

## **ASSESSMENT IN THE EFFICACY OF LYCOPENE CAPSULES IN ORAL SUBMUCOUS FIBROSIS.**

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### **ABSTRACT**

Oral Submucous Fibrosis is a chronic debilitating disorder affecting the oral cavity, pharynx and the upper digestive tract. The present research assesses the role of Lycopene capsules in the management of Oral Submucous Fibrosis considering various parameters like improvement in mouth opening and reduction in burning sensation in the oral cavity on 30 patients. The study concluded that the administration of Lycopne capsules showed improvement in mouth opening and decrease in the burning sensation in the oral cavity.

**KEYWORDS:** Oral Submuocus Fibrosis, Lycopene Capsules.

### **INTRODUCTION**

Oral Submucous Fibrosis is defined as an insidious, chronic disease which affects any part of the oral cavity and sometimes the pharynx<sup>[1]</sup> and is occasionally preceded by and/or associated with vesicle formation<sup>[2]</sup> and is always associated with a juxta-epithelial inflammatory reaction which is followed by progressive hyalinization of the lamina propria<sup>[3]</sup> leading to stiffness of the oral mucosa and deeper tissues with progressive limitation in opening of the mouth and protrusion of the tongue leading to difficulty in eating, swallowing and phonation.<sup>[3,4]</sup>

It is a precancerous condition seen most commonly in the Indian sub-continent and has a reported incidence of between 0.2–1.2% of the urban population who attend the dental clinic and the condition shows a female:male predilection of 3:1 and characteristically first presents in adulthood between the ages of 45–54 years.<sup>[5]</sup>

The etiology is multifactorial origin for this condition and the various hypothesis implicated include the role of local irritants such as capsaicin<sup>[6]</sup>, tobacco<sup>[7]</sup>, areca nut<sup>[8-12]</sup>, pungent and spicy foods<sup>[13]</sup> and alcohol<sup>[14]</sup>, iron and vitamin B-complex deficiency, anaemia<sup>[15]</sup> and a genetic predisposition to the disease.<sup>[12]</sup>

There are different treatment modalities for this condition, here one such treatment modality in the form of administration of antioxidants in the form of Lycopene capsules was carried out on 30 patients who attended the Outpatient Department of OMR.

**Aim of the study:** To assess the efficacy of Lycopene capsules in the management of patients with Oral Submucous Fibrosis.

## MATERIALS AND METHODS

### Source of data.

Thirty (30) adult patients who enrolled with signs and symptoms of OSMF were included in the study. Following parameters were included in the establishment of diagnosis and these 2 parameters were satisfied for inclusion in the study. A. Positive history of chewing of areca nut or one of its commercial preparations, difficulty in chewing and swallowing, and having burning sensation on eating spicy food. B. Restricted mouth opening.

Following establishment of diagnosis, each patient was informed about the condition, its precancerous potential and advised to discontinue use of areca nut in all forms. A detailed case history including habit of history with details of duration, in years, frequency of chews per day was taken. All patients underwent oral prophylaxis to remove extrinsic stains, in order to motivate the patient towards recovery and to inform the investigator if patient resumes habit. Each patient was screened for diagnosis and inclusion, examined on three occasions, day 1 which is the first day of starting treatment, day 30, day 60, day 90 which is the fourth and last day of evaluation. Each patient was administered Lycopene 4 mg capsules, 2 capsules twice a day for 90 days.

**Method of data collection**

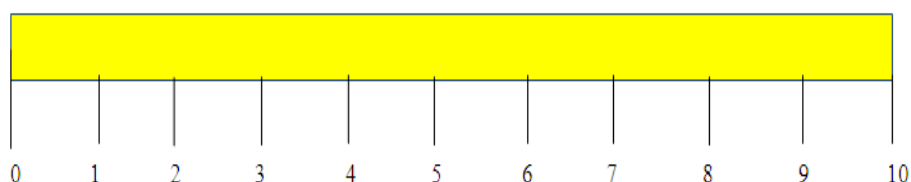
Patients were evaluated for the following criteria

1. Mouth opening based on interincisal separation: Distance between the upper and lower central incisors when maximally extended with mouth wide open. Normal values: Males-35-45 mm. Females-30-42 mm.



**Figure 1.**

2. Burning sensation present or not and if so, degree to be determined by use of a Verbal Analogue Scale.(VAS).

**VERBAL ANALOGUE SCALE FOR BURNING SENSATION**

0 – Absent

1 - Occasional

2 - Slight on eating hot and spicy

3 - Frequent during meals

4 - Frequent during and between meals

5 - Moderate

6 - Continuous on stimulation

7 - Almost continuous

8 - Continuous

9 - Severe

10 - Intolerably severe

### Inclusion Criteria

Patients suffering from chronic oral mucous fibrosis lesions characterised by burning sensations in the mouth, particularly while taking hot and spicy foods. Adult patients of either sex aged between 18-50 years were included. Patients who had not participated in a similar investigation in past four weeks. Patient willing to give a written informed consent and follow the schedule.

### Exclusion criteria

Patients suffering from severe systemic disorders pertaining to cardiac, respiratory, central nervous system, renal or hepatic disorders. Patient who have participated in a similar clinical investigation in the past four weeks. Patient who has used a similar product in the past four weeks. Patients who refused to sign informed consent. Patients having a known history or present condition of allergic response to similar pharmaceutical products, pre-existing systemic disease necessitating long-term medications and pregnant and lactating women were excluded from the study.

### Method of data analysis.

Results were analysed statistically by means of a paired t-test analysis.

## RESULTS

**Table No.1: Distribution of Mean And Sd Values of Mouth Opening (Mm) At Day 0, At Day 30, At Day 60 And At Day 90.**

Duration	Mouth Opening(mm) (n=30)	Student's Paired 't' test value	'p' value	Significance
	Mean $\pm$ SD			
Day 0	28.19 $\pm$ 7.80	50.11	p<0.01	Highly significant
Day 30	29.23 $\pm$ 7.86			
Day 60	30.04 $\pm$ 8.02			
Day 90	30.66 $\pm$ 8.07			

By applying Student's Paired 't' test there is a highly significant increase in mean mouth opening (mm) from starting treatment i.e. day 0 to last day of evaluation i.e. day 90 (p<0.01). The average increase is 2.46 mm $\pm$ 1.08 mm.

**Table No.2: Distribution of Mean And Sd Values of Burning Sensation (Vas) At Day 0, At Day 30, At Day 60 And At Day 90.**

Duration	Burning Sensation (VAS) (n=30)	Student's Paired 't' test value	'p' value	Significance
	Mean $\pm$ SD			
Day 0	2.97 $\pm$ 0.96	73.26	p<0.01	Highly significant
Day 30	2.77 $\pm$ 0.93			
Day 60	2.27 $\pm$ 0.90			
Day 90	2.03 $\pm$ 0.88			

By applying Student's Paired 't' test there is a highly significant decrease in mean **Burning Sensation (VAS)** from starting treatment i.e. day 0 to last day of evaluation i.e. day 90 (p<0.01). The average decrease is 0.94 mm $\pm$ 0.02 mm.

## DISCUSSION

Oral submucous fibrosis is a precancerous condition affecting the buccal mucosa of the oral cavity most commonly leading to marked rigidity and inability to eat<sup>[16,17]</sup> however any part of the oral cavity may be involved including the pharynx<sup>[18]</sup> eventually leading to decrease in mouth opening.

Malignant transformation rate of OSMF is as high as 7.6% in a study conducted in the Indian subcontinent over a 17 year period.<sup>[19]</sup> Treatment options include initially stoppage of habit followed by avoidance of spicy food and ingestion of chillies followed by intralesional steroid injections, placental extracts, pentoxifylline, lycopene, surgical excision and laser therapy<sup>[17]</sup> can be used to a greater effect in reducing the signs and symptoms of OSMF.

Lycopene is an effective antioxidant from tomato extract and has been proved to be the most potent radical scavenger. It has the mechanism of action like antioxidant activity, inhibition of cancer cell proliferation, restoration of gap junctions, regulation of transcription, interfere with growth factor. It was successfully tried in leukoplakia where it has given excellent and favorable results. It is also used in lichen planus, oral cancer, gingivitis, diabetes, AIDS and periodontitis. It is a potent anticarcinogenic and has demonstrated profound benefits in precancerous lesions and conditions. Abhinav Kumar et al that there was marked improvement in mouth opening and in noticeable reduction of burning sensation in OSMF patients with help of lycopene treatment than patients treated with placebo. This curative effect of lycopene may be due to inhibition of abnormal fibroblasts, up regulation of lymphocyte resistance to stress and suppression of inflammatory response.<sup>[16]</sup>

Sunderaj et al (2012) conducted a study in subjects receiving 16 mg lycopene in divided doses and assessed bimonthly for four months. and found overall average improvement in mouth opening was 2 mm. There was reduced burning sensation. As compared to our study we done study on 30 subjects receiving 16 mg lycopene in divided doses for three months with bimonthly follow up. In our study we found that there was reduced in burning sensation in all subjects and improvement in mouth opening.<sup>[17]</sup>

## SUMMARY AND CONCLUSION

In this study the efficacy of Lycopene capsules was evaluated in 30 OSMF patients. Lycopene capsules due to its special antioxidant properties were found to be effective in the improvement of signs and symptoms of Oral Submucous Fibrosis. It is effective in reducing the objective signs of OSMF thereby improving the mouth opening (percentage of which was 8.05%) and decreasing the burning sensation (percentage of which was 31.54%). Thus, it can be concluded that Lycopene capsules appear to be a very promising drug in the improvement of the symptoms and management of Oral Submucous Fibrosis.

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