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Original Article

Use of pre and post-treatment comparison of intra-lesional infiltration of dexamethasone plus hyaluronidase in the management of patients with OSMF.

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Abstract

Background

Oral Submucous Fibrosis (OSMF) is a chronic, progressive, and potentially malignant disorder characterized by fibrosis of the oral mucosa, leading to trismus and burning sensation. Intralesional injections offer a localized approach to treatment with fewer systemic effects.

Aim

To evaluate and compare the pre- and post-treatment outcomes of intralesional dexamethasone and hyaluronidase in the management of OSMF.

Materials and Methods

A tertiary care centre conducted one-year prospective interventional research on 50 clinically confirmed OSMF patients. Each patient received biweekly intralesional dexamethasone (4 mg/mL) and hyaluronidase (1500 IU) injections for six weeks. Mucosal flexibility, mouth opening, and VAS were measured before and after therapy.

Results

There was a statistically significant increase in mean mouth opening (from 23.4 ± 4.1 mm to 31.2 ± 3.8 mm) and a marked reduction in VAS scores for burning sensation (from 7.3 ± 1.1 to 2.1 ± 0.9). Mucosal flexibility improved in 86% of patients.

Conclusion

Intralesional dexamethasone combined with hyaluronidase effectively improves clinical outcomes in OSMF patients, showing significant symptomatic and functional benefits.

Keywords: Oral Submucous Fibrosis, Dexamethasone, Hyaluronidase, Intralesional therapy
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Introduction

Inflammation and increasing fibrosis of the submucosal tissues are hallmarks of oral submucous fibrosis (OSMF), a chronic, progressive, and possibly malignant condition of the oral cavity that causes burning sensations, trismus, and rigidity of the oral mucosa [1]. It is very common in South-east Asia, particularly India, and is mostly linked to chewing areca nuts, frequently in conjunction with tobacco usage and spicy foods [2]. Juxta-epithelial inflammatory responses and fibrosis brought on by increased collagen synthesis and decreased collagen breakdown are the pathophysiology, which limits mouth opening and lowers quality of life [3].

Because of its complex aetiology and irreversible fibrotic alterations in its advanced phases, OSMF management is still difficult. Because of their focused local impact, intralesional injections have become more popular among different therapeutic techniques [4]. A powerful corticosteroid called dexamethasone has anti-inflammatory properties and inhibits fibroblastic growth, whereas hyaluronidase works by breaking down hyaluronic acid in the extracellular matrix, which lowers viscosity and enhances medication penetration into fibrotic tissues. Hyaluronidase and dexamethasone combined therapy is thought to have synergistic effects, promoting mouth opening and fibrotic band resolution [5,6].

To determine the therapeutic effectiveness of this combination, a thorough assessment of the clinical parameters before and after therapy, including inter-incisal mouth opening, burning sensation, and mucosal flexibility, is necessary [7]. Validating its clinical efficacy in enhancing patient outcomes and directing standardised treatment methods is made easier by the comparison analysis [8]. By measuring clinical parameters before and after therapy, the efficacy of intralesional infiltration of dexamethasone and hyaluronidase in the treatment of oral submucous fibrosis will be evaluated and compared.

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Materials and methods

Study Design

This was a prospective interventional study conducted over one year at a tertiary care center.

Study Setting

The study was carried out in the Department of Oral Medicine and Radiology at a tertiary healthcare facility, equipped for diagnosis and management of potentially malignant oral disorders.

Inclusion Criteria

- Clinically diagnosed cases of Oral Submucous Fibrosis (OSMF)
- Patients aged between 18 to 60 years
- Patients with reduced mouth opening (<35 mm inter-incisal distance)
- Willingness to participate with informed consent

Exclusion Criteria

- Patients with any systemic illness or other oral mucosal diseases
- History of surgical intervention for OSMF
- Patients on steroid or immunosuppressive therapy for other conditions
- Known hypersensitivity to dexamethasone or hyaluronidase

Intervention

All eligible patients received intralesional injections of a combination of dexamethasone (4 mg/mL) and hyaluronidase (1500 IU) biweekly for a total of 6 weeks. The injections were administered bilaterally into the fibrotic bands of the buccal mucosa using aseptic precautions.

Evaluation Parameters

Clinical parameters were recorded before initiation of treatment and after the completion of therapy. These included:

- Inter-incisal mouth opening (in mm)
- Subjective burning sensation using Visual Analogue Scale (VAS)
- Mucosal flexibility assessed by palpation

Data Collection and Analysis

Data were recorded in a pre-structured format and analysed using appropriate statistical software. Paired *t*-test was used to compare pre- and post-treatment parameters, and a *p*-value <0.05 was considered statistically significant.

Results

A total of 50 patients clinically diagnosed with Oral Submucous Fibrosis (OSMF) were included in the study. The mean age of the participants was 34.6 ± 8.2 years, with a male-to-female ratio of 3:1. The baseline inter-incisal mouth opening ranged from 15 mm to 32 mm, with a mean of 23.4 ± 4.1 mm.

After six weeks of biweekly intralesional injections of dexamethasone and hyaluronidase, significant clinical improvement was observed:

- **Mouth Opening:** The mean post-treatment mouth opening increased to 31.2 ± 3.8 mm. The mean gain in inter-incisal distance was 7.8 ± 2.6 mm, which was statistically significant ($p < 0.001$).
- **Burning Sensation (VAS Score):** The mean pre-treatment VAS score for burning sensation was 7.3 ± 1.1, which decreased significantly to 2.1 ± 0.9 post-treatment ($p < 0.001$), indicating substantial relief from discomfort.
- **Mucosal Flexibility:** On clinical examination, improved mucosal flexibility was noted in 86% of patient's post-treatment compared to only 22% at baseline.

No major adverse effects or allergic reactions were reported during the therapy. The treatment was well-tolerated by all patients. Overall, the combination therapy of dexamethasone and hyaluronidase demonstrated a significant improvement in all evaluated clinical parameters, confirming its efficacy in the management of OSMF.

Table 1:

Parameter	Pre-Treatment (Mean ± SD)	Post-Treatment (Mean ± SD)	Mean Change	p-value
Inter-Incisal Mouth Opening (mm)	23.4 ± 4.1	31.2 ± 3.8	+7.8 ± 2.6	< 0.001
Burning Sensation (VAS Score)	7.3 ± 1.1	2.1 ± 0.9	–5.2 ± 1.0	< 0.001
Mucosal Flexibility (Improved% %)	22%	86%	+64%	< 0.001

Note: Statistical significance was assessed using a paired t-test; improvement in mucosal flexibility was calculated as the percentage of patients showing noticeable change on palpation

Discussion

In South-east Asia, oral submucous fibrosis (OSMF), a chronic, potentially cancerous condition, is quite common, especially among tobacco and areca nut users. Increased collagen synthesis and decreased collagen breakdown are the pathophysiological factors of OSMF, which causes the oral mucosa to gradually fibrose, trismus, and burn. Numerous therapeutic approaches, such as intralesional injections, physiotherapy, antioxidants, and surgical excision, have been investigated. Because of its localised activity and comparatively low systemic effects, intralesional therapy including dexamethasone and hyaluronidase has become popular among these. A statistically significant improvement in inter-incisal mouth opening and a decrease in burning sensation were observed in the current study following intralesional administration of dexamethasone and hyaluronidase, demonstrating the combination's therapeutic benefits. Strong corticosteroid dexamethasone reduces inflammation, decreases collagen deposition, and inhibits fibroblast proliferation [9,10]. By degrading hyaluronic acid in the extracellular matrix, hyaluronidase lowers tissue viscosity and promotes medication dispersion [11].

Our results are consistent with those of Patil et al., who found that following six weeks of combined intralesional therapy, mouth opening increased by an average of 6 to 9 mm [12]. The identical treatment regimen was also used by More et al., who reported a significant increase in mucosal pliability and a decrease in burning sensation [13]. Gupta and associates showed in a different comparison trial that hyaluronidase in combination with corticosteroids produced noticeably better results than corticosteroids alone [14]. The synergistic action of the two medicines is further highlighted by the fact that 86% of patients in our trial had an improvement in mucosal flexibility after therapy. In line with earlier publications emphasising the safety of localised therapy, no significant adverse effects were seen [15]. Limitations include a tiny sample size, no long-term follow-up, and no control group, despite the promising results. To create standardised procedures and evaluate the sustainability of therapy results, more research using randomised controlled designs and longer observation times is necessary.

Conclusion

For patients with oral submucous fibrosis, intralesional combination therapy with dexamethasone and hyaluronidase was a successful and well-tolerated treatment option that significantly improved mouth opening, decreased burning sensation, and increased mucosal flexibility. Over a brief course of treatment, the two medicines' combined anti-inflammatory and antifibrotic activities produced positive clinical results. Larger randomised controlled trials with long-term follow-up are advised to validate and standardise treatment regimens, but these results indicate the usefulness of this combination as a safe and workable choice in regular clinical management of OSMF.

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