

## Original Research

### A comparison of different treatment modalities of management of OSMF

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#### ABSTRACT:

**Background:** Oral submucous fibrosis (OSMF) is a chronic, complex, irreversible precancerous condition. This study compared colchicine with hydrocortisone and hyaluronidase in cases of OSMF. **Materials & Methods:** 84 patients of OSMF of both genders were divided into 2 groups of 42 patients. In group I, patients were administered 0.5 ml intralesional injection Hyaluronidase 1,500 IU and 0.5 ml intralesional injection hydrocortisone acetate 25 mg/ml in each buccal mucosa once a week alternatively and in group II, patients were administered tablet colchicine orally, 0.5 mg twice daily and 0.5 ml intralesional injection Hyaluronidase 1,500 IU into each buccal mucosa once a week. Parameters such as mouth opening and burning sensation (VAS) were recorded at 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> weeks of treatment. **Results:** Group I comprised of 21 grade II and 21 grade III patients and group II had 20 grade II and 22 grade III patients. The difference was non-significance ( $P > 0.05$ ). Group II had >35 mm opening in 3 patients, 5 in group I and 6 in group II had 30-35 mm opening, 8 in group I and 10 in group II had 25-30 mm opening, 10 in group I and 11 in group II had 20-25 mm, 12 in group I and 8 in group II had 15-20 mm and 7 in group I and 4 in group II had 10-15 mm mouth opening. The difference was significance ( $P < 0.05$ ). At 2<sup>nd</sup> week, 24 patients in group I and 30 in group II showed reduction in burning sensation, at 3<sup>rd</sup> week, 10 in group I and 6 in group II and at 4<sup>th</sup> week, 8 in group I and 6 in group II showed reduction. The difference was significance ( $P < 0.05$ ). **Conclusion:** Colchicine found to be effective in management of cases of OSMF as compared to other treatment modalities.

**Key words:** Oral submucous fibrosis, Hyaluronidase, colchicine

Received: 13 October, 2022

Accepted: 17 November, 2022

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**This article may be cited as:** Porwal B, Mukherjee A, Singh Y, Kumar K, Bansal M, Wani QA. A comparison of different treatment modalities of management of OSMF. J Adv Med Dent Sci Res 2022;10(12):63-66.

#### INTRODUCTION

Oral submucous fibrosis (OSMF) is a chronic, complex, irreversible precancerous condition characterised by juxta-epithelial inflammatory reaction and progressive fibrosis of the submucosal tissue i.e. lamina propria and deeper connective tissue.<sup>1</sup> Oral submucous fibrosis is a chronic disease affecting the oral mucosa, as well as the pharynx and the upper two-thirds of the esophagus. There is substantial evidence that lends support to a critical role of areca nuts in the etiology behind oral submucous fibrosis.<sup>2</sup> It is generally observed that the onset of OSMF is insidious and takes about 2-20 years

to present with symptoms. Submucosal fibrosis of different areas of the oral mucosa leads to difficulty in opening the mouth. Blanching of the oral mucosa is an important clinical feature seen in the early stage of OSMF.<sup>3</sup>

Although numerous etiological factors have been advocated in the literature, the precise role of these factors in the initiation and spread of this condition is still uncertain since it is encountered even in individuals with none of the etiological factors.<sup>4</sup> Treatment includes intralesional injections of placental extract, corticosteroid such as hydrocortisone and injection hyaluronidase. The

pharmacodynamics of colchicine as an anti-fibrotic agent is well-established in the treatment of various diseases associated with fibrosis.<sup>5</sup> This study compared colchicine with hydrocortisone and hyaluronidase in cases of OSMF.

**MATERIALS & METHODS**

The present study comprised of 84 patients of OSMF of both genders. All gave their written consent for participation in the study. Demographic data of each patient such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 42 patients. In group I, patients were

administered 0.5 ml intralesional injection Hyaluronidase 1,500 IU and 0.5 ml intralesional injection hydrocortisone acetate 25 mg/ml in each buccal mucosa once a week alternatively and in group II, patients were administered tablet colchicine orally, 0.5 mg twice daily and 0.5 ml intralesional injection Hyaluronidase 1,500 IU into each buccal mucosa once a week. Parameters such as mouth opening and burning sensation (VAS) were recorded at 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> weeks of treatment. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

**RESULTS**

**Table I Distribution of patients**

Grade	Group I	Group II	P value
II	21	20	0.91
III	21	22	

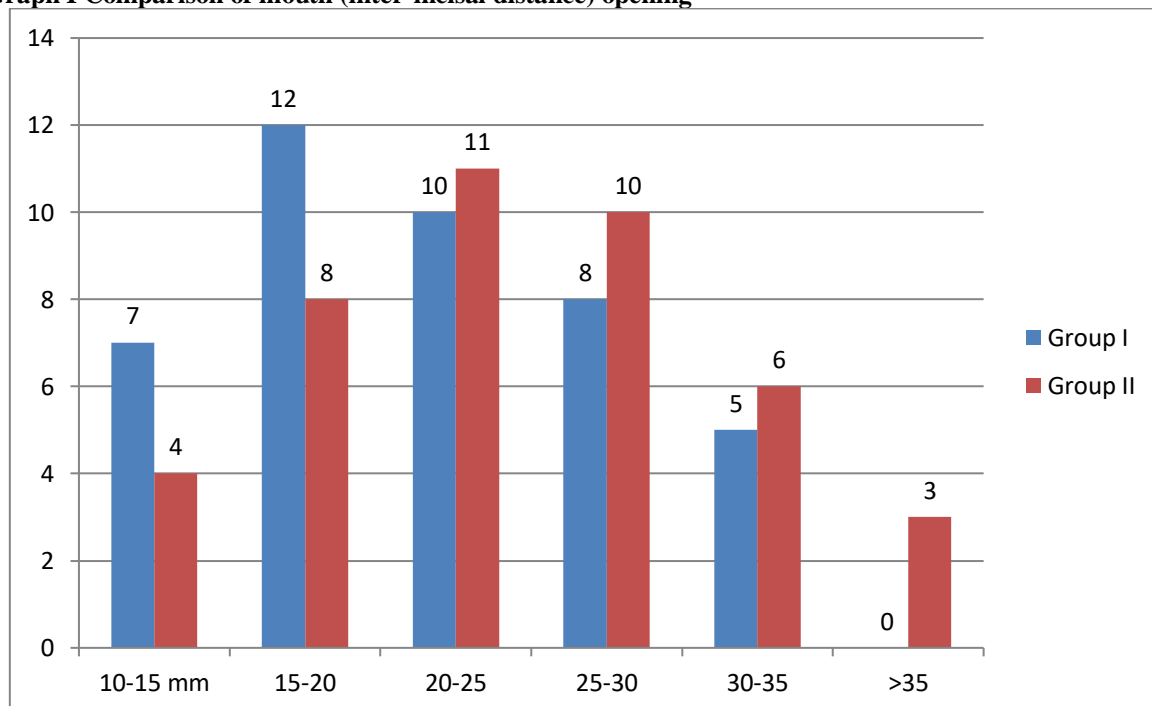
Table I shows that group I comprised of 21 grade II and 21 grade III patients and group II had 20 grade II and 22 grade III patients. The difference was non-significance (P> 0.05).

**Table II Comparison of mouth (inter-incisal distance) opening**

Inter-incisal distance (mm)	Group I	Group II	P value
10-15	7	4	0.05
15-20	12	8	
20-25	10	11	
25-30	8	10	
30-35	5	6	
>35	0	3	

Table II, graph I shows that group II had >35 mm opening in 3 patients, 5 in group I and 6 in group II had 30-35 mm opening, 8 in group I and 10 in group II had 25-30 mm opening, 10 in group I and 11 in group II had 20-25 mm, 12 in group I and 8 in group II had 15-20 mm and 7 in group I and 4 in group II had 10-15 mm mouth opening. The difference was significance (P< 0.05).

**Graph I Comparison of mouth (inter-incisal distance) opening**



**Table III Comparison of burning sensation**

Duration	Group I	Group II	P value
2 <sup>nd</sup>	24	30	0.02
3 <sup>rd</sup>	10	6	
4 <sup>th</sup>	8	6	

Table III shows that at 2<sup>nd</sup> week, 24 patients n group 1 and 30 in group II showed reduction in burning sensation, at 3<sup>rd</sup> week, 10 in group 1 and 6 in group II and at 4<sup>th</sup> week, 8 in group I and 6 in group II showed reduction. The difference was significance (P< 0.05).

**DISCUSSION**

Oral submucous fibrosis (OSMF) is a potentially malignant disorder that primarily affects any part of the oral cavity and sometimes the pharynx.<sup>6</sup> The disease is chronic, insidious, and progressive in nature. This generalized condition of the mouth eventually becomes a debilitating disease with mucosal rigidity causing discomfort, burning, and limitation of opening of the mouth.<sup>7</sup> People with OSMF carry a high- risk for development of oral cancer. OSMF is predominantly found among the people of South Asia and is closely associated with the habit of betel quid chewing.<sup>8</sup> Several case control studies show evidence that areca nut, a constituent of betel quid, greatly contributes towards exaggerating the occurrence of OSMF.<sup>9,10</sup> This study compared colchicine with hydrocortisone and hyaluronidase in cases of OSMF.

We found that group I comprised of 21 grade II and 21 grade III patients and group II had 20 grade II and 22 grade III patients. Goel S et al<sup>11</sup> compared the efficacy of oral lycopene and injection betamethasone with control group in the management of oral submucous fibrosis. Out of 270 cases 223 (82.59%) were males and 47 (17.40%) were females which showed a male predominance and the ratio was 5:1. In stage I it was found that both the test groups, i.e., injection betamethasone and capsule lycopene had a significant improvement in mouth opening than control group. In stage II, it was found that the test group injection betamethasone showed 24 better results as compared to capsule lycopene this could be because of better accessibility of the fibrotic bands for injecting betamethasone solution at the site of the lesion and showed highly significant difference (P < 0.0001). In stage III, it was found that the capsule lycopene showed better results as compared to injection betamethasone and the difference was highly significant (P < 0.0001). This could be because of restricted mouth opening and inability to reach the site for injecting betamethasone solution.

We observed that group II had >35 mm opening in 3 patients, 5 in group I and 6 in group II had 30-35 mm opening, 8 in group I and 10 in group II had 25-30 mm opening, 10 in group I and 11 in group II had 20-25 mm, 12 in group I and 8 in group II had 15- 20 mm and 7 in group I and 4 in group II had 10-15 mm mouth opening. Kothari et al<sup>12</sup> compared buccal pad of fat (BPF) and bovine collagen membrane in the management of oral submucous fibrosis. The mean age of patients was 27.3 years. A 12 mm was mean

preoperative mouth opening. Intraoperative mouth opening was 37 mm in all the patients and maintained at 36 mm at the 6th-month postoperative period. No significant difference was observed between both sides pertaining to pain on maximal mouth opening, burning sensation, or postoperative infection. However, there was a significant difference in the time taken for epithelization on both sides.

We observed that at 2<sup>nd</sup> week, 24 patients n group 1 and 30 in group II showed reduction in burning sensation, at 3<sup>rd</sup> week, 10 in group 1 and 6 in group II and at 4<sup>th</sup> week, 8 in group I and 6 in group II showed reduction. Krishnamoorthy et al<sup>13</sup> studied effects of colchicine in the management of oral submucous fibrosis. Fifty OSF patients were divided randomly into two groups and treated for 12 weeks. Group 1- Patients were administered tablet colchicine orally, 0.5 mg twice daily and 0.5 ml intralesional injection Hyaluronidase 1,500 IU into each buccal mucosa once a week. Group 2-Patients were administered 0.5 ml intralesional injection Hyaluronidase 1,500 IU and 0.5 ml intralesional injection Hydrocortisone acetate 25 mg/ml in each buccal mucosa once a week alternatively. Thirty-three percent in group 1 got relief from burning sensation in the second week. Inter group comparisons of increase in mouth opening and reduction in histological parameters indicated that group 1 patients responded better than group 2. The shortcoming of the study is small sample size and short follow up.

**CONCLUSION**

Authors found that colchicine found to be effective in management of cases of OSMF as compared to other treatment modalities.

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