

## Original Research

### To evaluate the effectiveness of before and post comparison of intralesional infiltration of dexamethasone + hyaluronidase in the treatment of individuals with oral submucous fibrosis

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#### ABSTRACT:

**Aim:** To evaluate the effectiveness of before and post comparison of intralesional infiltration of dexamethasone + hyaluronidase in the treatment of individuals with oral submucous fibrosis (OSMF). **Materials and methods:** This research was done among patients who were attended to at the Department of Otorhinolaryngology. The research protocol was evaluated by the Ethical Committee of the Hospital and was approved for ethical clearance. This research comprised subjects aged 18-50 years who provided informed permission and patients with a favourable history of habits. **Results:** The average age of the participants in the research was  $33.25 \pm 2.96$  years. A study demonstrates a clear prevalence of males, accounting for 70% of the population. The measurements for mouth opening before and after the procedure were  $24.45 \pm 1.25$  and  $28.11 \pm 2.19$ , respectively. The corresponding values for the Visual Analogue Scale (VAS) were  $6.13 \pm 0.88$  and  $3.45 \pm 0.99$ . The statistical analysis showed a significant difference with a p-value of less than 0.05. **Conclusion :** The current investigation determined that there was a notable improvement in mouth opening, accompanied by a substantial decrease in the burning sensation VAS ratings before to and during treatment. Insufficient knowledge and study in this domain need additional investigation to ascertain the effectiveness.

**Keywords:** Corticosteroids, Mouth Opening, OSMF, VAS

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#### INTRODUCTION

Oral Submucous Fibrosis (OSMF) is a chronic disorder that affects the oral mucosa. It is characterised by the gradual deposition of thick collagen tissue inside the submucosa, sometimes spreading to the throat and oesophagus. The exact cause of OSMF is unclear. The condition is distinguished by the whitening and rigidity of the tissue lining the mouth, difficulty in opening the mouth, a sense of burning, limited movement of the tongue, and loss of the ability to taste.<sup>1</sup> Majority of these cases are seen in Indian population<sup>2</sup> and its prevalence varies from 0.20-0.5%.<sup>3</sup>

The WHO definition for an oral precancerous condition was stated as: 'A generalized pathological state of the oral mucosa associated with a significantly increased risk of cancer.'<sup>4</sup> Later on in 2007 Warnakulasuriya et al.<sup>5</sup> termed OSMF as a potentially

malignant disorder. The condition is found in 4/1,000 adults in rural India and as many as 5 million young Indians are suffering from this precancerous condition. OSMF is predominantly seen in people in south Asian countries<sup>6</sup>, such as India, Bangladesh, Bhutan, Pakistan and Sri Lanka, or in South Asian immigrants to other parts of the world.<sup>7,8</sup>

OSMF has been a dilemmatic condition both in terms of its ill configured etiopathogenesis and confusion in management. Although a number of factors have been worked upon, no single pathophysiology has been agreed on and, hence, no effective treatment has come to light. Thus, the management of OSMF poses a great challenge.

Keeping in mind the studies that have been conducted so far and the therapeutic effects of corticosteroids, we conducted a study with the aim of evaluating the

effect of intra-lesional corticosteroids in management of patients with OSMF.

**MATERIALS AND METHODS**

This research was done among patients who were attended to at the Department of Otorhinolaryngology. The research protocol was evaluated by the Ethical Committee of the Hospital and was approved for ethical clearance. This research comprised subjects aged 18-50 years who provided informed permission and patients with a favourable history of habits. Those who was not give informed consent, History of allergy to the product and Patients with history of systemic diseases, endocrinal or metabolite in nature were excluded from the study. Before the commencement of the study, the examiner was standardized and calibrated in the Department of ENT by the senior faculty member to ensure uniform interpretations and consistent examination. Intra-examiner reliability was calculated using Kappa statistics. The kappa value was 0.87, which denoted substantial level of agreement between the examinations. 100 patients were included in this study.

**METHODOLOGY**

Patient demographics and general condition were recorded in the preformed questionnaire. Patients were given intralesional infiltration of 2 ml

dexamethasone (4 mg/ml) + hyaluronidase 1500 IU dissolved in 0.5 ml of 2% lignocaine twice a week for 8 weeks. The responses were assessed clinically on a tri-monthly basis. Every time the patient was recalled, the patient’s mouth opening and burning sensation on Visual Analogue Scale (VAS) was recorded and compared.

**STATISTICAL ANALYSIS**

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2010) and then exported to data editor page of SPSS version 22.0 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics included computation of percentages, means and standard deviations were calculated. The statistical tests applied for the analysis was student t-test. For all tests, confidence interval and p-value were set at 95% and  $\leq 0.05$  respectively.

**RESULTS**

The average age of the participants in the research was 33.25±2.96 years. A study demonstrates a clear prevalence of males, accounting for 70% of the population. The measurements for mouth opening before and after the procedure were 24.45±1.25 and 28.11±2.19, respectively. The corresponding values for the Visual Analogue Scale (VAS) were 6.13±0.88 and 3.45±0.99. The statistical analysis showed a significant difference with a p-value of less than 0.05.

**Table 1: Demographic profile of the study population**

Variables	Number	Percentage
<b>Gender</b>		
Male	70	70
Female	30	30
<b>Age</b>		
18-25 Years	14	14
25-35Years	54	54
35-45 Years	22	22
>45 Years	10	10
Mean±SD	33.25±2.96	
<b>Education</b>		
Read and write	21	21
Primary	50	50
Higher Secondary	20	20
Graduate	9	9
<b>Occupation</b>		
Un-employed	17	17
Skilled	31	31
Un-skilled	52	52
<b>Residence</b>		
Rural	50	50
Urban	27	27
Peri-Urban	23	23

**Table 2: Mean Improvement in Mouth opening**

Variable	Mouth opening	
	Pre -treatment	Post -treatment
Mean±SD	24.45±1.25	28.11±2.19

p-value	0.001
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**Table 3: Mean Improvement in VAS**

Variable	VAS	
	Pre -treatment	Post -treatment
Mean±SD	6.13±0.88	3.45±0.99
p-value	0.001	

**DISCUSSION**

In the present study 54% of the patients were in the age group of 25–35 years, mean age was 33.25±2.96 years. Our results are in accordance with previous studies by Arakeri et al.<sup>9</sup> with reported mean age of 29.12 years and 21–40 years by Ranganathan et al.<sup>10</sup> The prevalence of OSMF in this group can be related to changing lifestyles of individuals, peer influence, stress, addiction, etc. The present study shows a definite male predominance (70%). It is in accordance with the previous studies conducted by Rupak et al.<sup>11</sup> and Ganapathy et al.<sup>12</sup> Higher males skew is predominantly due to easy product accessibility and changing lifestyles of the youngsters.<sup>13</sup> According to the review of medical interventions for OSF by Kerr et al.<sup>14</sup> in 2011, a total of 21 studies which have used immunomodulatory agents as a treatment of OSF were identified. Out of those 16 studies had principally used intralesional injections of corticosteroids. Dexamethasone and Triamcinolone diacetate had been the agent of choice in majority of studies, mean while methylprednisolone, betamethasone and hydrocortisone were less commonly used. In the present study, dexamethasone (2 ml Decadron 4 mg/ml) injection and hyaluronidase 1500 IU with 2% lignocaine was administered. In the present study, dexamethasone (2 ml Decadron 4 mg/ml) injection and hyaluronidase 1500 IU with 2% lignocaine was administered, and there was significant improvement in mouth opening, which showed a significant reduction in the burning sensation VAS scores before and after treatment. The reduction in VAS score for burning sensation in mouth was similar to the study conducted by Galchar et al.<sup>15</sup>, contrary to our findings Cox and Zoellner, study revealed that injection of steroids and hyaluronidase had not significantly improved mouth opening.<sup>16</sup>

**CONCLUSION**

The current investigation determined that there was a notable improvement in mouth opening, accompanied by a substantial decrease in the burning sensation VAS ratings before to and during treatment. Insufficient knowledge and study in this domain need additional investigation to ascertain the effectiveness. Given the limited duration of this study, it is necessary to conduct more research using a longitudinal study design and a bigger sample size in order to get more conclusive findings.

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