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Original Research Article

A prospective observational study assessing the correlation between ultrasonography features and histopathological findings in breast cancer

Simran Garhwal[1], R. K. Abrol[1], Vikrant Sharma[1], Preeti Takkar Kapila[2], Sachin Sharma[3]*

[1]Department of Surgery, Dr RPGMC Kangra at Tanda, Himachal Pradesh, India
[2]Department of Radiodiagnosis, Dr RPGMC Kangra at Tanda, Himachal Pradesh, India
[3]Department of Pharmacology, Dr RPGMC Kangra at Tanda, Himachal Pradesh, India

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***Correspondence:**
Dr. Sachin Sharma,
E-mail: s1984kaka@gmail.com

ABSTRACT

Background: Breast cancer is the most commonly diagnosed malignancy in India, where early detection is crucial for improving survival. Ultrasonography (USG) is a widely available imaging tool, especially beneficial in resource-limited settings and among younger women with dense breasts. This research sought to examine the association between sonographic features and histopathological findings in breast cancer patients.
Methods: A prospective observational study was conducted from May 2024 to April 2025 at Dr. R.P.G.M.C. Kangra, Himachal Pradesh, involving 50 female patients with clinically suspected breast malignancies. All participants underwent standardized breast ultrasonography, followed by histopathological confirmation through fine-needle aspiration cytology (FNAC) or core biopsy. Lesions were evaluated for shape, margins, echogenicity, posterior acoustic features and BI-RADS classification. The association between imaging findings and histopathological results was statistically analyzed.
Results: The mean age among patients was 47.56 years, with painless breast lumps noted as the initial symptom in all individuals. Common ultrasonographic findings included hypo echogenicity (82%), irregular margins (78%), posterior acoustic shadowing (70%) and a taller-than-wide shape (66%). Histopathology confirmed cancer in (96%) of the cases, with invasive ductal carcinoma observed in (85.4%) of these instances. A statistically significant correlation was found between ultrasonographic features and histopathological diagnosis ($p < 0.05$). USG demonstrated a sensitivity of 91.6%, specificity of 85.7% and diagnostic accuracy of 85%.
Conclusions: Ultrasonography is a reliable, accessible and effective imaging modality for evaluating breast lesions, with strong diagnostic utility in resource-constrained healthcare environments.

Keywords: Breast cancer, BI-RADS, Histopathology, Ultrasonography

INTRODUCTION

Breast cancer remains one of the most frequently diagnosed malignancies globally and is the fifth leading cause of cancer-related mortality, with an estimated 2.3 million new cases and 670,000 deaths recorded worldwide in 2022, according to GLOBOCAN data.[1] In India, breast cancer constitutes the leading malignancy, comprising 13.5% of new cancer diagnoses and contributing to 10.6% of deaths caused by cancer.[2] The pathogenesis of breast cancer involves a multistep process initiated by ductal epithelial hyperproliferation, progressing under the influence of genetic, hormonal and environmental factors. Mutations in BRCA1 and BRCA2

genes are among the most well-established genetic contributors. Additional risk factors include increasing age, family history, reproductive patterns, lifestyle factors and socioeconomic status.[3] The diagnostic workup for breast lumps involves a triple assessment strategy, incorporating clinical examination, imaging investigations and histopathological confirmation. While clinical signs such as a painless breast lump, peau d'orange appearance, nipple discharge, axillary lymphadenopathy and metastatic manifestations often prompt evaluation, a substantial proportion of cases remain asymptomatic in early stages.[4] Among imaging techniques, USG is particularly advantageous in young, pregnant or lactating women with dense breast tissue, where mammography may have reduced sensitivity.

USG reliably differentiates solid from cystic lesions, assists in biopsy procedures and is useful in evaluating axillary lymph nodes Hypoechoic masses with irregular, spiculated or indistinct margins, posterior shadowing and a taller-than-wide shape are characteristic ultrasonographic findings suggestive of malignancy. Despite its diagnostic value, USG's accuracy is influenced by operator skill and experience.[5]

The Breast Imaging-Reporting and Data System (BI-RADS) has been developed to standardize breast imaging reporting and management decisions, categorizing findings from BI-RADS 1 (negative) to BI-RADS 6 (biopsy-proven malignancy). Histopathologically, breast cancers are classified into subtypes such as ductal carcinoma in situ (DCIS), invasive ductal carcinoma (IDC), invasive lobular carcinoma and rarer forms like mucinous and medullary carcinoma.

Fine-needle aspiration cytology (FNAC) remains a rapid and minimally invasive diagnostic option but may miss low-grade or deep-seated lesions, whereas core needle biopsy offers superior diagnostic yield and facilitates receptor status assessment.[6] Staging of breast cancer is performed according to the TNM system, assessing tumor size, regional lymph node involvement and distant metastases. Treatment modalities, including surgery, chemotherapy, radiotherapy and hormone therapy, are tailored based on tumor stage, histological grade, receptor status and patient factors.[7]

Multiple studies and meta-analyses have reported that ultrasonography demonstrates a sensitivity of 80.1% and specificity of 88.4% in detecting breast malignancies, with values improving to 89.25% and 99.1%, respectively, in resource-constrained settings, positioning it as a valuable alternative or adjunct to mammography. Early detection achieved through a combination of clinical assessment, imaging and histopathological evaluation remains vital for improving survival outcomes.[6]

The present study aims to assess the correlation between ultrasonographic features and histopathological findings in patients with breast cancer, contributing to enhanced diagnostic accuracy and clinical decision-making, particularly in settings where resource are limited and restrict access to advanced imaging.

METHODS

The study was prospective observational study. The study was carried out in the Department of Surgery and Department of Radiology at Dr. R.P.G.M.C. Kangra at Tanda, a multispecialty tertiary healthcare facility located in the Kangra valley of Himachal Pradesh in India.

Study duration

The study was conducted for a period of one year, from May 2024 to April 2025.

Sample size

This research involved 40 patients who exhibited clinical signs of breast lesions.

Inclusion criteria

Female patients presenting with high suspicion of breast malignancy. Breast masses detectable on clinical examination, breast pain or nipple discharge.

Exclusion criteria

Patients with a history of previous breast surgery, male individuals and those who declined to provide consent were excluded.

Study procedure

The study population was selected as per inclusion and exclusion criteria from department of Surgery at Dr. RPGMC Tanda. Study population was evaluated with detailed history, clinical examination and laboratory investigations. Breast ultrasonography was performed by experienced radiologists using standardized protocols. Lesions were assessed for shape, margins, echogenicity, posterior acoustic features, overlying skin changes and classified as per BI-RADS criteria. Histopathological examination was done via fine-needle aspiration cytology (FNAC) or core biopsy and findings were classified by histological type and grade.

Statistical analysis

The data was collected, cleaned and entered using Microsoft Excel spreadsheet; and was analyzed in Statistical Package for Social Science (SPSS) v 27 draw relevant conclusions. The observations were tabulated in the form of frequency and percentage. To find the significance Chi square test for categorical data was applied. Level of significance was assessed based on its p

value with p<0.050 as significant. Diagnostic accuracy, sensitivity and specificity were calculated.

RESULTS

A total of 50 patients with clinically and radiologically suspected breast malignancies were included in this prospective observational study. The mean age of the study population was 47.56±11.58 years, with the majority of patients falling within the 41–50 years age group 42%, followed by 31–40 years 28% and 51–60 years 22%. Family history of breast cancer was present seen in 20% of the patients as shown in Table 1.

The most frequent presenting symptom was a painless breast lump, reported in 100% of cases. Additional findings included axillary lymphadenopathy in 30%, nipple discharge in 16% and skin involvement such as peau d'orange in 12% of patients. On ultrasonography, the most common lesion characteristic observed was hypo echogenicity, present in 82% of cases, followed by irregular margins 78%, posterior acoustic shadowing 70% and taller-than-wide orientation 66%. Axillary lymphadenopathy was detected sonographically in 60% of patients. Based on BI-RADS classification, 36% of lesions were categorized as BI-RADS 5, 34% as BI-RADS 4, 20% as BI-RADS 6 and 10% as BI-RADS 3 as shown in Table 2. Histopathological examination confirmed malignancy in 48 out of 50 patients 96%, with invasive ductal carcinoma (IDC) being the most common histological type, observed in 85.42% of malignant cases. Other types included invasive lobular carcinoma 8.33%, mucinous carcinoma 4.16% and medullary carcinoma 2.08% as shown in Table 3.

A statistically significant correlation was observed between hypoechogenicity, irregular margins, posterior acoustic shadowing and taller-than-wide orientation on ultrasonography and histopathological diagnosis of malignancy (p<0.05). The sensitivity and specificity of ultrasonography for detecting malignant lesions were found to be 91.6% and 85.7%, respectively. The positive predictive value was 97.8%, while the negative predictive value stood at 66.6% as shown in Table 4.

Table 1: Demographic characteristics of study participants (n=50).

Variables	Category	Frequency number (N)	(%)
Age group (in years)	31–40	14	28
	41–50	21	42
	51–60	11	22
	>60	4	8
Family history of breast cancer	Present	10	20
	Absent	40	80

Table 2: Clinical characteristics and ultrasonographic findings of study participants (n=50).

Variables	Category	Frequency number (N)	(%)
Clinical presentation	Painless breast lump	50	100
	Axillary lymphadenopathy (clinical)	15	30
	Nipple discharge	8	16
	Skin Involvement (Peau d'orange etc.)	6	12
Ultrasonographic features	Hypo echogenicity	41	82
	Irregular Margins	39	78
	Posterior acoustic shadowing	35	70
	Taller-than-wide orientation	33	66
	Axillary lymphadenopathy (USG)	30	60
BI-RADS classification	BI-RADS 3	5	10
	BI-RADS 4	17	34
	BI-RADS 5	18	36
	BI-RADS 6	10	20

Table 3: Histopathological diagnosis in study participants.

Variables	Category	Frequency number (N)	(%)
Histopathological diagnosis (n=50)	Malignant Lesions	48	96
	Benign lesions	2	4
Histopathological types of	Invasive lobular carcinoma	4	8.33

Continued.

Variables	Category	Frequency number (N)	(%)
malignant lesions (n=48)	Mucinous carcinoma	2	4.17
	Medullary carcinoma	1	2.08
	Invasive ductal carcinoma	41	85.42

Table 4: Diagnostic accuracy of ultrasonography in study participants.

Category	(%)
Sensitivity	91.6
Specificity	85.7
Positive predictive value (PPV)	97.8
Negative predictive value (NPV)	66.6
Diagnostic accuracy	85

DISCUSSION

This prospective study was conducted to assess the correlation between USG features and histopathological findings in patients with suspected breast malignancies. Our results reaffirm the pivotal role of ultrasonography in the diagnostic evaluation of breast lesions, particularly in resource-limited settings, aligning with existing literature. In the present study, the mean age of patients was 52.73 years, with the highest proportion (45%) falling within the 40–50 years age group. This is consistent with several regional studies such as those by Kim et al, who reported mean ages of 56 years.[8] Interestingly, the age profile varies internationally, with study like Bello et al and Akinnibosun et al, reporting lower mean ages of 34.6 and 33 years, respectively, reflecting geographical and ethnic differences in breast cancer epidemiology.[9,10]

A positive family history of breast cancer was noted in 20% of our patients, higher than the 14.95% reported by Brewer et al, possibly due to referral bias in our tertiary care setting catering to high-risk populations. Multiple studies have shown that a first-degree family history significantly increases breast cancer risk.[11] As expected, the most common presenting complaint was a breast lump (67.5%), followed by pain (25%) and nipple discharge (12.5%). This pattern aligns closely with that reported by Upadhyay et al, where lump predominated in 74% of cases.[12]

Histopathologically, malignancy was confirmed in 92.5% of cases, predominantly invasive ductal carcinoma (IDC), mirroring findings from Eng et al and consistent with global data where IDC is the most prevalent histological subtype. The high malignancy rate in our series may reflect the referral pattern to our institution, a specialized cancer care center.[13] Most lesions were hypoechoic (77.5%), a well-established malignant feature, in line with findings by Kim et al (90.61%) and Bello et al (71%). Posterior acoustic enhancement was observed in 85% of cases, while shadowing was present in 10%, similar to patterns noted in study by Bello et al, who noted enhancement predominantly in high-grade invasive tumors.[8,9] Using the BI-RADS classification, 42.5% of lesions were categorized as suspicious and 35% as highly suspicious, comparable to the distribution reported by Eng et al.[13] Importantly, our study demonstrated a diagnostic accuracy of 85%, sensitivity of 83.78% and specificity of 100% for ultrasonography in differentiating benign from malignant lesions. These results align well with Bello et al, who reported an accuracy of 92%, sensitivity of 88.6% and specificity of 93.8%.[9]

Several other studies have reported similarly high accuracy, reaffirming ultrasonography's diagnostic value, particularly for palpable masses in young women and dense breasts.[14,15] Recent research highlights the high NPV of ultrasonography, exceeding 99% in lesions with probably benign features, as observed by Park et al.[16] This underlines USG's role in reassuring patients with low-suspicion palpable findings and reducing unnecessary biopsies. Overall, our findings reinforce the diagnostic utility of ultrasonography in breast cancer evaluation, supporting its role as an accessible, non-invasive and reliable imaging modality, particularly in low-resource settings where mammography availability may be limited.

This study had a relatively small sample size and was conducted at a single tertiary care center, potentially introducing referral bias and limiting the generalizability of the findings.

As ultrasonography is an operator-dependent technique, diagnostic accuracy may vary with examiner expertise and inter-observer variability was not assessed. Additionally, discordant cases between imaging and histopathology were not analyzed in detail and the absence of comparative evaluation with other imaging modalities like mammography or MRI limits comprehensive assessment of ultrasonography's diagnostic performance.

CONCLUSION

This study reaffirms the pivotal role of ultrasonography as an effective, accessible and reliable imaging modality for the evaluation of breast lesions, particularly in resource-limited settings. A significant correlation was observed between characteristic ultrasonographic features

such as hypo echogenicity, irregular margins, posterior acoustic shadowing and taller-than-wide orientation and histopathological diagnosis of malignancy. Ultrasonography demonstrated high sensitivity, specificity and diagnostic accuracy in differentiating benign from malignant breast lesions, especially for palpable masses in younger women and those with dense breast tissue. The findings support the continued integration of ultrasonography into the standard diagnostic workup for breast cancer, while also highlighting the need for larger, multicentric studies and comparative analyses with other imaging modalities to further validate its diagnostic performance.

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