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# Diagnostic Accuracy of Fine Needle Aspiration Cytology of Breast Masses, and Morphologic Patterns of Breast Lesions, Hawassa, Sidama Ethiopia: A Five-Year Review

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**Abstract:** Most breast diseases are presented as mass lesions that can be easily detected by the patients or during clinical examination and breast imaging. Fine needle aspiration biopsy of the breast is an unquestionably useful test in differentiating various benign and malignant breast lesions however its diagnostic accuracy is still poorly known. Therefore, this study was conducted to evaluate the validity and diagnostic performance of fine needle aspiration cytology (FNAC) in diagnoses of breast masses and describe morphologic patterns of breast pathology in Hawassa University Comprehensive Specialized Hospital. This is a five years retrospective cross-sectional study of all breast lumps that underwent fine needle aspiration cytology and subsequent histopathology evaluation in the Department of Pathology, Hawassa university comprehensive specialized hospital Sidama, Ethiopia from September 2015 to August 2019. Sensitivity, specificity, positive and negative predictive value, and diagnostic accuracy were calculated and morphologic patterns of breast pathology were described. Fibroadenoma and invasive ductal carcinoma were the most common benign and malignant breast lesions, respectively. The sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of fine needle aspiration cytology of breast lumps were found to be 97.64%, 95.89%, 96.5%, 97.2%, and 96.8% respectively. FNAC is a valid method with high sensitivity and specificity for preoperative diagnosis of breast lesions, and we recommend the popularization of FNAC in our practice to complement histological diagnosis of breast lesions for early diagnosis and optimum treatment of our patients.

**Keywords:** Sensitivity, Specificity, Predictive Value, Diagnostic Accuracy

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## 1. Introduction

Breast cancer is the leading cause of cancer-related mortality in women in Ethiopia and worldwide. Most breast

diseases are presented as mass lesions that can be easily detected by the patients or during clinical examination and breast imaging. However, benign lesions can also present with mass which is difficult to differentiate from malignant tumors.

A triple test of FNAC, physical examination, and breast imaging have played an important role in the preoperative assessment of suspicious breast swellings and avoid inappropriate open surgery and its complications. [2, 14]

A triple test is regarded as the gold standard for identifying breast lumps and lowers the likelihood of breast cancer diagnoses being missed by less than 1%. [11]. The main concern of the surgeon and the responsibility of the pathologist lies in the ability to distinguish benign from cancer as it is the most common cause of cancer death in women worldwide with an increased burden in developing countries.

Fine needle aspiration biopsy is certainly beneficial in resource-poor nations like Ethiopia because of its evident benefits. It is an affordable, quick, and accurate diagnostic technique. To avoid frequent unnecessary open surgery and to give immediate psychological relief to the patients, the diagnosis has to be convincingly reliable with minimum false positive and negative results.

False negative FNAC diagnoses are more common than false positive results. The reliability of FNAC is affected by various factors, including the experience of the pathologist performing aspiration and the microscopic examination, the tumor's histological type, the patient's circumstances, and the tumor's size and consistency. [2, 12] FNAC can be more reliable in distinguishing benign from cancer, but it should be noted that specific diagnosis of breast masses with cytologic studies can be difficult. [13]

Recognizing the accuracy of FNAC in identifying breast mass in our setup compared to other settings and identifying important factors that affect the quality is important to improve our performance and helps clinicians in the confident and proper management of breast masses. Additionally, understanding the different morphologic forms of breast cancer is crucial for managing patients well and selecting the right treatment option. [3]

The study assessed the accuracy of fine needle aspiration cytology diagnosis in the context of Hawassa university comprehensive specialized hospital and assessed the possible limitations and diagnostic pitfalls in comparison with the performance of other setups. This study aims to evaluate the effectiveness of FNAC in patients with breast lesions by correlating with the findings of histopathological diagnosis and identifying the morphologic pattern of breast lesions because there hasn't been a recent study on the validity of FNAC in the diagnosis of breast masses in HUCSH.

## 2. Material and Methods

### 2.1. Study Area

An institution-based retrospective cross-sectional descriptive study of all patients coming to the HUCMHS pathology department laboratory with a complaint of breast mass on which FNAC is performed and with subsequent histopathological study from September 2015 to August 2019.

### 2.2. Study Period

All patients with breast lumps underwent FNAC and subsequent biopsies at HSCH from September 2015 to August 2019.

### 2.3. Study Population

We collected all available samples which fulfilled the eligibility criteria i.e. 158 cases. All cytology and histopathology reports of breast lumps from September 2015 to August 2019 were collected from the patient's archives and cards. Patients with recurrent breast carcinoma and only cytology reports but without subsequent biopsy were excluded from the study. Cytology results were grouped into five diagnostic categories according to the IAC Yokohama system for reporting FNAB of the breast as follows. [18]

- 1) Inadequate or inconclusive
- 2) Benign
- 3) Atypical
- 4) Suspicious of malignancy
- 5) Malignant

## 3. Results

Out of the 158 patients who fulfilled eligibility criteria, 6 of them were men, making the male-to-female ratio 1:25. Their average age was 36.23 14.079 years, with ages ranging from 15 to 90. In the age range of 31 to 40 years, breast lumps were most common (51/ 32.27%). 121 (79.6%) of females had a history of at least one pregnancy. The majority of patients presented with breast lumps of 2 cm and above (143/ 90.5%) and a duration of less than 1 year (103/ 65.2%). No significant variation on the side of the breast is involved as shown in Table 2.

*Table 1. Statistical measures, definitions, and their equations.*

Statistical measure	Definition	Calculation
Sensitivity	The ability of an FNAC of the breast to correctly identify those with malignancy.	$TP/(TP + FN)$
Specificity	The ability of an FNAC to correctly identify those without malignancy.	$TN/(TN + FP)$
Positive predictive value	The probability that subjects with a breast malignancy on FNAC truly have the malignancy.	$TP/(TP + FP)$
Negative predictive value	The probability that subjects with a negative for malignancy truly don't have the disease.	$TN/(TN + FN)$
Diagnostic accuracy	The ability of an FNAC to discriminate between and/or predict malignant and benign.	$TP+TN/(TP+TN+FP+FN)$

TP, True positive, FN, False negative, TN, True negative, FP, False positive

FNAC results were benign in 63 (39.9%), positive for malignancy in 72 (45.9%), atypical in 10 (6.3%), and

suspicious for malignancy in 13 (8.3 %) of patients. No inadequate / inconclusive diagnosis was made as shown in

Table 3.

**Table 2. Patients demographic and clinical characteristics.**

Variable	Frequency	Percent	
Age	≤20	21	13.3
	21-30	45	28.5
	31-40	51	32.3
	41-50	23	14.6
	51-60	10	6.3
	>60	8	5.1
Sex	Male	6	3.8
	Female	152	96.2
Parity	Nulliparous	31	20.4
	Parous	121	79.6
Duration	<1 year	103	65.2
	>1 year	55	34.8
Size	<2cm	15	9.5
	2-4cm	64	40.5
	>4cm	79	50.0
Side	Right	73	46.2
	Left	78	49.4
	Bilateral	2	1.3
	Not specified	5	3.2
	Total	158	100.0

**Table 3. Diagnostic categories of FNAC.**

FNAC category	Frequency	Percent
Inadequate	0	0.0
Benign	63	39.9
Atypical	10	6.3
Suspicious	13	8.2
Malignant	72	45.5
Total	158	100%

**3.1. The Morphologic Pattern of Breast Lesions on Histology**

Out of 158 cases, 86 (54.4%) were malignant and 72 (45.6) were benign at histopathology. Fibroadenoma (41/25.9%) and fibrocystic change (10/6.3%) were frequently diagnosed as benign lesions while invasive ductal carcinoma, NOS (61/38.6%), and invasive lobular carcinoma (10/5.7%) were frequent malignant diagnosis as shown table 4.

**Table 4. Histomorphologic pattern of breast lesions.**

Morphologic patterns	Frequency	Percent
Fibroadenoma	41	25.9
FCC	10	6.3
Acute mastitis	7	4.4
Granulomatous/tuberculosis	3	1.9
Plasma cell mastitis	1	.6
Sclerosing lesion/ radial scar	1	.6
Chronic lymphocytic mastitis	1	.6
Adenoma	2	1.3
Gynecomastia	2	1.3
Other benign	4	2.5
High-grade DCIS	1	.6
LCIS	1	.6
IDC, NOS	61	38.6
ILC	9	5.7
Tubular carcinoma	1	.6
Metaplastic carcinoma	4	2.5
Neuroendocrine carcinoma	1	.6
High-grade sarcoma	1	.6
Mixed carcinoma	5	3.2
Metastatic carcinoma	1	.6
Mucinous carcinoma	1	.6
Total	158	100.0

The mean, standard deviation, lowest, and highest age limits were  $42.384 \pm 13.529$ , 22, and 90 years, respectively. The majority of malignancy diagnoses (52/60.4%) were made in patients between the ages of 30 and 50. Overall malignant to benign ratios are 1.19:1, high (7.2:1) above 40 years of age with the highest at the age range of 41-50 (10.5:1) and low below 40 years of age (0.746:1).

67 (77.9%) malignancies were seen in lump sizes more than 4 cm and duration of less than 1 year and 80 (97.5%) out of 82 females with breast malignancy had a history of at least one pregnancy as shown in Table 5.

Histopathologic categories of breast lesions with respect to different patient characteristics are depicted in Table 6.

**Table 5. Morphologic patterns in age groups.**

	Morphologic patterns of breast lesions							Total
	FA	FCC	Inflammatory	Other benign	Ductal, NOS	Lobular carcinoma	Other malignant	
<20	11	0	1	1	0	0	0	13
20-40	29	11	9	6	40	7	4	105
41-60	1	0	1	1	17	2	10	2
>60	0	0	1	1	4	0	2	8
total	41	11	12	9	61	9	16	158

**Table 6. Histopathologic categories of breast lesions with respect to different patient characteristics.**

Variables	Biopsy category		Total
	Benign	Malignant	
Parity	Nulliparous	29	31
	Parous	41	121
Duration	<1 year	36	103
	>1 year	36	55

Variables	Biopsy category		Total	
	Benign	Malignant		
Size	<2cm	13	2	15
	2-4cm	47	17	54
	>4cm	12	67	79
Side	Right	33	40	73
	Left	35	43	78
	Bilateral	2	0	2
	Unknown	2	3	5
Total	72	86	158	

### 3.2. FNAC to Histopathology Correlation

All cases reported as benign and positive for malignancy were confirmed as benign and malignant at histopathology respectively. Of the 10 cases reported as atypical at FNAC, 7 (70.0%) were benign and 3 (30.0%) turned out to be malignant at histopathology. As indicated in Table 7, out of 13 cases that were suspected to be cancerous, 11 were found to be cancerous, and two were benign. Benign and atypical categories of FNAC diagnosis were grouped into benign

whereas suspicious and malignant categories were grouped into malignant. Histopathology diagnoses were also classified into benign and malignant.

The diagnostic performance of FNAC, as compared to histopathology which is a gold standard diagnostic modality, was calculated according to the formula and shown in Table 8. FNAC & histopathology diagnosis were strongly correlated which is statistically significant ( $p = <0.05$ ).

Those key statistical measures, definitions, and equations are depicted in Table 1.

Table 7. Comparison of biopsy category to FNAC category.

		Biopsy category				Total		
		Benign		Malignant				
FNAC category	Benign	Benign	63	70 (TN)	0	3 (FP)	63	73
	Atypical		7		3		10	
	Suspicious		2		11		13	
	Malignant	Malignant	0	2 (FN)	72	83 (TP)	72	85
	Total		72		86		158	

Table 8. The diagnostic performance of FNAC.

Statistical Measure	Calculation	Value
Sensitivity	TP/(TP + FN)	97.64%
Specificity	TN/(TN + FP)	95.89%
Positive Predictive Value	TP/(TP + FP)	96.5%
Negative Predictive Value	TN/(TN + FN)	97.2%
Diagnostic Accuracy	TP+TN/(TP+TN+FP+FN)	96.8%

## 4. Discussion

In this retrospective cross-sectional descriptive study of 158 breast lesions with cytopathologic and histopathologic evaluation during 5 years from September 01, 2015, to August 30, 2019, The majority of the patients were female and between the ages of 20 and 40. The most prevalent benign diagnosis was a fibroadenoma, and the most frequent malignant diagnosis was an invasive ductal carcinoma. These results concur with some earlier studies. [6, 7]

With a mean age of 42.384 13.529 years and a range of 22-90 years, the peak age incidence for malignant breast lesions was 31-40 (36.05%) years. The peak age range for malignant breast lesions in our study was 10 years younger than that reported in earlier studies. [6] The younger age at presentation in this study may be a result of our patients' fictitious low-age documentation. The inconclusive or inadequate diagnosis was not identified in our study unlike most previous studies done on black lion and others as shown

in Table 9. This may be due to on-site evaluation of the smears and the inadequate aspirates repeated by more senior pathologists manually or image-guided. On the other hand, few of the FNAC reports signed out as inconclusive have no subsequent histopathology report which was an exclusion criterion from the study.

All of the 72 cases of breast cancer that were listed on FNAC as being malignant were shown to be malignant upon histological examination. However, of the 13 cases that were reported as suspicious for malignancy at FNAC, 2 (15.4%) cases turned out to be benign following excision biopsy and histopathology. Therefore, core needle biopsy or incisional biopsy is advised before deciding to mutilate surgeries like mastectomy for an equivocal FNAC diagnosis. A 45-year-old woman presents with a breast swelling and tenderness diagnosed as suspicious for malignancy on FNAC and biopsy was recommended for definitive diagnosis on the report. The biopsy was done; the atrophic breast with chronic lymphocytic mastitis was reported on histopathology. The other case was a 31-year-old woman diagnosed on the FNAC

as suspicious for malignancy found to be cellular fibroadenoma with complex features on histopathology. The common cause of false positive results was a cellular fibroadenoma, FCC, papillary lesions, and inflammatory atypia. [7]

Out of the 63 cases reported as benign, all were confirmed as benign at biopsy while 3 (30%) atypical cases turned out to be malignant on histopathology. All cases were signed out with a recommendation of excisional biopsy, and the subsequent histopathology was invasive lobular carcinoma, well-differentiated ductal carcinoma, and at least lobular carcinoma in-situ which later turned out to be lobular carcinoma after mastectomy. Therefore, all excision biopsy specimens should undergo histopathology, especially in cases of indeterminate diagnosis. The common cause of false negative results was lobular carcinoma and other low-grade malignancies.

In this study, FNAC had a sensitivity of 97.64%, a specificity of 95.89%, a positive predictive value of 96.5%, and negative predictive value of 97.2%, and diagnostic

accuracy of 96.8%. Other studies revealed a similar sensitivity ranging from 87.1% to 100% and specificity between 87.5% and 100%.<sup>1-7</sup> Triangulation of clinical information, imaging report, and FNAC, and repeat FNAC preferably under ultrasound guidance in case of equivocal diagnosis may reduce false positives, in the context of triple assessment tests including clinical evaluation and imaging reports, FNAC is sufficiently accurate to diagnose a breast lesion and diagnosis of a breast lesion and to decide on the definitive treatment in our practice. This finding is particularly important in our setting patient’s waiting time the patients’ waiting time for treatment. This is because while FNAC results are obtained within 24 hours in our practice, other forms of pathologic diagnosis (core needle biopsy and excisional or incisional biopsy and histopathology) may take much longer time, averaging 3 weeks.

We compare our fine needle aspiration cytology diagnostic category findings with previous studies done at different institutions. (Table 9)

**Table 9.** FNAC category in comparison to other studies.

Category	Our study	Black Lion	Shazia Aslam et al.	Hamid Rasheed et al.
Inadequate	0.0	9.5%	0.0%	4.34%
Benign	39.9%	44.9%	55.5%	44.56%
Atypical	6.3%	-	1.78%	6.52%
Suspicious	8.2%	13.0%	1.78%	7.60%
Malignant	45.5%	32.6%	41.1%	36.95%

## 5. Conclusion

The results of this study demonstrated that FNAC is a reliable diagnostic technique with good specificity and sensitivity. It helps the physician on deciding on the appropriate management of the breast lesions and alleviates the patient’s anxiety. Common causes of equivocal diagnosis with false positive and false negative reports were overlapping cellular features.

Even though FNAC is a rapid procedure, it should be examined carefully before reporting. Strict rules should be applied like repeat FNAC for indeterminate diagnosis and correlation with clinical findings and imaging reports. When improperly and insufficiently prepared smears are used, FNAC should be repeated possibly under image guidance. When smears are definitely malignant, surgery or other therapies should begin right once. While for gray lesions like atypical and suspicious smears, core needle biopsy or excision biopsy is advised.

FNAC is a reliable approach for the early identification of breast lesions in our practice, as evidenced by the high sensitivity, specificity, and diagnostic accuracy that we reported. Therefore, for early detection and best patient care, we advocate for the widespread use of FNAC in our practice as a supplement to the histological diagnosis of breast lesions.

## Abbreviations

FNAC: Fine needle aspiration cytology

CB: Core Biopsy

HUCSH: Hawassa university comprehensive specialized hospital

USA: United States of America

WHO: World health organization

UDH: Usual ductal hyperplasia

ADH: Atypical ductal hyperplasia

ALH: Atypical lobular hyperplasia

IDC: Invasive ductal carcinoma

IILC: Invasive Lobular Carcinoma

DCIS: Ductal Carcinoma Insitu

LCIS: Lobular Carcinoma Insitu

TC: Tubular carcinoma

## Ethical Approval and Informed Consent

Ethical clearance and approval of the study were obtained from HUCSH institutional review board (IRB). A formal letter was obtained from the Department of Pathology, HUSCH, to collect report formats and to get patients’ medical record charts. The confidentiality of the study patients will be kept secret.

## Consent for Publication

The consent for publication was also obtained from the HUCSH institutionalized review board (IRB) and the Department of Pathology, HUCSH.

## Data Availability

All data are included in the manuscript.

## Conflict of Interests

All the authors do not have any possible conflicts of interest.

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