

Original Research Article

Evaluation of Efficacy of Spirulina in Management of Oral Submucous Fibrosis

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Abstract: Objective: Oral submucous fibrosis (OSF) is a chronic condition of the oral cavity which results in permanent disability. A number of studies have proven that the management of premalignant diseases should include antioxidants. Therefore, a study was carried out to evaluate the efficacy of spirulina in the management of 40 oral submucous fibrosis in Uttar Pradesh. **Materials and Method:** An study was conducted on 40 oral submucous fibrosis cases, 40 patients given spirulina capsules systematically 500 mg twice daily for period of 6 months. The results were analyzed with tukey test and ANNOVA test. **Result:** The result showed statistically significant improvement in burning sensation whereas it was clinically significant in mouth opening and tongue protrusion. **Conclusion:** Spirulina can bring about clinical improvements in OSF patients. The observed effects suggest that spirulina can be used in management of OSF patients. However, studies involving larger samples and longer period of treatment follow up are suggested in the future.

Keywords: Spirulina, oral submucous fibrosis, areca nut, irreversible, crippling, tocopherols.

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1. INTRODUCTION

Oral submucous fibrosis (OSMF) has been studied intensively over decades, one might say centuries still it is hardly recognized and is poorly understood across the globe and in literature still remains elusive of a cure [1]. OSMF is defined as 'a debilitating, progressive, irreversible collagen metabolic disorder induced by chronic chewing of areca nut leading to mucosal stiffness and functional morbidity; and has a potential risk of malignant transformation [2]. It is commonly seen in male in 2nd and 3rd decades. OSMF is also characterized by reduced movement and depapillation of the tongue, blanching and leathery texture of the oral mucosa, gradual reduction of mouth opening, and shrunken uvula [1]. There have not been any efficacious treatment methods described in literature till now [3]. Newer treatment tactics like gamma interferon, pentoxifylline, tea pigments, alovera, spirulina etc has been found to be advantageous [4]. The blue green algae, spirulina is rich in carotenoids and other micronutrients possessing chemo preventive potential. It has been used to test the clinical activity in reversing the oral precancerous

lesions like leukoplakia [3]. *Spirulina* is a blue green algae found in warm water alkaline volcanic lakes. It exhibit antioxidant, anti-inflammatory and immunomodulating properties along with high nutritional value [5].

Thus here we have planned and performed a study and conducted it on 40 subjects just to observe how beneficial and efficient is spirulina in treatment of OSMF.

2. MATERIAL AND METHODS

The study was conducted in the department of oral medicine and radiology. The study included 40 diagnosed osmf patients.

2.1 Inclusion Criteria

Patients between the age group of 18-60 years and patients with clinically diagnosed OSMF.

2.2 Exclusion Criteria

Individuals with known history of hypersensitivity to spirulina, peptic ulcer, systemic

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disorders like hypertension, diabetes mellitus ,bleeding disorders, cardiac disorders and Individual with anaemic stomatitis, radiation fibrosis, scleroderma, immunosuppressive disorders.

All the patients’ demographic characteristics, habit history with clinical parameters will be recorded in a pre-determined proforma and be subjected to statistical analysis. Patient’s demographic data and clinical parameters, i.e., burning sensation, mouth opening, tongue protrusion were recorded using structured pro forma.

1. The intensity of burning sensation was measured using visual analog scale (VAS) of 1–10.
2. Mouth opening was measured from the mesioincisal angles of maxillary central incisor to mandibular central incisor, using Vernier caliper.
3. Tongue protrusion (mm) was recorded using divider from the mesioincisal angle of upper

central incisor to the tip of the tongue when the mouth is wide open and tongue is at its maximum extension.

All patients were given spirulina 500 mg twice a day for 6 months. The patients were followed up and outcomes were measured (MO, BS and TP) over the periods (pre-treatment, 1 month, 3 month and 6 month) in OSMF patients.

3. RESULTS AND OBSERVATION

The mean age of the patients enrolled in the present study was ranged from 20-43 yrs with mean (\pm SD) 32.68 ± 6.56 yrs and median 33 yrs. Moreover, 15 (37.5%) patients were ≤ 30 yrs aged and 25 (62.5%) were >30 yrs aged. Further, among patients, 10 (25.0%) were females and 30 (75.0%) were males (Table 1 and Fig. 1). The study population was thus male predominance with 1:3 female to male ratio.

Table 1: Baseline demographic characteristics of OSMF patients

Demographic characteristics	No. of patients (n=40) (%)
Age (yrs):	
≤30	15 (37.5)
>30	25 (62.5)
Sex:	
Female	10 (25.0)
Male	30 (75.0)

The improvement in mean MO increases 4.89% from baseline (pre-treatment) to end of treatment (6 month). Though, the net increase of 4.89% in MO

did not reach statistical significance but may be considered as clinical significant.

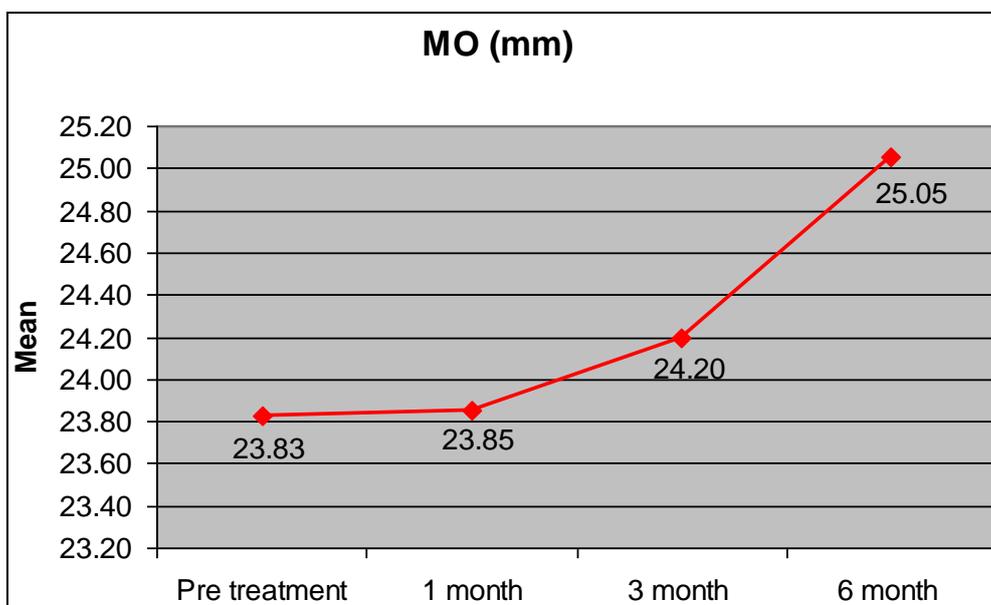


Fig. 1: Mean MO of OSMF patients over the periods

The reduction in burning sensation was statistically highly significant that is the mean BS score

showed net decrease of 87.07% at final evaluation (6 month) as compared to baseline (pre-treatment).

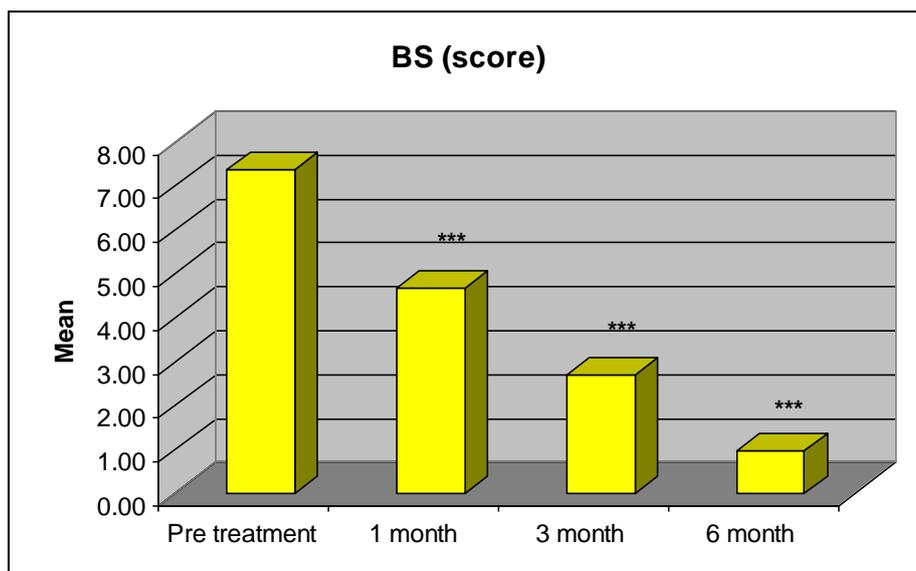


Fig. 2: Comparisons of difference in mean BS score of OSMF patients between four periods
 ****P* < 0.001- as compared to Pre-treatment. ****P* < 0.001: highly significant.

The next parameter was the tongue protrusion in which, mean TP increase 5.47% from baseline (pre-treatment) to end of treatment (6 month). Though, the

net increase of 5.47% in TP did not reach statistical significance but may be clinically significant.

Table 2: Pre and post TP (mm) of OSMF patients

Period/Group	N	Mean ± SD	F value	P value
Pre treatment	40	12.10 ± 2.46	0.73	0.537
1 month	40	12.10 ± 2.46		
3 month	40	12.18 ± 2.57		
6 month	40	12.80 ± 2.57		

The TP of OSMF patients at four periods were summarised in Mean ± SD and compared by repeated measures analysis of variance (RM ANOVA). F value: ANOVA F value. *P* = 0.537: not significant or *P* > 0.05

4. DISCUSSION

A condition resembling OSMF was described as early as 600 BC by Sushruta, and it was named ‘vidari’ In 1952, Schwartz described five Indian women from Kenya with a condition of the oral mucosa including the palate and pillars of the fauces, which he called “atrophia idiopathica (tropica) mucosae oris [6]. Oral submucous fibrosis is a disease of multifactorial etiology [7]. The main causative agent is “areca nut. The prevalence rates in India from 0.2% to 1.2%, an epidemiologic survey done a decade ago. OSF is characterized by inflammation and a progressive fibrosis of the lamina propria. The major presenting complaint is a progressive inability to open the mouth because of the accumulation of inelastic fibrous tissue in the juxtaepithelial region of the oral mucosa, along with concomitant muscle degeneration. Patients describe a gradual onset of burning pain when eating spicy food that previously had caused no distress. The fibrosis also leads to difficulty in mastication, speech, and swallowing and pain in the throat and ears [8]. Many treatment protocols for oral sub mucous fibrosis have been proposed to alleviate the signs and symptoms of the disorder but none have given the promising results. The method or the treatment chosen in our study

was the evaluation of efficacy of one the alternative medicine widely used nowadays for different purposes. The alternative therapy used is spirulina capsules given systemically, 500mg twice a day. It exhibits antioxidant, immunomodulatory, anti-inflammatory and anticancer properties [9] and has long been used as a remedy for countless medical conditions without any reported side effects. A number of clinical trials have assessed the efficacy of spirulina in the management of OSMF patients with varied results.

In the present study Burning sensation is the most common representation among the patients of OSMF and is caused by epithelial atrophy preceded by juxtaepithelial inflammation [10]. However, the mean BS score showed statistically significant net decrease of 87.07% at final evaluation (6 month) as compared to baseline (pre-treatment). Many studies were conducted with the similar effect of spirulina in reduction of the burning sensation like an comparative study was conducted by shetty [11] *et al.*, between spirulina and intralesional steroid injection betamethasone they found that spirulina was more effective in reducing burning sensation [11]. This reduction in burning sensation is accredited due to its beta carotene, phenolic acid,

tocopherol and micronutrient content [5]. Likewise, another comparative study was conducted by Mulk [4] *et al.*, between spirulina and pentoxifylline where significant reduction in burning sensation was seen in spirulina [4]. The next parameter taken in our study is the reduced mouth opening which is considered to be the emblematic feature of OSMF, which is ascribed to increase collagen production and decreased breakdown of collagen. Increased fibrosis is due to increased cross-linking of collagen through up-regulation of lysyl oxidase activity [12]. However, a net mean increase/improvement in inter incisal distance of OSMF patients was found to be 4.89%. Which was statistically insignificant but it was clinically significant. Similarly, a study was conducted by Mulk [4] *et al.*, between two drugs spirulina and pentoxifylline. On comparing both the drugs statistically insignificant results were obtained for mouth opening [4]. Furthermore, another comparative study was performed by Santosh Patil [13] *et al.*, between spirulina and aloe vera for 3 months. The patients taking spirulina systematically showed significant clinical improvement in mouth opening and ulcers/erosions/vesicles. However, there was no significant improvement in burning sensation and pain associated with the lesion was observed among the patients applying aloe vera gel topically [13]. Another study was conducted by Wadegar [14] *et al.*, where the effectiveness of antioxidants Spirulina and Lycopene were compared as an adjuvant to corticosteroid (triamcinolone acetonide) injection in the management of oral submucous fibrosis (OSMF). There was improvement in the mouth opening with both the drugs [14]. The last parameter to be considered in our study was the tongue protrusion where the pre (pre-treatment) and post (1, 3 and 6 month) TP of OSMF patients increases linearly with time. Due to fibrosis there is reduction in mouth opening resulting in loss of elasticity due to which tongue protrusion is hampered. However, the mean TP increase 5.47% from baseline (pre-treatment) to end of treatment (6 month). Though, the net increase of 5.47% in TP did not reach statistical significance but may be clinically significant. Another study conducted by Vrushi Zamare [15] *et al.*, in which better results were obtained with spirulina in conjunction with turmeric [15]. The improvement could be attributed to the fact that spirulina contains vitamin B group, carotene and trace elements which has antioxidant, anti-inflammatory properties.

In the present study the reason for getting clinically significant improvement in mouth opening and tongue protrusion but not statistically significant could be possibly due to smaller sample size and less period of follow up time. Even the tongue protrusion can be directly proportional to the mouth opening as it is affected by the elasticity of the oral tissues.

Thus, one thing that we can conclude from the above mentioned various studies that spirulina was the choice of medicament in all the above discussed studies

and in the study conducted by us there was statistically significant improvement in burning sensation whereas clinically significant improvement in mouth opening and tongue protrusion was observed thus portraying how effective spirulina is in management of oral submucous fibrosis.

5. CONCLUSION

Our study was primarily designed to estimate and figure out how effective can spirulina be in patients with OSMF. Oral sub mucous fibrosis is one of the most unsatisfactorily treated diseases. In the present study with the use of spirulina statistically significant results were obtained for burning sensation whereas clinically significant improvement was observed in mouth opening and tongue protrusion. This can be attributed to the antioxidant, anti-inflammatory, and immunomodulating properties, and high nutritional content presents in spirulina. But the compulsory requirement is patient due compliance, regular follow up, timely consumption of the drug and that it takes time to show result. But more studies and researches still need to be conducted for its significance to be legitimized.

REFERENCES

1. Rao, N. R., Villa, A., More, C. B., Jayasinghe, R. D., Kerr, A. R., & Johnson, N. W. (2020). Oral submucous fibrosis: a contemporary narrative review with a proposed inter-professional approach for an early diagnosis and clinical management. *Journal of Otolaryngology-Head & Neck Surgery*, 49(1), 1-11.
2. Gupta, S., & Jawanda, M. K. (2021). Laser as a promising non-invasive technique to treat oral submucous fibrosis: A systematic review of the literature. *The Saudi dental journal*, 33(7), 413-423.
3. Sheriff, A. H., & Dharman, S. (2019). Role of spirulina in the management of oral submucous fibrosis—A systematic review. *Drug Invention Today*, 10(8), 101-5.
4. Mulk, B. S., Deshpande, P., Velpula, N., Chappidi, V., Chintamaneni, R. L., & Goyal, S. (2013). Spirulina and pentoxifylline—A novel approach for treatment of oral submucous fibrosis. *Journal of clinical and diagnostic research: JCDR*, 7(12), 3048.
5. Desai, K. M., Hallikermath, S., & Kale, A. (2011). Spirulina: An emerging treatment modality for the management of oral submucous fibrosis. *Int J Oral Care Res*, 5, 328-31.
6. Devi, P., Singh, I., Setru, R., Tyagi, K., Singh, D., & Thiyam, B. (2015). Evaluation of hearing deficit in patients with oral submucous fibrosis. *Journal of oral science*, 57(2), 109-113.
7. Gupta, S., & Jawanda, M. K. (2021). Oral submucous fibrosis: An overview of a challenging entity. *Indian Journal of Dermatology, Venereology and Leprology*, 87(6), 768-777.

8. Pillai, R., Balam, P., & Reddiar, K. S. (1992). Pathogenesis of oral submucous fibrosis. Relationship to risk factors associated with oral cancer. *Cancer*, 69(8), 2011-2020.
9. Karkos, P. D., Leong, S. C., Karkos, C. D., Sivaji, N., & Assimakopoulos, D. A. (2011). Spirulina in clinical practice: evidence-based human applications. *Evidence-based complementary and alternative medicine*, 2011.
10. Anuradha, A., Patil, B., & Asha, V. R. (2017). Evaluation of efficacy of Aloe vera in the treatment of oral submucous fibrosis—a clinical study. *Journal of Oral Pathology & Medicine*, 46(1), 50-55.
11. Shetty, P., Shenai, P., Chatra, L., & Rao, P. K. (2013). Efficacy of spirulina as an antioxidant adjuvant to corticosteroid injection in management of oral submucous fibrosis. *Indian Journal of Dental Research*, 24(3), 347.
12. Sudarshan, R., Annigeri, R. G., & Sree Vijayabala, G. (2012). Aloe vera in the treatment for oral submucous fibrosis—a preliminary study. *Journal of oral pathology & medicine*, 41(10), 755-761.
13. Patil, S., Al-Zarea, B. K., Maheshwari, S., & Sahu, R. (2015). Comparative evaluation of natural antioxidants spirulina and aloe vera for the treatment of oral submucous fibrosis. *Journal of oral biology and craniofacial research*, 5(1), 11-15.
14. [https://www.worldwidejournals.com/international-journal-of-scientific-research-\(IJSR\)/recent_issues_pdf/2019/September/comparison-of-effectiveness-of-spirulina-and-lycopene-as-an-adjuvant-to-corticosteroid-triamcinolone-acetonide-injection-in-the-management-of-oral-submucous-fibrosis-randomized-controlled-trial_September_2019_1567256636_8505849.pdf](https://www.worldwidejournals.com/international-journal-of-scientific-research-(IJSR)/recent_issues_pdf/2019/September/comparison-of-effectiveness-of-spirulina-and-lycopene-as-an-adjuvant-to-corticosteroid-triamcinolone-acetonide-injection-in-the-management-of-oral-submucous-fibrosis-randomized-controlled-trial_September_2019_1567256636_8505849.pdf)
15. Zamare, V., Bhowate, R. R. Comparative Evaluation of the Effectiveness of Spirulina and Turmeric in the Management of Oral Submucous Fibrosis-Study Protocol.

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