International Journal of Medical and Health Research
ISSN: 2454-9142
Received: 18-09-2020; Accepted: 04-10-2020; Published: 18-10-2020
www.medicalsciencejournal.com
Volume 6; Issue 10; 2020; Page No. 38-40

Use of intra-lesional infiltration of 2 ml dexamethasone plus hyaluronidase 1500 IU twice a week in the management of patients with OSMF: A comparative study

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Abstract.
Aim: The effect of intra-lesional infiltration of 2 ml dexamethasone plus hyaluronidase 1500 IU twice a week in the management of patients with Oral Submucus Fibrosis (OSMF)
Materials and Methods: The present clinic-observational study was conducted among 100 diagnosed patients of OSMF who attended the OPD of ENT Department, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India from January 2018 to January 2019. The 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 and VAS were found (24.18±2.61, 28.01±3.23) and (6.08±1.28, 3.11±2.11) respectively ($p<0.05$).
Conclusion: The present study concluded that there was significant improvement in mouth opening and also significant reduction in the burning sensation VAS scores before and after treatment.

Keywords: corticosteroids, mouth opening, OSMF, VAS

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 [1]. Majority of these cases are seen in Indian population [2] and its prevalence varies from 0.20-0.5% [3].

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 [4]. Later on in 2007 Warnakulasuriya *et al*. [5] 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 [6], such as India, Bangladesh, Bhutan, Pakistan and Sri Lanka, or in South Asian immigrants to other parts of the world [7, 8].

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 the management of patients with OSMF.

Materials and Methods

Study Design, Population, Setting

The present clinic-observational study was conducted among patients attended the OPD of department of ENT, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India from January 2018 to January 2019.

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

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 metabolic 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 $P \leq 0.05$ the sample size arrived was 54 participants.

Methodology

Patient demographics and general condition were recorded in the preformed questionnaire. Patients were given intra-lesional 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 ≤ 0.05 respectively

Results

Table 1: Demographic profile of the study population

Variables	N (%)
Gender	
Male	71 (71%)
Female	29 (29%)
Age	
18-27 Years	15 (15%)
28-37 Years	51 (51%)
38-47 Years	23 (23%)
>47 Years	11 (11%)
Mean±SD	
Education	
Illiterate/ Read and write	22 (22%)
Primary	48 (48%)
Higher Secondary	21 (21%)
Graduate	9 (9%)
Occupation	
Un-employed	16 (16%)
Skilled	30 (30%)
Un-skilled	54 (54%)
Residence	
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*. [9] with reported mean age of 29.12 years and 21–40 years by Ranganathan *et al*. [10] 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*. [11] and Ganapathy *et al*. [12] higher males skew is predominantly due to easy product accessibility and changing lifestyles of the youngsters [13].

According to the review of medical interventions for OSMF by Kerr *et al*. [14] in 2011, a total of 21 studies which have used immunomodulatory agents as a treatment of OSMF 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, meanwhile 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*. [15], contrary to our findings Cox and Zoellner, study revealed that injection of steroids and hyaluronidase had not significantly improved mouth opening [16].

Conclusion

The present study concluded that there was significant improvement in mouth opening, and also 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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