

## **A Comparative Evaluation Of Efficacy Of Intralesional Placental Extract And Triamcinolone Acetonide In Patients With Osmf**

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### **Abstract**

**Aim:** To compare intralesional placental extract and triamcinolone acetonide in patients with OSMF.

**Materials & Methods:** Group I patients were given 1 ml of 40mg/ml triamcinolone acetonide and group II patients were administered 2 ml intralesional injections of aqueous placental extract on both buccal mucosa at weekly intervals for 10 weeks. Parameters such as burning sensation, pain (VAS), tongue protrusion, mouth opening and cheek flexibility were recorded pre-operatively and on follow up visits. Each group had 16 patients.

**Results:** Both groups showed reduction in burning sensation, pain (VAS) and improvement in mouth opening, cheek flexibility and tongue protrusion.

**Conclusion:** Intralesional injection of triamcinolone acetonide found to be superior than placental extract in patients with OSMF.

**Key words:** Oral submucous fibrosis, triamcinolone acetonide, placental extract

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## Introduction

Oral submucous fibrosis (OSMF) is one of the potentially malignant disorders, earlier classified under premalignant condition. It is a crippling disease leading to great difficulties in patient's daily habits such as swallowing, speaking and talking.<sup>1</sup> The clinical presentation of the disease can be observed under three stages viz, stage of stomatitis and vesiculation, stage of ulceration and stage of complications and sequelae.<sup>2</sup>

The peculiar feature of this disease is occurrence of burning sensation to spicy food. Presence of vertical fibrotic bands especially on buccal mucosa bilaterally helps in diagnosis of the disease. The mucosa loses its elasticity and becomes fibrotic. Fibrosis is also seen on labial mucosa, tongue, lips, soft palate etc.<sup>3</sup> Uvula becomes fibrotic, shrunken and hockey stick like. Lips become leathery and difficult to evert. Cases are classified into mild, moderate, moderately advanced and severely advanced based on clinical features of burning sensation, tongue protrusion, mouth opening etc.<sup>4</sup>

Slight male predilection has been seen since the habit of arecanut which is the main causative agent is commonly encountered in males. Part from arecanut, tobacco, genetic predisposition, nutrition deficiency etc. also plays an important role.<sup>5</sup>

Different treatment modalities have resulted less or more improvement in patient condition. A successful treatment outcome is measured in terms of improvement in mouth opening (normal 35-50 mm), tongue protrusion and cheek flexibility.<sup>6</sup> In most of the cases, treatment starts with topical steroid such as triamcinolone acetonide. However, in severe cases, systemic steroids are recommended.<sup>7</sup> Few prefer intralesional placental extract which is also found to be effective. Considering this, we select both these drugs such as intralesional placental extract and triamcinolone acetonide and treatment outcomes were compared.

## Methodology

A total of thirty-two adult patients in age ranged 18-46 years irrespective of sex were selected for this prospective, single blinded observational study. Enrolled patients were made aware of the importance of the study and after convincing them, a written consent was obtained in vernacular language. Helsinki's guidelines were followed for the study and research and review committee approval was sorted before commencing the study. Inclusion criteria were grade II and III OSMF patients, those which fall within specified age group and giving consent. Exclusion criteria were patients on any kind of medication and pregnant women.

A simple stratified random sampling technique was followed for grouping the patients. Group I patients were given 1 ml of 40mg/ml triamcinolone acetonide and group II patients were administered 2 ml intralesional injections of aqueous placental extract on both buccal mucosa at weekly intervals for 10 weeks. Parameters such as burning sensation, pain (VAS), tongue protrusion, mouth opening and cheek flexibility were recorded pre-operatively and on follow up visits. Mann Whitney U test was used for comparison of parameters between both groups setting level of significance below 0.05 as significant.

## Results

The mean value of burning sensation in group I at baseline was 68.2, at 5 weeks was 40.6 and at 10 weeks was 24.8. In group II, it was 66.8, 48.5 and 32.6 at baseline, 5 weeks and 10 weeks

respectively. A significant difference was observed on intergroup and intragroup comparison ( $P < 0.05$ ) (Table 1).

The mean value of pain (VAS) in group I at baseline was 54.0, at 5 weeks was 42.3 and at 10 weeks was 30.6. In group II, it was 56.4, 48.2 and 32.8 at baseline, 5 weeks and 10 weeks respectively. A significant difference was observed on intragroup comparison ( $P < 0.05$ ) (Table 2).

The mean value of mouth opening (mm) in group I at baseline was 20.4, at 5 weeks was 26.8 and at 10 weeks was 30.5. In group II, at baseline it was 21.4, at 5 weeks was 27.6 and at 10 weeks was 31.6. A significant difference was observed on intragroup comparison ( $P < 0.05$ ) (Table 3).

The mean value of cheek flexibility (mm) in group I at baseline was 0.87, at 5 weeks was 0.92 and at 10 weeks was 0.96. In group II, at baseline it was 0.90, at 5 weeks was 0.95 and at 10 weeks was 1.04. A significant difference was observed on intragroup and intergroup comparison ( $P < 0.05$ ) (Table 4).

The mean value of tongue protrusion (mm) in group I at baseline was 3.08, at 5 weeks was 3.26 and at 10 weeks was 3.41. In group II, at baseline it was 3.12, at 5 weeks was 3.36 and at 10 weeks was 3.71. A significant difference was observed on intragroup and intergroup comparison ( $P < 0.05$ ) (Table 5).

## Discussion

OSMF is one of the potential malignant disorders of middle age population with male predominance. It is also considered as collagen vascular disease.<sup>8,9</sup> The main concern of the patient is severe burning sensation, restricted tongue movement and dysphagia. The progressive nature of the disease poses difficulty in complete cure.<sup>10,11,12</sup> Not a single treatment modality such as physiotherapy, drugs and surgical intervention have been cure disease completely. Nowadays, soft tissues laser is being widely used.<sup>13</sup> In present study we compared intralesional triamcinolone with intralesional injection of placental extract.

Our study found a significant difference in reduction in burning sensation on intergroup and intragroup comparison. The mean value of burning sensation in group I at baseline was 68.2, at 5 weeks was 40.6 and at 10 weeks was 24.8. In group II, it was 66.8, 48.5 and 32.6 at baseline, 5 weeks and 10 weeks respectively. Shinde et al<sup>14</sup> in their study enrolled 40 grade II and III OSMF patients who received either triamcinolone acetonide or placental extract in the lesion on right and left buccal mucosa. It was found that there were significant reductions in pain, burning sensation, increase in mouth opening, tongue protrusion and cheek flexibility. However, triamcinolone acetonide resulted better outcome of treatment.

We found that the mean value of pain (VAS) in group I at baseline was 54.0, at 5 weeks was 42.3 and at 10 weeks was 30.6. In group II, it was 56.4, 48.2 and 32.8 at baseline, 5 weeks and 10 weeks respectively. It was found that the mean value of mouth opening (mm) in group I at baseline was 20.4, at 5 weeks was 26.8 and at 10 weeks was 30.5. In group II, at baseline it was 21.4, at 5 weeks was 27.6 and at 10 weeks was 31.6. A significant reduction in pain on VAS scale was observed in both groups. Naik et al<sup>15</sup> conducted a study in which 30 patients of OSMF received combination of triamcinolone acetonide and hyaluronidase and 30 patients received placentrex injection intralesionally for 8 weeks. Authors found that combination treatment were ore effective in

improving mouth opening, tongue protrusion and cheek flexibility as compared to placentrex injection alone.

We observed that there was improvement in cheek flexibility as well as tongue protrusion in both groups. Yadav et al<sup>16</sup> in their study on 30 OSMF patients received combination of triamcinolone acetonide, hyaluronidase and oral physiotherapy exercise for mouth opening and cheek flexibility and found significant improvement in all parameters. Samuel et al<sup>17</sup> conducted a study on 75 patients of OSMF in which group A patients received weekly intralesional triamcinolone (40 mg/ml) injections, group B received oral lycopene 6 mg daily, and group C received both weekly steroid injection and oral lycopene for 2 months respectively. It was observed that mouth opening values for the patients showed a mean increase of 6.56 mm, 3.04 mm and 7.56 mm in Groups A, B and C, respectively. Lycopene showed an early reduction in the burning sensation with a mean score of 4.8 in group B by the 1st week itself which was highly significant.

The shortcoming of the study is small sample size and short follow up. Only 2 drugs were compared in our study.

### **Conclusion**

Intralesional injection of triamcinolone acetonide found to be superior than placental extract in patients with OSMF.

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### **References**

1. Samdariya S., Kumar D, Kumar A, Porwal P, Pareek P. Oral submucous fibrosis – a short review. *Int J Med Sci Public Health*.2014;3(11):1308-12.
2. Murti PR, Bhonsle R. B, Gupta C, Daftary DK, Pindborg J J, Mehta Fali S. Etiology of oral submucous fibrosis with special reference to the role of areca nut chewing. *J Oral Pathol Med* 1995;24: 145-52.
3. Chole RH, Gondivkar SM, Gadbail AR, Balsaraf S, Chaudhary S, Dhore SV, et al. Review of drug treatment for oral submucous fibrosis. *Oral Oncology* 2012; 393–98.
4. Sikdar SD, Bagchi SS, Sood M. Efficacy of intralesional triamcinolone acetonide and hyaluronidase compared with that of placental extract in the treatment of OSMF: A comparative clinical study. *Int J Women Dentist* 2014;1:55-9.
5. Panigrahi R, Maheshwari A. A prospective, randomized double blind study comparing intralesional triamcinolone acetonide and hyaluronidase combination versus triamcinolone acetonide alone in the treatment of oral submucosal fibrosis. *J Pharm Biomed Sci*. 2014; 04(04):365-370.
6. Khan M K, Murthuza M. Oral submucous fibrosis - efficacy of conservative management with hydrocortisone & hyaluronidase against dexamethasone & hyaluronidase against triamcinolone & hyaluronidase. *Int J Advanced Res*. 2015;3(8):615-624.
7. More CB, Gupta S, Joshi J, Verma SN. Classification system for oral submucous fibrosis. *J Indian Acad Oral Med Radiol*2012;24:24-9.

8. Seshadhari S, Kailasam S, Elangovan S, Ravi VR, Sarkar S. Autologous bone marrow concentrate (mononuclear stem cell) therapy in the treatment of oral submucous fibrosis. *J Indian Acad Oral Med Radiol* 2015;25:1-4.
9. Aggarwal G, Bansal R, Chhabra V, Popli G, Sethi S, Khatri A. Oral submucous fibrosis- a review on clinical presentation, histology, epidemiology, aetiology, pathogenesis, malignant potential and management. *J Med Sci Clin Res.* 2016; 04(02):9174-82.
10. Singh M, Niranjana HS, Mehrotra R, Sharma D, Gupta SC. Efficacy of hydrocortisone acetate/hyaluronidase vs triamcinolone acetonide/hyaluronidase in the treatment of oral submucous fibrosis. *Indian J Med Res* 2010;131:665-9.
11. Katharia SK, Singh SP, Kulshreshtha VK. The effects of placenta extract in management of oral submucous fibrosis. *Indian J Pharmacol* 1992;24:181-3.
12. Vaidya S, Sharma VK. Oral submucous fibrosis. *World Artic Ear Nose Throat* 2009;2:1-4.
13. Dr. Aarushi Kataria, Dr. Naveen Nandal and Dr. Ritika Malik, Shahnaz Husain -A Successful Indian Woman Entrepreneur, *International Journal of Disaster Recovery and Business Continuity* Vol.11, No. 2, (2020), pp. 88–93
14. Malik, R., Nandal, Naveen and Gupta, Prakhar. (2021), The Impact of online shoppers to price and quality: a survey study in Delhi-NCR, *Efflatounia*, 5 (2), pp. 376 – 389.
15. Ameer NT, Shukla RK. A cross sectional study of oral submucous fibrosis in Central India and the effect of local triamcinolone therapy. *Indian J Otolaryngol Head Neck Surg* 2012;64:240-3.
16. Shinde CV, Saawarn N, Kohli S, Khare P, Singh A, Sagar KM. Comparative efficacy of intralesional placental extract and intralesional triamcinolone acetonide in the management of OSMF. *J Indian Acad Oral Med Radiol* 2019;31:328-32.
17. Naik SM, Appaji MK, Ravishankara S, Goutham MK, Devi NP, Mushannavar AS, et al. Comparative study of intralesional triamcinolone acetonide and hyaluronidase vs placental extract in 60 cases of oral submucous fibrosis. *Int J Head Neck Surg* 2012;3:59-65.
18. Yadav A, Nair G, Naidu GS, Makkad RS, Nagi R, Dewangan G. Intralesional Steroid plus Hyaluronidase and Oral Physiotherapy in the management of Oral submucous fibrosis: Clinicians Experience. *J Adv Med Dent Scie Res* 2020;8(10):122-129.
19. Samuel HT, Renukananda GS. Comparative study between intralesional steroid injection and oral lycopene in the treatment of oral submucous fibrosis. *Int J Sci Study* 2015;2:20-2.

**Legends for illustration**

**Table**

**Table 1: Comparison of burning sensation between both groups**

| Time interval | Group I | Group II | P value |
|---------------|---------|----------|---------|
| Baseline      | 68.2    | 66.8     | 0.81    |
| 5 weeks       | 40.6    | 48.5     | 0.90    |
| 10 weeks      | 24.8    | 32.6     | 0.05    |
| P value       | 0.02    | 0.01     |         |

Mann Whitney U test, Significance, P < 0.05

**Table 2: Comparison of pain between both groups**

| Time interval | Group I | Group II | P value |
|---------------|---------|----------|---------|
| Baseline      | 54.0    | 56.4     | 0.94    |
| 5 weeks       | 42.3    | 46.2     | 0.86    |
| 10 weeks      | 30.6    | 32.8     | 0.71    |
| P value       | 0.04    | 0.05     |         |

Mann Whitney U test, Significance,  $P < 0.05$

**Table 3: Comparison of mouth opening(mm) between both groups**

| Time interval | Group I | Group II | P value |
|---------------|---------|----------|---------|
| Baseline      | 20.4    | 21.4     | 0.92    |
| 5 weeks       | 26.8    | 27.6     | 0.98    |
| 10 weeks      | 30.5    | 31.6     | 0.82    |
| P value       | 0.03    | 0.04     |         |

Mann Whitney U test, Significance,  $P < 0.05$

**Table 4: Comparison of cheek flexibility(mm) between both groups**

| Time interval | Group I | Group II | P value |
|---------------|---------|----------|---------|
| Baseline      | 0.87    | 0.90     | 0.97    |
| 5 weeks       | 0.92    | 0.95     | 0.82    |
| 10 weeks      | 0.96    | 1.04     | 0.05    |
| P value       | 0.05    | 0.02     |         |

Mann Whitney U test, Significance,  $P < 0.05$

**Table 5: Comparison of tongue protrusion(cm) between both groups**

| Time interval | Group I | Group II | P value |
|---------------|---------|----------|---------|
| Baseline      | 3.08    | 3.12     | 0.84    |
| 5 weeks       | 3.26    | 3.36     | 0.71    |
| 10 weeks      | 3.41    | 3.71     | 0.05    |
| P value       | 0.03    | 0.01     |         |

Mann Whitney U test, Significance,  $P < 0.05$