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# "ROLE OF LYCOPENE & OTHER NUTRIENTS IN TREATMENT OF ORAL SUBMUCOUS FIBROSIS – A CLINICAL STUDY"

[1]Dr Ashish Bhaskar Zope, [2]Dr Lata Madhukar Kale, [3]Dr Jyoti Dasharath Magare, [4]Dr Aishwarya Madhukar Kale

[1]PhD Scholar, Lecturer, Department of Oral Medicine and Radiology, Chhatrapati Shahu Maharaj Shikshan Sanstha's Dental College and Hospital, Chhatrapati Sambhajinagar, MS

[2]Dean, Professor and HOD, Department of Oral Medicine and Radiology, Chhatrapati Shahu Maharaj Shikshan Sanstha's Dental College and Hospital, Chhatrapati Sambhajinagar, MS

[3]Professor, Department of General Pathology and Microbiology, Chhatrapati Shahu Maharaj Shikshan Sanstha's Dental College and Hospital, Chhatrapati Sambhajinagar, MS

[4]Periodontist, Private Practitioner, Chhatrapati Sambhajinagar, MS

***Abstract:*** Aim: To study the effects of multidrug therapy in Oral Submucous Fibrosis patients. Study Design: 30, Oral Submucous Fibrosis patients were selected based on clinical criteria of mouth opening. They were administed capsules containing lycopene, selenium, zinc, selenium, manganese, copper etc., to be consumed once a day, in evening, after meals for a month. After a month they were recalled for checking the improvement in mouth opening. Results: 19 patients out of 30 displayed increment in mouth opening at follow up appointments. Conclusion: A positive clinical response was seen in patients in this study.

**Keywords:** Oral Submucous Fibrosis, inter incisal distance, lycopene.

## I. INTRODUCTION

Oral submucous fibrosis (OSMF) is a precancerous condition of the oral cavity. If it is not treated promptly, it may progress to invasive squamous cell carcinoma. Some habits like smoking, pan chewing and tobacco addiction in other forms, are causing various diseases, the major ones being OSMF, leukoplakia and erythroplakia. Free radicals have more recently emerged as mediators of other phenotypic and genotypic changes that lead from mutation to neoplasia. The role of free radicals in the various oxidation processes in the body has lead to the identification of antioxidants in inhibiting and reversing the disease process. Lycopene is a safe antioxidant & is very important. It is a bright red carotene, carotenoid pigment and phytochemical. It is mainly found in tomatoes and other red fruits and vegetables, such as red carrots, watermelons and papayas.[1]

Dietary intakes of tomatoes and tomato products containing lycopene are associated with decreased risk of chronic diseases such as cancer.[2]

Lycopene is a safe drug in the management of OSMF. It is a noninvasive option, resulting in significant improvements in the symptoms as well as objective signs of the condition. It should therefore be used as a first line drug that would increase the motivation and compliance of patients with this debilitating condition.[3]

## II. Materials & Methods:

Ethical clearance for the study was obtained from Institutional Ethical Committee (CSMSS/DCH/EC/SS/24/2022). The study included 30 participants, having stage 2 OSMF[4], visiting OPD of Dental College, selected by convenience sampling[5]. A written consent was obtained from all of them. The participants were aged between 18 to 65. There were no gender restrictions for the participants. They were dispensed capsule Mrich Vita (Mensa Futura, Gurugram, Gurgaon), to be consumed once a day in the evening, after meals for a month. The patients were recalled after a month & improvement in symptoms.

## III. Mouth Opening:

Mouth opening was assessed by measuring the interincisal distance from the mesioincisal edge of the maxillary right central incisor to the mesioincisal edge of the mandibular right central incisor using vernier callipers. Mouth opening was recorded before the start of the treatment and after 1 month follow up.

## IV. Statistical Analysis:

The paired t test was carried out online. The two tailed P value was less than 0.0001. By conventional criteria, this difference was considered to be extremely statistically significant.

## V. Results:

19 patients out of 30 displayed increment in mouth opening at follow up appointments.

## VI. Adverse Effects:

No adverse effects were reported during the treatment period as well as during follow-up.

## VII. Discussion:

Lycopene is a powerful antioxidant obtained from tomatoes. It has been shown to inhibit various types of cancers and has been shown to have potent benefits in oral premalignant lesions such as leukoplakia, where it has been shown to modulate dysplastic changes[6]. This study evaluated the efficacy of lycopene in the management of oral submucous fibrosis. OSMF is an incurable disease. No treatment modality, either surgical or medical has been successful in completely eliminating the disease. In view of the strong relationship between oral cancer and pre cancerous lesions, chemo-prevention 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[1]. Many authors are of the opinion that conservative treatment is preferable than the conventional ones[7].

## VIII. Conclusion:

A positive clinical response was seen in patients in this study. Lycopene was seen to be a safe, reliable drug in the management of oral submucous fibrosis. It is a noninvasive option as compared to other treatment modalities and it yields significant improvement in the condition. Hence it should be used as a first line drug that would further motivate the patients with this debilitating condition to comply with the treatment. Further trials in this regard should be carried out to investigate the mechanisms by which lycopene exerts it's effect, with different dosages and over other time frames.

## IX. Sources of Funding:

Nil.

## X. Conflict of Interest:

Nil.

## XI. Figure & Table:

Measurement of interincisal distance.

| Sr. no. | M/F | Inter incisal distance (mm) | |
|---|---|---|---|
| | | Pre | Post |
| 1 | M | 48 | 49 |
| 2 | M | 45 | 47 |
| 3 | M | 27 | 28 |
| 4 | M | 27 | 29 |
| 5 | M | 25 | 26 |
| 6 | M | 35 | 35 |
| 7 | M | 30 | 31 |
| 8 | M | 30 | 30 |
| 9 | M | 22 | 23 |
| 10 | M | 27 | 28 |
| 11 | M | 30 | 30 |
| 12 | M | 25 | 26 |
| 13 | M | 27 | 27 |
| 14 | F | 30 | 32 |
| 15 | M | 22 | 22 |
| 16 | M | 27 | 27 |
| 17 | M | 20 | 21 |
| 18 | M | 20 | 22 |
| 19 | F | 31 | 32 |
| 20 | M | 29 | 29 |
| 21 | M | 28 | 28 |
| 22 | M | 30 | 31 |
| 23 | M | 29 | 29 |
| 24 | M | 30 | 31 |
| 25 | M | 31 | 32 |
| 26 | M | 32 | 33 |
| 27 | M | 29 | 29 |
| 28 | M | 30 | 31 |
| 29 | M | 29 | 29 |
| 30 | M | 30 | 31 |

Pre & post treatment difference in interincisal distance.

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