

Efficacy of spirulina with isometric exercises in the management of oral submucous fibrosis

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Abstract

Background: Oral submucous fibrosis (OSMF) is a chronic inflammatory, potentially malignant oral disorder. Spirulina with its antioxidant, anti-inflammatory, and immunomodulating properties has shown promising results in the management of OSMF. Few studies involving isometric exercises are stated in literature as physiotherapy modalities for OSMF.

Aim: This study aims to evaluate the efficacy of spirulina with isometric exercises in the management of OSMF.

Materials and Methods: A study consisted of 15 clinically diagnosed OSMF patients. All patients were given spirulina 500 mg twice a day for 3 months. Patients were instructed to perform isometric mouth exercises for 20 min, twice daily. Patients were evaluated every 15 days for the assessment of clinical parameters. Results were analyzed with SPSS software.

Results: There was a significant reduction in burning sensation (59%) and increment of 3.2 mm in mouth opening with $P = 0.001$. The present study also showed significant improvement in cheek flexibility and tongue protrusion ($P < 0.05$).

Conclusion: Spirulina along with isometric exercises was well tolerated by patients. All the clinical parameters (burning sensation, mouth opening, tongue protrusion, and cheek flexibility) showed a statistically significant improvement. Thus, the present combined modality was non-invasive, cost-effective, and beneficial in the management of OSMF.

Introduction

Oral submucous fibrosis (OSMF) is a chronic premalignant condition, with high prevalence in developing countries like India. OSMF is mainly associated with the habit of chewing betel quid with areca nut and characterized by inflammation of oral mucosa and formation of fibrotic bands in the oral and perioral tissues, leading to restricted mouth opening. It affects an estimated 2.5 million people, mostly in Indian subcontinent with malignant transformation rate of 7–13%.^[1,2]

Various treatment modalities have been tried in the management of OSMF ranging from medicinal treatment, i.e., steroids, enzymes, antioxidants, lycopene, levamisole, turmeric, placental extract, etc., to surgical management stated in literature for relieving signs and symptoms, but there is no definite widely accepted treatment for the condition. Combination therapies including drugs and physiotherapy exercises have been said to be effective rather than the use of either drugs or physiotherapy alone.^[3]

Spirulina is fresh water microalgae known to exhibit antioxidant, anti-inflammatory, and immunomodulating properties along with its high nutritional content. Spirulina is considered as superfood as it contains phenolic acid, tocopherols, beta-carotene, and other

micronutrients. It has been successfully used in relieving signs and symptoms of OSMF and leukoplakia.^[4]

Various physiotherapy modalities such as isometric exercises, tongue blades, threaded tapered screws, and dynasplint have been successfully used in the management of OSMF. Physiotherapy restores the normal oral structure by increasing the vascularity, along with reversal of mucosal atrophic changes.^[5] Physiotherapy is generally considered the mainstay for the management of restricted mouth opening and is often used alone or in combination with other modalities. Hence, this study was taken up to evaluate the efficacy of spirulina with isometric exercises in the management of OSMF.

Materials and Methods

A total of 15 clinically diagnosed OSMF patients (based on history and characteristic of clinical examination) were enrolled in the study. The present clinical study was carried out at the Department of Oral Medicine and Radiology, College of Dental Sciences, Davangere. Patients who quitted or willing to quit the habit and not undergone any treatment for OSMF were included in the study while the

patients with coexisting systemic illness or had taken the treatment for OSMF were excluded from the study. Written informed consent was obtained from each patient. The study protocol was approved by the ethical committee of the institutional review board.

Patient's demographic data and clinical parameters, i.e., burning sensation, mouth opening, tongue protrusion, and cheek flexibility were recorded using structured pro forma. The intensity of burning sensation was measured using visual analog scale (VAS) of 1–10. Mouth opening was measured from the mesioincisal angles of maxillary central incisor to mandibular central incisor, using Vernier caliper. The patients were clinically classified based on the mouth opening into following groups:

- Stage I: >40 mm
- Stage II: 31–40 mm
- Stage III: 21–30 mm
- Stage IV: <20 mm.

Cheek flexibility (mm) was measured using Mathur and Jha method^[6] and tongue protrusion (mm) was recorded using Vernier caliper 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 3 months. Patients were instructed to perform isometric mouth exercises such as:

- Open their mouth until they perceive pain and then advised to hold for few seconds and relax.
- Put their fingers intraorally in the buccal mucosa and stretch for few seconds and relax.
- Blow their cheeks and advised to hold for few seconds.
- To push the dorsum of the tongue against the palate as hard as possible.
- To perform protrusive and lateral movements of tongue.

Patients were instructed to repeat these exercises twice daily for 20 min.

Baseline was considered as the clinical parameters recorded on the first visit. The patients were followed up every week for a minimum period of 6 weeks with seven readings for each patient from baseline to sixth visit. The patients were asked for any side effects of the drug. For intragroup comparison, paired *t*-test was used. For all the tests, *P* = 0.05 or less was considered for statistical significance.

Results

The mean age of the patients enrolled in the present study was 38.33 ± 12.79 years ranging between 20 and 70 years. Of 15 patients, 13 were male and 2 were female. Majority (93.33%) of patients were in Stage 3 while one (6.7%) belongs to Stage 1.

Patients reported mainly with the chief complaint of burning sensation and restricted mouth opening. Blanching of buccal and labial mucosa and palpable fibrous bands were shown in all the patients. Gutkha or areca nut (pan masala) chewing habit was present in all the patients. Of 15 patients, 7 (46.66%) patients chewed gutkha, 5 (33.3%) patients chewed areca nut (pan masala), and 3 (6.6%) patients chewed gutkha with areca nut (pan masala).

The mean VAS score for burning sensation at baseline was 6.4 ± 2.3 which was significantly reduced to 2.6 ± 1.7 with *P* = 0.001. The improvement in mouth opening was highly significant from 25.5 ± 4.9 mm at baseline to 28.8 ± 5.17 mm at sixth visit (*P* = 0.001). There was statistically significant mean improvement in tongue protrusion and cheek flexibility of 2.4 mm and 0.7 mm, respectively (*P* = 0.001) [Table 1 and Graph 1].

Discussion

All the OSMF patients lied in the spectrum of 20–70 years. The study demonstrated that maximum patients were above the third decade of their life which is in well consonance with various previous studies published in 2007 and 2012.^[7,8] This is due to cheap and easily available gutkha and pan masala products in nearby shops along with their aggressive campaigning and marketing in social media.

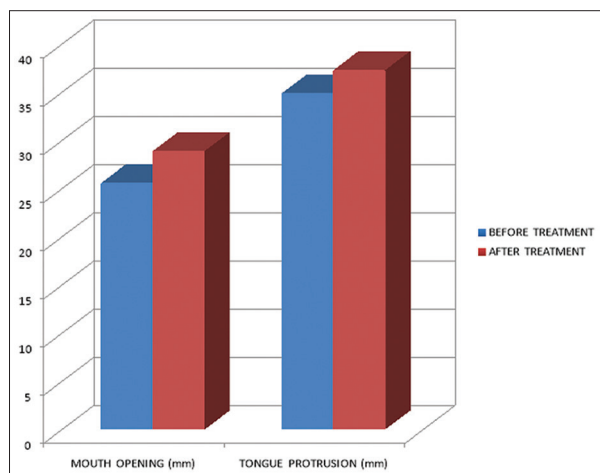
The present study showed male predominance with only two were female, which is in well accordance with diverse studies showing male predominance.^[9,10] High male-to-female ratio can be due to the reason that females are more conscious about their appearance and may feel uncomfortable to buy the products in market.

Burning sensation was a consistent feature in all (100%) of the patients which is in accordance with the study published in 2012 and 2014 stating that burning sensation was the major

Table 1: Comparison of clinical parameters from baseline to sixth visit

| Visits mean (SD) | Burning sensation (VAS) | Mouth opening (mm) | Tongue protrusion (mm) | Cheek flexibility (mm) |
|------------------|-------------------------|--------------------|------------------------|------------------------|
| Baseline | 6.4 (2.3) | 25.5 (4.9) | 34.8 (7.9) | 1.8 (0.5) |
| 1 | 5.9 (2.0) | 25.6 (4.8) | 34.9 (7.9) | 1.9 (0.5) |
| 2 | 5.6 (2.0) | 26.2 (4.7) | 35.3 (7.8) | 2.0 (0.6) |
| 3 | 4.9 (1.8) | 26.7 (4.9) | 35.8 (8.0) | 2.2 (0.6) |
| 4 | 4.2 (1.9) | 27.5 (4.9) | 36.3 (8.0) | 2.3 (0.6) |
| 5 | 3.5 (1.9) | 28.2 (5.3) | 36.9 (8.0) | 2.5 (0.7) |
| 6 | 2.6 (1.7) | 28.8 (5.1) | 37.2 (8.0) | 2.6 (0.7) |
| <i>P</i> value | 0.001* | 0.001* | 0.001* | 0.001* |

SD: Standard deviation, VAS: Visual analog scale. * *P*<0.05 were considered as significant



Graph 1: Comparison of mouth opening and tongue protrusion (mm) - before and after treatment

reason for visiting clinic in 95% and 93.3% of the patients.^[11] The present study showed a statistically significant improvement of 59% with successive follow-ups with complete diminution in three patients which is in well congruence with diverse studies with intralesional injections of triamcinolone acetonide and hyaluronidase, oxtard (71.6%), antoxid (86.6%), and black pepper along with *Nigella sativa* (78.91%). Studies with turmeric (87.90%) and pentoxifylline (86.6%) have shown better results than the present study.^[12-15]

The mean improvement in mouth opening stated in studies conducted on OSMF patients using spirulina was 0.35 mm, 5.75 mm, 4.1 mm, 5 mm, and 5.8 mm which is in congruence with the present study with a mean increment of 3.3 mm.^[4,16-19] Like above-mentioned studies, no side effects were observed. Various studies are stated in literature with significant mean improvement in mouth opening using levamisole (2.9 mm), micronutrients (2.9 mm), antoxid (3.1 mm), intralesional hydrocortisone with hyaluronidase and lycopene (3.4 mm and 5.38 mm), pentoxifylline with garlic pearls (5 mm), turmeric with tulsi (3–4 mm), turmeric with black pepper (3.8 mm), and intralesional dexamethasone with placental extract (3.5 mm) which is in favor of our study while studies published using intralesional INF-gamma (8 mm) and oxtard (12 mm) have shown better results.^[7,13,14,20-28]

The present study with isometric exercises is in consonance with the studies published on micronutrients with isometric exercises (3.1 mm), tongue blade (3.1 mm), and ultrasound (3.74 mm) and better results were shown in dynasplint (7 mm) and Therabite (10 mm).^[21,29-31]

The mean increment in tongue protrusion and cheek flexibility was 2.4 mm and 0.7 mm, respectively, which was comparable with topical *Aloe vera* gel, turmeric and black pepper, *Nigella sativa*, and pentoxifylline together.^[14,15,32]

Although the intralesional injections have shown good results in terms of mouth opening and in shorter time period, these treatment modalities are associated with the disadvantage of

pain, discomfort, invasiveness, lesser acceptability, and chances of post-treatment fibrosis.

Our treatment modality using isometric exercises has shown comparable results with the above-mentioned studies without any discomfort, having good patient compliance, safety, acceptability, and without any distress of post-treatment fibrosis. Physiotherapy is generally considered the mainstay for the management of restricted mouth opening and is often used alone or in combination with other modalities. Regular physical exercise resulted in improved muscle vascularity, increased muscle mass and protein metabolism, decreased muscle fatigability and increased strength, reversal of atrophic changes within the mucosa, and restoration of the normal structure.

Heterogeneous distribution of the patients was done in various clinical stages is the major limitation in the present study. In future, studies with homogenous distribution larger sample size, longer follow-ups, and in combination with various drugs should be recommended.

Conclusion

Spirulina along with isometric exercises was well tolerated by the patients with statistically significant improvement in all the clinical parameters. This can be attributed to the antioxidant, anti-inflammatory, and immunomodulating properties, and high nutritional content presents in spirulina along with the constant motivation to perform isometric exercises daily by the health professionals. Thus, the present combined modality was non-invasive, cost-effective, and beneficial in the management of OSMF.

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