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ISSN: 2663-9491 e-ISSN: 2789-6897

ORIGINAL ARTICLE

Predictors of Malignancy in Patients Presenting with Breast Lumps: A Multivariable Analysis from a Tertiary Surgical Center

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Received: 19 August 2026
Accepted: 24 August 2026
Published Online: 26 August 2026

Published by:
Gopalganj Medical College, Gopalganj, Bangladesh

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DOI: 10.5281/zenodo.22115597

ABSTRACT

Background: *Breast cancer is the prevalent type of cancer among women globally and in Bangladesh. While the majority of breast lumps are non-cancerous, identifying malignant tumors can be difficult. Clinical and ultrasound characteristics can aid in predicting cancer, whereas histopathology offers a conclusive diagnosis. Data on independent factors predicting cancer in breast lump patients in Bangladesh is still scarce. This research sought to determine clinical and imaging factors independently linked to malignancy through multivariable analysis.* ***Methods & Materials:*** *An analytical observational study based in a hospital took place at Bangladesh Medical University from March 2025 to February 2026, involving 244 patients aged 18 years and older with noticeable breast lumps. Demographic, clinical, imaging, and histopathological information was gathered. Histopathological evaluation confirmed malignancy, and independent predictors were determined through multivariable logistic regression. Statistical significance was established at p<0.05.* ***Results:*** *Among 244 patients, 70 (28.7%) had malignant lesions, with invasive carcinoma NST being the predominant histological type. Multivariable analysis identified older age, positive family history, larger lump size, skin/nipple changes, and BI-RADS 4–5 as independent predictors of malignancy. BI-RADS 4–5 showed the strongest association (aOR 11.21, 95% CI: 4.72–26.62; p<0.001), followed by age >50 years (aOR 4.57) and lump size ≥5 cm (aOR 3.91).* ***Conclusion:*** *Older age, positive family history, larger breast lump size, skin/nipple changes, and BI-RADS 4–5 were independent predictors of malignancy. Integrating these clinical and imaging features may improve early identification and timely diagnosis of breast cancer among patients presenting with breast lumps.*

Keywords: *Breast Lumps, Malignancy, Predictors, Breast cancer*

(The Insight 2026; 9(3): 719-723)

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INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among women worldwide and remains a major public health concern, with approximately 2.4 million new cases and 694,000 deaths reported globally in 2024 [1]. In Bangladesh, breast cancer is also the leading cancer among women, representing a substantial public health burden. Early diagnosis is crucial because localized disease is more amenable to curative treatment and is associated with better survival than advanced disease [2,3].

A breast lump is a common reason for presentation to breast clinics and surgical services. Although most palpable breast lumps are benign, a clinically important proportion are malignant. Therefore, any new or persistent breast lump requires appropriate evaluation, as breast cancer may initially present as a painless mass [4,5]. Differentiating benign from malignant lumps can be challenging because of overlapping clinical features. Age, lump characteristics, skin or nipple changes, axillary lymphadenopathy, and family history may help assess malignancy risk; however, malignancy can occur in the absence of recognized risk factors [6,7].

Certain clinical findings, including hard or irregular masses, fixation, skin or nipple changes, and axillary lymphadenopathy, may raise suspicion for malignancy, although early breast cancer may present as a small, painless, mobile mass. Imaging is therefore essential, with ultrasound generally preferred in younger women and diagnostic mammography or tomosynthesis recommended for women aged 40 years or older. BI-RADS 4–5 lesions generally require tissue sampling [8,9]. Suspicious ultrasound features such as irregular shape, spiculated margins, non-parallel orientation, marked hypoechogenicity, and posterior acoustic shadowing are associated with malignancy. Combining these features with age, family history, and lesion stiffness may further improve malignancy prediction [10,11]. Histopathological examination remains the definitive method for diagnosing breast malignancy. Core needle biopsy provides tissue architecture and enables pathological and immunohistochemical assessment, making tissue diagnosis essential for confirming malignancy and guiding treatment [12,13].

Previous research on predictors of malignancy in patients presenting with breast lumps has emphasized the value of clinical, imaging, pathological, and biomarker-related factors in distinguishing malignant from benign lesions [14,15]. Studies from Bangladesh have demonstrated a broad histopathological spectrum of breast lesions and highlighted the importance of tissue sampling, including true-cut biopsy and FNAC, in evaluating breast lumps [16,17].

Despite these findings, evidence on independent predictors of malignancy among patients presenting with breast lumps

ISSN: 2663-9491 e-ISSN: 2789-6897

remains limited in Bangladesh, particularly in tertiary surgical settings. Therefore, this study aimed to identify clinical and imaging factors independently associated with malignancy among patients presenting with breast lumps using multivariable analysis.

METHODS & MATERIALS

Study Design and Setting

A hospital-based analytical observational study was conducted to identify demographic, clinical, and imaging predictors of malignancy among patients presenting with breast lumps. The study was conducted at Bangladesh Medical University (BMU), Dhaka, a tertiary-level referral center, over a period of one year from March 2025 to February 2026**.**

Study Population

The study population comprised patients aged 18 years or older who presented to the surgical service of BMU with a clinically detectable breast lump during the study period. Patients who fulfilled the predefined eligibility criteria and had a definitive histopathological diagnosis were included in the study. A total of 244 patients were included in the final analysis.

Inclusion and Exclusion Criteria

Patients aged 18 years or older who presented with a palpable breast lump, underwent clinical assessment and breast imaging, and had a definitive histopathological diagnosis were included. Patients with previously diagnosed breast malignancy presenting for follow-up, recurrent breast cancer, incomplete clinical or imaging records, or unavailable histopathological results were excluded from the study.

Sampling Technique and Sample Size

A consecutive sampling technique was used to recruit eligible patients during the study period. All patients presenting with breast lumps who fulfilled the inclusion criteria were considered for enrollment, resulting in a final sample of 244 participants over the one-year study period.

Data Collection

Data were collected using a structured data collection form based on patient interviews, clinical examinations, imaging reports, and histopathological records. Information included age, sex, family history of breast cancer, parity, breastfeeding history, oral contraceptive use, presenting symptoms, location and size of the breast lump, skin or nipple changes, imaging findings, BI-RADS category, and final histopathological diagnosis.

Clinical Assessment

All participants underwent clinical examination of the breast and regional lymph nodes. Presenting symptoms, including painless or painful breast lump, nipple discharge, and skin or nipple changes, were recorded. The anatomical location of each lump was documented according to the breast quadrant. Lump size was measured in centimeters and categorized as <2 cm, 2–4.9 cm, and ≥5 cm for statistical analysis.

Imaging Assessment

Breast imaging was performed using ultrasonography and/or mammography, according to the patient's age and clinical indication. Imaging findings were assessed using the Breast Imaging Reporting and Data System (BI-RADS) classification. For analysis, lesions were categorized into BI-RADS 2–3 **and** BI-RADS 4–5 groups.

Histopathological Assessment

Histopathological examination of biopsy or surgical specimens was considered the reference standard for determining the final diagnosis. Based on histopathological findings, patients were classified into benign and malignant groups. The primary outcome of the study was histopathologically confirmed malignancy.

Statistical Analysis

Data were entered, cleaned, and analyzed using IBM SPSS Statistics version 27. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Associations between selected demographic and clinical characteristics and malignancy were assessed using the Chi-square test or Fisher's exact test, as appropriate. Variables showing significant associations in the univariable analysis were entered into a multivariable binary logistic regression model to identify independent predictors of malignancy. Adjusted odds ratios (aORs) with 95% confidence intervals (CIs) were reported. Clinically relevant reference categories included age ≤30 years, absence of family history, lump size <2 cm, absence of skin/nipple changes, and BI-RADS 2–3. A p-value <0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the appropriate Institutional Review Board/Ethics Committee of Bangladesh Medical University before initiation of the study. Written informed consent was obtained from participants where applicable. Patient confidentiality was maintained throughout data collection, analysis, and reporting, and all information was used exclusively for research purposes.

RESULTS

Baseline Characteristics of the Study Participants

Table I shows total of 244 patients with breast lumps were included. The mean age was 43.6 ± 12.7 years (range: 18–78 years). Most participants were aged 31–40 years (69, 28.3%) or ≤30 years (66, 27.0%), and 236 (96.7%) were female. A positive family history of breast cancer was reported by 31 (12.7%) participants. Most were parous (207, 84.8%) and had a history of breastfeeding (198, 81.1%), while 72 (29.5%) reported oral contraceptive use. The most common presentation was a painless breast lump (154, 63.1%), followed by a painful lump (53, 21.7%), nipple discharge (22, 9.0%), and skin or nipple changes (15, 6.1%). The upper outer quadrant was the most frequently affected site (109, 44.7%), followed by the upper inner quadrant (47, 19.3%) and lower outer quadrant (36, 14.8%).

ISSN: 2663-9491 e-ISSN: 2789-6897

Table I: Sociodemographic and Clinical Characteristics of the Study Participants (*n*=244)

Characteristics	Frequency (n)	Percentage (%)
Age group (years)		
≤30	66	27.0
31–40	69	28.3
41–50	57	23.4
>50	52	21.3
Sex		
Female	236	96.7
Male	8	3.3
Family history of breast cancer		
No	213	87.3
Yes	31	12.7
Parity		
Nulliparous	37	15.2
Parous	207	84.8
History of breastfeeding		
No	46	18.9
Yes	198	81.1
Oral contraceptive use		
No	172	70.5
Yes	72	29.5
Presenting symptom		
Painless lump	154	63.1
Painful lump	53	21.7
Nipple discharge	22	9.0
Skin/nipple changes	15	6.1
Site of lump		
Upper outer quadrant	109	44.7
Upper inner quadrant	47	19.3
Lower outer quadrant	36	14.8
Lower inner quadrant	24	9.8
Central/other	28	11.5

Histopathological Diagnosis

Table II shows histopathological examination revealed that 70 (28.7%) patients had malignant breast lesions, while 174 (71.3%) had benign lesions. Among the malignant lesions, invasive carcinoma of no special type was the predominant histological diagnosis (57, 81.4%), followed by invasive lobular carcinoma (6, 8.6%), other invasive/combined carcinomas (4, 5.7%), and other malignant lesions (3, 4.3%). Among the benign lesions, fibroadenoma was the most frequent diagnosis (71, 40.8%), followed by fibrocystic disease (41, 23.6%), benign phyllodes tumour (18, 10.3%), breast cyst (16, 9.2%), and other benign lesions (28, 16.1%).

Table II: Histopathological Diagnosis of Breast Lumps (*n*=244)

Histopathological diagnosis	Frequency (n)	Percentage (%)
Benign lesions	174	71.3
Fibroadenoma	71	29.1
Fibrocystic disease	41	16.8
Benign phyllodes tumour	18	7.4
Breast cyst	16	6.6
Other benign lesions	28	11.5
Malignant lesions	70	28.7
Invasive carcinoma NST	57	23.4
Invasive lobular carcinoma	6	2.5
Another invasive/combined carcinoma	4	1.6
Other malignant lesions	3	1.2

Association Between Clinical Characteristics and Malignancy

Table III presents malignancy increased significantly with age, from 4 (6.1%) cases among patients aged ≤30 years to 31 (59.6%) among those aged >50 years (p<0.001). A positive family history was also associated with malignancy (51.6% vs. 25.4%, p=0.003). Malignancy was more frequent among patients with painless lumps than painful lumps (35.1% vs. 17.0%, p=0.018). Skin or nipple changes were strongly associated with malignancy (66.7% vs. 26.2%, p<0.001). Larger lump size was also significantly associated with malignancy, increasing from 9.3% for lumps <2 cm to 51.4% for lumps ≥5 cm (p<0.001).

ISSN: 2663-9491 e-ISSN: 2789-6897

Table III: Association Between Selected Clinical Characteristics and Malignancy (*n*=244)

Variable	Benign n (%)	Malignant n (%)	p-value
Age group			<0.001
≤30 years	62 (93.9)	4 (6.1)	
31–40 years	57 (82.6)	12 (17.4)	
41–50 years	35 (61.4)	22 (38.6)	
>50 years	21 (40.4)	31 (59.6)	
Family history			0.003
No	159 (74.6)	54 (25.4)	
Yes	15 (48.4)	16 (51.6)	
Painless lump	100 (64.9)	54 (35.1)	0.018
Painful lump	44 (83.0)	9 (17.0)	
Skin/nipple changes	5 (33.3)	10 (66.7)	<0.001
Lump size			<0.001
<2 cm	68 (90.7)	7 (9.3)	
2–4.9 cm	88 (70.7)	36 (29.3)	
≥5 cm	18 (48.6)	19 (51.4)	

Imaging Findings and Malignancy

Imaging characteristics demonstrated a strong association with histopathological malignancy. As shown in *Table IV*, among patients classified as BI-RADS 2–3, only 7 (5.1%) had malignant lesions, whereas malignancy was identified in 63 (59.1%) patients classified as BI-RADS 4–5 (p<0.001). Irregular lesion margins were observed in 45 (64.3%) malignant cases compared with 27 (15.5%) benign cases (p<0.001). Microcalcifications were present in 30 (42.9%) malignant lesions compared with 21 (12.1%) benign lesions (p<0.001). Similarly, heterogeneous echotexture and suspicious axillary lymph nodes were significantly more common among malignant lesions (p<0.001 for both).

Table IV: Imaging Characteristics According to Histopathological Diagnosis (*n*=244)

Imaging characteristic	Benign n (%)	Malignant n (%)	p-value
BI-RADS category			<0.001
BI-RADS 2–3	130 (94.9)	7 (5.1)	
BI-RADS 4–5	44 (40.9)	63 (59.1)	
Irregular margins	27 (15.5)	45 (64.3)	<0.001
Microcalcifications	21 (12.1)	30 (42.9)	<0.001
Heterogeneous echotexture	38 (21.8)	40 (57.1)	<0.001
Suspicious axillary lymph nodes	14 (8.0)	28 (40.0)	<0.001

Multivariable Logistic Regression Analysis

Variables significantly associated with malignancy in the univariable analysis were entered into a multivariable logistic regression model, including age, family history, presenting symptom, lump size, skin/nipple changes, and BI-RADS category. As shown in Table 5, age remained an independent predictor, with higher odds of malignancy among patients aged 41–50 years (aOR 3.18, 95% CI: 1.01–10.03, p=0.048) and >50 years (aOR 4.57, 95% CI: 1.47–14.19, p=0.009) compared with those aged ≤30 years. Positive family history (aOR 2.76, 95% CI: 1.19–6.40, p=0.017), lump size ≥5 cm (aOR 3.91, 95% CI: 1.46–10.49, p=0.007), and skin/nipple changes (aOR 3.63, 95% CI: 1.27–10.38, p=0.016) were also independent predictors. BI-RADS 4–5 showed the strongest association with malignancy (aOR 11.21, 95% CI: 4.72–26.62, p<0.001). Painless presentation was not independently significant after adjustment (aOR 1.48, 95% CI: 0.71–3.08, p=0.296) *Table V*.

Table V: Multivariable Logistic Regression Analysis of Predictors of Malignancy (*n*=244)

Predictor	Adjusted OR	95% CI	p-value
Age 31–40 years vs. ≤30 years	1.69	0.51–5.61	0.391
Age 41–50 years vs. ≤30 years	3.18	1.01–10.03	0.048
Age >50 years vs. ≤30 years	4.57	1.47–14.19	0.009
Positive family history	2.76	1.19–6.40	0.017
Painless presentation	1.48	0.71–3.08	0.296
Lump size 2–4.9 cm vs. <2 cm	2.37	1.01–5.56	0.047
Lump size ≥5 cm vs. <2 cm	3.91	1.46–10.49	0.007
Skin/nipple changes	3.63	1.27–10.38	0.016
BI-RADS 4–5 vs. BI-RADS 2–3	11.21	4.72–26.62	<0.001

Overall, older age, positive family history of breast cancer, larger lump size, skin or nipple changes, and BI-RADS 4–5 was independently associated with increased odds of malignancy among patients presenting with breast lumps

DISCUSSION

In the present study, the mean age of participants was 43.6 ± 12.7 years, with the largest proportion aged 31–40 years, followed by those aged ≤30 years; females constituted 96.7% of the study population. Most participants were parous and had a history of breastfeeding, while 12.7% reported a family history of breast cancer. Painless breast lump was the most common presentation, and the upper outer quadrant was the most frequently affected site. These findings are broadly consistent with previous studies reporting a predominance of younger and middle-aged women, marked female predominance, breast lump as the commonest presentation, and frequent involvement of the upper outer quadrant [18,19].

Histopathological examination showed that most breast lumps were benign, while 28.7% were malignant. Fibroadenoma was the commonest benign lesion, whereas invasive carcinoma of no special type predominated among malignant lesions. Similar histopathological patterns, with fibroadenoma as the leading benign lesion and invasive carcinoma as the major malignant diagnosis, have been reported previously [20]. These findings emphasize that although benign lesions predominate, histopathological examination remains essential for definitive diagnosis.

Several clinical characteristics were significantly associated with malignancy. The proportion of malignant lesions increased from 6.1% among patients aged ≤30 years to 59.6% among those >50 years. Positive family history, painless presentation, skin/nipple changes, and larger lump size were also associated with malignancy, with the highest proportions observed in patients with skin/nipple changes and lumps ≥5 cm. Previous studies have similarly identified increasing age and suspicious clinical features, including skin or nipple changes and larger breast masses, as indicators of malignancy [5,8]. These findings highlight the importance of careful clinical assessment, particularly in patients with multiple suspicious features.

Imaging findings further demonstrated strong discriminatory value. Malignancy was substantially more frequent among BI-RADS 4–5 lesions than BI-RADS 2–3 lesions, while irregular margins, microcalcifications, heterogeneous echotexture, and suspicious axillary lymph nodes were significantly more common in malignant lesions. This is consistent with previous evidence demonstrating a significant correlation between radiological and histopathological findings in breast lesions [21]. Thus, imaging assessment, particularly BI-RADS classification, can provide important guidance for identifying lesions requiring tissue diagnosis.

In multivariable analysis, older age, positive family history, larger lump size, skin/nipple changes, and BI-RADS 4–5 remained independent predictors of malignancy. BI-RADS 4–5 demonstrated the strongest association, followed by age >50 years, lump size ≥5 cm, and skin/nipple changes. Similar evidence has emphasized the importance of age, clinical risk factors, and suspicious imaging findings in predicting breast malignancy [5,8,9]. Overall, the findings indicate that integrating demographic, clinical, and imaging characteristics may improve risk stratification and facilitate timely diagnosis of breast cancer.

CONCLUSION

Older age, positive family history, larger breast lump size, skin/nipple changes, and BI-RADS 4–5 were independent predictors of malignancy among patients presenting with breast lumps. The strong association of suspicious BI-RADS categories with malignancy highlights the importance of appropriate imaging assessment. Combining demographic, clinical, and imaging characteristics may improve risk stratification, facilitate earlier identification of malignant lesions, and support timely biopsy and definitive management.

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