



St. Paul's Hospital Millennium Medical College Graduate Study Program

**Diagnostic accuracy of breast core needle biopsy at St. Paul's Hospital
Millennium Medical College**

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Addis Ababa, Ethiopia

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Millennium Medical College from June 2018 to December 2023.

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Acronyms and Abbreviations

ADH	Atypical ductal hyperplasia
ALH	Atypical lobular hyperplasia
BIRAD	Breast imaging reporting and data system
CIS	Carcinoma in situ
CB	Core biopsy
CNB	Core needle biopsy
DCIS	Ductal carcinoma in situ
ER	Estrogen Receptor
H&E	Hematoxylin and Eosin
HER2	Human epidermal growth factor receptor 2
LCIS	Lobular carcinoma in situ
NPV	Negative predictive value
PPV	Positive predictive value
PR	Progesterone Receptor
SPHMMC	St Paul's Hospital millennium medical college
UDH	Usual ductal hyperplasia
VAB	Vacuum aspirated biopsy

Abstract

Background: Breast core needle biopsy (CNB) is a critical diagnostic method for assessing breast lesions. This cross-sectional study (June 2018 – December 2023) at St. Paul Hospital Millennium Medical College aims to the diagnostic accuracy of breast CNB samples and understand factors influencing diagnostic accuracy.

Objectives: To assess the diagnostic accuracy of breast CNB and identify factors influencing diagnostic accuracy at St. Paul's hospital millennium medical college (SPHMMC), Addis Ababa, from June 2018 to December 2023 G.C.

Methods: Cross sectional study was conducted and all breast core needle biopsy samples from June 2018 to December 2023 G.C with subsequent open surgical biopsy diagnosis were included. A total of 68 cases were analyzed for accuracy and associated factors.

Results- In the study sensitivity, specificity, PPV and NPV of CNB diagnosis in relation to open surgical biopsy result was 91.7%, 90.0%, 95.7% and 81.8%. The accuracy of CNB in detecting breast lesions was 91.17 %. Number of cores taken was the only factor found to be correlated with the accuracy.

Keywords: Breast core needle biopsy, St. Paul Hospital Millennium Medical College, Ethiopia, Breast cancer.

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1. Introduction

1.1 Background

Breast cancer is the most commonly diagnosed cancer worldwide, and its burden has been rising over the past decades.[1][2] Breast cancer is the leading cancer among women in Ethiopia.[3][4][5]

There are different ways to diagnose breast cancer, among those CNB is a safe and cost-effective method for obtaining a non-operative diagnosis of breast lesions. CNB technique uses wide hallow needle (14-, 12-, 11- or 8-gauge needles) [6]to take out pieces of breast tissue from the area of concern. This can be done with the doctor either palpating the area or while using an imaging test to guide the needle. The needle may be attached to a spring-loaded tool that moves the needle in and out of the tissue quickly, or it may be attached to a suction device that helps pull breast tissue into the needle (known as a vacuum-assisted core biopsy).[7][8]

Two main types of CNBs are in use:

1. The cutting core biopsy (CCB) is a 12–14-gauge spring-loaded device that fires a cutting needle into the breast tissue. Multiple insertions are needed for sampling the target. [7][8] (8)
2. Vacuum Assisted Biopsy (VAB) uses 8–11-gauge needles and adds a vacuum system to draw tissue into the cutting chamber to facilitate sample collection. As a result, larger specimens are obtained, with just one shot. VAB is increasingly utilized in practice, being useful in both diagnostic and therapeutic approaches.[6]

CNB may be used in palpable and in non-palpable masses, attached to mammographic stereotactic units, ultrasound guidance, or Magnetic Resonance Imaging (MRI). This allows imaging localization of suspicious lesions with concomitant staging of the axilla, reducing the open surgical biopsies and their morbidity. The biopsy method used depends on which modality

best depicts the abnormality, location and size of the abnormality within the breast, patient factors, and the operator's experience and preference. [8]

Open surgical biopsy removes suspicious tissue through a surgical incision. This procedure requires either a general or local anesthetic and closure of the incision with sutures. CNB is rapid, more convenient, and linked to reduced discomfort and complications when compared with open surgical biopsy.[9]

Breast cancer is now increasingly diagnosed preoperatively rather than at excision biopsy.[10] Globally core biopsy has largely superseded fine-needle aspiration cytology in the diagnosis of breast cancer,[11] not only because of its increased sensitivity, but also because of its ability to differentiate CIS from invasive disease. It is regarded as a highly accurate method of diagnosing breast cancer.[12][13][10] Triple assessment (clinical examination, imaging and biopsy) is the gold standard for all palpable breast cancers.[14] CNB result should not be interpreted in isolation. If the result is indeterminate or discordant with clinical and radiologic finding repeat biopsy or surgical excision is indicated to rule out malignancy. [14] [6] the fragmented nature or the small size of the sample, may cause diagnostic pitfalls and precise radiologic-histopathologic correlation is needed for optimal patient management.[6]

1.2. Statement of the Problem

Breast cancer is the most commonly diagnosed cancer and leading cause of cancer death among women worldwide[1][2] accounting for 1 in 8 cancer diagnoses and a total of 2.3 million new cases in 2020 in both sexes combined.[1] Breast CNB is an essential diagnostic tool for accurately assessing breast lesions globally. [14][6]

In Ethiopia breast cancer is the leading cause of cancer, [4][5][3] with 16,133 (20.9%) new case in 2020. In Ethiopia, breast core needle biopsy (CNB) is a relatively new procedure with less than a decade of experience. As a result, there is currently a lack of research on the diagnostic accuracy and utilization of breast CNB at St. Paul's Hospital Millennium Medical College (SPHMMC). Thus, there is a need to investigate the diagnostic accuracy and morphologic spectrums observed in CNB samples. Additionally, understanding the factors that influence the accuracy of breast CNB is crucial for improving the reliability of this diagnostic procedure. Therefore, this research aims to address the following questions:

1. How does the accuracy of breast CNB in diagnosing malignancy vary based on the observed morphologic spectrums?
2. What are the different morphologic spectrums observed in breast CNB samples at SPHMMC?
3. What are the factors, including needle size, number of cores taken, radiological guidance, and the presence of calcifications, that affect the accuracy of breast CNB at SPHMMC?

1.3. Rationale of the Study

Breast cancer is one of the most common cancers both globally and in Ethiopia.[1][3] [4] [15] Early detection and accurate diagnosis are crucial for improving survival rates and reducing

morbidity. Core needle biopsy (CNB) is used diagnostic tool for breast lesions in Ethiopia along with FNAC. However, there is no research done in Ethiopia regarding the diagnostic accuracy of CNB, which can be affected by various factors such as lesion size, sampling techniques, processing and morphology.

The rationale for this research is to assess the diagnostic accuracy of CNB and identify factors affecting accuracy. By identifying the factors that affect the accuracy of CNB, clinicians can better select patients who would benefit from CNB and those who require further evaluation. Moreover, this study will provide valuable information on the morphologic spectrums of breast lesions diagnosed by CNB in our setting.

2. Literature review

Worldwide CNB as part of triple assessment for preoperative evaluation and diagnosis of breast cancer, is now considered as an established, highly accurate method for diagnosing breast cancer that has replaced either fine needle aspiration cytology or excisional biopsy as the initial diagnostic biopsy procedures in many institutions. In addition to its primary role in establishing an accurate histological diagnosis, CNB can potentially provide important additional pathological prognostic information which may be of direct clinical value in certain situations, such as patients being considered for preoperative (neoadjuvant) therapy.[16]

Breast CNB is used for sampling breast lesions in both the screening and diagnostic context.[17] Published data suggest that the use of core biopsy has increased the preoperative diagnosis rate in screen detected breast cancers. [8] Based on a study done in Florence, Italy the overall sensitivity of CNB is 94.2% (92.9–95.5%) and specificity is 88.1% (86.6–89.6%), positive and negative predictive values are 84.8% (82.9–86.7%) and 95.6% (94.6–96.6%), respectively. The study also shows in sampling microcalcification, the overall underestimation of malignancy is 26.6% (22.9–30.3%): underestimation is significantly higher for automated CB relative to VAB, the absolute difference in underestimation being 14% (5–23%); sensitivity is higher for VAB than automated CB but specificity is significantly higher for automated CB (14G) relative to VAB (11G) and the overall accuracy of the two methods is similar.[17] Sensitivity of CNB improved with experience (over time and in relation to caseload). Accuracy was not substantially affected by lesion palpability or image-guidance method, and was similar for both masses and calcification but lower for lesions depicted as distortions on mammography. [17] Inadequacy was very low and decreased with greater operator caseload, and was not associated with core gauge or image-guidance methods. [17] False negatives occurred in 4.4% (3.4–5.4%) of cases,

and where core histology was benign but discordant with (suspicious) imaging and/or clinical findings the likelihood of malignancy was 33.1% (18.5–47.7%), emphasizing the importance of correlating all test information in breast diagnosis.[17]

Research done in India showed 71.4% overall concordance between CNB and final excision, 8/10 discordant cases were from benign category. For detection of malignancy overall sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy were 90.4%, 100%, 100%, 87.5% and 94.2% respectively. Sensitivity, specificity, PPV, NPV and accuracy in biopsies with more than 3 cores was 100%.

Most studies of the accuracy of CNB have originated from centers that have pioneered CNB and shown its accuracy in expert hands.[18][19] Palpability had no effect on accuracy, which would be expected since all lesions were sampled under imaging guidance regardless of whether they were clinically apparent (palpable) or not.[17] In settings where neoadjuvant chemotherapy is used, the histologic information obtained by CNB may be the only information available making assessment of diagnostic accuracy of CNB very important. [20]

Diagnostic accuracy- The highest levels of diagnostic accuracy in the non-operative diagnosis of breast disease are achieved by means of a triple approach, combining the results of imaging and clinical examination with fine needle aspiration cytology and/or needle core biopsy[6][14][21] Diagnostic performance is comparable to excisional specimens but tumor grade in invasive carcinoma may differ. [22] Multiple factors, such as methodology, case selection, needle size, number of cores taken, amount of clinical material, presence of calcification, operator and pathologist expertise can impact the accuracy of CNB in diagnosing malignancy and the information obtained from it.[16]

Size of lesion and radiologic feature –

Some researches show that inevitably inadequate and false negative results are more frequent for impalpable lesions.[21][23] In other researches palpability had no effect on accuracy.[17]

Sampling technique-

Slightly better results were documented in ultrasound-guided NCB and vacuum-assisted biopsies than in stereotactic, spring-loaded and freehand biopsies[24][25][26][27][23] and for diagnosis of palpable masses than for calcifications.[23] Some researchers have noted that an important issue when evaluating pathological factors on core needle biopsy (NCB) specimens is the insufficient sampling of the most informative areas.[28] Therefore, it is recommended to obtain a sufficient volume of biopsy material, especially when dealing with large-sized tumors and cases involving calcifications.[25][29] Stereotactic LCNB can safely replace open breast biopsy in patients with nonpalpable suspicious breast lesions and that in the case of a benign LCNB diagnosis no surgical excision is warranted.[22]

Number and length of cores - The accuracy of CNBs is known to increase when a higher number of CNB tissue strips are collected. [30]

Reasons to obtain a sufficient, but not excessive, number of biopsy specimens include the minimization of procedure time, patient discomfort, and breast trauma.[31] The value of core needle biopsy for obtaining tissue samples of breast lesions is well known. For ultrasound guided CNB a minimum of four specimens, preferably those that are non-fragmented and that sink, should be obtained with 14-gauge US-guided breast biopsy.[31] Previous studies have shown that 4 to 5 specimens are required to obtain a definitive diagnosis, but few studies have focused on the optimal number of biopsy cores required to obtain a reliable pathological diagnosis. There

is abundant information to suggest that four to five cores are optimal for diagnosis[32][33][34][31][35] But some studies show an increase in accuracy with the obtention of up to 2 cores only and no further increasement in accuracy was observed with additional cores. However, there is a need to obtain more cores whenever the operator is not confident that the tissue obtained so far is representative of the tumor.[36] A study done in China by Tao Sun and colleagues indicates that a minimum of 2 strips are required to determine a diagnosis of malignancy, while 4 or more specimens are recommended to achieve complete concordance of the pathology parameters (ER, PR, HER2 status, and tumor grade) between CNBs and surgically excised specimens.[30]

Processing- The amount of sectioning necessary to detect all atypical finding is not well established. [37] According to some studies, it is suggested that obtaining five sections of breast core needle biopsy specimens is necessary to ensure adequate sampling of all atypical small acinar proliferations and atypical ductal hyperplasia lesions.[37][38] Study done in Virginia Commonwealth University conclude that exhaustive searching for microcalcifications in CNB yields a small increase in specific diagnostic information and a high technical cost. In individual cases, the additional information may be critical for appropriate patient management. [39] After processing, H&E-stained sections from one level are usually sufficient for core biopsies from mass lesions, but core biopsies taken for the investigation of microcalcification should have a minimum of three levels examined. In practice, most laboratories choose to examine all core biopsies from screen detected lesions at a minimum of three levels initially. In problematic cases further levels and immunohistochemical studies may be helpful.[21]

3. Objectives

3.1. General Objective:

To assess the diagnostic accuracy of breast core needle biopsy (CNB) at SPHMMC from June 2018 to December 2023.

3.2. Specific objectives

1. Assess the diagnostic accuracy of CNB in distinguishing between benign and malignant breast lesions.
2. Document diverse morphologic spectrums in breast lesions encountered on CNB
3. Assess factors affecting the diagnostic accuracy

4. Methods

4.1. Study area:

St. Paul's Hospital Millennium Medical College, situated in Addis Ababa's Gullele sub-city near 1271 Swaziland Street, stands as one of Ethiopia's largest hospitals. Notably, its pathology service, established as a medical specialty in the college in 2014 G.C., has been pivotal evaluating around 8000 biopsy, 6000 cytology and 1500 hematology specimens annually making it one of the leading centers in the country.

4.2. Study Period:

June 2018 to December 2023

Data collection and analysis- from November 2023 to February 2024 G.C.

4.3. Study Design:

An institution based cross sectional study design was employed.

4.4. Source Population:

All patients who had presented to SPHMMC for breast evaluation during the study period.

4.5. Study Population:

All patients who had breast core needle biopsy and whose samples are sent to SPHMMC, anatomic Pathology department between time period of June 2018 to December 2023.

4.6. Selection criteria:

Inclusion criteria

- All patients who had breast CNB with in the specified time period (from June 2018 to December 2023).

Exclusion criteria

- Individuals who underwent breast CNB beyond the specified study period.

- Patients who had neoadjuvant chemotherapy or radiotherapy treatment between the time of CNB and open surgical biopsy.
- Cases without finalized pathology report.

4.7. Sample size

From 170 cases of breast core needle biopsy done with in the study period 68 cases with subsequent open surgical biopsy and no history of neoadjuvant chemotherapy were included.

4.8. Data Collection and Procedures:

In this study, the data source was the medical records of patients who underwent breast CNB at SPHMMC.

The data collection tool consists of a structured data collection form that includes fields for capturing patient demographics, biopsy procedure details, grossing findings and histopathology reports.

Data was collected from anatomic pathology and radiology record files and patients medical chart using structured, self-prepared and anonymous questionnaire.

4.9 Study Variables:

Dependent variable

Histopathologic data (Diagnosis)

Independent variable

1. Demographic
2. Laterality of the lesion

3. Radiologic findings

4. Sampling variables

- A. Technique of sampling
- B. Size of core needle used
- C. Number of cores
- D. Total length of cores

5. Processing

- A. Number of sections (Number of levels)

4.10. Quality assurance

Data collection was carried out by medical professionals with knowledge of biopsy procedures and knowledge of medical terminology. The data collectors received specific training on the data collection tool, study objectives, and ethical considerations. They were also familiarized with the medical records system at SPHMMC. Data collection was done under adherence to strict privacy and confidentiality measures to protect patient information.

4.11. Data management and analysis

Data was collected through a structured checklist and entered into epidata. The coded data was then exported to statistical package for social science (SPSS) version 26.0 for analysis. Categorical variables were presented in frequencies and percentages, whereas numerical variables were expressed in means and standard deviations. Sensitivity, specificity, positive and negative predictive values and accuracy of CNB category were calculated compared to open surgical biopsy result.

4.12 Operational Definitions:

Breast diagnostic categories

Radiologic category –

The BIRADS (Breast Imaging Reporting and Data System) Assessment Categories [6]

Birads category	Significance
Birads 0	Incomplete
Birads 1	Negative
Birads 2	Benign
Birads 3	Probably Benign
Birads 4a	Low suspicion for malignancy (2-9%)
Birads 4b	Moderate suspicion for malignancy (10-49%)
Birads 4c	High suspicion for malignancy (50-94%)
Birads 5	Highly suggestive of malignancy >95% probability of malignancy
Birads 6	Known biopsy-proven malignancy

Histopathologic Spectrum: The range of histological findings observed in breast CNB specimens including inflammatory changes, neoplastic alterations, and other relevant histologic patterns.

Histologic diagnostic categories

1. B1, Normal tissue - indicates a CNB with normal tissue where breast glandular structures may be present or not.[14][6][21]
2. B2, Benign - fibroadenomas, fibrocystic changes, sclerosing adenosis, UDH and duct ectasia and breast inflammatory lesions. [14][6][21]
3. B3, Uncertain malignant potential- atypical intraductal epithelial proliferation (ALH and ADH), fibroepithelial lesion with cellular stroma, radial scar, papillary lesions without

atypia, adenomyoepithelioma, mucocoele-like lesions without atypia, nipple adenomas, microglandular adenosis, granular cell tumor, spindle cell lesions, flat epithelial atypia, papillary neoplasms, classic LCIS and radial scar . [14][6][21]

4. B4, Suspicious of malignancy - Cores that probably contain a carcinoma but it is not unequivocal in the sample. [14][6][21]

5. B5, Malignant - DCIS, Pleomorphic or Florid LCIS, invasive carcinoma. [14][6][21]

- Diagnostic Accuracy: The ability of breast core needle biopsy to correctly predict corresponding histopathological findings up on open surgical biopsy. Assessed using sensitivity, specificity, positive predictive value and negative predictive value.

For purpose of assessing sensitivity and specificity i classified cases in two

1. Malignant cases – Are cases which are diagnosed under category B4 (suspicious) and B5 (malignant)
 2. Nonmalignant cases- Include B1, B2, B3 and non-diagnostic cases.
- Concordant VS Discordant
 - ✓ Concordant cases- When the CNB diagnostic category is similar with the final open surgical biopsy diagnosis
 - ✓ Discordant- When there is discrepancy between the CNB diagnosis and the final open surgical biopsy diagnosis

4.13. Ethical Consideration:

Before conducting the research, permission was obtained from SPHMMC research office and research ethics committee. Permission to collect data was also obtained from the department of

pathology and radiology. To ensure confidentiality, the name of patients was not recorded on the data collection format.

4.13. Dissemination of Results:

By the end of the research analysis, the information will be disseminated by hard copy and softcopy to SPHMMC, pathology department. I will also try my best to publish the paper in peer reviewed journals.

5. Results

5.1 Sociodemographic data

Over the time interval of study period total of 171 breast CNB was done, from which 68 cases were included in this study using strict inclusion and exclusion criteria. Majority of the patients were in the 4th and 5th decade of life (60.6%). The youngest patient was 15 and the oldest was 85 with a mean age of 40.2.

Table 1- Age distribution

Age	Frequency	Percent (%)
<20	1	1.5
21-30	12	17.6
31-40	30	44.1
41-50	18	26.5
>50	7	10.3
Total	68	100.0

67 (98.5%) of the study participants are female, only one patient (1.5%) was male. In 55.9% (38) of the cases the lesion was located on the right breast, the remaining 30 (44.1%) cases were from the left breast.

5.2 Ultrasound finding

Most of the cases 25 (36.8%) were located in the upper outer quadrant followed by upper inner, lower inner quadrants and diffuse (> one quadrant involvement).

Table 2-Location of lesion, Quadrant

	Frequency	Percent
Upper outer quadrant	25	36.8
Upper Inner quadrant	10	14.7
Lower outer quadrant	10	14.7
Upper inner quadrant	6	8.8
Central	7	10.3
Diffuse	10	14.7
Total	68	100.0

65 patients (95.6%) present with palpable breast lump, 3 patients (2.9%) present with breast pain and non-palpable breast lump detected on ultrasound and one patient (1.5%) present with mammography detected calcification.

Up on ultrasound evaluation majority of the lesions (57.3%) were BIRAD category 4.

Table -3 BIRAD Category

	Frequency	Percent
BIRAD 1	1	1.5
BIRAD 2	1	1.5
BIRAD 3	3	4.4
BIRAD 4	35	51.5
BIRAD 4B	1	1.5
BIRAD 4C	4	5.9
BIRAD 5	23	33.8
Total	68	100.0

5.3 CNB diagnostic categories (Histologic finding)

The commonest diagnostic category up on histologic evaluation is malignant followed by benign B2category.

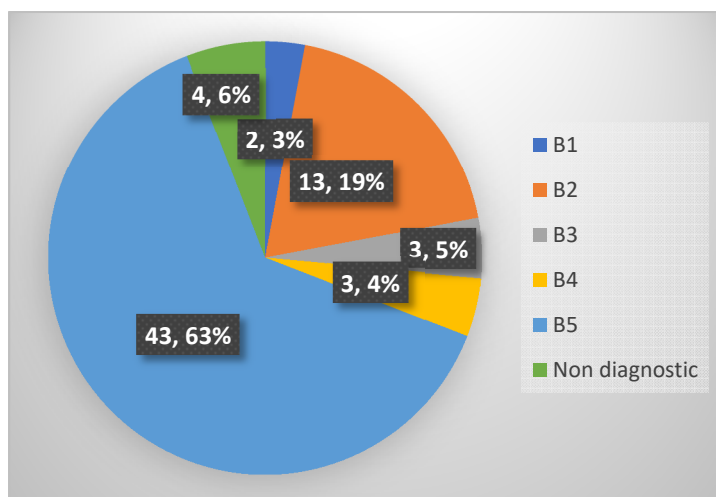


Figure 1- Frequency of cases based on histologic CNB diagnosis categories.

All lesion diagnosed under category B3 were intraductal papilloma. Fibroadenoma along with unspecified fibroepithelial lesions and granulomatous mastitis are the commonest lesions under B2 category.

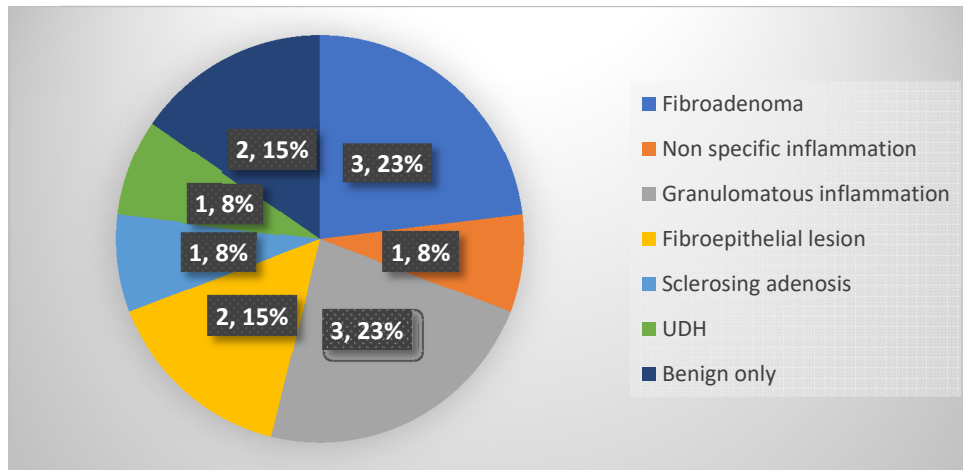


Figure 2- Frequency and percentage of specific diagnosis under benign (B2) category.

Invasive carcinoma of no special type accounts for the majority (63%) of lesions under malignant (B5) category. Invasive lobular carcinoma and DCIS each account for around 5 % of B5 category. Mixed ductolobular carcinoma, invasive carcinoma with medullary features and neuroendocrine tumor and malignant non-specific diagnosis contributes for the remaining B5, malignant categories.

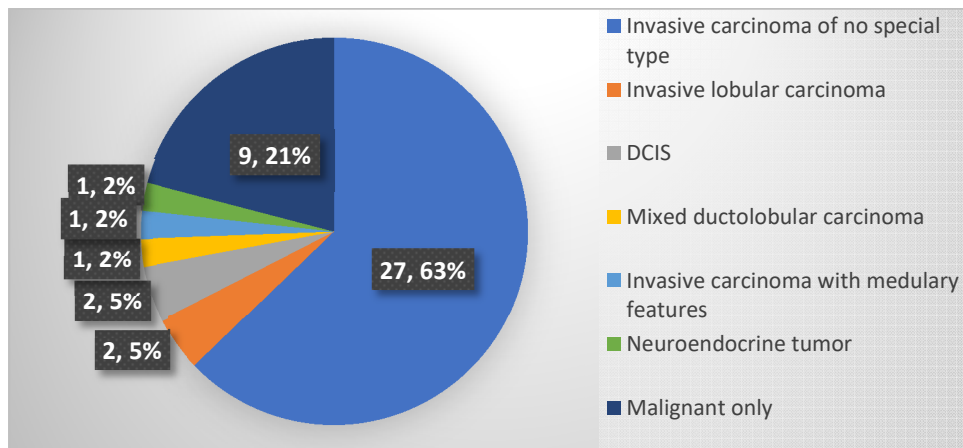


Figure 3 – Frequency and percentage of specific diagnosis under malignant B5 category

5.4 Accuracy of CNB compared with open surgical biopsy

In the study sensitivity, specificity, PPV and NPV of CNB diagnosis in relation to open surgical biopsy result is 91.7%, 90.0%, 95.7% and 81.8%. The accuracy of CNB in detecting breast lesions was 91.17 %.

Table -5 Sensitivity, Specificity, PPV and NPV of CNB

			Open surgical biopsy diagnosis		
			Malignant	Non malignant	Total
CNB diagnosis	Malignant	Count	44 (TP)	2 (FP)	46
		%	Sensitivity (91.7%)		
			PPV (95.7%)		
	Non malignant	Count	4 (FN)	18 (TN)	22
		%		Specificity (90.0%)	
				NPV (81.8%)	
Total		Count	48	20	68

Among the 2 cases of normal breast (B1) category one was found to be malignant (invasive lobular carcinoma) on excisional biopsy and the other was found to be normal breast. The 1st discordant benign case has previous FNAC which was signed out as suspicious. The FNAC was revised by pathologist who evaluated CNB and surgical biopsy was recommended which turned out to be malignant.

From the 13 cases in benign (B2) category 12 cases (92.3%) were concordant up on open surgical biopsy and only one case (7.7%) was found to be malignant (Invasive carcinoma of no special type) on subsequent biopsy. All the three B3 category cases were concordant with open surgical biopsy diagnosis. All suspicious lesions on CNB were confirmed to be malignant on subsequent biopsy.

From the 43 cases of B5 category 41cases (95.3%) were concordant while two cases were found to be discordant with final diagnosis. One of the cases was initially diagnosed as malignant (DCIS) on CNB but excisional biopsy shows fibrocystic change only. The second discordant case was diagnosed as well differentiated ductal carcinoma for which mastectomy was done and specimen was thoroughly evaluated but showed adenosis with intraductal proliferation only. Among the 4 non diagnostic cases two were found to be malignant (Invasive carcinoma of no special type) on excisional biopsy and the other two were benign ((Usual ductal hyperplasia, Florid type+ Fibrocystic change) and Chronic suppurative inflammation with foreign body reaction.).

Table 6- Diagnosis on core needle biopsy * out come on open surgical biopsy across different CNB categories

		Out come on open biopsy		Total
		Malignant	Non malignant	
Diagnosis on core needle biopsy	B1, Normal breast	1	1	2
	B2, Benign	1	12	13
	B3, Uncertain malignant potential	0	3	3
	B4, Suspicious	3	0	3
	B5, Malignant	41	2	43
	Non diagnostic	2	2	4
Total		48	20	68

5.5 Assessment of possible factors affecting accuracy

Independent samples t-tests and binary logistic regression and was applied to identify if there is relation between the accuracy and size of the lesion, number of cores, length of cores, number of sections assessed as well as BIRAD category.

The finding suggests that the size of the lesion, number of sections or levels, and length of the longest core and BIRAD category do not significantly affect accuracy of CNB in this study. The

number of cores taken is only variable found to be associated with accuracy of CNB with a significance value less than 0.05 (P value of 0.021) and odds ratio of 4.313.

Table 7 - Multivariable logistic regression of the variables

	Sig.	OR	95% C.I. for EXP(B)	
			Lower	Upper
Number of passes or cores taken	.021	4.313	1.249	14.894
longest core	.628	.297	.002	40.280
Number of sections or levels	.956	1.020	.503	2.067
Size of the lesion	.987	.996	.628	1.579
BIRAD Category	.999			
BIRAD Category(1)	1.000	19296470.435	.000	.
BIRAD Category(2)	1.000	413338314.899	.000	.
BIRAD Category(3)	.999	36456999.543	.000	.
BIRAD Category(4)	.568	.423	.022	8.056
BIRAD Category(5)	1.000	124610524.699	.000	.
BIRAD Category(6)	.547	.311	.007	13.961
Constant	.937	.759		

The mean number of passes or cores taken was 2.17 (SD = 0.98) for the discordant group and 3.94 (SD = 1.30) for the concordant group, with a standard error of the mean of 0.40 and 0.17, respectively.

Table -8 Comparison of the mean number of cores taken for concordant and discordant groups

	Concordant or discordant	N	Mean	Std. Deviation	Std. Error Mean
Number of passes or cores taken	Discordant	6	2.1667	.98319	.40139
	concordant	62	3.9355	1.30410	.16562

For cases with number of cores ≥ 3 the sensitivity specificity PPV and NPV will increase from 91.7%, 90.0%, 95.7% and 81.8% to 95.35 %, 93.3% 97.6 % and 87.5% respectively. Fore cases with core number of ≥ 4 sensitivity, specificity, PPV, NPV as well as accuracy is 100%.

Table 9 – CNB DX vs final DX for cases with ≥ 4 Crosstabulation

			Out come on gold standard test		Total
			Malignant	Benign	
CNB DX	Malignant	Count	15	0	15
		% within Out come on gold standard test	100.0%	0.0%	78.9%
	Benign	Count	0	4	4
		% within Out come on gold standard test	0.0%	100.0%	21.1%
Total	Count		15	4	19
	% within Out come on gold standard test		100.0%	100.0%	100.0%

6. Discussion

CNB is a globally recognized and accurate method for diagnosing breast cancer, replacing fine needle aspiration cytology and excisional biopsy in many institutions. Besides its role in histological diagnosis, CNB can offer valuable prognostic information, particularly for patients undergoing preoperative therapy. [16] [17] [8] [20]

6.1. Diagnostic accuracy

The best diagnostic accuracy for non-operative breast disease diagnosis is achieved through a triple approach combining imaging, clinical examination, and fine needle aspiration cytology or needle core biopsy. [6][14] [21] If done by expertise hand (both radiologist and pathologists) the diagnostic performance is comparable to excisional specimens. [22] Several factors, including methodology, case selection, needle size, number of cores taken, amount of clinical material, presence of calcification, and operator and pathologist expertise, can influence the accuracy of CNB in diagnosing malignancy.[16]

This study analyzes the diagnostic accuracy and possible factors which might affect the accuracy by studying 68 case of core needle biopsy which have subsequent open surgical biopsy diagnosis. In this study the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the core needle biopsy (CNB) diagnosis in relation to the open surgical biopsy result were 91.7%, 90.0%, 95.7%, and 81.8%, respectively. Additionally, the overall accuracy of CNB in detecting breast lesions was reported to be 91.17%.

On the other hand, the other factors assessed in this study, including the size of the lesion, number of sections assessed, length of cores, and BIRAD category of the lesion, did not

demonstrate a statistically significant relationship with the diagnostic accuracy of breast core needle biopsy.

It is worth noting that while these factors were not found to be statistically significant in this study, it is possible that they may still have some clinical relevance or impact on diagnostic accuracy. The lack of significance could be attributed to a variety of factors, such as small sample size and sampling technique. Further investigation with larger sample sizes or different patient populations may provide additional insights into the potential influence of these factors on diagnostic outcomes.

Most studies of the accuracy of CNB have originated from centers that have pioneered CNB and shown its accuracy in expert hands.[18][19] Considering that we have short period of experience at our set up it is expected to have lower rate of accuracy. Based on a study done in Florence, Italy by Stefano Ciatto and his colleague the overall sensitivity of CNB is 94.2% (92.9–95.5%) and specificity is 88.1% (86.6–89.6%), positive and negative predictive values are 84.8% (82.9–86.7%) and 95.6% (94.6–96.6%), respectively. [17] Compared to the finding in the current study the slight difference in sensitivity might be attributed to difference in core needle size and sampling technique. In our set up all breast CNB was taken under ultrasound guidance and using 16-gauge needle which has smaller caliber size compared with the 14-gauge and 11-gauge needles which are used in the study done in Florence, Italy. The specificity in the above study appears to be comparable with the current research.

Research done in India showed 71.4% overall concordance between CNB and final excision. For detection of malignancy overall sensitivity, specificity, and accuracy were 90.4%, 87.5% and 94.2% respectively. [11]

6.2 Size of lesion and radiologic feature

Some researches show that inevitably inadequate and false negative results are more frequent for impalpable lesions.[21][23] In other researches palpability had no effect on accuracy and accuracy was not substantially affected by image-guidance method, and was similar for both masses and calcification but lower for lesions depicted as distortions on mammography. [17]

Similarly in the current study size of the lesion (palpability) don't show statically significant correlation with the accuracy of diagnosis. Absence of correlation between the size (palpability) of the lesion might be because all samplings were taken under image guidance irrespective of the size or palpability which increases the probability of proper sampling . [17]

6.3 Number and length of cores

Some researchers have noted that an important issue when evaluating pathological factors on core needle biopsy (NCB) specimens is the insufficient sampling of the most informative areas.[28] Therefore, it is recommended to obtain a sufficient volume of biopsy material, especially when dealing with large-sized tumors and cases involving calcifications.[25][29] The accuracy of CNBs is known to increase when a higher number of CNB tissue strips are collected. [30] Reasons to obtain a sufficient, but not excessive, number of biopsy specimens include the minimization of procedure time, patient discomfort, and breast trauma.[31] For ultrasound guided CNB a minimum of four specimens, preferably those that are non-fragmented and that sink, should be obtained with 14-gauge US-guided breast biopsy.[31] Previous studies have shown that 4 to 5 specimens are required to obtain a definitive diagnosis, but few studies have focused on the optimal number of biopsy cores required to obtain a reliable pathological diagnosis. There is abundant information to suggest that four to five cores are optimal for

diagnosis[32][33][34][31][35] But some studies show an increase in accuracy with the obtention of up to 2 cores only and no further increasement in accuracy was observed with additional cores. However, there is a need to obtain more cores whenever the operator is not confident that the tissue obtained so far is representative of the tumor.[36] A study done in China by Tao Sun and colleagues indicates that a minimum of 2 strips are required to determine a diagnosis of malignancy, while 4 or more specimens are recommended to achieve complete concordance of the pathology parameters (ER, PR, HER2 status, and tumor grade) between CNBs and surgically excised specimens.[30] Research done in India by anchan Snehal Kothari and colleagues showed sensitivity, specificity, PPV, NPV and accuracy in biopsies with more than 3 cores was 100%. [11] In our study, having three or more cores during CNB increased sensitivity, specificity, PPV, and NPV. Specifically, sensitivity increased from 91.7% to 95.35% and specificity increased from 90.0% to 93.3%. For cases with four or more cores, sensitivity, specificity, PPV, NPV, and accuracy were all 100%.

6.4 Processing

The amount of sectioning necessary to detect all atypical finding is not well established. [37] Some studies suggest obtaining at least five sections to adequately sample atypical small acinar proliferations and atypical ductal hyperplasia lesions [37][38]. Some studies suggest that one level of H&E-stained sections is sufficient for core biopsies from mass lesions, while a minimum of three levels is recommended for investigating microcalcifications. Laboratories often examine all core biopsies from screen-detected lesions at a minimum of three levels, and additional levels and immunohistochemical studies may be beneficial in complex cases [21]. In our study the number of levels (sections) assessed is no significantly associated with the accuracy.

7. Strengths and Limitations of the Study

7.1 Strength

- ✓ The data was a retrospective data which was collected from medical records of patients hence preventing patients from additional exhaustion while maintaining professionally recorded objective data.

7.2 Limitations of the study

- ✓ Poor data keeping and recording.
- ✓ This study uses retrospective data which depends on existing data, recall bias and potential for inaccurate information.
- ✓ The study includes cases with subsequent open surgical biopsy with generally tends to be malignant as compared with the overall cases with CNB creating possible sampling bias.

8. Conclusion and recommendation.

8.1 Conclusion

In conclusion the study found that the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of CNB diagnosis compared to open surgical biopsy were 91.7%, 90.0%, 95.7%, and 81.8%, respectively. The overall accuracy of CNB in detecting breast lesions was 91.17%. The number of cores taken was identified as the only factor correlated with the accuracy of CNB. In contrast, the study did not find a statistically significant relationship between the diagnostic accuracy of breast core needle biopsy and other factors evaluated, including lesion size, number of sections assessed, length of cores, and BIRAD category. However, it is important to note that although these factors did not show statistical significance in this particular study, they may still have clinical relevance or impact on diagnostic accuracy. The lack of significance could be attributed to factors such as a small sample size or variations in the sampling technique. Conducting further research with larger sample sizes or different patient populations may provide additional insights into the potential influence of these factors on diagnostic outcomes.

8.2 Recommendation

- ✓ Based on the findings from this research it is strongly recommended to take adequate representative samples (at least >2) from breast lesions in order to acquire accurate diagnosis.
- ✓ When ever there is discrepancy between the CNB diagnosis and previous FNAC, clinical presentation or BIRAD category it is strongly recommended to do repeat CNB or to do surgical biopsy.

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10. Annex

Questionnaire

1. Demographic and clinical data

A. Age

B. Sex

2. Laterality of the lesion

i. Left

ii. Right

iii. Bilateral

3. Radiologic data

A. Size of lesion

B. BIRAD category

C. Radiologic appearance of lesion

i. Non palpable calcification only

ii. Palpable breast lesion

4. Sampling data

A. Technique of sampling

i. Palpation guided

ii. Ultrasound guided

B. Size of core needle used

C. Number of cores

D. Total length of cores

5. Processing data

Number of sections (Number of levels)

6. Histopathologic data

Diagnosis on CNB

A. Non diagnostic (Inadequate sample)

B. Normal breast tissue

C. Benign lesion

D. Lesions with uncertain malignant potential

E. Suspicious of malignancy

F. Malignant

Diagnosis on open surgical biopsy

A. Non diagnostic (Inadequate sample)

B. Normal breast tissue Benign lesion

C. Lesions with uncertain malignant potential

D. Suspicious of malignancy

E. Malignant