ABSTRACT

Objectives: The study was conducted to assess the efficacy of lycopene in the treatment of oral submucous fibrosis (OSMF) among patients visiting Dental College in Jaipur, Rajasthan, aged 15 years and above.

Materials and methods: Twenty OSMF patients were randomly divided into two groups A and B. Group A, patients received combination of lycopene (16 mg) in divided doses. Group B, patients received combination of multivitamin preparation. Treatment outcome was evaluated on the basis of improvement in symptom score, sign score. The statistical analysis was done with SPSS software, version 11.5.

Results: The result showed that OSMF patients receiving lycopene have more improvement in burning sensation and with some improvement in mouth opening.

Conclusion: The observations and findings of the study clearly indicate that efficacy of lycopene is higher compared to multivitamin preparation.

Keywords: Treatment, Oral submucous fibrosis, Lycopene, Multivitamin preparation.


INTRODUCTION

Oral submucous fibrosis (OSMF) has a very interesting history. Sushruta, a renowned Indian physician who lived in the era from 2500 to 3000 BC, had already recognized it as a mouth and throat malady and had labeled it as Vidhari. The features of which were described as a progressive narrowing of the mouth, blanching of the oral mucosa, pain and burning sensation on taking food, hypomobility of the soft palate and tongue, loss of gustatory sensation and occasional mild hearing impairment due to the blockage of the eustachian tube. There has been nearly no change in these symptoms till today.1-4

The World Health Organization (WHO) definition for an oral precancerous condition ‘A generalized pathological state of the oral mucosa associated with a significantly increased risk of oral cancer’, accords well with the characteristics of OSMF. The disease is predominantly seen in India, Bangladesh, Sri Lanka, Pakistan, Taiwan, Southern China and other countries.5-8

People visiting Outpatient Department, NIMS Dental College, Jaipur, Rajasthan, commonly use areca nut and tobacco products like mawa, pan, gutkha and khaini, etc. and some of them were suffering from OSMF.

Lycopene is a safe antioxidant of utmost importance. Lycopene is a bright red carotene and carotenoid pigment and a phytochemical found in tomatoes and other red fruits and vegetables, such as red carrots, watermelons and papayas. Preliminary research has shown an inverse correlation between the consumption of tomatoes and cancer risk. It has been shown to have several potent anticarcinogenic and antioxidant properties and has demonstrated profound benefits in precancerous lesions, such as leukoplakia. Lycopene exhibits the highest physical quenching rate constant with singlet oxygen.9,10

The main aim and objective of this study was to evaluate the clinical response of OSMF to the antioxidant lycopene.

MATERIALS AND METHODS

A cross-sectional study was conducted in Outpatient Department, NIMS Dental College and Hospital, Jaipur, Rajasthan. Total of 20 patients diagnosed with OSMF were divided equally into treatment groups A and B.

Subjects aged 15 years and above who were willing to participate were included in the study. Subjects with any systemic diseases and malignancy were excluded from the study. An ethical clearance was obtained from ethical committee of NIMS Dental College and Hospital, Jaipur. Oral consent was obtained from each participant prior to the study.

The examination was done by principal examiner and trained recording clerk was present to record the data in the predesigned proforma. The clinical diagnosis of OSMF was made when subject showed characteristic features of OSMF, blanching and stiffness of the oral mucosa, presence of palpable bands in the buccal or labial mucosa and difficulty in mouth opening and protruding the tongue.11-13

In this study, the clinical parameters that were evaluated are as follows:14

1. Symptomatic relief in the form of absence of burning sensation in the mouth and spontaneous healing of the ulcers when present.
2. Change in the color of the mucosa and its texture.
3. Improvement in mouth opening.

Patients in group A received lycopene (LycoRed, Jagsonpal Pharmaceutical Company, New Delhi, India) capsule containing 100% natural lycopene with zinc, selenium and added phytonutrients, which was given 16 mg in two divided doses and those in group B received multivitamin preparation (Revital, Ranbaxy Laboratories Limited) twice daily for a time period of 4 months from July 2010 to October 2010. Treatment responses are assessed clinically by bimonthly evaluation with clinical examination.

The responses were classified as follows:14

1. Complete
   • When the color of the mucosa turned from blanched white to normal pale pink.
   • When there was a definite improvement in the burning sensation, which reduced to an appreciable extent.
   • When there was an increase in the mouth opening which ranged from 2 to 3 mm.
2. Partial
   • When there was a partial improvement in the above said signs and symptoms and the mouth opening was increased by 0.4 to 1 mm.
3. Stable
   • When there was no response and no improvement.
4. Disease progression
   • When there was a progressive increase in the signs and symptoms in spite of having undergone the treatments.

Armamentariums used were measuring calliper, sterile mouth mirror, explorer, tweezers, kidney tray instrument pouch, savlon, disposable surgical latex gloves, disposable mouth mask and questionnaires. The statistical analysis was done with SPSS software, version 11.5.

RESULTS

Table 1 shows distribution of patients in group A which were treated with lycopene. Out of all the patients there were seven male patients and three female. The patients treated with lycopene, eight patients showed complete response to the treatment and two patient showed partial responses.

Table 2 shows distribution of patients in group A which were treated with lycopene. Out of all the patients there were six male patients and four female patients. The patients treated with multivitamin preparation, three patients showed complete response to the treatment and four patient showed partial response and three patients were stable.

Table 3 shows the response data of patients in groups A and B which were treated with lycopene and multivitamin preparation. Of the patients treated with lycopene, 80% showed complete response to the treatment and 20% patient showed partial response compared with patients in group B which showed 30% complete, 40% partial and 30% stable response.

DISCUSSION

OSMF is a disease associated with the habit of betel nut chewing and it is characterized by extensive collagen deposition in the soft tissues of the mouth. Various researchers, in their studies on the mutagenic properties of areca nuts have found that the constituents and the extracts of the nuts cause chromosomal aberrations and DNA damage. In the review of literature, starting from Pay Master, 1959 to JN Khanna, 1995, everyone is of the opinion that submucous fibrosis is a precancerous condition with a malignant transformation rate which varies from 3 to 7.6%.15-17

The present study shows improvement in mouth opening and burning sensation in patients which were treated with lycopene compared with patient receiving multivitamin preparation. The patients treated with lycopene showed 80% complete response to the treatment and 20% patient showed partial response.

OSMF is an incurable disease. No treatment modality, either surgical or medical has been successful in completely

| Table 1: Patients of group A (lycopene) having OSMF: Pretreatment and post-treatment |
|---|---|---|---|---|
| S. no. | Age/sex (mm) | Mouth opening | Improvement (mm) | Burning sensation |
| | | Prior to treatment | Post-treatment | Prior to treatment | Post-treatment | Response |
| 1. | 17/M | 27 | 30 | 3 | Severe | Subsided | Complete |
| 2. | 25/M | 15 | 17 | 2 | Moderate | Subsided | Complete |
| 3. | 27/M | 20 | 22 | 2 | Severe | Subsided | Complete |
| 4. | 25/F | 16 | 16 | 1 | Mild | Subsided | Complete |
| 5. | 29/M | 18 | 20 | 2 | Moderate | Subsided | Complete |
| 6. | 37/M | 17 | 19 | 2 | Severe | Subsided | Complete |
| 7. | 31/F | 29 | 33 | 4 | Mild | Subsided | Complete |
| 8. | 34/M | 19 | 20 | 1 | Moderate | Reduced | Partial |
| 9. | 33/M | 20 | 21 | 1 | Moderate | Subsided | Complete |
| 10. | 22/F | 18 | 20 | 2 | Severe | Subsided | Complete |
eliminating the disease. In view of the strong relationship between oral cancer and precancerous lesions, chemoprevention is said to be feasible and practicable. A safe and simple mode of treatment as described in this study, along with proper habit restriction is required in OSMF to ensure that the progression of the disease is retarded and that maximum relief is obtained by the patient.16,17

Other treatment modalities are extensive and include the use of micronutrients and minerals, carbon dioxide laser, pentoxifylline, interferon-γ, turmeric, hyalase, chymotrypsin and collagenase. As fibrosis cannot be reversed, when mouth opening is severely limited surgical interventions, such as myotomy, coronoidectomy and excision of fibrotic bands, are required. Reconstruction using such techniques as buccal pad flap, superficial temporal flap and forearm flap can also be performed. Alternative procedures, such as insertion of an oral stent, physiotherapy, local heat therapy, mouth exercises using acrylic carrots and ice cream sticks, have been tried with variable rates of success. In most cases, depending on the stage of disease and extent of oral involvement, therapy consisting of a combination of the above-mentioned drugs and surgery might be used.18-20

**CONCLUSION**

A positive clinical response was seen in study groups in this study when compared with multivitamin. Lycopene was seen to be efficacious as a safe, reliable drug in the management of OSMF. In contrast to other management modalities for submucous fibrosis, it offers a noninvasive option that yields significant improvements in the symptoms as well as objective signs of the condition.

This was a short-term study with a small sample size. A long-term study with a larger sample size with all the above variables being taken into consideration would be necessary to get a clear picture about the utility of the drug.

**REFERENCES**


**Table 2:** Patients of group B having OSMF: Pretreatment and post-treatment

<table>
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<tr>
<th>S. No</th>
<th>Age/sex</th>
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**Table 3:** Response data

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<td>Progression</td>
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<td>–</td>
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</tbody>
</table>
An in vivo Study to determine the Efficacy of Lycopene as compared to Multivitamin Preparation in the Treatment


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