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Risk and Associations of Lymphadenopathy in Idiopathic Granulomatous Mastitis: Clinical and Ultrasound Findings from a Cross-Sectional Study

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ABSTRACT

Background: Idiopathic granulomatous mastitis (IGM) is a rare inflammatory breast disease posing diagnostic challenges. This study aimed to investigate the risk of lymphadenopathy (LAP) associated with clinical signs, demographic factors, and ultrasound parameters in IGM patients.

Methods: This cross-sectional study was conducted at the Breast Clinic of a university-affiliated hospital. Data were collected from the medical records of patients diagnosed with IGM between January and February 2023. Patients with complete medical records and diagnosed with IGM were included. Logistic regression analysis was performed to investigate the association between LAP and clinical signs, demographic factors, and ultrasound parameters.

Results: Overall, 140 patients with GM were included in this study. The prevalence of LAP among IGM patients was 20%. The logistic regression analysis revealed a nonsignificant association between LAP and IGM (adjusted OR, 0.823; 95% CI, 0.154–4.39; $P=0.819$). Similarly, clinical history variables, including age, breastfeeding, breast invasion, and marital status, did not show significant associations with IGM.

Conclusion: These findings highlight the complex interplay between clinical and imaging features in IGM, with axillary LAP and nodular LAP emerging as particularly interrelated characteristics.

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INTRODUCTION

Granulomatous mastitis (GM) is a rare disorder primarily affecting young women with a breastfeeding history, occurring in approximately 2.4 cases per 100,000 women.¹ This non-infectious inflammatory disease specifically affects breast tissue, characterized histopathologically by a granulomatous inflammatory response containing giant cells.² Despite its unknown cause, GM typically

occurs in young women following breastfeeding, within a 5-year postpartum period, presenting as either a localized palpable mass with enlarged lymph nodes or a diffuse condition.³

Clinically, GM is a benign, chronic inflammatory breast condition that mimics breast cancer symptoms, making diagnosis challenging and crucial. Although the exact cause of idiopathic GM (IGM) is unclear, associations with autoimmune disorders, oral contraceptive use, pregnancy, hyperprolactinemia, and alpha-1 antitrypsin deficiency have been suggested.^{4,5} IGM primarily affects women of reproductive age with breastfeeding histories, exhibiting varied signs and symptoms, including

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acute onset of unilateral breast edema, redness, palpable masses, fever, and lymphadenopathy (LAP), with rare axillary lymph node involvement and failure to respond to antibiotics or surgical interventions.^{2,6}

The diagnosis of IGM is challenging due to its clinical and radiological similarities with carcinoma, necessitating histopathological confirmation. While consensus on ideal therapeutic management is lacking, wide local excision and corticosteroid therapy are commonly used treatment strategies for IGM, requiring careful consideration of its unique characteristics.^{7,8} On the other hand, the imaging findings of GM significantly overlap with malignant lesions, rendering ultrasound, mammography, and magnetic resonance imaging (MRI) nonspecific. Common ultrasound findings include multiple contiguous hypoechoic masses, posterior acoustic shadows or enhancement, fluid accumulation, cavities, skin fistulas in advanced cases, and hypervascularity detectable by Doppler imaging.^{9,10} Notably, 15% to 55% of cases present axillary LAP on the same side. Studies report a LAP prevalence of 15.4% on ultrasound and MRI, with axillary LAP affecting 20.6% of cases, predominantly on the left side (53.5%) and right side (44.8%), and bilaterally in 1.7% of cases.^{6,11,12} These findings underscore the challenges in differentiating IGM from malignant lesions based on imaging alone, emphasizing the importance of histopathological confirmation.

The low prevalence of IGM has resulted in limited understanding of LAP's diagnostic and therapeutic implications. Thus, this study aimed to investigate the association between the clinical signs, demographic factors, and ultrasound parameters with LAP in patients with IGM.

METHODS

This study was written based on the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.¹³ This cross-sectional study was conducted on patients diagnosed with IGM in Khuzestan Province between January and February 2023. The study included patients referred to the Breast Clinic with various symptoms (mass, pain, and inflammatory symptoms) who underwent diagnostic procedures (ultrasound, biopsy, mammography, and MRI) at the referral center and had complete and legible medical files.

Patients with a confirmed diagnosis of IGM based on histopathological examination, aged 18 years or older, and with complete medical records—including clinical, radiological, and pathological data—were included in this study. Patients with a history of breast cancer or other malignancies, or a

history of breast surgery or radiation therapy, were excluded from the study.

This study investigated various variables related to IGM and LAP. The outcome variables were LAP status (present/absent) and IGM diagnosis. Predictor variables included clinical signs, mammography results, ultrasound results, age, marital status, history of breastfeeding, side of breast involvement, and presence of a palpable mass. Data collection methods involved reviewing medical records, conducting patient interviews, and analyzing diagnostic imaging reports.

The data collected for this study included medical records of patients diagnosed with IGM at the Breast Clinic for demographic and clinical information, diagnostic imaging reports (mammography, ultrasound, MRI), and pathology reports (biopsy results). Measurement tools comprised a patient questionnaire, clinical examination forms, imaging report templates, and pathology report forms.

Variables were measured as follows: age in years, marital status (single/married), history of breastfeeding (yes/no), clinical signs (breast cancer history in family, clinical signs (inflammatory signs, breast lumps, LAP, sinus tract, and nipple retraction), ultrasound parameters, LAP status (present/absent), and IGM diagnosis (positive/negative).

Data collection involved reviewing retrospective medical records, supplemented by imaging and pathology report analysis. Rigorous data quality control ensured accuracy through validation, cross-checking, missing data resolution, and data cleaning and normalization.

Statistical methods

For quantitative variables, means and standard deviations are reported, and for qualitative variables, frequencies and percentages are reported.

Logistic regression analysis was performed to investigate the association between LAP and clinical signs, demographic factors, and ultrasound parameters. Adjusted odds ratios (OR) with 95% confidence intervals (CI) were calculated. Statistical significance was set at $P < 0.05$.

Correlation analysis was conducted to assess the relationships between clinical and imaging variables. Pearson's correlation coefficient (r) was used for normally distributed continuous variables, while Spearman's rank correlation coefficient was used for non-normally distributed variables. The strength of correlation was interpreted as follows: weak (0.1–0.3), moderate (0.3–0.5), and strong (>0.5). A heatmap and correlation matrix were generated to analyze patterns and correlations among the variables.



All analyses were performed using IBM SPSS Statistics version 27 (SPSS Inc., Chicago, IL, USA) and R software (Version 4.4.2). This approach allowed us to assess individual relationships between each explanatory variable (e.g., clinical signs, demographic factors, and imaging parameters) and the outcome of interest (LAP status).

RESULTS

In this study, 140 patients were examined. The average age of the patients was 33.87 years, with a standard deviation of 5.09 years (ranging from 21 to 46 years). The marital status distribution was as follows: 8.57% single and 91.43% married. Analysis of breastfeeding history revealed that 79.28% of participants reported no prior breastfeeding experience. Among the 140 patients studied, the most prevalent clinical findings were as follows: 97.86% patients had inflammatory signs, 35.71% had a sinus tract, and 45% had a breast lump. The prevalence of LAP among IGM patients was 20% (Table 1). Clinical findings showed that inflammatory signs were highly prevalent (97.86%), with significant differences between the groups ($P<0.001$).

Ultrasound findings revealed notable variations, particularly in parenchymal heterogeneity and irregular lesion borders, which were more common in the LAP group. These results highlight key clinical and imaging differences between patients with and without LAP, contributing to a better understanding of the condition's characteristics. Further patient characteristics are presented in Table 1.

The logistic regression analysis revealed a nonsignificant OR for LAP in patients with IGM (adjusted OR, 0.823; 95% CI, 0.154–4.39; $P=0.819$). Furthermore, clinical history variables, including age (OR, 1.08; 95% CI, 0.945–1.25; $P=0.249$), breastfeeding (OR, 1.12; 95% CI, 0.562–2.24; $P=0.744$), breast invasion (OR, 1.08; 95% CI, 0.369–3.14; $P=0.893$), and marital status (OR, 0.225; 95% CI, 0.0126–4.04; $P=0.311$), did not show significant associations with IGM (Table 2 and Figure 1). The correlation analysis identified several key associations among clinical and imaging variables (Figure 2). A strong positive correlation was observed between axillary LAP and nodular LAP ($r=0.932$, $P<0.001$), suggesting a significant relationship between these features.

Table 1. Clinical Details and Characteristics of All Patients

Variables		Total (N=140)	With LAP (n=28)	Without LAP (n=112)	P-value
Age in years, mean \pm SD (range)		33.87 \pm 5.09 (21–46)	32.61 \pm 5.27	36.87 \pm 4.7	0.78
Marital status (married), n (%)		128 (91.43)	26 (92.86)	102 (91.07)	0.58
History of breastfeeding, n (%)	0	111 (79.28)	15 (53.57)	96 (85.71)	0.91
	1	2 (1.42)	0	2 (1.79)	
	2	15 (10.71)	2 (7.14)	13 (11.61)	
	3	8 (5.71)	3 (10.71)	5 (4.46)	
	4	3 (2.14)	3 (10.71)	0	
	5	1 (0.71)	1 (3.57)	0	
Side of breast involvement	Right	54 (38.6)	12 (42.86)	42 (37.50)	0.95
	Left	68 (48.6)	16 (57.14)	52 (46.43)	
	Both	18 (12.9)	4 (14.29)	14 (12.50)	
Breast cancer family history, n (%)		26 (18.57)	7 (25.00)	19 (16.96)	0.37
Clinical findings, n (%)	Inflammatory signs	137 (97.86)	27 (96.42)	110 (98.21)	<0.001
	Breast lump	63 (45)	11 (39.29)	52 (46.43)	
	Sinus tract	50 (35.71)	5 (17.86)	45 (40.18)	
	Nipple retraction	6 (4.28)	1 (3.57)	5 (4.46)	
Ultrasound findings, n (%)	Parenchymal	18 (12.86)	12 (42.86)	6 (5.36)	<0.001
	Heterogeneity				
	Irregular lesion border	24 (17.14)	14 (50.00)	10 (8.93)	
	Axillary lymphadenopathy	1 (0.71)	1 (3.57)	0	
	Fistula	13 (9.28)	8 (28.57)	4 (3.57)	
	Hyperkeratosis	10 (7.14)	4 (14.29)	6 (5.36)	
	Well-defined, heterogeneous lesion	5 (3.57)	4 (14.29)	1 (0.89)	

LAP, lymphadenopathy

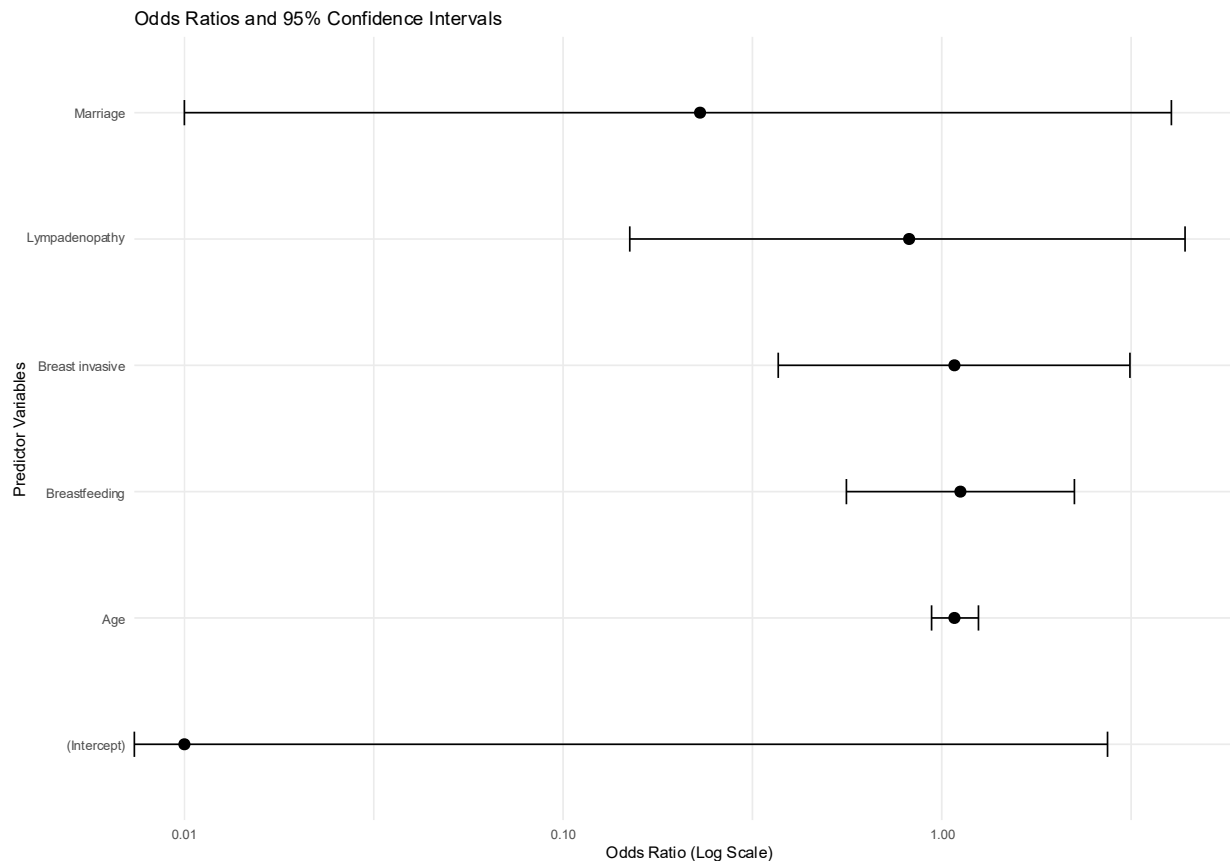


Figure 1. Forest Plot of Odds Ratios (OR) and 95% Confidence Intervals (CI) for Factors Associated with Lymphadenopathy in Idiopathic Granulomatous Mastitis Patients. The squares represent the ORs, and the horizontal lines indicate the 95% CIs. The vertical dashed line represents the null value (OR, 1), where values crossing this line suggest no significant association.

Pathological findings demonstrated moderate correlations with irregular border heterogeneous lesions ($r=0.254$, $P=0.002$) and inflammatory signs ($r=0.223$, $P=0.037$), indicating possible associations. In contrast, irregular border heterogeneous lesions exhibited a strong negative correlation with well-defined heterogeneous lesions ($r=-0.845$, $P<0.001$), highlighting an inverse relationship between these imaging features. Other clinical variables, including age, breastfeeding, breast invasion, marital status, and family history, demonstrated weak or negligible correlations with the primary outcomes of interest. Notably, sinus tract formation displayed a borderline positive correlation with pathology

($r=0.183$, $P=0.029$), warranting further investigation. These findings suggest that axillary and nodular LAP are highly interrelated, while certain imaging features may have potential diagnostic value in IGM. The multivariate and univariate analyses further supported these observations. None of the evaluated clinical variables, including age, breastfeeding, breast invasion, marital status, and LAP, showed statistically significant associations with IGM. The OR for LAP remained nonsignificant in both multivariate analysis (adjusted OR, 0.823; 95% CI, 0.154–4.39; $P=0.819$) and univariate analysis (OR, 0.88; 95% CI, 0.17–4.6; $P=0.88$), indicating that LAP may not be a strong predictor of IGM (Figure 1).

Table 2. Univariate and Multivariate Logistic Regression Analysis of Lymphadenopathy and Clinical History Variables in IGM Patients

Variables	Univariate				Multivariate			
	OR	Lower CI	Upper CI	P-value	OR	Lower CI	Upper CI	P-value
Age	1.08	0.94	1.24	0.29	1.08	0.945	1.25	0.249
Breastfeeding	0.90	0.50	1.62	0.73	1.12	0.562	2.24	0.744
Breast invasive	1.02	0.35	2.95	0.98	1.08	0.369	3.14	0.893
Marriage	0.33	0.04	3.16	0.34	0.225	0.0126	4.04	0.311
Lymphadenopathy	0.88	0.17	4.60	0.88	0.823	0.154	4.39	0.819

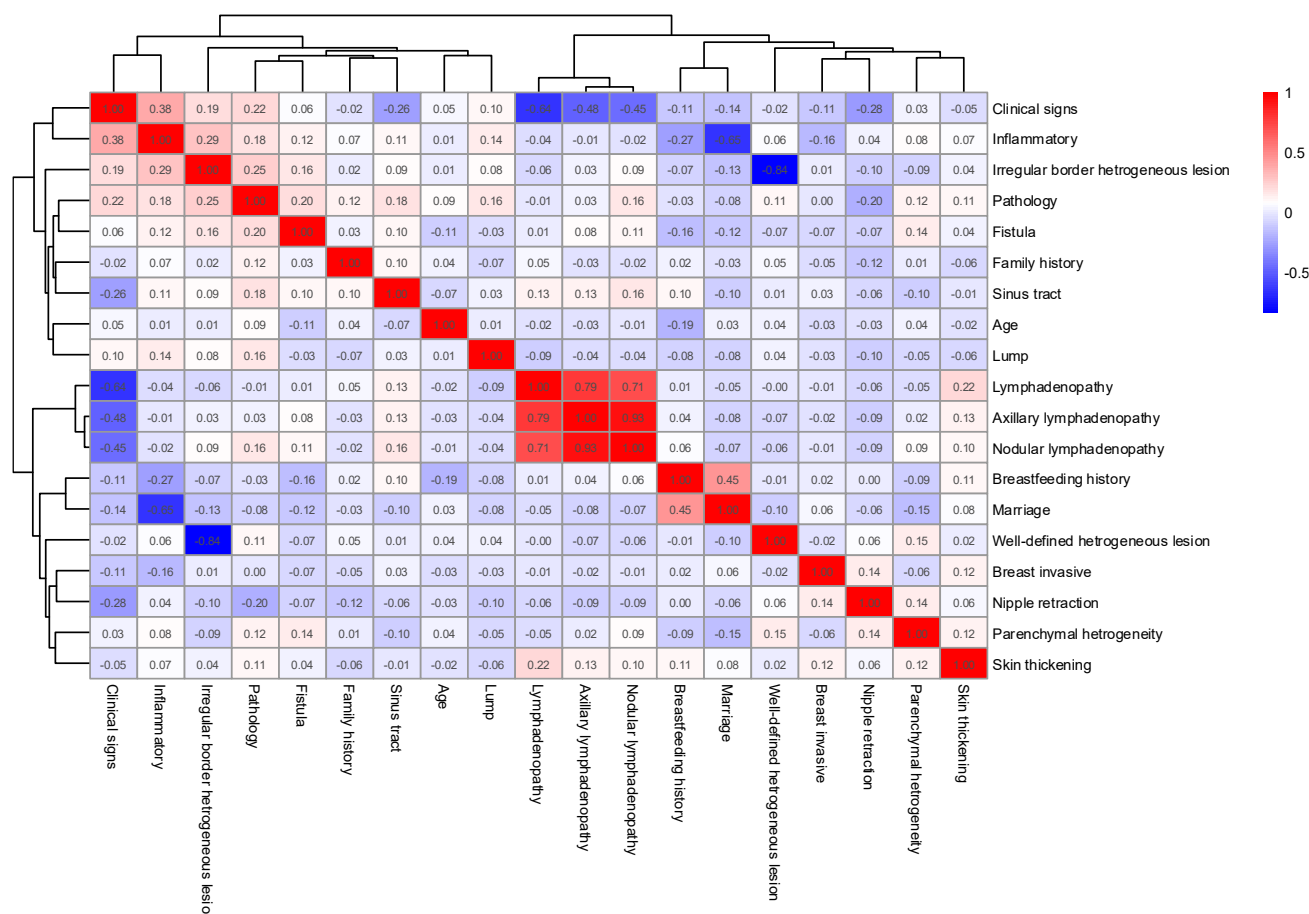


Figure 2. Heatmap of Correlation Matrix Between Variables. Red indicates strong positive correlations, while blue represents strong negative correlations. White areas signify weak or no correlation.

DISCUSSION

This study provides significant insights into IGM characteristics and LAP predictors. A notable finding was the high prevalence of LAP (20%) among IGM patients. The findings of this study provide valuable insights into the clinical and imaging characteristics of IGM patients, particularly in relation to LAP and its associations with other variables.

The logistic regression analysis demonstrated that LAP was not significantly associated with IGM (adjusted OR, 0.823; 95% CI, 0.154–4.39, $P=0.819$), suggesting that the presence of LAP does not serve as a predictive factor for IGM in this cohort.

Additionally, key clinical history variables, including age, breastfeeding history, breast invasion, and marital status, did not exhibit significant correlations with LAP, indicating that these factors may not play a substantial role in LAP occurrence among IGM patients. These findings align with the existing literature, highlighting the importance of LAP and axillary LAP in IGM diagnosis.^{14,15}

The correlation analysis revealed several noteworthy relationships among clinical and imaging findings. The strong positive correlation between axillary LAP and nodular LAP ($r=0.932$, $P<0.001$) underscores a significant interdependence, suggesting

that these features often present together in IGM patients. This finding may have diagnostic and prognostic implications, emphasizing the need for further exploration of LAP characteristics in IGM management. Pathological findings were moderately correlated with both irregular border heterogeneous lesions ($r=0.254$, $P=0.002$) and inflammatory signs ($r=0.223$, $P=0.037$), supporting the notion that these imaging features may be indicative of underlying pathological changes. Interestingly, irregular border heterogeneous lesions showed a strong negative correlation with well-defined heterogeneous lesions ($r=-0.845$, $P<0.001$), suggesting that these 2 imaging characteristics may represent distinct pathological stages or subtypes of the disease. Other clinical variables, such as age, breastfeeding, breast invasion, marriage, and family history, exhibited weak or negligible correlations with key outcomes, indicating that their impact on disease presentation may be limited. However, sinus tract formation demonstrated a borderline significant correlation with pathology ($r=0.183$, $P=0.029$), warranting further investigation into its potential role as a clinical marker.



Nonetheless, most studies on IGM are case reports, making it difficult to evaluate the consistency of these results. Research has shown that LAP is a significant concern in IGM patients, with axillary LAP being more common in tuberculous mastitis (TM) patients (50%) compared to IGM patients (20.6%).^{11,16} This highlights the importance of considering LAP in the differential diagnosis of GM. Moreover, the majority of GM patients are premenopausal women, with a mean age of 33.5–35.8 years^{11,16–18}, which is consistent with the findings of this study, showing that IGM occurred in women with a mean age of 33.87 ± 5.09 years.

Common symptoms include breast mass, pain, ulceration, and abscess. Bilateral involvement and multiple masses are also seen in GM patients.¹⁹ Notably, axillary LAP is more common in TM patients.¹¹ Moreover, Seo HR *et al.* demonstrated that the prevalence of LAP was 20.6%, which is similar to 20% observed in the present study.

Ultrasonography reveals distinct features in IGM patients, including abscess and/or sinus tract formation, heterogeneous hypoechoic mass, heterogeneous parenchyma or parenchymal edema, axillary LAP, and cysts.¹⁶ “Finger-like” structures, duct ectasia, abscesses, and LAP are typical ultrasound signs of IGM.⁶ This study revealed that the most prevalent ultrasound signs of GM are Irregular Lesion Border (17.14%), Parenchymal Heterogeneity (12.86%), and Fistula (9.28%), with the least prevalent ultrasound signs being Hyperkeratosis (7.14%), well-defined heterogeneous lesions (3.57%), and Axillary LAP (0.71%). In the study by Fazzio *et al.*, axillary lymph nodes appeared reactive on ultrasound, with LAP observed in 3 out of 17 patients (17%).²⁰ Similarly, Wolfrum *et al.* reported LAP in 15% of the patients.¹² Vanovcanova *et al.* also found LAP in 15.4% of the patients.⁶ Jarrah *et al.* observed that a small number of their patients had a mass with an abscess associated with axillary LAP, affecting 10% of the patients.²¹ Rajendran *et al.* noted axillary LAP in 15% of cases diagnosed with Chronic GM (CGM).²² Furthermore, Deliveri *et al.* reported axillary LAP in 28% of the patients with IGM.²³

GM should be suspected in young, premenopausal women presenting with breast mass and axillary LAP in endemic regions. IGM requires exclusion of other granulomatous lesions in the breast. A multidisciplinary approach, including bacteriology and histopathology, is necessary for diagnosis.^{19,24}

Alikhassi *et al.*'s findings revealed that 8.3% of the patients had no history of breastfeeding.¹⁷ This supports a strong link between granulomatous mastitis and breastfeeding history.²⁵ Jafari *et al.* reported pain as a frequent symptom in 53.8% of the

patients, with palpable mass being the most common physical finding (53.8%).¹⁸ Breast involvement patterns varied across studies. In our study, most patients (66 cases, 50%) had left breast involvement. Conversely, Topete *et al.* found right-sided involvement in 44.4% (4 patients), left-sided in 33.3% (3 patients), and bilateral manifestations in 22.2% (2 patients).²⁶ Omranipour *et al.* reported left breast involvement in 56% (43 patients) and right breast involvement in 44%.²⁷ Fatih *et al.* observed right breast involvement in 53.8% of the patients (14 cases).²⁸ However, several studies reported a higher occurrence in the right breast (61% to 69%).²⁹ Notably, bilateral breast involvement was relatively rare. Most previous studies have confirmed that bilateral cases are less common.²⁰ Our findings align with these studies, showing bilateral breast involvement in only 12.1% of the patients.

Our study has several limitations that should be acknowledged. Firstly, the relatively small sample size may limit the generalizability of our findings, making it essential to conduct larger studies to confirm our results. Additionally, the retrospective design of this study may introduce biases and limitations in data collection, which could impact the accuracy of our conclusions. Furthermore, our study's demographic characteristics may not accurately represent diverse populations, highlighting the need for future research to prioritize inclusivity. The absence of extended follow-up data also restricts our understanding of long-term outcomes, emphasizing the importance of longitudinal studies. Moreover, no comprehensive genetic analysis was conducted to explore potential genetic predispositions, representing a significant knowledge gap. Diagnosis relied heavily on imaging and histopathology, potentially overlooking subtle variations that could impact treatment decisions. Lastly, as a single-center study, our findings may be specific to our institution and not universally applicable, underscoring the need for multicenter collaborations to validate our results.

CONCLUSION

Overall, these findings highlight the complex interplay between clinical and imaging features in IGM, with axillary LAP and nodular LAP emerging as particularly interrelated characteristics. The results showed that IGM commonly affects married women in their mid-30s with a history of breastfeeding, with 20% exhibiting LAP. While logistic regression did not identify significant predictive factors for LAP, correlation analysis provided valuable insights into potential diagnostic patterns. Further studies with larger sample sizes and longitudinal designs are recommended to validate these findings and explore



their implications for disease progression and management.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

DATA AVAILABILITY

The data supporting the findings of this study are available from the corresponding author upon request.

ETHICAL CONSIDERATIONS

The study obtained ethical approval from the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (AJUMS), Iran (IR.AJUMS.HGOLESTAN.REC.1402.165). Informed consent was obtained from the participants, and the study was conducted in accordance with the Declaration of Helsinki.

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