

Potency and Accuracy of Spirulina in the treatment of Oral Submucous Fibrosis

¹Dr. Somi Fatima, Assistant Professor, Department of Oral Medicine and Radiology, Career post Graduate institute of Dental sciences and hospital, Lucknow, Uttar Pradesh, India.

²Dr. Nitin Agarwal, Professor & HOD, Department of Oral Medicine and Radiology, Career post Graduate institute of Dental sciences and hospital, Lucknow, Uttar Pradesh, India.

³Dr. Sudhir Shukla, Associate Professor, Department of Oral Medicine and Radiology, Career post Graduate institute of Dental sciences and hospital, Lucknow, Uttar Pradesh, India.

⁴Dr. Mohammad Umar, Assistant Professor of Department of Prosthodontics Crown and Bridge, Career post Graduate institute of Dental sciences and hospital Lucknow, Uttar Pradesh, India.

⁵Dr. Neha Agarwal, Associate Professor, Department of Oral Medicine and Radiology, Career Post Graduate Institute of Dental Sciences and Hospital, Lucknow, Uttar Pradesh, India.

⁶Dr. Krishan Kant Choudhary, Assistant Professor, Department of Oral Medicine and Radiology, Career post Graduate institute of Dental sciences and hospital, Lucknow, Uttar Pradesh, India.

Corresponding Author: Dr. Somi Fatima, Assistant Professor, Department of Oral Medicine and Radiology, Career post Graduate institute of Dental sciences and hospital, Lucknow, Uttar Pradesh, India.

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Abstract

Introduction: Oral Sub mucous fibrosis is well-recognised potentially malignant disorder affecting oral cavity and pharynx. It is most commonly seen in south east population since age's. There are many researches held in this field, its treatment still remains a challenge, in this short study we managing osmf with spirulina. Spirulina modulates the immune system favourably and it has strong anti-oxidant and anti-inflammatory effects.

Aim: To evaluate the potency and accuracy of Spirulina in the treatment of Oral sub mucous fibrosis.

Material and method: In this study we included 20 patient age between 20-40 year male and female both clinically diagnosed with OSMF to spirulina 500mg tab bd for a period of three months. All the patients were instructed to perform mouth opening physiotherapy exercises. At each visit parameters like relief in burning sensation, tongue protrusion, cheek flexibility, intra-incisal distance and there is no side effects of spirulina.

Results: At the end of three months, there were increases the values of cheek flexibility and intra-incisal distance and tongue protrusion and burning sensation.

Conclusion:- spirulina 500mg tab bd for a period of three months . it improve and provide relief from burning sensation but also result in increased mouth opening, tongue protrusion and cheek flexibility.

Keyword: spirulina, pre-malignant lesion, trismus, tongue protrusion, cheek flexibility, burning sensation

Introduction

Oral submucous fibrosis (OSMF), now globally accepted as an Indian disease, has one of the highest rates of malignant transformation amongst potentially malignant oral lesions and conditions. The history of this disease trails to antiquity when it was first described by Sushruta in 400B.C. It was first reported from India in 1953 and now has become an epidemic with 2.5 million people being affected per year with this disease¹. The hallmark of the disease is submucosal fibrosis that affects most parts of the oral cavity, pharynx and upper third of the esophagus leading to dysphagia and progressive trismus due to rigid lips and cheeks.

Pindborg et al., proposed a definition for OSMF which includes almost all its features, which says OSMF is “an insidious chronic disease affecting any part of oral cavity especially pharynx. Although it may be preceded and or associated with vesicle formation it is always associated with juxtaepithelial inflammatory reaction followed by fibroblastic changes of lamina propria with epithelial atrophy leading to stiffness of oral mucosa causing trismus and inability to eat.”²

Oral submucous fibrosis is a chronic debilitating and a well recognised potentially malignant condition associated with areca nut chewing, an ingredient of betel quid and is prevalent in South Asian population³. Oral Submucous fibrosis is diagnosed on the basis of clinical

criteria including oral ulceration, paleness of the oral mucosa and burning sensation (particularly in the presence of spicy foods), hardening of the tissue and presence of characteristic fibrous bands. The fibrosis involves the lamina propria and the submucous and may often extend into the underlying musculature resulting in the deposition of dense fibrous bands giving rise to the limited mouth opening⁴. The treatment of oral submucous fibrosis postulates a major challenge for oral physicians. There are various advancements in treatment modalities. osmf till date remains a disorder that causes irreversible and irreparable damage to the tissues. Thus the aim of this study to relieving the patient from various symptom of osmf like restricted mouth opening, burning sensation and tongue movement.

The treatment modalities have been tried to relieve these symptoms. It has been tried by both surgical and non-surgical approach.

Current medical treatment modalities include the use of micro-nutrients and minerals (Vitamin A, B complex, C, D, E, iron, copper, calcium, zinc, magnesium selenium etc.), lycopene, turmeric, interferon, steroids, placental extracts and physiotherapy. But each one has its own limitations⁵.

Pathologically, excessive deposition of collagen fibers leads to occluded blood vessels which in s turn lead to hyper-coagulability of blood. Hyper coagulated blood acts as an obstacle in the path of nutrients and therapeutic substances to reach the affected tissues⁶. This may be one of the prime reasons behind failure of drug treatment in OSMF. Extrapolating this reason. Spirulina 500mg tab bd for a period of three months.

Aim

The aim of the present study was determined the potency and accuracy of spirulina in treatment of oral sub mucous fibrosis

Material and Methods

Study design: The randomised clinical study was conducted in the Department of Oral medicine and radiology career dental college Lucknow, Uttar Pradesh, India from Oct 2017 to Jan 2019. The parameters are based on the clinical bases. Thus the study included 20 patients with clinically diagnosed by OSMF. There are no inclusion or exclusion criteria of this study because there is no side effects of spirulina prior to the study an informed written consent was requested from every participant. After the consent we taken the case history and patient divided according to their grade of OSMF to the criteria proposed by More CB et al. in 2012 which are as followed⁸.

Clinical

STAGE I (S1): Stomatitis and or blanching of oral mucosa.

STAGE II (S2): Presence of palpable fibrous bands in buccal mucosa and/or oropharynx with or without stomatitis.

STAGE III (S3): Presence of palpable fibrous bands in buccal mucosa and/or oropharynx and in any other part of oral cavity with or without stomatitis.

STAGE IV (S4)

a. Any one of the above stage with premalignant lesions like leukoplakia, oral erythroplakia etc.

b. Any of the above stages with oral carcinoma.

Functional

M1: Interincisal mouth opening is up to or more than 35mm.

M2: Interincisal mouth opening is between 25mm-35mm.

M3: Interincisal mouth opening is between 15mm-25mm.

M4: Interincisal mouth opening is less than 15mm.

Before proceeding with the treatment, blood pressure monitoring, pulse recording, and blood test performed

Parameters Studied

Base line value, tongue protrusion, cheek flexibility, burning sensation and intra- incisal distance, intra-incisal is the distance between the mesio-incisal angle of maxillary central incisor and mandibular central incisor of maximum mouth opening and burning sensation (using visual analog scale) were recorded. The intra-incisal distance is measured by keeping vernier caliper and asking the patient to open the mouth to the maximum and noted in millimeter, tongue protrusion is the distance between the mesio-incisal angles of mandibular central incisor to the tip of the tongue when maxillary extended with mouth wide open and the cheek flexibility is measured as the distance between two point marked on the ala tragus line, if we divided the ala tragus line in the three equal halves, then V2 is point marked at 1st one-third from angle of mouth and V1 is the same point when the patient instructed to below his cheeks flexibility (V2-V1) and burning sensation is the subjective assessment of the patient pain expressed in term of 0-10 rated numeric scale, when 0 means no pain and 10 means maximum pain.

Treatment Modalities

The patient were given: spirulina 500mg tab bd for a period of three months improvement in mouth opening, tongue protrusion, relief in burning sensation and cheek flexibility 20 patient age between (20 – 60 year both sex). All the patient were instructed to performed mouth opening physiotherapy exercise at home.

Assessment for Potency of Treatment

At each follow up visit improvement in mouth opening tongue protrusion, relief in burning sensation and cheek flexibility was measured and recorded in proforma.

Assessment For Accuracy

Careful monitoring of patient was done by investigator during and after given the spirulina 500mg tab and proper

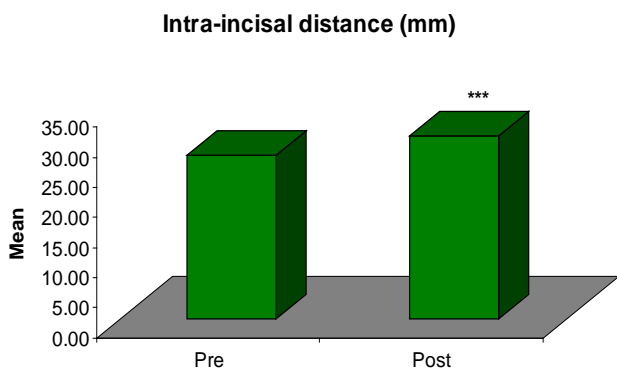
investigate each and every step following the treatment and seen the any improvement in mouth opening, tongue protrusion, relief in burning sensation and cheek flexibility side effect due to the drug if the any side effect were noted in the proforma and appropriate treatment given.

Statistical Analysis

B. OSMF

Intra-incisal distance: The pre and post intra-incisal distance (mm) of OSMF patients is summarised in Fig. 1. The intra-incisal distance of patients at pre ranged from 15 to 36 mm with mean (\pm SE) 25.10 ± 1.40 mm and median 26 mm whereas at post it ranged from 16 to 38 mm with mean (\pm SE) 28.38 ± 1.40 mm and median 31 mm. The intra-incisal distance increased (improved) comparatively at post as compared to pre.

Comparing the pre and post intra-incisal distance, paired t test showed significant increase (improvement) in intra-incisal distance (8.5%) at post as compared to pre (25.20 ± 1.60 vs. 28.40 ± 1.40 , $\text{diff.} = 1.20 \pm 0.17$, 93% CI of $\text{diff.} = 1.61$ to 1.59 , $t = 15.15$, $p < 0.001$) Fig-1)



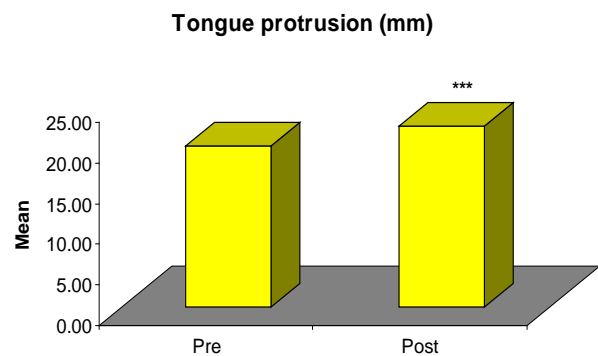
***p<0.001- as compared to Pre

Fig. 1: Comparison of pre and post mean intra-incisal distance of OSMF patients.

Tongue protrusion: The pre and post tongue protrusion (mm) of OSMF patients is summarised in Fig 2 . The tongue protrusion of patients at pre ranged from 11 to 26 mm with mean (\pm SE) 17.70 ± 0.63 mm and median 10

mm whereas at post it ranged from 13 to 29 mm with mean (\pm SE) 20.38 ± 0.95 mm and median 20 mm. The tongue protrusion increased (improved) comparatively at post as compared to pre.

Comparing the pre and post tongue protrusion, paired t test showed significant increase (improvement) in tongue protrusion (9.2%) at post as compared to pre (17.70 ± 0.63 vs. 20.38 ± 0.71 , $\text{diff.} = 1.50 \pm 0.15$, 95% CI of $\text{diff.} = 1.12$ to 1.64 , $t = 12.47$, $p < 0.001$)



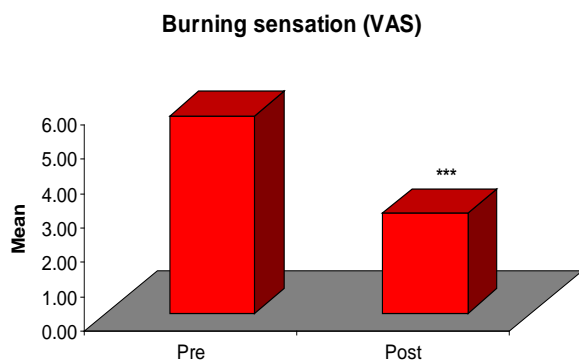
***p<0.001- as compared to Pre

Fig. 2: Comparison of pre and post mean tongue protrusion of OSMF patients

Burning sensation

The pre and post burning sensation (VAS) of OSMF patients is summarised in Fig. 3. The burning sensation of patients at pre ranged from 0 to 6 with mean (\pm SE) 3.53 ± 0.25 and median 4 mm whereas at post it ranged from 0 to 4 with mean (\pm SE) 1.70 ± 0.25 and median 2. The burning sensation decreased (improved) comparatively at post as compared to pre.

Comparing the pre and post burning sensation, paired t test showed significant decrease (improvement) in burning sensation (27.6%) at post as compared to pre (3.53 ± 0.25 vs. 1.70 ± 0.25 , $\text{diff.} = 1.63 \pm 0.10$, 93% CI of $\text{diff.} = 1.11$ to 1.24 , $t = 5.23$, $p < 0.001$) .



***p<0.001- as compared to Pre

Fig. 3: Comparison of pre and post mean burning sensation of OSMF patients

Discussion

In this study, we tried to investigate the potency and accuracy of Spirulina in treatment of OSMF. OSMF is a complex precancerous condition of oral cavity. It is considered as major oral health problem with high degree of malignant potential. Lack of a specific treatment modality pose a greater challenge in treating this condition. Spirulina is a one of them. Spirulina is blue green algae with rich natural source of proteins, carotenoids and other micronutrients⁹. It has been primarily assessed in treating leukoplakia with promising results. The chemo preventive capacity to reverse precancerous lesions of spirulina is attributed to the antioxidant property with high amount of beta carotene and superoxide dismutase. The present study is the first of its kind in which spirulina has been tried in oral submucous fibrosis¹⁰. Highly significant results were obtained with all three parameters namely burning sensation, mouth opening and tongue protrusion. When efficacy of Spirulina, statistically insignificant results were found for 3 month opening and tongue protrusion, cheek flexibility, tongue protrusion. However the difference for burning sensation was statistically significant. Spirulina performed better with patient showing more satisfaction as the subjective symptom was

reduced. It also showed no side effects which was similar to the study by Mathew et al^{11,12}. Spirulina has emerged as the wonder food supplement. Several leading organizations are utilizing this beneficial action¹³. Very few adverse effects have been reported with the use of spirulina which include headache, muscle pain, flushing of the face, sweating and difficulty in concentrating. Skin reactions have also been reported in some individuals, there are various study has been tried in the management of osmf¹⁴. The potential health benefits of spirulina must be adequately recognized and implemented thus making full use of this nature's gift Conventional therapies include intralesional injections of corticosteroids, placental extracts, hyaluronidase, physiotherapy and surgery]¹⁵. The effect of spirulina in 20 osmf patient. Patient relief burning sensation and improve intra incisal distance and mouth opening and cheek flexibility. However Spirulina are found to be effective in the management of Oral sub mucous fibrosis

Limitation

In this study we propose spirulina as an efficacious cost effective and safe drug for recalcitrant cases of Osmf and the two major limitations less number of patient and lack of Histopathologic confirmation.

Conclusion

Spirulina given the promising results .it relief the burning sensation and improved in cheek flexibility, mouth opening, tongue protrusion and also intra-incisal distance. The potency and accuracy of Spirulina is satisfactory in OSMF patient

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