Review Article
Volume 08:01, 2025

Journal of Anesthesiology and Pain Research

ISSN: 2684-5997 Open Access

Idiopathic Granulomatous Mastitis: Challenges, Treatments and Advancing Care Strategies

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Abstract

Idiopathic Granulomatous Mastitis (IGM) is a rare, benign, chronic inflammatory condition of the breast with an unknown cause. It often presents with a prolonged or recurring course, making diagnosis challenging due to its similarity to other breast conditions and requiring the exclusion of other granulomatous diseases. Without established management guidelines, treatment approaches remain inconsistent and range widely from observation to surgery, immunosuppressive therapy, or multimodal treatment. The recurrence rate is high, and there is no universal consensus on long-term management.

Keywords: Idiopathic Granulomatous Mastitis (IGM) • Chronic breast pain • Breast painful lesion • Granulomatous breast disease • Chronic breast inflammation • Non-caseating granulomas • Breast abscesses • Breast autoimmune diseases • Intralesional steroids • Methotrexate for mastitis • Granulomatous Lobular Mastitis (GLM) • Microwave ablation therapy • Rheumatology and breast conditions • Surgical management of mastitis

Introduction

Idiopathic Granulomatous Mastitis (IGM), also known as granulomatous lobular mastitis, was first described in 1972 as a non-caseating granulomatous inflammation primarily affecting the breast lobules. Although historically considered a rare, chronic inflammatory breast condition, its incidence has risen significantly over the past 20 years, particularly in regions such as the Middle East, Central Asia, and East Asia, potentially due to genetic, environmental, or clinical practice differences [1,2]. IGM is a benign, chronic inflammatory breast disease with an uncertain cause. It predominantly affects women of reproductive age, particularly within five years after childbearing, and often presents with symptoms like those of breast carcinoma or infection, including palpable masses, pain, swelling, and erythema. This clinical similarity complicates both diagnosis and treatment [1-4].

Diagnosis of IGM is largely based on exclusion, requiring the elimination of other granulomatous diseases such as tuberculosis, fungal infections and sarcoidosis. Diagnostic methods include clinical examination, imaging, microbiological cultures, and histopathological analysis. While mammography and ultrasound are common, they often yield nonspecific findings. Histopathological examination remains essential, revealing sterile, non-caseating, lobulocentric granulomatous inflammation. Cultures for bacteria, fungi, and mycobacteria are typically negative, and systemic granulomatous diseases are absent, supporting the diagnosis of IGM [1,5].

The management of IGM is complex and varied, encompassing conservative options like antibiotics and immunosuppressant's, as well as surgical interventions. Corticosteroids are frequently used, but they carry significant side effects and high recurrence rates. Methotrexate, a non-steroidal immunosuppressive, has shown mixed results in treatment. Surgical interventions such as abscess drainage, wide local excision, or mastectomy are generally reserved for cases that are unresponsive to other treatments or recur frequently. Due to high recurrence rates and inconsistent treatment outcomes, more effective management strategies are needed. This study aims to provide a comprehensive overview of the clinical strategies for diagnosing and treating IGM.

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Received: 02 December, 2024, Manuscript No. japre-24-154708; **Editor Assigned:** 04 December, 2024, PreQC No. P-154708; **Reviewed:** 18 December, 2024, QC No. Q-154708; **Revised:** 23 December, 2024, Manuscript No. R-154708; **Published:** 26 February, 2025, DOI: 10.37421/2684-5997.2025.8.279

Literature Review

Etiology and risk factors

The etiology of Idiopathic Granulomatous Mastitis (IGM) remains uncertain, but several factors have been associated with its development. These include pregnancy, hyperprolactinemia, bacterial colonization by skin flora such as corynebacterium and other diphtheroid species, oral contraceptive use, and autoimmune mechanisms [6-8]. Autoimmune diseases that affect breast tissue, including IGM, are most common in young women of childbearing age [1,9]. Conditions such as Wegener's granulomatosis, giant cell arteritis, and α1-antitrypsin deficiency are known to increase the risk of autoimmune mastitis. Therefore, all patients diagnosed with IGM should be evaluated for underlying autoimmune and infectious diseases, such as tuberculosis [9].

Though rare, granulomatous mastitis can occasionally present as the initial clinical manifestation of sarcoidosis. The co-occurrence of granulomatous mastitis, Erythema Nodosum (EN), and arthritis—termed "GMENA syndrome"—is a distinctive presentation linked to autoimmune rheumatic diseases. GMENA syndrome highlights the need for heightened clinical vigilance, accurate diagnosis, and individualized treatment strategies [10]. Granulomatosis with Polyangiitis (GPA), previously called Wegener's granulomatosis, should also be considered in cases of refractory IGM, even in the absence of classic systemic manifestations. Early diagnosis of GPA allows for appropriate immunosuppressive therapy and avoids unnecessary surgical interventions [11]. Prolactin may play an immunomodulatory role in the pathogenesis of Granulomatous Lobular Mastitis (GLM), necessitating the assessment of potential prolactinoma in undiagnosed cases [12].

GLM primarily affects women aged 30–45, typically within five years postpartum and are uncommon during pregnancy or breastfeeding. Multiple pregnancies and breastfeeding episodes are significant risk factors for recurrence, as increased ductal permeability allows milk to enter lobules, triggering immune responses. Studies have shown that T-cell-mediated immune reactions play a critical role in GLM pathogenesis, with bilateral cases exhibiting a statistically significant increase in CD^{4+}T lymphocytes compared to unilateral cases.

Nipple retraction is an independent risk factor for recurrent GLM. Congenital nipple retraction often results from underdeveloped supporting tissues and terminal mammary ducts, leading to ductal obstruction and milk retention. This increased ductal pressure can cause leakage into surrounding tissues, initiating autoimmune responses and pathological changes characteristic of GLM. Clinicians should closely monitor individuals with nipple retraction or other high-risk features to mitigate the risk of contralateral disease onset.

Additional independent risk factors for unilateral recurrence include nipple discharge, skin trauma, breast abscess, surgical history, and smoking. Meanwhile, fertility, nipple inversion, and alterations in CD4/CD8 ratios are predictive of contralateral disease development [2]. The genetic predisposition to IGM is unclear, with familial cases being rare [13]. Further research into genetic, environmental, and immune-mediated triggers is necessary to enhance our understanding of IGM and its pathogenesis.

Clinical presentation

The clinical presentation of Idiopathic Granulomatous Mastitis (IGM) is highly variable, ranging from a gradually enlarging mass to a painful unilateral breast mass, swelling, fluid collections, skin thickening, redness, *peau d'orange* appearance, skin ulceration, areolar retraction, fistula formation, and axillary lymphadenopathy [6,8,9]. The most common presentation is a breast mass, which may rapidly progress to abscess formation and rupture, accompanied by draining skin sinuses [2,14]. Approximately half of the patients present with moderate symptoms, while the remainder experience either mild or severe presentations [3].

Bilateral or multifocal disease occurs in 12% of cases [6], with the median interval between the onset of bilateral Granulomatous Lobular Mastitis (GLM) being seven months. This highlights the need for patient education, emphasizing vigilance for risk factors within 18 months after the onset of unilateral GLM to prevent contralateral disease. Bilateral GLM is typically more severe, involves a longer disease course, and poses greater challenges in achieving remission compared to unilateral disease. Patients with nipple inversion are three times more likely to develop bilateral GLM, underscoring the importance of close monitoring in this population [15]. IGM often follows a relapsing and remitting course, a pattern that may also extend to its systemic manifestations [16]. This unpredictable nature can significantly impact patients' quality of life and complicate management for clinicians.

Discussion

Differential diagnosis

Differentiating Idiopathic Granulomatous Mastitis (IGM) from similar conditions, such as periductal mastitis, cystic neutrophilic mastitis, corynebacterium kroppenstedtii* infection and Tuberculous Mastitis (TBM), is essential for accurate diagnosis and appropriate management [9]. Symptoms of Granulomatous Lobular Mastitis (GLM) typically include irregular, firm breast masses with limited mobility, often accompanied by axillary lymphadenopathy. These features can mimic malignant breast tumors, leading to misdiagnosis [2].

Tuberculosis mastitis, a rare form of extra pulmonary tuberculosis, must be considered in patients with refractory breast abscesses or persistent sinuses, particularly those from high-risk groups or endemic areas. TBM most frequently affects young women, including nulliparous and lactating individuals. For patients with breast lesions unresponsive to antibiotics, especially in regions with high tuberculosis prevalence, breast tuberculosis should be suspected. The cornerstone of treatment for TBM is Ant Tubercular Therapy (ATT) [16,17]. Interestingly, some studies suggest that ATT might also be an effective treatment option for GM patients, regardless of their clinical presentation [18]. The excellent and rapid radiological response to ATT in certain cases highlights the importance of maintaining a high index of suspicion for TBM, particularly in endemic regions, even when microbiological tests yield negative results [17].

Diagnosis

In terms of initial diagnostic testing patients with suspected Idiopathic Granulomatous Mastitis (IGM) typically undergo radiological studies such as breast ultrasound and mammography. However, due to clinical and radiological similarities with breast cancer, core needle biopsy remains the gold standard for confirming the diagnosis of IGM [9]. Accurate and vigilant diagnostic practices are essential to prevent misdiagnosis or delayed diagnosis.

Imaging: Ultrasound (US) is the preferred initial imaging modality for IGM. Both conventional and Contrast-Enhanced Ultrasound (CEUS) can improve diagnostic accuracy and assist in treatment planning. Typical ultrasound findings include irregular, heterogeneous hypo echoic masses with tubular extensions, skin thickening, and enlarged axillary lymph nodes. These features can resemble the ultrasonography appearance of breast cancer. CEUS has significant diagnostic value in distinguishing IGM from Invasive Ductal Carcinoma (IDC) [2,6,14,19]. On mammography IGM often appears as irregular masses or areas of focal or diffuse asymmetry. These findings are frequently classified as BI-RADS 4a to 4c, indicating a suspicion of malignancy that warrants further evaluation. Magnetic Resonance Imaging (MRI) is not routinely used in the diagnostic workup of IGM.

Histopathology: Core needle biopsy pathology results are critical for diagnosing IGM. Pathological findings consistently show inflammatory granulomatous changes with negative cultures. Key histological features include non-caseating granulomas, organized micro-abscesses, multinucleated giant cells, lymphocytes, plasma cells and epithelioid histiocytes [4,9]. This combination of imaging and histopathological evaluation is essential for accurately diagnosing IGM and differentiating it from malignancies and other mimicking conditions.

Treatment

There is currently no international consensus on the management of Idiopathic Granulomatous Mastitis (IGM). While the condition can be self-limiting, resolving within 5–20 months without intervention, some patients, particularly those with large (>5 cm), bilateral lesions or complications like abscesses and fistulae, may require treatment [6].

Below are the treatment options available:

Antibacterial therapy: Although antibiotics are often initiated while awaiting biopsy and culture results, bacterial cultures in biopsy-proven cases of IGM usually show no significant growth or only identify skin flora contaminants.

Some studies suggest that cotrimoxazole has a high success rate in reducing inflammation, pain, discharge, and abscess formation. It may be a favorable alternative to high-dose corticosteroids or comparable to low-dose corticosteroids for reducing recurrence. Further research is needed to establish its efficacy [6,20].

Oral Steroids (OS)

Oral steroids are widely regarded as a first-line treatment for IGM due to their anti-inflammatory and immunosuppressive properties.

Effectiveness: OS can minimize the need for surgery or reduce the extent of surgical intervention. Studies report a complete response rate of 86% within an average of six months. Recurrence rates are approximately 25% but are significantly reduced when combined with Methotrexate (MTX).

Regimens: Dosing protocols vary widely, including fixed doses (e.g., 32 mg/day) or weight-based regimens (0.5–1 mg/kg/day, depending on lesion

size and severity). Tapering schedules often extend over four to five months. It could be is like following: 50 mg/day for two weeks followed by 25 mg/day for 1 month, then 12.5 mg/day 1 month, then 10 mg/day for 1 month and 5 mg/day for 1 month. The mean complete response time was reported as 6 months and the overall complete response rate was 86%. The recurrence rate is about 25%. Rate of recurrence is notably low when it is used win combination with MTX.

Side effects: Common adverse effects include weight gain, hyperglycemia, opportunistic infections, and Cushing syndrome, occurring in about 10% of patients.

Methotrexate (MTX)

MTX is primarily used as a steroid-sparing agent for patients who do not respond to prednisolone, but its efficacy is controversial and its adverse effect profile, especially among women of reproductive age, has resulted in limited use of this treatment modality [6]. Methotrexate is definitely not a first-line treatment option, it is as second-line treatment for patients who are referred as non-responders to prednisolone

Dosing: Weekly doses of 40 mg over three months have been reported.

Effectiveness: While MTX can be effective in refractory cases, its use is limited due to potential adverse effects, particularly in women of reproductive age. It is generally reserved as a second-line treatment.

Intralesional Steroids (ILS)

There is heterogeneity of Intra-Lesional Steroid (ILS) regimens based on common denominators such as the severity, number, and size of the lesions.

Regimens: Commonly used steroids include triamcinolone, methylprednisolone, and betamethasone, administered from single dose to four times per week depending on the area that is involved. Most studies report using 20 mg/cm^3 of triamcinolone acetonide (or similar steroid) either alone, with saline, or with lidocaine then injected into the center of the lesion, or at multiple sites depending on lesion size and severity. Sometimes it is combined by oral prednisolone or topical steroids like triamcinolon or prednisolone.

Outcomes: Response rates are high, with 93% of patients achieving complete resolution within an average of 2.6 months. Recurrence rates are low (6%), and adverse effects (e.g., skin atrophy and hematoma) occur in only 4% of cases. High-dose steroid (40mg and 80mg) treatment was shown that was effective in burnout lesions, and it was found to be statistically significant in lowering number of treatments irrespective of grade [14].

Surgery

Surgical intervention is typically reserved for severe or refractory cases.

Approach: Local excision is the most common surgical treatment, with mastectomy reserved for diffuse or recurrent disease [6]. Because of possible malignancy risk with chronic IGLM, patients should not delay surgical excision if their condition remains refractory to medical therapy alone.

Outcomes: Recurrence rates are around 31% at 12 months. Complications, such as infections, poor wound healing, and scarring, occur in 8% of patients. Surgery is often considered a last resort due to its potential for disfigurement and the desire to preserve breast tissue and quality of life.

Emerging and alternative treatments

Hyperbaric Oxygen Therapy (HBOT): Effective in refractory cases, HBOT reduces steroid doses and treatment duration. Prospective studies are needed to evaluate its long-term efficacy and cost-effectiveness [21].

Microwave Ablation (MWA): A minimally invasive option, MWA offers high cure rates, low recurrence and excellent cosmetic outcomes, making it an alternative for patients with complex conditions requiring surgery [22].

The management of IGM requires a personalized approach, considering the disease severity, patient preferences, and the risks and benefits of each treatment modality. Ongoing research and consensus development are needed to standardize treatment protocols and improve outcomes.

Approach to patient

Idiopathic Granulomatous Mastitis (IGM) is an autoimmune breast condition predominantly affecting women of non-white ethnicities, including Southeast Asians, Middle Easterners, and Hispanics. It commonly presents as a painful breast mass, and patients often undergo invasive diagnostic or surgical procedures, which can result in disfiguring scars. Early diagnosis and treatment with immunosuppressive medications can reduce the need for invasive interventions. Previously managed with a primarily surgical approach, IGM is now recognized as an inflammatory, autoimmune disease, shifting patient care toward medical treatment, often with rheumatological consultation [9]. Treatment strategies are evolving, with recent literature highlighting the efficacy of conservative management using steroids and immunosuppressive therapies. Surgery is now generally reserved for complicated or refractory cases [5].

Mild to moderate symptoms: For patients with mild to moderate symptoms, intralesional steroid injections combined with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are recommended for up to three months. If symptoms persist or relapse, oral immunosuppressive therapy should be considered, alongside a rheumatology consultation when available.

Severe symptoms: In severe cases, limited surgical intervention may be required for symptom relief or to address local wound concerns. Concurrently, oral steroid therapy should be initiated, and a rheumatology consult sought to optimize management.

Refractory or relapsing symptoms: For persistent or recurrent symptoms, methotrexate or azathioprine combined with intralesional steroids can be effective.

Surgery: If symptoms persist beyond one year, surgical management should be considered.

Infectious complications: A small subset of patients with biopsy-confirmed Granulomatous Mastitis (GM) and active bacterial infections may benefit from concurrent antibiotic therapy [3]. A symptom-based treatment algorithm can aid clinical decision-making [4]. Diagnostic and procedural steps should align with the primary presenting symptom:

Breast lump: Core needle aspiration is recommended to confirm pathology.

Abscess: If an abscess is present, a tissue biopsy should be performed, followed by either percutaneous drainage or ultrasound-guided incision and drainage for larger abscesses [15]. This approach balances medical management and minimally invasive procedures to optimize outcomes while minimizing scarring and preserving breast aesthetics (Figure 1) [23-27].

While Granulomatous Mastitis (GM) can follow a prolonged course, most patients experience symptom improvement within one year, though fewer than one-third see resolution or significant improvement within the first month. Immunosuppressive therapy has demonstrated the greatest benefit, offering the fastest symptom resolution and is recommended as a first-line intervention. For mild to moderate cases, intralesional steroids are preferred over oral immunosuppression due to their efficacy and lower risk of systemic side effects. In more severe cases, oral immunosuppression, with or without limited surgical intervention, may be required [8].

Comparison of intralesional steroids and oral immunosuppression: Several studies comparing systemic oral immunosuppression to intralesional steroid therapy have shown either equal or superior outcomes with intralesional steroids, with fewer systemic adverse effects. Specifically:

Response Rate (RR): Intralesional steroids demonstrated a higher response rate compared to systemic therapy or surgery.

Adverse Effects (AE): Intralesional steroids were associated with significantly fewer adverse effects without an increase in recurrence rates.

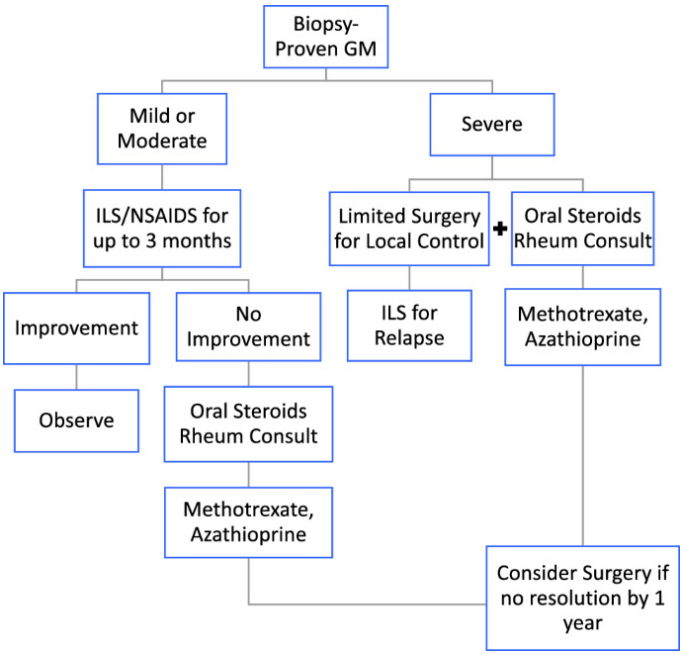

Figure 1. Treatment of biopsy- confirmed granulomatous mastitis. GM: Granulomatous Mastitis, ILS: Intralesional Stroids, Nsaids: Non-Steroidal Anti-Inflammatory Drugs, Rheum: Rheumatology.

No significant differences in symptom improvement or resolution at one year were observed between patients treated with oral immunosuppression alone, intralesional steroids alone, or a combination of the two. Consequently, intralesional steroids are recommended as the first-line treatment for mild to moderate symptoms to minimize systemic side effects, such as weight gain, hyperglycemia, osteoporosis and increased susceptibility to infections. Alternative immunosuppressive options for patients with protracted GM, or those who are intolerant or resistant to oral steroids, other immune-modulating therapies such as methotrexate and azathioprine have shown promise. These agents, traditionally managed by rheumatologists, can achieve relapse-free remission rates ranging from 58% to 100%. Surgeons managing GM should be familiar with these alternatives, as they may be particularly useful in patients experiencing severe adverse effects from prolonged oral steroid use or in cases of refractory disease. Collaborative care with rheumatologists may optimize outcomes for patients with challenging or persistent GM symptoms [4,27-38].

Conclusion

Idiopathic Granulomatous Mastitis (IGM) is a rare breast condition with uncertain causes and no universally agreed-upon treatment guidelines. Most patients with IGM experience symptom improvement within one month to one year. In managing biopsy-confirmed granulomatous mastitis, immunosuppressive therapy offers the most rapid symptom resolution and is recommended as the first-line intervention. For mild to moderate cases, intralesional steroids are preferred over oral immunosuppressants, while more severe cases may require oral immunosuppression. Surgical intervention remains an option in select cases.

Although uncommon, IGM requires breast surgeons to adopt a multimodal, symptom-focused approach, emphasizing the importance of comprehensive, multidisciplinary care. Further research is essential to uncover the inflammatory mechanisms behind IGM, investigate potential environmental, genetic, and immune-related risk factors, and develop tailored management approaches. Future studies should also explore the optimal extent of surgical intervention and the most effective immunosuppression protocols to better inform clinical decisions. A large-scale, multidisciplinary effort to establish a comprehensive registry could enhance understanding of the disease's ideology and support more informed treatment strategies.

Acknowledgement

None.

Conflict of Interest

None.

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How to cite this article: Zaji, Nita and Nargol Salimi. "Idiopathic Granulomatous Mastitis: Challenges, Treatments and Advancing Care Strategies." *J Anesth Pain Res* 8 (2025): 279.