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Diagnostic Accuracy of Ultrasound in Evaluation of Breast Lump in Correlation with FNAC

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ABSTRACT

Introduction: Breast lumps are among the most common clinical presentations encountered in surgical practice. Ultrasonography is a widely used, non-invasive, and cost-effective imaging modality that plays a crucial role in the initial assessment of palpable breast lumps, while fine-needle aspiration cytology (FNAC) provides valuable cytological confirmation. The present study was conducted to assess the diagnostic accuracy of ultrasonography in palpable breast lumps by correlating its findings with FNAC. **Methods & Materials:** This cross-sectional study was conducted in the Department of Radiology & Imaging, Popular Medical Centre Limited Sylhet, Bangladesh from January 2025 to December 2025. A total of 104 consecutive patients presenting with clinically palpable breast lumps were enrolled using purposive sampling. Data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 26.0. **Result:** Among the 104 patients included in the study, fibroadenoma was the most common breast lesion on both ultrasonography (44.2%) and FNAC (Fine Needle Aspiration Cytology) (42.3%), while malignant lesions accounted for 21.2% and 22.1% of cases, respectively. Ultrasonography showed excellent agreement with FNAC ($\kappa = 0.86$, $p < 0.001$) and demonstrated high diagnostic performance, with a sensitivity of 87.0%, specificity of 97.5%, positive predictive value of 90.9%, negative predictive value of 96.3%, and an overall diagnostic accuracy of 95.2%. BI-RADS categories were significantly associated with FNAC findings ($p < 0.001$), with the likelihood of malignancy increasing progressively from BI-RADS 2 to BI-RADS 5. **Conclusion:** Ultrasonography seems to show high diagnostic accuracy in the assessment of palpable breast lumps when compared with FNAC, exhibiting excellent concordance and effective discrimination between benign and malignant lesions. Being a non-invasive, widely accessible, and cost-effective imaging technique, ultrasonography is a valuable first-line diagnostic modality. Its complementary use with FNAC improves diagnostic precision, supports timely diagnosis, and aids clinicians in selecting appropriate management strategies for patients presenting with breast lumps.

Keywords: *Ultrasound, FNAC, Breast Lump*

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INTRODUCTION

Breast lumps are among the most common clinical presentations encountered in surgical and breast clinics, accounting for a substantial proportion of referrals among women of all age groups. Although the majority of breast lumps are benign, including fibroadenoma, fibrocystic changes, and cysts, the possibility of breast carcinoma necessitates prompt and accurate evaluation. Breast cancer remains the most frequently diagnosed malignancy and the leading cause of cancer-related mortality among women worldwide, with an estimated 2.3 million new cases and approximately 670,000 deaths reported in 2022 [1,2]. The diagnostic approach to a breast lump relies on the principle of the triple assessment, which comprises clinical examination, imaging, and pathological evaluation. Imaging plays a pivotal role in distinguishing benign from malignant lesions, guiding biopsy procedures, and determining the need for surgical intervention. Among the available imaging modalities, ultrasonography has emerged as an indispensable diagnostic tool because it is non-invasive, widely available, radiation-free, cost-effective, and capable of providing real-time assessment of breast lesions [3,4]. Breast ultrasonography is particularly valuable in women younger than 40 years and in those with dense breast tissue, where mammographic sensitivity is often reduced. High-frequency ultrasound effectively differentiates cystic from solid lesions and characterizes lesion morphology based on shape, orientation, margins, echogenicity, posterior acoustic features, and vascularity. Standardized reporting using the Breast Imaging Reporting and Data System (BI-RADS) has improved communication among clinicians, enhanced diagnostic consistency, and provided evidence-based recommendations for patient management [4]. Despite these advances, imaging findings alone cannot establish a definitive diagnosis in many breast lesions. Tissue diagnosis therefore remains essential whenever malignancy is suspected. Fine-needle aspiration cytology (FNAC) is a minimally invasive, rapid, inexpensive, and highly acceptable procedure for obtaining cytological material from breast masses. FNAC has become an important component of the triple assessment, particularly in resource-limited settings where it offers an affordable alternative to more invasive diagnostic techniques [5]. Numerous studies have demonstrated high sensitivity, specificity, and overall diagnostic accuracy of breast ultrasonography when correlated with cytological or histopathological findings. Nevertheless, the diagnostic performance of ultrasound may vary depending on lesion characteristics, breast density, operator expertise, equipment quality, and adherence to BI-RADS criteria. Similarly, although FNAC exhibits excellent diagnostic accuracy, false-negative and indeterminate results may occur because of inadequate sampling, overlapping cytological features, or technical limitations [6-8]. In developing countries such as Bangladesh, where breast cancer awareness, screening programs, and access to advanced diagnostic facilities remain limited, ultrasound combined with FNAC represents a practical, accessible, and economical diagnostic strategy. Furthermore, evaluating the concordance between these two diagnostic modalities may help strengthen diagnostic protocols and improve patient care in tertiary healthcare settings [2,8]. The present study was conducted to assess the diagnostic accuracy of ultrasonography in palpable breast lumps by correlating its findings with FNAC.

METHODS & MATERIALS

This cross-sectional study was conducted in the Department of Radiology & Imaging, Popular Medical Centre Sylhet, Bangladesh from January 2025 to December 2025. A total of 104 consecutive patients presenting with clinically palpable breast lumps were enrolled using purposive sampling after obtaining written informed consent. Female patients aged ≥18 years with palpable breast lumps who underwent both breast ultrasonography and fine-needle aspiration cytology (FNAC) were included, whereas patients with previously diagnosed breast malignancy, recurrent breast tumors, prior breast surgery, incomplete investigations, or inadequate FNAC samples were excluded. Demographic and clinical information were recorded using a pretested case record form. All patients underwent high-resolution breast ultrasonography using a high-frequency linear transducer (7.5–12 MHz), and the lesions were characterized according to the American College of Radiology Breast Imaging Reporting and Data System (ACR BI-RADS) based on lesion morphology, margins, echogenicity, posterior acoustic features, orientation, and associated findings. Subsequently, FNAC was performed under aseptic precautions by experienced surgeons/pathologists, and cytological diagnosis was considered the reference standard. Ultrasonographic findings were compared with FNAC diagnoses to determine the diagnostic performance of ultrasonography. Data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 26.0. Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized as mean ± standard deviation. The association between ultrasonographic diagnosis and FNAC findings was assessed using the Chi-square test, and the level of agreement between the two modalities was calculated using Cohen's Kappa (κ) coefficient. Diagnostic indices including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated using FNAC as the gold standard. A p-value <0.05 was considered statistically significant throughout the analysis.

RESULTS

Most patients belonged to the 21–30 years age group (32.7%), followed by 31–40 years (26.0%) and 41–50 years (18.3%). The mean age was 37.1 ± 12.2 years (range: 18–72 years) (*Table I*).

Table I
Distribution of patients according to age (*n*=104).

Age group (years)	Frequency	Percentage (%)
≤20	8	7.7
21–30	34	32.7
31–40	27	26.0
41–50	19	18.3
51–60	10	9.6
>60	6	5.8
Total	104	100.0

Ultrasonography identified fibroadenoma as the most common lesion (44.2%), followed by malignant lesions (21.2%), simple cysts (15.4%), fibrocystic disease (13.5%), and breast abscesses (5.8%) (*Table II*).

Table II
Ultrasonographic diagnosis of breast lumps (*n*=104).

Diagnosis	Frequency	Percentage (%)
Fibroadenoma	46	44.2
Simple cyst	16	15.4
Fibrocystic disease	14	13.5
Breast abscess	6	5.8
Malignant lesion	22	21.2
Total	104	100.0

FNAC confirmed fibroadenoma as the most frequent lesion (42.3%), followed by malignant lesions (22.1%), simple cysts (16.3%), fibrocystic disease (13.5%), and breast abscesses (5.8%) (*Table III*).

Table III
FNAC diagnosis of breast lumps (*n*=104).

Diagnosis	Frequency	Percentage (%)
Fibroadenoma	44	42.3
Simple cyst	17	16.3
Fibrocystic disease	14	13.5
Breast abscess	6	5.8
Malignant lesion	23	22.1
Total	104	100.0

Ultrasonographic diagnosis showed a highly significant association with FNAC findings ($\chi^2 = 76.58$, $p < 0.001$). Cohen's kappa coefficient ($\kappa = 0.86$) demonstrated almost perfect agreement between ultrasonography and FNAC, indicating excellent concordance between the two diagnostic modalities (*Table IV*).

Table IV
Agreement between ultrasonographic diagnosis and FNAC diagnosis (*n*=104).

Ultrasound diagnosis	FNAC Benign	FNAC Malignant	Total	p-value
Benign	79	3	82	<0.001
Malignant	2	20	22	
Total	81	23	104	

Using FNAC as the reference standard, ultrasonography demonstrated a sensitivity of 87.0%, specificity of 97.5%, positive predictive value of 90.9%, negative predictive value of 96.3%, and an overall diagnostic accuracy of 95.2% for detecting malignant breast lesions (*Table V*).

Table V
Diagnostic performance of ultrasonography using FNAC as the reference standard (*n*=104).

Parameter	Value (%)
Sensitivity	87.0
Specificity	97.5
Positive Predictive Value	90.9
Negative Predictive Value	96.3
Diagnostic Accuracy	95.2

The proportion of malignant lesions increased progressively with increasing BI-RADS category. All BI-RADS 2 lesions were benign, while 95.6% of BI-RADS 2 and 3 lesions combined were benign. In contrast, 76.5% of BI-RADS 4 lesions and 100% of BI-RADS 5 lesions were confirmed as malignant on FNAC. The association between BI-RADS category and FNAC diagnosis was statistically highly significant ($p < 0.001$) (*Table VI*).

Table VI
Distribution of BI-RADS categories according to FNAC diagnosis (*n*=104).

BI-RADS category	Benign	Malignant	Total	Malignancy rate (%)
BI-RADS 2	34	0	34	0.0
BI-RADS 3	43	2	45	4.4
BI-RADS 4	4	13	17	76.5
BI-RADS 5	0	8	8	100.0
Total	81	23	104	-

$\chi^2 = 78.91$, $df = 3$, $p < 0.001$

DISCUSSION

In the present study, the majority of patients belonged to the 21–30 years age group (32.7%), followed by 31–40 years (26.0%), with a mean age of 37.1 ± 12.2 years. A similar age distribution was reported by Pathak et al., where the mean age was 38.67 years, with benign lesions occurring at a mean age of 36.22 years and malignant lesions at 46.71 years, indicating that breast malignancy is more common in older women [9]. Likewise, a recent cytopathological study by Manasa et al. reported that benign breast lesions predominantly affected women in the third and fourth decades of life, with fibroadenoma being the most frequent diagnosis [10]. In our study, ultrasonography identified fibroadenoma in 44.2% of patients, while FNAC confirmed fibroadenoma in 42.3%, making it the commonest lesion by both modalities. Malignant lesions accounted for 21.2% on ultrasonography and 22.1% on FNAC. Similarly, Pathak et al. reported 76.7% benign and 23.3% malignant lesions on ultrasonography, while FNAC confirmed 78.3% benign and 21.7% malignant lesions, with fibroadenoma being the most common benign pathology [9]. Evans et al. also emphasized that ultrasonography is particularly effective in identifying benign lesions such as fibroadenoma in younger women and forms an essential component of the triple assessment [11]. The present study demonstrated excellent agreement between ultrasonography and FNAC ($\kappa = 0.86$, $p < 0.001$) with a highly significant association ($\chi^2 = 76.58$, $p < 0.001$). This high level of agreement indicates that ultrasonography can reliably differentiate benign from malignant breast lesions before cytological confirmation. The use of standardized BI-RADS descriptors has been shown to improve diagnostic consistency and communication among clinicians, thereby enhancing agreement with pathological diagnosis [11]. Using FNAC as the reference standard, ultrasonography showed a sensitivity of 87.0%, specificity of 97.5%, PPV of 90.9%, NPV of 96.3%, and an overall diagnostic accuracy of 95.2%. These findings are comparable with those of Pathak et al., who reported a sensitivity of 95.74%, specificity of 92.3%, PPV of 97.8%, NPV of 85.7%, and diagnostic accuracy of 95.0% for ultrasonography in palpable breast lesions [9]. Furthermore, Musnipalli et al. reported that FNAC achieved 88.57% sensitivity, 97.27% specificity, 91.18% PPV, 96.40% NPV, and 95.17% accuracy, supporting the complementary role of ultrasonography and FNAC in the assessment of breast lumps [12]. Bukhari et al. further demonstrated in a systematic review that FNAC sensitivity ranged from 35% to 96.61%, specificity from 48% to 100%, and diagnostic accuracy from 71.4% to 96.6%, emphasizing that diagnostic performance varies according to lesion characteristics and operator expertise [13]. The BI-RADS classification also showed excellent predictive value in the present study. The malignancy rate increased from 0% in BI-RADS 2 to 4.4% in BI-RADS 3, 76.5% in BI-RADS 4, and 100% in BI-RADS 5 ($p < 0.001$). These findings are in agreement with the recommendations of the European Society of Breast Imaging, which state that BI-RADS categories are strongly associated with the probability of malignancy and provide a standardized framework for patient management [11].

LIMITATIONS

The study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings. FNAC, although used as the reference standard, is operator-dependent and may occasionally yield inadequate or false-negative results. Histopathological confirmation was not available for all cases, particularly those with benign FNAC findings, and inter-observer variability in

ultrasonographic interpretation was not assessed.

CONCLUSION

Ultrasonography seems to have high diagnostic accuracy in the evaluation of palpable breast lumps when correlated with FNAC, showing good agreement and reliable differentiation between benign and malignant lesions. As a non-invasive, readily available, and cost-effective imaging modality, ultrasonography serves as an excellent initial diagnostic tool, and its combined use with FNAC enhances diagnostic confidence and facilitates appropriate clinical decision-making in patients presenting with breast lumps.

RECOMMENDATION

Ultrasonography can be routinely used as the initial imaging modality for the evaluation of palpable breast lumps and interpreted using the BI-RADS classification system. Correlation with FNAC is recommended, particularly for suspicious or indeterminate lesions, to improve diagnostic accuracy and guide appropriate patient management. Further multicenter studies with larger sample sizes and histopathological confirmation are recommended to validate these findings.

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CONFLICT OF INTEREST

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