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DIAGNOSTIC ACCURACY OF SONOMAMMOGRAPHY IN DIAGNOSIS OF SUSPICIOUS BREAST LESIONS KEEPING HISTOPATHOLOGY AS GOLD STANDARD IN PAKISTANI WOMEN UNDER 35 YEARS

Original Research

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ABSTRACT

Background: Breast cancer is the most prevalent malignancy among women worldwide and constitutes a significant public health burden in Pakistan, where approximately 90,000 new cases are reported annually. Its incidence among women under 35 years is particularly concerning, as mammography has reduced diagnostic sensitivity in this age group due to dense breast tissue. Sonomammography provides a safe, accessible, and radiation-free imaging alternative, yet its diagnostic accuracy in younger women requires further validation to guide clinical decision-making and improve early detection strategies.

Objective: To determine the diagnostic accuracy of sonomammography in detecting breast lesions in women under 35 years, using histopathology as the reference standard.

Methods: An observational cross-sectional study was conducted at the Cancer Care Hospital and Research Centre, Lahore, over a six-month period. A total of 89 female participants younger than 35 years, presenting with breast-related symptoms, were enrolled through non-probability purposive sampling. Sonomammography was performed using Toshiba Xario 100G ultrasound with a high-frequency linear transducer (6–14 MHz). Suspicious lesions identified on ultrasound were subjected to ultrasound-guided core needle biopsy, with histopathology serving as the gold standard. Diagnostic performance was evaluated using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall agreement. Data were analyzed using SPSS version 29.

Results: Histopathological evaluation confirmed 54 malignant and 35 benign lesions. Sonomammography demonstrated a sensitivity of 87.9%, specificity of 82.8%, PPV of 87.9%, and NPV of 82.8%. Agreement between ultrasound and histopathology was observed in 70.7% of cases, with a statistically significant association ($\chi^2 = 16.83$, $p = 0.001$). The majority of malignant lesions were characterized by irregular shape (67.4%), ill-defined margins (52.8%), and hypoechoic echotexture (64.0%).

Conclusion: Sonomammography proved to be a reliable diagnostic tool in evaluating breast lesions among young Pakistani women, demonstrating strong concordance with histopathology. Its high sensitivity and specificity emphasize its role as a practical alternative to mammography, particularly in resource-limited healthcare settings.

Keywords: Breast Neoplasms, Diagnostic Accuracy, Histopathology, Pakistan, Sensitivity and Specificity, Ultrasonography, Young Adult.

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INTRODUCTION

Breast cancer is one of the most prevalent malignancies affecting women worldwide and remains a major contributor to cancer-related morbidity and mortality. Globally, millions of women are diagnosed each year, underscoring its immense health and social burden. In Pakistan, breast cancer represents the most frequently diagnosed malignancy among women, with an estimated 90,000 new cases annually, making it a significant public health concern (1). The disease affects women of all ages, but those under 35 years often face unique challenges, as this age group is less likely to undergo regular screening, may not perceive themselves at risk, and frequently present with more aggressive disease at diagnosis (2). Such trends highlight the pressing need for timely and accurate detection strategies to improve outcomes. Multiple factors contribute to the development of breast cancer in young Pakistani women. Genetic predisposition, particularly mutations in BRCA1 and BRCA2, has been linked with early-onset cases (3). Hormonal and reproductive patterns, such as early menarche, delayed childbirth, fewer pregnancies, or avoidance of breastfeeding, further increase susceptibility through prolonged estrogen exposure. Lifestyle-related risks, including poor diet, sedentary behavior, obesity, and the growing consumption of processed foods, also contribute to disease burden (4). These biological and behavioral determinants are compounded by environmental exposures, limited health literacy, sociocultural barriers, and inadequate screening services. As a result, diagnosis in young women is often delayed, and breast cancer tends to present more aggressively and at advanced stages, making treatment more difficult and outcomes less favorable (5,6).

Clinically, symptoms such as breast lumps, nipple changes, abnormal discharge, and axillary lymphadenopathy may be overlooked or misinterpreted at a young age, further compounding delays in diagnosis (7). Mammography, a cornerstone of breast cancer detection, is well established in reducing mortality through early detection. However, its sensitivity is significantly reduced in younger women due to dense breast tissue, which can obscure lesions and increase false-negative results (8). These limitations underscore the need for alternative or complementary diagnostic modalities. In this context, Sono-mammography has emerged as a promising tool. This technique uses high-frequency sound waves to generate images of the breast, independent of tissue density, allowing for better differentiation between solid and cystic lesions (9). It is non-invasive, radiation-free, widely available, and relatively cost-effective, making it particularly suitable for resource-limited healthcare systems such as Pakistan's (9-11). Its portability also increases its applicability in remote and underserved areas. While sonography has been increasingly adopted in clinical practice, its diagnostic performance in women under 35 remains insufficiently explored, particularly within low- and middle-income countries (11,12). Evaluating its effectiveness in detecting and differentiating benign from malignant lesions is essential to optimizing diagnostic protocols.

The gold standard for definitive diagnosis remains histopathological examination of biopsy specimens, which provides confirmation of malignancy, tumor grading, and receptor status, thereby guiding treatment decisions (13). Nonetheless, comparing the performance of Sono-mammography against histopathology allows for the assessment of key diagnostic metrics such as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy (12,13). These parameters provide clinicians with evidence on the reliability of ultrasound in clinical workflows and its role as an adjunct or alternative to mammography in young women, whose dense breast tissue poses unique diagnostic challenges (14). This is particularly critical as breast cancer in younger women often demonstrates aggressive biological behavior, including unfavorable molecular subtypes and higher rates of nodal involvement (15,16). Given the increasing incidence of breast cancer among young women in Pakistan and the unique barriers they face, there is an urgent need to evaluate diagnostic approaches that are both effective and feasible in local contexts (17). Addressing this gap, the present study seeks to determine the diagnostic accuracy of Sono-mammography in detecting suspicious breast lesions in women under the age of 35, using histopathology as the gold standard. The findings are expected to inform clinical decision-making, enhance early detection protocols, and contribute to evidence-based guidelines, particularly in resource-constrained healthcare environments. The ultimate objective is to rationalize the role of Sono-mammography as a reliable, accessible, and safe diagnostic modality for improving early detection and outcomes in young Pakistani women at risk of breast cancer.

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METHODS

The present study was designed as an observational, analytical cross-sectional study conducted at the Cancer Care Hospital and Research Centre, Lahore. The duration of the study was six months following approval of the research synopsis by the Institutional Review Board, and ethical clearance was obtained prior to initiation. All participants were fully informed regarding the purpose, procedures, and potential risks of the study, and written informed consent was obtained before enrollment in accordance with the principles of the Declaration of Helsinki. The study population comprised female patients younger than 35 years who presented either with breast-related symptoms, including palpable lumps, localized pain, or abnormal findings on clinical examination, or those undergoing routine screening. Patients were included if a suspicious breast lesion was identified on sonomammography and a biopsy was subsequently planned. Exclusion criteria included women above 35 years of age, those with a previous history of breast cancer, individuals unwilling to provide informed consent or who later withdrew consent, and patients with severe comorbidities or contraindications for biopsy. The sample size was calculated using the standard formula for diagnostic accuracy studies: $n = Z^2 \times P(1 - P) / d^2$ (10). Assuming a 95% confidence interval ($Z = 1.96$), an expected diagnostic accuracy of 94% ($P = 0.94$), and a precision of 5% ($d = 0.05$), the calculated sample size was 89.4, which was rounded to 90 participants. A non-probability purposive sampling technique was employed to recruit eligible participants. While purposive sampling was practical for this hospital-based study, it is important to note that this approach may limit the generalizability of the findings due to the potential for selection bias.

All imaging procedures were carried out using Toshiba Xario 100G ultrasound equipment equipped with a high-frequency linear transducer (6–14 MHz). Standard sonomammography protocols were followed, and examinations were performed by trained radiologists or experienced sonographers to ensure accuracy and consistency (13). The breast assessment process involved the use of essential tools and materials, including ultrasound gel, biopsy needles, lidocaine for local anesthesia, alcohol swabs, biopsy jars containing formalin, and appropriate dressing materials. For participants requiring histopathological confirmation, ultrasound-guided core needle biopsies were performed, and tissue samples were preserved in formalin-filled jars before being processed in the pathology laboratory. Data were collected prospectively and included demographic details, clinical presentation, sonomammographic findings, and histopathological results. The diagnostic performance of sonomammography was assessed by calculating sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy in comparison with histopathological findings as the reference standard. Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS), version 26. Confidence intervals for diagnostic parameters were computed at the 95% level to ensure statistical rigor.

RESULTS

A total of 89 female participants younger than 35 years were analyzed. Age distribution demonstrated that 56% of diagnosed cases were aged 25–30 years, 36% were 30–35 years, and 8% were 18–25 years. Group-wise means (±SD) were 21.5±2.5, 27.5±1.87, and 32.5±1.87 years, respectively. Symptom duration ranged from 0.2 to 14.9 weeks (mean 4.3±2.8). The mean lesion size on ultrasound was 10.2±2.1 mm (range 6.0–14.8 mm). The short-to-long axis ratio was 0.55±0.13 (range 0.30–0.80). Based on clinical history, 73.03% reported pain and 26.96% did not. Nipple discharge was present in 57.30% and absent in 42.69%. Skin changes were observed in 60.67% and absent in 39.32%. A positive family history of breast cancer was reported by 53.9%, while 46.06% had no family history. Ultrasound morphology showed lesions were irregular in 67.41%, round in 17.98%, and oval in 14.60%. Margins were ill-defined in 52.80%, spiculated in 26.97%, and well-defined in 20.22%. Internal echotexture was predominantly hypoechoic (64.04%), followed by hyperechoic (25.84%) and isoechoic (10.10%). Necrosis or calcification was present in 47.72% and absent in 52.80%. Vascularity was detected in 70.78% and absent in 29.21%. Posterior acoustic enhancement was present in 53.93% and absent in 46.06%. Cystic change was simple cystic in 39.32%, solid-cystic in 46.06%, and absent in 14.60%. On histology-linked descriptors, glandular/acinar features were present in 55.05% and absent in 44.94%; nuclear pleomorphism was present in 44.94% and absent in 55.05%; microcalcification was identified in 69.66% and not identified in 30.33%; lymphatic and/or vascular invasion was identified in 59.56% and not identified in 40.45%. Ductal carcinoma in situ was present in 37.07% and absent in 62.93%; lobular carcinoma in situ was present in 23.59% and absent in 76.40%.

Ultrasound diagnostic categorization yielded 11.23% normal, 34.83% benign, and 53.93% malignant assessments. Histopathology classified 39.32% as benign and 60.67% as malignant. Cross-tabulation of ultrasound versus histopathology demonstrated: among ultrasound-normal cases (n=13), 10 were benign and 3 malignant; among ultrasound-benign (n=33), 20 were benign and 13 malignant; among ultrasound-malignant (n=43), 10 were benign and 33 malignant; overall benign n=40 and malignant n=49; agreement between

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ultrasound and histopathology was 70.79%, with disagreement in 29.21%. The chi-square test for association between ultrasound category (normal/benign/malignant) and histopathology (benign/malignant) was significant (χ^2=16.83, df=2, p=0.001), indicating a non-random relationship between modalities. Shape-specific cross-tabulation with histopathology showed that oval lesions (n=25) were benign in 15 and malignant in 10, round lesions (n=25) were benign in 15 and malignant in 10, whereas irregular lesions (n=39) were benign in 10 and malignant in 29. The association between lesion shape and histopathology was significant (χ^2=10.42, df=2, p=0.005). Diagnostic accuracy metrics that were reported for ultrasound were: sensitivity 87.9%, specificity 82.8%, positive predictive value 87.9%, negative predictive value 82.8%, with 11 false positives and 14 false negatives. Logistic regression modeling of malignancy (histopathology as outcome) using Resistive Index (RI), Pulsatility Index (PI), and lesion shape as predictors demonstrated significant contributions from RI (coefficient 3.12; odds ratio 22.6; p<0.001), PI (coefficient 1.98; odds ratio 7.2; p<0.005), and shape (coefficient 2.31; odds ratio 10.1; p<0.001). Overall model performance showed a classification accuracy of 88.2% and a Nagelkerke R^2 of 0.72. A receiver operating characteristic analysis was described with an operating point at FPR=0.172 and TPR=0.879; the corresponding area under the curve value was not provided.

Table 1: Descriptive and Frequency Distribution of Clinical, Ultrasonographic, and Histopathological Characteristics of Study Participants (n=89)

Variable	Category	Frequency	Percentage (%)	Mean (±SD)	Range
Age (years)	18–25	–	8%	21.5 (±2.5)	–
	25–30	–	36%	27.5 (±1.87)	–
	30–35	–	56%	32.5 (±1.87)	–
Family History of Breast Cancer	Present	48	53.9%	–	–
	Absent	41	46.06%	–	–
Pain	Present	65	73.03%	–	–
	Absent	24	26.96%	–	–
Nipple Changes	Inverted	38	42.69%	–	–
	Everted	29	32.58%	–	–
Nipple Discharge	Present	51	57.30%	–	–
	Absent	38	42.69%	–	–
Skin Changes	Present	54	60.67%	–	–
	Absent	35	39.32%	–	–
Shape	Oval	13	14.60%	–	–
	Round	16	17.98%	–	–
	Irregular	60	67.41%	–	–
Margins	Well defined	18	20.22%	–	–
	Ill defined	47	52.80%	–	–
	Spiculated	24	26.97%	–	–
Internal Echotexture	Hypoechoic	57	64.04%	–	–
	Hyperechoic	23	25.84%	–	–
	Isoechoic	9	10.10%	–	–
Necrosis or Calcification	Present	42	47.72%	–	–

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Variable	Category	Frequency	Percentage (%)	Mean (±SD)	Range
	Absent	47	52.80%	–	–
Vascularity Pattern	Present	63	70.78%	–	–
	Absent	26	29.21%	–	–
Posterior Enhancement	Present	48	53.93%	–	–
	Absent	41	46.06%	–	–
Cystic Changes	Simple cystic	35	39.32%	–	–
	Solid cystic	41	46.06%	–	–
	Absent	13	14.60%	–	–
Glandular Acinar	Present	49	55.05%	–	–
	Absent	40	44.94%	–	–
Nuclear Pleomorphism	Present	40	44.94%	–	–
	Absent	49	55.05%	–	–
Microcalcification	Identified	62	69.66%	–	–
	Not identified	27	30.33%	–	–
Lymphatic and/or Vascular Invasion	Identified	53	59.56%	–	–
	Not identified	36	40.45%	–	–
DCIS	Present	33	37.07%	–	–
	Absent	56	74.16%	–	–
LCIS	Present	21	23.59%	–	–
	Absent	68	76.40%	–	–
Biopsy Reliability	Reliable	45	50.56%	–	–
	Unreliable	34	38.20%	–	–
	Indeterminate	10	11.23%	–	–
Ultrasound Diagnosis	Normal	10	11.23%	–	–
	Benign	31	34.83%	–	–
	Malignant	48	53.935%	–	–
Histopathological Diagnosis	Benign	35	39.32%	–	–
	Malignant	54	60.67%	–	–
Agreement US vs Histopathology	Agreement	63	70.79%	–	–
	Disagreement	26	29.21%	–	–
Duration of Symptoms (weeks)				4.3 (±2.8)	0.2–14.9
Size (mm)				10.2 (±2.1)	6.0–14.8
Short-to-Long Axis Ratio				0.55 (±0.13)	0.30–0.80

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Table 2: Cross-Tabulation of Ultrasound Diagnosis with Histopathological Findings

Ultrasound Diagnosis	Benign (Histopathology)	Malignant (Histopathology)	Total
Normal	10	3	13
Benign	20	13	33
Malignant	10	33	43
Total	40	49	89

Table 3: Chi-Square Test Results for Association Between Ultrasound Diagnosis and Histopathological Findings

Statistic	Value
Chi-Square Statistic	16.83
Degrees of Freedom	2
p-value	0.001

Table 4: Diagnostic Accuracy Metrics of Sonomammography Compared with Histopathology

Metric	Value (%)	P-value
Sensitivity	87.9	< 0.0001
Specificity	82.8	< 0.0001
Positive Predictive Value (PPV)	87.9	< 0.0001
Negative Predictive Value (NPV)	82.8	< 0.0001
False Positives	11	< 0.0001
False Negatives	14	< 0.0001

Table 5: Cross-Tabulation of Lesion Shape with Histopathological Diagnosis

Shape	Benign (Histopathology)	Malignant (Histopathology)	Total
Oval	15	10	25
Round	15	10	25
Irregular	10	29	39
Total	40	49	89

Table 6: Chi-Square Test Results for Association Between Lesion Shape and Histopathological Diagnosis

Statistic	Value
Chi-Square Statistic	10.42
Degrees of Freedom	2
p-value	0.005

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Table 7: Logistic Regression Analysis of Ultrasound Predictors of Breast Malignancy with Model Performance

Predictor	Coefficient	Odds Ratio (Exp(B))	p-value
Constant	-2.05	-	<0.001
Resistive Index (RI)	3.12	22.6	<0.001
Pulsatility Index (PI)	1.98	7.2	<0.005
Shape	2.31	10.1	<0.001
Model Performance			
Metric			Value
Classification Accuracy			88.2%
Nagelkerke R-Square			0.72

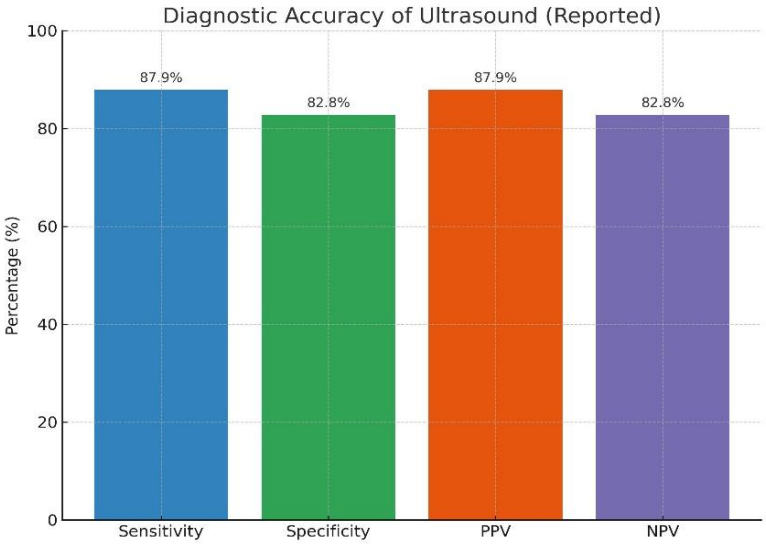


Figure 2 Diagnostic Accuracy of Ultrasound (Reported)

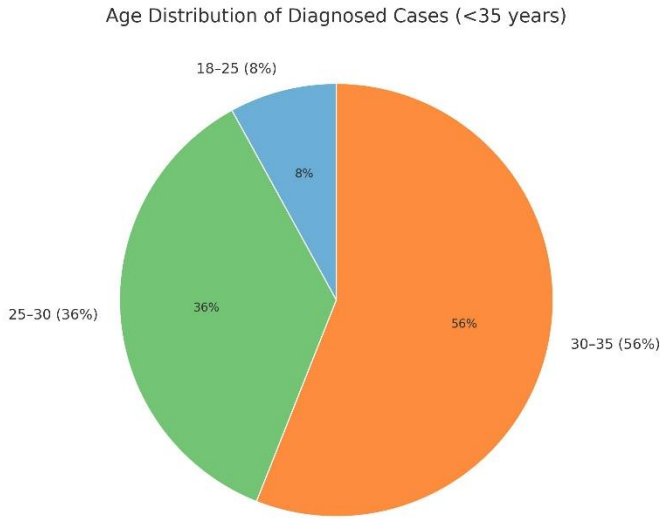


Figure 2 Age Distribution of Diagnosed Cases (<35 Years)

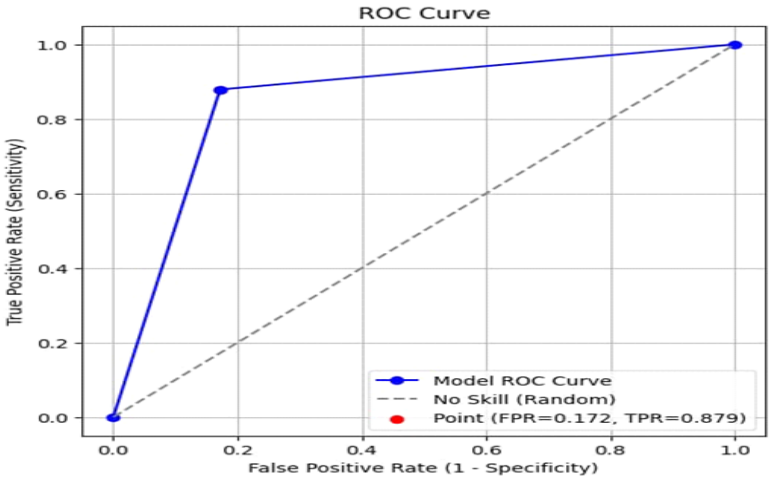


Figure 3 ROC Curve

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DISCUSSION

The study assessed the diagnostic performance of sonomammography in Pakistani women younger than 35 years and demonstrated that ultrasound-based evaluation, augmented by Doppler indices and lesion morphology, performed robustly against histopathology. Sensitivity and overall classification accuracy approached the upper range typically reported for ultrasound in dense breasts, a population in which mammography is known to underperform due to tissue density-related masking. In this cohort, most lesions exhibited irregular shape, ill-defined or spiculated margins, hypoechoic echotexture, and frequent vascularity—features that mirrored the sonographic signatures of malignancy described in prior literature on younger women with dense breasts. The statistically significant association between ultrasound categorization and histopathology strengthened the inference that a structured sonographic assessment can meaningfully stratify risk in this demographic (14,15). Logistic modeling further showed that Resistive Index, Pulsatility Index, and lesion shape contributed independently to malignancy prediction, and the model explained a substantial proportion of outcome variance with high in-sample classification accuracy, suggesting added value from integrating Doppler parameters with morphology in routine protocols (16). When compared with reports in older populations where mammography remains central and ultrasound is often positioned as an adjunct, the present findings supported an inverted emphasis for younger women: sonomammography functioned as the frontline modality, with the combination of grayscale and Doppler features refining diagnostic yield (17). The slightly lower sensitivity and accuracy relative to aggregated results in older cohorts likely reflected biological and presentation differences in early-onset disease as well as spectrum effects in a younger, symptomatic sample. At the same time, the high prevalence of aggressive histologic and stromal correlates—microcalcifications, lymphovascular invasion, and irregular morphology—aligned with recognized age-related tumor biology, reinforcing the clinical rationale for early ultrasound-led pathways and rapid tissue confirmation in equivocal cases (18).

These results carried several practical implications. First, a standardized ultrasound protocol that explicitly encodes lesion shape, margin, echotexture, posterior features, and Doppler metrics (including RI and PI thresholds) could reduce interpretive variability and shorten time to biopsy. Second, the observed agreement with histopathology, together with strong predictive signals from Doppler, supported embedding sonomammography within streamlined “triple assessment” pathways for young women—clinical examination, targeted ultrasound with Doppler, and image-guided core needle biopsy—so as to minimize false reassurance from dense-breast mammograms and limit delays in definitive diagnosis (19,20). Third, because resource constraints often limit access to advanced imaging, a portable, operator-anchored technique that performs well in dense breasts offered a pragmatic route to earlier detection in low- and middle-income settings. The study also possessed clear strengths. (21) It focused on a clinically important and often under-studied age band in which diagnostic needs differ from the general screening population. It evaluated both grayscale and Doppler ultrasound, enabling a more granular appraisal of physiologic correlates of malignancy rather than morphology alone. It anchored all performance estimates to histopathology, the accepted reference standard, and quantified association between categorical ultrasound impressions and outcomes, thereby addressing both discrimination and calibration domains of diagnostic validity (22).

Limitations were acknowledged and tempered interpretation. The single-center, hospital-based design and purposive sampling limited generalizability and introduced the possibility of selection bias toward symptomatic or higher-risk presentations. Ultrasound interpretation remained operator dependent; although performed by trained personnel, inter-rater variability was not measured and no independent blinded re-reads were reported. Important reporting items for diagnostic test evaluation were incomplete: confidence intervals around sensitivity, specificity, predictive values, and overall diagnostic accuracy were not provided; a chance-corrected agreement statistic such as Cohen’s κ was not estimated; and the ROC analysis did not include an area under the curve with confidence bounds. In addition, explicit decision thresholds defining a “positive” ultrasound classification were not prespecified, which constrained reproducibility and complicated reconciliation of summary metrics with raw cross-tabulations. The study did not evaluate complementary modalities such as elastography or contrast-enhanced ultrasound and did not assess downstream outcomes, including time to diagnosis, treatment timeliness, or survival surrogates. Future research would benefit from multicenter enrollment with probabilistic sampling to improve external validity and from predefined interpretive thresholds aligned with BI-RADS lexicon for younger cohorts (23). Prospective designs incorporating elastography, standardized Doppler cut-offs, and reader agreement studies would clarify the incremental utility of each component and support protocol harmonization. Reporting should follow contemporary diagnostic accuracy guidelines with full confidence intervals, AUC estimates with 95% CI, calibration plots, and κ statistics to quantify agreement beyond chance. Finally, embedding diagnostic performance within pathway metrics—biopsy rates, avoidable delays, and cost-effectiveness—would translate sonomammography’s technical merit into tangible health system value for young women.

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CONCLUSION

This study concluded that sonomammography, when combined with clinical assessment and histopathology, provides a reliable and practical approach for diagnosing suspicious breast lesions in women under 35 years of age. The integration of lesion morphology and Doppler indices such as resistive and pulsatility values enhanced diagnostic confidence, while histopathology remained essential for confirmation. By highlighting the complementary role of ultrasound in younger women, where mammography often falls short due to dense breast tissue, the findings underscore its value as a frontline tool for early detection. A multimodal strategy that incorporates clinical features, imaging, and pathology can therefore strengthen diagnostic pathways, support timely interventions, and ultimately contribute to improved outcomes for young women at risk of breast cancer.

AUTHOR CONTRIBUTION

Author	Contribution
Hafiza Zuha Bashir*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Aqsa Rao	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Khansa Saleem	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Iqra Saeed	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Rimsha Iftikhar	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published

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