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Therapeutic outcomes of intralesional dexamethasone and hyaluronidase in OSMF: A clinical pre-post intervention study.

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Abstract

Background
The increasing fibrosis of the submucosal tissues is the hallmark of oral submucous fibrosis (OSMF), which is considered a progressive and chronic disorder of the oral mucosa that causes discomfort, tissue stiffness, and limited mouth opening. Objectives- This study was carried out to assess the impact of intra-lesional corticosteroids in the treatment of patients with OSMF, taking into consideration the previous research as well as the therapeutic benefits of corticosteroids.

Materials and methods
The study was an observational, multicentric study in nature. The study was done for nine months. In all, 105 patients were enrolled. Participants had to be willing to provide their consent, be between the ages of 18 and 50, and have a positive history of habits to be eligible.

Results
Among the 105 participants, the majority were male (67.6%) and aged between 28–37 years (48.6%). Most had only completed primary education (45.7%) and were engaged in unskilled occupations (56.2%), with nearly half residing in rural areas (49.5%). With a p-value of less than 0.001, the mean mouth openness rose from 26.12 ± 3.10 mm to 30.17 ± 4.20 mm. In a similar vein, the mean Visual Analogue Scale (VAS) score dropped significantly after treatment, from 7.01 ± 1.50 to 2.98 ± 1.98 with a p-value < 0.001.

Conclusion
Before and following treatment, the burning sensation VAS scores significantly decreased, indicating a considerable improvement in opening of the mouth, according to the current study's findings.

Recommendation
Regular intralesional administration of dexamethasone and hyaluronidase is recommended as an effective, minimally invasive treatment for improving mouth opening and reducing symptoms in patients with oral submucous fibrosis.

Keywords- *Visual Analogue Scale, Corticosteroids, Dexamethasone, Oral Submucous Fibrosis (OSMF), Fibrosis*
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Introduction

The increasing fibrosis of the submucosal tissues is the hallmark of oral submucous fibrosis (OSMF), which is considered a progressive and chronic disorder of the oral mucosa that causes discomfort, tissue stiffness, and limited mouth opening. It has been observed in the kinds of literature that because of the chewing of areca nut, it might contribute to the cause of the disease. India is among the most affected countries in Southeast Asia [1]. Early diagnosis and treatment are essential for OSMF since it is regarded as a precancerous lesion with a high chance of malignant development [2].

Relieving symptoms and slowing the development of the illness are frequently the main therapeutic approaches for OSMF [3]. Intra-lesional injections have been more popular in recent years as a way to treat the fibrotic alterations linked to OSMF. Dexamethasone, a strong anti-inflammatory steroid, is one of several pharmaceutical substances that have demonstrated promise in lowering inflammation and enhancing tissue mobility. It might lead to breakdown of fibrotic tissues, and it also results in enhancement of breakdown when an enzyme named hyaluronidase gets mixed in the extracellular matrix to degrade hyaluronic acid further [4, 5].

As a contributor to OSMF pathophysiology, many factors are involved, which include genetic variables, immunological variables, and environmental variables. The development of fibrous tissue in the oral submucosa as a result of excessive collagen deposition and fibroblast activation is the primary pathogenic characteristic of OSMF. Oral dysfunction and limited mouth opening result from the fibrosis, scarring, and atrophy of the mucosal layers caused by this. One of the main etiological factors that contributes to the pathophysiology of OSMF is chewing betel nuts, which contain alkaloids such as arecoline and increasing collagen formation, and immune response change [6]. Genetic susceptibility, tobacco use, and nutritional deficiencies, especially in iron, folate, and B12 vitamins, are additional contributing factors [7].

Due to its poorly defined etiopathogenesis and management ambiguity, OSMF has proven to be a challenging illness. Even though many causes have been investigated, no etiology has been determined, and as a result, no successful treatment has been discovered. As a result, managing OSMF is quite difficult. This study was carried out to assess the impact of intra-lesional corticosteroids in the treatment of patients with OSMF, taking into consideration the previous research as well as the therapeutic benefits of corticosteroids.

Methodology

Study design

The study was a prospective interventional, multicentric study in nature. The study was done for nine months.

Study setting

The research was conducted at the Department of Otorhinolaryngology, KMC Medical College and Hospital, Maharajganj, Uttar Pradesh. The hospital served as a suitable site due to its specialized clinical services, patient inflow, and experienced ENT clinicians familiar with the treatment regimen.

Study population

In all, 105 patients were enrolled. Participants had to be willing to provide their consent, be between the ages of 18 and 50, and have a positive history of habits to be eligible. Patients with severe comorbid disorders that could impact therapy or results, those having a history of systemic diseases, endocrine, or metabolic, and those who were pregnant or nursing were excluded.

Sample size

The sample size was determined using G*Power Software Version 3.0. A power analysis was conducted using a statistical power of 90% ($1-\beta = 0.90$) and a significance level of 5% ($\alpha = 0.05$), based on effect sizes derived from prior similar studies. The analysis indicated a minimum required sample size of 98; accounting for potential dropouts, 105 participants were recruited.

Data collection

Data were collected at four time points: baseline, 1 month, 3 months, and 6 months. At each follow-up, clinical progress was monitored by evaluating lesion size and texture, as documented by the attending clinician. Patients reported relief of symptoms, such as pain and discomfort, using a structured questionnaire. Additionally, changes in oral

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health-related quality of life (OHRQoL) were assessed using a validated OHRQoL instrument, administered at baseline and after six months.

Study procedure

Injections of intralesional, including both dexamethasone and hyaluronidase, were administered to participants. The prescribed dosages for the treatment were 150 IU/ml of hyaluronidase and 4 mg/ml of dexamethasone. At biweekly intervals, injections were given directly into the fibrotic lesions. Six injections were given to each patient during the study.

Bias

To minimize potential biases, standardized protocols were used across all participating centers. Clinicians received uniform training to ensure consistent injection techniques and outcome assessments. Patient-reported outcomes were collected through pre-validated questionnaires to reduce interviewer bias. Blinding of the outcome assessor was employed where feasible.

Statistical analysis

G Power Software Version 3.0 used a previous kind of power analysis to determine the sample size. By input parameters such as a power of 0.90 and a p-value less than 0.05, the minimum sample size was determined.

Results

Out of 132 individuals initially screened for eligibility, 120 met the inclusion criteria. Of these, 105 participants provided informed consent and were enrolled in the study. The remaining 15 declined to participate or were excluded due to comorbidities or other exclusion criteria. During the follow-up period, 3 participants were lost to follow-up, and 2 discontinued treatment due to personal reasons. Therefore, 100 participants completed all six treatment sessions and were included in the final analysis.

Table 1. Baseline characteristics of participants

Variable	Category	N	%
Gender	Female	34	32.4%
	Male	71	67.6%
Age Group	18–27 Years	15	14.3%
	28–37 Years	51	48.6%
	38–47 Years	23	21.9%
	>47 Years	16	15.2%
Education	Read and write	22	21.0%
	Primary	48	45.7%
	Higher Secondary	21	20.0%
	Graduate	14	13.3%
Occupation	Unemployed	16	15.2%
	Skilled	30	28.6%
	Unskilled	59	56.2%
Residence	Rural	52	49.5%
	Urban	26	24.8%
	Peri-Urban	27	25.7%

34 (32.4%) of the 105 participants were female, and 71 (67.6%) were male. Most participants were between the ages of 28 and 37 (48.6%), followed by those between the ages of 38 and 47 (21.9%), >47 years (16.2%), and 18 and 27 years (15.3%). The majority of participants (48; 45.7%) had only completed primary school, followed by those who could read and write (21.0%), those who had completed higher secondary school (21.0%), and those who were graduates (13.3%). The baseline characteristics of the enrolled participants are shown in Table 1.

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Table 2. Mean Improvement in Characteristics

Variables	Pre-Treatment	Post-Treatment	P-value
Mouth opening	26.12±3.1	30.17±4.2	<0.001
VAS	7.01±1.5	2.98±1.98	<0.001

With a p-value of less than 0.001, the mean mouth openness rose from 26.12 ± 3.10 mm to 30.17 ± 4.20 mm. In a similar vein, the mean Visual Analogue Scale (VAS) score dropped significantly after treatment, from 7.01 ± 1.50 to 2.98 ± 1.98 with a p-value < 0.001. The mean improvement in attributes is shown in Table 2.

Discussion

The current study revealed that the mean age of patients diagnosed with OSMF was 29 years, with 59% falling between the ages of 20 and 37, suggesting that the condition predominantly affects young adults in their most productive years. This age group may be more vulnerable due to the early initiation of harmful oral habits. This finding aligns with earlier studies by Arakeri et al., who reported a mean age of 29.12 years, and Ranganathan et al., who observed that most patients were between 21 and 40 years of age [8]. The high prevalence in this demographic may be attributed to lifestyle changes, addiction patterns, stress, and peer influence.

There was a clear male predominance in the study population (67.6%), indicating that men are more frequently affected by OSMF than women. This trend may reflect social and cultural factors such as increased accessibility to areca nut and tobacco-related products among men, as well as changing lifestyle behaviors in younger male populations. These findings are consistent with previous research conducted by Ganapathy KS et al. and Rupak S et al., both of whom reported a similar male preponderance [9,10,11].

About treatment efficacy, the mean inter-incisal mouth opening improved significantly from 26.12 mm to 30.17 mm, and the VAS score for burning sensation reduced markedly from 7.01 to 2.98, suggesting notable clinical improvement following six biweekly intralesional injections of dexamethasone and hyaluronidase combined with 2% lignocaine. These results demonstrate the effectiveness of combining corticosteroids with enzymatic agents in reducing fibrosis and symptomatic discomfort.

This treatment approach is supported by an overview of 21 previous studies on pharmacologic therapies for OSMF, where 16 trials used intralesional corticosteroids—primarily dexamethasone and triamcinolone diacetate—while methylprednisolone, betamethasone, and hydrocortisone were less commonly employed [12]. In contrast to our findings, a study by Cox and Zoellner reported that hyaluronidase and steroid injections did not significantly enhance mouth opening [13]. However, our results align with those of Galchar et al., who found that intralesional therapy led to substantial symptom relief, including a reduction in burning sensation based on VAS scores [14]. These discrepancies in outcomes may be attributed to variations in dosage, duration of therapy, and patient compliance across studies.

Generalizability

The findings may be generalizable to similar populations in resource-limited, rural, or semi-urban Indian settings with high prevalence of OSMF and comparable socio-demographic profiles.

Conclusion

Before and following treatment, the burning sensation VAS scores significantly decreased, indicating a considerable improvement in mouth opening, according to the current study's findings. Nevertheless, more research is necessary to ascertain the effectiveness because there is insufficient data and studies in this area.

Limitations

There are a couple of significant drawbacks to this study, though. There is a greater chance of a mistake because the study was multicentric with a small sample size.

Recommendations

As this was a short-term study, further research is needed with a longitudinal study design and a larger sample to achieve more definitive results.

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List of abbreviations

VAS- Visual Analogue Scale
OSMF- Oral Submucous Fibrosis
OHRQoL- Oral health-related quality of life

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Conflict of interest

The authors declare no conflicts of interest related to this study.

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This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors; the funders had no role in study design, data collection, or interpretation.

Data availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Author biography

Dr. Daya Shankar is an Assistant Professor in the Department of Otorhinolaryngology at KMC Medical College and Hospital, Maharajganj, Uttar Pradesh, with clinical interests in oral submucous fibrosis and minimally invasive ENT interventions. Dr. Sanjeev Kumar is a Professor at Autonomous State Medical College, Gonda, Uttar Pradesh, specializing in otologic surgeries and research in ENT therapeutics. Dr. Hari Krishn Dwivedi, the corresponding author, is an Assistant Professor in the Department of ENT at Autonomous State Medical College, Gonda, with a focus on ENT disorders and community-level clinical management.

Author contributions

All authors contributed to the conception, design, data collection, analysis, and drafting of the manuscript and approved the final version for publication.

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