

## Original research article

**Use of Pre and post comparison of intra-lesional intralesional infiltration of dexamethasone plus hyaluronidase in management of patients with OSMF.****Harsh Vardhan<sup>1</sup>, Baban Kumar<sup>2</sup>, Tulika Singh<sup>3</sup>, Tribhuwan Kumar<sup>4</sup>**<sup>1</sup>Senior Resident, Department of ENT, Patna Medical College and Hospital Patna, Bihar, India.<sup>2</sup>Senior Resident, Department of ENT, Patna Medical College and Hospital Patna, Bihar, India.<sup>3</sup>Junior Resident, Department of Pathology, IGIMS, Patna, Bihar, India<sup>4</sup>Associate Professor, Department of ENT, Patna Medical College and Hospital Patna, Bihar, India.

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**Abstract**

**Aim:** The effect of intra-lesional intralesional infiltration of 2 ml dexamethasone plus hyaluronidase 1500 IU twice a week in management of patients with OSMF **Materials and Methods:** the present clinic-observational study was conducted among 100 diagnosed patients of OSMF who attended the Department of ENT, Patna Medical College and Hospital Patna, Bihar, India. from November 2018 to December 2019. collected data were subjected to statistical analysis using SPSS version 20 software. **Results:** mean age of the study population was 30.02 years. Study shows a definite male predominance (71%). Pre and post mean mouth opening (24.18±2.61, 28.01±3.23) and VAS (6.08±1.28, 3.11±2.11) p<0.05 respectively. **Conclusion:** The present study concluded that there was significant improvement in mouth opening, which showed a significant reduction in the burning sensation VAS scores before and after treatment.

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

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**Introduction**

Oral Submucous Fibrosis (OSMF) is defined as an insidious chronic condition of unknown etiology affecting the oral mucosa characterized by dense collagen tissue deposition within submucosa, occasionally extending to the pharynx and esophagus. The disease is characterized by blanching and stiffness of oral mucosa, trismus, burning sensation, loss of mobility of tongue and loss of gustatory sensation.<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****Study Design, Population, Setting**

The present clinic-observational study was conducted among patients attended Department of ENT, Patna

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Medical College and Hospital Patna, Bihar, India, from November 2018 to December 2019.

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance.

#### Inclusion criteria

- 1) Subjects within the age group of 18-50 years
- 2) Those who will give informed consent.
- 3) Patients who will give positive habit history

#### Exclusion criteria

- 1) Those who will not give informed consent
- 2) History of allergy to the product
- 3) Patients with history of systemic diseases, endocrinal or metabolite in nature

#### Training and Calibration

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

#### Sample selection

The sample size was calculated using a prior type of power analysis by G\* Power Software Version 3.0.1.0

(Franz Faul, Universitat Kiel, Germany). The minimum sample size was calculated, following these input conditions: power of 0.90 and  $P \leq 0.05$  and sample size arrived were 54 participants.

#### 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.

#### Follow-up

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 20 (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

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

Variables	N (%)
<b>Gender</b>	
Male	71 (71%)
Female	29 (29%)
<b>Age</b>	
18-27 Years	15 (15%)
28-37 Years	51 (51%)
38-47 Years	23 (23%)
>47 Years	11 (11%)
Mean±SD	
<b>Education</b>	
Read and write	22 (22%)
Primary	48 (48%)
Higher Secondary	21 (21%)
Graduate	9 (9%)
<b>Occupation</b>	
Un-employed	16 (16%)
Skilled	30 (30%)
Un-skilled	54 (54%)
<b>Residence</b>	
Rural	52 (52%)
Urban	26 (26%)
Peri-Urban	22 (22%)

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

Variable	Mouth opening	
	Pre -treatment	Post -treatment
Mean±SD	24.18±2.61	28.01±3.23
p-value	0.001 (Sig.)	

Test applied: paired sample t-test

**Table 3: Mean Improvement in VAS**

Variable	VAS	
	Pre -treatment	Post -treatment
Mean±SD	6.08±1.28	3.11±2.11
p-value	0.001(Sig.)	

Test applied: paired sample t-test

### Discussion

In the present study 51% of the patients were in the age group of 20–37 years, mean age was 30.02 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 (71%). 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 present study concluded that there was significant improvement in mouth opening, which showed a significant reduction in the burning sensation VAS scores before and after treatment. However, there is not enough information and research in this field, and therefore, further research is required to determine the efficacy. As this was a short-term study, further research is needed with longitudinal study design and larger sample to achieve more definite results.

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