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Granulomatous Mastitis: A Systematic Review of Diagnosis and Management

Majid Montazer Bavil Olyaee [1], Ehsan Mohammadzadeh Abachi[2*]

[1]Associate Professor of Thoracic Surgery, Department of Cardiovascular Surgery, School of Medicine, Tabriz University of Medical Sciences, Tabriz

[2]Assistant Professor of Surgery, Department of General Surgery, School of Medicine, Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, Tabriz, Iran

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ABSTRACT

Granulomatous mastitis is a rare chronic inflammatory breast disease that often mimics malignancy and presents diagnostic and therapeutic challenges. Its unclear etiology, variable clinical course, and lack of standardized management have led to diverse treatment approaches. A comprehensive evaluation of current evidence is essential to optimize diagnosis, guide therapy, and improve patient outcomes. This systematic review synthesizes current evidence on the diagnosis and management of granulomatous mastitis, aiming to clarify clinical approaches and inform evidence-based decision-making in practice. Granulomatous mastitis is a benign but clinically challenging breast disease characterized by diagnostic ambiguity, heterogeneous pathogenesis, and variable treatment responses. Its frequent clinical and radiologic overlap with breast malignancy and infection contributes to delayed diagnosis and inconsistent management. The immune-mediated and multifactorial nature of the disease explains its chronic course and risk of recurrence, particularly when inflammation is insufficiently controlled. Variability in therapeutic strategies largely reflects the absence of standardized guidelines and high-quality evidence. These factors collectively result in diverse clinical outcomes and highlight the need for individualized, evidence-based management supported by robust prospective research.

Introduction

Granulomatous mastitis is a rare, benign, chronic inflammatory disease of the breast that predominantly affects women of reproductive age and often poses significant diagnostic and therapeutic challenges. First described several decades ago, this condition remains incompletely understood and is frequently mistaken for breast carcinoma due to its clinical and radiologic resemblance to malignant lesions. Patients commonly present with a unilateral breast mass, pain, erythema, skin thickening, or fistula formation, features that may closely mimic inflammatory breast cancer and lead to considerable anxiety for both patients and clinicians (1). The etiology of granulomatous mastitis is multifactorial and continues to be a subject of debate. Idiopathic granulomatous mastitis represents the most commonly recognized form, in which no specific infectious or systemic cause can be identified. Proposed mechanisms include autoimmune reactions, localized immune dysregulation, hormonal influences, and reactions to extravagated secretions from breast lobules. The lack of a clearly defined pathophysiological pathway has contributed to heterogeneity in diagnostic approaches and treatment strategies across different clinical settings (2). Hormonal and reproductive factors appear to play an important role in the development of granulomatous mastitis. The disease is most frequently observed in parous women, often within a few years after pregnancy or breastfeeding. Hyperprolactinemia, oral contraceptive use, and a history of recent lactation have been suggested as potential risk factors. These observations support the hypothesis that hormonal stimulation of breast tissue

*Corresponding Author: ***Ehsan mohammadzadeh Abachi*** *(ehsanabachi@gmail.com - ORCID: 0009-0009-9410-1657)*
1 Email: mmontazer@gmail.com - ORCID: 0000-0001-7846-0128)

may predispose susceptible individuals to an exaggerated inflammatory response, ultimately resulting in granuloma formation (3).

Infectious agents have also been implicated in certain cases of granulomatous mastitis, particularly species of Corynebacterium. Advances in microbiological techniques have enabled improved detection of these organisms in breast tissue samples, raising questions about whether some cases previously labeled as idiopathic may in fact have an infectious origin. Nevertheless, the causal role of bacteria remains controversial, as many patients do not respond consistently to antibiotic therapy alone, suggesting that infection may act as a triggering rather than a sustaining factor (4).

Clinically, granulomatous mastitis exhibits a highly variable course, ranging from self-limited inflammation to aggressive, recurrent disease with abscess formation and sinus tract development. The unpredictable natural history complicates decision-making and often necessitates prolonged follow-up. Some patients experience spontaneous resolution, whereas others endure repeated flares over months or years, significantly impairing quality of life and psychological well-being (5).

Radiologic evaluation is an essential component of the diagnostic workup but rarely provides definitive answers. Mammography, ultrasound, and magnetic resonance imaging often demonstrate nonspecific findings such as irregular masses, architectural distortion, or fluid collections. These imaging characteristics overlap considerably with those of breast malignancy, reinforcing the need for tissue diagnosis. As a result, radiologic assessment primarily serves to guide biopsy and exclude alternative pathologies rather than establish a conclusive diagnosis (6).

Histopathological examination remains the gold standard for diagnosing granulomatous mastitis. Characteristic findings include non-caseating granulomas centered on breast lobules, composed of epithelioid histiocytic, multinucleated giant cells, lymphocytes, and plasma cells. The exclusion of other granulomatous diseases, such as tuberculosis, sarcoidosis, and fungal infections, is a critical step in confirming the diagnosis. This often requires special stains, cultures, and correlation with clinical and laboratory data (7).

The differential diagnosis of granulomatous mastitis is broad and encompasses both benign and malignant conditions. Failure to accurately distinguish this entity from breast cancer may lead to unnecessary radical surgery or overtreatment. Conversely, misattributing malignant disease to benign inflammation can result in delayed cancer diagnosis. Therefore, a high index of suspicion and a multidisciplinary approach involving surgeons, radiologists, pathologists, and infectious disease specialists are essential for optimal patient care (8).

Management of granulomatous mastitis remains controversial, with no universally accepted treatment algorithm. Therapeutic options include observation, antibiotics, corticosteroids, immunosuppressive agents, and surgical intervention. The choice of treatment is often individualized, based on disease severity, presence of infection, patient preferences, and clinician experience. This variability reflects the limited high-quality evidence available to guide clinical practice (9).

Corticosteroid therapy has been widely used due to its anti-inflammatory and immunosuppressive effects and has demonstrated favorable outcomes in many patients. However, steroid treatment is associated with potential adverse effects, including weight gain, glucose intolerance, osteoporosis, and increased susceptibility to infection. Relapse after steroid tapering is also common, highlighting the need for careful patient selection and monitoring (10).

Immunosuppressive agents such as methotrexate and azathioprine have emerged as alternative or adjunctive therapies, particularly in steroid-resistant or recurrent cases. These agents may allow for lower steroid doses and reduced treatment duration. Nevertheless, concerns regarding toxicity, long-term safety, and limited evidence from controlled studies have restricted their widespread adoption, underscoring the importance of further research (11).

Surgical management, ranging from abscess drainage to wide local excision, has historically played a prominent role in treatment. While surgery may provide rapid symptom relief in selected cases, it is associated with risks of poor wound healing, fistula formation, cosmetic deformity, and high recurrence rates if performed during active inflammation. Consequently, many experts now advocate for a more conservative approach, reserving surgery for refractory or complicated disease (12). The recurrence of granulomatous mastitis represents a major clinical challenge. Recurrence rates vary widely in the literature, reflecting differences in patient populations, treatment modalities, and follow-up duration. Identifying predictors of recurrence, such as disease extent, treatment choice, and underlying risk factors, is crucial for optimizing long-term outcomes and counseling patients regarding prognosis (13).

Beyond physical symptoms, granulomatous mastitis exerts a substantial psychosocial burden. Chronic pain, visible breast changes, prolonged treatment courses, and fear of malignancy can contribute to anxiety, depression, and impaired body image. Addressing these aspects through patient education, reassurance, and psychological support is an integral yet often overlooked component of comprehensive care (14). Despite growing awareness of granulomatous mastitis, significant gaps remain in

our understanding of its pathogenesis, optimal diagnostic strategies, and most effective treatments. The rarity of the condition, combined with heterogeneous study designs and small sample sizes, has limited the strength of existing evidence. As a result, clinical practice is frequently guided by institutional experience rather than robust data (15). Given these uncertainties, a systematic synthesis of available evidence is essential to clarify current knowledge, compare diagnostic modalities, evaluate treatment outcomes, and identify areas requiring further investigation. Accordingly, the present study aims to systematically review the literature on granulomatous mastitis, with a focus on diagnostic approaches and management strategies, to provide a comprehensive and evidence-based overview for clinicians and researchers.

Material and methods

This study was conducted as a systematic review to comprehensively evaluate the available evidence regarding the diagnosis and management of granulomatous mastitis. A structured and systematic literature search was performed across multiple electronic databases, including PubMed/MEDLINE, Scopus, Web of Science, Embase, Cochrane Library, and Google Scholar. The search strategy was developed using a combination of controlled vocabulary and free-text terms related to the condition and its management, including "granulomatous mastitis," "idiopathic granulomatous mastitis," "diagnosis," "treatment," "management," "therapy," and "breast inflammation." Boolean operators were applied to optimize the search strategy (e.g., "granulomatous mastitis" AND "diagnosis" OR "treatment"). Relevant articles were identified without restriction on study design, and reference lists of selected studies were manually screened to ensure completeness. This study was approved by the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.FMD.REC.1404.318).

Results

Diagnosis of Granulomatous Mastitis

Granulomatous mastitis (GM) is an uncommon, benign inflammatory disease of the breast defined by granuloma formation predominantly involving the lobular units. From an etiological perspective, GM is divided into idiopathic granulomatous mastitis (IGM) in which no specific cause can be identified and secondary granulomatous mastitis, which arises in the context of identifiable conditions such as infections, systemic granulomatous disorders, or local foreign-body reactions. IGM mainly affects women of reproductive age and frequently occurs in temporal association with pregnancy or lactation, supporting hypotheses related to immune dysregulation, hormonal influences, and autoimmune mechanisms rather than a single causative factor (16,17).

The clinical presentation of GM is highly variable but most often includes a unilateral breast mass that is firm, tender, and progressively enlarging. Inflammatory signs such as skin erythema, edema, fistula formation, and abscesses are common, while nipple retraction and axillary lymphadenopathy may further complicate the clinical picture. These manifestations closely resemble those of inflammatory or locally advanced breast carcinoma, making GM a frequent diagnostic pitfall and emphasizing the importance of a systematic diagnostic approach to avoid misdiagnosis and overtreatment (18,19).

Breast imaging contributes to evaluation but lacks specificity for definitive diagnosis. On ultrasonography, GM typically appears as irregular hypoechoic masses, heterogeneous parenchymal distortion, or tubular hypoechoic extensions, sometimes associated with collections suggestive of abscesses. Mammography may show focal asymmetry or ill-defined masses, whereas MRI often demonstrates segmental or regional non-mass enhancement with inflammatory changes. Despite their utility in assessing disease extent and complications, these imaging modalities cannot reliably distinguish GM from malignancy, underscoring their inherent diagnostic limitations (20,21).

Histopathological examination is the diagnostic cornerstone of GM. Core needle biopsy usually reveals noncaseating granulomas composed of epithelioid histiocytic, multinucleated giant cells, lymphocytes, and plasma cells, centered on breast lobules. The absence of caseous necrosis favors idiopathic disease but is not exclusive, necessitating careful correlation with clinical and microbiological findings. Pathology is also essential for excluding invasive carcinoma and specific infectious granulomatous processes, thereby guiding appropriate management strategies (22,23).

A thorough differential diagnosis is mandatory and should particularly address breast cancer, tuberculous mastitis, and systemic granulomatous diseases such as sarcoidosis. Microbiological evaluation including cultures and molecular assays has gained increasing relevance with growing evidence linking Corynebacterium species, especially Corynebacterium kroppenstedtii, to a subset of GM cases. Identification of an infectious component not only refines the diagnosis but also has therapeutic implications, reinforcing the concept of GM as a heterogeneous disease entity with multiple pathogenic pathways (24,25) (figure 1).

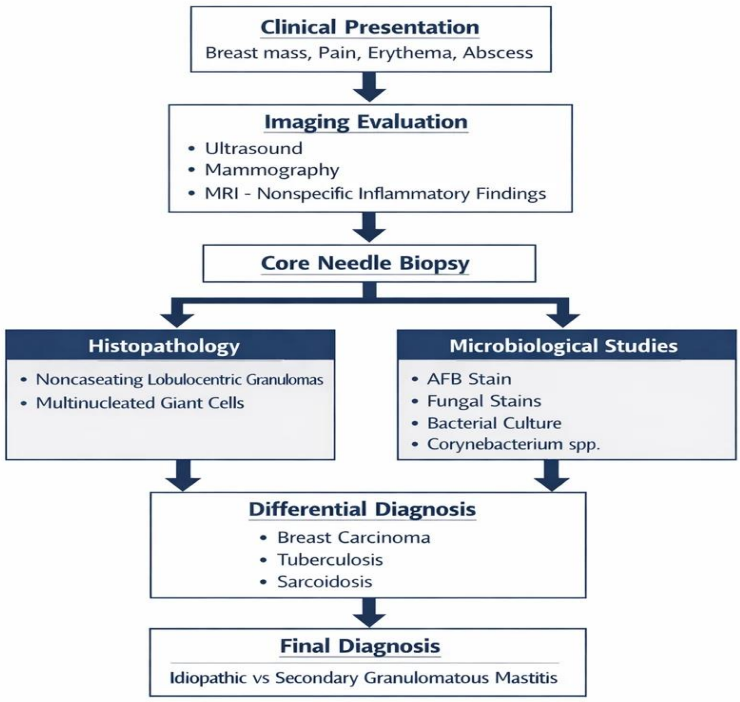

Figure 1. Diagnostic Algorithm for Granulomatous Mastitis

Management and Treatment Strategies in Granulomatous Mastitis

The management of granulomatous mastitis (GM), particularly idiopathic granulomatous mastitis (IGM), is complex and remains controversial due to its unpredictable clinical course and heterogeneous response to therapy. While GM is a benign condition, its tendency to mimic malignancy and its potential for chronicity and recurrence necessitate a carefully balanced treatment strategy. Current approaches emphasize individualized management based on disease severity, symptom burden, extent of breast involvement, and patient-related factors, rather than a uniform treatment algorithm. This paradigm reflects increasing recognition that overtreatment may result in unnecessary morbidity, whereas under treatment can prolong symptoms and impair quality of life (26,27).

Conservative management, including observation with close clinical follow-up, has emerged as a reasonable initial strategy for selected patients with mild, localized disease and minimal symptoms. This approach is predicated on histopathologic confirmation of GM and exclusion of specific infectious or systemic causes. Several studies have demonstrated that spontaneous resolution may occur over time, supporting watchful waiting as a valid option in carefully monitored cases. Nonetheless, conservative management requires vigilant follow-up to promptly identify progression, abscess formation, or fistulization that would warrant escalation of therapy (28,29).

Antibiotic therapy occupies a selective role in the treatment of GM and should not be routinely administered in the absence of infection. Antibiotics are most appropriately used when there is microbiological evidence of bacterial involvement, secondary infection, or abscess requiring drainage. Increasing attention has been directed toward Corynebacterium species, particularly Corynebacterium kroppenstedtii, which have been isolated in a subset of patients and may influence therapeutic decision-making. In such cases, targeted and often prolonged antibiotic regimens may be beneficial, underscoring the importance of culture-directed therapy rather than empiric use (30,31).

Systemic corticosteroids constitute a cornerstone of treatment for moderate to severe GM due to their potent anti-inflammatory effects and ability to induce relatively rapid clinical improvement. Typical regimens involve an initial moderate dose followed by gradual tapering over weeks to months; however, relapse during dose reduction or after cessation is common. Additionally, the potential for significant adverse effects including weight gain, glucose intolerance, hypertension, osteoporosis, and increased infection risk limits long-term use. These concerns have prompted growing interest in steroid-sparing strategies and careful patient selection to optimize the risk–benefit balance (32,33).

Immunosuppressive agents such as methotrexate and azathioprine have been increasingly employed as adjuncts or alternatives in patients with recurrent disease, corticosteroid dependence, or contraindications to steroid therapy. Observational studies suggest favorable disease control and reduced relapse rates when these agents are used judiciously. Surgical intervention, once considered a

primary treatment modality, is now generally reserved for specific indications such as persistent abscesses, refractory localized disease, diagnostic uncertainty, or significant cosmetic deformity. Comparative analyses indicate that combined medical approaches often achieve lower recurrence rates and better cosmetic outcomes than surgery alone, reinforcing the shift toward multidisciplinary, medically driven management strategies (34,35) (figure 2).

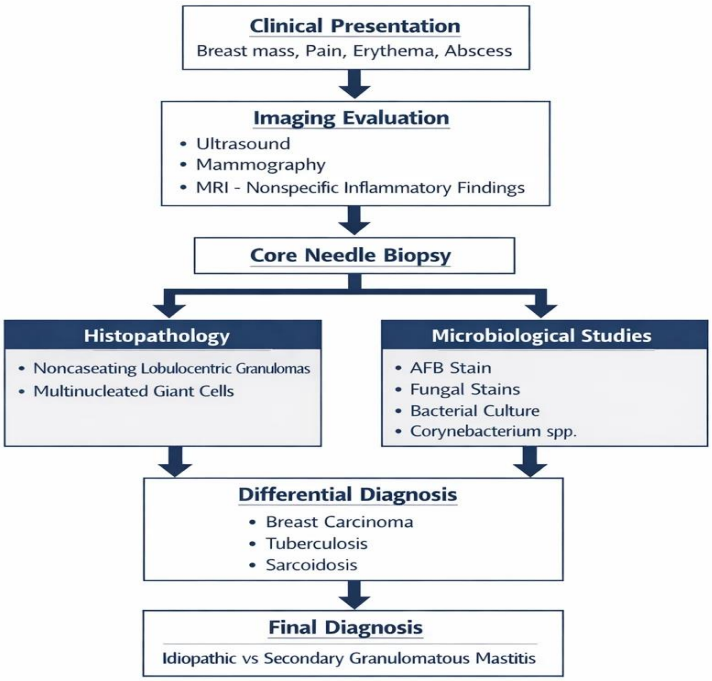

Figure 2. Management and Treatment Strategies in Granulomatous Mastitis

Challenges, Outcomes, and Evidence Gaps in Granulomatous Mastitis

Granulomatous mastitis (GM), particularly idiopathic granulomatous mastitis, poses substantial diagnostic and therapeutic challenges in routine clinical practice, largely because its clinical and radiologic appearance often mimics breast carcinoma and infectious mastitis. Distinguishing GM from malignancy requires a high index of suspicion and timely core needle biopsy, yet even histopathologic interpretation may be complicated by overlapping features with specific granulomatous infections and systemic granulomatous disorders. On the therapeutic side, clinicians must navigate a heterogeneous evidence base when choosing between conservative management, immunomodulatory therapy, and surgical approaches, often in the context of limited local expertise and varying patient expectations (37,38).

Disease recurrence represents a key concern in the longitudinal care of patients with GM, with reported relapse rates ranging widely depending on population, phenotype, and treatment modality. Recurrence has been variably associated with factors such as extensive parenchymal involvement, delayed diagnosis, inadequate initial control of inflammation, premature tapering of corticosteroids, and the absence of steroid-sparing agents in patients with aggressive disease. However, the predictive value of these factors remains inconsistent across studies, in part due to small sample sizes, retrospective designs, and differences in outcome definitions, making it difficult to derive robust, generalizable prognostic models for routine clinical use (39,40).

Beyond somatic outcomes, GM imposes considerable clinical and psychological burden on affected women, who are often in reproductive age and may experience pain, disfigurement, recurrent abscesses, and prolonged treatment courses that interfere with work, family responsibilities, and breastfeeding. Anxiety is frequently heightened by the initial suspicion of malignancy, repeated imaging, and invasive procedures, while chronic inflammation and scarring may contribute to persistent body image disturbance and depressive symptoms. Despite these observations, formal assessment of quality of life, mental health outcomes, and patient-reported experience remains scarce, and these domains are rarely incorporated as primary endpoints in interventional studies of GM (41,42).

A major structural challenge in the field is the absence of a unified, evidence-based international guideline for the diagnosis and management of GM, leading to marked variation in practice patterns across institutions and regions. Current recommendations are largely derived from single-center experiences, small case series, and expert opinion, resulting in divergent strategies regarding

the timing and intensity of immunosuppressive therapy, the role of surgery, and the appropriateness of conservative observation. This lack of standardization complicates shared decision-making, hinders comparability of outcomes between cohorts, and may contribute to both under- and overtreatment in different clinical settings (43,44).

The existing literature on GM is limited by methodological constraints, including retrospective designs, small sample sizes, inconsistent diagnostic criteria, variable follow-up durations, and heterogeneity in treatment protocols and outcome measures. These limitations impede firm conclusions regarding the relative effectiveness and safety of different treatment strategies and obscure true recurrence patterns over time. There is a clear need for well-designed prospective studies, ideally multicenter and randomized where feasible, as well as rigorously conducted systematic reviews and meta-analyses that apply standardized inclusion criteria and critical appraisal tools. Such higher-quality evidence is essential to synthesize current data, identify knowledge gaps, and ultimately support the development of consensus guidelines that can improve patient outcomes and reduce unwarranted practice variation (45,46) (figure 3).

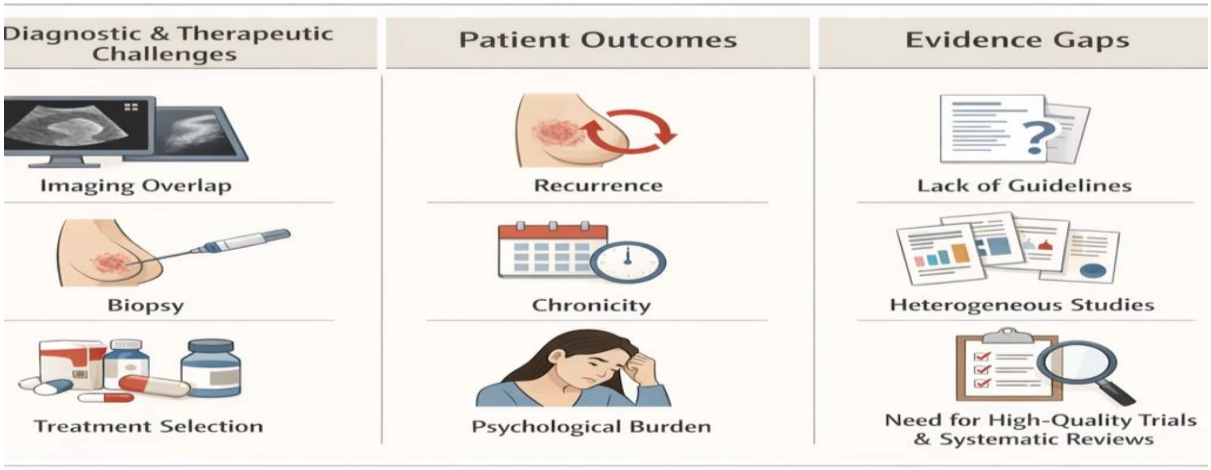

Figure 3. Conceptual Framework of Clinical Challenges, Patient Outcomes, and Evidence Gaps in Granulomatous Mastitis

Discussion

The findings summarized in this study reflect the inherently heterogeneous nature of granulomatous mastitis (GM) and help explain why variability in diagnosis, management, and outcomes persists across clinical settings. The frequent diagnostic difficulty arises from the substantial overlap between GM, breast malignancy, and infectious mastitis at both clinical and imaging levels, which often delays definitive diagnosis and appropriate treatment initiation. This delay may contribute to more extensive disease at presentation and partly explains the chronic or recurrent course observed in a subset of patients. Moreover, the lack of specific radiologic or laboratory markers reinforces reliance on histopathology, which itself may be subject to interpretive variability depending on sampling adequacy and exclusion of secondary causes (47).

The observed recurrence rates and their wide range across studies are likely multifactorial and closely linked to both disease biology and treatment strategies. GM is increasingly understood as an immune-mediated inflammatory condition rather than a purely infectious process, which may explain why incomplete suppression of inflammation such as premature corticosteroid tapering or reliance on surgery alone predisposes to relapse. Additionally, extensive lobular involvement and delayed immune control may establish a self-perpetuating inflammatory milieu, increasing susceptibility to recurrence. Variability in reported predictors reflects inconsistent definitions of recurrence, heterogeneous follow-up durations, and non-standardized treatment protocols across studies (48).

The clinical and psychological burden observed among patients with GM is a direct consequence of its chronic, relapsing nature and the demographic profile of those affected, predominantly young women of reproductive age. Recurrent abscesses, fistula formation, prolonged immunosuppressive therapy, and cosmetic deformity can significantly disrupt daily functioning, employment, and family roles. Psychological distress is further amplified by the initial fear of malignancy and the uncertainty surrounding disease course and treatment duration. The limited attention given to patient-reported outcomes in existing studies likely underestimates the true impact of GM on quality of life and mental health (49).

Another key factor underlying the reported outcomes is the absence of a unified, evidence-based guideline for GM management. In the absence of standardized recommendations, treatment decisions are often guided by local experience, specialty

preference, and clinician familiarity with immunomodulatory therapies. This results in substantial inter-center variability, ranging from early surgical excision to prolonged conservative management or aggressive immunosuppression. Such heterogeneity not only affects individual patient outcomes but also complicates comparison across studies, thereby perpetuating uncertainty regarding optimal care pathways (50).

Finally, the limitations of the existing evidence base largely explain why definitive conclusions regarding best practice remain elusive. Most available studies are retrospective, single-center analyses with small sample sizes, heterogeneous inclusion criteria, and variable outcome measures, limiting both internal and external validity. These methodological constraints hinder robust comparisons between treatment modalities and obscure long-term outcomes such as true recurrence rates and sustained remission. Consequently, there is a pressing need for high-quality prospective studies and well-conducted systematic reviews to integrate existing data, reduce bias, and support the development of consensus-driven clinical guidelines for GM (51).

Conclusion

In conclusion, granulomatous mastitis represents a complex benign breast disease in which diagnostic ambiguity, heterogeneous pathogenesis, and variable therapeutic responses collectively shape clinical outcomes. The frequent overlap with malignancy and infection explains delays in diagnosis, while the immune-mediated and potentially multifactorial nature of the disease underlies its chronicity and tendency toward recurrence. Variability in management strategies largely reflects the absence of high-quality evidence and unified guidelines, contributing to inconsistent outcomes and patient burden. Addressing these challenges requires a more standardized diagnostic framework, greater integration of medical rather than surgical approaches, and robust prospective research incorporating both clinical endpoints and patient-reported outcomes to inform evidence-based, patient-centered care.

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Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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