

The Neoadjuvant-Like effect of Steroids in Idiopathic Granulomatous Mastitis Management

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Introduction: Idiopathic granulomatous mastitis (IGM) management is considered a current dilemma. However the benign nature of the disease mimics breast carcinoma both clinically and radiologically and has a great rate of relapse and recurrence. Steroids are nowadays implemented in the management of IGM. In our study, we standardized the corticosteroids as a presurgical management in management of idiopathic granulomatous mastitis due its neoadjuvant-like effect in decreasing the size of the lesion, to control the disease progression and to decrease the recurrence rates.

Aim of work: To verify the effect of steroids in the treatment of idiopathic granulomatous mastitis.

Patients and methods: This is a prospective study which includes patients diagnosed with idiopathic granulomatous mastitis from Ain-Shams University Hospital's breast clinic and Egyptian railway medical center breast surgery unit between 2018 to 2024. Fifty-three patients were included in our study, all patients received corticosteroid therapy followed by surgical excision for the residual lesion.

Results: Clinical and radiological regression was reported after steroid administration resulting in volume reduction from 7.49 ± 2.216 to 1.73 ± 1.158 cm³ and complete clinical and radiological regression was observed in 11 cases. 40 patients were proceeded to wide local excision for the residual granulomatous lesions. 7 patients were presented with ipsilateral recurrence with average disease-free interval ranging from 2 to 6 months after discontinuation of steroids. All those patients showed complete resolution after steroids therapy and didn't perform a wide local excision. Cosmetic outcome was excellent in 49.1%.

Conclusion: Corticosteroid therapy has a neoadjuvant-like effect resulting in significant reduction of the lesion burden and improving surgical feasibility and cosmetic results.

Key words: Corticosteroid, granulomatous mastitis, breast abscess.

Introduction

Granulomatous mastitis (GM) is a general term for granulomatous inflammation of the breast, independent of the underlying aetiology. It may be idiopathic or secondary to other conditions such as parasite infection, sarcoidosis, or tuberculosis (TB). In 1972, Kessler and Wolloch published the first written description of it.¹ In 1987, it was suggested by Going et al that the name "idiopathic granulomatous lobular mastitis (IGLM)" be used instead of the more general term "granulomatous mastitis".² Recurrent sterile breast abscesses and persistent non-necrotizing granuloma development in the lobules are the hallmarks of idiopathic granulomatous mastitis, a rather uncommon benign illness.³ IGM is difficult to diagnose since it might mimic breast cancer and a bacterial abscess. IGM is often diagnosed after all other differential diagnoses have been ruled out.⁴

Premenopausal women who have just been pregnant or nursing are often the high risk group.⁵ Granulomatous mastitis is less than 1% common among all breast diseases worldwide, however it is more common in Hispanic women,⁶⁻⁸ and women of Mediterranean ancestry.⁹

IGM is diagnosed by particular histological data given from a core needle biopsy, however clinical information and the description of IGM's radiographic characteristics may aid in distinguishing it from breast cancer.¹⁰ Multinucleated giant cells, plasma cells, polymorphonuclear leukocytes, lymphocytes, and rarely sterile micro abscesses are the pathological hallmarks of IGM.⁴

Treatment for granulomatous mastitis is difficult and requires patience as well as long-term monitoring. The majority of IGM patients were treated only with surgical excision prior to 1980s. More recently, the first-line treatment choice prior to surgery was thought to be conservative therapy with oral steroids and imaging monitoring.¹¹ The use of steroids to treat granulomatous mastitis was first suggested by Freeman et al. Although it's not the best method, steroid treatment can be used after excision in cases that are resistant to heal and to reduce recurrence, or in patients who have only had an incisional biopsy. In cases where there are large, irresectable lesions, it may also be wise to administer steroids prior to surgery in order to facilitate excision with good cosmesis.¹²

Because it may reduce the recurrence rate, slow down the progression of IGM, and preserve more

breast tissue to achieve better cosmetic, we consider that steroids have a neoadjuvant like effect comparable to the effect of neoadjuvant chemotherapy in the management of breast cancer

So the presurgical management of IGM with corticosteroids is the standard of care in our setting in the study.

Aim of work: To verify the effect of steroids in the treatment of idiopathic granulomatous mastitis.

Patients and methods

This is a prospective study which included patients diagnosed with idiopathic granulomatous mastitis presented to Ain-Shams University Hospital's breast surgery unit and Egyptian railway medical center breast surgery unit between 2018 to 2024. Fifty-three patients were included in our study; all those patients received corticosteroid therapy with consideration of the severity of each case followed by surgical excision for the residual lesion if present. Repeated U/S guided aspiration was done in case of abscess formation.

Every patient had a thorough history and clinical examination as part of a triple assessment.

All of the included patients had ultrasounds (US) performed. Twenty-five patients had their mammograms and ultrasounds combined based on their age and breast density. Five patients had magnetic resonance imaging (MRI) as a result of MMG's insufficient evaluation.

All patients had core needle biopsies, and the pathological criteria used to establish the diagnosis of IGM were the lack of any specific criteria of particular underlying causes and the presence of non-caseating granulomatous inflammation centred in the breast lobules. In order to rule out TB mastitis or infectious mastitis, patients who presented with collection or discharging sinuses underwent culture and sensitivity testing.

All the patients were counselled about the disease course, potential treatment options, and potential corticosteroid side effects. To record the recurrence rate and evaluate the cosmetic result, all patients were followed up on for a period of one to three years. The Statistical Package for the Social Sciences (IBM SPSS 31) computer program was used to conduct the statistical analysis. The mean, standard deviations, and ranges were used to display the quantitative data. Qualitative factors were also shown as percentages and numbers. Because the predicted count in some cells was less than 5, the Fisher exact test was used to compare the qualitative data across subgroups. The interpretation of the p-value was as follows: P-value > 0.05 indicates non-significant (NS), P-value <

0.05 indicates significant (S), and P-value < 0.01 indicates highly significant (HS).

Results

Table 1 displays each patient's demographic information and clinical characteristics. The study population's average age was 36.23 ± 5.173 , with a range of (29 to 47). 75.5% of them were between the ages of 30 and 39 (40 out of 53 patients). Almost all patients had a history of lactation during the last five years with a mean interval from the last lactation to diagnosis of 27.3 ± 14 months (range: 7–60). 43.4% of the patients had previously used oral contraceptives. (**Table 1**)

Seven patients had a positive family history of breast cancer, and none of the patients had a history of tuberculosis. The patient's medical history revealed that only one patient had type 2 diabetes under control, another had hyperthyroidism one year before IGM presentation, and one patient had systemic lupus five years prior IGM diagnosis. (**Table 1**)

Clinical presentation

All patients were diagnosed with unilateral breast IGM, 30 Patients (56.6%) and 22 patients (41.5%) presented with left side and right side IGM respectively, and only one patient was diagnosed with metachronous bilateral breast IGM. (**Table 2**)

The most common presentation was a palpable mass in the breast seen in 49 patients (92.5 %) (**Fig. 1**). The other presentations were abscess formation (**Fig. 2**) which was found in 31 (58.5%) patients, skin sinus was seen in 3 patients (5.7%) (**Fig. 3**) and erythema and redness were found in 30 patients (56.6%) (**Fig. 2**).



Fig 1: Granulomatous Mass.



Fig 2: Abscess formation.



Fig 3: Multiple skin sinus.

Radiological assessment

The lesion's radiological evaluation in accordance with the BIRADS classification was recorded.

Twelve patients (22.6%) reported having BIRADS 4 lesion, while twenty-eight patients (52.8%) reported having BIRADS 4a lesion. Thirteen patients (24.5%) had benign breast finding classified as BIRADS 3. **(Table 2)**

Sonographic finding was variable between ill-defined hypoechoic lesion with or without interstitial edema and in some cases fluid collection and impending abscess were the hallmark of the study.

Mammographic finding varied from an ill-defined mass in most of cases and architectural distortion with or without skin thickening. MRI was performed in some cases showing ring-like abscess formation with benign kinetic curve **(Fig. 4)**.



Fig 4: MRI finding in IGM.

Histopathology evaluation

All patients underwent core needle biopsy, and histological evaluation which confirmed the diagnosis of nonspecific granulomatous mastitis. Culture and sensitivity was done in 58.5% of patients those who presented with an abscess (31 patients) and showed negative growth in all cases with exclusion of TB.

Management and outcome

Following confirmation of the IGM diagnosis, all of the individuals in our research started steroids administration at doses ranging from 30 to 60 mg daily for an average of 2.10 months, with tapering of the dose in accordance with the radiological and clinical response.

In every patient receiving steroid treatment, there was a documented clinical and radiological regression. The lesion's mean volume dropped from $7.49 \pm 2.216 \text{ cm}^3$ to $1.73 \pm 1.158 \text{ cm}^3$, and Eleven cases showed complete radiological and clinical regression. **(Table 3)**

40 patients had wide local excision for the remaining granulomatous lesions while receiving low-dose steroids (10–15 mg daily), which were discontinued two weeks post-operatively. No further recurrences were seen throughout the follow-up period, which lasted one to three years. **(Table 4)**

Recurrence was observed in 8 of the patients **(Table 5)**, 7 presented with ipsilateral recurrence with average disease-free interval about 3 months ranging from 2 to 6 months after discontinuation of steroids. All patients showed complete resolution after steroids therapy and didn't perform a wide local

excision while 3 of them presented with abscess formation so repeated aspiration was done alone and these patients were later treated with surgical excision. Only one patient developed a contralateral recurrence after 18 months of management with steroids and the WLE with repeated aspiration. (Fig. 5).



Fig 5: View of the right and left metachronous IGM after wide local excision of the residual granulomatous, the red arrows show the scars of both side operation.

We compared each management type against the rest to assess significance and we found that patients who underwent excision only had significantly (p-value 0.035) fewer recurrences than other patients while patients who underwent aspiration alone (4 recurrences / 8 cases) (p-value=0.001) had significantly higher recurrence rate than other methods. (Table 5)

Patients who didn't need further management (3 recurrences / 5 cases) (p-value=0.003) had a significant higher recurrence rate, but the small sample size limits reliability. The patient who experienced recurrence in the Excision + Aspiration group had a contralateral recurrence which may bias the results.

Cosmetic outcome was excellent in 49.1% and good in 43.4% and fair in 7.5% of the cases as the lesions decreased in size markedly so the excised part didn't cause disfigurement in most of the cases. (Table 4, Figs. 5,6).



Fig 6: View of the same patient in figure 1 after excision of the reduced size granulomatous mass preserving good breast contour and volume.

Table 1: Demographic data of the study population

No. = 53		
Age	Mean±SD	36.23 ± 5.173
	Range	29 – 47
Last lactation by months	Mean±SD	27.3 ± 14
	Range	7– 60
History of OCP	No	30 (56.6%)
	Yes	23 (43.4%)
History of Pregnancy in last 5 years	No	4 (7.5%)
	Yes	49 (92.5 %)
History of TB	No	53 (100.0%)
	Yes	0 (0.0%)
Family history of Breast cancer	No	46 (86.8 %)
	Yes	7 (13.2 %)
Chronic diseases	No	50 (94.3)
	Hyperthyroidism	1 (1.9 %)
	DM	1 (1.9 %)
	SLE	1 (1.9 %)
Associated symptoms	No	52 (98.1%)
	skin allergy	1 (1.9 %)

Table 2: Clinical presentation of the study population

		No.	%
Side	Left	30	56.6 %
	Right	22	41.5 %
	Bilateral	1	1.9 %
Mass	No	4	7.5 %
	Yes	49	92.5 %
Abscess	No	22	41.5 %
	Yes	31	58.5 %
Sinus	No	50	94.3%
	Yes	3	5.7%
Skin changes (erythema, redness)	No	23	43.4%
	Yes	30	56.6%
Radiological investigation	Ultrasound	53	100.0 %
	Mammogram	25	47.2 %
	MRI	5	9.4%
Score of the findings	BIRADS 3	13	24.5 %
	BIRADS 4	12	22.6%
	BIRADS 4a	28	52.8%
Core biopsy	IGM	53	100.0
Culture and sensitivity	No	22	41.5
	Done and results was negative	31	58.5
	Done and results was positive	0	0%

Table 3: Response of steroids therapy

PREVIOS VOL	Mean±SD	7.49 ± 2.216
	Range	3 cm3 – 12cm3
AFTER STEROID VOL	Mean±SD	1.726 ± 1.1584
	Range	0 - 4.0
Difference	Mean±SD	5.764 ±1.4129
	Range	3.0 - 9.0

Table 4: Management and Outcome

Excision	No	13	24.5 %
	Yes	40	75.5 %
Repeated Aspiration	No	22	41.5 %
	Yes	31	58.5 %
Recurrence	No	45	84.9 %
	Yes	8	15.1 %
Cosmetic outcome	Fair	4	7.5%
	Good	23	43.4%
	Excellent	26	49.1%

Table 5: Recurrence rate

Type of management	Recurrence	Non-recurrence	%	p-value	
Total cases	8	45	15.1%		
Excision only	0	17	0%	0.035	S
Aspiration only	4	4	50%	0.001	HS
No further management (complete resolution)	3	2	60%	0.003	S*
Excision & Aspiration	1**	22	4%	0.024	S**

* Significant (but the number of patients is small) ** Recurrence in Excision & Aspiration group occurred on the contralateral side, meaning it may not be a true recurrence of the original lesion but a new occurrence. This could affect interpretation so its significance is negligible - P-value > 0.05: Non-significant (NS), P-value < 0.05: Significant (S), P-value < 0.01: Highly significant (HS).

Discussion

The majority of IGM occurs in females in the child bearing period.¹³ In our study, 75.5% of patients were at reproductive age (30 to 39 years old) and 92.5 % of patients were parous in last 5 years with 43.4% of them having a history of OCP use.

Although the exact cause of IGLM is still debatable, the majority of authors point to a number of potential contributing factors, including local chemical irritants, undetected viruses, mycotic infections or bacterial microorganisms, diabetes mellitus, smoking, autoimmune reactions, hyperprolactinemia, or even lactation itself.¹⁴ This was particularly evident in our study population, as nearly all patients had experienced lactation within the previous five years, with a mean interval before diagnosis of 27.3 ± 14 months.

These findings support the hormonal aetiology of IGM and are in line with researches that correlate it to autoimmune triggers and hyperprolactinemia.¹⁵ The predominance of reproductive-age women (30–39 years) mirrors cohorts from Turkey and Iran,¹⁶ supporting a global pattern.

A unilateral painful, hard, tender, and ill-defined lump in the breast that may occur in any quadrant of the breast is the most typical presentation of IGM.¹⁷

Clinically, the most common manifestation in our study was a palpable breast mass (92.5%), which was followed by abscess formation (58.5%), erythema and redness (56.6%), and skin sinus (5.7%). The majority of our patients presented with mixed symptoms, and one patient had extramammary symptoms which was skin red patches on both lower limbs.

IGM is recognised to resemble bacterial abscesses or breast cancer, and the literature has extensively reported this range of clinical characteristics, which include palpable masses, abscesses, and skin manifestation.¹⁸ One patient (6.7%) in the surgery group of Patmano et al.'s study had metachronous bilateral disease, a rare but recognised presentation,

whereas the majority of patients presented with unilateral IGM. In contrast, no bilateral involvement was seen in the surgery plus steroid group.¹⁹

Mammography (MG) and ultrasonography (US) may be utilised to rule out malignancy rather than to establish a diagnosis of IGM, even if IGM radiologically resembles breast cancer. Although there isn't a clear agreement on the radiological findings in IGM, physicians should be alerted to the likelihood of IGM by focal asymmetrical density on MG and large heterogeneous hypo echogenicity with internal hypoechoic tubular lesions on US. If there are no significant pathological findings on MG or US, MRI should be considered for the diagnosis. A focal homogeneously enhancing mass with irregular borders and parenchymal distortion might be seen on MRI, but all three imaging modalities have a limited role in distinguishing IGM from breast cancer.²⁰

Five patients in our study were underwent MRI for better assessment due to either highly dense breast, having positive family history of breast cancer or inadequate data given by sonomammography so upgrading the radiological modality was justified in those cases.

For the diagnosis of IGM, the histopathological examination is considered the gold standard. The major histological finding is a maggregation of non-caseating granulomas centered in lobules. Microscopically, the granulomas contain Langhans giant cells, epithelioid histiocytes, and are associated with lymphocytes and plasma cells. Neutrophilic micro abscesses may also be seen. In the newly known cystic neutrophilic granulomatous mastitis, cystic vacuoles are often present within the granulomas and are lined by neutrophils. Gram-positive coryneform bacilli may be present within the cysts. Therefore, pathological analysis is strictly recommended.²¹

Although some authors used both excisional biopsy and FNAC in histopathological diagnosis of IGM, such as Al-Jarrah et al.,²² who suggested core-needle biopsy or excisional biopsy instead of fine-needle

biopsy for diagnosis, Tru-cut biopsy was regarded as the standard of care in our setting and was used in all cases because it is more informative than FNAC and is not aggressive. Ozturk, M. et al²³ used excisional biopsy in diagnosing all patients while Parlakgümüş, A. et al²⁴ reported core-needle biopsy in 61.7% of patients.

The neoadjuvant-like effect of steroids in IGM management

There isn't a standardised therapy for IGM at the moment. The severity of the symptoms, the size of the lesions, the patient's presentation, the surgeon's chosen treatment approach, and the patient's accessibility to a healthcare system all influence the course of therapy. Although there are several treatment strategies in the literature, none of them are generally acknowledged. Despite being a benign condition, it requires efficient therapy to control its symptoms and prevent relaps.⁴

Prior to 1980, surgery was the standard of care for IGM, and many authors still favour it today.²⁵ However, according to Neel et al,²⁶ 80% of GLM patients relapsed after surgical treatment, and women who had received upfront surgery tended to have more deformed scars. These findings suggest that first-line surgical therapy did not lower the likelihood of recurrence in a long-term follow-up.

DeHertogh et al. first highlighted the function of corticosteroids in the therapy of IGM in 1980. Both early case studies and later research including several patients demonstrated that corticosteroids were effective in treating IGM.²⁷

Sakar et al established the 'ductal origin' hypothesis of IGM. They found ductal disruption and periductal or intraductal granuloma in more than 70% of cases so WLE of the mass with total duct excision was done in patients enrolled in group C, who had the best and most predictable curative outcome compared with the other two groups.²⁸

Following the same principle, Maher et al, comparative study major duct excision added to WLE was documented in most of cases in group B (the combined steroid plus surgery group) and there was no significant recurrence reported in such group of patients.²⁹

Based on a lot of data from the literature that suggested shrinking the size for complex and resistant cases or diffuse lesions prior to excision by corticosteroids, we used combination treatment in our trial because we believe in the neo-adjuvant-like effect of steroids.¹⁸ Other reports have indicated favorable outcomes following co-administration of oral steroid together with topical steroids for cutaneous diseases. Steroid alone was proved to

have a curative effect in cases not complicated with abscess or infection.³⁰ However, the optimal dose and duration of steroid administration has not been established.

Consequently, based on the severity of the case and the extent of the lesion, all of the patients in our research got corticosteroid medication in the beginning (30–60 mg/day for an average of 2.10 months), which led to clinical and radiological regression in every case. To improve the healing process and reduce wound gapping and sinus formation, the majority of cases were kept on low dose steroids (10 mg/day) until the operation and postoperative period. The mean lesion volume significantly decreased from 7.49 ± 2.216 to 1.73 ± 1.158 . The dosage was tapered based on each patient's response individually.

This outcome was similar to that of a research by Mizrakli et al. that found systemic corticosteroids to be a successful treatment option for IGM that can lead to full disease resolution.²⁰

Recurrence was observed in 8 of 53 patients (15.1%). Interestingly, 7 of these were ipsilateral recurrences, occurring at an average of 3 months after steroid discontinuation, in patients who had achieved complete resolution with steroids but did not undergo wide local excision. This highlights a critical finding: patients who achieved complete resolution with steroids but did not receive subsequent surgical excision for residual lesions were at a higher risk of recurrence (P-value=0.003) however the small sample size limits reliability in our study.

While the patients who underwent excision and aspiration approach had a 4% recurrence rate (1/23), this single patient experienced recurrence on the contralateral side after 18 months despite proper management with steroids and wide local excision with repeated aspiration, indicating no failure of the primary treatment. This suggests that this combined method is highly effective for preventing same-site recurrence. In contrast, patients who underwent repeated aspiration alone and those who needed no further management due to complete resolution showed higher rates of same-site recurrence (50% and 60%, respectively), highlighting the importance of combined excision for local control.

Comparing our recurrence rates with the literature reveals varied outcomes depending on the treatment strategy. Sarkar et al. reported significantly different recurrence rates across treatment groups: 73.6% for wide local excision (WLE) alone, 35.0% for steroid therapy alone, and a markedly lower 5.0% for WLE with total or partial duct excision. While our study used a sequential approach (steroids then surgery for residual), the 15.1% overall recurrence

rate, particularly the high rate in the steroid-only group, suggests that medical therapy alone might not always be sufficient for long-term remission, especially without addressing potential residual lesions.²⁸

Patmano et al. observed recurrence in 6.7% of the surgery group and 20% in the steroid group, though without a statistically significant difference between them. Our findings, particularly the recurrence in patients with complete steroid response but no subsequent WLE, align with the concept that complete lesion removal or a more aggressive combined approach may be necessary to minimize recurrence.¹⁹

The observed recurrence patterns in our study, particularly the 7 ipsilateral recurrences in patients who demonstrated complete clinical and radiological response to steroid therapy but did not undergo wide local excision, align with hypotheses presented in recent literature. Hasan Karanlik et al. (2014) hypothesized that the residual area or the "previous lesion bed" that was excised after steroid therapy might serve as the site responsible for persistent autoimmunity against breast epithelial cells and subsequent IGM relapses. To address this, their approach involved sonographic guided metallic marker placement within the lesion's center in patients showing significant mass shrinkage after initial steroid therapy, aiming to facilitate precise localization of the original lesion site for potential later excision. Preoperative mammographically guided needle localization was also employed for non-palpable lesions to guide surgical orientation.³¹

Karanlik's team found that 63% of their patients achieved a complete radiological response after two months of low-dose steroid therapy, with half of these responses further confirmed by MRI.

Crucially, they noted that the diagnosis of IGM was definitively confirmed by histopathological examination following surgical resection in all patients, including those who had demonstrated a complete radiological response prior to surgery. This finding is highly significant, as it suggests that despite apparent complete resolution on imaging, microscopic granulomatous inflammation may persist at the original lesion site.³¹

This persistence of microscopic disease, even in the face of complete radiological and clinical resolution post-steroids, directly explains the recurrences observed in our study among patients who showed such complete responses but did not undergo subsequent surgical excision. It highlights the concept that without removal of the microscopic nidus of inflammation within the original lesion bed, the underlying autoimmune process may reactivate, leading to clinical recurrence. Therefore, our findings

support the importance of surgical removal for the original lesion site, even after significant steroid-induced regression.

Our management strategy, involving initial corticosteroid therapy followed by surgical excision for residual lesions, effectively utilized steroids in a manner analogous to neoadjuvant therapy in breast cancer management. In oncology, neoadjuvant treatment is administered before the primary surgical intervention to shrink tumors, facilitating less extensive surgery, improving resectability, and potentially assessing treatment response in vivo. Similarly, in our study, systemic corticosteroid therapy led to a significant mean lesion volume decrease from 7.49 ± 2.216 to 1.73 ± 1.158 , demonstrating a substantial reduction in lesion burden prior to surgery.

This "neoadjuvant-like" effect of steroids allowed for more conservative surgical excisions for residual granulomatous lesions in 40 patients. By shrinking the inflammatory mass, steroids facilitated smaller resections, which subsequently contributed to the favorable cosmetic outcomes (49.1% excellent, 43.4% good, and only 7.5% fair). This sequential approach mitigates the need for potentially disfiguring extensive surgeries often required for large, active IGM lesions, thereby optimizing both disease control and patient quality of life.

Conclusion

Corticosteroid therapy is considered an effective first-line agent, with a neoadjuvant-like effect resulting in significant reduction of the lesion burden and improving surgical feasibility and cosmetic results. However, to minimize the risk of recurrence, particularly in cases with an initial complete response to steroids, the meticulous identification and surgical removal of the original lesion bed appears to be critical.

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