

An Observation Research to Evaluate the Effect of Intra-Lesional Corticosteroids in Management of Patients with OSMF

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Conflict of interest: Nil

Abstract

Aim: The effect of intra-lesional corticosteroids 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 OPD of Department of ENT, Nalanda Medical College and Hospital, Patna, Bihar, India. The collected data were subjected to statistical analysis using SPSS version 20 software.

Results: Mean age of the study population was 29.12 years. Study shows a definite male predominance (74%). Statistical analysis revealed that there was a significant improvement in the mouth opening and VAS.

Conclusion: The present study concluded that 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 and VAS.

Keywords: Dexamethasone, Mouth Opening, OSMF, VAS

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Introduction:

Oral submucous fibrosis (OSMF) has been mentioned in the Indian medical literature, since the time of ‘Sushruta’ “who named it as ‘Vidari’. The disease was first reported in 1952 by Schwartz to which he ascribed the descriptive term ‘Atrophica idiopathica (tropica) mucosa oris’ and its precancerous nature was reported by ‘Paymaster’ in 1956.

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[1]. Later on in 2007 Warnakulasuriya et al.[2] 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[3], such as

India, Bangladesh, Bhutan, Pakistan and Sri Lanka, or in South Asian immigrants to other parts of the world[4,5]

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[6].

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 100 diagnosed patients of OSMF who attended the OPD of Department of ENT, Nalanda Medical College and Hospital, Patna, Bihar, India for 1 year.

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 0.88, 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 94 participants. The final sample achieved was 100.

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 were Pearson's chi-square test (χ^2) and 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 | 74 (74%) |
| Female | 26 (26%) |
| Age | |
| 18-27 Years | 16 (16%) |
| 28-37 Years | 50 (50%) |
| 38-47 Years | 24 (24%) |
| >47 Years | 10 (10%) |
| Mean±SD | |
| Education | |
| Illiterate/ Read and write | 24 (24%) |
| Primary | 46 (46%) |
| Higher Secondary | 23 (23%) |
| Graduate | 7 (&%) |
| Occupation | |
| Un-employed | 14 (14%) |
| Skilled | 28 (28%) |
| Un-skilled | 58 (58%) |
| Residence | |
| Rural | 54 (54%) |
| Urban | 28 (28%) |
| Peri-Urban | 18 (18%) |

Mean age of the study population was 29.12 years. Study shows a definite male predominance (74%).

Table 2: Mean Improvement in Mouth opening

| Variable | Mouth opening | |
|----------|----------------|-----------------|
| | Pre -treatment | Post -treatment |
| Mean±SD | 25.38±2.98 | 29.31±3.26 |
| p-value | 0.001 (Sig.) | |

Test applied: paired sample t-test

Mean value of mouth opening before treatment was 25.38 mm and after treatment it was increased to 29.31. The pre and post difference was found statistically significant (p=0.001)

Table 3: Mean Improvement in VAS

| Variable | VAS | |
|----------|----------------|-----------------|
| | Pre -treatment | Post -treatment |
| Mean±SD | 5.18±1.28 | 3.31±2.16 |
| p-value | 0.001(Sig.) | |

Test applied: paired sample t-test

Mean value of VAS (pain) before treatment was 5.18 mm and after treatment it was decreased to 3.31. The pre and post difference was found statistically significant (p=0.001)

Discussion

Global estimates of OSMF show confinement among Indians and Southeast Asians, with the overall prevalence rate in India ranging from 0.2% to 0.5%[7]. The etiology of OSMF is considered multifactorial. The habit of areca nut chewing is the common etiological factor of OSMF in the Indian subcontinent.

To date, no previous studies using large sample sizes exists regarding the efficacy of intralesional corticosteroid injections as a treatment modality of OSF. Kumar et al.[8] reported a study which included 58 subjects, while Cox and Zoellner used a sample size of 28 subjects[9]. In the meantime a more recent study by Chetan et al.[10] had 40 subjects. Comparatively we had a fairly large sample size of 100 in the present study.

According to the review of medical interventions for OSF by Kerr et al.[11] 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 50% of the patients were in the age group of 20–37 years. Our results are in accordance with previous studies by Arakeri et al.[12] with reported mean age of 29.12 years, 20–40 years by Galchar et al.[13], and 21–40 years by Ranganathan et al.[14]. 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 (74%). It is in accordance with

the previous studies conducted by Rupak et al.[15] and Ganapathy et al.[16] Higher males skew is predominantly due to easy product accessibility and changing lifestyles of the youngsters[17].

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.[13], contrary to our findings Cox and Zoellner, study revealed that injection of steroids and hyaluronidase had not significantly improved mouth opening[9].

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