

Moderate-Dose Prednisolone as an Effective Substitute for High-Dose Prednisolone in the Treatment of Idiopathic Granulomatous Mastitis: A Retrospective Study

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Abstract- Corticosteroids, generally prescribed at high doses, have been used with good results in the treatment of idiopathic granulomatous mastitis (IGM). However, side effects of steroids are a serious concern, and prescribing lower doses sound safer if they provide similar efficacy. Thus, this study was performed to investigate the effect of moderate-dose versus high-dose prednisolone on IGM. Medical records of IGM patients were evaluated retrospectively. Patients who received prednisolone were classified as the moderate-dose group (MDG, <25 mg/day) and the high-dose group (HDG, ≥25 mg/day); their response and recurrence rates were compared. Among 108 patients, 82.5% in HDG and 85.3% in MDG responded to treatment ($P=0.7$). Total recurrence was 21.7% and 22% in HDG and MDG, respectively ($P=0.984$). Moderate doses of corticosteroids may be used to treat IGM patients without decreasing the treatment efficacy. Prospective randomized trials are necessary to further clarify this issue.

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Introduction

Idiopathic granulomatous mastitis (IGM), first reported in 1972 (1), is a rare inflammatory disease of the breast with unknown etiology. Several probable etiologies have been proposed so far: metabolic or hormonal factors, local trauma, smoking, chemical irritation, autoimmune disorders, Corynebacteria and unknown microbiological agents (2). It is more prevalent in Turkey and Iran, followed by China, the United States (mainly Hispanics), and India (3).

IGM mostly occurs in young women in childbearing age with a history of pregnancy and lactation (4). Patients most commonly present with a breast mass; thickening, dimpling, nipple retraction, edema, erythema, fistulae, abscesses, and ulcers. Biopsy with thorough pathologic

examination to exclude malignancy and other granulomatous diseases is necessary for definite diagnosis (2).

There is no consensus regarding the best treatment for IGM. The present existing treatment options consist of observation; surgical treatment including mass excision, abscess drainage, and even mastectomy; medical treatment with oral antibiotics, anti-inflammatory and immunosuppressive agents like NSAIDs, corticosteroids, methotrexate, and azathioprine; topical treatments, or intra-lesional injections of steroids (5). The treatment modality is chosen according to the physician preference, and the disease presentation or severity.

Regarding the inflammatory entity of this disease, corticosteroids have been used with relatively good results (6-8). However, their use is limited by their

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inherent side effects including increased blood pressure, impaired glucose homeostasis, increased weight, cushingoid appearance, and osteoporosis among others (2,8); especially in higher doses. Therefore, the use of lower doses is more appealing, given that the therapeutic efficacy is not influenced.

Currently, steroids are the most frequently used treatment for IGM; and among them, oral prednisolone is administered more commonly (9). The dosage of prednisolone that is effective in the treatment of IGM is not known, and physicians prescribe various doses according to their own point of view or their institution routines.

There is no standard definition for the classification of the dosage of steroids, and clinicians have used different categories and nominations according to their practice. Nonetheless, everyone would presumably consider a dose of 5 mg/day of prednisolone as low-dose, 25 mg/day as moderate-dose, and 50 mg/day as high-dose; but without clear dividing lines between these assumed classes. A subjective categorization is to consider low-dose, moderate-dose, and high-dose prednisolone as <7.5, 7.5 - 40, and 40-60 mg/day; respectively (<https://www.drugs.com/medical-answers/considered-high-dose-prednisone-3561211>). To our knowledge, there is only one study comparing two different doses of steroids for the treatment of IGM; and that one has compared a high-dose and a low-dose regimen. In our institutions, regardless of the disease presentation and severity, surgeons have different approaches regarding the optimum prednisolone dose administered to IGM patients. Therefore, we designed this study to compare the response and recurrence rates in IGM patients treated with moderate-dose and high-dose prednisolone according to our classification.

Materials and Methods

In this retrospective study, medical records of patients attending two hospitals (***** and *****) affiliated with *****, from November 2012 to December 2020 were evaluated. Written informed consent for using data in research activity had been obtained from all participants included in the study at the time they attended the hospital for their first visit. The data was available only to research members, and no identifiable data of patients were revealed to unrelated members. Inclusion criteria consisted of a histologically- proven IGM, the first episode of the disease, no treatment received before attending the study clinics, the administration of prednisolone as the first-line treatment and a recorded

follow-up of the patient after recovery. Exclusion criteria consisted of incomplete data records, use of other steroids types, and no follow-up.

According to our institutions' policy, tuberculosis (TB), fungal, and other infections had been ruled out by specialized staining and assessments on tissue specimens in all patients; PCR assay to rule out TB was done in nearly one-third of patients, too. During treatment, as our institutional guideline indicates, bacterial infection was managed by non-steroidal anti-inflammatory drugs (NSAIDs) and antibiotics; and aspiration or surgical drainage of pus, as per needed.

Patients' demographic data, disease characteristics, treatment details and outcome (including prednisolone dose, additional treatments, response status, time to healing, recurrence, time to recurrence, and duration of follow up) were gathered.

Response to treatment was defined as complete or substantial improvement of presenting symptoms recorded by the responsible physician, with no recurrence after the first month follow up. Time to healing was defined as the time interval between treatment initiation and complete resolution of symptoms. Recurrence was defined as any new symptoms following primary healing later than one month from resolution.

According to the range (0.08-0.8 mg/kg/day: 10-50 mg/day) and average (0.4 mg/kg/day: 25 mg/day) dose of prednisolone used in our practice and considering the highest received dose during treatment, patients were classified as the Moderate-dose Group (MDG), receiving less than 25mg daily (<0.4 mg/kg/day) prednisolone; and the High-dose Group (HDG), receiving 25mg or more daily (>0.4 mg/kg/day) prednisolone.

The response and recurrence rates between the two groups were compared. Data were analyzed with SPSS software (version 22 for Windows; SPSS Inc., Chicago, Illinois, U.S.A). Comparisons between continuous variables were made by t-test. Comparisons between categorical variables were based on Pearson's ki-square test or Fisher's exact test. $P < 0.05$ was considered significant.

Results

Patients and disease data

A total number of 108 patients were evaluated in this study. The characteristics of patients and the presentations of the disease are demonstrated in Table 1. While 91.6% of the patients had at least one pregnancy, the median parity was two. Also, the median duration of breastfeeding was 24 months among all participants.

Moderate-dose prednisolone in IGM

Considering underlying diseases, two patients had a history of diabetes, one rheumatoid arthritis, and one fibromyalgia.

Table 1. Patients and disease characteristics

| Variables | Frequency(percent) or Mean |
|---------------------------------|----------------------------|
| Age (years) | 35.27±7.82 |
| Oral contraceptive pill use | 28 (30.4%) |
| Previous pregnancy | 87 (91.6%) |
| History of breastfeeding | 75 (87.2%) |
| History of smoking | 5 (7.6%) |
| Family history of breast cancer | 9 (9.6%) |
| Presentation | |
| Mass or thickening | 95 (88%) |
| Inflammation signs* | 46 (42.6%) |
| Abscess | 28 (25.9%) |
| Fistula | 22 (20.4%) |
| Ulcer | 11 (10.2%) |
| Others | 2 (1.9%) |

* Including one or several of the following: erythema, edema, warmth and tenderness

Treatment and response data

There were 40 patients (37%) in HDG and 68 (63%) in MDG. The mean prescribed prednisolone dose in HDG and MDG was 34±11.4mg and 14.74±3.8mg, respectively. Tapering of the steroids had been done on an average of halving the dosage every 2-3 weeks to reach a maintenance dose of around 10-15 mg/day (1.6-2.4 mg/kg/day) in HDG, and a dose of 5 mg/day (0.8mg/kg/day) in MDG. In addition to corticosteroid as the main treatment, 53 (49.1%) received antibiotics for their acute infection, 12 (11.1%) received NSAIDs, and 22 (20.4%) undergone some type of surgery during

treatment (including abscess drainage or open biopsy).

The mean duration of follow up was 17.7±19.34 months (median 11 months). Totally, 84.3% of patients responded to corticosteroids, the mean time to healing was 129.01±131.78 days; the total rate of recurrence was 21.9% in patients who had responded to corticosteroids at first, and the mean time to recurrence was 10.63±18.58 months in all patients. The most common presentation at recurrence was breast mass or thickening (30.8%). Data regarding response to treatment in the two groups are shown in Table 2.

Table 2. Treatment and outcome data in patients with IGM treated with high- and moderate-dose prednisolone

| Variables | High-dose group | Moderate-dose group | P |
|-----------------------------|-----------------|---------------------|-------|
| Response | 33 (82.5%) | 58 (85.3%) | 0.7 |
| Time to healing (days) | 138.0 ± 104.9 | 123.8 ± 145.7 | 0.605 |
| Recurrence* | 5 (21.7%) | 9 (22%) | 0.984 |
| Time to recurrence (months) | 9.5 ± 7.8 | 10.9 ± 21.9 | 0.887 |

All data shown as number (percent) or mean±standard deviation. *Among those who had responded to treatment

Discussion

In this study, we compared the effect of high-dose and moderate-dose prednisolone in the treatment of IGM, and found no significant difference between these two groups in terms of response and recurrence rates.

The best treatment for IGM is unrecognized. Use of Corticosteroids as an anti-inflammatory and immunosuppressive agent to treat IGM was first reported in 1980 by DeHertogh *et al.*, (10). Since then, it has been widely used, mostly with acceptable responses, although the reported response rates and recurrence rates after the

cessation of oral steroids vary widely in different studies (7-9). In a retrospective study by Kaviani *et al.*, (9) on 374 patients with IGM, prednisolone was used in 41.7% of patients, with a 67.8% rate of complete or partial response; the recurrence rate following cessation of prednisolone was 24.8%. The dosage of prednisolone was not reported in this study, and their reported rate of recurrence is slightly higher than the overall rate in our study. Godazandeh *et al.*, (8) carried out a meta-analysis of clinical trials up to May 2019 that had used prednisolone for the treatment of IGM. They only considered studies that had released data about disease

recurrence. They analyzed collective data of 559 patients in 12 studies, and revealed a recurrence rate of 17.7%. The doses used in their included studies were in the range of high-dose according to our classification; and the recurrence is obviously less than in our study. However, many other studies have been held on prednisolone administered (or at least initiated) at high doses, according to our classification (above 25 mg/day) (11-19). The retrospective nature of most studies caused heterogeneity among patients and treatments details; furthermore, the definition of recovery is either not stated or varying among studies, the length of therapy and the tapering interval is largely diverse, and the time of follow-up is very different. Consequently, the figures for the rate of response and recurrence rate encompass a very wide array. When considering the high doses as two imaginary sub-classifications, among those that used a dose ≥ 50 mg/day or >0.5 mg/kg/day, the recurrence rates were around 6- 21% (11-15). These rates were 4-50% among studies that had prescribed < 50 mg/day or ≤ 0.5 mg/kg/day (16-19). Whether these figures constitute significant differences from a statistical point of view or not cannot be deduced from these crude figures.

Montazer *et al.*, (6) carried out an interesting randomized clinical trial where they compared low-dose (5 mg/day) prednisolone with high dose (50 mg/day for three days, tapered during 9 days to 5 mg daily) prednisolone in IGM patients. Each group included 15 patients; all patients received antibiotics and were followed for more than 12 months. Patients receiving high dose prednisolone had a significantly higher rate of remission compared to the low dose group (93.3% vs 53.3%). Among the resolved cases, recurrence was significantly higher in the low dose group (37.3% vs 0%, $P=0.04$). The authors concluded that high dose prednisolone has a high success rate with a lower recurrence rate in the treatment of IGM and could reduce the need for surgery. These results are in contrast with ours, as we did not find any significant difference between the two groups regarding treatment response and recurrence rate. However, the prednisolone dose of the low-dose group in their study was substantially lower than our MDG (5mg vs mean 14.74mg). This information might imply that low-dose prednisolone is less effective than high doses, but moderate doses may be as effective as the high dose.

This study had some limitations, including its retrospective design and the relatively small sample size. However, regarding the importance of decreasing the adverse effects of steroid therapy and the interesting results of this study, we propose a prospective study to be

held to compare the effects of these doses of steroids regarding response to treatment and adverse effects.

Corticosteroids have been widely used in the treatment of IGM with acceptable responses; however, the drawback of high-dose corticosteroids is their side effects; so, lower doses are more favorable, given that the therapeutic efficacy does not decline. Our study suggests that lower safe doses of corticosteroids in a range approximating 15 mg daily prednisolone may be used to treat IGM patients without decreasing the treatment efficacy. Prospective randomized trials with larger sample sizes and matched case-control groups are necessary to further clarify this issue.

This study was approved by the Ethics committee of the Deputy of Research of ***** (Approval ID: *****). We declare that all methods were carried out in accordance with relevant guidelines and regulations. Written informed consent for using data in research activity had been obtained from all participants included in the study at the time they attended the hospital for their visit.

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Moderate-dose prednisolone in IGM

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