

Evaluation of the efficacy of intralesional triamcinolone injection therapy in patients with granulomatous mastitis: a comparative study with oral methylprednisolone

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ABSTRACT

Aims: This study aims to compare the efficacy of oral steroid therapy with the combination of topical and intralesional steroid (TILS) therapy in patients with granulomatous mastitis (GM).

Methods: This is a single-center retrospective longitudinal study. Women with a diagnosis of GM who applied to Medipol University Pendik Hospital General Surgery Clinic between January 2020 and April 2022 were included in the study. Participants received TILS or peroral steroid (POS) treatment in sequential order, and each patient received only one of the treatment options. Participants were evaluated by physical examination, USG, and radiography before and after treatment to assess lesion size, side, number of foci, skin characteristics, and the presence of pain. The clinical and radiological findings were compared between the groups at the end of the 6-month follow-up and the participants were followed up for the next 12 months to demonstrate the efficacy.

Results: A total of 52 women participated in the study, with 26 in the POS group and 26 in the TILS group. The mean age was 33.33±6.94 years and similar between the two groups ($p=0.831$). Three patients (11.53%) in the TILS group and 7 patients (26.92%) in the POS group were nonresponders to treatment ($p=0.159$). Given the nonresponders, GM lesions persisted in one patient (3.84%) in the TILS group and 3 patients (11.53%) in the POS group at the end of the study ($p=0.610$). At the end of the 12-month follow-up, five patients (19.2%) in the TILS group and 20 patients (76.9%) in the POS group who achieved a complete remission at the posttreatment 6 months experienced disease recurrence ($p<0.001$). Cox regression analysis revealed that only foci in the breast ($p=0.043$) and abscess formation ($p=0.018$) were independent risk factors for GM recurrence. In the TILS group, intervention-related complications were not observed while blood pressure and glucose elevation, weight gain, and edema were found in the POS group ($p<0.05$).

Conclusion: TILS provides similar efficacy to systemic steroid therapy, with a lower recurrence rate and potential for side effects.

Keywords: Granulomatous mastitis, Intralesional steroid, breast abscess

INTRODUCTION

Granulomatous mastitis (GM) is a rare, chronic, and benign inflammatory disease of the breast. It involves squamous metaplasia of the milk ducts and ectasia of the mammary ducts, leading to non-caseating granulomas located around the breast lobules and ducts, without any involvement of traumatic or foreign bodies pathologically.¹⁻⁴ GM can be categorized into idiopathic granulomatous mastitis, also known as granulomatous lobular mastitis (GLM), and secondary granulomatous mastitis. The secondary form occurs as a rare complication of various other conditions, such as tuberculosis, fungal infections, sarcoidosis, Wegener's disease, foreign body reactions, and hormonal and

metabolic diseases. Importantly, during the differential diagnosis of GM, malignancy should be excluded.⁵⁻⁷

The treatment of GM remains challenging, and the literature does not describe any standardized or definitive treatment method. The primary point of distinction between different treatment approaches is the choice between conservative or surgical options. Conservative treatment includes antibiotics, anti-inflammatory drugs (topical or systemic corticosteroids, or non-steroidal anti-inflammatory drugs), and immunosuppressants.⁷⁻⁹ On the surgical aspect, interventional methods such as wide surgical resection and mastectomy are advocated as primary curative treatments.⁸⁻¹⁰

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The current study aims to compare the efficacy of topical and intralesional steroid (TILS) treatment with peroral steroid (POS) treatment, in patients with GM.

METHODS

The study was carried out with the permission of the Medipol University Ethics Committee (Date: 26.07.2022, Decision No: 650). All procedures were conducted in accordance with ethical rules and the principles of the Declaration of Helsinki.

This single-center, retrospective, and longitudinal study was conducted between January 2020 and April 2022 at the General Surgery Clinic of Medipol University Pendik Hospital. Women who were diagnosed with GM were enrolled in the study. The demographic and clinical features of the patients, including the presence of diabetes, thyroid hormone status, prolactin level, and parity, were recorded.

Inclusion and Exclusion Criteria

The study included women over 18 years of age with a histologic diagnosis of GM. Patients with active infections proven by bacterial culture were eligible for inclusion after receiving appropriate antibiotic therapy, while those with abscesses were included in the study following surgical drainage. Patients who were diagnosed with secondary GM (history of breast cancer, previous surgical intervention), who received medical treatment for GM within the previous 3 months, who were pregnant, or who had contraindications for steroid use were excluded from the study. Patients who did not complete the full treatment regimen were also excluded.

Study Groups and Treatment Protocol

The patients were divided into two groups: the systemic peroral steroid (POS) group, which received Prednol tablets (Mustafa Nevzat İlaclari, İstanbul, Turkey), and the TILS group, which received Hypocort Forte 1% cream (ORVA İlaç, İzmir, Turkey) + Kenacort-A 40 Mg, 1 ml (Deva Holding, İstanbul, Turkey). Depending on the severity of GM, oral methylprednisolone treatment was administered at a dose of 0.5 mg/kg/day (for patients with painful, <5.0 cm, single lesion, and unilateral involvement) or 1 mg/kg/day (for patients experiencing pain, fistula, ulceration, bilateral involvement, or multiple lesions). The treatment was completed over a period of 4 weeks, gradually decreasing the steroid dose. Participants had been informed about potential drug-associated side effects and its administration. Intralesional triamcinolone acetonide (ILS) was applied locally under ultrasonography (USG) guidance. The dosage for ILS was 20 mg 0.5 ml for single foci less than 5 cm or 40 mg 1 ml for multifocal lesions larger than 5 cm. Local anesthesia was not used for injection. In case of intolerance or complications, the

treatment was discontinued, and the patient data were excluded from the analysis. Patients in the TILS group were also prescribed hydrocortisone topical treatment to be applied twice daily, covering the entire breast surface.

Outcome Parameters

All patients underwent physical examination, USG, and radiography before and after treatment to assess lesion size, location, number of foci, skin characteristics, and the presence of pain. Post-treatment evaluations were conducted at 1, 3, 6, 12, and 18 months. During these evaluations, the presence of pain, redness, retraction, atrophy, ulceration, fistula formation, and abscesses were recorded. The absence of these findings was considered a cure. Changes in lesion size were assessed radiographically and documented. The findings were then compared between the two treatment groups. Adverse reactions, including weight gain, blood glucose or blood pressure elevations, and psychiatric disturbances, were also noted at each hospital visit.

Measurements

Body mass index (BMI) was calculated using the formula: $BMI = \text{weight (kg)} / (\text{height (m)} \times \text{height (m)})$.

Statistical Analysis

The variables were analyzed using SPSS Version 25.0 for Windows (IBM Corporation, Armonk, New York, United States) and Medcalc 14 (Acaciaaan 22, B-8400 Ostend, Belgium). Quantitative variables were presented in tables as mean (standard deviation) and median (minimum/maximum), while categorical variables were expressed as n and (%). The analysis was performed at a 95% confidence level, and a p-value less than 0.05 was considered statistically significant. The distribution of the variables was assessed using the Shapiro-Wilk Francia test, and the homogeneity of variance was evaluated using the Levene test. For comparing parametric continuous variables, the Independent samples t-test was used. For nonparametric continuous variables, the Mann-Whitney U test was employed. Categorical variables were compared using the Pearson Chi-Square test, the Fisher-Freeman-Halton test, and the Fisher exact test Monte Carlo Simulation technique. Cox regression analysis, in combination with the Backward method, was utilized to measure the effects of other prognostic variables on the recovery time of disease recurrence. Statistical significance was assumed at a p-value of less than 0.05.

RESULTS

Sixty patients with a biopsy-proven diagnosis of GM were initially evaluated. However, 2 patients could not continue treatment due to financial problems, and 6 patients were excluded due to non-adherence to treatment. Therefore,

a total of 52 patients (26 in the POS group and 26 in the TILS group) were included in the study. The mean age of the patients was 33.33±6.94 years and was similar between the groups (p=0.831). BMI was between 18.5 and 25 kg/m² in 90.41% of the patients. Fourteen patients (26.9%) had lesions in both breasts, while 50 patients (96.2%) had lesions in more than one focus. Skin lesions were present in 37 (71.2%) patients.

Table 1. A general summary of the findings.

	n (%)
BMI	
10 - 18.5	2 (3.8)
18.5 - 25	47 (90.4)
>25	3 (5.8)
Parity	
No	11 (21.2)
Yes	41 (78.8)
Diabetes Mellitus	
Absent	44 (84.6)
Present	8 (15.4)
Hyperprolactinemia	
Absent	50 (96.2)
Present	2 (3.8)
Hypothyroidism	
Absent	48 (92.3)
Present	4 (7.7)
Place of Lesion	
Single	38 (73.1)
Double	14 (26.9)
Focal in the breast	
Single	2 (3.8)
Multiple	50 (96.2)
Pain	
Absent	1 (1.9)
Present	51 (98.1)
Fistula	
Absent	14 (26.9)
Present	38 (73.1)
Abscess	
Absent	39 (75)
Present	13 (25)
Skin lesion	
Absent	15 (28.8)
Present	37 (71.2)
Size	
1 - 3 cm	23 (44.2)
3 - 5 cm	25 (48.1)
> 5 cm	4 (7.7)
	Mean (SD)
	median (min/Q1/Q3/max)
Age	33.33 (6.94)
	32 (22/28/38/50)
Breastfeeding duration (month)	13.65 (6.33)
	12 (3/12/18/24)

SD: Standard deviation, min: minimum, Q1: Percentile 25, Q3: Percentile 75, max: Maximum

Pretreatment of various breast skin lesions, such as fistula (100%), erythema, swelling, areolar retraction, ulceration, etc., was common in the TILS group (96.2%), while abscess formation (46.2%) was more prevalent in the POS group (p<0.001). The comparison of the two intervention groups is given in **Table 2**.

Table 2. Comparison of findings according to study groups

	TILS, n=26	POS, n=26	P value
Age, yeras	33.12±7.66	33.54±6.29	0.831 ¹
Breastfeeding duration (month)	12 (3/24)	12 (3/24)	0.999 ^u
BMI, kg/m²			
<18.5	0 (0)	2 (7.7)	
18.5 - 25	24 (92.3)	23 (88.5)	
>25	2 (7.7)	1 (3.8)	
Parity	20 (76.9)	21 (80.8)	0.999 ^c
Diabetes Mellitus	4 (15.4)	4 (15.4)	0.999 ^f
Hyperprolactinemia	1 (3.8)	1 (3.8)	-
Hypothyroidism	1 (3.8)	3 (11.5)	0.610 ^f
Bilateral Lesion	10 (38.5)	4 (15.4)	0.116 ^c
Multiple lesion	25 (96.2)	25 (96.2)	-
Pain	26 (100)	25 (96.2)	-
Fistula	26 (100)	12 (46.2)	<0.001 ^c
Abscess	1 (3.8)	12 (46.2)	0.001 ^c
Skin lesion	25 (96.2)	12 (46.2)	<0.001 ^c
Size			
1 - 3 cm	14 (53.8)	9 (34.6)	0.400 ^{ff}
3 - 5 cm	10 (38.5)	15 (57.7)	
> 5 cm	2 (7.7)	2 (7.7)	

¹Independent Samples t test (Bootstrap), ^uMann Whitney-U test (Monte Carlo), ^cPearson Chi-Square test (Monte Carlo), ^fFisher exact test (Monte Carlo), ^{ff}Fisher-Freeman-Halton test (Monte Carlo), SD: Standard Deviation, min: Minimum, max: Maximum, BMI; body mass index

At the end of the 6-month follow-up, three patients (11.53%) in the TILS group and seven patients (26.92%) in the POS group did not respond to treatment (p=0.159). These nonresponders received additional treatment regimens with a combination of steroids and TILS. Among the nonresponders, lesions persisted in one patient (3.84%) in the TILS group and three patients (11.53%) in the POS group at the end of the study (p=0.610).

Following a complete remission, the disease recurred in five patients (19.2%) in the TILS group and 20 patients (76.9%) in the POS group (p<0.001). The recurrences occurred with a median interval of 4 (range: 3-12) months, and similar treatment was provided for the recurrent cases. Lesions healed in a median of 2 months (range: 1-12) in the TILS group, which was significantly shorter than that in the POS group (p=0.002).

Additionally, all participants in the POS group received an antibiotic regimen, while only 19.2% of those in the TILS group required antibiotic therapy (p<0.001).

Excision of the lesion was required in one case in the TILS group, while five patients required excision of the lesion, and one patient underwent a mastectomy in the POS group (**Table 3**).

Table 3. Comparison of results between the treatment groups			
	TILS (n = 26) n(%)	POS (n = 26) n(%)	P
Recurrence, n (%)	5 (19.2)	20 (76.9)	<0.001 ^c
Excision of lesion from the breast, n (%)	1 (3.8)	5 (19.2)	0.191 ^f
Mastectomy, n (%)	0 (0)	1 (3.8)	-
Additional antibiotic use, n (%)			<0.001 ^c
Absent	21 (80.8)	0 (0)	
Present	5 (19.2)	26 (100)	
	median (min/max)	median (min/max)	
Duration of regression of lesions (month)	2 (1/12)	4 (1/12)	0.002 ^u

^uMann Whitney-U test (Monte Carlo), ^cPearson Chi-Square test (Monte Carlo), ^fFisher exact test (Monte Carlo), min: Minimum, max: Maximum

Foci in the breast (p=0.043) and abscess formation (p=0.018) were determined as independent risk factors for GM recurrence among all patients. These patients underwent surgical interventions. Similarly, in the POS group, abscess formation (p=0.030) emerged as an independent risk factor for disease recurrence, while no significant statistical pattern for recurrence was observed in the TILS group (Table 4).

Table 4. Regression analysis of possible risk factors for disease recurrence			
Independent Variables	B±Sh	P value	Odds Ratio (95% C.I.)
Total (n=52)			
Focal in the breast	2.414±1.194	0.043	11.18 (1.1-116)
Abscess	1.440±0.606	0.018	4.22 (1.3-13.8)
Oral corticosteroid (n=26)			
Abscess	1.107 (0.0511)	0.030	3.03 (1.11-8.23)
G.M topical+intralesional steroid (n=26)			
No significant pattern was obtained			
Dependent variable: relapse			
Cox Regression-Backward Stepwise (Wald) Method, C.I.: Confidence interval B; regression coefficients SE: Standard error			

In the TILS group, no adverse events were noted, while in the POS group, three patients experienced blood pressure elevation, three patients had elevated blood glucose levels (all were diabetic), two patients gained weight, and one patient experienced mood changes following steroid use.

DISCUSSION

GM is a heterogeneous disease with variable clinical presentations. Since the etiology is not clear in GM, the treatment strategies are also not uniform and the available treatment options are controversial. The main findings of the study demonstrate faster recovery, lower disease recurrence, and side effects with TILS compared to POS therapy. On the other hand, the number of foci in the breast and the presence of an abscess were independent risk factors for disease recurrence, rather than the treatment modality.

Systemic meta-analyses have revealed that managing IGM with only steroids may be less effective than the combination of steroids and surgery.^{5,11} Moreover, surgical management may have a high complete remission rate with a relatively low recurrence rate, with or without steroids.⁵ However, surgical treatment is associated with a high risk of wound infection, sinus formation, and cosmetic problems. Therefore, the pharmaceutical approach is considered in the first step, while surgical indications are limited to more specific conditions such as abscesses and resistance to medical treatment.^{11,12} Besides it was emphasized that the GM may regress over time and therefore aggressive treatments should be chosen carefully.^{13,14} The current literature assumes that there is no significant difference between nonsurgical approaches (systemic and local steroids, and immunosuppressive therapies) and a surgical approach on residual disease or recurrence in the treatment of GM. Given all, there is not yet a widely accepted algorithm based on scientific evidence in the literature to guide the therapeutic management of GM, and the debate on conservative and surgical treatment approaches continues to date.

The literature indicates that GM primarily occurs among women in childbearing age and usually two years after breastfeeding at a median age of 30 years.⁴ In this study, the mean age was 33.33±6.94 and the duration from previous breastfeeding to GM development was 13.65±6.33 months. Prolactin is known to facilitate ductal ectasia and milk stagnation, while also exhibiting a proinflammatory effect. The assessment of serum prolactin levels is mostly not performed in patients with GM.¹⁵ In this cohort, hyperprolactinemia prevalence was found 3.8%.

The primary symptom of GM is a painful mass, and as many as 50% of patients experience erythema and swelling as signs of inflammation in the affected breast. Additional symptoms may include hyperemia, areolar retraction, fistula, and ulceration. Approximately 37% of cases present signs of an abscess.¹⁶ 71.1% of patients had one clinical finding of erythema, swelling, areolar retraction, and ulceration and 25.0% of patients had abscess formation in our cohort.

Several previous studies reported the efficacy of TILS in GM. Toktas et al.¹⁷ first recommended the treatment of GM. DeHerthogh et al.¹⁸ proposed a high-dose corticosteroid therapy involving prednisolone at 30 mg/day for a minimum of 2 months in the treatment of GM. This treatment typically results in a reduction in the lesion's diameter; however, it also brings about various side effects like weight gain, hyperglycemia, and the potential risk of Cushing's syndrome. Similarly, in this study, cases of blood pressure and glucose elevation, weight gain, and mood change were noted in the POS group, while there was no adverse reaction in the TILS group.

Previous studies have also reported corticosteroid treatment success in GM, however, the unfavorable part of this treatment modality is the high recurrence rates after stopping or decreasing the dose of steroids. GM recurs in 30-50% of patients who achieve remission following steroid use.^{19,20} In this study, 76.9% of patients in the POS and 19.2% of patients in the TILS group developed a recurrence of the disease. However, it should be kept in mind that GM can occur at any time in the future following a successful treatment course. So, we don't claim that TILS has a sustained superior effect against POS in regard to disease recurrence. However, TILS substantially prevented surgical intervention in the following 12 months of the treatment.

TILS as a first-line treatment in patients with GM. Yıldıırım et al.²¹ compared the TILS injection (ILS, n=17) and POS groups (n=19) in a prospective randomized controlled study in patients with newly diagnosed GM. In this study, they reported that 4 patients (23.5%) in the ILS group and 5 patients (26.3%) in the POS group had required repeated treatment interventions. At the end of the six-month follow-up, 78.9% of patients in the TILS group and 88.2% of patients in the POS group had responded to treatment, but there was no significant difference between the rates. They also reported no statistically significant difference between the two groups regarding side effects and recovery rates.²¹

GM recurrence rates range from 0 to 46% with different treatment approaches within a 10-year follow-up period.^{22,23} Systematic meta-analyses indicate that the combination of systemic steroid and surgical treatment is superior to systemic steroid therapy alone or surgery alone for treatment success and disease recurrence.^{5,11} The increased risk of recurrence identified in patients with breast fistulae, more than three complaints at the time of diagnosis, erythema nodosum, and multicentric disease may be attributed to a delay in treatment.^{24,25} In this study, GM recurrence was 48% and dominantly was seen in the POS group. This may be due to a relatively short treatment duration with oral steroids which was 1 month. It is interesting that at the onset of the study, fistula prevalence was 100% in the TILS group and after treatment, the prevalence was lower than seen in the POS group. Additionally, the treatment response was faster in the TILS group. Together with the different results in similar studies, this study shows that the main factors in disease recurrence are the GM rather than the treatment groups.

Systematic meta-analyses indicate that the combination of systemic steroid and surgical treatment is superior to systemic steroid therapy alone or surgery alone for treatment success and disease recurrence.^{5,11} While

topical treatments are recommended in addition to other treatments in uncomplicated cases with prominent skin lesions and generally in limited indications, there is insufficient data in the literature regarding TILS applications.^{5,10,17} With limited literature information, TILS alone has at least similar efficacy to systemic steroid therapy and is safer in terms of side effects. It can also be combined with other treatment modalities that have demonstrated efficacy, such as surgery or systemic steroids. Nevertheless, TILS can be recommended as an effective and safe treatment in patients, who are not suitable for surgery and/or who are afraid of systemic steroid side effects, such as in the case of pregnant patients.

There is no data regarding the association between the pathological findings of GM and the potential risk of recurrence of the disease. In this study, foci in the breast and abscess formation were independent risk factors for GM recurrence. These results provide support for the notion that delayed treatment or the presence of severe inflammation may be associated with an increased likelihood of GM recurrence.

Limitations of the Study

The study includes a small sample size. Larger sample sizes would increase the statistical power and reliability of the results. The study design is non-randomized, as patients were allocated to treatment groups based on sequential order rather than through random assignment. This can introduce selection bias and impact the validity of the results. The study's follow-up period is only 12 months, which might not be sufficient to capture long-term outcomes, especially in a chronic condition like GM where recurrence can occur over an extended period. The study does not provide detailed information about the treatment history, medical conditions, and other factors that could influence the outcomes. Failure to control for these confounding factors could affect the study's internal validity. A placebo group would have provided a better control for assessing the true efficacy of the interventions. Without a placebo group, it is challenging to attribute treatment effects solely to the interventions being studied. The study was conducted in a single center, which might limit its generalizability to other populations or settings with different patient demographics and healthcare practices. While the study reports no adverse events in the TILS group, the short follow-up period may not be sufficient to assess the long-term safety of ILS injections. The study demonstrates several comparisons with p-values close to the significance threshold ($p < 0.05$). With a small sample size, some of these comparisons may lack adequate statistical power to detect significant differences.

CONCLUSION

The findings of this study suggest that TILS offers a comparable level of effectiveness to systemic steroid therapy, with the advantage of a lower recurrence rate and fewer potential side effects. Patients treated with TILS experienced faster recovery, and the therapy proved to be a viable alternative to surgical intervention in preventing disease recurrence.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of the Medipol University Pendik Hospital Non-interventional Clinical Researches Ethics Committee (Date: 26.07.2022, Decision No: 650).

Informed Consent: A written consent form is not available since the study is retrospective.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: While the author Tuba Mert was carrying out the study, Mehmet Emin Demir, MD provided statistics support and advisory and deserves special thanks in this regard.

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