, GAIMS, Bhuj. The FNAC register covering a six-month period month of May, 2025 to October 2025 was reviewed and 214 FNAC records were analysed. Cases were categorized as inadequate/non-diagnostic, atypia of undetermined significance (AUS), difficult interpretation, suspicious/indeterminate and conclusive/diagnostic. For comparison with previously published literature, the strict inconclusive cohort comprised inadequate/non-diagnostic, AUS and difficult-interpretation cases. Repeat/guided FNAC was recorded when repeat, repeated, USG-guided or other guided aspiration was documented in the register. **Result:** Of 214 FNAC samples, 30 (14.0%) were classified as strictly inconclusive. These comprised 13 (6.1%) inadequate/non-diagnostic, 14 (6.5%) AUS, and 3 (1.4%) difficult-interpretation cases. An additional 17 (7.9%) cases were classified as suspicious/indeterminate. Lymph node/neck lesions accounted for the largest number of strict inconclusive cases, 13/30 (43.3%). However, the highest site-specific rate of inconclusive cytology was observed in salivary gland lesions (6/22; 27.3%), followed by thyroid (4/21; 19.0%) and breast (6/35; 17.1%). Repeat/guided FNAC was documented in 43/214 cases (20.1%) overall and in 10/30 cases (33.3%) within the strict inconclusive cohort. **Conclusion:** Inconclusive and inadequate FNAC constituted an important proportion of cytological examinations in this six-month study. Inadequate sampling was particularly observed in lymph node/neck and salivary gland lesions, while salivary gland lesions demonstrated the highest site-specific rate of inconclusive cytology. Attention to sampling adequacy, appropriate use of image guidance, clinical-radiological correlation and standardized reporting systems may help reduce inconclusive FNAC results.

INTRODUCTION

Fine needle aspiration cytology is an established diagnostic procedure used for the evaluation of a wide spectrum of lesions. Its advantages include minimal invasiveness, rapid turnaround time, relatively low cost and the ability to provide a preliminary or definitive diagnosis without an initial surgical procedure. FNAC is particularly useful in the evaluation of lymph nodes, thyroid, breast, salivary glands and soft-tissue lesions.[1,2]

Despite its widespread use, FNAC is not invariably diagnostic. An aspirate may be inadequate because of insufficient cellularity, hemorrhage, necrosis, cystic degeneration or sampling error. Alternatively, a specimen may contain sufficient material but demonstrate atypical or overlapping cytological features that preclude a definitive diagnosis. Such cases are commonly reported as atypical, indeterminate or difficult to interpret.[2,3]

An inconclusive FNAC result can have important clinical consequences. Patients may require repeat aspiration, ultrasound-guided sampling, core needle

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biopsy or surgical biopsy. Repeated procedures may increase patient anxiety, healthcare expenditure and diagnostic delay.[2,4]

Previous studies have demonstrated that inadequate sampling is one of the major causes of inconclusive FNAC. Chennimalai and Vincent, in a five-year study of inconclusive FNAC reports, reported an overall inconclusive rate of 10.8%, with inadequate smears representing the major contributing factor.[5] Their study also demonstrated variation in inconclusive rates according to anatomical site, with salivary gland and thyroid specimens showing relatively high rates.[5]

The development of standardized cytological reporting systems has helped reduce ambiguity and improve communication between cytopathologists and clinicians. The Bethesda System for Reporting Thyroid Cytopathology provides standardized diagnostic terminology for thyroid FNAC, while the Yokohama System for breast cytology and Milan System for salivary gland cytology provide structured approaches to reporting in these organs.[6-8]

Image-guided aspiration can also improve sampling in lesions that are small, deep-seated or difficult to access clinically. Appropriate clinical information, radiological correlation and communication between the treating clinician, radiologist and cytopathologist are additional factors that may improve diagnostic adequacy.[2,9]

The present study was undertaken to analyse the frequency and pattern of inconclusive or inadequate FNAC reports in a six-month FNAC register at a tertiary-care teaching hospital in Bhuj, Kachchh. The study also assessed the anatomical distribution of these cases and the documentation of repeat or guided aspiration.

MATERIALS AND METHODS

Study design and setting: This was a retrospective observational study conducted in the Department of Pathology, Gujarat Adani Institute of Medical Sciences (GAIMS), Bhuj, Kachchh, Gujarat, India.

The study analysed the FNAC register covering a six-month period.

Study population: All 214 FNAC records available in the study-period register were included.

The register contained information regarding the anatomical site, clinical/radiological impression, cytological findings, repeat or guided aspiration where documented, and relevant comments.

Cytological classification

For the purpose of this study, FNAC reports were categorized into five broad groups:

1. Inadequate smear/non-diagnostic
2. AUS
3. Difficult interpretation
4. Suspicious/indeterminate
5. Conclusive/diagnostic

The strict inconclusive cohort was defined as:

- Inadequate/non-diagnostic cases;
- AUS cases; and
- Difficult- interpretation cases.

Suspicious/indeterminate cases were retained as a separate category because they represent cytological uncertainty rather than technical inadequacy.

This approach was adopted to facilitate comparison with the published study by Chennimalai and Vincent.[4]

Anatomical classification

The lesions were grouped into:

- Breast
- Thyroid
- Lymph node/neck
- Salivary gland
- Soft tissue
- Others

Repeat/guided FNAC: A case was classified as repeat/guided FNAC documented when the register contained terms such as:

- repeat aspiration;
- repeat FNAC;
- USG-guided aspiration; or
- CT guided aspiration.

Statistical analysis: Data analysed descriptively. Frequencies and percentages were calculated for cytological categories, anatomical sites and repeat/guided FNAC status.

No inferential statistical analysis was performed because the primary objective was descriptive characterization of inconclusive FNAC.

RESULTS

Overall distribution [Table 1]

A total of 214 FNAC samples were analysed.

The strict inconclusive cohort comprised 30 cases (14.0%). Of these, 13 (6.1% of all FNACs) were inadequate/non-diagnostic, 14 (6.5%) were AUS and 3 (1.4%) were difficult to interpret.

A further 17 cases (7.9%) were classified as suspicious/indeterminate.

Thus, 47/214 cases (22.0%) fell into the broader potentially inconclusive/indeterminate group.

Anatomical distribution [Table 2]

Lymph node/neck lesions represented the largest group, with 113/214 cases. Among strict inconclusive cases, lymph node/neck lesions contributed the greatest absolute number, accounting for 13/30 cases (43.3%).

However, when the number of inconclusive cases was considered relative to the total number of FNACs performed at each anatomical site, salivary gland lesions showed the highest proportion of inconclusive results (27.3%).

Pattern of strict inconclusive cytology [Table 3]

Inadequate/non-diagnostic cytology was most frequent among lymph node/neck lesions [Figure 1,2], accounting for 7 of the 13 inadequate cases.

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AUS was particularly represented among breast [Figure 3,4] and lymph node/neck lesions.

Repeat/guided FNAC [Table 4]

Repeat/guided aspiration was documented in 43 of 214 cases (20.1%).

Within the strict inconclusive cohort, repeat/guided FNAC was documented in 10 of 30 cases (33.3%). [Table 5,6].

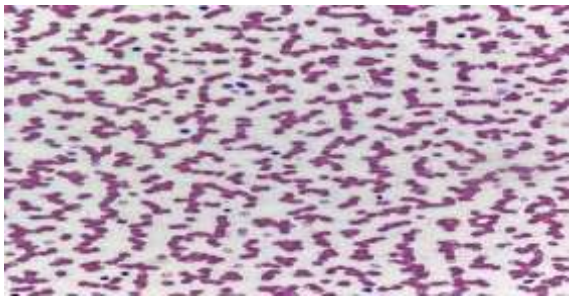


Figure 1: Inadequate lymph node FNAC (40X), H&E stain

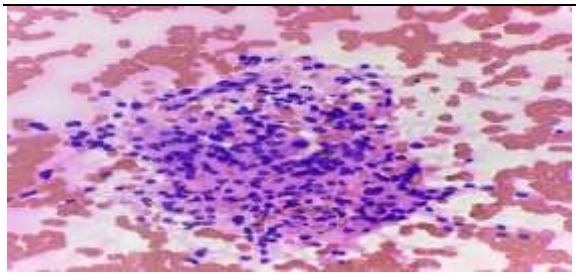


Figure 2: Repeat lymph node FNAC (40X), H&E stain

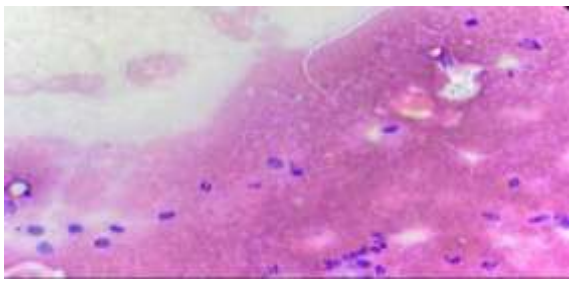


Figure 3: Inadequate breast FNAC (40X) H&E stain

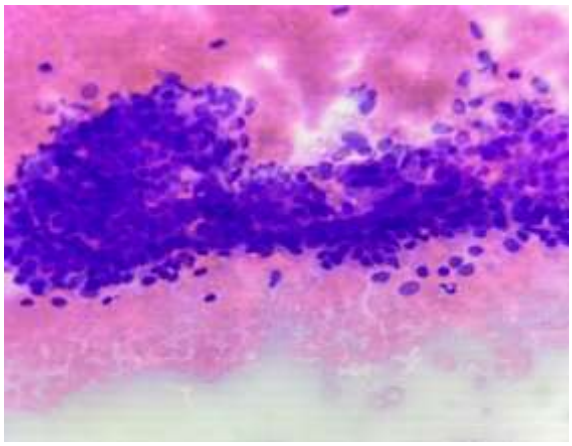


Figure 4: Repeat breast FNAC (40X) H&E stain.

Table 1: Distribution of FNAC cases according to cytological category

Cytological category	No. of cases	Percentage
Inadequate smear/non-diagnostic	13	6.1
AUS	14	6.5
Difficult interpretation	3	1.4
Suspicious/indeterminate	17	7.9
Conclusive/diagnostic	167	78.0
Total	214	100.0

Table 2: Anatomical distribution of strict inconclusive FNAC cases

Anatomical site	Total FNACs	Strict inconclusive	Inconclusive rate (%)
Breast	35	6	17.1
Thyroid	21	4	19.0
Lymph node/neck	113	13	11.5
Salivary gland	22	6	27.3
Soft tissue	8	1	12.5
Others	15	0	0
Total	214	30	14.0

Table 3: Distribution of strict inconclusive categories according to anatomical site

Anatomical site	Inadequate/non-diagnostic	AUS	Difficult interpretation	Total
Breast	0	5	1	6
Thyroid	1	3	0	4
Lymph node/neck	7	5	1	13
Salivary gland	5	1	0	6
Soft tissue	0	0	1	1
Others	0	0	0	0
Total	13	14	3	30

Table 4: Overall repeat/guided FNAC status

Repeat/guided FNAC status	No. of cases	Percentage
Repeat/guided FNAC documented	43	20.1
No repeat FNAC	171	79.9
Total	214	100.0

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Table 5: Repeat/guided FNAC among strict inconclusive cases

Cytological category	Total cases	Repeat/guided FNAC	No repeat
Inadequate/non-diagnostic	13	7	6
AUS	14	1	13
Difficult interpretation	3	2	1
Total	30	10	20

Table 6: Repeat/guided FNAC according to anatomical site among strict inconclusive cases

Site	Strict inconclusive cases	Repeat/guided FNAC	% with repeat/guided FNAC
Breast	6	1	16.7
Thyroid	4	0	0
Lymph node/neck	13	6	46.2
Salivary gland	6	2	33.3
Soft tissue	1	1	100.0
Others	0	0	—
Total	30	10	33.3

DISCUSSION

The present study evaluated 214 FNAC examinations performed over a six-month period at a tertiary-care teaching hospital in Bhuj, Kachchh. The principal finding was that 30 cases (14.0%) fulfilled the predefined criteria for strict inconclusive cytology.

The frequency of inconclusive FNAC reported in the literature varies according to the population studied, anatomical sites included, definition of inadequacy and availability of image-guided sampling.[2,5]

Chennimalai and Vincent reported an overall inconclusive rate of 10.8% in a five-year study involving 4369 FNAC samples.[5] Their study found the highest site-specific rates in salivary gland, thyroid and breast specimens, while lymph node/neck lesions had a lower rate.[5]

The strict inconclusive rate of 14.0% observed in the present study was comparable to the rate reported by Chennimalai and Vincent; however, direct comparison should be made cautiously because of differences in study design, duration, case mix and classification criteria.[5]

Inadequate cytology

Inadequate/non-diagnostic sampling accounted for 13/214 cases (6.1%) in the present study.

Among the strict inconclusive cases, inadequate cytology represented 13/30 cases. Lymph node/neck lesions contributed the largest number of inadequate cases, followed by salivary gland lesions.

Chennimalai and Vincent reported inadequate smear as the predominant cause of inconclusive cytology, accounting for approximately 72% of their inconclusive cases.[5] They suggested that image-guided aspiration, appropriate clinical correlation and multiple aspirations could reduce the frequency of inadequate samples.[5]

The lower proportion of inadequate samples in the present study may reflect differences in case selection, sampling practices and patient population. Nevertheless, inadequate cellularity remains an important quality indicator in cytopathology.[2,3]

Anatomical variation: The present study demonstrated considerable variation in the frequency of inconclusive cytology between anatomical sites.

Although lymph node/neck lesions contributed the greatest absolute number of inconclusive cases because they constituted the largest proportion of the total FNAC workload, salivary gland lesions had the highest site-specific inconclusive rate at 27.3%.

This finding is comparable with the observation of Chennimalai and Vincent, who reported salivary gland specimens as having the highest inconclusive rate (14.2%), followed by thyroid (14.0%) and breast (13.8%).[5]

Salivary gland cytology can be challenging because of the wide morphological spectrum of salivary gland lesions and overlapping cytological features.[7,8] The Milan System was introduced to standardize reporting and provide clinically meaningful categories for salivary gland FNAC.[7,8]

Thyroid lesions demonstrated a 19.0% strict inconclusive rate in the present study. The Bethesda System has provided a standardized framework for reporting thyroid cytology and helps guide management of indeterminate categories.[6]

AUS: AUS represented the largest individual strict inconclusive category in the present series, accounting for 14/214 cases (6.5%).

Atypical findings may occur because of reactive changes, inflammation, degenerative changes, limited cellularity or genuine neoplastic processes. The interpretation of such cases requires integration of cytomorphology with clinical and radiological findings.[3,6]

The use of standardized terminology is particularly important in such situations. The Bethesda System for thyroid cytology, Yokohama System for breast cytology and Milan System for salivary gland cytology all aim to reduce variation in terminology and provide clinically relevant risk categories.[6-8]

Repeat/guided aspiration: Repeat/guided FNAC was documented in 43/214 cases (20.1%) in the overall study population. Similar audit-based studies have evaluated repeat FNAC as an important component of cytopathology practice and quality assessment.[4,5,9]

Within the strict inconclusive cohort, 10/30 cases (33.3%) had documented repeat/guided FNAC.

The highest number of repeat/guided procedures among strict inconclusive cases occurred in lymph

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node/neck lesions. Among the cytological categories, inadequate/non-diagnostic cases demonstrated the greatest number of repeat/guided procedures, with 7/13 cases.

This association is clinically logical because a non-diagnostic sample provides insufficient material for diagnosis and may require additional sampling.[4,9]

Role of image guidance: Image guidance is particularly useful for lesions that are small, deep-seated or difficult to access clinically.[9]

The use of image-guided FNAC, combined with careful lesion targeting and appropriate clinical-radiological information, can potentially improve sample adequacy and reduce repeat procedures.[9]

Rapid on-site evaluation, where available, may further help determine whether adequate diagnostic material has been obtained, particularly in lesions with a high likelihood of non-diagnostic sampling.[10]

CONCLUSION

In this six-month retrospective analysis of 214 FNAC samples, 30 cases (14.0%) were classified as strictly inconclusive.

AUS constituted the largest individual category, followed by inadequate/non-diagnostic samples and difficult interpretation. Lymph node/neck lesions contributed the largest absolute number of inconclusive cases, while salivary gland lesions demonstrated the highest site-specific inconclusive rate.

Repeat/guided FNAC was documented in 43/214 cases (20.1%) overall and in 10/30 (33.3%) of the strict inconclusive cases.

The findings emphasize that adequacy of sampling remains an important determinant of FNAC diagnostic performance. Appropriate lesion selection, image-guided aspiration when indicated, adequate clinical and radiological information, standardized reporting terminology and periodic audit of non-diagnostic cases may help reduce inconclusive cytology and improve patient management.

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