



Original Article

The Diagnostic Accuracy of Conventional Breast Ultrasound in Diagnosing Malignant Breast Lesions Taking Histopathology as Gold Standard

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ABSTRACT

Breast cancer is a prominent worldwide health issue, with difficulties in detection worsened by the presence of dense breast tissue. Ultrasound and other alternative diagnostic methods have demonstrated potential to enhance detection rates, especially in situations involving thick breast tissue. **Objective:** To evaluate how well conventional breast ultrasonography can accurately differentiate between benign and malignant tumors, using histopathology as the most reliable method of comparison. **Methods:** A cross-sectional study was conducted at a tertiary care hospital to evaluate 185 female patients with breast lesions using sonographic examination. Demographic information, ultrasonography results and histopathological data were gathered and examined using SPSS version 26.0. Calculations were performed to determine the sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy. **Results:** The study demonstrated that conventional breast ultrasound has a high diagnostic accuracy rate, with ratings of 91.07%, 83.57%, 89.47%, 85.92%, and 88.11% for sensitivity, specificity, positive predictive value and negative predictive value, respectively. Statistically significant differences in diagnostic accuracy were observed when stratification was performed based on age, duration of disease, parity, and history of breastfeeding. **Conclusions:** The findings indicated that ultrasound is highly effective in differentiating between benign and malignant breast lesions, with substantial diagnostic precision. However, false positives remain a concern, necessitating ongoing research for optimizing ultrasound efficacy, especially in high-risk cohorts.

INTRODUCTION

Breast cancer is one of the most prevalent malignancies worldwide and it contributes to a significant number of cancer related mortalities and morbidities. With an estimated 2.3 million new cases globally, the disease is still a major public health issue that needs to be managed [1]. One notable challenge in breast cancer diagnosis is the presence of dense breast tissue, complicating the detection of abnormalities through standard mammography and increasing the risk of undetected malignancies [2]. This limitation underscores the need for alternative diagnostic modalities, such as ultrasound, which has demonstrated potential in improving detection

rates, particularly in cases of dense breast tissue [3]. Ultrasound guided core biopsy offers a less invasive and more convenient alternative to surgical biopsy for evaluating suspicious breast lesions, significantly reducing patient discomfort and healthcare costs [4, 5]. However, the high incidence of benign findings in pathologic reports highlights the importance of accurate differentiation between benign and malignant lesions [6]. Imaging features observed on ultrasound have shown promise in distinguishing between these lesion types, potentially reducing the need for invasive diagnostic procedures [7]. Histopathology remains the gold standard

for confirming breast cancer diagnoses, but its invasive nature, costliness, and patient reluctance underscore the importance of exploring non-invasive alternatives [8]. The Breast Imaging Reporting and Data System (BI-RADS) is a standardized format and terminology that “The American College of Radiology” has implemented. This system is essential for the production of imaging reports. Traditional B-mode ultrasonography examines breast lesions and the tissues around them by measuring a number of parameters. The Breast Imaging Recording and Data System (BIRADS) categorizes these ultrasonic characteristics according to their size, shape, margin, border, posterior acoustic features, echo pattern and calcification. Benign tumors have BIRADS values of 2 or 3, whereas malignant ones have scores of 4 or 5. Nevertheless, BIRADS classification is still up in the air when there is a lot of overlap in the ultrasonography characteristics of a lesion [9]. In our local context, literature is scarce on the accuracy of mammography and ultrasonography in distinguishing between malignant and benign breast masses, particularly in the context of BI-RADS classification, which categorizes findings on a scale from grade zero to grade six, with higher numbers indicating a higher likelihood of malignancy [10]. Consequently, the objective of our investigation was to evaluate the precision of sonography and mammography features, as well as their “BI-RADS” grades, in the diagnosis of breast malignancies in accordance with pathology findings. Although ultrasound has the capacity to accurately diagnose breast lesions, the reported sensitivity and specificity values exhibit substantial variation among studies. Consequently, the objective of this investigation is to evaluate the diagnostic proficiency of conventional breast ultrasound in the differentiation of benign and malignant lesions, employing histopathology as the gold standard.

This research aimed to improve clinical practice, reduce the need for superfluous interventions and alleviate patient burden by providing local evidence on the reliability of ultrasounds.

METHODS

The study recruited female patients presenting with breast lesions for sonographic evaluation at the Department of Radiology, Combined Military Hospital, Sialkot. Patients underwent conventional breast ultrasound, with subsequent biopsy for histopathological confirmation. From December 2022 to May 2023, a descriptive, cross-sectional study was implemented to prospectively gather relevant data. With a 25% breast cancer prevalence and a 95% confidence interval, an online sample calculator was used to establish that 185 individuals would be the appropriate sample size [11]. Consecutive sampling was employed to collect data for the study. Inclusion criteria

encompassed female patients aged 25-75 years with palpable breast masses undergoing biopsy. Exclusion criteria included patients undergoing chemotherapy, those with breast implants and those unable to provide informed consent. Demographic and clinical data were collected and patients underwent conventional breast ultrasound. The “Toshiba Xario 200 US machine” was used to do conventional US and characteristics, with probe frequencies ranging from “7.5 to 13 MHz”. The lesion’s size and other features were investigated by running the analysis in B-mode in every conceivable plane. Bi-RADS scores were recorded and patients were categorized as positive or negative based on operational definitions. Biopsy was performed by a consultant surgeon, with histopathology reports verified by pathologists. The research and ethics committee of AFGMI reviewed and approved the study proposal (RE: 344-AAA-ERC-AFGMI) on August 16, 2022. Informed consent was obtained from all participants and data confidentiality was ensured throughout the study. The data analysis was conducted using SPSS version 26.0. Quantitative data were presented as mean and standard deviation, while qualitative variables were reported as frequency and percentage. Sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of ultrasonography were assessed using 2x2 tables. The data were categorized by age, parity, duration of symptoms, and history of nursing, followed by the calculation of “sensitivity, specificity and diagnostic accuracy”.

RESULTS

The study included a total of 185 participants, with 97 (52.43%) falling in the age range of 25-50 years and 88 (47.57%) in the 51-75 years age group. Regarding the duration of disease, 112 (60.54%) participants had been experiencing symptoms for six months or less, while 73 (39.46%) had symptoms for more than six months. In terms of parity, 20 (10.81%) participants were primiparous and 165 (89.19%) were multiparous. Additionally, 134 (72.43%) participants had a history of breast feeding, while 51 (27.57%) did not as shown in table 1.

Table 1: Demographic Characteristics of the Study Sample

Variables	Number of Patients N (%)
Age (Years)	
25-50	97 (52.43)
51-75	88 (47.57)
Duration of Disease	
≤ 6 Months	112 (60.54)
>6 Months	73 (39.46)
Parity	
Primiparous	20 (10.81)
Multiparous	165 (89.19)
History of Breastfeeding	
Yes	134 (72.43)
No	51 (27.57)

The diagnostic accuracy of conventional ultrasonography in distinguishing between benign and malignant breast lesions was assessed. Among the patients with positive results on histopathology, ultrasound detected True Positive (TP) cases in 102 instances, indicating accurate identification of malignant lesions. However, there were also 12 False Positive (FP) results, where ultrasound incorrectly identified benign lesions as malignant. Conversely, among patients with negative results on histopathology, ultrasound correctly identified True Negative (TN) cases in 61 instances, indicating accurate identification of benign lesions. However, there were 10 False Negative (FN) results, where ultrasound failed to identify malignant lesions. The p-value of 0.0001 indicates a statistically significant difference in the diagnostic accuracy of conventional breast ultrasound. Using histology as the gold standard, conventional breast ultrasonography had a sensitivity of 91.07%, specificity of 83.57%, positive predictive value of 89.47%, and negative predictive value of 85.92% and diagnostic accuracy of 88.11% when it came to differentiating benign from malignant breast lesions as shown in table 2.

Table 2: The Accuracy of Conventional Breast Ultrasonography in Distinguishing between Benign and Malignant Breast Lesions, with Histology Serving as the Reference Standard

Ultrasonography	Histopathology		p-Value
	Positive	Negative	
Positive	102 (TP)	12 (FP)	0.0001
Negative	10 (FN)	61 (TN)	

“TP=True positive; FP=False positive; FN=False negative; TN=True negative”

Significant insights were obtained with statistically significant p-values ($p < 0.001$) from the stratification of diagnostic accuracy according to age groups, length of illness, parity and history of nursing. With a sample size of 97 individuals ranging from 25 to 50 years old, ultrasonography demonstrated a sensitivity of 92.73%, specificity of 78.57%, PPV of 85.0%, NPV of 89.19%, and diagnostic accuracy of 86.60%. In contrast, the diagnostic accuracy was 89.77%, sensitivity was 90.47%, specificity was 90.32%, PPV was 94.44% and NPV was 82.35% in the group of people aged 51-75 ($n=88$). The ultrasonography had a sensitivity of 92.19%, specificity of 79.17%, PPV of 85.51%, NPV of 88.37% and diagnostic accuracy of 86.61% about the length of the disease, for cases with a duration of 6 months or less ($n=112$). With a sensitivity of 91.0%, specificity of 84.62%, PPV of 90.09%, NPV of 85.94% and diagnostic accuracy of 88.48% among 165 multiparous women, the results were favorable. A sensitivity of 93.55%, specificity of 90.0%, PPV of 93.55%, NPV of 90.0%, and diagnostic accuracy of 92.16% were recorded for non-breastfeeding women ($n=51$), while a sensitivity of 82.76%, specificity of 87.95%, PPV of 85.71%, and diagnostic accuracy of 87.05% were recorded for breastfeeding

women ($n=134$) as shown in table 3.

Table 3: Stratification of Diagnostic Accuracy Concerning Demographic Variables

Variables	Ultrasonography	Histopathology		p-Value
		Positive	Negative	
Age				
25-50 Years ($n=97$)	Positive	51 (TP)	09 (FP)	0.001*
	Negative	04 (FN)	33 (TN)	
51-75 Years ($n=88$)	Positive	51 (TP)	03 (FP)	0.001*
	Negative	06 (FN)	28 (TN)	
Duration of Disease				
≤ 6 Months ($n=112$)	Positive	59 (TP)	10 (FP)	0.001*
	Negative	05 (FN)	38 (TN)	
> 6 Months ($n=73$)	Positive	38 (TP)	9 (FP)	0.001*
	Negative	6 (FN)	20 (TN)	
Parity				
Primiparous ($n=20$)	Positive	11 (TP)	02 (FP)	0.001*
	Negative	01 (FN)	06 (TN)	
Multiparous ($n=165$)	Positive	91 (TP)	10 (FP)	0.001*
	Negative	09 (FN)	55 (TN)	
H/O Breastfeeding				
Yes ($n=134$)	Positive	73 (TP)	10 (FP)	0.001*
	Negative	08 (FN)	48 (TN)	
No ($n=51$)	Positive	29 (TP)	02 (FP)	0.001*
	Negative	02 (FN)	18 (TN)	

*= $P < 0.05$

The ROC curve (the blue line) was closer to the top-left corner, indicating ultrasound as strong classifier. Following an appropriate range of cutoff values, a successful diagnostic test should have a minimal false positive and false negative rate, as seen in the graph. Ultrasonography had high classification performance, with an AUC-ROC value of 0.85 as shown in figure 1.

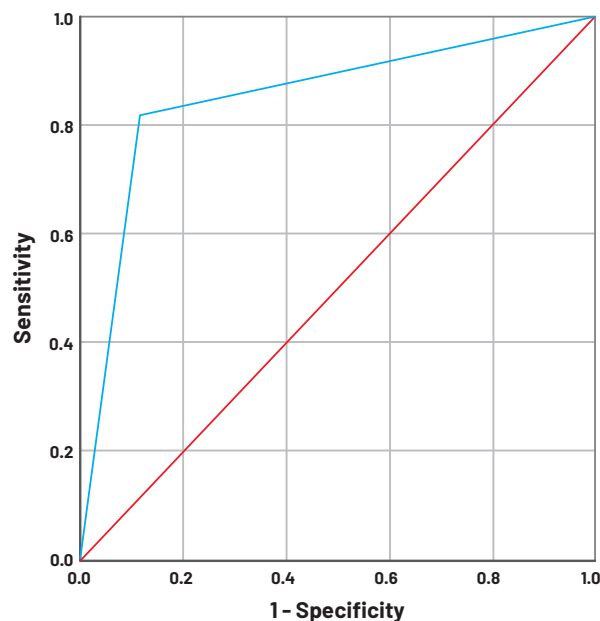


Figure 1: ROC Curve for Breast Ultrasonography

DISCUSSION

Numerous non-invasive and sonographically-based approaches are the subject of active investigation with the goal of decreasing the frequency of invasive biopsies used to diagnose cancerous breast lesions. In recent years, ultrasonography has assumed a more crucial role in the detection of breast cancer. Ultrasound of the breast is the technique of choice when a patient is experiencing symptoms during a clinical assessment. When performed on asymptomatic individuals, breast ultrasonography is thought to offer a greater sensitivity for detecting breast cancer in high-risk women, those younger than 50 and those with dense breast tissue. If a breast mammogram only revealed part of a lump or nodule, if there is the mammographic asymmetry in the area of a palpable lesion, if there are breast implants, if there has been a lumpectomy or segmentectomy or if there is no abnormality detected on mammography, then a breast Ultrasound-Guided Biopsy (USG) may be necessary. In 10-40% of cases, ultrasound may discover tumors that are not visible on mammography; the incidence of detection varies with patient age and breast density [12, 13]. Our study found that conventional breast ultrasound had "diagnostic accuracy, specificity, sensitivity and positive and negative predictive values" of 88.11%, 83.57%, 89.47%, 85.92%, and 81.07% in distinguishing benign from malignant breast lesions, respectively, when compared to histopathology, the gold standard. These results are consistent with previous studies. Ultrasonography had a sensitivity of 72.6% and a specificity of 88.5%, according to a study that compared USG with mammography [14]. Additional research has shown that breast ultrasonography is 86.8% sensitive and 72.4% specific in terms of distinguishing benign breast lesions from malignant [11]. According to the research done by Guyer PB and Dewbury KC the specificity was 97.2% and the sensitivity was 91.2%. [15]. A local study in Pakistan found that ultrasonography has a "sensitivity and specificity" of 95.24% in detecting breast cancer and a "specificity" of 68.75% [16]. According to another research by Akhtar MS et al., USG has a specificity of 70.0%, sensitivity of 77.8%, and accuracy of 75.7% when it comes to diagnosing malignant tumors [17]. It may be noted that the significance of ultrasonography in the context of breast cancer evaluations has heightened, which is evident from studies pointing to increased reliance on this diagnostic method in pragmatic clinics. Similar findings were found in our study that around 61% of patients were found to have malignant breast lesions from ultrasound, indicating the diagnostic value of the technique. The malignance of the lesion was further substantiated by the histopathological examination, which reported the condition in 60.86% of the patients. The results mean that the method is legitimate in the identification of lesions, which can be considered suspicious based on the ultrasound results. Interestingly, more than 90% of the patients that found coverage in the

positive group had true malignant breast lesions, and still, the need for histopathology results is necessary to clarify the presence of false positives in this group. In this vein, false positives are represented in the form of two patients set against a total of 21 positive patients. In this sense, two out of 21 cases in the positive ultrasound group were false positives. It may be noted that the interpretation of ultrasound findings needs to be looked at cautiously and needs to be validated by histopathology. In the case of the negative group, the histopathology results showed that 16 patients included in the group were diagnosed with malignant breast lesions. In this vein, in 25% of the cases within this group, there has been a risk of false negatives. However, the majority of the cases falling in this specific group were true negatives 75%. It, therefore, means that the method was able to identify the benign lesions appropriately in the negative group. It may be worth mentioning here that situations, where breast ultrasound may be necessary, include studies indicating a palpable mass not satisfying the limitations of mammography, studies showing cysts to be distinguished from solid nodules and palpable abnormalities corresponding to mammographic asymmetry [16]. Importantly, ultrasound can detect mammographically occult cancers in a significant percentage of cases, highlighting its potential as a diagnostic tool in cancer detection [18]. Literature has shown that the most accurate way to diagnose breast disorders, including cancer, is by using a mix of imaging techniques and histological examination. Magnetic Resonance Imaging (MRI) has been demonstrated to be very sensitive and accurate in diagnosing breast cancer, however, mammography and ultrasound are also vital in this process [17-19]. Furthermore, prior research has shown that advanced ultrasonography methods, such as Doppler, might be used to selectively image breast tumors [20, 21]. Histopathology is the gold standard for confirmation, but a combination of digital mammography and ultrasound greatly improves sensitivity, diagnostic accuracy, and negative predictive value in detecting malignant breast neoplasms [22]. Sometimes a breast ultrasound may be a helpful diagnostic tool, especially in situations when a biopsy is not required. There is also the possibility that ultrasound screening may provide findings that are falsely positive. Therefore, in the future, research should be conducted to determine whether or not ultrasonography is beneficial in detecting breast cancer in those who are at high risk for developing the disease. One radiologist was responsible for carrying out all of the ultrasonography in this study. This was done in an attempt to eliminate any possibility of bias that could have been present. It is possible to test it with a large number of operators in order to guarantee that it is accurate in terms of diagnosis and to achieve inter-observer reliability. This is because the procedure is dependent on talent. The current study is the first of its kind in the local community and it

demonstrates the potential of ultrasonography in the diagnosis of breast tumors that are cancerous. The findings of this study suggest that ultrasound need to be the first method of investigation for female patients who present with breast lumps; if the ultrasonography reveals the presence of cancer, a biopsy ought to be carried out. The use of this technology has the potential to significantly reduce the number of biopsies that are carried out on benign breast tumors.

CONCLUSIONS

The research findings indicated that ultrasonography showed high levels of specificity, sensitivity and negative and positive predictive values in distinguishing between benign and malignant breast masses. Diagnostic ultrasonography is a highly efficient method for differentiating between benign and malignant breast abnormalities.

Authors Contribution

Conceptualization: SQA

Methodology: SB, SG, SK

Formal analysis: SQA

Writing, review and editing: HM, HS

All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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