



Re-evaluating if observation continues to be the best management of idiopathic granulomatous mastitis



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ABSTRACT

Background: The presentation of idiopathic granulomatous mastitis can mimic breast cancer. Therefore, awareness of the condition is important for surgeons. The current series is the largest in a US population. **Methods:** Retrospective chart review of patients treated at a county, safety-net hospital in Arizona. Cases were identified from January 2006 to January 2019. Sociodemographic information, clinical history, management, and outcomes were collected.

Results: There were 145 occurrences of idiopathic granulomatous mastitis among 120 women. Most of the patients (92%) were of Hispanic ethnicity and born outside (87%) of the United States. The average age was 35 years. Nearly all patients (95%) were parous, with an average of 3 pregnancies. Most (88%) presented with a palpable mass, and more than half (54%) of these masses were painful. Six patients had prolactinomas or hyperprolactinemia, 11 patients were pregnant, and 5 were postpartum. Early in the time period studied, 6 patients underwent excision of the masses. The remaining 114 underwent planned observation after biopsy confirmation of the diagnosis. Two patients were lost to follow-up, and the other 112 patients with idiopathic granulomatous mastitis resolved spontaneously. Nineteen had more than 1 episode. Average time to resolution was 5 months (range 0–20). Adjusted log-normal regression analysis found that later age of first live birth was associated with greater time to resolution ($P < .01$).

Conclusion: Idiopathic granulomatous mastitis is a self-limited, benign condition that waxes and wanes and eventually resolves without resection. After diagnosis, medications are unnecessary, and operations can be limited to drainage procedures for fluid collections.

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Introduction

Idiopathic granulomatous mastitis (IGM) is a benign inflammatory disease of the breast first reported in 1972 by Kessler and Wolloch.¹ The etiology of IGM is poorly understood, but studies have implicated that pathogenesis may be explained by non-specific lobulitis owing to lobule deformation, trauma as seen in multifocal granulomatous thyroiditis, and others.^{2,3}

IGM may have a hormonal component to the etiology, because IGM most commonly effects parous women of reproductive age. In our study, as in most others in the literature, Hispanic women immigrating to the United States, particularly from Mexico, tend to have a greater incidence of IGM.^{4–7} IGM also correlates with the use of oral contraceptives, previous and current pregnancy, and breast-feeding, yet no causal relationships have been reported.⁸ IGM rarely occurs in men.⁹ Prolactin has also been implicated, because there have been patients who presented with concurrent prolactinomas or hyperprolactinemia who were not being treated at the time of their IGM diagnosis.^{4,5,10,11}

Although benign, IGM remains important to recognize, because it can present with clinical features very similar to breast carcinoma

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and infection. Therefore, it is crucial to obtain a timely and accurate diagnosis to allow appropriate directed management and prevent unwarranted and potentially disfiguring procedures. IGM typically manifests as a palpable unilateral mass, although bilateral presentation has been reported as well. Associated clinical findings have included erythema, edema, a draining sinus, pain, and ulceration. Suspicion for IGM can be made based on clinical presentation and appearance on imaging, using mammogram and ultrasonography. Diagnosis with core needle biopsy is required to confirm the diagnosis. Diagnosis of IGM can be made by histologic findings characterized by a granulomatous, inflammatory reaction centered on lobules and composed of epithelioid histiocytes, multinucleated giant cells with admixed lymphocytes, plasma cells, and eosinophils, in addition to exclusion of other possible diagnoses (ie, malignancy, tuberculosis infection, sarcoidosis, and Wegener's granulomatosis).⁴

Currently, there is no gold standard regarding the management and treatment of IGM, but treatments used have included observation, steroids, operative intervention, or immunosuppressant therapy (eg, methotrexate).^{12,13} Simple incision and drainage and antibiotic therapy have been used but without promising success.^{4,10} Because of the unknown pathogenesis of IGM and lack of unanimity on treatment, medications with substantial side effects and medically unnecessary mastectomies have been performed. Despite these extensive interventions, recurrence has been reported postmastectomy.^{4,11,14} The current study was performed to evaluate the outcomes of patients with IGM managed by observation, patient education, and supportive care. To our knowledge, this is the largest IGM study from the United States to date.

Methods

This study was conducted at Maricopa Medical Center and was approved by our institutional review board. Maricopa Medical Center is the safety-net hospital for Maricopa County which includes the city of Phoenix and the surrounding metropolitan area. Maricopa County is the state's most populous area with nearly 4 million of the 6.5 million inhabitants in Arizona. Our medical center serves a patient population of whom 78% are from racial or ethnic minority groups, and 79% are underinsured, uninsured, or insured by Medicaid.

This retrospective chart review involved all patients from January 2006 to January 2019 seen in our breast clinic. All patients with a pathologic diagnosis of granulomatous (lobular) mastitis on biopsy specimens were included in the study. Pathologic criteria for the diagnosis of IGM were determined by the presence of non-caseating inflammatory granulomas within lobules that contained lymphocytes, plasma cells, eosinophils, epithelioid histiocytes, and multinucleated giant cells. The presence of abscess formation, fat necrosis, and fibrosis were also seen. Tissue stains for acid-fast bacilli and gomori methenamine silver (fungi) were performed on 79% (95 of 120) of patients. All patients were evaluated for sociodemographic characteristics, clinical presentation, clinical management, and outcome. A remote history of breast feeding was not collected routinely. Patients were informed that their condition was benign and would not require medication or invasive operative intervention. The management plans were discussed with the patients to involve close observation with patient education. Patients were reassured that their condition would resolve with time. Patients were told, however, that the management would require patience, the natural history of the disease process sometimes does result in exacerbation before resolution, and the time to resolution could be up to 20 months. Operative intervention was limited to core needle biopsy for diagnosis and incision for drainage as needed for fluid collections related to necrosis. Cultures were not

Table 1
Patient sociodemographic characteristics

	Patients (N = 120)
Mean age in years (range)	35 (19–61)
Race/ethnicity	
Hispanic	111 (92%)
African American	2 (2%)
Non-Hispanic White	6 (5%)
Native American	1 (1%)
Birth country	
United States	16 (13%)
Mexico	101 (84%)
Guatemala	2 (2%)
Kenya	1 (1%)
Menarche in years (range)	13.0 (9–17)
Mean pregnancies (range)	3.0 (0–11)
Mean live births (range)	2.6 (0–8)
Mean age first live birth (range)	21.6 (14–35)
Smoking status	
Never	108 (90%)
Former	4 (4%)
Current	8 (6%)
Body mass index, kg/m ² (range)	30.1 (17.3–50.6)
Patients with hormonally active condition	
Prolactinoma, hyperprolactinemia	6 (5%)
Pregnant	11 (9%)
Breast feeding	3 (3%)
Postpartum	2 (2%)
Insurance status	
Insured	19 (15%)
Uninsured	101 (85%)
Education	
Elementary (6 y or less)	23 (19%)
Middle school (7–8 y)	12 (10%)
High school (9–12 y)	67 (55%)
Some college (13 y or more)	18 (15%)

performed on fluid collections. No patient received immunosuppressant therapy during the time of observation. One pregnant patient did receive amphotericin at the insistence of an infectious disease physician, but this resulted in no improvement of the presenting mass.¹⁰ Patients were considered clinically resolved when no palpable mass in the breast was present and there was no residual wound. Factors which could affect time to resolution were evaluated using log-normal regression. The relative risk ratio was the geometric mean ratio derived from log-normal regression. Factors found to be statistically significant in the unadjusted analysis were included in the adjusted analysis.

Results

A total of 120 patients, all females, were identified with IGM during the study period. Nineteen patients had more than 1 episode for a total of 145 occurrences reported. The sociodemographic information is shown in Table 1. The average age was 35 years old. Most patients (92%) were of Hispanic ethnicity and born outside (87%) of the United States. The majority of patients were born in Mexico or were born in the United States to Mexican parents. Fully 95% of patients were parous, with an average of 3.0 pregnancies. Eleven patients were pregnant, and 3 were breast feeding at time of presentation. Very few patients (10%) in the current study were smokers.

The clinical findings are shown in Table II. The average duration of symptoms before presentation was 3 months. The most common clinical finding was a palpable mass in 88% of the patients and more than half these masses (54%) were painful. Most patients (78%) did not receive prescription pain medications and only used acetaminophen or nonsteroidal anti-inflammatory medications. Of the 27 patients who did receive pain medication, 20 received the

Table II
Clinical presentation and outcome of patients

	Patients (N = 120)
Duration of symptoms at presentation, months (range)	3.1 (0.2–72)
Palpable mass	104 (88%)
Painful mass	57 (47%)
Mean size, cm (range)	4.3 (0.4–19)
Bilateral symptoms	6 (5%)
Seen in emergency department	49 (41%)
Laboratory tests done	66 (55%)
Mammogram done	80 (67%)
Ultrasound done	99 (82%)
BIRADS	
5	10 (8%)
4	59 (49%)
3	12 (10%)
2	3 (2%)
1	1 (1%)
Not reported	13 (10%)
Antibiotics	35 (29%)
Cephalexin	25
Amoxicillin, Amoxicillin/Clavulanate	4
Trimethoprim/Sulfamethoxazole	3
Dicloxacillin	2
Clindamycin	1
Prescription pain medication	27 (23%)
Oxycodone/acetaminophen 5/325	15
Hydrocodone bitartrate/acetaminophen 5/325	5
Hydrocodone bitartrate/acetaminophen 5/500	4
Oxycodone hydrochloride 10	1
Oxycodone hydrochloride 5	1
Acetaminophen with codeine #3	1
Incision and drainage required	
0	79 (72%)
1	21 (18%)
2 or more	11 (10%)
Resolved with observation	112
Mean time to resolution, months (range)	5.1 (0–20)
0–6 mo	78 (65%)
7–12 mo	28 (23%)
Longer than 12 mo	6 (5%)
Excision of mass	6 (5%)
Lost to follow up after diagnosis	2 (3%)
Patients with recurrent episodes	19 (16%)

BIRADS, breast imaging-reporting and data system.

medication from the emergency department. The medications used are included in Table II. Other clinical signs included erythema, edema, draining sinus, ulceration, pain, and nipple retraction, but there was no evidence of peau d'orange skin changes. Six patients presented with bilateral masses. Forty-eight patients presented with masses which were at least 5 cm on clinical examination. Although not checked uniformly in all patients reviewed, 6 patients had hyperprolactinemia or preexisting prolactinomas that were not being treated at the time of IGM development. Figure 1 shows a 29-year-old, G2P2 female with right breast erythema and a mass that was present for the previous month that increased in size and did not resolve with antibiotics prescribed in the emergency department.

Most patients (82%) underwent breast imaging. Two thirds (67%) had mammograms and 82% had ultrasonography. Of these patients, 59 (49%) were classified as having a breast imaging reporting and data system of 4, and 10 (8%) were classified as breast imaging reporting and data system 5. Figure 2 demonstrates diagnostic ultrasonography of a 38-year-old, G2P2 female with a poorly defined right breast mass with pain and swelling. The imaging shows multiple, ill-defined, hypodense collections with hyperemia throughout the breast tissue in the lower outer quadrant.

Diagnosis was made by core needle biopsy in 114 patients. The remaining patients were diagnosed via excisional biopsies, which occurred early on in the study period before our familiarization



Fig 1. A 29-year-old female with right breast mass causing the majority of the breast to feel hardened. There were superficial areas of erythema around the areola, 1:00, and 10:00 lateral areas.

with the diagnosis. The most common reason for excision was a discordant result with suspicious imaging and benign pathology. Tissue stains for acid-fast bacilli and fungi were performed on 79% (95 of 120) of patients and all were negative. Two patients were lost to follow-up and their condition remains unknown. After our institutional awareness of the diagnosis and natural history of the process, the primary management strategy adopted for the remaining 112 patients was observation with patient education and reassurance. Operative procedures were limited to core biopsy to obtain the diagnosis and drainage of fluid collections when required in 28% of patients. Two patients required operative drainage. One patient had 1 clinic-based incision and drainage and the second patient had 2 clinic-based incision and drainage procedures before going to the operating room. A draining sinus or fistula were not common in the patients; only 4 developed sites of drainage, which resolved in 1, 3, 3, and 5 months. One patient was breast feeding. One of the patients did not have an incision and drainage and spontaneously developed a site of drainage, which resolved in 3 months. The disease process resolved within 6 months or less in 78 patients (65%), 28 patients (23%) required between 7 and 12 months to resolve, and 6 patients (5%) required greater than 12 months to resolve. The average time for resolution after presentation of symptoms was 5 months (range 0–20 months). The time to resolution decreased from 7.4 months in the earlier experience to 4.5 months after July 2013 ($P < .01$).

Characteristics which may affect the time to resolution (TTR) were examined. The TTR for solid masses versus mixed cystic and solid masses did not differ (4.7 months vs 5.2 months; $P = .52$). Table III shows factors associated with TTR. Unadjusted analysis found that larger masses required a greater time to resolution. Use of antibiotics and need for incision and drainage procedures were also associated with a greater time to resolution. In the adjusted analysis, however, later age of first live birth was the only factor that appeared to be associated with greater time to resolution.

Nineteen (16%) of the patients with IGM in whom the disease resolved spontaneously had second episodes, 5 of whom had more

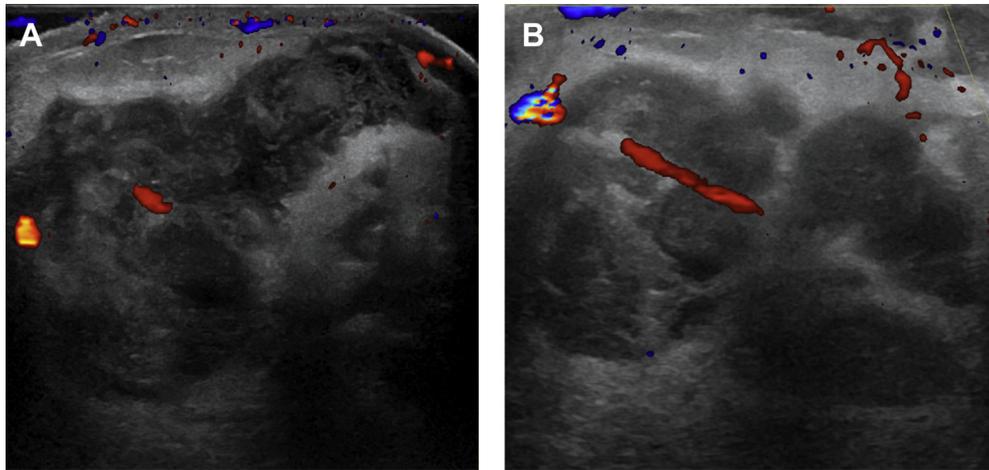


Fig 2. Diagnostic ultrasound images of a 38-year-old female with poorly defined right breast mass with pain and swelling. The imaging shows multiple ill-defined hypodense collections with hyperemia throughout the breast tissue in the lower outer quadrant.

Table III
Identification of factors associated with TTR using log-normal regression

Variable	Unadjusted		Adjusted	
	RR* (95% CI)	P	RR (95% CI)	P
Hispanic ethnicity	1.56 (0.72–3.35)	.26		
Diabetic	0.98 (0.59–1.63)	.94		
Use of antibiotics	1.50 (1.15–1.94)	< .01	1.30 (0.96–1.77)	.09
Incision & drainage performed	1.48 (1.14–1.93)	< .01	1.32 (0.97–1.80)	.08
Age of menarche	0.98 (0.90–1.07)	.66		
Number of gestations	0.96 (0.90–1.05)	.38		
Age of first live birth	1.033 (1.005–1.062)	.02	1.04 (1.01–1.07)	< .01
Body mass index (kg/m ²)	1.01 (0.99–1.03)	.41		
Size of mass	1.005 (1.001–1.008)	< .01	1.001 (0.997–1.006)	.54

* Ratio of geometric mean derived from log-normal regression.

than 2 episodes. The mean time from resolution of the first episode to onset of the second episode was 17 months; however, the range was highly varied from 1 month to 8 years. Second and third episodes appeared to resolve in a much shorter time frame, only 1 to 2 months, compared with the initial episode.

Discussion

The current study shows that IGM is a self-limited process and resolves spontaneously in an average of 5 months. After the diagnosis with needle biopsy, medications were not utilized, and any operative intervention was limited to drainage of fluid collections. To our knowledge, this is the largest study of IGM in the United States and shows that the time to resolution does not differ from other studies using various modes of therapy. Spontaneous resolution in patients with IGM was demonstrated with observation, supportive care, and patient education. The time to resolution appears to have decreased (from 7.4 months to 4.5 months) in the subsequent time period, possibly owing to better knowledge of the natural history and awareness of follow-up.

With its rare incidence and lack of guidelines for treatment, patients with IGM have undergone varying treatments by different physicians. Operative excision remains a common treatment modality for this disease. A study from Thailand by Chirappapha et al found that only 65% (15 of 23) of patients who underwent excision of the lesion led to its resolution.¹⁵ Two of the 8 patients underwent subsequent mastectomy. Similarly, Bashir et al and Shin et al reported that 66% (6 of 9) and 75% (15 of 20) of patients, respectively, resolved after excision.^{16,17} The size of the lesions or volume of excision were not reported; if, however, the sizes of the masses

were similar to other reported studies, the volume of excision was likely clinically relevant and deformed the shape of the breast. Shin et al concluded that “wide excision resulted in high recurrence and left extensive scarring.”¹⁷ Additionally, mastectomy for benign pathology that does not increase risk for malignancy could be considered extreme. In our patient population, 43 patients (40%) had masses 5 cm or greater. Management with operative excision would have likely resulted in substantial cosmetic deformity in most, if not all, of these patients.

Erozgen et al reported on 25 patients who had a similar mean age of 35 years but smaller mean size of the masses, 3.6 cm, at presentation.¹⁸ All 25 of the patients received steroids over 2 months, 9 had steroids after excision of the mass; the mean time of follow up was 7 months (range 1–48 months).¹⁸

Lei et al reviewed the literature to determine treatment-related complete remission and recurrence rate.¹³ Fifteen studies were found. For patients who underwent operative management, the complete remission rate was 90% and the recurrence rate was 7%; for oral steroids, the complete remission rate was 72% and the recurrence rate 21%. The management which had the greatest complete remission rate (98%) was topical steroids, however, there were only 38 patients; in contrast, observation alone had a complete remission rate of 95%. The authors of this review concluded that operative treatment was acceptable for IGM, however, the potential for stress, fear, scars, and postresection breast asymmetry might raise concern for patients and cause patients to seek more conservative treatment.¹³ More recent studies have focused on recurrence rates rather than time to resolution. We found that 16% (19 of 120) of patients had recurrence of their symptoms; despite this recurrence rate, the subsequent episodes were attenuated

compared with the initial presentation because the symptoms resolved in 1 to 2 months in all patients.

Some surgeons refer patients to rheumatology, whereas others test for tuberculosis, *Corynebacterium*, and for other potential etiologies. One patient in the current series was referred to our rheumatology group and then had an extensive battery of testing performed, including but not limited to antibody screen for antibodies to *coccobacilli*, myeloperoxidase antibody, serine protease 3 antibody, quantiferon tuberculosis, rheumatoid factor, antinuclear antibody IgG regulatory factor X, double-stranded DNA, ribonucleoprotein, Smith, anti-Ro 53, anti-Ro 60, anti-La, and cyclic citrulline peptide antibody. Based on the results of this testing, no intervention was recommended and the patient was treated with conservative management.

Owing to the size of masses at presentation and the possibility of recurrence even after a mastectomy, both bilateral and unilateral, excision is not advised as definitive treatment for IGM. In addition, breast cancer has never been reported as a coexisting presentation in patients with a breast mass determined to be IGM. This evidence suggests that once pathologic examination confirms the diagnosis, operative management of IGM is not warranted, and operative intervention should be limited to drainage of fluid collections. In the current study, a 29-year-old patient, who was in follow-up after being diagnosed with a BRCA 1 mutation, developed a 5-cm breast mass. The mass had the typical appearance of granulomatous mastitis. The diagnosis was confirmed with needle biopsy. The patient required an incision and drainage for a fluid collection, but the mass completely resolved in 8 months.

A study from Hong Kong by Co M et al examined patients treated predominantly with corticosteroids but did not report time to resolution. They did find that patients who were smokers, presented with an abscess, or had *Corynebacterium kroppenstedtii* were at greater risk for second episodes.¹⁹

The current study examined factors that may affect time to resolution. As expected, unadjusted analysis found that a larger size of the mass at presentation and need for an incision and drainage procedure was associated with greater time to resolution. Use of antibiotics did not shorten time to resolution but rather were associated with greater time to resolution. Interestingly, however, in the adjusted analysis, the only factor associated with a greater time to resolution was a later age of first live birth (Table III). It is known that a later age of first live birth along with other factors related to hormone exposure are associated with a slightly increased risk for breast cancer.²⁰ The finding in the current study adds support to the hypothesis that IGM may have a hormonal component to the etiology, as appeared to be the case with women of reproductive age, previous and current pregnancy, breast-feeding, and prolactin.^{4,5,8,10,11}

Limitations of the current study include the small sample size and retrospective design. This study, however, is the largest study from the United States published to date. Further, a prospective study is unlikely to be performed for a benign disease process because such a study would be an inappropriate use of resources when oncologic studies are constantly needed. The true influence of hormones on IGM in this study could not be determined but should be examined in future studies. Hormonal contraception and prolactin levels were not collected routinely on all patients. The ethnic makeup of this study population was predominantly Hispanic with Mexican ancestry, and therefore application to other races and ethnicities or even in Hispanic patients from other countries (other than Mexico) would need to be verified in other populations.

This study found that IGM will resolve spontaneously, independent of medical intervention in approximately 5 months but could range up to 20 months. Factors that may affect the natural history and therefore the time to resolution, include the size of mass, the age of patient, and hormonal influences, such as

pregnancy, breast feeding or lactation, and prolactin. Recurrent episodes of IGM can occur at varied time points after resolution. Similar management of subsequent episodes is recommended because they appear to resolve in only 1 to 2 months. It is critical to reassure and educate patients in order to avoid procedures, which could cause unsightly deformity and unnecessary medications with potential side effects and additional costs to patient and medical care. Close observation, reassurance, and patient education should be the favored management for IGM.

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Conflict of interest/Disclosures

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