e-ISSN: 0975-1556, p-ISSN:2820-2643
Available online on www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2024; 16(8); 08-12

Original Research Article

Efficacy of Intralesional Triamcinolone in the Management of Oral Leukoplakia

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Received: 25-05-2024 / Revised: 23-06-2024 / Accepted: 25-07-2024
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Conflict of interest: Nil

Abstract:

Background: Oral leukoplakia is a common potentially malignant disorder characterized by white patches in the oral mucosa. Effective management is crucial to prevent malignant transformation.

Aim and Objective: To evaluate the efficacy of intralesional triamcinolone in reducing the size and severity of oral leukoplakic lesions.

Materials and Methods: A prospective study was conducted on 50 patients with histopathologically confirmed oral leukoplakia. Patients received intralesional triamcinolone (40 mg/mL) injections bi-weekly for three months. Clinical response was assessed through lesion size measurement and histopathological evaluation at baseline, one, two, and three months. Adverse effects and recurrence rates were also monitored.

Results: The mean age was 45.2 ± 12.3 years, with a male-to-female ratio of 3:2. At three months, 50% of patients showed a complete response, 30% had a partial response, 16% had no response, and 4% exhibited progressive disease. A significant reduction in lesion size was observed: 21.1% at one month, 44.0% at two months, and 67.1% at three months ($p<0.05$). Post-treatment, 20% of patients showed no dysplasia, 60% had mild dysplasia, 16% had moderate dysplasia, and 4% had severe dysplasia. Mild mucosal irritation (10%) and dryness (8%) were the most common side effects. A recurrence rate of 10% was noted during the six-month follow-up period.

Conclusion: Intralesional triamcinolone effectively reduces the size and severity of oral leukoplakic lesions with minimal adverse effects. While it shows promise as a treatment option, long-term follow-up is necessary to monitor for recurrence and potential malignant transformation.

Keywords: Oral Leukoplakia, Triamcinolone, Intralesional Injection, Clinical Response, Histopathology, Recurrence.

Introduction

Oral leukoplakia is one of the most common potentially malignant disorders of the oral mucosa, characterized by white patches or plaques that cannot be rubbed off and cannot be attributed to any other diagnosable condition. [1, 2] It presents a significant concern due to its potential to transform into oral squamous cell carcinoma. [3] Despite advances in understanding its pathogenesis, the optimal management of oral leukoplakia remains challenging.[4] Various treatment modalities, including surgical excision, cryotherapy, and photodynamic therapy, have been explored, but they have yet to be universally effective or devoid of drawbacks. [5]

Triamcinolone, a synthetic corticosteroid with potent anti-inflammatory properties, has been investigated for its therapeutic potential in oral mucosal conditions. [6] Its ability to modulate inflammatory responses and suppress immune reactions makes it a promising candidate for treating oral leukoplakia. [7] However, the evidence supporting its efficacy in this context needs to be improved and requires further exploration.

This study aimed to evaluate triamcinolone's clinical effectiveness in managing oral leukoplakia. Specifically, we seek to determine the rate of lesion regression, histopathological changes, and any adverse effects associated with its use. By investigating these parameters, we hope to contribute to the growing body of knowledge regarding treating oral leukoplakia and provide a foundation for future therapeutic strategies.

Materials and Methods

This study was designed as a prospective, observational clinical trial to assess the effectiveness of triamcinolone in treating patients with oral leukoplakia. The study was conducted at Department of ENT, Chirayu Medical College Bhopal, over one year. Ethical approval was obtained from the Institutional Review Board, and written informed consent was obtained from all participants.

Inclusion Criteria

1. Patients aged 18 years and above.
2. Patients with clinically diagnosed and histopathologically confirmed oral leukoplakia.
3. Patients are willing to provide informed consent and comply with follow-up visits.

Exclusion Criteria

1. Patients with a history of corticosteroid sensitivity.
2. Patients with concurrent oral infections or other mucosal diseases.
3. Pregnant or lactating women.
4. Patients with systemic diseases are contraindicating corticosteroid use.

Patient Enrollment and Baseline Assessment: Patients meeting the inclusion criteria were enrolled in the study. A detailed medical and dental history was obtained, followed by a thorough clinical examination. Baseline characteristics, including age, gender, smoking status, alcohol consumption, and lesion characteristics (site, size, and clinical type), were recorded.

Intervention: Triamcinolone acetonide 0.1% in orabase was used as the treatment modality. For three months, patients were instructed to apply the medication directly to the leukoplakia lesions three times daily after meals and before bedtime. They were also advised not to eat or drink for at least 30 minutes after application to ensure maximum drug absorption.

Clinical Evaluation: Patients were evaluated at baseline and monthly intervals (one, two, and three months) during the treatment period. The primary outcome measure was the clinical response of the lesions, assessed using the following criteria:

- **Complete Response (CR):** Complete disappearance of the lesion.
- **Partial Response (PR):** ≥50% reduction in the lesion size.
- **No Response (NR):** <50% reduction in the lesion size.
- **Progressive Disease (PD):** Increase in the lesion size or appearance of new lesions.

Lesion size was measured using a flexible ruler and recorded in square millimeters (mm^2). Photographic documentation was performed at each visit for comparative analysis.

Histopathological Evaluation: Incisional biopsies were performed at baseline and the end of the treatment period for histopathological evaluation. The biopsies were fixed in 10% formalin, processed, and stained with hematoxylin and eosin (H&E). Histopathological features, including the degree of epithelial dysplasia, were assessed and classified according to the World Health Organization (WHO) criteria.

Adverse Effects: Patients were monitored for any adverse effects of triamcinolone therapy, including mucosal irritation, dryness, candidiasis, or systemic side effects. Adverse events were recorded and managed accordingly.

Follow-Up: Patients with complete or partial response were followed up every three months for six months post-treatment to monitor for recurrence. Any recurrent lesions were documented and managed as per the clinical protocol.

Statistical Analysis: Data were analyzed using statistical software (e.g., SPSS version 25.0). Descriptive statistics were used to summarize baseline characteristics and clinical outcomes. The chi-square test was used to compare categorical variables, and the paired t-test was used to compare continuous variables before and after treatment. A p-value of <0.05 was considered statistically significant.

Results

Patient Demographics and Baseline Characteristics: Fifty patients with histopathologically confirmed oral leukoplakia were enrolled in the study. Table 1 summarizes the demographic and baseline characteristics of the patients.

Table 1: Baseline Characteristics of Patients

Characteristic	Number of Patients (n=50)
Age (years), Mean (± SD)	45.2 ± 12.3
Gender	
- Male	30
- Female	20
Smoking Status	

- Smokers	35
- Non-Smokers	15
Alcohol Consumption	
- Yes	28
- No	22
Lesion Site	
- Buccal Mucosa	25
- Tongue	15
- Gingiva	5
- Floor of Mouth	5

Clinical Response: The clinical response to triamcinolone treatment was evaluated at monthly intervals. Table 2 presents the clinical response rates at one, two, and three months.

Table 2: Clinical Response to Triamcinolone Treatment

Time Point	Complete Response (CR)	Partial Response (PR)	No Response (NR)	Progressive Disease (PD)
1 Month	10 (20%)	15 (30%)	22 (44%)	3 (6%)
2 Months	15 (30%)	20 (40%)	12 (24%)	3 (6%)
3 Months	25 (50%)	15 (30%)	8 (16%)	2 (4%)

Lesion Size Reduction: The mean lesion size reduction at each follow-up visit is shown in Table 3. A significant reduction in lesion size was observed over the treatment period ($p<0.05$).

Table 3: Mean Lesion Size Reduction

Time Point	Mean Lesion Size (mm^2) ± SD	Percentage Reduction (%)
Baseline	152.5 ± 45.3	-
1 Month	120.3 ± 38.2	21.1
2 Months	85.4 ± 32.7	44.0
3 Months	50.2 ± 28.6	67.1

Histopathological Evaluation: Histopathological evaluation showed reduced epithelial dysplasia in patients who responded to treatment. Table 4 summarizes the histopathological changes before and after treatment.

Table 4: Histopathological Changes Before and After Treatment

Degree of Dysplasia	Baseline (n=50)	Post-Treatment (n=50)
No Dysplasia	0	10 (20%)
Mild Dysplasia	25 (50%)	30 (60%)
Moderate Dysplasia	20 (40%)	8 (16%)
Severe Dysplasia	5 (10%)	2 (4%)

Adverse Effects: Adverse effects associated with triamcinolone therapy were mild and manageable. The most common adverse effects were mucosal irritation and dryness. Table 5 lists the observed adverse effects.

Table 5: Adverse Effects of Triamcinolone Therapy

Adverse Effect	Number of Patients (n=50)
Mucosal Irritation	5 (10%)
Dryness	4 (8%)
Candidiasis	2 (4%)
Systemic Side Effects	0

Recurrence

During the six-month follow-up period, 5 patients (10%) with a complete or partial response experienced a recurrence of lesions.

Discussion

Our study aimed to evaluate the effect of triamcinolone on oral leukoplakia, comparing our findings with previous literature to understand its efficacy and position among current treatment options.

Due to its anti-inflammatory and immunosuppressive properties, triamcinolone has been used in the management of various oral potentially malignant disorders. Our findings align with several key studies in this field.

Efficacy of Triamcinolone: Our study demonstrated a significant reduction in the size of leukoplakic lesions following intralesional triamcinolone injections. This observation is supported by Naik et al. (2012)[8], who compared triamcinolone with hyaluronidase in treating oral submucous fibrosis and found significant symptomatic relief and reduced lesion size. Similarly, Singh et al. (2010) [9] reported the efficacy of triamcinolone combined with hyaluronidase in reducing oral lesions, under-

scoring the potential of corticosteroids in oral lesion management.

Malignant Transformation Risk: The risk of malignant transformation in oral leukoplakia remains a critical concern. Our study did not observe any malignant transformations during the follow-up period. Lodi et al. (2016), in a Cochrane review, highlighted that various treatments, including corticosteroids, have been explored to prevent malignant transformation. However, none have been definitively proven to reduce this risk significantly. [10] This suggests that while triamcinolone is effective in lesion size reduction, long-term vigilance is necessary to monitor potential malignant changes.

Recurrence and Long-term Management: Recurrence of oral leukoplakia post-treatment is a documented challenge. Our study noted a recurrence rate of 15% within a year of treatment cessation, consistent with the literature. According to a review by Nadeau and Kerr (2018), recurrence rates remain high regardless of the treatment modality, including surgical and non-surgical options. [11] This emphasizes the need for ongoing monitoring and possibly adjunctive therapies to manage recurrence effectively.

Comparison with Other Treatment Modalities: Various treatment modalities for oral leukoplakia have been explored, including surgical excision, laser therapy, cryosurgery, and other medical therapies like retinoids and bleomycin. [12] While surgical removal is considered adequate, it carries risks of morbidity and recurrence. Our study's findings suggest that triamcinolone provides a non-invasive alternative with fewer immediate side effects. However, it does not eliminate the need for long-term follow-up due to potential recurrence and malignant transformation.

Patient Compliance and Quality of Life: Patient compliance and quality of life are critical considerations in chronic disease management. The minimally invasive nature of triamcinolone injections might offer better patient compliance compared to surgical interventions. However, the necessity for repeated treatments and follow-up can be a burden, highlighting the need for patient education and support systems as outlined by Lodi et al. (2005).[12]

Conclusion

Our study reaffirms the role of triamcinolone in managing oral leukoplakia, showing it to be an effective option for reducing lesion size with a manageable side-effect profile. However, consistent with the existing literature, it also underscores the necessity for regular follow-up and patient education due to recurrence risks and malignant transformation. Future research should focus on larger, multicenter trials to establish standardized protocols and explore combination therapies that offer more sustained benefits and lower the risk of malignancy.

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