MAMMAGLOBIN EXPRESSION AND ITS ASSOCIATION WITH HORMONE RECEPTOR STATUS AND CLINICOPATHOLOGICAL CHARACTERISTICS IN INVASIVE BREAST CARCINOMA: IMMUNOHISTOCHEMICAL STUDY

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Abstract

Background

Breast cancer is a biologically heterogeneous malignancy, and reliable tissue biomarkers are needed to improve prognostic assessment. Mammaglobin, a breast-specific glycoprotein, has emerged as a promising immunohistochemical marker; however, evidence regarding its clinicopathological significance in Indian patients remains limited. The present study evaluated mammaglobin expression and its association with hormone receptor status and established clinicopathological parameters in invasive breast carcinoma.

Methods

This hospital-based cross-sectional study included 52 consecutive patients with histopathologically confirmed invasive ductal carcinoma (no special type) who underwent modified radical mastectomy between July 2024 and December 2025. Mammaglobin, estrogen receptor (ER), progesterone receptor (PR), and HER2 expression were assessed by immunohistochemistry. Associations between mammaglobin expression and clinicopathological variables were analyzed using the Chi-square test or Fisher's exact test, with $p<0.05$ considered statistically significant.

Results

Mammaglobin expression was observed in 31 of 52 tumors (59.6%). Positive expression showed a significant inverse association with histological grade, being more frequent in Grade II than Grade III tumors (80.0% vs. 46.9%; p=0.022). Mammaglobin positivity was also significantly associated with ER positivity (81.8% vs. 43.3%; p=0.009) and PR positivity (82.4% vs. 48.6%; p=0.034). No significant associations were identified with age, tumor size, lymphovascular invasion, lymph node status, or HER2 expression (all $p>0.05$).

Conclusion

Mammaglobin expression is significantly associated with lower histological grade and hormone receptor positivity in invasive breast carcinoma, supporting its role as a complementary immunohistochemical biomarker of favorable tumor biology. Although it was not associated with HER2 status or other clinicopathological variables, mammaglobin may provide additional prognostic information when interpreted alongside established pathological markers. Larger multicenter studies are warranted to validate its clinical utility.

Keywords: Breast Neoplasms, Mammaglobin-A, Immunohistochemistry, Estrogen Receptors, Progesterone Receptors

1. Introduction

reast cancer is the most frequently diagnosed malignancy among women worldwide and remains a major cause of cancer-related mortality.[1] Despite advances in screening and treatment, its incidence continues to rise, particularly in low- and middle-income countries. In India, breast cancer has surpassed cervical cancer as the leading cancer among women, with a steadily increasing incidence in both urban and rural populations.[2] Delayed presentation, limited awareness, and heterogeneous tumor biology contribute substantially to poor clinical outcomes.[3] According to GLOBOCAN 2020 estimates, India accounts for one of the highest global burdens of breast cancer, and the number of new cases is expected to increase considerably over the coming decades, emphasizing the need for reliable biomarkers that can improve diagnosis, prognostication, and therapeutic decision-making.[1,4]

Breast cancer is a biologically heterogeneous disease characterized by marked variations in histopathological features, molecular profiles, treatment response, and clinical outcome. Immunohistochemical evaluation of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor-2 (HER2) has become an integral component of routine pathological assessment because these biomarkers provide important prognostic information and guide targeted therapy.[5] Nevertheless, additional biomarkers capable of refining tumor characterization and predicting disease behavior continue to be investigated.

Mammaglobin-A (MGB-A), encoded by the SCGB2A2 gene on chromosome 11q13, is a member of the secretoglobin family and is highly expressed in normal mammary epithelium as well as in a large proportion of primary breast carcinomas. On immunohistochemistry, mammaglobin typically demonstrates cytoplasmic staining and has gained attention because of its high tissue specificity for breast epithelium.[6-7] Several studies have reported an association between mammaglobin expression and favorable clinicopathological features, including hormone receptor positivity, lower histological grade, and absence of lymph node metastasis. However, findings regarding its relationship with tumor stage, metastatic potential, HER2 expression, and overall prognosis remain inconsistent across different populations.[8-9]

Evidence regarding mammaglobin expression in Indian patients is relatively scarce, particularly studies evaluating its association with established prognostic markers and clinicopathological characteristics. Generating such data may help clarify the clinical significance of mammaglobin in the Indian population and determine its potential role as a complementary diagnostic and prognostic biomarker.

Therefore, the present study was undertaken to evaluate mammaglobin expression in invasive breast carcinoma, determine its association with ER, PR, and HER2 receptor status, and analyze its correlation with various clinicopathological parameters.

2. Materials And Methods

Study design and setting

This hospital-based cross-sectional study was conducted in the Department of Pathology, Sri Guru Ram Das Institute of Medical Sciences and Research (SGRDIMSAR), Sri Amritsar, Punjab, India, over an 18-month period from July 2024 to December 2025. The study included consecutive histopathologically confirmed cases of breast carcinoma received as modified radical mastectomy specimens for routine pathological examination.

Study participants

A total of 52 patients with histologically confirmed invasive breast carcinoma were enrolled. Cases that had received neoadjuvant chemotherapy or radiotherapy prior to surgery, lumpectomy specimens, recurrent tumors, autolyzed or inadequately preserved tissue samples, and specimens with insufficient tumor tissue for immunohistochemical evaluation were excluded from the study.

Institutional Ethics Committee approval was obtained before commencement of the study (IEC No. IEC/2024/015). Written informed consent was obtained from all participants, and the study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

Gland Surg
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Histopathological evaluation

All specimens were fixed in 10% neutral buffered formalin, processed routinely, embedded in paraffin, and sectioned at 3–5 μm thickness. Hematoxylin and eosin (H&E)-stained sections were examined to confirm the diagnosis. All included cases were identified as invasive ductal carcinoma of no special type (NST).

Histological grading was performed using the Nottingham modification of the Bloom–Richardson grading system based on three morphological parameters: tubule formation, nuclear pleomorphism, and mitotic count. The cumulative score was used to classify tumors into Grade I, Grade II, or Grade III. Axillary lymph nodes retrieved from the surgical specimens were examined microscopically for metastatic involvement.

Immunohistochemical analysis

Immunohistochemistry (IHC) was performed on representative paraffin-embedded tissue sections using commercially available monoclonal antibodies against estrogen receptor (ER), progesterone receptor (PR), HER2 (Diagnostic Biosystems, USA), and mammaglobin (Biocare Medical, USA).

Sections of 3–5 μm thickness were mounted on poly-L-lysine-coated slides and incubated overnight at 37°C. Following deparaffinization in xylene and rehydration through graded alcohols, antigen retrieval was carried out using the Decloaker method at 95°C for 1 hour. Endogenous peroxidase activity was blocked, followed by protein blocking to minimize nonspecific staining. Slides were incubated with the respective primary antibodies according to the manufacturers' recommendations, followed by post-primary reagent and polymer-based detection. Immunoreactivity was visualized using 3,3′-diaminobenzidine (DAB) chromogen, and sections were counterstained with hematoxylin before dehydration, clearing, and mounting.

ER and PR expression were considered positive when at least 1% of tumor cell nuclei showed brown nuclear staining. HER2 positivity was defined as complete circumferential membranous staining in more than 10% of invasive tumor cells. Mammaglobin expression was assessed by cytoplasmic staining, with normal breast epithelium serving as the positive control. Staining intensity was categorized according to the proportion of positive tumor cells as follows: score 0 (no staining), score 1+ (<10% positive cells), score 2+ (11–50% positive cells), and score 3+ (>50% positive cells). Tumors with a staining score of 1+ or higher were considered positive for mammaglobin expression.[10]

Study variables

The primary outcome was mammaglobin expression. Clinicopathological variables evaluated for association included patient age, histological grade, lymph node metastasis, ER status, PR status, and HER2 status.

Statistical analysis

Data were entered into Microsoft Excel and analyzed using IBM Statistical Package for the Social Sciences (SPSS) software (version 26.0; IBM Corp., Armonk, NY, USA). Categorical variables were summarized as frequencies and percentages. Associations between mammaglobin expression and clinicopathological variables were evaluated using the Chi-square test or Fisher's exact test, as appropriate based on expected cell frequencies. All statistical tests were two-tailed, and a p-value <0.05 was considered statistically significant.

3. Results

The study included 52 patients with histopathologically confirmed invasive ductal carcinoma (no special type). Patient age ranged from 29 to 80 years, with the highest proportion occurring in the 61–70-year age group (30.8%). The right breast was more frequently affected, and the upper outer quadrant was the most common tumor location (44.2%). Tumor size ranged from 1.0 to 10.5 cm, with most lesions measuring 2–5 cm (71.2%).

Histopathological evaluation showed that 32 tumors (61.5%) were Grade III and 20 (38.5%) were Grade II; no Grade I tumors were identified. Lymphovascular invasion (LVI) was present in 30 cases (57.7%).

Gland Surg
VOL-11 NO 1 (2026)
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Axillary lymph node metastasis was observed in 30 patients (57.7%), comprising 11 (21.2%) N1, 14 (26.9%) N2, and 5 (9.6%) N3 cases.

Immunohistochemically, ER positivity was observed in 22 cases (42.3%), PR positivity in 17 cases (32.7%), and HER2 positivity in 14 cases (26.9%).

Mammaglobin immunoreactivity demonstrated distinct cytoplasmic granular staining in tumor cells (Figures 1). Overall, 31 of 52 tumors (59.6%) showed positive mammaglobin expression. Based on the staining score, 5 cases (9.6%) exhibited 1+ expression, 14 (26.9%) showed 2+ expression, and 12 (23.1%) demonstrated 3+ expression (Figure 2).

No significant association was found between mammaglobin expression and age (p=0.110), tumor size (p=0.600), lymphovascular invasion (p=0.947), lymph node status (p=0.218), or HER2 status (p=0.825) (Tables 1-3).

A statistically significant inverse association was observed between mammaglobin expression and histological grade (p=0.022). Mammaglobin positivity was significantly higher in Grade II tumors (80.0%) than in Grade III tumors (46.9%), indicating reduced expression with increasing tumor grade (Table 2).

Mammaglobin expression also showed a significant positive association with hormone receptor status. Positive staining was observed in 81.8% of ER-positive tumors compared with 43.3% of ER-negative tumors (p=0.009). Similarly, 82.4% of PR-positive tumors expressed mammaglobin compared with 48.6% of PR-negative tumors (p=0.034) (Table 3).

Figures 1-2 illustrate the characteristic cytoplasmic staining pattern and distribution of mammaglobin expression, while Tables 1-3 summarize its relationship with clinicopathological and immunohistochemical parameters.

tumors at 81.8% and 82.4% respectively (Table: 3).

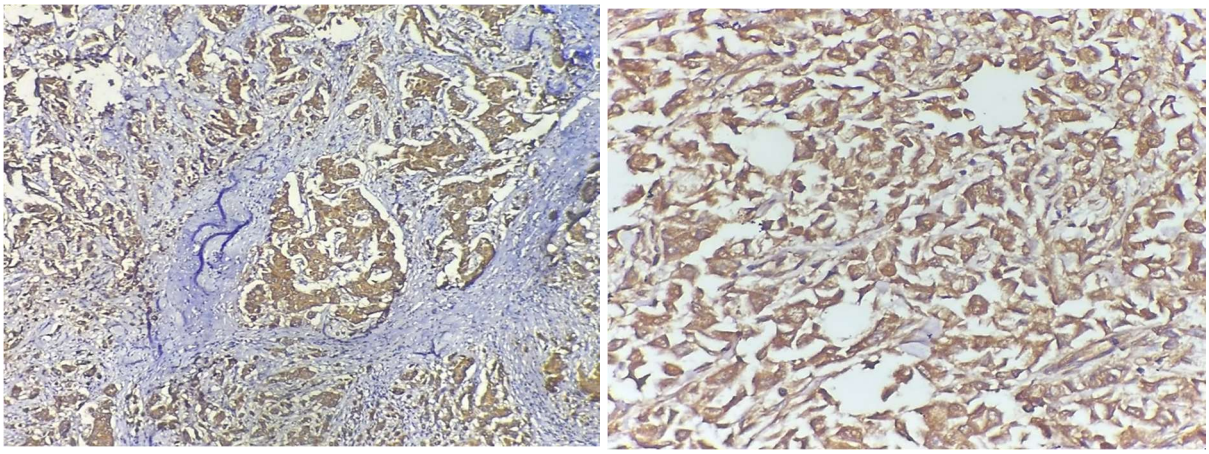

Figure 1: Immunohistochemical demonstration of mammaglobin expression in invasive ductal carcinoma (no special type), highlighting diffuse cytoplasmic granular staining at 100 and 400 magnification.

Gland Surg
VOL-11 NO 1 (2026)
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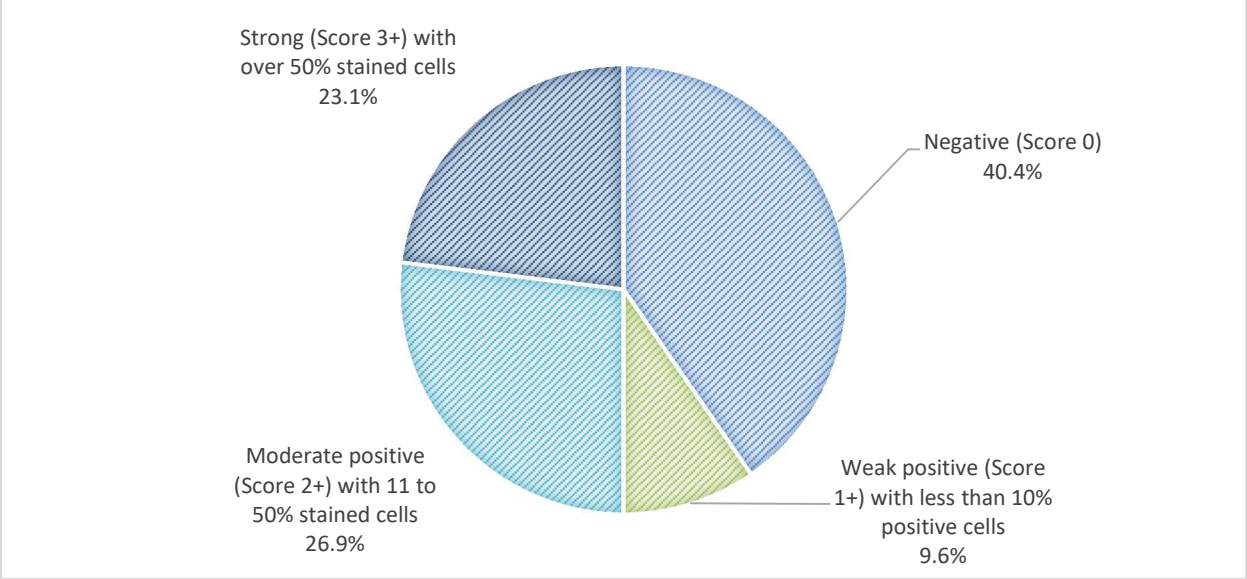

Figure 2: Immunohistochemical grading of mammaglobin expression based on the proportion of positively stained tumor cells

Table 1: Distribution of Mammaglobin Expression According to Age Group

Parameter	Category	Total (n)	Mammaglobin positive n (%)	Mammaglobin negative n (%)	χ^2 (df)	p-value
Age Group (Years)	≤40	10	5 (50.0)	5 (50.0)	7.608 (4)	0.110
	41-50	12	9 (75.0)	3 (25.0)		
	51-60	8	4 (50.0)	4 (50.0)		
	61-70	16	7 (43.8)	9 (56.2)		
	71-80	6	6 (100.0)	0 (0.0)		

Table 2: Association Between Mammaglobin Expression and Clinicopathological Characteristics

Parameter	Category	Total (n)	Mammaglobin positive n (%)	Mammaglobin negative n (%)	χ^2 (df)	p-value
Tumor Size	<2 cm	5	4 (80.0)	1 (20.0)	1.247 (2)	0.600
	2-5 cm	37	22 (59.5)	15 (40.5)		
	>5 cm	10	5 (50.0)	5 (50.0)		
Histological Grade	Grade I	0	0 (0.0)	0 (0.0)	5.609 (1)	0.022
	Grade II	20	16 (80.0)	4 (20.0)		
	Grade III	32	15 (46.9)	17 (53.1)		
LVI Status	Present	30	18 (60.0)	12 (40.0)	0.004 (1)	0.947
	Absent	22	13 (59.1)	9 (40.9)		
Lymph Node Status	N0	22	13 (59.1)	9 (40.9)	4.562 (3)	0.218
	N1	11	4 (36.4)	7 (63.6)		
	N2	14	11 (78.6)	3 (21.4)		
	N3	5	3 (60.0)	2 (40.0)		

Table 3: Association Between Mammaglobin Expression and Hormone Receptor (ER/PR) and HER2 Status

Parameter	Category	Total	Mammaglobin	Mammaglobin	χ^2 (df)	p-value

Gland Surg
VOL-11 NO 1 (2026)
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		(n)	positive n (%)	negative n (%)		
ER Status	Positive	22	18 (81.8)	4 (18.2)	7.808 (1)	0.009
	Negative	30	13 (43.3)	17 (56.7)		
PR Status	Positive	17	14 (82.4)	3 (17.6)	5.424 (1)	0.034
	Negative	35	17 (48.6)	18 (51.4)		
HER2 Status	Positive	14	8 (57.1)	6 (42.9)	0.049 (1)	0.825
	Negative	38	23 (60.5)	15 (39.5)		

4. Discussion

Breast cancer remains the most common malignancy among women in India and represents a major public health challenge owing to its increasing incidence and biological heterogeneity. Identification of reliable tissue biomarkers that complement conventional prognostic parameters is essential for improving risk stratification and therapeutic decision-making. In the present study, mammaglobin expression was evaluated in relation to established clinicopathological variables and hormone receptor status in invasive breast carcinoma.

The majority of patients belonged to the 61–70-year age group, reflecting the increasing incidence of breast cancer with advancing age. Although the peak age reported in Indian studies varies, our findings are broadly consistent with those of Sharma et al.[11], observed the highest incidence among women aged 40–60 years. Right-sided breast involvement predominated in our cohort, similar to the findings of Piplani et al.[12] The upper outer quadrant was the commonest tumor location, a finding that has been consistently reported and is generally attributed to the greater volume of glandular tissue in this region. Most tumors measured 2–5 cm, comparable to the observations of Sagar et al.[13], suggesting that a substantial proportion of patients continue to present with relatively large primary tumors.

Histopathological assessment demonstrated a predominance of Grade III tumors, indicating that a considerable number of patients presented with biologically aggressive disease. Similar findings were reported by Piplani et al.[12], whereas Sood & Nigam,[14] observed a higher frequency of Grade II tumors. Differences in sample size, referral patterns, and patient demographics may partly explain these variations. More than half of the patients in the present study showed lymphovascular invasion and axillary lymph node metastasis, underscoring the advanced pathological stage at presentation and highlighting the need for biomarkers that may improve prognostic assessment beyond routine histopathological evaluation.

The frequencies of ER (42.3%), PR (32.7%), and HER2 (26.9%) positivity were comparable with previous Indian studies. Kanwar et al.[15] reported similar ER and PR positivity rates, while Shukla et al.[16] documented HER2 positivity in approximately one-third of breast carcinomas. These observations indicate that the molecular profile of our study population is broadly representative of previously reported Indian cohorts.

Overall, 59.6% of tumors expressed mammaglobin, which falls within the range reported in the literature (approximately 50–84%). Comparable positivity rates have been documented by Kong et al.[17] and Baker et al.[18], whereas Raica et al.[10] reported relatively higher expression. Such variability is likely related to differences in patient populations, antibody clones, immunohistochemical protocols, scoring criteria, and tumor characteristics. Nevertheless, the consistently moderate-to-high expression across studies supports the value of mammaglobin as a breast-specific immunohistochemical marker.

No significant association was observed between mammaglobin expression and patient age, tumor size, lymphovascular invasion, or axillary lymph node status. Similar findings have been reported by Raica et al.[10], and Yadav et al.[19] suggesting that mammaglobin expression is largely independent of these clinicopathological variables. Although mammaglobin positivity appeared more frequent in smaller tumors, the absence of statistical significance indicates that tumor size alone is unlikely to influence its

Gland Surg
VOL-11 NO 1 (2026)
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expression.

A notable finding of the present study was the significant inverse association between mammaglobin expression and histological grade. Mammaglobin positivity was substantially higher in Grade II tumors than in Grade III tumors, indicating progressive loss of expression with increasing tumor dedifferentiation. Similar observations have been reported by Yadav et al.[19] and Ricks-Santi et al.[20] both of whom demonstrated significantly greater mammaglobin expression in lower-grade tumors. In contrast, Baker et al.[18] and Rehman & Nagi.[21] found no significant relationship between mammaglobin expression and tumor grade. Differences in sample size, grading distribution, and methodological approaches may account for these conflicting findings. The decline in mammaglobin expression with increasing histological grade may reflect reduced cellular differentiation in biologically aggressive tumors.

Another important observation was the significant association between mammaglobin expression and hormone receptor positivity. Mammaglobin expression was markedly higher in ER-positive and PR-positive tumors than in receptor-negative tumors, corroborating the findings of Ricks-Santi et al.[20] This association suggests that mammaglobin is preferentially expressed in hormonally responsive breast carcinomas, which generally exhibit a more favorable biological behavior and better response to endocrine therapy. In contrast, HER2 status showed no significant relationship with mammaglobin expression, indicating that mammaglobin expression appears to be more closely linked to hormone receptor pathways than to HER2-driven tumor biology.

Taken together, these findings indicate that mammaglobin expression is associated with lower histological grade and hormone receptor positivity, both established indicators of favorable prognosis. Although mammaglobin was not associated with tumor size, lymphovascular invasion, nodal status, or HER2 expression, its strong relationship with ER and PR status suggests that it may serve as a useful adjunctive biomarker for characterizing breast carcinoma. Larger multicenter studies incorporating molecular subtyping and long-term survival data are warranted to further define its prognostic and predictive value in routine clinical practice.

Limitations

The present study has certain limitations. It was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings. The cross-sectional design precluded assessment of disease-free survival, overall survival, and treatment response. In addition, molecular subtyping and long-term follow-up data were not available to further evaluate the prognostic significance of mammaglobin expression. Larger prospective multicenter studies incorporating survival outcomes are needed to validate these observations.

5. Conclusion

Mammaglobin was expressed in nearly 60% of invasive breast carcinomas and demonstrated significant associations with lower histological grade and positive ER and PR status. These findings indicate that mammaglobin is preferentially expressed in biologically less aggressive, hormone-responsive tumors and may serve as a useful adjunct to routine immunohistochemical evaluation. Although no significant relationship was observed with age, tumor size, lymphovascular invasion, lymph node status, or HER2 expression, mammaglobin provides complementary prognostic information when interpreted with established clinicopathological parameters. Further multicenter studies with larger cohorts and long-term follow-up are required to establish its prognostic and predictive value in routine clinical practice.

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Conflict of Interest: The authors declare no conflict of interest.

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Gland Surg
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