



## ASSESSING THE DIAGNOSTIC ACCURACY OF ULTRASONOGRAPHY AND MAMMOGRAPHY IN DETECTING BREAST MASSES: A CLINICAL CORRELATION WITH HISTOPATHOLOGICAL FINDINGS

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### ABSTRACT

**Objective:** To evaluate the efficacy of ultrasonography and mammography as a primary diagnostic tool for breast masses.

**Methodology:** This retrospective study involved 90 women aged 20 to 80 years with palpable breast lumps admitted in Services Hospital Lahore from 1<sup>st</sup> January 2020 to 30<sup>th</sup> January 2022. Medical records of patients who underwent ultrasound or mammography and histopathological evaluation were systematically reviewed. Ethical approval was obtained from the Institutional Review Board vide letter No. IRB/2024/1496/SIMS dated 17-12-2024. The data was collected with information extracted on socio-demographic, clinical, and imaging findings, keeping identity of patient anonymous. Data were analyzed applying descriptive statistics, the Chi-square test for correlations, and the Kappa statistic to assess agreement between ultrasound and histological findings.

**Results:** Majority patients were between 20-30 years (21.1%). Most participants were married (41.1%) or single (38.9%), and 76.7% were housewives. In terms of breast lump characteristics, 98.9% had unilateral lumps, and 94.4% had a single lesion. Oval-shaped lumps were most common (83.3%), and 80% had irregular outlines, often associated with malignancy. The BI-RADS classification showed 52.2% as BI-RADS 4 (suspicion of malignancy), and 24.4% as BI-RADS 5 (high suspicion). Needle biopsy was performed in 93.3% of cases. The Kappa value of 0.479 indicated moderate agreement between ultrasound and histology, with a p-value of 0.000, showing significant correlation. While ultrasound is useful, histopathology remains the gold standard for diagnosis.

**Conclusion:** The overall efficacy of breast ultrasound and mammography in distinguishing between breast lumps was satisfactory; however, the prevalence of discordant cases underscores the necessity of clinical, radiological and pathological correlation to minimize diagnostic errors.

**Keywords:** Breast lumps, Ultrasound diagnosis, Histopathology, BI-RADS classification, Accuracy

## INTRODUCTION

There is a spectrum of breast masses, ranging from benign and inflammatory lesions to cancerous ones. Breast cancer is the most prevalent form of cancer among females, accounting for about 11.7% percent of the all other cancers.<sup>1</sup> There is a wide range of benign and malignant neoplasms that fall under the umbrella of breast disease in women. Pain in the breasts, discharge from the nipple, and a palpable lump are the three most prevalent breast issues that prompt women to seek medical attention.<sup>2</sup> Various factors like increased lifetime exposure to estrogen and progesterone, consequently elevates the risk of breast cancer. It include smoking, alcohol use and family history.<sup>3</sup> Screening and detection of breast cancer at an early stage are very important because they reduce the mortality rate associated with breast cancer and increase the likelihood of favorable results when complete medical treatment is administered.<sup>4</sup>

Multiple criteria may be used to assess breast masses. Based on their form, they may exhibit irregular, oval, round, or lobulated forms, with borders that may be spiculated, hidden, smooth, or uneven. There are two primary categories of breast lesions: malignant and benign lesions. Malignant neoplasms whether lobular or ductal or any other histological subtype have irregular, infiltrative borders. In contrast, benign lesions, such as galactocoele, fibroadenoma, abscess, and cyst, often are circumscribed with regular borders.<sup>2</sup> The timely detection and precise diagnosis can be efficiently achieved via screening programs. Pregnancy is also many a times associated with breast lumps and typically, a thorough assessment including a physical examination and follow up can rule out breast cancer.<sup>5</sup>

The clinical breast examination (CBE), breast imaging (including mammography, breast ultrasound (BUS), and magnetic resonance imaging (MRI), and breast cytology or biopsy for histological diagnosis are all components of the triple evaluation procedure, which is used to examine individuals who are experiencing symptoms.<sup>6</sup> Ultrasound is helpful in both the detection of breast masses and the differentiation of masses seen on mammography. Moreover, ultrasonography is safe to detect abnormalities in younger women with dense breast tissue, especially in these women who are pregnant or nursing.<sup>6,7</sup> Given its significant role in interventional procedures and the differentiation between benign and malignant breast masses, it functions as a supplementary test to clinical assessment and mammography.<sup>8-12</sup>

A breast biopsy may be performed in a variety of ways to acquire tissue for histopathological analysis. These include fine needle aspiration biopsy, or tru-cut biopsy, as well as open surgical biopsy.<sup>13</sup>

To get optimal diagnostic precision, it is frequently necessary to convene a team of doctors, radiologists, and pathologists in an open and collaborative forum to thoroughly analyze each case. Core needle biopsy is very sensitive in detecting breast cancer. Research has shown that integrating clinical examination, imaging techniques (such as mammography and ultrasound), and biopsy findings may greatly improve diagnostic accuracy and decrease the likelihood of misdiagnosis.<sup>14</sup>

The purpose of this work is to investigate the diagnostic efficacy of ultrasonography and mammography in evaluating and categorizing as benign and malignant, breast masses by comparing the ultrasound results with related histopathological data. Ultrasonography is well acknowledged for its ability to identify breast masses, whether they are benign or cancerous, by analyzing sonographic characteristics including form, borders, echo pattern, and posterior acoustic properties. Nevertheless, the definitive determination of whether a tumor is malignant or benign frequently requires histopathological assessment, underscoring the need of combining biopsy data with imaging results. This association was established using U/S-guided Tru-Cut biopsy, a very efficient and minimally invasive technique for acquiring tissue samples for conclusive histological diagnosis. This study is aimed to assess the dependability of ultrasonography and mammography in clinical decision-making and its capacity to accurately distinguish between benign and malignant breast tumors, thus facilitating the prompt and suitable diagnostic option followed by early treatment of patients.

## METHODOLOGY

This observational study was carried out on the women who had palpable breast lumps and were admitted in Services Hospital Lahore from 1<sup>st</sup> January 2020 to 30<sup>th</sup> January 2022. A total of 90 women's data with age from 20 to 80 years was retrieved from Pathology Department of Services hospital, Lahore. The medical information of women who presented themselves with breast lumps had an ultrasound and histological evaluation within the specified time period was included. Those with history of abscess and fibrocystic diseases were excluded from the study. Following the retrieval of files from the hospital's archives, a comprehensive and methodical sampling procedure was carried out. The records that were included in the research were limited to those that had extensive clinical, imaging, and histology data. Ultrasound findings were available in patients less than 40 years of age whereas mammographic findings were retrieved from patients request forms and radiology department in patients older than 40 years of age. In order to guarantee that the research was carried out in an ethical manner, the institutional review board (IRB) of Services Hospital Lahore, issued their official certification vide letter No. IRB/2024/1496/SIMS dated 17-12-2024. All of the data were anonymized and processed in line with the relevant data protection standards in order to ensure that the anonymity of the persons involved was preserved.

The process of data collection may start after the necessary authorizations, such as ethical clearance and institutional approval, have been obtained. An exhaustive review of the relevant literature served as the foundation for the development of data extraction form. The information that was extracted from historical records consisted of three basic components: socio-demographic data, clinical information, and imaging findings. For the sake of protecting the confidentiality of the patients, no one other than the records department of the hospital was engaged in the collection of this data.

The data was entered and analyzed through SPSS-22. In order to assess the degree of correlation between variables, the Chi-square test was used. Additionally, the Kappa statistic was utilized to ascertain the level of concordance that exists between ultrasonography and histological diagnosis. If the p-value was lower than 0.05, then the analysis was considered to be statistically significant.

## RESULTS

The majority of them were between 20 to 30 years 21.1%, followed by those who were between 81 to 90 years 17.8%. While the age group ranging from 61 to 70 years old made up 12.2% of the whole population, other age groups, such as those aged 51 to 60 and 71 to 80, each accounted for 13.3% of the total population. Of the participants, those aged 31 to 40 (11.1%) and those aged 41 to 50 (11.1%) made up a lesser share. Regarding the marital status of the participants, the majority of them were either married (41.1% of them) or single (38.9% of them), with twenty percent of them being widows. Based on this, it seems that the population under investigation consisted of a varied group of women who were in various stages of their lives, which reflects a comprehensive representation of society. As far as educational attainment is concerned, fifty percent of the participants had finished their secondary school, while thirty- four point four percent had completed their elementary education. A lesser percentage of the population, 15.6%, has completed higher education. This indicates that while the majority of participants had completed some degree of formal education, the percentage of participants who had completed higher education was lower. According to the statistics on occupations, the bulk of the women were housewives (76.7%), while just 17.8% of them were working outside the home responsibilities. 5.6% of the participants were students, which highlights a larger proportion of women who were not working in the study. This may be a reflection of the roles that women play in society as well as the economic constraints that exist.

The great majority of subjects (98.9%) had unilateral breast lumps, whereas only 1.1% had bilateral breast lumps. This indicates that unilateral breast lumps are more common than bilateral breast lumps. According to the number of lesions that were present in each participant, 94.4% of them had a single lesion, while 5.6% of them had multiple lesions. This indicates that the majority of the

women who reported with breast lumps had a single lump. The bulk of the breast lumps were oval (83.3%), followed by round (12.2%) and dysmorphic (4.4%). This was determined by evaluating the form of the breast lumps. On the basis of this distribution, it seems that oval-shaped lumps were the most prevalent. This is a characteristic that is often linked with benign lesions; nevertheless, form alone is not adequate for diagnosis. A large amount of diagnostic knowledge was also offered by the contours of the breast masses. Eighty percent of the lumps had irregular contours, whereas just twenty percent had conventional outlines. The high proportion of malignancies that were discovered in the histological data may be explained by the fact that irregular outlines are often considered to be related with malignant tumors.

The BI-RADS classification of the lumps, which is used to predict the possibility of malignancy based on imaging characteristics, found that 52.2% of the participants were categorized as BI-RADS 4, which indicates a suspicion of malignancy. This classification was based on the imaging features associated with the lumps. BI-RADS 5, which indicates a high suspicion of malignancy, accounted for 24.4% of cases, whereas BI-RADS 2 (benign) and BI-RADS 3 (possibly benign) accounted for 11.1% and 8.9% of cases, respectively. BI-RADS 5 is the one that signals the highest suspicion of malignancy. There were a tiny percentage of patients that were classed as BI-RADS 6, which indicates that the malignancy was already recognized.

In terms of the method of sampling, a needle biopsy was used in 93.3% of the instances, whilst surgical excision was carried out in 6.7% of the cases. Because of its minimally invasive nature, needle biopsy is the procedure of choice for first diagnosis. On the other hand, surgical excision is normally reserved for situations in which more tissue analysis is necessary or when the findings of the biopsy are equivocal (Table 1).

When the findings of the ultrasonography were compared with the findings of the histological examination, the Kappa value and the Chi-square test were used in order to examine the data. According to the findings of the histopathological examination, 34 of the 90 individuals had benign tumors, whereas 56 of them had malignant tumors. In a total of 18 instances, the ultrasound predicted benign diagnosis; however, histology verified 16 of those cases as benign, while the other two cases were really malignant. There were 72 instances in which ultrasound was able to predict the presence of cancer; of those, but 54 were found to be malignant, while 18 were found to be benign following histological examination. (Figs. 1-3)

There was a moderate level of agreement between the results of the ultrasonography and the histology, as shown by the Kappa value of 0.479 (Table 2). This suggests that the ultrasound was relatively accurate, but it was not completely accurate in distinguishing benign lumps from malignant masses. The Chi-square test yielded a p-value of 0.000, which indicates that the agreement between ultrasonography and histology was statistically significant. Furthermore, the likelihood of this agreement being the result of random chance is very low. Histopathology continues to be the gold standard for final diagnosis, despite the fact that the ultrasonography exhibited a decent capacity to anticipate malignancy via its abilities. According to the Kappa value, there is a modest level of agreement between the two diagnostic modalities, which indicates the need of integrating them in order to achieve more accurate and trustworthy breast cancer diagnosis and therapy.



Fig. 1: The mammography shows a dense speculated lesion in central upper quadrant of breast overlying skin thickening and nipple retraction is seen. BI-RADS 6 breast lesion

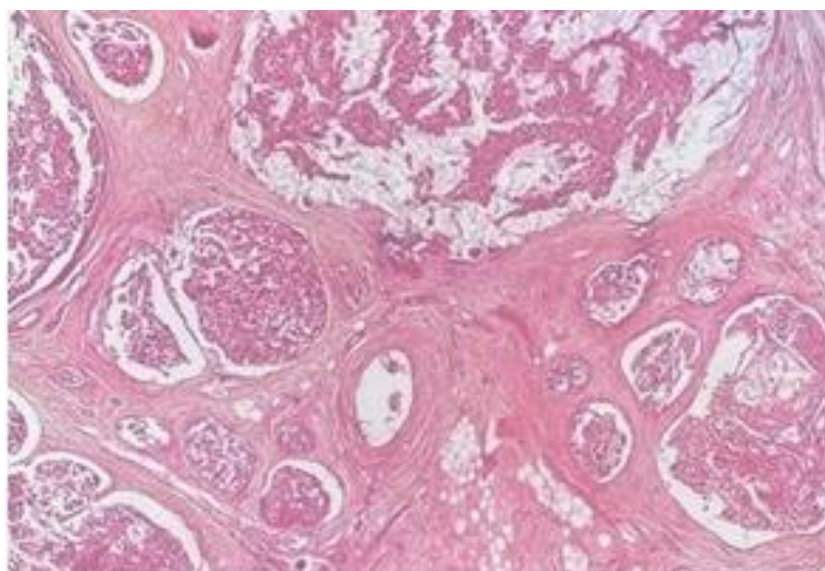
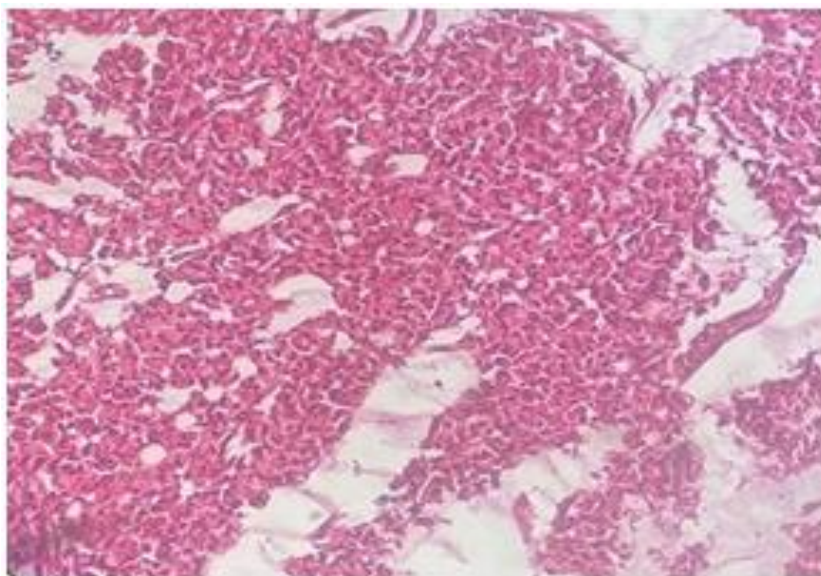


Fig. 2: The H&E stained sections show invasive breast ductal carcinoma with mucinous differentiation (10%), grade 3



**Fig. 3: High power view (40x) showing nests of neoplastic cells and surrounding mucin pools**

**Table 1: Breast lump features of the participants (n=90)**

Variable	No.	%
<b>Laterality</b>		
Unilateral	89	98.9
Bilateral	1	1.1
<b>No. of lesions</b>		
Unique	85	94.4
Multiple	5	5.6
<b>Shape</b>		
Oval	75	83.3
Round	11	12.2
Dysmorphic	4	4.4
<b>Outlines</b>		
Regular	18	20
Irregular	72	80
<b>BI-RADS Classification</b>		
1	-	-
2	10	11.1
3	8	8.9
4	47	52.2
5	22	24.4
6	3	3.3
<b>Sampling Technique</b>		
Needle biopsy	84	93.3
Surgical excision	6	6.7

**Table 2: Correlation between histopathology and radiographic findings**

Ultrasound	Histopathology		Total	Kappa Value	Chi-square Test
	Benign	Malignant			
Benign	16	2	18	0.479	0.000
Malignant	18	54	72		
Total	34	56	90		



## DISCUSSION

We compared our results with a study by Eng et al<sup>15</sup> similarly found significant insights into the age distribution of participants presenting with breast lumps. Eng et al<sup>15</sup> reported a mean age of  $46.3 \pm 11.4$  years, which is consistent with the mean age seen in similar studies like those conducted by Akinnibosun-Raji et al<sup>2</sup> and Bello et al<sup>16</sup> who found mean ages of  $33.03 \pm 12.32$  and  $34.66 \pm 13.99$  years, respectively. This aligns with the trend that younger, premenopausal women tend to present with non-proliferative breast diseases, as was also observed in our study.

The distribution of benign versus malignant lesions differed notably between Eng et al<sup>15</sup> and our study. Eng et al<sup>15</sup> also reported that 6.4% of lumps were benign, and 93.6% were malignant, with ductal carcinoma being the most common malignant lesion, present in 81.6% of cases. This is consistent with our findings, where 81.6% of lesions were malignant, predominantly ductal carcinoma. Eng et al<sup>15</sup> showed lower percentage of benign lesions may be attributed to its focus on a tertiary care facility that manages more advanced cancer cases.

In terms of lesion characteristics, irregular margins are common features of malignant lesions. And oval shaped smooth lesions on ultrasound are usually benign.<sup>17</sup> In this study the many of the lumps were oval but they had irregular margins.

In previous studies, BI-RADS 4 and BI-RADS 5 classifications were most frequently observed, indicating a high suspicion of malignancy. In our study, 52.2% of cases were classified as BI-RADS 4 and 24.4% as BI-RADS 5, closely mirroring the 52.1% and 26.1% reported by Eng et al.<sup>15</sup> The consistency between our results and those of the Eng et al<sup>14</sup> who emphasizes the utility of the BI-RADS system for assessing breast lumps.

The present study, however, showed that the overall ability of ultrasound to differentiate between malignant and benign lesions had a moderate agreement with histopathology, reflected by a Kappa value of 0.479, slightly higher than the 0.332 reported by Eng et al.<sup>15</sup> This moderate agreement is consistent with previous studies, and while the positive predictive value (PPV) and negative predictive value (NPV) in our study were lower, both being 26.2%, other studies reported significantly higher PPV and NPV values, indicating the variability depending on inclusion criteria and disease prevalence and subjective differences in diagnosis.<sup>16-22</sup>

Finally, previous studies highlighted the importance of integrating histopathological analysis with imaging findings, as discrepancies can arise from inappropriate sampling or targeting of lesions during imaging and sometimes due to reporting errors.<sup>22</sup> Ghafoor et al<sup>23</sup> reported that concordance rates between radiology and histopathology can vary significantly and Eng et al<sup>15</sup> reported 85.1% concordance rate, slightly higher than ours but consistent with the general trend of significant, though not perfect, diagnostic agreement.

The findings of this study and other previous data highlight the strengths and limitations of ultrasound in diagnosing breast lumps, reaffirming the need for combining imaging techniques with histopathological analysis for accurate diagnosis.

## LIMITATION OF THE STUDY

This study has several limitations that must be acknowledged. Firstly, the sample size is relatively small, consisting of only a limited number of cases. The small sample size reduces the generalizability of our findings. Secondly, the data was collected from a single institution, which may introduce institutional biases and limit the applicability of the results to other settings or populations. Moreover, this study does not cover various Histopathological subtypes of breast cancer and other factors like staging. Future research should aim to include larger, multicenter cohorts and incorporate comprehensive pathological and clinical data to validate and extend the findings of this study.

## CONCLUSION

In terms of distinguishing between benign and malignant lesions, ultrasonography and mammography demonstrated a high level of performance. The discordant instances, on the other

hand, bring to light the need of clinical, radiological and pathological correlation to minimize diagnostic errors.

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## CONFLICT OF INTEREST

Not to declare.

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Not to disclose.

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