ORIGINAL ARTICLE

European Journal of BREAST HEALTH

DOI: 10.4274/ejbh.galenos.2026.2026-1-11
Eur J Breast Health 2026;22(2):199-208

Pittsburgh Classification and Treatment Algorithm for Idiopathic Granulomatous Mastitis: A Multicenter Cohort Study

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ABSTRACT

Objective: Idiopathic granulomatous mastitis (IGM) is a rare inflammatory breast condition lacking standardized treatment and with unpredictable outcomes. To address these issues, using clinical and ultrasound findings from an initial subset, we created the Pittsburgh Classification to stratify severity and developed a corresponding treatment algorithm for IGM, then evaluated its effectiveness in a larger cohort of IGM patients.

Materials and Methods: This retrospective multicenter study reviewed clinical and sonographic findings and outcomes of women with biopsy-proven IGM treated at multiple breast centers between 2020 and 2025. The Pittsburgh clinical classification ranges from Type 1 (minimal skin irritation) to Type 5 (widespread involvement); ultrasound classification spans Type A (localized mass ≤2 cm) to Type D (diffuse disease). Treatments were assessed utilizing the Pittsburgh algorithm, with responses classified as full response (CR), near-complete response (nCR), or no response (NR). Chi-square tests assessed associations ($p<0.05$).

Results: Of 522 patients included (mean age 37.0±8.8 years), 86.4% ($n = 451$) received algorithm-concordant treatment, achieving CR in 68.7% ($n = 310$), nCR in 35.3% ($n = 159$) and NR in 11.8% ($n = 53$). Among these, 65.4% (295/451) of patients with CR were concordant with the Pittsburgh treatment algorithm, whereas 13.6% ($n = 71$) patients received discordant treatments, with a significantly lower CR rate of 21.1% (15/71) ($p<0.001$). Multifocal disease was significantly more prevalent in NR (83.0%, 44/53) and nCR (70.4%; 112/159) patients compared to CR (20.6%; 64/310) ($p<0.001$), although lesion-based response rates were similar (CR 56.8%, nCR 57.0%, NR 56.6%). Regarding concordance with treatment algorithm, clinical Type 4 IGM was more prevalent in NR (67.9%; 36/53) and nCR (72.9%, 116/159), whereas in clinical Type 1 IGM, NR, nCR, and CR were 1.8% (1/53), 4.4% (7/159), and 30.6% (95/310), respectively ($p<0.001$). Surgery at presentation was preferred in 16.9% ($n = 88$) of patients, with 6% ($n = 30$) requiring subsequent surgical treatments to treat residual disease.

Conclusion: Concordance with the proposed IGM treatment algorithm based on clinical and ultrasound findings resulted in significantly higher CR rates. Multiple foci and stratified clinical types correlated with outcomes. Prospective global research is needed to validate these findings.

Keywords: Idiopathic; granulomatous; mastitis; classification; algorithm

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Received: 26.01.2026 **Accepted:** 10.02.2026 **Available Online Date:** 24.03.2026
Cite this article as: Soran A, Tokoçin M, Aytaç HÖ, Nazlı MA, Özbaş S, Yiğit B, et al. Pittsburgh classification and treatment algorithm for idiopathic granulomatous mastitis: a multicenter cohort study. Eur J Breast Health. 2026;22(2):199-208
*This study was presented at the American Society of Breast Surgeons Annual Meeting in 2025 in Las Vegas, USA.

KEY POINT

- Concordance with the proposed idiopathic granulomatous mastitis treatment algorithm based on clinical and ultrasound findings resulted in significantly higher complete response rates. Multiple foci and stratified clinical types correlated with outcomes.

Introduction

Despite ambiguous incidence and prevalence data, the number of referrals for idiopathic granulomatous mastitis (IGM) to breast clinics has been increasing. Breast care providers may be challenged by IGM, an inflammatory breast disease, from diagnosis to treatment. Although the exact cause of the condition is unknown, unusual genetic variations, autoimmune reactions, infections, and hormone imbalances are thought to be contributing factors (1-5).

IGM clinical presentation ranges from mild parenchymal changes to severe inflammation with fistulae, often mimicking malignancy (6). Although IGM commonly occurs in peripheral areas of the breast, like periductal mastitis IGM may also present in the central breast. Ultrasonography (US), which can identify hypoechoic masses, ductal extension, and abscess collections, remains the recommended imaging method. Histological confirmation is necessary for the diagnosis of IGM once secondary granulomatosis has been ruled out following investigation of hormonal, microbiological, and autoimmune marker tests. As clinical and imaging features of IGM may overlap with malignancy, clinics with less experience commonly order magnetic resonance imaging (MRI) for IGM patients (7), but MRI has little impact on management.

The lack of established classification of IGM leads to inconsistent treatment choices, which range from observation to repeated aspiration of collections, intralesional steroid (ILS) injections, systemic therapies, and surgical operations alone or in combination (8-10). In contrast to the severe side effects of systemic therapy, ILS injections typically heal the lesion with minimal morbidity (10, 11).

Globally, IGM challenges healthcare systems, particularly in low-resource settings where advanced diagnostics are limited (6). It would be widely beneficial for patients and clinicians if a validated consensus treatment algorithm based on standardized clinical and imaging classifications was available. A treatment regimen has not been established because of the absence of agreed-upon clinical and radiological classification for IGM, and IGM treatments described in the literature have been devised based solely on clinical presentation. While some researchers have suggested that IGM classification and grading methods integrate clinical presentation with images, no recommended therapeutic algorithms have been evaluated in a large patient population (12-14).

Our multidisciplinary IGM group developed the Pittsburgh classifications and standardized treatment algorithm for histologically proven IGM management by integrating clinical and radiologic findings; we have presented this approach in scientific meetings (15). In this ambidirectional study, we sought to evaluate alignment of treatment with the Pittsburgh clinical and US classification with outcomes.

Materials and Methods

Study Design and Participants

Ethical Approval

The study was approved by the University of Health Sciences Türkiye, Bağcılar Training and Research Hospital Non-Interventional Clinical Research Ethics Committee Ethical Board of the lead center (date: 12.07.2024, protocol number: 2024/07/12/065) and all participating centers adhered to ethical standards in accordance with the Declaration of Helsinki.

This ambidirectional cohort study analyzed data from a large cohort of women with biopsy-proven IGM treated at multiple breast centers (from January 2020 to January 2025) including university hospitals, state/public/community hospitals, and stand-alone breast centers. Inclusion criteria were female sex, age ≥18 years, histologically confirmed IGM, and complete medical electronic records. Medical record data included age, follow-up, details of skin inflammation [erythema, mild skin thickening, skin discoloration, symptoms/signs of abscess (fever, pain, drainage, fluctuation)], skin ulcers, fistulae, number of IGM foci, and other ultrasound finding such as vascularity, surrounding tissue inflammation, skin thickening, and presence of any mass. Treatment of IGM was classified based on the choice of observation, oral systemic therapy, ILS injection, and/or surgery.

IGM was diagnosed based on histopathological examination of ultrasound-guided ≥14-g core needle or excisional biopsy samples. The diagnostic criteria included the presence of non-caseating granulomas, composed of epithelioid histiocytes, multinucleated giant cells, and lymphocytes, within the breast parenchyma, in the absence of identifiable infectious or systemic causes (2). Special stains, including Ziehl-Neelsen for acid-fast bacilli and periodic acid-Schiff for fungi, were routinely performed to rule out infectious etiologies, such as tuberculosis or fungal infections. In addition, other differential diagnoses, including malignancy and systemic autoimmune diseases, were excluded through

clinical evaluation, imaging, and histopathological analysis to confirm the idiopathic nature of the disease, ensuring diagnostic accuracy and consistency across all participating centers.

Exclusion criteria included incomplete data, secondary granulomatous mastitis, malignancy, or prior IGM treatment elsewhere. Data were extracted from electronic records, including demographics, clinical findings, US images, treatments, follow-up and outcomes.

Single-focus IGM was defined as a single, localized lesion or abscess within the breast, confirmed by ultrasound and histopathology, with no additional foci of disease. Multifocal IGM was characterized by the presence of two or more distinct lesions or abscesses, either within the same breast or bilaterally, as identified by ultrasound imaging. In this study, the numbers of multiple foci were recorded (i.e., 2, 3, or 4 foci) to assess the impact of variation in foci count on treatment outcomes. This distinction guided treatment decisions, with multiple foci often requiring more aggressive intervention, such as systemic steroids or surgical excision, due to their association with poorer response rates.

Pittsburgh Classifications

The Pittsburgh Classifications were developed through a collaborative effort involving breast surgeons, radiologists, and histopathologists to standardize the assessment and management of IGM.

Clinical classification Types 1–5 were established based on the severity and extent of clinical manifestations. These are defined as: No or minimal skin irritation (Type 1); minimal and solitary skin inflammation associated with abscess symptoms/signs, skin ulcers or fistulae (Type 2); palpable mass(es) with skin inflammation, without symptom/signs of abscess, skin ulcers or fistulae (Type 3); evident skin inflammation with or without symptom/signs of abscess, skin ulcers or fistulae (Type 4); and widespread involvement with fistulae and necrosis (Type 5) (Table 1). These categories were defined by consensus, based on clinical presentations observed in a preliminary cohort of IGM patients, with input from multidisciplinary team discussions.

Radiologic classification Types A-D were created based on sonographic findings, categorizing lesions from localized mass ≤2 cm with discrete boundaries (Type A), localized mass >2 cm with discrete boundaries (Type B), regional type with a mass >2 cm, duct extension and lacking discrete margins (Type C), and diffuse disease with extensive parenchymal involvement (Type D) (Table 2). The classifications were designed to integrate clinical and radiologic features to guide treatment decisions, ensuring consistency and reproducibility across different healthcare settings. These classifications were evaluated retrospectively, and the patient responses to treatments were documented.

Treatments

Proposed treatment recommendations (Table 3) were aligned with clinical and sonographic classifications. Less aggressive clinical Type 1 and US Type A treatment recommendation is observation, but, for clinical Type 5 or US Type D, treatment is more aggressive and ranges from oral steroid treatment to total mastectomy.

The standardized ILS protocol was 40 mg triamcinolone acetonide (diluted with 10 cc saline) per 2 cm lesion every 28–30 days with US guidance until resolution. For multiple lesions, 40 mg triamcinolone acetonide was injected per lesion up to 200 mg total dosage. Patients were monitored for injection site pain, skin atrophy, acne-like skin lesions, and allergic reactions.

Topical steroid protocol was 0.01% topical triamcinolone twice a day, starting the day after ILS until the ILS treatment was completed. Patients were again monitored for skin atrophy, acne-like skin lesion, and allergic reactions.

When methotrexate was chosen as the steroid for intralesional treatment, the IL methotrexate protocol was 12.5 mg for lesion ≤2 cm and 25 mg for a lesion >2 cm every 4 weeks until complete responce. Patients were monitored for injection site pain, allergic reactions, renal and hepatic failure.

The systemic steroid starting dose was 0.5–1 mg/kg/day of oral prednisone (maximum 60 mg/day), tapered over 4–8 weeks based on clinical response. Treatment duration varied depending on

Table 1. Idiopathic granulomatous mastitis Pittsburgh clinical classification

Type 1	No or minimal and solitary skin inflammation (erythema, mild skin thickening, limited skin discoloration (≤2 cm) without abscess symptoms/signs (i.e., fever, pain, drainage, fluctuation), skin ulcers and fistulae. No palpable mass(es)
Type 2	Minimal and solitary skin inflammation (erythema, mild skin thickening, limited skin discoloration (≤2 cm) associated with abscess symptoms/signs (i.e., fever, pain, drainage, fluctuation), skin ulcers and fistulae. No palpable mass(es)
Type 3	Palpable mass(es) with skin inflammation (any degree), without abscess (i.e., fever, pain, drainage, fluctuation), skin ulcers and fistulae symptoms/signs
Type 4	Evident skin inflammation (>2 cm area but less than half the breast or multiple erythema, moderate skin thickening) with or without abscess symptoms/signs (i.e. fever, pain, drainage, fluctuation), skin ulcers and fistulae. With or without mass(es)
Type 5	Widespread involvement (more than half of the breast) or recurrence after any treatment modality or progressive disease

symptom resolution, with a median duration of 6 weeks (range: 4–12 weeks). Patients were monitored for side effects, including weight gain, hyperglycemia, and mood changes, with dose adjustments made accordingly. In cases of inadequate response, second-line immunosuppressants, such as methotrexate, were considered.

Surgical excision was defined as the complete removal of IGM-affected breast tissue, including granulomatous lesions or abscesses. This procedure was reserved for refractory or recurrent cases of Type 3–4 IGM with radiologic Type C or D findings or Type 4–5 with Type D findings, as specified in the treatment algorithm. Excision typically involved wide local excision to achieve clear margins, minimizing residual disease. In severe cases, mastectomy was performed. To reduce the risk of recurrence, surgical excision of the residual disease was done in certain cases following a course of ILS injections.

Treatment Protocol Adherence and Outcome Measures

All treatments were performed following a consensus decision among breast surgeons and radiologists at each center. Furthermore, all treatment choices were retrospectively compared with the Pittsburgh IGM treatment algorithm recommendations.

Clinical response to treatment was categorized as follows:

• Complete response (CR): Resolution of all clinical and sonographic findings

• Near-complete response (nCR): Sonographic findings persist, but clinical symptoms resolved

• No response (NR): Persistent or worsening symptoms or emergence of new disease foci

Statistical Analysis

All statistical analyses were conducted using SPSS version 25.0 (IBM Inc., Armonk, NY, USA). Descriptive statistics were used for demographic and clinical data. The chi-square test was used to compare categorical variables. A p-value <0.05 was considered statistically significant.

Results

Among the 522 women included, with a mean age of 37.0±8.8 years (range 21–71) and a mean follow-up of 15.3±10.8 months, 491 (94.1%) had unilateral and 31 (5.9%) had bilateral IGM, yielding a total of 872 lesions. Single-focus disease was present in 302 patients (57.8%), whereas 220 (42.2%) had multifocal disease (124 with 2 foci, 62 with 3 foci, and 34 with 4 foci).

Based on the most severe lesion presentin each patient, 103/522 women had Type 1 (19.7%), 109 Type 2 (20.9%), 147 Type 3 (28.2%), 152 Type 4 (29.1%), and 11 Type 5 (2.1%) IGM (Table 4).

When considering all lesions (n = 872), the distribution was Type 1 (14.6%, n = 127), Type 2 (15.3%, n = 133), Type 3 (26.5%, n =

Table 2. Idiopathic granulomatous mastitis Pittsburgh ultrasound classification

Type A	Localized Mass(es): solid ± collection(s)	**Size: ≤2 cm** **Findings:** Single or multiple mass(es) with discrete boundaries. **Vascularity:** Internal vascularity on Doppler (solid); or no vascularity (suggesting collection). **Surrounding tissue:** Inflammation (increased echogenicity due to edema, ± dilated lymphatics, increased vascularity). **Skin:** No thickening (>2 mm) or fistula formation.
Type B		**Size: >2 cm** **Findings:** Single or multiple mass(es) with discrete boundaries. **Vascularity:** Internal vascularity on Doppler (solid); or no vascularity (suggesting collection). **Surrounding tissue:** Inflammation (increased echogenicity due to edema, ± dilated lymphatics, increased vascularity). **Skin:** No thickening (>2 mm) or fistula formation.
Type C	Regional type	**Size: >2 cm** **Findings:** Mass(es), duct extension, lacking discrete margins. **Vascularity:** Internal vascularity on Doppler (solid); or no vascularity (suggesting collection). **Surrounding tissue:** Increased echogenicity due to edema, ± dilated lymphatics, increased vascularity. **Skin:** No thickening (>2 mm) ± fistula formation.
Type D	Diffuse type	**Size:** Involves multiple quadrants. **Findings:** Mass(es), duct extension. **Vascularity:** Internal vascularity on Doppler (solid); or no vascularity (suggesting collection). **Surrounding tissue:** Increased echogenicity due to edema, ± dilated lymphatics, increased vascularity. **Skin:** Skin involvement (>2 mm, intradermal collection, direct extension of mass to involve overlying skin) ± irregular sinus tract.

231), Type 4 (38.1%, *n* = 332), and Type 5 (5.6%, *n* = 49) (Table 4A). Ultrasound types included Type A (22.4%, *n* = 195), Type B (17.3%, *n* = 151), Type C (33.3%, *n* = 290), and Type D (27.1%, *n* = 236) (Table 4B). Erythema nodosum was seen in 10 patients (1.9%).

Of the treatments given to the 522 women, 451 (86.4%) were concordant with the Pittsburgh Classifications algorithm and 71 (13.6%) were discordant. Among the 310 women who experienced CR, treatments included aspiration + ILS (46.1%, *n* = 143), observation (21.6%, *n* = 67), surgical excision alone (9.4%, *n* = 29), aspiration + systemic steroids (6.5%, *n* = 20), aspiration alone (6.1%, *n* = 19), surgical excision + ILS (3.9%, *n* = 12), ILS alone (2.6%, *n* = 8), systemic steroids alone (2.3%, *n* = 7), and surgical drainage + ILS (1.6%, *n* = 5). Overall, ILS (alone or combined) was used in 168/310 (54.2%) and systemic steroids in 27/310 (8.7%) of CR patients (Table 5). Pittsburgh treatment algorithm concordance and CR rates differed significantly by clinical type (both $p<0.001$). Patients with clinical Type 4 disease had the lowest concordance rate (67.1%) whereas ultrasound type had no significant impact on either Pittsburgh treatment algorithm concordance ($p = 0.42$) or CR ($p = 0.18$).

Topical steroids were used in 28.2% (*n* = 147) patients, independent of the algorithm, and erythema nodosum occurred in 1.9% (*n* = 10).

Treatment concordant with the Pittsburgh algorithm was strongly associated with response ($p<0.001$, Table 6). Among the 451 women with concordant treatment, 65.2% (295/451) achieved CR, 25.9% (117/451) nCR, and only 8.6% (39/451) exhibited NR. In contrast, among the 71 patients with discordant treatment, CR dropped to only 21.1% (15/71), while 59.2% (42/71) had nCR and 19.7% (14/71) were NR.

Compared to women receiving discordant treatment, algorithm-concordant patients had half the NR rate (8.6% *vs.* 19.7%) and a three-fold greater CR rate (65.2% *vs.* 21.1%) ($p<0.001$).

Topical steroids were applied in 28.2% (*n* = 147) of all patients. Primary surgery was performed in 16.9% (*n* = 88) patients; 15.3% (*n* = 69) in the algorithm-concordant group and 26.8% (*n* = 19) in the discordant group. An additional 30 procedures (27 wide local excisions, 3 mastectomies) were performed for residual or recurrent disease.

Multifocal disease (≥2 foci) was significantly more frequent in nCR (70.4%, 112/159), and NR (83%, 44/53) patients than in CR patients (20.6%, 64/310) ($p<0.001$).

All 31 bilateral cases were managed concordant with the algorithm, with CR in 51.6% (*n* = 16), nCR in 29 (*n* = 9), and NR in 19.4% (*n* = 6). None of the patients in this cohort received oral or intralesional methotrexate or other immunosuppressants.

Table 3. Idiopathic granulomatous mastitis Pittsburgh treatment algorithm

Clinical	Ultrasound	Recommended treatment
Type 1	**Type A** (no collection)	Observation
	Type B, C (no collection)	ILS or surgical removal of lesion with intraoperative ILS
Type 2	**Type A, B, C**	US-guided aspiration (possible I&D), then continue with ILS
Type 3	**Type A, B, C** (no collection)	ILS or Surgical removal of lesion with intraoperative ILS
	Type A, B, C (with collection)	US-guided aspiration + ILS where applicable
Type 4	**Type B, C** (no collection)	ILS + Low dose systemic therapy
	Type B, C (with collection)	US-guided aspiration (possible surgical I&D), then continue with ILS + Low dose systemic therapy
Any	**Type D**	Wide-spread involvement (more than half of the breast) or uncontrolled recurrence after any treatment modality; High dose systemic treatment + ILS if applicable, possible surgery (partial or total mastectomy), consider oral low dose or intralesional methotrexate injection
Type 5	**Any**	

If clinical inflammation seen, topical steroid should be added; ILS: Intralesional steroid injection; Uncontrolled refers to any disease that failed previous treatment; I&D: Incision and drainage

Table 4. Distribution of Pittsburgh clinical and ultrasound types

Clinical type	Patients (*n* = 522)	%	Lesions (*n* = 872)	%	Ultrasound type	Lesions (*n* = 872)	%
Type 1	103	19.7%	127	14.6%	Type A	195	22.4%
Type 2	109	20.9%	133	15.3%	Type B	151	17.3%
Type 3	147	28.2%	231	26.5%	Type C	290	33.3%
Type 4	152	29.1%	332	38.1%	Type D	236	27.1%
Type 5	11	2.1%	49	5.6%	-	-	-
Total	**522**	**100%**	**872**	**100%**	**Total**	**872**	**100%**

Table 4A. Pittsburgh clinical classification (patient-based *n* = 522, lesion-based *n* = 872), concordance with treatment algorithm, and response distribution

Clinical type	Patients (*n* = 522)	Lesions (*n* = 872)	Concordant treatment n (%)	CR patients n (%)	nCR patients n (%)	NR patients n (%)	CR lesions n (%)
Type 1	103	127	98 (95.1%)	95 (92.2%)	7 (6.8%)	1 (1.0%)	118 (92.9%)
Type 2	109	133	102 (93.6%)	100 (91.7%)	8 (7.3%)	1 (0.9%)	122 (91.7%)
Type 3	147	231	138 (93.9%)	115 (78.2%)	28 (19.0%)	4 (2.7%)	178 (77.1%)
Type 4	152	332	102 (67.1%)	0 (0%)	116 (76.3%)	36 (23.7%)	0 (0%)
Type 5	11	49	11 (100%)	0 (0%)	0 (0%)	11 (100%)	0 (0%)
Total	**522**	**872**	**451 (86.4%)**	**310 (59.4%)**	**159 (30.5%)**	**53 (10.1%)**	**418 (47.9%)**

CR: Complete response; nCR: Near-complete response; NR: No response

Table 4B. Pittsburgh ultrasound classification (patient-based *n* = 522, lesion-based *n* = 872), concordance with treatment algorithm, and response distribution

US type	Patients (*n* = 522)	Lesions (*n* = 872)	Concordance with treatment, n (%)	CR patients n (%)	nCR patients n (%)	NR patients n (%)
Type A	118	195	110 (93.2%)	98 (83.1%)	16 (13.6%)	4 (3.4%)
Type B	98	151	90 (91.8%)	84 (85.7%)	12 (12.2%)	2 (2.0%)
Type C	176	290	156 (88.6%)	134 (76.1%)	36 (20.5%)	6 (3.4%)
Type D	130	236	115 (88.5%)	104 (80.0%)	22 (16.9%)	4 (3.1%)
Total	**522**	**872**	**451 (86.4%)**	**310 (59.4%)**	**159 (30.5%)**	**53 (10.1%)**

CR: Complete response; nCR: Near-complete response; NR: No response

Table 5. Treatment modalities and treatment algorithm discordance

Treatment modality	CR (*n* = 310)	nCR (*n* = 159)	NR (*n* = 53)
Observation only	*67 (21.6%) **(0%)	7 (4.4%) 2 (28.6%)	0 (0%) (N/A)
Aspiration only	19 (6.1%) (0%)	20 (12.6%) 2 (10%)	10 (18.9%) 9 (90.0%)
Intralesional steroid (ILS) injection only	8 (2.6%) (0%)	3 (1.9%) (0%)	6 (11.3%) 3 (50.0%)
Aspiration + ILS	143 (46.1%) (0%)	51 (32.1%) 13 (25.5%)	5 (9.4%) (0%)
Systemic steroids only	7 (2.3%) 2 (28.6%)	20 (12.6%) 5 (25.0%)	2 (3.8%) 1 (50.0%)
Aspiration + systemic steroids	20 (6.5%) 2 (10.0%)	31 (19.5%) 2 (6.5%)	15 (28.3%) (0%)
Surgical drainage + ILS	5 (1.6%) (0%)	11 (6.9%) 6 (54.5%)	4 (7.5%) (0%)
Surgical excision + ILS	12 (3.9%) (0%)	2 (1.3%) (0%)	2 (3.8%) (0%)
Surgical excision only	29 (9.4%) 11 (37.9%)	14 (8.8%) 1 (7.1%)	9 (17.0%) 1 (11.1%)
Overall algorithm concordance	295/310 (95.2%)	117/159 (73.6%)	39/53 (73.6%)
Topical steroid use*	No	375 (71.8%)	
	Yes	147 (28.2%)	

CR: Complete response; nCR; Near complete response; NR: No response

*Numbers and percentages indicate the proportion of patients receiving each treatment.

**Numbers and percentages indicate discordance with the Pittsburgh algorithm.

N/A indicates that no patients received the treatment. Topical steroid use is reported for the entire cohort and is independent of specific treatment modalities

Table 6. Clinical, treatment, and response characteristics of IGM patients (*n* = 522)					
Characteristic	**Overall (*n* = 522)**	**CR (*n* = 310)**	**nCR (*n* = 159)**	**NR (*n* = 53)**	***p*-value**
					0.212
Unilateral breast IGM	491 (94.1%)	294 (94.8%)	150 (94.3%)	47 (88.7%)	
Bilateral breast IGM	31 (5.9%)	16 (5.2%)	9 (5.7%)	6 (11.3%)	
Number of Foci					<0.001
1	302 (57.9%)	246 (79.4%)	47 (29.6%)	9 (17.0%)	
2	124 (23.8%)	49 (15.8%)	55 (34.6%)	20 (37.7%)	
3	62 (11.9%)	9 (2.9%)	35 (22.0%)	18 (34.0%)	
4	34 (6.5%)	6 (1.9%)	22 (13.8%)	6 (11.3%)	
Multiple foci (≥2)	220 (42.1%)	64 (20.6%)	112 (70.4%)	44 (83.0%)	
Concordance with Pittsburgh treatment algorithm					<0.001
No	71 (13.6%)	15 (4.8%)	42 (26.4%)	14 (26.4%)	
Yes	451 (86.4%)	295 (95.2%)	117 (73.6%)	39 (73.6%)	
CR: Complete response, nCR; Near complete response, NR: No response; IGM: Idiopathic granulomatous mastitis					

Discussion and Conclusion

IGM is a rare, chronic inflammatory condition that primarily affects women between the ages of 30 and 45 years (1, 2, 16). In our cohort of 522 women, the mean age was 37.0 years. The unclear etiology of IGM, potentially involving hormonal, microbiological, rare genetic variants and autoimmune factors continues to challenge the standardization of treatment protocols (1, 2, 16-18). The broader age range observed in our cohort (21–71 years), including both younger and postmenopausal patients, highlights the heterogeneous nature of the clinical presentation of IGM. The autoimmune etiology of this disease is currently being discussed, as IGM patients respond well to immunosuppressive medications. This hypothesis may explain why IGM occurs in pre- and post-menopausal women (19).

Although microbiological agents such as Corynebacterium species have been proposed as an etiological mechanism, the histopathological analyses in our cohort, which used specific stains to rule out infectious etiologies, suggest that such microbiological agents may be present in the process only once the main trigger for IGM has occurred or infectious agents contribute to the progression of IGM (1, 17). Multifactorial etiology complicates treatment decisions.

In our series, patients with multiple foci (42.0% of our cohort) or severe clinical types (Type 4: 37.9%, Type 5: 5.6%) exhibited poorer response rates, potentially reflecting more aggressive inflammatory processes driven by a combination of these factors, though those with bilateral disease did not have worse outcomes. This variability underscores the value of a standardized approach, such as the Pittsburgh classifications, which integrates clinical and sonographic features to tailor interventions, addressing the challenge of heterogeneous disease presentations. For instance, the greater frequency of Type 4 disease in non-responders (67.9%) suggests that in order to improve outcomes, severe cases might need to be escalated to systemic therapy or surgery earlier. Future studies should explore biomarkers, such as cytokine profiles or hormonal receptor expression, to elucidate the relative contributions of these etiological factors and guide personalized treatment strategies (18).

Multiple classification and grading proposals are available in the literature but none of them have been adopted extensively worldwide. One of the reasons for this is that there is no commonly accepted IGM classification because of a lack of radiologic uniformity of diagnosis. The most common imaging modalities are US, mammography, and MRI. Radiological characteristics of IGM are non-specific and can overlap with those of malignant tumors. Irregular masses and focal asymmetry are common mammographic findings, but mammography can cause severe discomfort and pain, especially in patients with extensive swelling, infection, or abscesses. Ultrasound is considered the first-line imaging modality in IGM patients, and MRI in selected patients, especially to distinguish from malignancy (20-24).

The first proposed management algorithm based on imaging modalities was reported in 2017, but there was no detailed clinical and imaging characterization of lesions, such as size, abscess formation, or number of lesions in the same breast (8). Later, scoring and staging systems were developed to predict recurrence and steroid response. In this study, patients received corticosteroid treatment for three months and then the dose was tapered in three days. Surgical excision of IGM was the treatment approach in patients with incomplete response, recurrence and in patients who were non-complaint with the corticosteroid treatment. The authors created a prediction score for recurrence, taking statistically significant variables into consideration including number of births, duration of lactation, body mass index, presence of fistulae, abscess formation detected on US examination and luminal inflammation. The presence of each

risk factor was given 1 point and then a total risk score was then calculated for each patient. The mean IGM score was significantly different in with and without recurrence patients (5.1 *vs.* 1.9, respectively; $p<0.001$) (14).

Another study considered US-based staging and the estimate of ILS injection response (25). These authors used their own classification and graded from I to IV. Grade I was irregular mass, grade II with tubular extensions and skin thickening, grade III with extensive fistula/sinus tracts draining to the skin and grade IV A sequela of any grade mostly characterized by hypoechoic foci. They compared 40 and 80 mg methylprednisolone sodium injection dosage in 230 patients. ILS injections were done every three weeks. It was concluded that high-dose of ILS injection was effective in grades II and III and also hypothesized that observation for management of grade I should be considered.

Four clinical patterns (A, B, C, D) were proposed in 68 patients in another study (12). Clinical patterns were classified as A: painless breast mass, B; painful breast mass with gross inflammation, C; a breast abscess-like presentation and D: a subacute presentation with ulceration, sinus, or fistula formation. In this study the patients in pattern A received no steroid treatment and although the median follow-up time was not given, the authors stated that patients in this pattern who had wide local excision had zero recurrence. Oral prednisolone was given in 49% of patients in patterns B, C and D and overall recurrence rate was 32%. This study did not provide a treatment algorithm based on clinical patterns but gives information of the high recurrence risk in severe clinical patterns.

In another study the authors classified IGM as diffuse type, sheet hypoechoic type, localized abscess type and localized hypoechoic mass type in 30 patients (26). Their treatment was initial dosage of methylprednisolone was 20 mg/day, which was reduced to 16, 12, 8, 4 mg/day every 1–2 weeks until the drug was stopped. They performed minimally invasive rotary cutting surgery in patients with no obvious acute inflammation and the mass remained stable and localized after glucocorticoid therapy, or when the diameter of the newly diagnosed lesion was less than 2 cm, or there were contraindications for glucocorticoid use or the patient refused to use glucocorticoid. The median follow-up was 12 (4–42) months. Recurrence was seen in 3 cases (10.00%) and they were all in the sheet hypoechoic type. Although this alternative minimally invasive approach for treatment of IGM showed promising results, US classification made no mention of multiple IGM lesions and clinical correlation was missing.

Recently a consensus report and Turkish Clinical classification was published (13). This consensus report for treatment and follow-up was reached with 62 medical professionals experienced in managing IGM. Type 1 to Type 4 clinical variables were size, skin inflammation, skin ulcers/sinus, presence of systemic findings, multiple foci, recurrence and treatment resistance. The majority of this consensus voted for observation of 81% in Type 1 and 85% patients in pregnancy/lactation. For Type 2 disease, ILS injection (66%), observation ± drainage (62%), and topical steroids (60%) were similarly favored as first-line treatments, and for Type 3 disease, systemic steroids achieved consensus as the first-line treatment (84%). For Type 4 resistant cases, consensus was reached on combination therapies (82%). This paper provided a clinical classification that did not include combination with imaging. Data-driven prospective research should be used to test survey-based studies.

The Pittsburgh Classification offers a comprehensive framework by integrating clinical (Types 1–5) and radiological (A-D) features to guide treatment strategies. In the present study we tested our classification and treatment algorithm in a cohort of 522 patients with histopathologically confirmed IGM. In this analysis, 86.4% of patients received treatment in accordance with this algorithm, yielding a CR rate of 65.4% among compliant patients compared to only 21.1% in the non-compliant group ($p<0.001$). Notably, all bilateral cases (5.9% of the cohort) were managed according to the algorithm. In a subgroup analysis, patients with multifocal disease ($n = 220$) had significantly lower CR (29.1%, $n = 64$) compared to those with single-focus disease (81.4%, $n = 246$) ($p<0.001$, Table 6).

Regarding treatment methods, the combination of aspiration and ILS injections emerged as the most often used and effective technique among patients who achieved CR (46.1%; 143/310). Corticosteroid phobia, which is defined as fear of the side effects of corticosteroids, is one of the primary causes (80%) of poor treatment compliance, even though oral steroid treatment was previously advised as a first-line treatment for IGM (27). In contrast, ILS injections have a great healing rate and few side effects, and it is well-accepted by patients as well as physicians (10,11). In the literature it has been reported that high dose systemic corticosteroids and immunosuppressants were reserved for severe or recurrent cases (28-30). In our study, no patient received oral or IL methotrexate and azathioprine.

Primary surgical intervention was performed in 16.9% (88/522) of patients overall and was significantly less frequent among algorithm-compliant patients (15.3%, 69/451) compared to the non-compliant group (26.8%, 19/71). An additional 30 surgical procedures were required for residual or recurrent diseases. Our findings support current recommendations that surgical intervention should be considered only after failure or intolerance of conservative approaches (31-34).

Our study outcomes support the view that for effective management and to prevent needless procedures, an accurate diagnosis of IGM is essential. Clinical, radiological, and histological findings must be integrated using a multidisciplinary team approach.

Study Limitations

The ambidirectional design of the study limits our ability to establish causal relationships. The median follow-up duration of 15.3 months may not fully capture long-term recurrence rates. In certain subgroup analyses, direct chi-square comparisons were limited. Minor discrepancies in the initial classification of clinical types were corrected following data review. In this study we did not evaluate the complications of each treatment. Although the literature suggests using MRI as a tool in differential diagnosis and disease assessment (21, 35), our study did not include MRI data in addition to US. Finally, the relatively small number of bilateral cases (n = 31) limits the generalizability of subgroup-specific conclusions.

IGM requires a multidisciplinary, tailored therapeutic approach due to its heterogeneous clinical presentation. The Pittsburgh Classification and treatment algorithm have demonstrated clinical efficacy in standardizing treatment decisions and significantly improved CR rates (65.4% *vs.* 21.1%, $p<0.001$). In particular, patients with multifocal disease and more severe clinical types (Type 4–5) are more likely to experience poor treatment outcomes if not managed according to algorithmic guidance. Early consideration of systemic therapies or surgical intervention may enhance outcomes in this subgroup. Prospective and long-term studies are needed to confirm these findings and assess recurrence rates.

Ethics

Ethics Committee Approval: The study was approved by the University of Health Sciences Türkiye, Bağcılar Training and Research Hospital Non-Interventional Clinical Research Ethics Committee Ethical Board of the lead center (date: 12.07.2024, protocol number: 2024/07/12/065) and all participating centers adhered to ethical standards in accordance with the Declaration of Helsinki.

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Concept: A.S., M.T., H.Ö.A., M.A.N., S.Ö., B.Y., E.B.M., W.A.B.; Design: A.S., M.T., H.Ö.A., M.A.N., S.Ö., B.Y., E.B.M., W.A.B.; Data Collection or Processing: A.S., M.T., H.Ö.A., M.A.N., S.Ö., B.Y.; Analysis or Interpretation: A.S., M.T., H.Ö.A., M.A.N., S.Ö., B.Y., E.B.M., W.A.B.; Literature Search: A.S., M.T., H.Ö.A., M.A.N., S.Ö., B.Y., E.B.M., W.A.B.; Writing: A.S., M.T., H.Ö.A., M.A.N., S.Ö., B.Y., E.B.M., W.A.B.

Conflict of Interest: Atilla Soran MD is section editor in European Journal of Breast Health. He had no involvement in the peer-review of this article and had no access to information regarding its peer-review.

Financial Disclosure: The authors declared that this study received no financial support.

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