ORIGINAL RESEARCH

Validating the Diagnosis of Palpable Breast Lumps: A Comparative Analysis of Fine Needle Aspiration Cytology and Histopathology

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ABSTRACT

Background: The identification of palpable breast lumps and the differentiation between benign and malignant lesions are essential aspects of breast healthcare. When patients present with palpable breast lumps at outpatient clinics, it is crucial to provide them with a reliable, efficient, and patient-friendly diagnostic method. This study was designed to assess the diagnostic accuracy of FNAC in distinguishing between benign and malignant lesions in palpable breast lumps, with the added benefit of histopathological correlation. Methods: In this prospective study, a total of 100 patients who presented with palpable breast lumps underwent Fine Needle Aspiration Cytology (FNAC). The FNAC procedure was conducted using a 23G needle to aspirate material from the breast lump. Subsequently, the aspirated material and histopathological sections were stained with Hematoxylin and Eosin (H&E) for microscopic analysis. The cytological diagnosis obtained from FNAC was meticulously compared with the results of histopathological examination. To assess the diagnostic accuracy of FNAC, various parameters including specificity, sensitivity, accuracy, and predictive values were calculated using established standard formulas. Results: This study revealed that fibroadenoma was the most common benign lesion, while infiltrating ductal carcinoma emerged as the most prevalent malignant lesion among the patients with palpable breast lumps. The diagnostic accuracy of Fine Needle Aspiration Cytology (FNAC) in this study was calculated at 86.6%. FNAC demonstrated an overall sensitivity of 87.71% in diagnosing palpable breast lumps. Moreover, it exhibited excellent specificity at 100%, a positive predictive value of 100%, and a negative predictive value of 93.55%. These findings underscore the utility of FNAC as a reliable and accurate diagnostic tool for distinguishing between benign and malignant breast lesions, offering high sensitivity and specificity. Conclusion: The diagnostic effectiveness, sensitivity, and specificity demonstrated by Fine Needle Aspiration Cytology (FNAC) in this study were found to be in line with those obtained through histopathological examination. Consequently, FNAC emerges as a valuable and trustworthy first-line diagnostic method for the preoperative diagnosis of both benign and malignant breast lesions. Furthermore, the study uncovered a positive correlation between the Robinson cytological grading system used in FNAC and the Scarff-Bloom-Richardson histological grading system, strengthening the reliability and consistency of FNAC as a diagnostic tool for assessing breast lesions.

Keywords: FNAC; Breast lumps; HPE; Comparison; Benign Lesion; Malignant Lesion

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INTRODUCTION

The class Mammalia is distinguished by the evolution of modified skin appendages known as mammary glands or breasts, which play a crucial role in providing complete nourishment and immunological protection to the young. In humans, these paired mammary glands are located in the upper chest wall, resting on the pectoralis muscle. The breast is a complex organ composed of specialized epithelial tissue and stroma, which can give rise to various benign and malignant lesions specific to this organ. The female breast primarily consists of lobules, ducts, and stroma. Among the conditions affecting the

breast, carcinoma, or cancer, is the most common non-skin malignancy in women and is second only to lung cancer as a leading cause of cancer-related deaths^{1,2,3}. The prevalence of breast cancer remains a significant concern, with statistics indicating that a woman who lives to the age of 80 has a one in eight chance of developing this disease. As the "baby boomer" generation continues to demographic bulge of older individuals is expected to lead to a roughly one-third increase in the number of women diagnosed with breast cancer over the next 20 years. It is both ironic and tragic that a neoplasm originating in an organ that is easily accessible for

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self-examination and clinical diagnosis continues to impose such a heavy burden on individuals and society. In response to this challenge, fine needle aspiration cytology (FNAC) has gained increasing importance as a diagnostic tool for preoperatively evaluating breast cancer⁴. FNAC is employed to determine various prognostic parameters, enabling healthcare professionals to offer the most appropriate and effective therapy to patients.

Fine needle aspiration cytology (FNAC) is not only valuable for its rapid and accurate diagnostic capabilities but also holds therapeutic significance, especially in cystic conditions⁵. Moreover, the scope of cytology has expanded to include the identification of subtypes within benign and malignant breast lesions. FNAC provides additional information regarding intrinsic tumor features, which can be beneficial in prognosticating tumor factors like nuclear grading, mitotic index, and DNA content^{6,7}. Therefore, FNAC plays a pivotal role as a critical preoperative assessment procedure when combined with clinical evaluation and imaging, collectively known as the "Triple test." Importantly, cytologic grading has demonstrated a positive correlation with histological grading, making cytologic grade a significant predictor of histopathologic grade prior to surgical intervention. Cytologic grade can furnish valuable insights into the biological behavior of tumors, making it a relevant parameter to consider when choosing neoadjuvant therapy. Fine needle aspiration cytology (FNAC) is a well-accepted and established method for characterizing breast lumps and becomes particularly important when clinical examination alone cannot definitively determine the nature of the breast lump. It has been demonstrated that FNAC has the potential to reduce the need for open breast biopsies8. Consequently, FNAC is now employed more frequently as the preferred diagnostic for clinically malignant approach masses.Critics have raised concerns about the potential for false negative reports, especially in cases of malignant lesions. However, with advancements in FNAC techniques and the expertise of cytologists, a FNAC report that unequivocally identifies malignancy is now widely considered sufficient evidence to proceed with definitive surgery. This study aimed to investigate how well the preliminary FNAC results for breast lumps correlated with the final histopathology reports to which all excised specimens were invariably subjected9. The study also assessed the accuracy of the needle tip in localizing the tumor by comparing aspirates of normal glandular cells with those of tumor cells. It's important to note that ultrasound guidance was not used for the needle aspiration cytology, as it was performed for palpable tumors.

MATERIALS AND METHODS

In this study, patients presenting with a palpable breast lump underwent fine needle aspiration cytology

(FNAC) using a 23-gauge needle. The aspirated material was used to prepare smears, which were routinely stained with hematoxylin and eosin. For histological analysis, sections of mastectomy and lumpectomy specimens were also stained with hematoxylin and eosin¹⁰. Cytological diagnoses were compared with histopathology findings whenever possible. The study calculated various diagnostic parameters, including specificity, sensitivity, accuracy, predictive values, P-value, and correlation, using standard formulas. This comprehensive analysis aimed to evaluate the diagnostic accuracy of FNAC in distinguishing between benign and malignant lesions in palpable breast lumps, with a focus on its correlation with histopathology.

This study was meticulously designed with a set of well-defined inclusion and exclusion criteria to ensure that the research focused on a particular group of individuals presenting with palpable breast lumps. 11 The inclusion criteria encompassed all female patients who sought medical attention due to palpable breast lumps and had not yet received a primary diagnosis for their condition. The study primarily aimed to investigate patients who were experiencing breast lumps but had not yet undergone definitive diagnostic procedures.

Conversely, the exclusion criteria were equally critical in refining the study's patient population:

- Patients with a history of recurrent malignancy were excluded from the study. This exclusion was necessary as individuals with recurrent cancer might have different disease trajectories and complications compared to those without recurrent malignancy.
- 2. Patients with a history of past or current chemotherapy or prevention treatments were also not included in the study. This exclusion was aimed at focusing on patients who had not undergone these treatments, as such treatments could significantly influence their clinical and pathological profiles.
- 3. Patients who underwent fine needle aspiration cytology (FNAC) but did not subsequently receive a histopathological diagnosis were not part of the study. This exclusion helped ensure that the study included patients for whom both FNAC and histopathological data were available.
- 4. Patients in whom FNAC yielded acellular or nondiagnostic results, or showed signs of inflammation, were also excluded. This exclusion was necessary to ensure that the study included patients with more conclusive FNAC results.
- 5. Male patients with breast cancer and those with gynecomastia were not considered in the study. Excluding these cases was essential, as male breast cancer and gynecomastia are distinct conditions with different characteristics and considerations compared to breast lumps in females.

The meticulous application of these inclusion and exclusion criteria allowed the study to focus on a specific group of patients whose clinical scenarios and

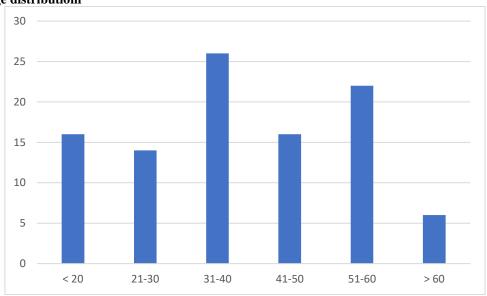
characteristics were directly relevant to the research objectives.

RESULTS

Table 1: Distribution of patients according to age (n=100)

AGE (YEARS)	Frequency
<20	16
21-30	14
31-40	26
41-50	16
51-60	22
>60	6
Total	100

FIG 1: Age distributiom



In this study involving 100 patients with palpable breast lumps, the age distribution of the participants spanned from 15 to 70 years. Among these patients, the most prevalent age group presenting with palpable breast lumps was in the range of 31 to 40 years, with 13 patients, constituting 26% of the total study population. The second most common age group was between 51 and 60 years, comprising 11 patients, or

22% of the study cohort¹². The mean age of the participants in the study was calculated to be 38.2 years. This age range diversity allowed for a comprehensive assessment of palpable breast lumps across different stages of life and age groups, providing valuable insights into the condition's incidence and characteristics in various demographics.

Table 2: Age wise distribution of Benign and Malignant cases

		Benign		Malignant		Total
		Frequency	Percent	Frequency	Percent	
Age in years	< 20	16	30.6	0	0.0	16
	21-30	12	23.1	2	4.1	14
	31-40	12	23.1	14	29.2	26
	41-50	8	15.3	8	16.7	16
	51-60	4	7.7	18	37.5	22
	>60	0	0.0	6	12.5	6
Total		54	100.0	48	100.0	100

In this study encompassing 100 patients, the age distribution for benign breast lesions ranged from 15 years to 60 years, with a calculated mean age of 28.55 years and a standard deviation of 7.57 years. On the other hand, the age distribution for malignant breast

lesions ranged from 30 to 65 years, with a mean age of 52.67 years and a standard deviation of 9.84 years. Among patients with benign lesions, the most common age group was between 21 and 40 years, while for those with malignant lesions, the most

common age group fell within the range of 51 to 60 years. These age-specific findings provide important insights into the age-related incidence and

characteristics of benign and malignant breast lesions among the study participants.

Table 3: Distribution of patients according to presenting complaints

		Present		Absent	
		Frequency	Percent	Frequency	Percent
Clinical features	Lump	100	100.0	0	0.0
	Pain	92	92.0	8	8.0
	Discharge	12	12.0	88	88.0
	Family history	6	6.0	94	94.0
	Any other symptoms	14	14.0	86	86.0

In the current study involving 100 patients, all of the cases were primarily characterized by the presence of breast lump, indicating that this was the predominant symptom. The second most common symptom reported among the patients was pain, suggesting its significant prevalence in this cohort¹³. An overwhelming majority of patients, 84 out of 92%, experienced both pain and a breast lump, highlighting the frequent co-occurrence of these symptoms. Additionally, 12% of patients presented with nipple discharge in addition to the breast lump. In a smaller subset of cases, 14%, other symptoms such as peaud'orange (skin changes resembling the texture of an orange peel) and ulceration were observed alongside the breast lump. These diverse clinical presentations underscore the need for comprehensive approach to diagnosis and management in patients with breast-related concerns.

DISCUSSION

This study aimed to evaluate the diagnostic accuracy of Fine Needle Aspiration Cytology (FNAC) by comparing it with histopathology, considered the gold standard, to validate accurate diagnoses of palpable breast lumps. The study included 100 female patients, each presenting with a palpable breast lump. These patients underwent FNAC of the breast lump, followed by excisional surgery, either in the form of a lumpectomy or a definitive surgical procedure like a mastectomy, depending on the diagnosis obtained through aspiration cytology¹⁴. For patients with inconclusive FNAC diagnoses, incisional or true-cut biopsies were recommended to confirm the findings. The results of the aspiration cytology were then compared with the final histology report to assess the degree of correlation between cytology and histology. The 100 women selected for this study ranged in age from 15 to 70 years, with an average age of 38.50 years. For benign lesions, the age incidence ranged from 15 to 45 years, with a mean age of 28.55 years. In contrast, the incidence of malignant lesions spanned the ages of 30 to 70 years, with a mean age of 54.66 years. The most common age group for benign lesions fell between 25 to 34 years, while for malignant lesions, it was between 44 to 64 years, indicating age-related variations in the presentation of breast lumps among these patients. The age range in

this study was consistent with prior research conducted by A. Khemka et al., with patients aging from 15 to 61 years and an overall mean age of 37.5 years. Peak incidence for benign lesions was observed in the second and third decades of life, while malignant lesions were more common above the age of 40, with a peak incidence between 40 and 44 years. This age distribution mirrored findings in similar studies conducted by Homesh et al. 15, Tiwari, Alam et al., and Ghimire et al. 16, highlighting the consistency of age patterns among patients with breast lumps across various studies.

In this study, the left breast was affected in 30 patients, while the right breast was involved in 19 patients¹⁷. Bilateral involvement was observed in only 2 patients. Both benign and malignant lesions were more common in the left breast than in the right. A study by A. Khemka et al. reported a similar pattern, with 29 patients having left breast involvement and 22 patients with right breast involvement.

The location of the breast lump within the breast was also assessed. In this study, the central quadrant was the most common site for lumps, with 15 patients (30%) presenting lumps in this region, followed by the upper inner quadrant with 14 patients (28%). Among benign cases, upper inner quadrant lumps were the most prevalent, accounting for 11 out of 26 (42.3%) benign cases. Malignant lumps were more common in the central quadrant, followed by the upper inner and upper outer quadrants. Out of the total 24 malignant cases, 14 (58.33%) had lumps in the central quadrant.

This distribution of breast lump location was in line with a study by O.N. Alema et al. 18, where 49 cases out of a total of 85 had lumps in the upper outer quadrant, and among them, 6 cases (12.2%) were malignant. Another study by Hussain reported 29 patients (58%) with lumps in the upper and outer quadrant, 9 with lumps in the upper and inner quadrant, and 4 patients with palpable lumps in the lower and outer quadrant 19. These findings highlight the variability in breast lump location and its association with benign or malignant lesions. The findings of this study align with a study conducted by Raina V et al., where breast lump was also identified as the primary presenting symptom among patients. This shared symptom presentation emphasizes the

significance of early detection and evaluation of breast lumps, as they can be indicative of both benign and malignant conditions. In this study, out of 100 the FNAC cytological findings were categorized according to the NHSBSP criteria, resulting in the classification of cases into 5 categories, denoted as C1 to C5. The distribution among these categories was as follows: C1 had 1 case, C2 had 42 cases, C3 had 8 cases, C4 had 10 cases, and C5 had 38 cases²⁰. The categorization criteria reflect the diverse nature of breast lumps and the need to accurately classify them to determine appropriate management strategies.Regarding the cytological diagnosis, 50 patients (52%) were diagnosed with benign lumps, while 48 patients (48%) were diagnosed with malignant lumps based on FNAC findings. This balanced distribution underscores the necessity for an accurate and reliable diagnostic tool like FNAC in distinguishing between benign and malignant breast lumps. It's worth noting that only 2 cases (2%) were reported as inadequate for cytological diagnosis, with scant cellularity observed even after repeated aspiration. In these instances, Tru cut biopsy was performed, leading to the diagnosis of infiltrating ductal carcinoma poorly differentiated on histopathological examination (HPE). This experience underscores the importance of thorough evaluation methods and the need to adapt diagnostic techniques when necessary, especially in cases where FNAC may not yield conclusive results.

CONCLUSION

Fine needle aspiration cytology (FNAC) serves as a crucial diagnostic tool in the management of patients with breast lumps, offering several notable advantages. This study reinforces the significance of FNAC as the primary diagnostic modality in the preoperative assessment of both benign and malignant palpable breast lumps. The high diagnostic accuracy of FNAC, particularly when conducted by experienced practitioners, underscores its effectiveness in providing valuable diagnostic insights.

FNAC is characterized by its ease of implementation, reliability, repeatability, patient-friendliness, and simplicity. These attributes make it an attractive diagnostic test that can be readily employed in busy clinic settings. Furthermore, FNAC does not demand extensive preparation or the use of expensive equipment, contributing to its accessibility and applicability as a diagnostic tool. The study emphasizes the pivotal role of FNAC in streamlining the diagnostic process for breast lumps, enabling efficient decision-making regarding further treatment and management. Its diagnostic capabilities and user-friendly nature position FNAC as an invaluable resource for healthcare providers in the evaluation of breast lesions.

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