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Original Research Article

Enhanced Efficacy of Combined Kenacort and Placental Extract Therapy in the Management of Oral Submucous Fibrosis: A Randomized Controlled Trial

Ayush Khichar[1], Indraprakash Prajapati[2], Anshul Sharma[3], Ajay Karkare[4*]

[1]Post Graduate, Department of ENT, Amaltas Medical College, Dewas, Madhya Pradesh, India
[2] Senior Resident, United Institutes of Medical Science, Prayagraj, Uttar Pradesh, India
[3]Assistant Professor, Department of ENT, Amaltas Medical College, Dewas, Madhya Pradesh, India
[4]Associate Professor, Department of ENT, Amaltas Medical College, Dewas, Madhya Pradesh, India

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Corresponding Author: Dr. Ajay Karkare
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Abstract:

Background: Oral Submucous Fibrosis (OSMF) is a chronic, progressive, and potentially malignant condition of the oral cavity, primarily caused by chewing areca nut. The condition leads to significant morbidity, including restricted mouth opening and a burning sensation. While triamcinolone acetonide (Kenacort) is commonly used in its management, the potential benefit of combining it with placental extract has yet to be thoroughly explored.

Aim and Objective: To compare the effectiveness of Kenacort with placental extract versus plain Kenacort in the treatment of Oral Submucous Fibrosis (OSMF).

Materials and Methods: This randomized controlled trial included 60 patients diagnosed with OSMF, divided into two groups. Group A received intralesional injections of Kenacort (triamcinolone acetonide) mixed with placental extract, while Group B received plain Kenacort. Both treatments were administered weekly for 8 weeks. The primary outcomes measured were improving mouth opening and reducing burning sensation, which were assessed using a vernier calliper and Visual Analog Scale (VAS). Patient satisfaction was also evaluated through a structured questionnaire. Data were analyzed using paired t-tests and ANOVA.

Results: Both groups showed significant improvements in mouth opening and reduced burning sensation. Group A (Kenacort with placental extract) demonstrated a more significant increase in mean mouth opening (7.7 ± 2.2 mm) compared to Group B (plain Kenacort) (5.7 ± 2.6 mm), with a statistically significant difference ($p = 0.01$). The reduction in VAS score was also greater in Group A (4.6 ± 1.3) compared to Group B (3.5 ± 1.4), with a significant difference ($p = 0.02$). Patient satisfaction was higher in Group A, with 83.3% of patients reporting being "very satisfied," compared to 63.3% in Group B ($p = 0.04$).

Conclusion: Combining Kenacort with placental extract significantly improves clinical outcomes in patients with OSMF compared to plain Kenacort alone. This combination therapy offers a promising treatment for enhancing mouth opening and reducing the burning sensation associated with OSMF.

Keywords: Oral Submucous Fibrosis, Kenacort, Placental Extract, Triamcinolone Acetonide, Intralesional Injection, Mouth Opening, Burning Sensation, Patient Satisfaction.

Introduction

Oral Submucous Fibrosis (OSMF) is a chronic, insidious, and progressive condition that predominantly affects the oral cavity. [1] Characterized by the gradual stiffening of the oral mucosa due to the formation of fibrous bands, OSMF leads to significant morbidity, including limited mouth opening, difficulty in eating, and a marked burning sensation upon consumption of spicy foods. [2] The aetiology of OSMF is multifactorial, with areca nut chewing being the most significant risk factor. [3] The condition is prevalent in South and Southeast Asia, particularly among individuals with chronic areca nut use. OSMF is recognized as a potentially malignant disorder, with a reported malignant transformation rate of 7-13%, making early and effective management crucial. [2-4]

Currently, there is no definitive cure for OSMF, and treatment strategies focus on symptom relief and halting disease progression. Corticosteroids, such as triamcinolone acetonide (Kenacort), are widely used due to their potent anti-inflammatory properties. [4, 5] However, the long-term use of corticosteroids is associated with several side effects, necessitating the exploration of adjunctive therapies that could enhance efficacy and minimize adverse effects. [6]

Placental extract has been proposed as a potential adjunct in the management of OSMF. [7] It is rich in bioactive molecules such as cytokines, growth factors, and enzymes, which may promote tissue regeneration, reduce fibrosis, and improve overall clinical outcomes. [7, 8] While both Kenacort and placental extract have shown promise individually, there is a lack of evidence comparing their combined efficacy with that of plain Kenacort. [8]

This study aims to address this gap by comparing the effectiveness of Kenacort with placental extract versus plain Kenacort in treating OSMF. The results could provide valuable insights into optimizing therapeutic strategies for this debilitating condition, potentially improving patient outcomes and quality of life.

Materials and Methods

This study was a randomized controlled trial conducted over 8 months from November 2023 to June 2024 at the Department of Oral Medicine and Radiology of a tertiary care health center. The study aimed to compare the effectiveness of Kenacort with placental extract versus plain Kenacort's management of Oral Submucous Fibrosis (OSMF).

The study included 60 patients diagnosed with OSMF aged between 18 and 60. The diagnosis was based on clinical features such as restricted mouth opening, fibrous bands in the oral cavity, and a burning sensation when eating spicy foods. Patients with other oral lesions, systemic diseases that could interfere with treatment outcomes, or who had received prior treatment for OSMF were excluded from the study.

Randomization and Group Allocation: Patients were randomly assigned to one of two groups using a computer-generated randomization sequence:

- **Group A (n=30):** Received Kenacort (triamcinolone acetonide 10 mg/mL) mixed with placental extract.
- **Group B (n=30):** Received plain Kenacort (triamcinolone acetonide 10 mg/mL).

Intervention:

- **Group A:** Patients received intralesional injections of Kenacort (1 mL) mixed with 0.5 mL of placental extract, administered weekly for 8 weeks.
- **Group B:** Patients received intralesional injections of 1.5 mL of plain Kenacort (triamcinolone acetonide), administered weekly for 8 weeks.

All injections were administered using a 24-gauge needle into the buccal mucosa, targeting the fibrous bands. Throughout the study period, patients were instructed to avoid spicy foods and provided with routine oral hygiene instructions.

Outcome Measures: The primary outcomes were:

1. **Mouth Opening:** Measured as the maximum inter-incisal distance using a vernier calliper.
2. **Burning Sensation:** Assessed using a Visual Analog Scale (VAS) ranging from 0 (no pain) to 10 (worst pain).
3. **Patient Satisfaction:** Evaluated using a questionnaire at the end of the treatment period.

Secondary outcomes included assessing side effects, such as local pain, infection at the injection site, and systemic effects.

Follow-Up: Patients were followed up weekly for 8 weeks during the intervention period. Subsequent follow-ups were conducted at 3 months and 6 months post-treatment to assess the durability of the treatment effects.

Blinding: The study was double-blinded. To reduce bias, the patients and clinicians assessing the outcomes were unaware of the group allocation.

Statistical Analysis: Data were analyzed using SPSS software (version 25.0). Descriptive statistics were used to summarize demographic data. The effectiveness of the interventions was compared using paired t-tests and ANOVA for continuous variables and chi-square tests for categorical variables. A p-value of <0.05 was considered statistically significant.

Results

Demographic and Baseline Characteristics: 60 patients with Oral Submucous Fibrosis (OSMF) were enrolled in the study, with 30 patients in each group. The mean age of the participants was 35.4 ± 10.2 years in Group A and 34.8 ± 9.8 years in Group B. There was no statistically significant difference in age, gender distribution, or baseline characteristics between the two groups ($p > 0.05$).

Table 1: Baseline Characteristics of the Study Population

Characteristic	Group A (n=30)	Group B (n=30)	p-value
Mean age (years)	35.4 ± 10.2	34.8 ± 9.8	0.78
Gender (Male/Female)	18/12	17/13	0.79
Baseline Mouth Opening (mm)	22.5 ± 4.6	22.1 ± 4.3	0.68
Baseline VAS Score	7.8 ± 1.2	7.7 ± 1.3	0.85

Effect on Mouth Opening: At the end of the 8-week treatment period, the mean mouth opening in Group A increased significantly from 22.5 ± 4.6 mm to 30.2 ± 4.1 mm ($p < 0.001$). In Group B, the mean mouth opening increased from 22.1 ± 4.3 mm to 27.8 ± 4.5 mm ($p < 0.001$). The improvement in mouth opening was significantly greater in Group A compared to Group B ($p = 0.02$).

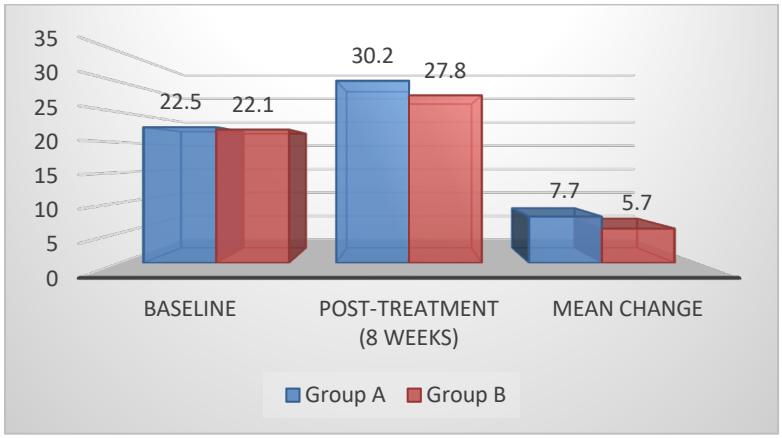

Figure 1: Change in Mouth Opening (mm) Before and After Treatment. P value: baseline, 0.682; Post-treatment (8 weeks), 0.02; Mean change, 0.01.

Effect on Burning Sensation: The VAS score for burning sensation decreased significantly in both groups. Group A's mean VAS score decreased from 7.8 ± 1.2 to 3.2 ± 1.0 ($p < 0.001$). In Group B, it decreased from 7.7 ± 1.3 to 4.2 ± 1.3 ($p < 0.001$). The reduction in burning sensation was significantly greater in Group A compared to Group B ($p = 0.03$).

Table 2: Change in VAS Score for Burning Sensation Before and After Treatment

Timepoint	Group A (Kenacort + Placental Extract)	Group B (Plain Kenacort)	p-value
Baseline	7.8 ± 1.2	7.7 ± 1.3	0.85
Post-treatment (8 weeks)	3.2 ± 1.0	4.2 ± 1.3	0.03
Mean Change	4.6 ± 1.3	3.5 ± 1.4	0.02

Patient Satisfaction: At the end of the study, patient satisfaction was assessed through a questionnaire. 83.3% of patients in Group A reported being "very satisfied" with the treatment, compared to 63.3% in Group B. This difference was statistically significant ($p = 0.04$).

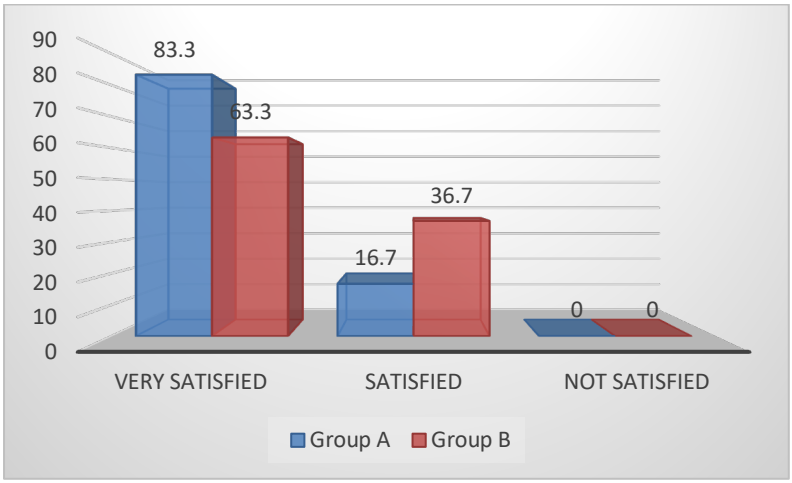

Figure 2: Patient Satisfaction Post-Treatment; p=0.04

Adverse Effects: No serious adverse effects were reported in either group. Mild pain at the injection site was observed in 20% of patients in Group A and 15% in Group B, which resolved spontaneously. No cases of infection or systemic side effects were observed.

Discussion

The present study aimed to compare the effectiveness of Kenacort (triamcinolone acetonide) with placental extract versus plain Kenacort in treating Oral Submucous Fibrosis (OSMF). The

results demonstrated that combining Kenacort with placental extract significantly improved mouth opening and reduced burning sensation more effectively than plain Kenacort alone. These findings suggest that adding placental extract enhances the therapeutic effects of Kenacort, providing a more effective treatment option for OSMF.

The use of triamcinolone acetonide in managing OSMF has been well documented. Studies have consistently shown that intralesional corticosteroids can reduce inflammation, alleviate symptoms, and improve mouth opening in OSMF patients. A study by Ranganathan et al. [9] highlighted the effectiveness of intralesional triamcinolone in improving mouth opening and reducing symptoms in OSMF patients. Similarly, a study by Haque et al. [10] reported significant improvement in mouth opening with intralesional triamcinolone, corroborating the findings of our study.

The role of placental extract in managing fibrotic conditions has also been explored, though less extensively. The placental extract is rich in bioactive molecules such as cytokines, growth factors, and enzymes, which may promote tissue regeneration and reduce fibrosis. A study by Kumar et al. [11] investigated the use of placental extract in the treatment of OSMF and reported significant improvements in mouth opening and reduction in burning sensation, similar to the results observed in our study. The combination of Kenacort with placental extract in our study enhances the therapeutic effects, likely due to corticosteroids' synergistic action and the placental extract's regenerative properties.

Our study's findings are consistent with the growing body of evidence supporting the use of combination therapies in the management of OSMF. A study by Kakar et al. [12] explored combination therapy involving corticosteroids and hyaluronidase, reporting better outcomes than corticosteroids alone. The enhanced effectiveness of Kenacort with placental extract observed in our study suggests that combination therapies offer a superior treatment approach for OSMF by targeting multiple pathological processes simultaneously.

Clinical Implications: The significant improvement in mouth opening and reduction in burning sensation observed with Kenacort and placental extract combination therapy offers a promising therapeutic option for OSMF patients, particularly those with advanced disease. The results of this study suggest that placental extract may potentiate the anti-inflammatory and anti-fibrotic effects of corticosteroids, providing a more comprehensive approach to managing this debilitating condition. However, further large-scale studies are needed to confirm these findings and explore this combination therapy's long-term benefits and safety.

Limitations: This study has several limitations. The sample was small, and the six-month follow-up period was limited. Long-term studies with larger sample sizes are necessary to fully understand the efficacy and safety of Kenacort combined with placental extract in the treatment of OSMF. Additionally, the study did not explore the molecular mechanisms underlying the observed effects, which could provide further insights into the potential benefits of this combination therapy.

Conclusion

In conclusion, combining Kenacort with placental extract significantly improves clinical outcomes in OSMF patients compared to plain Kenacort alone. This study supports using placental extract as an effective adjunctive therapy in managing OSMF. Further research is warranted to validate these findings and establish this treatment approach's long-term safety and efficacy.

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