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## Original Research Article

## Comparative evaluation of efficacy of muscle relaxant, vasodilator and combined intralesional steroid with hyaluronidase use in oral submucous fibrosis

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## ABSTRACT

**Introduction:** Oral Sub Mucous Fibrosis (OSMF) is a disease, which predominately occurs in Indians and South East Asians. It is characterised by mucosal rigidity of varying intensity due to fibroelastic changes of the juxta-epithelial layer, resulting in a progressive inability to open mouth. The main concern in the condition is the management of trismus and burning sensation of oral mucosa.

**Aim:** this study was conducted to compare various medical treatment protocol of OSMF, so as to arrive at definitive and effective protocol for the management of OSMF.

**Material & Methods:** 105 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 (Dexa with hyaluronidase, Oral vasodilator, Muscle relaxant) in which the relief in symptoms was noted. Lycopene was given in all patients.

**Observation:** Group A, patients were given intralesional injection Dexamethasone with Hyaluronidase biweekly for five weeks and marked improvement was seen in cases of pain with spicy food 13 cases (76.47%), followed by decreased in mouth opening 9 cases (56.25%). In Group B, oral vasodilator Tablet Pentoxifylline 400 mg TDS was given and showed improvement in difficulty in protruding tongue in 9 cases (60%), pain with spicy food 8 cases (50%), decreased mouth opening 6 cases (37.5%), oral ulceration 3 cases (42.85%). In Group C with muscle relaxant Tablet Myosone 50 mg BD showed improvement pain with spicy food 8 cases (42.10%), decreased mouth opening 8 cases (42.10%), difficulty in swallowing 3 cases (37.5%). 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.

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## 1. Introduction

He who takes the medicines and neglects diets waste the skill of his doctor. "Prevention is better than cure". This paradigm applies for Oral Sub Mucous Fibrosis (OSMF) patients and emphasis has to be placed on its prevention, by their early application. OSMF is a disease, which predominately occurs in Indians and South East Asians.

It is characterised by mucosal rigidity of varying intensity due to fibroelastic changes of the juxta-epithelial layer, resulting in a progressive inability to open mouth.<sup>1</sup> In 1952 Schwartz described five Indian women from Kenya with a condition of the oral cavity (Atropica mucosae oris). Later Joshi termed it as oral submucous fibrosis, other names are diffuse oral submucous fibrosis, idiopathic scleroderma of the mouth, idiopathic palatal fibrosis, sclerosing stomatitis and juxta epithelial fibrosis.<sup>2</sup>

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It is an insidious, chronic disease affecting any part of the oral cavity and sometimes pharynx, associated with juxta – epithelial inflammatory reaction followed by progressive hyalinization of lamina propria. The onset of symptom is over 2-5 year. The prodromal symptoms include a burning sensation in the mouth when consuming spicy food, appearance of blisters especially in palate, ulcerations or recurrent generalized inflammation of the oral mucosa, excessive salivation, defective gustatory sensation and dryness of oral mucosa.<sup>3</sup> The various hypotheses put forward so far suggest a multifactorial origin for this condition. Alongside the role of local irritants such as capsaicin<sup>4</sup>, tobacco<sup>4</sup>, areca nut<sup>5</sup>, spicy food and alcohol<sup>6</sup>, underlying systemic predisposition is likely because of the geographical and ethnic distribution of OSMF.<sup>7</sup> Among the systemic factors, the main ones incriminated are chronic iron and vitamin B complex deficiency, anaemia and a genetic predisposition to the disease.<sup>8</sup> (Figures 1 and 2)

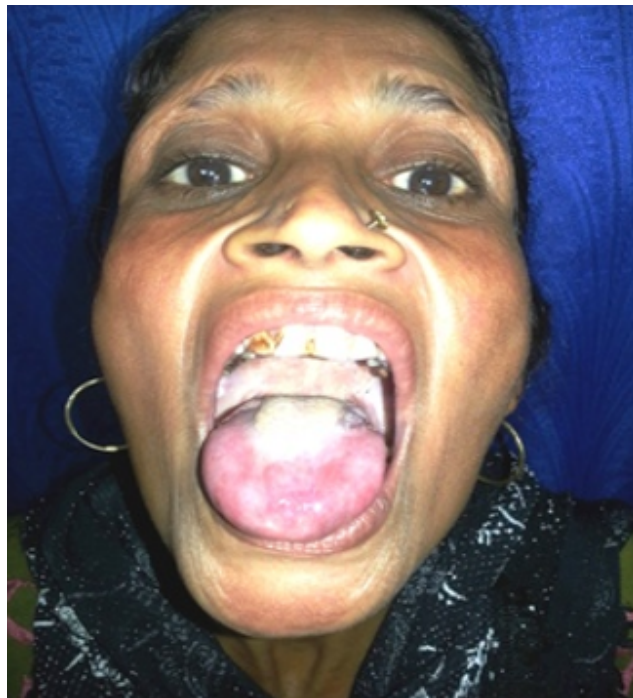
The main concern in the condition is the management of trismus and burning sensation of oral mucosa. A very large number of treatment modalities have been tried by both surgical and non-surgical modalities. The preventative management should be in the form of discontinuation of habit, which can be encouraged 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.<sup>9</sup>

In the current scenario, there are various non-surgical and surgical means of treatment available for OSMF, so this study was conducted to compare various medical treatment protocol of OSMF, so as to arrive at definitive and effective protocol for the management of OSMF.

## 2. Material and Methods

The study was a prospective study undertaken in the department of ENT and HNS of a tertiary care centre, India from August 2013 to July 2014. 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. The subjects were randomly divided into age sex matched into three groups in which the following drugs were administered.

In group A patients were given 2ml of a mixture of Inj Hyaluronidase with Inj Dexamethasone (40mg/ml). the injections were given biweekly intralesional for 5 weeks. In group B patients were given vasodilator (tablet Pentoxifylline 400mg TDS). In group C patients were given muscle relaxant (Tab Eprison Hydrochloride 50mg BD). Along with this oral antioxidant containing Lycopene



**Fig. 1:** Loss of papillae from tongue with extensive soft and hard palate fibrosis



**Fig. 2:** Whitish fibrous band on palate





**Fig. 3:** Whitish band on buccal mucosa with ulceration



**Fig. 5:** Ulceration over buccal mucosa & angular stomatitis



**Fig. 4:** Minimal mouth opening

10,000 mcg 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.

### 3. Observations & Results

#### 3.1. Group A

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 13 cases (76.47%), followed by decreased in mouth opening 9 cases (56.25%), difficulty 3 cases (60%), and in cases with difficulty in swallowing 2 cases (40%) and vesicular eruption 2 cases (100%) improvement respectively.

#### 3.2. Group B

In group B we had given oral vasodilator Tablet Pentoxifylline 400 mg TDS, which showed improvement in difficulty in protruding tongue 9 cases (60%), pain with spicy food 8 cases (50%), decreased mouth opening 6 cases (37.5%), oral ulceration 3 cases (42.85%), difficulty in swallowing 2 cases (40%), and dryness of mouth 2 cases (50%), vesicular eruption 2 cases (66.66%) improvement respectively.

**Table 1:** Group A analysis

Chief Complaints	Total number of Patients	Patients Improved	Patients not Improved	% Improved
Burning sensation with spicy food	17	13	4	76.47
Decreased mouth opening	16	9	7	56.25
Difficulty in protruding tongue	12	7	5	58.33
Oral ulceration	8	5	3	62.5
Dryness of mouth	5	3	2	60
Difficulty in swallowing	5	2	3	40
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	16	8	4	50
Decreased mouth opening	16	6	10	37.5
Difficulty in protruding tongue	15	9	6	60
Oral ulceration	7	3	5	42.85
Difficulty in swallowing	5	2	3	40
Dryness of mouth	4	3	2	50
Vesicular eruption	3	2	1	66.66

**Table 3:** Group C analysis

Chief Complaints	Total number of Patients	Patients Improved	Patients not Improved	% Improved
Pain with Spicy Food	19	8	11	42.1
Difficulty in Protruding Tongue	19	7	12	36.84
Decreased Mouth Opening	18	8	10	44.44
Difficulty in Swallowing	8	3	5	37.5
Oral ulceration	7	2	5	28.57
Vesicular Eruption	3	1	2	33.33
Dryness of Mouth	2	1	1	50

### 3.3. Group C

In this group C with muscle relaxant Tablet Myosone 50 mg BD showed improvement pain with spicy food 8 cases (42.10%), decreased mouth opening 8 cases (42.10%), difficulty in protruding tongue 7 cases (36.84%), difficulty in swallowing 3 cases (37.5%), oral ulceration 2 cases (28.57%), vesicular eruption 1 case (33.33%) and dryness of mouth 1 case (50%) improvement respectively.

## 4. Discussion

OSMF is a potentially malignant disorder that primarily affects any part of the oral cavity and sometimes the pharynx. The most common chief complaint observed in this study was burning sensation while taking spicy food which preceded by difficulty in opening mouth. Difficulty in swallowing food and ulcerations in the oral cavity has very few complaints. Even though OSMF has been recognised as disease entity long back its exact aetiology is unclear

as it is multifactorial disease. Most of the ideas have been derived from existing clinical and epidemiological data, Where the most common habit was gutka chewing. In this study patients were randomly divided in to three groups – A, B and C. (Figures 3 and 4)

### 4.1. Group A

In group A, we found marked improvement in cases with pain with spicy food 13 cases (76.47%), followed by decreased mouth opening 9 cases (56.25%), difficulty in protruding tongue 7 cases (58.33%), ulceration in 5 cases (65.5%), in dryness of mouth 3 cases (60%), and in difficulty in swallowing 2 cases (40%) and vesicular eruption 2 cases (100%). Nidhi Elizabeth et al.<sup>10</sup> 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.

Niranzana Panneer Selvam et al.<sup>11</sup> 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. Kakar PK et al.<sup>12</sup> divided 96 patients of Oral Submucous Fibrosis into four groups-local Dexamethasone, local Hyaluronidase, local combination of Dexamethasone and Hyaluronidase, and local Placental extract. They found that the group of patients receiving Hyaluronidase alone showed quicker improvement in symptoms although its combination with Dexamethasone gave somewhat better longer-term results.

#### 4.2. Group B

In group treated with vasodilator Tablet Pentoxifylline 400 mg TDS showed improvement in difficulty in protruding tongue 9 cases (60%), pain with spicy food 8 cases (50%), decreased mouth opening 6 cases (37.5%), ulceration 3 cases (42.85%), difficulty in swallowing 2 cases (40%), and dryness of mouth 2 cases (50%), vesicular eruption 2 cases (66.66%). In a similar study conducted by Rajendran R<sup>13</sup> (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, 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.<sup>14</sup> (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. Ravi Mehrotra et al.<sup>15</sup> (2011) compared the efficacy of Pentoxifylline with placebo in 75 patients of OSMF. They found 25 % improvement in patients with placebo treatment while there was 49.15 % improvement in patients with Pentoxifylline.

#### 4.3. Group C

In present study it was observed that with muscle relaxant Tablet Eprison Hydrochloride 50mg BD there was improvement in pain with spicy food in 8 cases (42.10%), decreased mouth opening 8 cases (42.10%), difficulty in protruding tongue 7 cases (36.84%), difficulty in swallowing 3 cases (37.5%), ulceration 2 cases (28.57%), vesicular eruption 1 case (33.33%) and dryness of mouth 1 case (50%) improvement respectively. Nichlani SS et al.<sup>16</sup> (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). They concluded that use of muscle relaxant adjuvant in the routine protocol of treatment of OSMF will not only

cater and halt the problem of fibrosis but also take care of the muscle spasm and inflammation which inadvertently contribute to the restricted mouth opening.(Figure 5)

### 5. Conclusion

As there is still paramount of controversy regarding the ethology of OSMF there is no definite treatment protocol. In this study we found out that group A 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.

### 6. Source of Funding

None.

### 7. Conflict of Interest

None.

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