



## Utility of Ultrasound-Guided Fine Needle Aspiration Cytology in Various Pathological Lesions: A Clinico-Pathological Audit

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### Abstract

**Background:** Fine Needle Aspiration Cytology (FNAC) is a simple investigation for the pre-operative diagnosis of palpable lesions of superficial organs. Ultrasound-guided FNAC provides an avenue for the characterization of masses by both the radiologist and the pathologist, facilitating better patient care. **Aim:** To evaluate the utility of ultrasound-guided fine needle aspiration cytology in various pathological lesions through a clinicopathological audit process.

**Materials and Methods:** This was a retrospective observational study conducted at a tertiary care referral institute from July 2020 to June 2021. All cases of USG-guided FNAC were included in the study. Repeat aspirations, cytological-clinical diagnostic concordance, and cytological-ultrasonography diagnostic concordance were analyzed. All statistical analyses were performed using Microsoft Excel 2007.

**Results:** Fifty-two cases were analyzed. The most common site of aspiration was the thyroid gland (50%). The most common clinical diagnosis was a solitary nodule of the thyroid (21.15%). The most common ultrasonography diagnosis was a colloid nodule of the thyroid (26.93%). The most common cytological diagnosis was a colloid nodule of the thyroid (28.85%). Repeat aspirations were performed in 31 cases (59.62%). Haemorrhagic material (46.15%) was the most common reason for repeat aspiration. Cytology-clinical diagnostic concordance was 83.33% based on partial concordance criteria. Cytology-ultrasonography diagnostic concordance was 95.65% based on partial concordance criteria.

**Conclusion:** Ultrasonography serves to specifically target lesions and enables accurate cytological diagnosis. Clinicians and radiologists should strive to provide more specific diagnoses for the benefit of patients. Such clinicopathological audits help identify and rectify gaps in patient care.

### Keywords:

*Patient, Thyroid gland, Diagnosis, Ultrasonography*

## Introduction

Fine needle aspiration cytology (FNAC) is a simple investigative modality employed for the preoperative diagnosis of palpable neoplasms of superficial organs [1]. The utility of FNAC has shifted the concept of initial diagnosis from complex, time-consuming histopathology to a safe, cost-effective, rapid, and relatively painless diagnostic procedure with minimal patient

discomfort [1,2]. FNAC has revolutionized patient management by providing an extremely useful method for detecting malignancy [2]. Aspiration cytology aids in differentiating between cystic and solid lesions, benign versus malignant neoplasms, or an abscess versus a neoplasm [3]. It plays a crucial role in diagnosing inoperable lesions and assists clinicians in planning treatment [1].

Ultrasonography offers several advantages when used as a biopsy guidance system. It is readily available, relatively inexpensive, and portable. Ultrasonography does not use ionizing radiation and can provide guidance in multiple planes, such as transverse, longitudinal, and oblique [3]. It can reliably differentiate between solid and cystic lesions [4].

Even though FNAC has high sensitivity and specificity, there is still a possibility of false-positive and false-negative results [5]. FNAC performed under ultrasound guidance helps to overcome the limitations of the procedure [2]. The presence of a pathologist during the ultrasound-guided aspiration procedure allows for combined consultation between the pathologist and the radiologist [3]. The incidence of wrong or inadequate tissue sampling by the pathologist can also be minimized [4]. The greatest advantage is that it allows real-time visualization of the needle tip as it passes through the tissue planes into the target area of the lesion [3]. Thus, ultrasound-guided FNAC provides an avenue for the characterization of lesions by both the radiologist and the pathologist, which can result in better patient care in the diagnostic arena [4].

A clinical audit is a methodical process intended to improve the quality of healthcare [6]. Clinical audits are useful in the laboratory for assessing and modifying prevailing laboratory and clinical practices, and for providing feedback to stakeholders [7]. Hence, the present study was undertaken as a clinicopathological audit to evaluate the utility of ultrasound-guided fine needle aspiration cytology.

## Materials and Methods

The study was conducted in the cytopathology section of the Department of Pathology in collaboration with the Department of Radiodiagnosis. It was a retrospective observational study conducted from July 2020 to June 2021 for a period of one year at a rural tertiary care referral institute. Informed consent was routinely obtained for each case before performing the USG-guided FNAC procedure. Ethical clearance was obtained from the Institutional Human Ethics Committee. Fifty-two cases of ultrasound-guided fine needle aspiration cytology of various pathological lesions were analyzed. All cases of USG-guided FNACs of various pathological lesions were included in the study. Cases in which a clinical diagnosis was not offered were excluded from the study.

For each case, patient details such as age, gender, clinical diagnosis, sonological diagnosis, and cytopathological diagnosis/interpretation were collected. Histopathological diagnosis was also documented in available cases. Cytopathological diagnosis, clinical diagnosis, and histopathological diagnosis were broadly categorized according to the site of involvement. Depending on the nature of the lesion, the lesions were categorized as neoplastic and non-neoplastic. Neoplastic lesions were further categorized as benign neoplasms and malignant neoplasms. Non-neoplastic lesions were further categorized into inflammatory lesions, cystic lesions, or others.

**Statistical Analysis:** Socio-demographic variables were represented using frequencies and percentages. For each case, clinical diagnosis and sonological diagnosis were compared with cytopathological diagnosis, concordance (complete/partial) was documented, and diagnostic accuracy was calculated. Cytopathological diagnosis was compared with histopathological diagnosis in available cases, and concordance (complete/partial) was documented and diagnostic accuracy was calculated. Statistical values were calculated using the Galen and Gambino method.

## Results

In the present study, 52 cases of USG-guided fine needle aspiration cytology of various pathological lesions were analyzed. The patients' age ranged from 9 years to 85 years. Clustering of cases was seen in the third decade (Mean = 39.94 years; Median = 38.5 years). Females were affected in the majority of cases [43 cases (82.69%)] with an M:F ratio of 1.46:1. The most common site of aspiration was the thyroid, constituting 26 cases (50%), followed by lymph nodes [17 cases (32.69%)], breast [8 cases (15.39%)], and parotid gland [1 case (1.92%)].

**Clinical diagnoses:** Clinically, the most common lesion was the thyroid lesion, constituting 26 cases (50%), followed by lymph node lesions [17 cases (32.69%)], breast lesions [8 cases (15.39%)], and parotid gland lesion [1 case (1.92%)]. The most common clinical diagnostic entity among thyroid lesions was solitary nodule, constituting 11 cases (21.15%), followed by multinodular goitre [8 cases (15.39%)], colloid nodule [2 cases (3.85%)], carcinoma thyroid [2 cases (3.85%)], chronic thyroiditis [2 cases (3.85%)], and hypothyroidism [1 case (1.92%)]. The most common clinical diagnostic entity among lymph node lesions was cervical lymphadenopathy, constituting 8 cases (15.39%), followed by non-specific cervical lymphadenitis [3 cases (5.77%)], tubercular lymphadenitis [4 cases (7.69%)], secondaries in cervical lymph node [1 case (1.92%)], and secondaries in inguinal lymph node [1 case (1.92%)]. The most common clinical diagnostic entity among breast lesions was fibroadenoma, constituting 5 cases (9.62%), followed by breast carcinoma [2 cases (3.85%)] and breast lump [1 case (1.92%)]. One case (1.96%) of a parotid lesion was clinically diagnosed as malignant parotid swelling. [Table 1]

**Ultrasonography diagnoses:** On ultrasonography, the most common lesion was a thyroid lesion, constituting 17 cases (32.69%), followed by lymph node lesions [10 cases (19.23%)] and breast lesions [6 cases (11.54%)]. No specific diagnoses were offered in 19 cases (36.54%). The most common ultrasonographic diagnostic entity among thyroid lesions was a colloid nodule, constituting 14 cases (26.93%), followed by suspicious nodules [2 cases (3.85%)] and benign thyroid nodule [1 case (1.92%)]. The common sonological diagnostic entity in lymph nodes was cervical lymphadenopathy and cervical lymphadenitis, each constituting 4 cases (7.69%), followed by metastasis [2 cases (3.85%)]. The common sonological diagnostic entity among breast lesions was invasive breast carcinoma, fibroadenoma, and benign breast disease, each constituting 2 cases (3.85%). [Table 1]

**Cytopathological diagnoses:** Cytologically, the most common lesion was the thyroid lesion, constituting 26 cases (50%), followed by lymph node lesions [17 cases (32.69%)], breast lesions [8 cases (15.39%)], and parotid gland lesion [1 case (1.92%)]. The most common cytological diagnostic entity among thyroid lesions was a colloid nodule (Bethesda system - Category II), constituting 17 cases (32.69%), followed by atypia of undetermined significance [3 cases (5.77%)] corresponding to Bethesda system - Category III, chronic lymphocytic thyroiditis [2 cases (3.85%)] corresponding to Bethesda system - Category II, follicular neoplasm [1 case (1.92%)] corresponding to Bethesda system - Category IV, and papillary thyroid carcinoma [1 case (1.92%)] corresponding to Bethesda system - Category VI. No specific diagnosis was offered in 2 cases (3.85%).

The most common cytological diagnostic entity among lymph node lesions was reactive lymphadenitis, constituting 8 cases (15.38%), followed by metastatic deposits of poorly differentiated carcinoma [2 cases (3.85%)], acute suppurative lymphadenitis [1 case (1.92%)], chronic nonspecific lymphadenitis [1 case (1.92%)], lymphoproliferative disorder [1 case (1.92%)], and necrotizing lymphadenitis [1 case (1.92%)]. No specific diagnosis was offered in 3 cases (5.77%). The cytological diagnostic entity among breast lesions included invasive breast carcinoma, benign phyllodes tumor, fibroadenoma, and lipoma, each constituting 1 case (1.92%). No specific diagnosis was offered in 4 cases (7.69%). The cytological diagnostic entity in the parotid salivary gland included one case (1.92%) of malignant salivary gland neoplasm. However, the exact nature of the malignant lesion

could not be determined. [Table 2]

**Table 1: Distribution of spectrum of clinical Diagnoses and ultrasonography diagnoses**

Clinical diagnoses (n=52)	Cases (%)
<b>Thyroid lesions</b>	<b>26 (50%)</b>
Solitary nodule	11 (21.15%)
Multi-nodular goitre	8 (15.38%)
Colloid nodule	2 (3.85%)
Carcinoma of thyroid	2 (3.85%)
Chronic thyroiditis	2 (3.85%)
Hypothyroidism	1 (1.92%)
<b>Lymph node lesions</b>	<b>17 (32.69%)</b>
Cervical lymphadenopathy	7 (13.46%)
Cervical lymphadenitis	3 (5.77%)
Tuberculosis	2 (3.85%)
Supraclavicular lymphadenopathy	1 (1.92%)
Cold abscess	1 (1.92%)
Tubercular lymphadenitis	1 (1.92%)
Secondaries in neck	1 (1.92%)
Squamous cell carcinoma of penis	1 (1.92%)
<b>Breast lesions</b>	<b>8 (15.38%)</b>
Carcinoma of right breast	<b>2 (3.85%)</b>
Fibroadenoma	5 (9.62%)
Right breast mass	1 (1.92%)
Parotid lesion	<b>1 (1.92%)</b>
Malignant parotid swelling	1 (1.92%)
<b>Total</b>	<b>52</b>
<b>Ultrasonography diagnoses (n= 52)</b>	<b>Cases (%)</b>
<b>Thyroid lesions</b>	<b>17 (32.69%)</b>
Colloid nodule	14 (26.93%)
Mild Suspicious nodule	1 (1.92%)
Moderate Suspicious nodule	1 (1.92%)
Benign thyroid nodule	1 (1.92%)
<b>Lymph node lesions</b>	<b>10 (19.23%)</b>
Cervical lymphadenopathy	4(7.69%)
Cervical lymphadenitis	4(7.69%)
Metastasis	2(3.85%)
<b>Breast lesions</b>	<b>6 (11.54%)</b>
Invasive breast carcinoma	2(3.85%)
Fibroadenoma	2(3.85%)
Bilateral breast disease	2(3.85%)
Non- specific diagnosis	<b>19 (36.59)</b>
<b>Total</b>	<b>52</b>

**Diagnostic accuracy of clinical diagnoses in comparison with cytopathological diagnoses:** For clinical diagnosis, the diagnostic accuracy was analyzed for 24 cases (46.15%). Those cases with non-specific diagnoses, either clinically or in cytology, were excluded from the analysis. The diagnostic accuracy was 66.66% by complete concordance and increased to 83.33% when applying partial concordance criteria. Parotid lesions and thyroid lesions showed better concordance than lymph node lesions and breast lesions by both complete concordance and partial concordance. Lymph node lesions and breast lesions showed low complete concordance. However, the concordance of the lesions increased when applying partial concordance criteria. [Table 3]

**Table 2: Distribution of spectrum of cytopathology diagnoses**

Cytopathology diagnoses (n= 52)	Cases (%)
<b>Thyroid lesions</b>	<b>26 (50%)</b>
Atypia of undetermined significance	3 (5.77%)
Colloid nodule	17 (32.69%)
Chronic lymphocytic thyroiditis	2 (3.85%)
Follicular neoplasm	1 (1.92%)
Papillary carcinoma of thyroid	1 (1.92%)
No specific diagnosis	2 (3.85%)
<b>Lymph node lesions</b>	<b>17 (32.69%)</b>
Reactive lymphadenitis	8 (15.39%)
Metastatic deposits	2 (3.85%)
Acute suppurative lymphadenitis	1 (1.92%)
Chronic non specific lymphadenitis	1 (1.92%)
Lympho-proliferative disease	1 (1.92%)
Necrotizing lymphadenitis	1 (1.92%)
Vascular lesion	1 (1.92%)
Non specific diagnosis	2 (3.85%)
<b>Breast lesions</b>	<b>8 (15.38%)</b>
Invasive breast carcinoma	1 (1.92%)
Phyllodes tumor	1 (1.92%)
Fibroadenoma	1 (1.92%)
Lipoma	1 (1.93%)
No specific diagnosis	4 (7.69%)
<b>Parotid gland lesion</b>	<b>1 (1.92%)</b>
Malignant salivary gland neoplasm	1 (1.92%)
<b>Total</b>	<b>52</b>

**Diagnostic accuracy of ultrasonography diagnoses in comparison with cytopathological diagnoses:** For ultrasonographic diagnosis, the diagnostic accuracy was analyzed for 23 cases (46.15%). Those cases with non-specific diagnoses, either on ultrasonography or cytology, were excluded from the analysis. The diagnostic accuracy was 82.61% by complete concordance and increased to 95.65% when applying partial concordance criteria. Lymph node lesions showed better concordance than thyroid lesions and breast lesions by both complete concordance and partial concordance. Thyroid lesions and breast lesions showed low complete concordance. However, the concordance of the lesions increased when applying partial concordance criteria. [Table 3]

**Diagnostic accuracy of cytological diagnoses in comparison with histopathological diagnoses:** For cytological diagnosis, the diagnostic accuracy was analyzed for 5 cases (9.62%), as the histopathological diagnosis was available for only 5 cases of thyroid lesions. The diagnostic accuracy was 40% by complete concordance and increased to 60% when applying partial concordance criteria. [Table 3]

**Diagnostic utility of clinical diagnosis:** Twenty-four cases were analyzed. For the detection of neoplastic lesions, clinical diagnosis had 15 true positive cases, 6 true negative cases, 2 false negative cases, 1 false positive case, a sensitivity of 88.24% (95% CI 63.56-98.54), specificity of 85.71% (95% CI 42.13-99.64), positive predictive value of 93.75% (95% CI 70.79-98.93), negative predictive value of 75% (95% CI 44.08-91.95), a false positive error rate of 4.17%, a false negative error rate of 8.33%, and a diagnostic efficacy of 87.50% (95% CI 67.64-97.34).

**Diagnostic utility of ultrasonography diagnosis:** Twenty-two cases were analyzed. For the detection of neoplastic lesions, sonological diagnosis had 20 true positive cases, 2 true negative cases, 0 false negative cases, and 0 false positive cases, a sensitivity of 100% (95% CI 83.16-100), specificity of 100% (95% CI 15.81-100), positive predictive value of 100% (95% CI

Table 3: Diagnostic accuracy of clinical diagnoses, ultrasonography diagnoses and cytopathology diagnoses

Diagnostic accuracy of clinical diagnoses in comparison with cytopathology diagnoses				
Cytopathology diagnoses	Clinical Diagnoses (n=24)			
	Cases	DACC-CC	DAPC-CC	Discordant-CC
<b>Thyroid lesions</b>	<b>12 (23.17%)</b>	<b>11 (91.66%)</b>	<b>11(91.66%)</b>	<b>1(8.33%)</b>
Colloid nodule	10(19.23%)	9 (90%)	9(90%)	1(10%)
Papillary carcinoma of thyroid	1(1.92%)	1 (100%)	1(100%)	0 (0%)
Chronic lymphocytic thyroiditis	1(1.92%)	1 (100%)	1(100%)	0 (0%)
<b>Lymph node lesions</b>	<b>7 (13.46%)</b>	<b>2 (28.57%)</b>	<b>5 (71.43%)</b>	<b>2 (28.57%)</b>
Metastasis	2(3.85%)	1(50%)	1(50%)	1(50%)
Reactive lymphadenitis	5(9.62%)	1(20%)	4(80%)	1(20%)
<b>Breast lesions</b>	<b>4(7.69%)</b>	<b>2(50%)</b>	<b>3(75%)</b>	<b>1(25%)</b>
Fibroadenoma	1(1.92%)	0 (0%)	1(100%)	0 (0%)
Phyllodes tumour	1(1.92%)	0 (0%)	1(100%)	0 (0%)
Invasive breast carcinoma	1(1.92%)	1(100%)	1(100%)	0 (0%)
Lipoma	1(1.92%)	0 (0%)	0 (0%)	1(100%)
Parotid lesions	<b>1(1.92%)</b>	<b>1(100%)</b>	<b>1(100%)</b>	<b>0 (0%)</b>
	1(1.92%)	1(100%)	1(100%)	0 (0%)
<b>Total</b>	<b>24(46.15%)</b>	<b>16(66.66%)</b>	<b>20(83.33%)</b>	<b>4(16.67%)</b>
Diagnostic accuracy of ultrasonography diagnoses in comparison with cytopathology diagnoses				
Cytopathology diagnoses	Ultrasonography diagnoses (n=23)			
	Cases	DACC-UC	DAPC-UC	Discordant-UC
<b>Thyroid lesions</b>	<b>16 (30.77%)</b>	<b>13 (81.25%)</b>	<b>15 (93.75%)</b>	<b>1 (6.25%)</b>
Colloid nodule	14 (26.93%)	13 (92.86%)	13 (92.86%)	1 (7.14%)
Atypia of undetermined significance	1 (1.92%)	0 (0%)	1 (100%)	0 (0%)
Follicular neoplasm	1 (1.92%)	0 (0%)	1 (100%)	0 (0%)
<b>Lymph node lesions</b>	<b>4 (7.69%)</b>	<b>4 (100%)</b>	<b>4 (100%)</b>	0 (0%)
Reactive lymphadenitis	2 (3.85%)	2 (100%)	2 (100%)	0 (0%)
Metastasis	2 (3.85%)	2 (100%)	2 (100%)	0 (0%)
<b>Breast lesions</b>	<b>3 (5.77%)</b>	<b>2 (66.66%)</b>	<b>3 (100%)</b>	0 (0%)
Phyllodes tumor	1 (1.92%)	0 (0%)	1 (100%)	0 (0%)
Invasive breast carcinoma	1 (1.92%)	1 (100%)	1 (100%)	0 (0%)
Lipoma	1 (1.92%)	1 (100%)	1 (100%)	0 (0%)
<b>Total</b>	<b>23 (44.23%)</b>	<b>19 (82.61%)</b>	<b>22 (95.65%)</b>	<b>1 (4.35%)</b>
Diagnostic accuracy of Cytopathology diagnoses in comparison with histopathological diagnosis				
Histopathology diagnoses	Cytopathology diagnoses (n=5)			
	Cases	DACC-CH	DAPC-CH	Discordant-CH
<b>Thyroid lesions</b>	<b>5 (9.62%)</b>	<b>2 (40%)</b>	<b>3 (60%)</b>	<b>2 (40%)</b>
Papillary carcinoma	2 (3.85%)	0 (0%)	0 (0%)	2 (100%)
Multi-nodular goitre	2 (3.85%)	2(100%)	2 (100%)	0 (0%)
Adenomatous hyperplasia	1 (1.92%)	0 (0%)	1 (100%)	0 (0%)
<b>Total</b>	<b>5 (9.62%)</b>	<b>2 (40%)</b>	<b>3 (60%)</b>	<b>2 (40%)</b>
<p>DACC-CC: Diagnostic Accuracy by Complete Concordance in Clinical diagnosis compared with cytological diagnosis;  DAPC-CC: Diagnostic Accuracy after Considering Partial Concordance in Clinical diagnosis compared with cytological diagnosis;  Discordance-CC: Discordant cases in Clinical diagnosis compared with cytological diagnosis;  DACC-UC: Diagnostic Accuracy by Complete Concordance on ultrasonography compared with cytological diagnosis;  DAPC-UC: Diagnostic Accuracy after Considering Partial Concordance on ultrasonography compared with cytological diagnosis.  Discordance-UC: Discordant cases in ultrasonography compared with cytological diagnosis;  DACC-CH: Diagnostic Accuracy by Complete Concordance in cytological diagnosis compared with histopathological diagnosis;  DAPC-CH: Diagnostic Accuracy after Considering Partial Concordance in Cytological diagnosis compared with histopathological diagnosis;  Discordance-CH: Discordant cases in cytological diagnosis compared with histopathological diagnosis;  “Complete concordance” was applied to cases in which the diagnosis in both diagnostic modalities was identical.  “Partial concordance” was applied to cases in which the diagnosis showed minor deviation between the two diagnostic modalities but the lesion belonged to the same category or the diagnosis matched partly with the better diagnostic modality.  “Discordance” was considered in cases where the diagnosis differed significantly from the final diagnosis with respect to better diagnostic modality.  For the sake of analysis of diagnostic accuracy, cytological diagnosis was considered better diagnostic modality with respect to clinical diagnosis and ultrasonography. Histopathology was considered as better diagnostic modality with respect to cytology.</p>				

83.16-100), negative predictive value of 100% (95% CI 15.81-100), a false positive error rate of 0%, a false negative error rate of 0%, and a diagnostic efficacy of 100% (95% CI 84.56-100).

**Reasons for discordance:** Clinically, 4 cases (16.67%) were misdiagnosed. Clinical diagnosis was compared with cytological diagnosis. One case (25%) of colloid nodule was misdiagnosed as chronic thyroiditis. The reason for misdiagnosis may be due to the atypical clinical presentation of the colloid nodule. One case (25%) of lipoma in the breast was misdiagnosed as fibroadenoma. The reason for misdiagnosis may be due to the atypical clinical presentation of lipoma. One case of metastatic carcinoma deposit (25%) in the lymph node was misdiagnosed as tuberculosis. The reason for misdiagnosis may be due to the similar clinical presentation of both diagnostic entities. One case (25%) of reactive lymphadenitis was misdiagnosed as metastatic squamous cell carcinoma. The reason for misdiagnosis may be due to the strong clinical suspicion of metastasis in the inguinal lymph node due to a primary malignant lesion in the penis.

On ultrasonography, only one case (4.35%) was misdiagnosed. Ultrasonography diagnosis was compared with cytological diagnosis. One case of colloid nodule was misdiagnosed as a suspicious nodule (mild). The reason for misdiagnosis may be due to similar radiological features.

Cytologically, two cases (40%) were misdiagnosed. Cytological diagnosis was compared with histopathological diagnosis. Both cases were those of papillary carcinoma of the thyroid (follicular variant). One case (50%) was misdiagnosed as a colloid nodule. The reason for misdiagnosis was due to the cystic presentation of the neoplasm, which yielded only colloid and cyst macrophages. The sample was not representative of the lesion. The other case (50%) was misdiagnosed as a follicular neoplasm. The reason for misdiagnosis was due to the follicular pattern of papillary carcinoma. It may be considered a morphological similarity. [Table 4]

**Table 4: Discordant cases in clinical diagnoses, ultrasonography diagnoses and cytological diagnosis**

<b>Discordant cases in clinical diagnoses in comparison with cytological diagnosis</b>			
<b>Cytological diagnosis</b>	<b>Discordant cases (n=4)</b>	<b>Clinical diagnosis</b>	<b>Probable cause of misdiagnosis</b>
<b>Colloid nodule</b>	1 (25%)	Chronic thyroiditis	Atypical clinical presentation
<b>Lipoma</b>	1 (25%)	Fibroadenoma	Atypical clinical presentation
<b>Metastasis</b>	1 (25%)	Tuberculosis	Similar clinical presentation
<b>Reactive lymphadenitis</b>	1 (25%)	Metastatic Squamous cell carcinoma	Strong clinical suspicion due to primary lesion in penis
<b>Discordant cases in ultrasonography diagnoses in comparison with cytological diagnosis</b>			
<b>Cytological diagnosis</b>	<b>Discordant cases (n=1)</b>	<b>Ultrasonography diagnosis</b>	<b>Probable cause of misdiagnosis</b>
<b>Colloid nodule</b>	1 (100%)	Mild suspicious nodule	Similar radiological features
<b>Discordant cases in cytological diagnoses in comparison with histopathological diagnosis</b>			
<b>Histopathological diagnosis</b>	<b>Discordant cases (n=2)</b>	<b>Cytological diagnosis</b>	<b>Probable cause of misdiagnosis</b>
<b>Papillary carcinoma (follicular variant)</b>	2 (100%)	Colloid nodule	Non-representative sample
		Follicular neoplasm	Morphological similarity (follicular pattern)

**Repeat aspirations under ultrasound guidance:** The fine needle aspiration procedure was repeated under ultrasound guidance in 31 cases (51.62%). The repeat aspiration was performed most commonly for thyroid lesions [19 cases (61.29%)], followed by lymph node lesions [8 cases (25.81%)], breast lesions [3 cases (9.68%)], and cystic material [1 case (3.23%)]. The most common reason for repeat aspiration was hemorrhagic material [24 cases (77.15%)], followed by inadequate material [6 cases (19.36%)].

and cystic material [1 case (3.23%)] obtained in the initial non-guided aspiration.

## Discussion

Fine needle aspiration cytology (FNAC) is a commonly used diagnostic procedure to assess any superficially palpable or deep-seated mass in the body [8]. It is a safe, easy, minimally invasive, fairly accurate, and cost-effective procedure [8, 9]. An accurate pathological diagnosis is essential for appropriate pre-operative staging and treatment of malignancy [8]. The purpose of FNAC is to prevent unnecessary operations for benign lesions and avoid misdiagnosis of malignant lesions as much as possible [5].

Ultrasonography (USG) is a potentially useful preoperative investigative modality as it offers several advantages. It is widely available, cost-effective, and avoids exposure to ionizing radiation [10]. The challenge for endocrinologists, surgeons, and pathologists is to achieve an accurate preoperative diagnosis of malignant neoplasms to ensure that patients receive appropriate treatment [5]. However, ultrasonography alone cannot accurately differentiate between benign and malignant neoplasms [10]. Hence, the integrated utility of USG and FNAC can help overcome deficiencies in both investigative modalities to some extent [11].

Ultrasonography has enabled the detection and location of lesions in sites that are not easily accessible to surgical biopsies, besides providing the opportunity for performing fine needle aspiration of deeper structures [3]. When compared to core needle biopsy and vacuum-assisted biopsy, ultrasound-guided FNAC is considered a valuable, rapid, accurate, economical, and safe diagnostic procedure that can be routinely used in the diagnosis of various neoplastic and non-neoplastic diseases [3, 12, 13].

An audit signifies a systematic and critical evaluation of the services [7]. Clinical audit involves procedures used for treatment and diagnosis along with resources and outcomes involved in patient care. A laboratory audit is usually undertaken to determine the quality of the service provided by the laboratory. Laboratory audits can be undertaken focusing on the “process” and “outcome” aspects of laboratory tests. An improved process always brings forth good outcomes [6].

The audit was undertaken to identify the lacunae in the laboratory and clinical services with respect to the utility of ultrasound-guided FNAC. The present study emphasizes the role of clinicopathological audit in the evaluation of the utility of ultrasound-guided fine needle aspiration cytology.

The total number of cases was highest in the studies conducted by Farras Roca JA et al. [12]. The least number of cases was seen in the study conducted by Mohson K and Jafaar MA [14]. In contrast to the other studies, the present study had fewer cases. Most of the studies documented more cases in comparison with the present study [2, 3, 5, 7, 8, 11, 12, 15-25]. In contrast to the present study, Rajyalakshmi R and Rajani V [1], Omonisi AE et al. [4], Mohson K and Jafaar MA [14], Omar AERA et al. [26], Rizwan TM et al. [27], and Heidar MAHA et al. [28] documented fewer cases in their study [Table 5].

In the present study, the clustering of cases was seen in the third decade. In contrast, Rajyalakshmi R and Rajani V [1] documented clustering of cases in the fifth decade. Similarly, Pujani M et al. [22] documented clustering of cases in the fifth and sixth decades. In the present study, the mean age of the patients was 39.94 years. In comparison, most studies documented a higher mean age [4, 5, 8, 11, 12, 16-18, 23-26]. In contrast, Marbaniang E et al. [19], Mohson K & Jafaar MA [14], and Gupta KP and Gupta S [21] observed a lower mean age in their study.

Females were predominantly affected in the majority of the studies, including the present study [2-5, 7, 18, 21, 23, 24, 26-28]. In contrast, Rajyalakshmi R and Rajani V [1], Bajantri SR et al. [8], Negahban S et al. [16], Marbaniang E et al. [19], Pujani M et



al. [22], and Neha et al. [25] documented male predominance in their study.

**Table 5: Comparison of preliminary parameters and diagnostic accuracy in various studies**

Authors	No of cases	Common site of the lesion	Common diagnosis	Diagnostic accuracy of USG guided FNAC
Hemalatha AL et al <sup>[3]</sup> (India, 2013)	90	Uterus& ovary	Appendicular abscess	96.3%
Mangla G et al <sup>[7]</sup> (India, 2015)	112	Intra-abdominal		
Koo DH et al <sup>[15]</sup> (Korea 2016)	502	Thyroid	Papillary thyroid carcinoma	
Negahban S et al <sup>[16]</sup> (Iran 2016)	102	Salivary gland (Parotid)	Pleomorphic adenoma	84.3%
Pujani M et al <sup>[22]</sup> (India, 2016)	54	Liver	Metastatic adenocarcinoma	100%
Rocca JAF et al <sup>[12]</sup> (France, 2017)	2601	Breast	Invasive breast carcinoma	88.9%
Omonisi AE et al <sup>[4]</sup> (Nigeria, 2018)	51	Thyroid	Colloid goiter	
Chakravarthy NS et al <sup>[2]</sup> (India, 2018)	290	Thyroid		81%
Zhang F et al <sup>[17]</sup> (China, 2018)	124	Axillary lymph node		
Kumari KA et al <sup>[18]</sup> (India, 2019)	1050	Thyroid		89.4%
Marbaniang E et al <sup>[19]</sup> (India, 2019)	854	Abdomen (Lymph node)		
Rizwan TM et al <sup>[27]</sup> (India, 2019)	33	Axillary lymph node		
Chieng JSL et al <sup>[20]</sup> (Singapore, 2019)	153	Thyroid	Papillary carcinoma	64.1%
Rajalakshmi R & Rajani V <sup>[1]</sup> (India, 2020)	38	Liver	Metastatic adenocarcinoma	
Li L et al <sup>[5]</sup> (China, 2021)	623	Thyroid	Papillary thyroid carcinoma	
Melese SS & Getaneh <sup>[23]</sup> [Ethiopia, 2021]	74	Liver	Metastasis	
Omar AERA et al <sup>[26]</sup> (Egypt, 2022)	30	Thyroid	Colloid nodule	
Gupta M & Acharya K <sup>[11]</sup> (India, 2022)	59	Thyroid		81.35%
Mohson K & Jafaar MA <sup>[14]</sup> [Iraq, 2022]	20	Cervical lymph node		
Heidar MAHA et al <sup>[28]</sup> (Egypt, 2022)	48	Thyroid		
Bajantri SR et al <sup>[8]</sup> (India, 2022)	334	Deep seated lesions (Lungs)	Metastatic carcinoma	85%
Kristo B et al <sup>[24]</sup> [Bosnia & Herzegovina, 2022]	92	Thyroid		90%
Gupta KP & Gupta SI <sup>[21]</sup> (India, 2023)	100	Thyroid		
Neha et al <sup>[25]</sup> [India, 2023]	119	Lymph node	Granulomatous lymphadenitis	91.6%
Present study	52	Thyroid	Colloid nodule of thyroid	60%

Thyroid was the most common site of the lesion in the majority of the studies, including the present study [2, 4, 5, 11, 15, 18, 20, 21, 24, 26, 28]. The liver was the most common site of the lesion in the study conducted by Rajyalakshmi R and Rajani V [1], Pujani M et al. [22], and Melese SS & Getaneh FB [23]. The axillary lymph node was the most common site of the lesion in studies conducted by Zhang F et al. [17] and Rizwan TM et al. [27]. The cervical lymph node was the most common site of the lesion in the study conducted by Mohson K & Jafaar MA [14] and Neha et al. [25]. The uterus and ovary were the most common sites of the lesion in the study conducted by Hemalatha AL et al. [3]. Intra-abdominal lesions were the most common site in the study conducted by Mangla G et al. [7]. The lungs were the most common site of the lesion in the study conducted by Bajantri S et al. [8]. The breast was the most common site of the lesion in the study conducted by Farras Roca JA et al. [12]. The parotid salivary gland was the most common site of the lesion in the study conducted by Negahban S et al. [16]. The intra-abdominal lymph node was the most common site of the lesion in the study conducted by Marbaniang E et al. [19] [Table 5].

Papillary carcinoma of the thyroid was the most common diagnostic entity in the study conducted by Li L et al. [5], Koo DH et al. [15], and Chieng JSL et al. [20]. A colloid nodule was the most common diagnostic entity in the study conducted by Omonisi AE et al. [4], Omar AERA et al. [26], and the present study. Metastatic carcinoma was the most common diagnostic entity in the study conducted by Rajyalakshmi R & Rajani V [1], Bajantri SR et al. [8], Pujani M et al. [22], and Melese SS & Getaneh FB [23]. Invasive ductal carcinoma was the most common diagnostic entity in the study conducted by Farras Roca JA et al. [12]. An appendicular abscess was the most common diagnostic entity in the study conducted by Hemalatha AL et al. [3]. Pleomorphic adenoma was the most common diagnostic entity in the study conducted by Negahban S et al. [16]. Granulomatous lymphadenitis was the most common diagnostic entity in the study conducted by Neha et al. [25]. However, the other studies had not clearly specified the most common diagnostic entity in their study [2, 7, 11, 14, 17-19, 21, 24, 27, 28] [Table 5].

In the present study, the diagnostic accuracy for ultrasonography was 96.5%. Mohson K & Jafaar MA [14] documented higher diagnostic accuracy in their study. In contrast, Zhang F et al. [17], and Gupta KP & Gupta S [21] documented lower diagnostic accuracy. In the present study, the diagnostic accuracy for USG-guided FNAC was 60%. This was because histopathological diagnosis was available in only five cases (9.62%). In contrast, other studies documented higher diagnostic accuracy [2, 3, 8, 11, 12, 16, 18, 20, 22, 24, 25]. However, other studies had not specified the diagnostic accuracy [1, 4, 5, 7, 14, 15, 17, 19, 21, 23, 26-28] [Table 5].

In most of the studies, criteria for diagnostic accuracy were not mentioned. In contrast to other studies, the criteria for complete concordance and partial concordance were clearly specified in the present study. This may be important because the clinical diagnosis or ultrasonographic diagnosis may not exactly match the histopathological diagnosis in all cases.

Statistical values do not always reflect the ground reality. In the present study, the low diagnostic accuracy in ultrasound-guided FNAC was primarily because histopathological diagnosis was available in a very small number of cases constituting only 5 cases (9.62%). Patients need to be counseled to optimally utilize the available clinical and laboratory services, undergo required surgical procedures, and thereby prevent the untoward progression of the disease process. The diagnostic accuracy was high for both clinical diagnosis (88.33%) and ultrasonography diagnosis (95.65%). However, the diagnostic accuracy could be analyzed in only 24 cases (46.15%) for clinical diagnosis and 23 cases (44.23%) for ultrasonography diagnosis. This is because a specific diagnosis was not offered in the rest of the cases. Hence, it may be suggested that clinicians should attempt to offer a more specific diagnosis in the request form for the benefit of the patients. Furthermore, radiologists should also attempt to offer a more specific diagnosis in the report whenever possible.

The reasons for clinical misdiagnosis were mainly due to atypical presentation, clinically similar presentations, and a strong suspicion of malignancy. The reason for misdiagnosis on ultrasonography was due to similar radiological features. The reasons for misdiagnosis on cytology were because of a non-representative sample and morphological similarity. However, the other studies had not clearly specified the reasons for misdiagnosis.

The fine needle aspiration procedure was repeated under ultrasound guidance in 31 cases (51.62%). In contrast, Amita K & Sanjay M [6], Mangla G et al. [7], and Goyal R et al. [29] documented a lower percentage of repeat aspirations. The repeat aspiration was performed most commonly for thyroid lesions [19 cases (61.29%)]. Amita K & Sanjay M [6] and Mangla G et al. [7] also documented similar observations in their study. In contrast, repeat aspiration was performed most commonly for breast lesions in their study. The most common reason for repeat aspiration was hemorrhagic material [24 cases (77.15%)]. In contrast, Amita K & Sanjay M [6], Mangla G et al. [7], and Goyal R et al. [29] documented inadequate aspirates as the most common reason for repeat aspirations in their study. It may be opined that the percentage of repeat aspirations may not always reflect the quality of laboratory services as it could be related to the inherent nature of the lesions.

The USG-guided FNAC may be a less cost-effective procedure compared to conventional FNAC. But the main advantage of USG-guided FNAC is that the lesion can be targeted to get adequate material. The repeat aspirations and the associated patient discomfort commonly encountered in conventional FNAC may be minimized by employing USG-guided FNAC.

**Limitations of the Study:** In the present study, the number of cases was relatively less compared to the other studies. The number of cases for which histopathological diagnosis was available was also very low. This could be attributed to poor patient compliance. The number of cases for which a specific clinical diagnosis was offered was less. Similarly, the number of cases for which a specific ultrasonographic diagnosis was offered was low. This could be due to the inherent nature of the lesion or due to overlapping features of differential diagnoses. Hence, it may be suggested that whenever possible, clinicians and radiologists should attempt to offer a more specific diagnosis for the benefit of the patients.

## Conclusion

Ultrasonography serves to specifically target the lesions and enables us to offer a fairly accurate cytological diagnosis. It may be suggested that clinicians should attempt to offer a more specific diagnosis in the request form to facilitate better patient care. Furthermore, radiologists should also attempt to offer a more specific diagnosis in the report whenever possible. Patients need to be counseled to optimally utilize the available clinical and laboratory services and thereby prevent the untoward progression of the disease process. The percentage of repeat aspirations may not always reflect the quality of laboratory services as it could be related to the inherent nature of the lesions. Such clinicopathological audits help us to identify and rectify the lacunae in patient care. It may be suggested to conduct a re-audit to complete the audit cycle in future studies to evaluate the effect of implementation.

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