

**ORIGINAL ARTICLE**DOI: <https://doi.org/10.3329/mediscope.v11i1.71639>**Efficacy of Oral Prednisolone in the Management of Idiopathic Granulomatous Mastitis*****TH Khan¹, S Huq², SMMH Chowdhury³, T Benzir⁴, AA Maruf⁵, F Mostafa⁶, SA Haque⁷****Abstract**

Background: Idiopathic granulomatous mastitis (IGM) is a benign inflammatory lesion of the mammary gland. Globally it possesses a major diagnostic and therapeutic problem. To date, there is no universally agreed treatment for this condition. Many treatment modalities have been attempted from conservative therapy to mastectomy but none of them has shown satisfactory results. Recent studies have shown promising results of corticosteroids on idiopathic granulomatous mastitis, so steroid therapy can be an effective treatment for idiopathic granulomatous mastitis. The goal of the study is to provide a therapeutic strategy in the future for idiopathic granulomatous mastitis. **Methods:** Our study included all patients with idiopathic granulomatous mastitis confirmed histologically by core needle/incisional biopsy at the general surgery unit of Chittagong Medical College Hospital and the private hospitals in the Chittagong Metropolitan City for a period of one year from October 2016 to September 2017. A total of seventy patients were included in the study provided they fulfilled predetermined criteria. All of them were included in this study by purposive sampling. After diagnosis oral prednisolone (1mg/kg/day) was given and the cases were observed by personal interview and through telephone interview. The patients were on follow-up for 06 months. Age, size of the breast lump, breast pain, nipple discharge, and skin changes were recorded in all cases. Results were analyzed using mean, percentage, and proportion as appropriate. **Results:** The mean age was 26.35 ± 13.5 years ranging from 19 to 40 years. Out of 70 patients, Core cut biopsy was done in 55 patients (78.58%), and incisional biopsy with abscess drainage was performed in 15 patients (21.42%). 59 patients (84.28%) had complete recovery after a single cycle of steroid treatment, remaining 11 patients (15.72%) had recurrence, among them 6 patients were cured after 2nd cycle of steroids but unfortunately, 5 patients did not respond. Though complications were found in 50 patients, all of them made good progress in the short term. **Conclusion:** We recommend steroid therapy as the first-line treatment in our study. However, prospective, randomized clinical trials are needed to determine the treatment algorithm.

Keywords: Idiopathic granulomatous mastitis, Corticosteroids treatment.

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Introduction

Idiopathic granulomatous mastitis (IGM) is an inflammatory disease of the breast that was described by Kessler and Wolloch in 1972.¹ The clinical and radiological findings of idiopathic granulomatous mastitis mimic breast carcinoma and differential diagnosis can only be confirmed histologically. Moreover, it is difficult to treat idiopathic granulomatous mastitis especially if presented with fistula and abscess formation.² The treatments for idiopathic granulomatous mastitis include corticosteroids^{2,3}, immunosuppressants⁴, antibiotics, abscess drainage, and surgical excision.⁵ Although a preferred therapeutic modality has not been established, corticosteroid therapy is effective for shrinking the granulomatous mass.^{2,6} Systemic corticosteroid therapy was first proposed by De Hertogh et al³, who investigated the efficacy of different treatments and concluded that a corticosteroid is an appropriate option for the treatment of the disease. Furthermore, Sukurai et al⁷ sought this pharmacological approach and they authenticated that corticosteroids could be efficient in 87% of patients without any relapse, whereas Maffini et al reported successful outcomes by administering systemic antibiotic therapy and 25 mg/kg/day prednisolone.⁸ On this basis a study can be done to evaluate the effectiveness of corticosteroid treatment for idiopathic granulomatous mastitis in our population.

Materials and methods

This is a prospective and descriptive type of observational study that was performed on 70 patients with idiopathic granulomatous mastitis confirmed histologically by core needle or incisional biopsy at the general surgery unit of Chittagong Medical College Hospital and a few renowned private hospitals in the Chittagong Metropolitan City. All of them were included by purposive sampling. The study period was 1 year from October 2016 to September 2017.

A protocol was approved by the Ethical Review Committee and Institutional Review Board at the

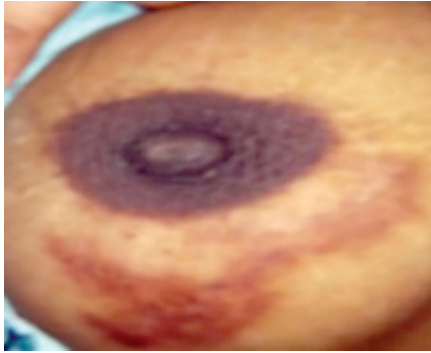
Chittagong Medical College Hospital. Patients were included in the study provided they fulfilled predetermined criteria and Written informed consent was taken from participants.

The study was performed prospectively on patients undergoing core-cut biopsy (14G x 15cm, Care Fusion France 309 S.A.S) or incisional biopsy depending on the clinical findings at the time of admission at the general surgery unit of Chittagong Medical College Hospital and the private hospitals in the Chittagong Metropolitan City. When the patients were diagnosed with idiopathic granulomatous mastitis, a case record form was used and a detailed review of the complaints of the patients at admission was performed. After diagnosis oral prednisolone (1mg/kg/day) was given and the cases were followed up by personal interviews and telephonic interviews. In the event of a recurrence within the 6 months, again two or three courses of steroids were given. At the end of the study, data were analyzed and the result of the study was prepared and submitted.

Data were processed and analyzed using computer software Statistical Package for Social Sciences version 16.0 for Windows (SPSS Inc., Chicago, Illinois, USA). All qualitative data (e.g. breast pain, skin changes, nipple discharge, etc.) were expressed by frequency and percentage, presented by Pie-chart and Bar chart, and tested by Chi-square test. All quantitative data (e.g. age, size of the breast lump, etc.) were expressed by mean and SD (standard deviation) and analyzed by t-test, and ANOVA test. P-value < 0.05 was considered as significant.



IGM patient presenting with painful lump with discharging sinus (before treatment)



Disappearance of lump and discharging sinus (after treatment)

Figure 01: Image showing improvement

Results

Table 01: The clinical symptoms and signs revealing idiopathic granulomatous mastitis (n=70)

Clinical symptoms and signs	Number of cases	Percentage (%)
Palpable, firm and ill-defined mass	70	100
Pain	70	100
Nipple discharge	08	11.42
Nipple retraction	02	2.9
Skin changes	28	40
Tethered	07	
Puckered	00	
Peau d'orange	00	
Erythema	18	
Sinus	02	
Ulcer	01	

Table 01 shows the pattern of presentation of patients diagnosed with IGM.

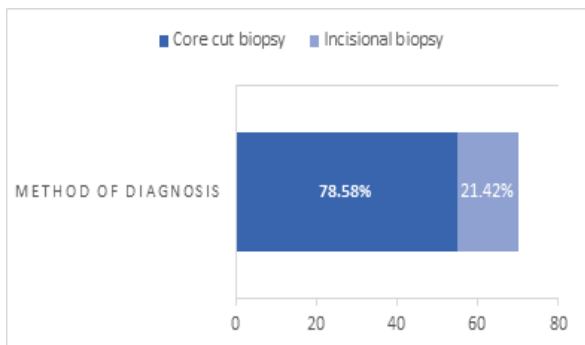


Figure 02: Methods of diagnosis (n=70)

Figure 02 shows the frequency of diagnostic methods used.

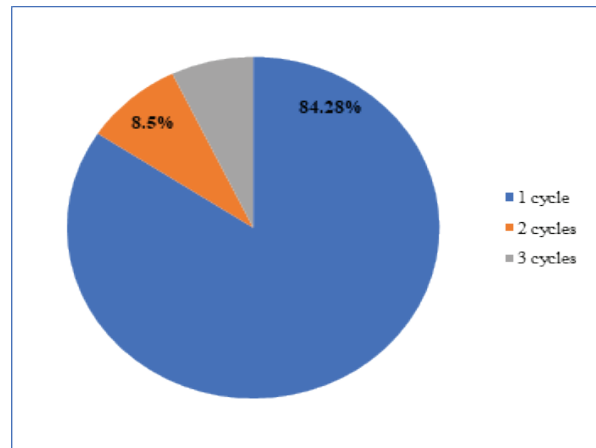


Figure 03: Number of steroid cycles needed

Figure 03 shows that most of the patients (59 patients, 84.28%) had complete recovery after a single cycle of steroids.

Table 02: Occurrence of side effects

Side effects	Number of cases	Percentage (%)
Peptic ulcer disease	13	18.57
Glucose intolerance	3	4.28
Cushingoid features	26	37.14
Others	8	11.42
Acne	4	
Weight gain	2	
Bone Pain	2	
None	20	28.57

Table 02 shows that the most commonly observed side effect was Cushingoid features.

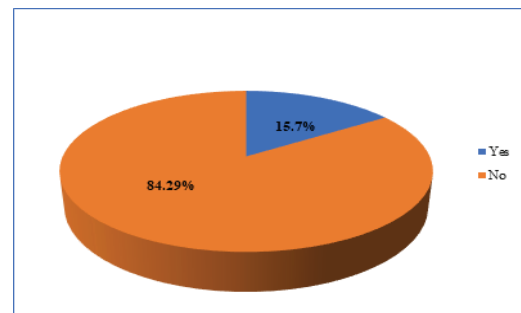


Figure 04: Recurrence of clinical cases

Figure 04 shows that 15.7% had a recurrence and were prescribed further courses of steroids.

Discussion

This study of 70 patients was undertaken in the Chittagong Medical College Hospital and the nearby private hospitals in Chittagong. Similar to other published series, affected women were nearly always parous and usually presented in their early thirties.

DeHertogh et al. in 1980 were the first who investigated the efficacy of different treatments and they concluded that corticosteroid is an appropriate option for the treatment of the disease. Furthermore, Sakurai et al. sought this pharmaceutical approach and they authenticated that corticosteroids could be efficient in 87% of patients without any relapse. The preceding results were validated by Hisuing et al. while their research implied that low doses of corticosteroids were efficient; though more investigations in this field were recommended by them. Moreover, in 2010, it was authenticated that corticosteroids provide appropriate treatment, whereas the first option should be allocated to surgery in the case of relapse, fistula, and abscess.² Pandey et al⁶ described their prospective study of 49 women with a mean age of 35 years and found that 80% were of Hispanic origin (OR = 3.00, 91% CI 1.42-6.24, P = 0.0032), 80% presented with a painful mass and 90% were prescribed steroids with an 80% complete resolution rate. The literature showed that steroids may exacerbate infectious disease of the breast, but in our study, no such evidence was found because we didn't prescribe steroids to any patient suffering from infectious disease of the breast along with IGM. Furthermore, the side effects of steroid therapy can include glucose intolerance, acne and cushingoid features.⁹ Based on these findings, oral corticosteroids were given at a dose of 60 mg/day and it was tapered weekly or biweekly according to clinical improvements. The median duration of corticosteroid treatment was two months. All patients were followed up at 15 days, 2 months, 3 months and 6 months intervals for one year. Out of 70 patients treated, 59 patients (84.28%) had complete recovery. In the study, recurrences were seen in eleven patients. All were

treated with 2nd cycle of steroids. Unfortunately, 5 patients had a further recurrence, so 3rd cycle was given and no relapse occurred to date.

In contrast to the works of literature that were reviewed, complications after using steroids in our study were more frequent. 13 patients developed peptic ulcer disease, 3 glucose intolerance, 26 cushingoid features, 4 weight gain, 2 acne, and 2 patients had bone pain. The small number of patients in their context might have caused this difference.

IGM was more common in our country contrary to the literature reviewed so further studies regarding the incidence of IGM in this subcontinent are needed.

Conclusion

Idiopathic granulomatous mastitis is not an uncommon breast disease in the subcontinent. Our study demonstrates that treatment with prednisolone was effective for IGM. Although prednisolone treatment requires a lengthy therapeutic period, it shows regression with good cosmetic results and a low recurrence rate. So, treatment of IGM with prednisolone can be the first choice as it is a noninvasive method of treatment. However, further studies with a greater number of patients are needed to formulate reasonable treatment algorithms for a successful outcome. Recurrent cases can be trialed with further cycles of prednisolone.

Recommendation

A larger multi-center prospective observational studies with a greater number of patients are needed to formulate reasonable treatment algorithms for a successful outcome.

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Disclosure

All the authors declared no competing interest.

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