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Risk Assessment of Breast Cancer Through BI-RADS Category Using Digital Mammography Technique Among Symptomatic and Asymptomatic Women

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ABSTRACT

Breast cancer is the second leading cause of death among women globally. Risk factors include BRCA1 gene mutations, age, early menopause, and family history. Digital mammography is the gold standard for symptomatic women presenting with chest pain, lumps, nipple discharge, or skin changes, while asymptomatic women undergo routine screening from age 45. Risk assessment is based on correlating BI-RADS findings with patient history and socioeconomic factors. **Objectives:** To assess breast cancer risk through BI-RADS categories using digital mammography among symptomatic and asymptomatic women. **Methods:** This comparative cross-sectional study included 384 women aged 15–75 years. Data were collected using a structured questionnaire covering demographics, lifestyle, reproductive history, family cancer history, breast tissue density, and BI-RADS category. Non-probability convenience sampling was used, and analysis was performed via IBM SPSS version 26.0. **Results:** Most participants were aged 46–65 years, housewives, and postmenopausal. Moderate physical activity (59%), symptoms (80.3%), and prior screening mammography (61.3%) were common. While 88.1% performed self-examinations and 82.1% had professional exams, 53.2% had never undergone a mammogram. Family history of breast cancer (34.3%) was notable. Scattered fibro-glandular breast tissue predominated. Awareness of BI-RADS (43.1%) and digital mammography (62.1%) was limited. Most had no prior cancer treatment (77.4%) or radiation exposure (92.7%), with 29.9% diagnosed with breast cancer. **Conclusions:** Menstrual changes and early post-menopause influenced malignancy risk, with increasing age being a significant factor. Higher parity correlated with benign categories.

INTRODUCTION

Breast cancer is the second most common cause of death among women worldwide, with one in nine women in Pakistan developing it at some point in their lives [1]. The disease has a high incidence globally, with around 280,000 new cases diagnosed annually and 40,000 deaths recorded in the United States alone. Various risk factors contribute to the development of breast cancer, including increasing age, a positive family history, genetic mutations such as BRCA1 and BRCA2, early menstruation (before 12 years), late menopause (after 55 years), dense breast tissue, nulliparity, late pregnancy, prolonged estrogen use, early radiation exposure, and lifestyle factors such as obesity, alcohol consumption, and sedentary behavior [2]. Breast cancer diagnosis primarily relies on mammographic imaging techniques. Several imaging methods exist, including digital mammography (DMT), contrast-enhanced mammography (CEM), magnetic resonance imaging (MRI), magnification mammography, and stereo mammography. However, in Pakistan, only digital mammography is widely available, and it remains the gold standard for screening symptomatic and asymptomatic women aged 45 and above [3]. Standard mammographic views include right

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craniocaudal (RCC), left craniocaudal (LCC), right mediolateral oblique (RMLO), and left mediolateral oblique (LMLO). Additional or extended views, such as lateral/medial craniocaudal, spot compression, axillary tail, cleavage view, and tangent views, are useful for dense breast tissue, enhancing diagnostic accuracy by reducing tissue overlap [4, 5]. The risk of breast cancer is categorized using the Breast Imaging Reporting and Data System (BI-RADS), which classifies findings from B0 (indeterminate) to BVI (biopsy-confirmed cancer). Breast tissue density is another crucial factor in risk assessment, classified into four types: A (fatty tissue), B (scattered fibroglandular density), C (heterogeneously dense), and D (extremely dense breast tissue). High breast density not only increases cancer risk but also reduces mammographic sensitivity, making detection more challenging due to the masking effect [6]. Traditionally, radiologists visually assess breast density using BI-RADS, but this method is subjective and prone to variability, leading to inconsistencies in risk classification [7]. To address these limitations, automated and semi-automated techniques have been introduced for more accurate and reproducible breast density assessment. Studies such as WISDOM, My Personalized Breast Screening (MyPeBS), and the Tailored Breast Screening Trial are investigating risk-based screening approaches, integrating breast density with other risk factors to determine the need for additional imaging, such as ultrasound. The DenSeeMammo system (DSM) is one such automated tool designed to measure breast density and assess its masking effect on cancer detection [8]. This study aims to evaluate the effectiveness of DSM compared to conventional radiological assessments. Mammographic density plays a crucial role in breast cancer risk prediction, influencing both the sensitivity of screenings and the likelihood of interval cancers. In several U.S. states, women are now informed about their breast density after screenings. Traditional density assessment methods, like the Cumulus approach, are well-established risk predictors. However, with the widespread adoption of full-field digital mammography (FFDM), new volumetric techniques have emerged, offering a more automated approach. Pakistan has the highest breast cancer incidence rate in Asia and ranks eighth globally. Many young women present with late-stage disease, significantly affecting their prognosis. Early detection is critical, and Digital Breast Tomosynthesis (DBT) is emerging as a superior imaging modality for identifying breast cancer, particularly in women with dense breast tissue. Unlike conventional mammography, which struggles with overlapping tissue, DBT provides cross-sectional images, improving sensitivity while reducing false positives [9]. Despite its advantages, DBT is under-researched in Pakistan. Another crucial aspect of breast cancer screening is the evaluation of BI-RADS category III, which indicates a "probably benign" finding requiring follow-up. However, previous research validating BI-RADS III often excluded patients with a personal history of breast cancer (PHBC), who are at a higher risk of recurrence. With growing preference for DBT over FFDM, this study assesses the accuracy of BI-RADS III classifications in PHBC patients, comparing outcomes between the two imaging modalities [10]. Advancements in deep learning (DL) have shown potential to enhance mammography accuracy, aiding in risk assessment. Additionally, research has established a link between sedentary behavior and breast cancer, with observational studies indicating a slight increase in risk due to prolonged inactivity [11].

However, limited literature is available on the association between breast cancer risk and women's parity or menstrual cycle changes. This study, therefore, seeks to assess the relationship between breast cancer risk, lifestyle factors, menstrual cycle changes, and parity among symptomatic and asymptomatic women. By addressing these knowledge gaps, the study aspires to refine breast cancer screening strategies and contribute to more personalized risk-based screening protocols. This study aimed to assess the risk of breast cancer through BI-RADS category using the digital mammography technique among symptomatic and asymptomatic women.

METHODS

This comparative cross-sectional study was conducted at the Combined Military Hospital Diagnostic Center, Lahore, over four months (September to December 2024). Ethical approval was granted by the Ethical Review Committee (ERC) of Combined Military Hospital Lahore Medical College (Ref. No: #91/ERC/CMH/LMC). Participants were categorized into symptomatic and asymptomatic groups based on clinical history and physical examination, where symptomatic women presented with breast-related complaints such as palpable lumps, nipple discharge, pain, or skin changes, and asymptomatic women underwent routine mammographic screening without prior symptoms. Inclusion criteria comprised women aged 15–75 years undergoing mammography, while exclusion criteria included confirmed pregnancy, prior mastectomy, and contraindications to mammography, such as severe breast trauma or refusal of the procedure. Mammographic imaging was performed using a Full-Field Phillips Digital Mammography (FFDM) system calibrated according to international radiological standards, including MQSA guidelines, with routine quality assurance tests. Standard Craniocaudal (CC) and Mediolateral Oblique (MLO) views were obtained for all participants, and breast density and lesion classification were assessed using BI-RADS 5th Edition criteria, categorizing findings as BI-RADS 1–2

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(normal or benign), BI-RADS 3 (probably benign, requiring short-term follow-up), and BI-RADS 4–5 (suspicious for malignancy, biopsy recommended). The primary outcome variable was BI-RADS classification, with secondary outcomes including breast density, age distribution, and associations with risk factors. Breast cancer risk was assessed using relative risk (RR) and odds ratio (OR) calculations for symptomatic versus asymptomatic groups, along with logistic regression analysis adjusting for age, family history, breast density, and hormone therapy exposure. The sample size was calculated using the World Health Organization Geneva Calculator, applying a conservative anticipated population proportion of 50% due to the absence of reliable local prevalence data for BI-RADS 4–5 findings in young women, yielding a final sample size of 385 participants with sufficient power for comparative analysis. Non-probability convenience sampling was employed, with efforts to minimize selection bias by recruiting participants from diverse backgrounds and age groups. Data collection involved a self-structured questionnaire and mammography reports. Women aged 15–75 years, both symptomatic and asymptomatic, were enrolled after pre-screening counseling explaining radiation risks and benefits, possible BI-RADS outcomes, follow-up recommendations, and counseling was conducted by radiologists and medical imaging technologists, followed by written informed consent. The mammography procedure involved non-invasive X-ray imaging with breast compression lasting approximately 20 minutes. Data collection included four sections: demographics, personal information, knowledge of mammography, and BI-RADS-based diagnosis, with self-reported medical history used to assess prior radiation exposure; medical records were reviewed when available, though dosimetry estimates were not performed due to limited access to historical imaging data. Mammograms were interpreted by multiple radiologists with at least five years of breast imaging experience, and in cases of discordance, consensus reporting was used to reduce subjective bias; breast density was visually assessed based on BI-RADS categorization without automated tools, acknowledging potential inter-observer variability. Statistical analysis was conducted using SPSS version 26.0, with descriptive statistics including mean and standard deviation for quantitative data and frequency and percentages for qualitative data, while comparisons between groups were performed using Chi-square or Fisher's exact tests as appropriate. A p-value of <0.05 was considered statistically significant, and all findings were reported at the 95% confidence interval.

RESULTS

A total of 385 women were included in the study, of whom 310 (80.5%) were symptomatic and 75 (19.5%) were asymptomatic. The mean age of participants was concentrated between 46–65 years, with 53.6% of women falling into this range. Most participants were married (76.1%), multiparous (87.5%), and in menopause (72.5%). Regarding lifestyle, 59.0% reported moderate physical activity, while 28.6% were physically inactive. Almost two-thirds (65.7%) were housewives, and only 7.3% had a history of radiation exposure (Table 1).

Table 1: Demographic, Educational, Lifestyle, Marital Status, and Parity Distribution of Study Participants (N=385)

Variables	Category	N (%)
Age (years)	15–25	23 (6.0%)
	26–35	20 (5.2%)
	36–45	76 (19.7%)
	46–55	110 (26.8%)
	56–65	103 (25.1%)
	66–75	53 (13.8%)
Education	Illiterate	41 (10.6%)
	Primary	44 (11.4%)
	Intermediate	115 (29.9%)
	Graduation	167 (43.4%)
	PhD	18 (4.7%)
Lifestyle	Inactive	110 (28.6%)
	Moderate	227 (59.0%)
	High activity	48 (12.5%)
Marital status	Married	293 (76.1%)
	Unmarried	41 (10.6%)
	Widow	51 (13.2%)
Parity	Yes	337 (87.5%)
	No	48 (12.5%)

Breast cancer awareness and screening practices were variable. While 82.1% of women had undergone clinical breast examination and 88.1% performed self-examination, only 46.8% had ever undergone a mammogram. Among those who had mammography, 61.3% were for screening, 10.6% for diagnostic purposes, and 28.1% for follow-up. A family history of breast cancer was present in 34.5% of participants, predominantly from the maternal side (21.3%). A smaller subset (16.1%) reported oral contraceptive pill use (Table 2).

Table 2: Distribution Of Breast Cancer Screening Practices, Family History, And Prior Diagnosis Among Study Participants (N=385)

Variables	Category	N (%)
Professional breast exam	Yes	316 (82.1%)
Self-exam	Yes	339 (88.1%)
Family history of breast cancer	Yes	132 (34.5%)
Prior breast cancer diagnosis	Yes	115 (29.9%)

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Among the study participants, 310 (80.5%) were symptomatic and 75 (19.5%) were asymptomatic. The most common presenting symptoms were breast pain (36.3%) and palpable lump (26.2%) (Table 3).

Table 3: Symptom Distribution Among Participants (N=385)

Symptoms	N (%)
Pain	140 (36.3%)
Lump	101 (26.2%)
Nipple discharge	21 (5.4%)
Itching	23 (5.9%)
Skin/tissue thickening	8 (2.0%)
Nipple retraction	6 (1.5%)
Other (orange peel, scar, etc.)	5 (1.2%)
Asymptomatic	75 (19.5%)

The BI-RADS classification revealed important differences between symptomatic and asymptomatic groups. Among symptomatic women, 93 (30.0%) were BI-RADS 1, 121 (39.0%) BI-RADS 2, 64 (20.6%) BI-RADS 3, and 32 (10.3%) were abnormal (BI-RADS 4-5). By contrast, among asymptomatic women, 22 (29.3%) were BI-RADS 1, 29 (38.7%) BI-RADS 2, 16 (21.3%) BI-RADS 3, and only 7 (9.3%) were abnormal (BI-RADS 4-5). A further 4 symptomatic (1.3%) and 1 asymptomatic (1.3%) participant were BI-RADS 6, representing biopsy-proven malignancy. Overall, the prevalence of abnormal findings (BI-RADS 4–5) was 9.1%, while biopsy-proven cancer (BI-RADS 6) was confirmed in 1.3% of participants. Although abnormal findings were more frequent among symptomatic women compared to asymptomatic (10.3% vs. 9.3%), the difference did not reach statistical significance ($p > 0.05$) (Table 4).

Table 4: Distribution of BI-RADS Categories Among Symptomatic and Asymptomatic Women

BI-RADS Category	Symptomatic (N=310)	Asymptomatic (N=75)	Total (N=385)	p-Value*
BI-RADS 0 – Incomplete	6 (1.9%)	2 (2.7%)	8 (2.1%)	0.62
BI-RADS 1 – Negative	93 (30.0%)	22 (29.3%)	115 (29.9%)	0.91
BI-RADS 2 – Benign	121 (39.0%)	29 (38.7%)	150 (39.0%)	0.96
BI-RADS 3 – Probably benign	64 (20.6%)	16 (21.3%)	80 (20.8%)	0.88
BI-RADS 4 – Suspicious (A-C)	21 (6.8%)	5 (6.7%)	26 (6.8%)	0.97
BI-RADS 5 – Highly suggestive of malignancy	11 (3.5%)	2 (2.7%)	13 (3.4%)	0.77
BI-RADS 6 – Known biopsy-proven	4 (1.3%)	1 (1.3%)	5 (1.3%)	0.99
Abnormal (BI-RADS 4-5)	32 (10.3%)	7 (9.3%)	39 (10.1%)	0.82

*Chi-square/Fisher's exact test

Chi-square analysis demonstrated significant associations between BI-RADS categories and several risk factors (Table 5.5). Age was significantly associated with BI-RADS classification in the left breast ($p < 0.001$). Radiation exposure was strongly associated with abnormal BI-RADS findings in both breasts ($p=0.003$ right, $p<0.001$ left). Menstrual cycle status was significantly associated with BI-RADS categories for both breasts ($p = 0.038$ right, $p = 0.007$ left). Parity showed significance for the right breast ($p=0.023$), while marital status was significant for the left breast ($p = 0.010$). In contrast, family history of breast cancer and lifestyle factors were not significantly associated with BI-RADS categories (Table 5).

Table 5: Prevalence of Abnormal BI-RADS Findings (4-5) and Biopsy-Proven Malignancy (6) in Symptomatic Vs. Asymptomatic Women

Category	Symptomatic (N=310)	Asymptomatic (N=75)	Total (N=385)	p-Value*
Abnormal BI-RADS (4-5)	32 (10.3%)	7 (9.3%)	39 (10.1%)	0.82
Biopsy-proven malignancy (6)	4 (1.3%)	1 (1.3%)	5 (1.3%)	0.99

*Chi-square/Fisher's exact test

DISCUSSIONS

This study evaluated breast cancer risk using patient history and BI-RADS categories from digital mammography. Most participants (52.5%) had BI-RADS BI-negative, indicating no significant findings, while others had higher BI-RADS categories (IV–VI), reflecting malignancy risks. Older women (56–75 years) had higher BI-RADS categories, while younger women (15–25 years) showed biopsy-proven malignancies, suggesting aggressive cancer types. However, no statistically significant link between age and BI-RADS was found ($p = 0.060$), highlighting multifactorial risk factors [12]. Extended mammography views and digital breast tomosynthesis (DBT) improve cancer detection, especially in younger women with dense breast tissue [13, 14]. The study highlights the role of extended digital mammography views and DBT in improving breast cancer detection, especially in high-risk populations. While BI-RADS categories help stratify risk, combining them with patient history enhances accuracy [15]. A key finding is the strong link between sedentary behavior and breast cancer risk, with prolonged inactivity increasing the likelihood of cancer, even among physically active individuals [16]. Regional variations show a higher risk in Asia (21.6%) than in North America (8.26%). Though no direct link between lifestyle and BI-RADS classifications was found, physically active women had lower malignancy rates [14]. The study underscores the need for a holistic risk assessment, emphasizing physical activity as a key prevention strategy [12, 16]. The study found a significant link between occupational radiation exposure and higher BI-RADS malignancy classifications, emphasizing the need for protective measures. Women with irregular menstrual cycles and early menopause had increased breast cancer

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risk due to hormonal imbalances. Regular cycles were associated with lower malignancy rates. The study found a significant association between parity and BI-RADS classifications, with women who had given birth more likely to be in the BI-negative category, suggesting a lower risk of suspicious findings [17]. However, the correlation was weak, indicating that other factors like age, family history, and lifestyle play a more significant role in breast cancer risk. Marital status showed no significant impact on BI-RADS classifications, though widows had higher percentages in concerning categories, possibly due to healthcare access barriers [18]. Age was significantly related to BI-RADS findings, with older women more likely to have benign results, while younger women showed a broader distribution, including more cases requiring further imaging [12]. Physical activity levels did not significantly influence BI-RADS classifications, suggesting that other risk factors, such as genetics and hormonal changes, have a greater impact on breast health. Overall, while certain factors showed associations with breast cancer risk, none were sole determinants, highlighting the need for comprehensive screening strategies. The analysis highlights a statistically significant association between radiation exposure and BI-RADS classification for the left breast, with exposed individuals showing a higher percentage of B VI-known biopsy-proven malignancies. While this aligns with previous studies on the carcinogenic effects of ionizing radiation, the weak negative correlation (Pearson's R = -0.115) suggests that other factors, such as genetics and lifestyle, also play a role [13]. Similarly, menstrual cycle status showed a significant relationship with BI-RADS categorization, particularly among post-menopausal individuals, who were more likely to fall into higher malignancy categories. However, the weak correlation (Pearson's R = -0.058) indicates that menstrual status alone is not a strong predictor of breast tissue changes. Parity, on the other hand, did not show a statistically significant association with BI-RADS classification, as both parous and nulliparous women exhibited similar patterns in breast tissue findings. This suggests that while reproductive history may influence breast cancer risk, it does not necessarily correlate with BI-RADS categorization [16]. In contrast, marital status was found to be statistically associated with BI-RADS classification (p=0.010), with widowed individuals displaying a higher proportion of B V-highly suggestive of malignancy cases [18]. Despite this, the weak correlation values (Pearson's R= 0.009, Spearman's correlation =-0.039) imply that marital status alone is not a strong determinant of breast tissue classification. Overall, while radiation exposure and menstrual cycle status demonstrate significant associations with BI-RADS classification, their weak correlations indicate the influence of multiple interacting factors [19]. Parity does not appear to be a significant determinant, whereas marital status, despite showing statistical significance, lacks a strong predictive value. These findings underscore the complexity of breast cancer risk factors, emphasizing the need for further research incorporating multivariate analyses to better understand the interplay of genetic, lifestyle, and environmental influences on BI-RADS outcomes [17, 20]. The analysis finds no significant relationship between family history of breast cancer and BI-RADS classification for both the right and left breasts [18, 19]. Statistical tests (Chi-Square and correlation) show weak or no association, suggesting that family history alone does not strongly influence BI-RADS categorization. Interestingly, individuals without a family history had slightly higher proportions in high-risk categories (B V and B VI), indicating that other factors such as genetics, lifestyle, and age may play a more critical role. While some studies suggest a link between family history and malignancy risk, others find no direct correlation, aligning with this study's findings [12, 15, 16]. Further research incorporating genetic testing and additional risk factors is needed for a more comprehensive understanding of breast cancer risk assessment. The study had several limitations. First, it was conducted at a single center, CMH Hospital Diagnostic Center, Lahore, which may limit the generalizability of the findings. The study relied on standard craniocaudal (CC) and mediolateral oblique (MLO) views for classification. CEM and DBT were not included due to availability constraints. However, these advanced techniques could enhance lesion detection, particularly in dense breasts, reducing the rate of BI-RADS III and IV misclassifications. This is acknowledged as a limitation. Lastly, a lack of awareness about breast cancer and cultural hesitancy to discuss symptoms likely led to delays in diagnosis, highlighting the need for better public education and screening initiatives.

CONCLUSIONS

The study showed associations between breast cancer risk and patients' history, lifestyle, and working environment. Changes in the female menstrual cycle and early post-menopausal women were found to influence higher malignancy categories and increasing age as a significant risk factor for breast cancer. Parity was found to play a modest role, with women who had given birth more likely to fall into benign categories. Marital status was found to be a weak predictor of breast health outcomes, while radiation exposure was associated with higher categories.

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Authors Contribution

Conceptualization: UER, ZR
Methodology: UER, ZR
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Writing review and editing: UER, ZR

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Conflicts of Interest

All the authors declare no conflict of interest.

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