

Efficacy of Squa Care Gel Versus Triamcinolone Acetonide in Oral Submucous

Fibrosis: A Split-Mouth Comparative Clinical Study

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ABSTRACT

Background

Oral Submucous Fibrosis (OSMF) is a chronic, progressive and potentially malignant disorder commonly associated with areca nut chewing. Patients usually present with burning sensation, stiffness of oral mucosa and reduced mouth opening. Different therapeutic modalities have been used for symptomatic relief, including corticosteroids and herbal preparations.

Aim

To evaluate and compare the efficacy of Ayurvedic preparation (Squa Care Gel) and Triamcinolone

acetonide in Oral Submucous Fibrosis patients.

Materials and Methods

A prospective split-mouth comparative clinical study was conducted among 50 clinically diagnosed Grade I and Grade II Oral Submucous Fibrosis patients (42 males and 8 females) aged between 18 and 60 years. All participants reported a history of areca nut, gutkha, betel quid, or related chewing habits. Habit history was recorded during clinical examination. Squa Care Gel) was applied on the right buccal mucosa and Triamcinolone acetonide (Kenacort 0.1%)

on the left buccal mucosa. Burning sensation was assessed using Visual Analog Scale (VAS), and mucosal elasticity/flexibility was evaluated over five visits.

Results

Both treatment modalities showed clinical improvement. However, Squa Care Gel demonstrated greater reduction in burning sensation and earlier improvement in mucosal elasticity. Mean VAS score reduced from 7.1 to 2.9 on the Ayurvedic side and from 7.1 to 4.2 on the Kenacort side. Elasticity improvement reached 100% with Squa Care Gel and 82% with Kenacort.

Conclusion

Squa Care Gel demonstrated superior efficacy compared to Triamcinolone acetonide in reducing burning sensation and improving mucosal elasticity in OSMF patients.

Keywords

Oral Submucous Fibrosis, Squa Care Gel, Triamcinolone acetonide, Ayurveda, Burning sensation, OSMF.

INTRODUCTION

Oral Submucous Fibrosis (OSMF) is a chronic, debilitating and potentially malignant disorder affecting the oral cavity and occasionally the pharynx. It is characterized by progressive fibrosis of the submucosal tissues leading to rigidity of oral mucosa and restricted mouth opening.¹

The condition is predominantly seen in the Indian subcontinent due to the widespread habit of areca nut and betel quid chewing. Patients commonly complain of burning sensation of oral mucosa, intolerance to spicy food, blanching, stiffness and gradual inability to open the mouth.²

The pathogenesis of OSMF involves chronic inflammation, excessive collagen deposition, altered collagen metabolism and oxidative stress. Due to the chronic progressive nature of the disease and its malignant transformation potential, early management is important.

Various treatment modalities such as antioxidants, steroids, hyaluronidase, placental extracts, interferons and surgical interventions have been attempted with varying success. Among these, corticosteroids like Triamcinolone acetonide are widely used because of their anti-inflammatory and immunosuppressive actions.³

Recently, Ayurvedic and herbal preparations have gained attention due to their antioxidant, anti-inflammatory and tissue regenerative properties. Squa Care Gel is a topical herbal preparation containing Ashwagandha, Tulasi, Nigaki, Maricha, Jeeraka and other herbal constituents which may help in reducing fibrosis and improving oral symptoms.

Ashwagandha possesses potent anti-inflammatory and rejuvenating properties.⁴ Tulasi demonstrates antioxidant and wound healing activity.⁵ Picrorhiza kurroa metabolites exhibit antioxidant effects, whereas myristicin-containing compounds possess anti-inflammatory and immunomodulatory properties.^{6,7}

Hence, the present study was undertaken to compare the efficacy of Squa Care Gel and Triamcinolone acetonide in OSMF patients.

AIM

To evaluate the efficacy of Ayurvedic topical preparation (Squa Care Gel) in comparison with Triamcinolone acetonide in Oral Submucous Fibrosis patients.

OBJECTIVES

1. To evaluate reduction in burning sensation using Visual Analog Scale (VAS).
2. To evaluate improvement in flexibility and elasticity of buccal mucosa.
3. To compare the efficacy of Squa Care Gel and Triamcinolone acetonide.

MATERIALS AND METHODS

A prospective split-mouth comparative clinical study was conducted in the Department of Oral Medicine and Radiology among 50 clinically [42 males, 8 females] diagnosed with Grade 1 and Grade 2 OSMF patients aged between 18–60 years. All participants reported a history of areca nut, gutkha, betel quid, or related chewing habits. Habit history was recorded during clinical examination. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants before enrolment.

Inclusion Criteria

- Clinically diagnosed OSMF patients (Grade 1 and Grade 2) with bilaterally equally involvement.
- Age group between 18–60 years.

Exclusion Criteria

- Patients already undergoing treatment for OSMF.
- Patients unwilling to participate in the study.

STUDY PROCEDURE

Each patient served as their own control. Squa Care Gel was applied topically to the right buccal mucosa, while Triamcinolone Acetonide oral paste (Kenacort 0.1%) was applied to the left buccal mucosa. Patients were instructed to apply the medications three times

daily after meals and to refrain from eating or drinking for at least 30 minutes following application.

Clinical evaluation was performed at baseline (Visit 0) and at four subsequent follow-up visits. Patients were also advised regarding cessation of areca nut and tobacco-related habits and maintenance of good oral hygiene practices throughout the study period.

PARAMETERS ASSESSED

1. Burning Sensation

Burning sensation was assessed using the Visual Analog Scale (VAS), where patients rated their symptoms on a scale ranging from 0 to 10, with 0 indicating no burning sensation and 10 indicating the most severe burning sensation imaginable. Scores were recorded at baseline and during each follow-up visit.

2. Flexibility and Elasticity of Buccal Mucosa

Flexibility and elasticity of the buccal mucosa were evaluated clinically at baseline and during each follow-up visit. The buccal mucosa was retracted laterally using a mouth mirror, and the degree of tissue extensibility, pliability, and resistance to retraction was assessed. Improvement was determined by increased mucosal mobility and reduced fibrotic stiffness compared with baseline findings. Clinical observations were recorded systematically at each visit and expressed as the percentage of patients demonstrating improvement during the follow-up period.

PHOTOGRAPHIC DOCUMENTATION

Standardized intraoral photographs were obtained at baseline and during each follow-up visit. Clinical photographs were captured while retracting the buccal mucosa using a mouth mirror under standardized

lighting conditions and camera settings. Care was taken to maintain a consistent angle, distance, and degree of retraction for all photographs. Serial photographic comparison was performed to evaluate changes in mucosal flexibility, elasticity, blanching, and fibrotic restriction throughout the treatment period. [Fig.1(a-e) & Fig.2 (a-e)]

STATISTICAL ANALYSIS

The collected data were tabulated and analyzed using descriptive statistical methods. Continuous variables were expressed as mean values, while categorical variables were expressed as percentages. The results were presented in tabular and graphical form.

RESULTS

A total of 50 clinically diagnosed Grade I and Grade II OSMF patients were included in the study. The study population comprised 42 males (84%) and 8 females (16%), showing a marked male predominance. All participants reported a history of areca nut, gutkha, betel quid, or related chewing habits.

Burning Sensation (VAS Score) [Table 1 & Graph 1]

Both groups demonstrated reduction in burning sensation over follow-up visits; however, the Ayurvedic preparation showed greater improvement. The Squa Care Gel side demonstrated a total reduction of 4.2 points, whereas the Kenacort side demonstrated a reduction of 2.9 points.

Elasticity and Flexibility [Graph 2]

Improvement in elasticity and flexibility was observed earlier on the Ayurvedic side beginning from Visit 1, whereas Kenacort demonstrated gradual improvement after Visit 2.

By Visit 4:

- Ayurvedic preparation: 100% improvement
- Kenacort: 82% improvement

COMPARATIVE OUTCOME

The Ayurvedic preparation showed faster and more consistent improvement in both burning sensation and mucosal elasticity compared to Triamcinolone acetonide.

DISCUSSION

OSMF is a chronic fibrotic disorder that significantly affects oral functions and quality of life. Management mainly focuses on symptomatic relief, reduction in fibrosis and prevention of malignant transformation.

In the present study, both Squa Care Gel and Triamcinolone acetonide demonstrated improvement in clinical symptoms. However, Squa Care Gel showed earlier and greater reduction in burning sensation and improved mucosal elasticity compared to Kenacort. The split-mouth design minimized inter-individual variability by allowing each patient to serve as their own control, thereby improving the reliability of treatment comparison.

The mean VAS score reduced from 7.1 to 2.9 on the Ayurvedic side, whereas the Kenacort side showed reduction from 7.1 to 4.2. Similarly, improvement in elasticity and flexibility was more pronounced on the Ayurvedic side.

The findings of the present study are comparable with those of Singh et al., who reported that Ashwagandha acts as a potent rejuvenator with significant anti-inflammatory and antioxidant properties.⁴ These properties may contribute to reduction of chronic inflammation and fibrosis in OSMF patients.

Almatroodi et al. Demonstrated that Ocimum sanctum possesses anti-inflammatory, antioxidant and wound healing activities.⁵ Similar findings may explain the

enhanced mucosal healing and reduction in burning sensation observed in the present study.

The observations of the present study are also supported by Almeleebia et al., who concluded that Picrorhiza kurroa exhibits significant antioxidant properties.⁶ Oxidative stress plays an important role in the pathogenesis of OSMF, and antioxidant activity may help in reducing disease progression and tissue damage.

Ramírez-Alarcón et al. Reported that myristicin-containing herbal compounds possess anti-inflammatory and immunomodulatory effects.⁷ These pharmacological properties may further contribute to improvement in mucosal flexibility and reduction in symptoms observed with Squa Care Gel.

Triamcinolone acetonide has long been considered an effective treatment modality because of its anti-inflammatory action and ability to suppress fibroblastic proliferation. Hamishehkar et al. Demonstrated that topical Triamcinolone effectively reduces oral inflammation and discomfort.³ In the present study, Kenacort also demonstrated symptomatic improvement; however, the response was slower and less effective than the Ayurvedic preparation.

The superior clinical response observed with Squa Care Gel may be attributed to the synergistic action of multiple herbal ingredients producing antioxidant, anti-inflammatory and tissue regenerative effects simultaneously. Additionally, herbal preparations may produce fewer adverse effects compared to prolonged corticosteroid therapy.

The present study supports the role of Ayurvedic topical preparations as an effective alternative therapeutic modality in the management of OSMF.

However, larger multicentric studies with longer follow-up duration and histopathological evaluation are recommended for further validation.

LIMITATIONS OF THE STUDY

1. The sample size was relatively small (50 patients), which may limit the generalizability of the findings.
2. The study duration and follow-up period were short, preventing assessment of long-term outcomes and recurrence.
3. Flexibility and elasticity assessment was based on clinical retraction and photographic evaluation rather than objective quantitative measurements and may therefore be subject to observer variability.
4. Histopathological evaluation was not performed to correlate clinical improvement with changes in fibrosis.
5. The study was conducted at a single center, limiting external validity.
6. Patient compliance with treatment application and habit cessation could not be completely standardized.

CLINICAL SIGNIFICANCE

The findings of the present study suggest that Squa Care Gel may serve as an effective non-invasive topical therapeutic option for the management of Oral Submucous Fibrosis. The preparation demonstrated earlier improvement in burning sensation and buccal mucosal flexibility compared with Triamcinolone acetonide, indicating its potential role in reducing fibrosis-related symptoms and improving oral function. Furthermore, the herbal formulation may offer a potentially safer alternative for long-term use, minimizing the adverse effects commonly associated

with prolonged corticosteroid therapy. These results support the incorporation of Ayurvedic topical preparations as an adjunctive or alternative treatment modality in the comprehensive management of OSMF patients.

FUTURE RECOMMENDATION:

Larger multicentric randomized controlled trials with objective measurements of mouth opening, cheek flexibility, and histopathological assessment are recommended to further validate these findings.

CONCLUSION

Within the limitations of the present study, Squa Care Gel demonstrated superior clinical efficacy compared with Triamcinolone acetonide in reducing burning sensation and improving buccal mucosal flexibility and elasticity in patients with Oral Submucous Fibrosis. The Ayurvedic preparation showed earlier and more consistent clinical improvement, suggesting its potential role as an effective therapeutic modality for OSMF. Further randomized controlled studies with larger sample sizes and longer follow-up periods are required to validate these findings.

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Fig 1: Right buccal mucosa (Application of Squa Care gel)

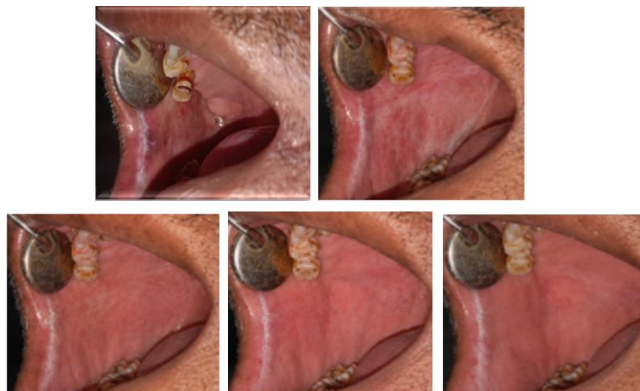


Fig.1: (a-e) - Visit 0,1,2,3 & 4

Fig 2: Left buccal mucosa (Application of Kenacort gel)

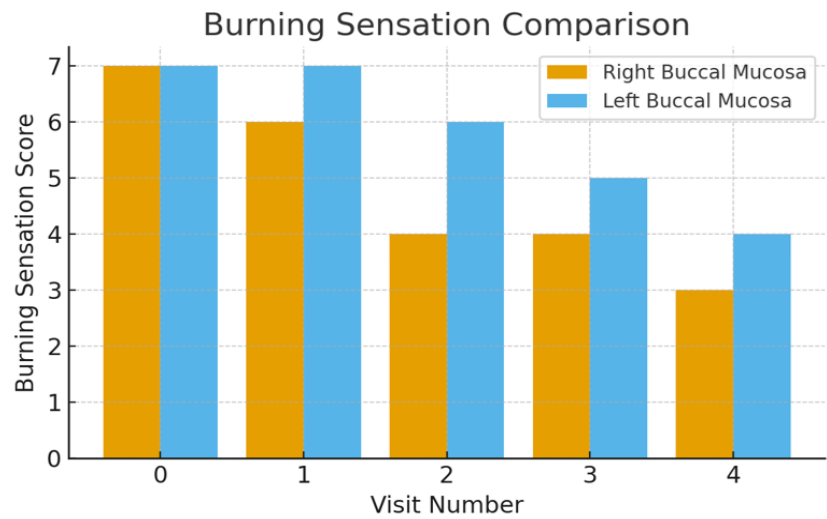


Fig.2 (a-e) - Visit 0,1,2,3 &4

Table 1: Mean VAS Scores

Visit	Ayurvedic Side	Kenacort Side
Visit 0	7.1	7.1
Visit 1	5.9	6.6
Visit 2	4.4	5.7
Visit 3	3.8	4.9
Visit 4	2.9	4.2

Graph: 1



Graph: 2

