European Review for Medical and Pharmacological Sciences 2023; 27: 9801-9808

Evaluation of early results of triamcinolone acetonide treatment in the treatment of idiopathic granulomatous mastitis introduction

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Abstract. – OBJECTIVE: Idiopathic granulomatous mastitis (IGM) is a rare, benign, chronic inflammatory breast disease with an unknown etiology. IGM patients may develop painful or painless masses, palpable lymph nodes, and skin findings that can mimic breast cancer, including retractions, skin edema, ulceration, and fistula formation. This presents a significant diagnostic challenge in clinical practice. The present study aimed to assess the early outcomes of triamcinolone acetonide treatment in patients with idiopathic granulomatous mastitis.

PATIENTS AND METHODS: After obtaining the necessary approvals from the ethics committee, patients who were admitted to the breast endocrine department of the general surgery clinic of our hospital between 2014 and 2022 with complaints of a mass, discharge, and fistula formation and who were histopathologically diagnosed with granulomatous mastitis after radiological examination by tru-cut biopsy were prospectively enrolled in the study.

RESULTS: Among the 136 patients with granulomatous mastitis, the mean age was 30.09±4.14 years, the symptom duration averaged 3 weeks (range: 1-5), the follow-up period extended for 20 weeks (range: 3-72), and the mean recurrence duration was 1.08±0.28 months. Complaints included discharge (52.2%), mass (51.5%), redness (45.6%), and pain (27.2%). Masses were predominantly on the left side (61.0%) compared to the right side (38.0%).

CONCLUSIONS: In conclusion, the heterogeneous phenotype of IGM and the lack of randomized controlled trials pose challenges. Long-acting triamcinolone acetonide proves effective in managing IGM by resolving the inflammatory process and the disease itself. Its low side effects and ease of use make it a valuable treatment modality.

Key Words:
Idiopathic granulomatous mastitis, Treatment, Triamcinolone acetonide.

Introduction

Idiopathic granulomatous mastitis (IGM) is a rare, benign, chronic inflammatory breast disease of unknown etiology. IGM can manifest as painful or painless masses, palpable lymph nodes, and skin abnormalities resembling breast cancer, including retractions, skin edema, ulceration, and fistula formation (Figure 1). These features create a significant diagnostic challenge in clinical practice[1]. It may even be initially mistaken for a simple breast abscess during clinical evaluation. This clinical similarity to infectious mastitis and inflammatory breast carcinoma, coupled with its aggressive presentation, often results in delayed diagnosis through radiological methods and diagnostic complexities[2].

IGM typically affects women in their third and fourth decades of life, occurring several years after childbirth. Most patients have a history of live births and breastfeeding[3]. Although usually unilateral, it can affect both breasts equally[4]. Despite various theories, the exact cause of IGM remains unclear[1-5]. Factors such as hormonal imbalances, autoimmunity, autoinflammatory diseases, microbial pathogens, smoking, and α1-antitrypsin deficiency have all been suggested as potential contributors. It is also thought to occur due to a local autoimmune or secondary reaction at birth.

Definitive diagnosis relies on histopathological examination *via* tru-cut biopsy, incisional biopsy, or excisional biopsy. A tru-cut biopsy is recommended for diagnosis due to the potential for disease regression in appropriate patients, the effectiveness of medical treatments, and the risks associated with extensive surgical treatment[5,6].

The treatment of this disease has evolved over the years. The shift towards alternative treatments has gained momentum, primarily due to the high

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Figure 1. Retractions, skin edema, ulceration, and fistula formation.

recurrence rate observed in patients who have undergone surgery alone. In some cases, repeated surgical resections are necessary to achieve a cure[2,7,8]. However, it is important to note that there is no consensus on the optimal treatment approach.

Treatment options range from observation without intervention to the use of antibiotics, steroids, and immunosuppressants (such as azathioprine)[5]. Continuing treatment without intervention has proven to be a successful option, particularly for patients with localized disease and mild symptoms[6,9].

In cases characterized by erythema, abscess formation, and induration at the initial diagnosis, various antibiotics are often prescribed, but it's essential to recognize that the efficacy of antibiotic treatment is limited and should only be employed in conjunction with culture and antibiogram results.

Medical treatment remains significant, particularly because post-surgical wound complications can be more complex than the primary lesion itself[10]. Corticosteroids play a crucial role in medical treatment[5,6]. However, it's worth noting that there is no standardized protocol for corticosteroid treatment, leading to the utilization of different regimens[11-13]. In cases where patients do not respond to steroids, immunosuppressants are considered as a second-line treatment option[14].

The present study aimed to evaluate the early outcomes of Triamcinolone Acetonide treatments in patients with idiopathic granulomatous mastitis.

Patients and Methods

This study is a retrospective case series study, and the expected level of evidence is level 4. After obtaining the required approvals from the ethics committee, we prospectively enrolled patients who presented at the Breast Endocrine Department of Ankara Dişkapi Yildirim Beyazid Training and Research Hospital's General Surgery Clinic between 2014 and 2022. These patients had complaints of a breast mass, discharge, or fistula formation and had received a histopathological diagnosis of granulomatous mastitis following radiological assessment *via* tru-cut biopsy.

Breast ultrasonography (USG) served as the initial imaging modality for all patients. For some patients, as deemed necessary, mammography and magnetic resonance imaging (MRI) were employed to evaluate the disease further, aid in differential diagnosis, and assess its extent.

All patients underwent a comprehensive evaluation for the differential diagnosis of tuberculosis by the Breast Disease Clinic. Various tests, including the tuberculin skin test, were performed to rule out the diagnosis of tuberculous mastitis.

Subsequently, after treatment options and potential side effects were thoroughly explained, informed consent from the patients was obtained. Patients who were planned for conservative treatment and those who did not agree to the treatment protocol were excluded from the study.

The study included patients whose biopsy results were consistent with granulomatous mastitis and who tested negative for tuberculosis (TBC). Patients with uncontrolled blood pressure and diabetes resulting from the side effects of steroid treatment, as well as those with a positive TBC test, were not included in the study.

Treatment Protocol

All patients exclusively received intramuscular triamcinolone acetonide 40 suspension for injection) as part of the standard protocol. No oral therapy was included. The Triamcinolone acetonide t dosage was set at 1 mg/kg, administered every 14 days for a total of 6 courses.

During the clinical follow-up of patients, breast ultrasonography (USG) was conducted at month 1 and month 3 post-treatment initiation. Subsequently, patients were monitored with breast USG every 3 months within the first year, and thereafter, at intervals of every 6 months.

Patients undergoing triamcinolone acetonide treatment were assessed for various parameters, including demographic characteristics, clinical and radiologic responses to treatment, recurrence rates, and their ongoing follow-up status.

Statistical Analysis

Continuous variables were expressed as mean±-standard deviation and/or median (min-max), and categorical data were expressed as numbers and percentages. Normality analyses of continuous variables were performed with the Kolmogorov-Smirnov goodness of fit test. Categorical data were compared with Fisher's Exact Test and Chi-square test. Univariate (binary) logistic regression analysis was applied to risk factors affecting recurrence risk. Analyzes were performed using the IBM SPSS Package Program version 22.0 (IBM Corp., Armonk, NY, USA). Cases in which the type 1 error level was $p<0.05$ were considered statistically significant.

Results

The mean age of patients with granulomatous mastitis (N=136) was 30.09±4.14 years, the duration of symptoms was 3 weeks (1-5), the follow-up time was 20 weeks (3-72), and the mean duration of recurrence was 1.08±0.28 months.

Concerning their primary complaints, fifty-two-point two percent (52.2%) of the patients reported discharge, fifty-one-point five percent (51.5%) reported a breast mass, forty-five point six percent (45.6%) reported redness, and twenty-seven point two percent (27.2%) reported pain. The location of the masses was predominantly on the left side in sixty-one-point zero percent (61.0%) of patients and on the right side in thirty-eight-point zero percent (38.0%). In terms of breast quadrants, the masses were most frequently found in the upper inner quadrant (36.8%), followed by the lower outer quadrant (27.2%) and the upper outer quadrant (24.3%). Among the patients, fifty-eight-point eight percent (58.8%) were breastfeeding, and thirty-nine-point zero percent (39.0%) were smokers.

During the follow-up period, treatment-related complications occurred in 8 patients (5.9%), accompanied by erythema nodosum in 9 patients (6.6%) and recurrences in 15 patients (11.0%) (Table I).

It was found that the recurrence rate was statistically significantly higher in patients without mass symptoms (18.2%) than in those with mass symptoms (4.3%) (p=0.013) (Table II).

It is suggested that hormonal irregularities due to OCS use and frequent follow-up in the postpartum period may also be a factor[4]. However, as in our cases, there may be no association with delivery or OCS use. In our cases, there was a history of oral contraceptive use in 7 patients (23.3%). The number of our patients who breastfed was 56, all giving birth.

IGM was reported to be not significantly associated with smoking, the body mass index of patients with IGM was higher, and relapses lasted longer in breastfeeding women. Smoking was present in 53 of our patients (39%).

While the infectious parameters' sedimentation value (upper limit of 20) was high in 20 patients, the CRP value (upper limit) was high in 24 patients.

Fifteen of our patients had erythema nodosum in addition to IGM. Patients using low-dose steroid therapy for this disease were discussed with the rheumatology department, and their treatment was switched to Triamcinolone Acetonide.

Breast ultrasonography (USG) was the initial diagnostic method for all patients, with mammography and breast MRI used as needed. The histopathological diagnosis was confirmed through tru-cut biopsy in all cases.

Table I. Some demographic and clinical characteristics of patients with granulomatous mastitis.

	min-max mean±SD (n=136)	
Age (year)	22-36	
Symptom duration (weeks)	1-5	
Number of pregnancies	0-3	
Follow-up time (months)	3-66	
Sedimentation (unit)	1-22	
Recurrence time (months)	1-56	
	N	**%**
Complaint (There is more than one complaint notification)		
Discharge	71	52.2%
Mass	70	51.5%
Redness	62	45.6%
Pain	37	27.2%
Localization		
Right	50	36.8%
Left	83	61%
Bilateral	3	2.2%
Breast Quadrant		
Upper outer	33	24.3%
Upper inner	50	36.8%
Lower outer	37	27.2%
Lower interior	13	9.6%
Multiple quadrants	3	2.2%
Breast Imaging		
Breast USG	125	91.9%
Breast USG + Mammography	9	6.6%
Breast USG + Mammography + Breast MRI	2	1.5%
Lactation		
None	56	41.2%
There is	80	58.8%
Cigarette		
None	83	61%
There is	53	39%
Treatment complication		
None	128	94.1%
Weight Gain	5	3.7%
Acne	2	1.5%
Cataract	1	0.7%
Erythema nodosum		
None	127	93.4%
There is	9	6.6%
Relapse		
None	121	89%
There is	15	11%

MRI: Magnetic resonance imaging; USG: ultrasonography.

Table II. Comparison of some demographic and clinical characteristics according to the presence of recurrence.

	No recurrence (n=121)		Recurrence (n=15)		*p*
	N	%	N	%	
Discharge complaint					0.592*
None	59	90.8%	6	9.2%	
There is	62	87.3%	9	12.7%	
Mass complaint					0.013*
None	54	81.8%	12	18.2%	
There is	67	95.7%	3	4.3%	
Redness complaint					0.589*
None	67	90.5%	7	9.5%	
There is	54	87.1%	8	12.9%	
Pain complaint					0.551*
None	89	89.9%	10	10.1%	
There is	32	86.5%	5	13%	
Lactation					1.000*
None	50	89.3%	6	10.7%	
There is	71	88.3%	9	11.3%	

*Fisher's Exact Test.

The median follow-up time was 26.87 months (1-56). During follow-up examinations, recurrence was observed in fifteen patients (11%). Ten of these patients received intramuscular Triamcinolone Acetonide t treatment, while the remaining five opted for alternative treatments as they did not accept intramuscular Triamcinolone Acetonide treatment.

Discussion

IGM, described by Kessler and Wolloch in 1972, is a rare, inflammatory autoimmune disease of unknown etiology that can sometimes be mistaken for malignancy. While it is most common in people of Hispanic and Asian descent, only a few series of patients have been published worldwide and in all races.

Ductal ectasia develops from inadequate clearance of proteinaceous secretions in the milk ducts. Subsequent perforation of the mammary ducts triggers an inflammatory response[3]. Immunologic presentation of mammary antigens triggers autoimmunity responsible for reactive T-cell mediated inflammation and centrilobular granuloma formation. The inflammation is chronic granulomatous inflammation due to cellular damage leading to the formation of granulomas with macrophages and multinucleated giant cells. It is characterized by noncaseating granulomas on pathologic examination.

IGM generally occurs more frequently in the reproductive age group. In our study, the mean age was 30.09 years. Patients usually present with complaints of a mass, treatment-resistant abscess, and fistula. Even though the breast skin is thickened, it may be accompanied by redness, a firm mass, and palpable lymph nodes. In our series, the most common complaint of the patients was discharge, while other complaints were mass, redness, and pain.

Ultrasound and mammography are commonly used as imaging modalities for diagnosis. Magnetic resonance imaging, on the other hand, has been used quite frequently in recent years[21]. Mammography findings are usually nonspecific and often present as ill-defined asymmetric densities, indistinct outlined masses without microcalcifications, or structural distortions. Besides, it should be remembered that mammography findings can be completely negative, especially in patients with young and dense breast parenchyma. Ultrasound is a directional and well-defined modality in the diagnosis of IGM, and its most important use is in the differentiation of solid cysts. IGM is often observed as contiguous hypoechoic tubular and nodular areas extending into the skin. The mammary parenchyma and adjacent structures may be heterogeneous. Finger-like appendages extending toward the skin may be fistulated, or abscesses may form. One of the most important uses of ultrasonography is to guide biopsy to make a definitive diagnosis. Color Doppler ultrasound (RDUS/

CDUS) often demonstrates increased blood circulation around lesions[22,23]. Magnetic resonance imaging is a modality that has recently been used frequently in the diagnosis of IGM and is aimed at characterizing the lesion and making the differential diagnosis of malignancy[24,25].

Mammographic findings of IGM, which are seen primarily in women of reproductive age and breastfeeding, are not diagnostic. On US examination, dense collections with tubular, finger-like extensions extending toward the skin and prone to fistula formation, as well as evidence of increased blood supply in these areas on CDUS examination, suggest this disease rather than malignancy. Although MRI findings are not characteristic, they can support the diagnosis when evaluated with US findings.

Although the diagnosis of the disease can be successfully made by the tru-cut biopsy method, incisional or excisional biopsies may be required in some cases, especially in complicated cases with secondary skin findings and abscesses since there is insufficient tissue to diagnose. All patients were diagnosed in our clinic by USG-guided tru-cut biopsy. The purpose of performing a tru-cut biopsy with USG is to increase the procedure's efficiency.

Although there is no consensus on the treatment of IGM, classifying the disease according to breast involvement and clinical severity and determining the treatment protocol according to the severity of the disease seems to be the most appropriate treatment protocol. Attempts are being made to determine diagnostic and treatment algorithms for managing the disease[5,6]. As in our study, the main goal of other treatment modalities in the literature is to achieve complete breast parenchymal wellness with minimal cosmetic deformity and to decrease the recurrence rate.

After a period of trying to achieve a clean surgical margin with surgical resection in treatment, treatment protocols are attempted according to the clinical severity and prevalence of the disease. Lai et al[9] found spontaneous resolution in four of the nine patients they treated conservatively after an average of 14.5 (2-24) months, whereas four patients still defined static disease at the 11th month, and a lumpectomy was performed in one patient. The standard surgical approach is recommended for drainage and culture, especially in patients with abscesses and complications. It has been reported that excision with a clean surgical margin is more ideal than limited surgical excision in uncomplicated cases with localized and limited disease[16,17]. Despite surgical resections, the recurrence rate is still reported to be 5%-50%, and cosmetic problems that occur after clean surgical margins in complicated cases make medical treatment topical[5,6,17]. With medical treatment, the goal can sometimes be to reduce recurrence after surgical resection and sometimes to reduce the size of the lesion to a size suitable for surgical resection in complicated and resistant cases[5,10].

The medical treatment protocols recommended for IGM may vary. While some recommend extensive empiric antibiotic treatment for up to two weeks at the beginning of treatment, some emphasize that antibiotics have no therapeutic effect[10]. Other chronic inflammatory breast diseases (such as tuberculosis, sarcoidosis, fungal infections, etc.) must be ruled out before undergoing medical treatment in IGM cases. Especially in countries where tuberculosis is endemic, treatment may exacerbate the disease if the diagnosis is misdiagnosed. Steroid therapy has been used in the treatment of IGM since the 1980s. While the earliest publications on steroid therapy recommended 4-week treatments with daily doses of 60 mg/day, more recent publications report that 3-6-month treatments with lower doses reduce recurrence rates[5,11,12]. Oran et al[13] administered 16 mg prednisolone twice daily for 2 weeks, then reduced the dose and discontinued it for 6 weeks. Azlina et al[4] reported a 50% recurrence rate after 4 weeks of treatment with a daily dose of 60 mg prednisolone. Several studies[5,17,19,20] in the literature use steroid therapy at varying doses of 5-60 mg from 1 week to 22 weeks. The complete resolution rate is 42-93.5% in patients treated with steroids[18,19]. Under our treatment with triamcinolone acetonide, relapse occurred in only 2 (66%) patients, although weight gain, hypertension, glucose intolerance, peptic ulcer disease, etc., occurred because of steroid treatment. Despite being reported that many side effects may occur, reversible weight gain occurred in 5 patients, steroid acne in 2 patients, and one patient developed a cataract during our follow-up period. Triamcinolone acetonide should be considered during treatment, especially since patient compliance with treatment is easy, and the recurrence rate and the rate of side effects are low. We believe the drug is well tolerated because the disease occurs in the young age group, and steroid side effects are generally less frequent. We consider the symptoms and concerns caused by IGM, especially in patients with fistula, abscess, and mass, to be less sensitive to patient response to treatment and side

effects. We think that patient-reported side effects are so low despite close follow-up because of the perception of improvement in the disease.

Methotrexate and azathioprine treatments have also been used as second-line treatments in cases that did not respond to steroid treatment[5,19]. Similarly, treatment protocols are combined with steroids, bromocriptine inhibitors, and azithromycin[5,20]. In our series, such combinations were not required.

Limitations

The fact that the treatment is intramuscular and administered every 14 days is important for patient compliance when compared to oral steroid treatment. However, a disadvantage is that the onset of action of the injected medication is delayed compared to oral treatment. The absence of a control group in our study or the non-use of other treatment methods creates limitations in terms of treatment effectiveness.

Conclusions

There is a heterogeneous phenotype and a lack of randomized controlled trials. Long-acting triamcinolone acetonide is an effective treatment modality in managing IGM, in the resolution of the inflammatory process and the resolution of the disease, with its low side effects and ease of use. We suggest that immunological studies on the etiology of this disease, in which corticosteroids and immunosuppressive therapy are effective, will help decide the treatment choice in the future.

Ethics Approval

The study was carried out with the permission of the Ethical Committee of SBÜ Dişkapi Yildirim Beyazid EAH (139/15).

Informed Consent

After treatment options and potential side effects were thoroughly explained, informed consent from the patients was obtained.

Conflict of Interest

The authors have no conflicts of interest to declare.

Funding

The authors declared that this study has received no financial support.

Authors' Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper and that they have approved the final version.

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