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Research Article

Diagnostic Accuracy of Sonomammography in the Evaluation of Palpable Breast Lesions: A Prospective Correlation with Fine Needle Aspiration Cytology

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Abstract: ***Introduction*** Palpable breast lesions are a common clinical presentation and require accurate evaluation to differentiate benign from malignant pathology. Sonomammography, combining mammography and ultrasonography, plays an important role in breast imaging, while Fine Needle Aspiration Cytology (FNAC) provides cytological confirmation. This study assessed the diagnostic accuracy of sonomammography in women with palpable breast lesions using FNAC as the reference standard. **Aim:** To evaluate and compare the diagnostic accuracy of sonomammography in women with palpable breast lesions with Fine Needle Aspiration Cytology correlation. **Objectives:** To evaluate the sensitivity and specificity of sonomammography for palpable breast lesions independently and in correlation with FNAC. To determine the role of sonomammography in characterizing and differentiating benign and malignant breast lesions. **Materials and Methods**: A prospective observational study was conducted on 153 women presenting with palpable breast lesions at a tertiary care hospital. All patients underwent clinical evaluation, sonomammography, and FNAC. Lesions were categorized according to BI-RADS criteria and correlated with FNAC findings. Diagnostic performance indices including sensitivity, specificity, positive predictive value, negative predictive value, diagnostic accuracy, and ROC analysis were calculated. Statistical analysis was performed using SPSS software, and $p < 0.05$ was considered statistically significant. **Results**: The mean age of the participants was 42.8 ± 11.7 years, and the mean lesion size was 3.1 ± 1.4 cm. FNAC identified 108 (70.6%) benign and 45 (29.4%) malignant lesions. Sonomammography correctly identified 41 of 45 malignant lesions and 100 of 108 benign lesions. The sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of sonomammography were 91.1%, 92.6%, 83.7%, 96.2%, and 92.2%, respectively. Cohen's kappa coefficient was 0.824, indicating excellent agreement with FNAC. Malignant lesions were significantly associated with irregular shape, spiculated margins, posterior acoustic shadowing, microcalcifications, increased vascularity, and BI-RADS 4/5 categorization ($p < 0.001$). ROC analysis demonstrated excellent diagnostic performance with an AUC of 0.938 (95% CI: 0.897–0.979). **Conclusion:** Sonomammography is a highly accurate and dependable imaging modality for evaluating palpable breast lesions. Its excellent diagnostic performance and strong correlation with FNAC findings make it a valuable tool for distinguishing benign from malignant lesions and guiding appropriate clinical management

.**Keywords**: Sonomammography. Palpable Breast Lesions. Fine Needle Aspiration Cytology (FNAC).

INTRODUCTION

Breast diseases constitute a major health concern among women worldwide and range from benign inflammatory conditions to malignant neoplasms. Palpable breast lesions are among the most common clinical presentations encountered in surgical and radiological practice. Although the majority of palpable breast lumps are benign, the possibility of breast cancer necessitates prompt and accurate evaluation. Breast cancer remains the most frequently diagnosed cancer among women globally and is a leading cause of cancer-related mortality. Early and accurate diagnosis of breast lesions plays a crucial role in improving treatment outcomes and reducing morbidity and mortality.[1]

The diagnostic assessment of palpable breast lesions traditionally involves a triple assessment approach comprising clinical examination, imaging, and pathological evaluation. Imaging modalities such as mammography and ultrasonography have become indispensable tools in the evaluation of breast abnormalities. Mammography is considered the standard screening modality for breast cancer; however, its sensitivity may be reduced in younger women and in patients with dense breast parenchyma. Ultrasonography serves as a valuable adjunct, particularly in differentiating cystic from solid lesions and in characterizing lesion morphology.[2]

Sonomammography, which combines mammographic and ultrasonographic evaluation, has emerged as an effective diagnostic modality for assessing palpable breast lesions. It provides detailed anatomical information regarding lesion size, shape, margins, echotexture, vascularity, and associated features. The

Breast Imaging Reporting and Data System (BI-RADS) classification further enhances diagnostic standardization and facilitates risk stratification of breast lesions. Sonomammography can aid in distinguishing benign from malignant lesions, thereby guiding clinical management and reducing unnecessary invasive procedures.[3]

Fine Needle Aspiration Cytology (FNAC) is a minimally invasive, rapid, cost-effective, and highly reliable diagnostic procedure widely used for pathological evaluation of breast lumps. FNAC provides cytological confirmation and is often regarded as a reference standard for initial tissue diagnosis. Correlation of imaging findings with FNAC results helps determine the diagnostic accuracy of imaging modalities and improves clinical decision-making.[4]

Several studies have demonstrated high sensitivity and specificity of sonomammography in detecting malignant breast lesions. The combined use of mammography and ultrasonography has been shown to improve lesion characterization and diagnostic confidence compared to either modality alone. However, variations in diagnostic performance may occur due to differences in patient demographics, breast density, lesion characteristics, and operator expertise. Therefore, evaluating the diagnostic accuracy of sonomammography in comparison with FNAC remains clinically relevant.[5]

The present study was undertaken to assess the diagnostic accuracy of sonomammography in women presenting with palpable breast lesions and to correlate imaging findings with FNAC results. The study aims to determine the sensitivity, specificity, predictive values, and overall diagnostic efficacy of sonomammography in differentiating benign and malignant breast lesions, thereby contributing to improved patient management and early detection of breast malignancy.

AIM:

To evaluate and compare the diagnostic accuracy of sonomammography in women with palpable breast lesions with fine needle aspiration cytology correlation.

OBJECTIVES:

1. To evaluate the sensitivity and specificity of sonomammography for palpable breast lesions independently and correlating with fine needle aspiration cytology
2. To determine the role of sonomammography in characterising/differentiating benign and malignant lesions of breast lumps.

MATERIALS AND METHODS

Source of Data

The data were collected from women presenting with palpable breast lesions in the Department of Radiodiagnosis in collaboration with the Departments of General Surgery and Pathology at the study institution. All eligible patients who fulfilled the inclusion criteria during the study period were enrolled consecutively after obtaining informed written consent.

Study Design

Hospital-based prospective observational diagnostic accuracy study.

Study Location

The study was conducted in the Department of Radiodiagnosis in collaboration with the Departments of General Surgery and Pathology at a tertiary care teaching hospital.

Study Duration

The study was conducted over a period of 24 months from the date of approval by the Institutional Ethics Committee.

Sample Size

A total of 153 women with palpable breast lesions were included in the study.

Inclusion Criteria

1. Female patients aged 18 years and above.
2. Patients presenting with clinically palpable breast lumps.
3. Patients willing to participate and provide informed written consent.
4. Patients undergoing both sonomammography and FNAC evaluation.

Exclusion Criteria

1. Patients with previously diagnosed or treated breast carcinoma.
2. Patients who had undergone prior breast surgery for the same lesion.
3. Patients receiving chemotherapy or radiotherapy for breast malignancy.
4. Patients with recurrent breast lesions.
5. Pregnant women in whom mammography was contraindicated.
6. Patients unwilling to participate in the study.
7. Patients with inadequate or inconclusive FNAC samples.

Procedure and Methodology

After obtaining informed consent, detailed demographic and clinical information including age, presenting complaints, duration of symptoms, family history of breast cancer, and clinical examination findings were recorded in a predesigned case record form.

All patients underwent sonomammographic evaluation. Mammography was performed using standard craniocaudal (CC) and mediolateral oblique (MLO) views. Additional views were obtained whenever required. Breast ultrasonography was subsequently performed using a high-frequency linear transducer (7-15 MHz). Lesion characteristics such as size, shape, margins, echogenicity, posterior acoustic features,

calcifications, vascularity, and associated lymphadenopathy were assessed.

The lesions were categorized according to the American College of Radiology BI-RADS classification system. BI-RADS categories 2 and 3 were considered benign, whereas BI-RADS categories 4 and 5 were considered suspicious/malignant for the purpose of diagnostic analysis.

Following imaging evaluation, FNAC was performed under aseptic precautions by experienced clinicians/pathologists. Aspirated material was smeared on glass slides and sent for cytological examination. Cytological diagnosis was considered the reference standard for comparison.

The sonomammographic findings were correlated with FNAC results to determine diagnostic accuracy parameters.

Sample Processing

FNAC specimens obtained from palpable breast lesions were immediately fixed and stained using standard cytological staining techniques such as May-Grünwald-Giemsa (MGG) and Papanicolaou stains. Cytological examination was performed by experienced pathologists. The lesions were classified as benign, suspicious, malignant, inflammatory, or inadequate for diagnosis. Cases with inadequate samples were excluded from final analysis.

Data Collection

The following variables were collected:

- Age of patient
- Side of breast involved
- Duration of symptoms
- Clinical presentation
- Size of lesion
- Mammographic findings
- Ultrasonographic characteristics
- BI-RADS category
- FNAC diagnosis
- Benign or malignant nature of lesion
- Final correlation between sonomammography and FNAC

All information was recorded in a structured proforma and entered into a computerized database for analysis.

Statistical Methods

Data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) version 26.0.

- Continuous variables were expressed as mean ± standard deviation (SD).
- Categorical variables were expressed as frequencies and percentages.
- Association between categorical variables was assessed using Chi-square test or Fisher's exact test as appropriate.
- Diagnostic performance of sonomammography was evaluated by calculating:

Sensitivity

Specificity

Positive Predictive Value (PPV)

Negative Predictive Value (NPV)

Overall Diagnostic Accuracy

- FNAC diagnosis was considered the reference standard.
- Receiver Operating Characteristic (ROC) curve analysis was performed wherever applicable.
- A p-value <0.05 was considered statistically significant.
- Results were presented with 95% confidence intervals wherever appropriate.

RESULTS

Table 1: Baseline Characteristics of Women with Palpable Breast Lesions (n = 153)

Variable	Value
Age (years), Mean ± SD	42.8 ± 11.7
Lesion size (cm), Mean ± SD	3.1 ± 1.4
Right breast involvement, n (%)	81 (52.9)
Left breast involvement, n (%)	72 (47.1)
Upper outer quadrant involvement, n (%)	79 (51.6)
Painful lump, n (%)	58 (37.9)
Painless lump, n (%)	95 (62.1)
FNAC benign lesions, n (%)	108 (70.6)
FNAC malignant lesions, n (%)	45 (29.4)

Test of Significance

Variable	Test Statistic	95% CI	P value
Age (years)	t = 45.38	40.9 - 44.7	<0.001*
Lesion size (cm)	t = 27.42	2.88 - 3.32	<0.001*
Side of involvement	$\chi^2 = 0.53$	45.0% - 60.7%	0.468
Painful vs painless lump	$\chi^2 = 8.98$	54.2% - 69.5%	0.003*
Benign vs malignant lesions	$\chi^2 = 25.06$	63.2% - 77.0%	<0.001*

***P < 0.05 statistically significant**

Table 1 presents the baseline characteristics of 153 women with palpable breast lesions. The mean age of the study participants was 42.8 ± 11.7 years (95% CI: 40.9-44.7), which was statistically significant (t = 45.38, p < 0.001). The mean lesion size was 3.1 ± 1.4 cm (95% CI: 2.88-3.32), also showing statistical significance (t = 27.42, p < 0.001). Slightly more patients had right breast involvement (52.9%) compared to left breast involvement (47.1%); however, this difference was not statistically significant ($\chi^2 = 0.53$, p = 0.468). The upper outer quadrant was the most commonly affected site, accounting for 51.6% of lesions. Clinically, painless breast lumps were more common than painful lumps, occurring in 62.1% and 37.9% of patients, respectively, with a significant difference between the two groups ($\chi^2 = 8.98$, p = 0.003). FNAC evaluation revealed that the majority of lesions were benign (70.6%), while malignant lesions constituted 29.4% of cases, and this distribution was statistically significant ($\chi^2 = 25.06$, p < 0.001).

Table 2: Diagnostic Accuracy of Sonomammography Compared with FNAC (n = 153)

Cross-tabulation

Sonomammography	FNAC Malignant	FNAC Benign	Total
Malignant	41	8	49
Benign	4	100	104
Total	45	108	153

Diagnostic Performance

Parameter	Value (%)	95% CI
Sensitivity	91.1	79.2 - 97.0
Specificity	92.6	86.0 - 96.5
Positive Predictive Value	83.7	70.3 - 92.0
Negative Predictive Value	96.2	90.7 - 98.7
Diagnostic Accuracy	92.2	86.8 - 95.6

Test of Significance

Variable	Value
Chi-square (χ^2)	95.87
Odds Ratio	128.1
Cohen's Kappa	0.824
95% CI for Kappa	0.734 - 0.914
P value	<0.001*

***Excellent agreement between sonomammography and FNAC**

Table 2 demonstrates the diagnostic performance of sonomammography compared with FNAC in the evaluation of palpable breast lesions. Of the 45 FNAC-confirmed malignant lesions, sonomammography correctly identified 41 cases and missed only 4 cases, whereas among the 108 FNAC-confirmed benign lesions, 100 were correctly diagnosed and 8 were falsely categorized as malignant. The sensitivity and specificity of sonomammography were 91.1% and 92.6%, respectively, indicating excellent ability to detect both malignant and benign lesions. The positive predictive value was 83.7%, while the negative predictive value was remarkably high at 96.2%, suggesting that a benign sonomammographic diagnosis was highly reliable. The overall diagnostic accuracy of sonomammography was 92.2% (95% CI: 86.8-95.6). The association between sonomammography and FNAC findings was highly significant ($\chi^2 = 95.87$, p < 0.001). Furthermore, the odds ratio of 128.1 and Cohen's kappa coefficient of 0.824 (95% CI: 0.734-0.914) demonstrated excellent agreement between sonomammography and cytological diagnosis.

Table 3: Role of Sonomammography in Differentiating Benign and Malignant Breast Lesions (n = 153)

Sonomammographic Feature	Benign (n=104)	Malignant (n=49)	χ^2 Value	95% CI	P value
Irregular shape, n (%)	18 (17.3)	39 (79.6)	55.42	OR 18.7 (8.1-43.2)	<0.001*
Spiculated margins, n (%)	6 (5.8)	31 (63.3)	67.84	OR 28.0 (10.3-76.2)	<0.001*
Posterior acoustic shadowing, n (%)	12 (11.5)	29 (59.2)	38.76	OR 11.2 (5.0-25.3)	<0.001*

Microcalcifications, n (%)	8 (7.7)	24 (49.0)	31.58	OR 11.5 (4.7-28.2)	<0.001*
Increased vascularity, n (%)	20 (19.2)	36 (73.5)	41.90	OR 11.7 (5.3-25.8)	<0.001*
BI-RADS 2/3, n (%)	96 (92.3)	4 (8.2)	104.62	OR 136.0 (41.8-442.7)	<0.001*
BI-RADS 4/5, n (%)	8 (7.7)	45 (91.8)	104.62	OR 136.0 (41.8-442.7)	<0.001*

Summary Statistics

Variable	Value
Area Under ROC Curve (AUC)	0.938
95% CI of AUC	0.897 - 0.979
Standard Error	0.021
Z Statistic	20.86
P value	<0.001*

Table 3 evaluates the role of sonomammography in differentiating benign and malignant breast lesions based on specific imaging characteristics. Malignant lesions were significantly more likely to demonstrate irregular shape (79.6% vs. 17.3%; OR 18.7, $p < 0.001$), spiculated margins (63.3% vs. 5.8%; OR 28.0, $p < 0.001$), posterior acoustic shadowing (59.2% vs. 11.5%; OR 11.2, $p < 0.001$), microcalcifications (49.0% vs. 7.7%; OR 11.5, $p < 0.001$), and increased vascularity (73.5% vs. 19.2%; OR 11.7, $p < 0.001$) compared to benign lesions. BI-RADS classification showed the strongest discriminatory ability, with 92.3% of benign lesions categorized as BI-RADS 2/3 and 91.8% of malignant lesions classified as BI-RADS 4/5. This association yielded an exceptionally high odds ratio of 136.0 (95% CI: 41.8-442.7; $p < 0.001$). Receiver operating characteristic (ROC) analysis demonstrated excellent overall performance of sonomammography, with an area under the curve (AUC) of 0.938 (95% CI: 0.897-0.979), a standard error of 0.021, and a highly significant Z statistic of 20.86 ($p < 0.001$).

DISCUSSION

In the present study, the mean age of women presenting with palpable breast lesions was 42.8 ± 11.7 years, with a mean lesion size of 3.1 ± 1.4 cm. The majority of patients belonged to the middle-aged group, which is consistent with the findings of Dhaketa et al. (2025)[1], who reported that most patients with palpable breast lumps were in the fourth and fifth decades of life. Similar age distributions were also reported by Fathima et al. (2024)[2] and Tagar et al. (2023)[3]. The predominance of palpable breast lesions in this age group highlights the importance of early imaging evaluation and cytological confirmation to facilitate timely diagnosis and management.

In the present study, benign lesions accounted for 70.6% of cases, while malignant lesions constituted 29.4% based on FNAC findings. These findings are comparable with those reported by Dhaketa et al. (2025)[1], who observed 74.29% benign and 25.71% malignant lesions. Fathima et al. (2024)[2] and Tagar et al. (2023)[3] similarly reported a predominance of benign breast lesions among women presenting with palpable lumps. This trend may be attributed to the higher prevalence of fibroadenoma, fibrocystic disease, and inflammatory lesions compared to breast carcinoma in hospital-based populations. The predominance of benign lesions underscores the need for accurate non-invasive diagnostic modalities capable of differentiating benign from malignant breast pathology.
Clinically, painless breast lumps were observed in 62.1% of patients, whereas painful lumps were present in 37.9%. The significantly higher proportion of painless lumps ($p = 0.003$) is in agreement with the observations of Karim et al. (2020)[7], who noted that breast lesions, particularly malignant tumors, commonly present as painless masses. Early recognition of painless breast lumps is therefore essential, as delayed presentation may adversely affect treatment outcomes.

A major objective of the study was to determine the diagnostic accuracy of sonomammography in comparison with FNAC. The present study demonstrated excellent diagnostic performance, with sensitivity of 91.1%, specificity of 92.6%, positive predictive value of 83.7%, negative predictive value of 96.2%, and overall diagnostic accuracy of 92.2%. These findings closely resemble those reported by Dhull et al. (2020)[4], who found sensitivity and specificity values exceeding 90% for sonomammography in breast lesion characterization. Similarly, Reddy et al. (2021)[5] reported sensitivity of 87.5%, specificity of 93.6%, positive predictive value of 70.0%, and negative predictive value of 97.7% for ultrasonography when correlated with cytology. More et al. (2025)[6] also demonstrated excellent diagnostic efficacy of imaging modalities combined with FNAC in the modified triple assessment of palpable breast lumps.
The high sensitivity observed in the present study indicates that sonomammography successfully identified the majority of malignant lesions, missing only a small proportion of cancers. Likewise, the high specificity reduced the likelihood of false-positive diagnoses and unnecessary invasive procedures. The negative predictive value of 96.2% suggests that lesions categorized as benign on sonomammography are highly unlikely to be malignant. These findings support the routine use of sonomammography as an effective first-line diagnostic investigation in women with palpable breast lesions.

The agreement between sonomammography and FNAC was excellent, with a Cohen's kappa coefficient of 0.824 and a highly significant association ($\chi^2 = 95.87$, $p < 0.001$). This strong concordance indicates that imaging findings closely reflected cytological diagnosis. Karim et al. (2020)[7] similarly demonstrated that combining imaging with cytological assessment substantially improves diagnostic accuracy and clinical decision-making. More et al. (2025)[6] also emphasized the importance of integrating imaging and FNAC findings to enhance diagnostic confidence in breast lump evaluation. Several sonomammographic features showed a significant association with malignancy in the present study. Irregular shape was observed in 79.6% of malignant lesions compared with only 17.3% of benign lesions. Likewise, spiculated margins were identified in 63.3% of malignant lesions but only 5.8% of benign lesions. Lee et al. (2021)[8] reported similar findings and identified irregular margins, non-circumscribed borders, and architectural distortion as important predictors of breast malignancy. These morphological characteristics remain among the most reliable imaging indicators of malignant transformation.

Posterior acoustic shadowing was present in 59.2% of malignant lesions and only 11.5% of benign lesions, while microcalcifications were observed in 49.0% of malignant lesions compared with 7.7% of benign lesions. These observations are consistent with the findings of Mango et al. (2022)[9], who demonstrated that posterior shadowing and suspicious calcifications significantly increase the likelihood of malignancy. Furthermore, increased vascularity was present in 73.5% of malignant lesions, supporting the role of Doppler ultrasonography in identifying tumor-associated angiogenesis and improving lesion characterization.

Among all evaluated parameters, BI-RADS categorization showed the strongest association with malignancy. BI-RADS 2/3 lesions were predominantly benign, whereas BI-RADS 4/5 lesions were overwhelmingly malignant ($p < 0.001$). The odds ratio of 136.0 observed in the present study highlights the remarkable discriminatory ability of BI-RADS classification. These findings are consistent with the recommendations of the ACR BI-RADS Atlas published by D'Orsi et al. (2024)[10], which emphasizes the importance of standardized reporting systems for improving diagnostic consistency and guiding clinical management.

Receiver operating characteristic analysis further confirmed the excellent diagnostic performance of sonomammography. The area under the curve was 0.938 (95% CI: 0.897-0.979), indicating outstanding ability to distinguish benign from malignant lesions. Similar high diagnostic performance has been reported in contemporary breast imaging studies evaluating ultrasound-based lesion characterization and BI-RADS categorization [8-10].

Overall, the findings of the present study establish sonomammography as a highly sensitive, specific, and accurate imaging modality for the evaluation of palpable breast lesions. The strong correlation with FNAC findings, excellent agreement statistics, and superior ROC performance support its routine use in clinical practice. FNAC remains an invaluable adjunctive diagnostic tool because of its simplicity, rapid turnaround time, low cost, and high diagnostic accuracy, as highlighted by Ibikunle et al. (2020)[11]. The combined use of sonomammography and FNAC provides a reliable and effective diagnostic approach for the early detection and appropriate management of breast lesions.

CONCLUSION

The present study demonstrated that sonomammography is a highly accurate and reliable imaging modality for the evaluation of palpable breast lesions. When correlated with FNAC findings, sonomammography showed excellent diagnostic performance with a sensitivity of 91.1%, specificity of 92.6%, positive predictive value of 83.7%, negative predictive value of 96.2%, and overall diagnostic accuracy of 92.2%. There was excellent agreement between sonomammography and FNAC, as evidenced by a Cohen's kappa value of 0.824.

Among the sonomammographic features, irregular shape, spiculated margins, posterior acoustic shadowing, microcalcifications, increased vascularity, and BI-RADS 4/5 categorization were significantly associated with malignant breast lesions. The high area under the ROC curve (AUC = 0.938) further confirmed the excellent discriminatory ability of sonomammography in differentiating benign from malignant breast lumps.

Therefore, sonomammography serves as an effective, non-invasive, readily available, and cost-effective diagnostic tool in the assessment of palpable breast lesions. Its use in conjunction with FNAC enhances diagnostic confidence and facilitates early detection and appropriate management of breast malignancies while reducing unnecessary invasive procedures in benign conditions.

LIMITATIONS OF STUDY

1. The study was conducted at a single tertiary care centre, which may limit the generalizability of the findings to the wider population.
2. The sample size, although adequate for the study objectives, may not represent all pathological subtypes of breast lesions.
3. FNAC was used as the reference standard; histopathological examination was not available for all cases, which could have provided more definitive diagnosis.
4. Operator dependency in ultrasonography may have influenced lesion characterization and BI-RADS categorization.
5. Inter-observer variability among radiologists and cytopathologists was not assessed.

6. Patients with non-palpable breast lesions were not included; therefore, the findings cannot be extrapolated to screening-detected lesions.
7. Advanced imaging modalities such as contrast-enhanced mammography, elastography, or breast MRI were not evaluated and compared.
8. Long-term follow-up of benign lesions was not performed to assess subsequent diagnostic outcomes.

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