

Evaluation of Three Different Treatment Protocol of OSMF

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Abstract

Aim: To compare various medical treatment protocol of OSMF, so as to arrive at definitive and effective protocol for the management of OSMF.

Material & Methods: A total of 150 patients of OSMF attending the ENT OPD and satisfying the criteria for inclusion were enrolled for the study. The subjects were randomly divided into age sex matched into three study groups (Dexamethasone with hyaluronidase, Oral vasodilator, Muscle relaxant) in which the relief in symptoms was noted. Lycopene was given in all patients.

Results: In group A, we have given intralesional injection Dexamethasone with Hyaluronidase biweekly for five weeks, which showed marked improvement in cases with pain with spicy food 16 cases (80%). oral vasodilator Tablet Pentoxifylline 400 mg TDS, which showed improvement in difficulty in protruding tongue 7 cases (53.8%). muscle relaxant Tablet Myosone 50 mg BD showed improvement pain with spicy food 10 cases (45.5%).

Conclusion: As there is still paramount of controversy regarding the ethology of OSMF there is no definite treatment protocol. Patients which received intralesional dexamethasone and hyaluronidase along with oral lycopene showed better clinical and symptomatic improvement in comparison to others groups, which at present appears to be the best option for OSMF.

Keywords: OSMF, intralesional steroid, Hyaluronidase, muscle relaxant

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Introduction

Oral submucous fibrosis (OSMF) is a chronic insidious premalignant condition of the oral mucosa.[1-3] it is an insidious, chronic change in fibro elasticity, characterized by a burning sensation in the oral cavity, blanching and stiffening of the oral mucosa and oropharynx and trismus.[4]

In recent years, the frequency in India has risen to 6.42 percent, with a greater

prevalence in the subcontinent's southern regions.[5] OSMF is most frequent in males between the ages of 20 and 40. Labial mucosa, buccal mucosa, retromolar pads, soft palate, and the floor of the mouth are all common locations. There have been reports of fibrotic alterations in the pharynx, esophagus, and Para tubal muscles of the Eustachian tubes. Burning sensations, hyper salivation/ xerostomia, and mucosal blanching with a marble-like

appearance are all early signs of OSMF. The mucosa becomes leathery and inelastic with time, with perceptible fibrous bands, limiting mouth opening. OSMF eventually causes tongue restrictions, swallowing difficulties, speech and hearing problems, and a loss of gustatory sense.^[6]

The various hypotheses put forward so far suggest a multifactorial origin for this condition. Alongside the role of local irritants such as capsaicin[7], tobacco[7], areca nut[8], spicy food and alcohol[9]; underlying systemic predisposition is likely because of the geographical and ethnic distribution of OSMF.[10] Among the systemic factors, the main ones incriminated are chronic iron and vitamin B complex deficiency, anaemia and a genetic predisposition to the disease. [11]

The preventative management should be in the form of discontinuation of habit, which can be encouraged through education and advocacy. Vitamins, iron and mineral rich diet should be advised to the patients. Intake of red tomatoes, fresh fruits and green leafy vegetables should be included in the regular diet. [12] **Hence, this study aims to** compare various medical treatment protocol of OSMF, so as to arrive at definitive and effective protocol for the management of OSMF.

Material and Methods:

The study was a prospective study undertaken in the Department of ENT, ANMMCH, Gaya, Bihar, India from over a period of 10 months. All untreated patients of OSMF attending the ENT OPD and fulfilling the criteria for inclusion were enrolled for the study, a detailed history was taken primarily keeping focus on various deleterious oral habits like chewing pan, gutka, betel nut and tobacco. The diagnosis of OSMF was established through an accepted clinical characteristic.

Written consent of patients diagnosed with OSMF was taken.

Methodology

A total of 150 patients were selected for this study. The subjects were randomly divided into age sex matched into three groups in which the following drugs were administered. Patients with definite signs and symptoms were selected for the allocation in study groups

In group A (50 patients), patients were given 2ml of a mixture of Injection Hyaluronidase with Injection Dexamethasone (40mg/ml). The injections were given biweekly intralesional for 5 weeks.

In group B (50 patients), patients were given vasodilator (tablet Pentoxifylline 400mg TDS).

In group C (50 patients), patients were given muscle relaxant (Tab Eprisonone Hydrochloride 50mg BD).

Along with this oral antioxidant containing Lycopene was given daily for 5 weeks to all patients included in study.

Patients were followed up and relief in symptoms were observed, noted and tabulated.

Results:

In group A, we have given intralesional injection Dexamethasone with Hyaluronidase biweekly for five weeks, which showed marked improvement in cases with pain with spicy food 16 cases (80%), followed by decreased in mouth opening 7 cases (53.8%) , difficulty 3 cases (60%), and in cases with difficulty in swallowing 2 cases (40%) and vesicular eruption 2 cases (100%) improvement respectively.

Group B

In group B we had given oral vasodilator Tablet Pentoxifylline 400 mg TDS, which showed improvement in difficulty in

protruding tongue 7 cases (53.8%), pain with spicy food 7 cases (52.9%), decreased mouth opening 5 cases (33.3%), oral ulceration 5 cases (62.5%), difficulty in swallowing 3 cases (50%), and dryness of mouth 3 cases, (60%), vesicular eruption 2 cases (50%) improvement respectively.

Group C

In this group C with muscle relaxant Tablet Myosone 50 mg BD showed

improvement pain with spicy food 10 cases (45.5%), decreased mouth opening 7 cases (43.7%), difficulty in protruding tongue 9 cases (45%), difficulty in swallowing 4 cases (44.4%), oral ulceration 3 cases (37.5%), vesicular eruption 2 case (40%) and dryness of mouth 1 case (33.3%) improvement respectively

Table 1: Group A analysis

Chief Complaints	Total number of Patients	Patients Improved	Patients not Improved	% Improved
Burning sensation with spicy food	20	16	4	80
Decreased mouth opening	13	7	6	53.8
Difficulty in protruding tongue	15	7	8	46.6
Oral ulceration	9	2	7	22.2
Dryness of mouth	6	2	4	33.3
Difficulty in swallowing	5	3	2	60
Vesicular eruption	2	2	0	100

Table 2: Group B analysis

Chief Complaints	Total number of Patients	Patients Improved	Patients not Improved	% Improved
Pain with spicy food	17	9	8	52.9
Decreased mouth opening	15	5	10	33.3
Difficulty in protruding tongue	13	7	6	53.8
Oral ulceration	8	5	3	62.5
Difficulty in swallowing	6	3	3	50
Dryness of mouth	5	3	2	60
Vesicular eruption	4	2	1	50

Table 3: Group C analysis

Chief Complaints	Total number of Patients	Patients Improved	Patients not Improved	% Improved
Pain with Spicy Food	22	10	12	45.5
Difficulty in Protruding Tongue	20	9	11	45
Decreased Mouth Opening	16	7	9	43.7
Difficulty in Swallowing	9	4	5	44.4
Oral ulceration	8	3	5	37.5
Vesicular Eruption	5	2	3	40
Dryness of Mouth	3	1	2	33.3

Discussion:

Oral submucous fibrosis is a widely prevalent oral mucosal lesion in Indian population and considering its premalignant potential and severe clinical manifestations many studies are done by many authors regarding various aspects of this condition such as etiology pathogenesis and treatment.

Etiology and pathogenesis of OSMF is obscure. Arecoline of *Areca catechu* is mostly attributed as the causative factors in addition to pan and tobacco in different combinations.[13, 14]

Arecoline, an active alkaloid found in betel nuts, stimulates fibroblasts to increase production of collagen by 150%.[15] Arecoline was found to elevate the mRNA and protein expression of cystatin C, a nonglycosylated basic protein consistently up regulated in a variety of fibrotic diseases, in a dose-dependent manner in persons with OSMF.[16]

Nidhi Elizabeth et al.[17] studied 38 patients and found that Lycopene in combination with intralesional steroids and Hyaluronidase, was highly efficacious in improving the mouth opening and reducing other symptoms in patients with Oral Submucous Fibrosis. Selvam et al. [18] in 45 patients also found Lycopene in combination with intralesional steroids and Hyaluronidase, to be effective in improving the symptoms in patients with Oral Submucous Fibrosis.

Flavanoid, catechin and tannin in betel nuts cause collagen fibers to cross-link, making them less susceptible to collagenase degradation.[19] This results in increased fibrosis by causing both increased collagen production and decreased collagen breakdown.[20]

OSMF remains active even after cessation of the chewing habit, suggesting that components of the arecanut initiate OSMF and then affect gene expression in the

fibroblasts, which then produce greater amounts of normal collagen.[21]

A study conducted by Rajendran R[22](2006) vasodilators were found to be effective in mouth opening, tongue protrusion and relief from perioral fibrotic bands. Subjective symptoms of intolerance to spices, burning sensation of mouth, tinnitus, and difficulty in swallowing, difficulty in speech showed marked improvement. They concluded that Pentoxifylline as an adjunct therapy for the treatment of OSMF. Bandage CJ et al.[23] (2013) compared the effectiveness of vasodilator Isoxsuprine with Dexamethasone and Hyaluronidase injections and physiotherapy in the treatment of OSMF. They found that mouth opening increased and burning sensation decreased significantly in vasodilator group.

Nichlani SS et al.[24] (2011) used muscle relaxant in treatment of OSMF and their was marked improvement in 17 out of the 20 test patients who received muscle relaxants for the treatment of OSMF. Marked improvement was seen in mouth opening with shift from grade 3 (<19 mm) to grade 1 (>40 mm) [25].

Conclusion:

As there is still paramount of controversy regarding the ethology of OSMF there is no definite treatment protocol. Patients which received intralesional dexamethasone and hyaluronidase along with oral lycopene showed better clinical and symptomatic improvement in comparison to others groups, which at present appears to the best option for OSMF.

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