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ORIGINAL ARTICLE

The effectiveness of local steroid injection for the treatment of breast-limited idiopathic granulomatous mastitis: A randomized controlled clinical trial study

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT:

Introduction: Idiopathic granulomatous mastitis (IGM) is a rare, non-specific inflammatory breast disease. There are several controversies regarding its standard treatment.

Aim: We aimed to evaluate the efficacy of local corticosteroid injection compared to systemic steroids and combined treatment of both in IGM patients.

Methods: In this randomized controlled clinical trial study, 115 IGM patients were randomly allocated to three groups of local steroid injection (Betamethasone, n = 37), systemic steroid treatment (Prednisolone + MTX, n = 37), or combined treatment of both (n = 41) for a follow-up period of 10 months. Clinical presentations and outcomes were compared between the groups.

Results: The mean age of the study patients was 35.6 years. The mean time to complete remission was 3.17, 4.33, and 6.37 months, and the relapse rate during the treatment was 0%, 5.26%, and 13.33% in the injection, combined, and systemic therapy groups, respectively. There was no significant difference between the clinical response to treatment rate and the recurrence rate during the follow-up between the groups. Four patients in the combined therapy group and 3 patients in the systemic therapy group had steroid side effects, with no side effects in the injection group.

Conclusions: Steroid injection therapy is more effective than combined therapy and systemic therapy in terms of remission and relapse rate during the treatment, and is as effective as systemic therapy in the clinical response to treatment rate and the recurrence rate during the follow-up period. Regarding the lack of side effects of the steroid injection therapy, this approach could be considered among the first-line treatment options.

KEYWORDS: idiopathic granulomatous mastitis, steroid injection, systemic steroid, treatment

ABBREVIATIONS

ANOVA – Analysis of Variance
CNB – core needle biopsy
CONSORT – Consolidated Standards of Reporting Trials
CRP – C-reactive protein
IGM – idiopathic granulomatous mastitis
IRCT – Iranian Registry of Clinical Trials
MRI – Magnetic Resonance Imaging
MTX – methotrexate
SD – standard deviation
SPSS – Statistical Package for the Social Sciences
WBC – white blood cell

INTRODUCTION

The incidence and mortality rates of breast cancer are influenced by various factors, including age, ethnicity, socioeconomic status, and tumor-related characteristics such as size, histological grade, and hormone receptor status [1]. Idiopathic granulomatous mastitis (IGM) is a rare, non-specific inflammatory breast condition of unknown etiology. Initially described by Kessler et al. [2], this benign yet challenging disease presents with diverse clinical manifestations, often characterized by painful, irregular breast masses and skin changes ranging from erythema to fistula formation, potentially mimicking malignant processes [3, 4]. Diagnostic confirmation relies on cytological or pathological examination following exclusion of more common breast pathologies [5]. While the precise cause remains elusive, proposed etiological factors include infection, inflammation, and hormonal influences [6]. Notably, IGM exhibits a higher prevalence among Middle Eastern and Hispanic populations compared to Western Caucasian populations, suggesting potential ethnic and genetic predispositions [7–9].

Consensus on the optimal management of IGM remains elusive. Corticosteroids, initially introduced by DeHertogh et al. in 1980, constitute the primary medical intervention [10]. Both systemic and topical corticosteroid regimens have been employed, with

Notably, no adverse effects related to topical or systemic steroid use were reported. These findings suggest that intralesional steroid injection may represent a viable treatment option for high-risk IGM patient populations.

The dense glandular composition of young women's breasts can pose challenges for intralesional steroid injection [36]. To optimize drug delivery, ultrasound-guided injections were targeted to the palpable breast mass and surrounding tissue. This approach facilitates enhanced absorption of the steroid into the breast tissue, potentially improving therapeutic efficacy.

The high efficacy and low recurrence rates in the local steroid injection therapy for IGM were verified in our study but the optimal treatment modality, including optimal steroid dosage and injection sites, remains unclear. Besides, different steroids should be evaluated in future studies to find the best steroid injection treatment algorithm for IGM patients. Regarding the side effects of the treatment, although we did not observe any steroid-related side effects in the injection group during the follow-up period, the exact amount of steroid systemic absorption is not clear and the side effects associated with oral steroid use could also occur with local steroid injection [37]. However, in general, the steroid dosage used for local injection is much lower than the dosage used for oral administration, and consequently, the possibility of systemic steroid complications should be much lower [38].

The present study corroborates the efficacy and reduced recurrence rates associated with local steroid injection in the management of IGM. However, optimal treatment parameters, including precise steroid dosage and injection site, require further elucidation. Comparative studies evaluating different steroid formulations are warranted to establish optimal treatment algorithms for IGM patients [19, 39]. While no local steroid--related adverse events were observed in this study, the exact extent of systemic steroid absorption following local injection remains uncertain [38]. Although the potential for systemic side effects exists, the significantly lower steroid doses employed in local injections compared to oral administration suggest a reduced risk of systemic complications [37].

Limitation of the study

A potential limitation of this study is the relatively short follow--up period, which may have influenced the accuracy of recurrence rate reporting. To comprehensively evaluate the efficacy and safety of local steroid injections in managing IGM, future large-scale, multicenter randomized controlled trials with extended follow--up periods are warranted.

CONCLUSIONS

Local steroid injection demonstrated superior efficacy compared to combined and systemic immunosuppressive therapies in accelerating time to remission and reducing relapse rates. Consequently, this therapeutic approach facilitated more rapid symptom control and shortened treatment duration relative to oral systemic treatments. While not surpassing systemic therapy in terms of overall clinical response or recurrence rates, local steroid injection emerged as a viable alternative to surgery or systemic corticosteroids. The absence of steroid-related adverse effects associated with local injections is anticipated to enhance patient adherence, positioning this modality as a potential first-line treatment option.

DECLARATIONS

Ethics approval and consent to participate

This study was performed in accordance with the Declaration of Helsinki. The ethics committee of Shiraz University of Medical Sciences approved the study protocol (reference number was IR.SUMS.MED.REC.1399.096). The written consent was obtained from all study participants. The trial was registered in the Iranian Registry of Clinical Trials (IRCT) with the registry number IRCT20200608047694N1, and the registration date was 21 July 2020. This study is reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines.

Consent for publication

The written informed consent for publication was obtained from all authors.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Trial registration

The trial registry number was IRCT20200608047694N1, and the registration date was 2020-07-21.

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