

EFFICACY OF SPIRULINA CAPSULES AS AN ADJUVANT IN MANAGEMENT OF  
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## ABSTRACT

**Aim:** A premalignant lesion which is closely associated with tobacco usage is oral leukoplakia. Evaluating the efficacy of spirulina algae capsules (500 mg) as an adjuvant in the management of oral leukoplakia. **Materials and Methods:** The study comprised 20 patients with a clinical diagnosis of oral leukoplakia. Over the course of 21 days, patients received 500 mg spirulina oral capsules, and clinical parameters were assessed at day 0, 7, 14, and 21 intervals. Chi square was used for data analysis. P value was set at 0.005. **Results:** Post hoc test showed statistically significant improvement ( $p=0.000$ ) of the mean rank of all parameters from day 0 to day 21. **Conclusion:** Higher lesion severity aligns with elevated burning sensation suggesting that lesion progression intensifies sensory symptoms. This study shows clinically significant improvements in the symptoms like burning sensation, inflammatory signs and size of lesion with Spirulina (500 mg) oral capsules as an adjuvant.

## INTRODUCTION

Leukoplakia is a mysterious yet significant condition, often manifesting as white patches on the mucous membrane, particularly in the mouth. While these patches may appear harmless at first glance, sometimes signalling the potential for more serious health concerns.<sup>[1]</sup> With its presence, leukoplakia serves as a silent reminder of the body's complex response to irritation, such as from tobacco alcohol or dental issues. In 1994, WHO defined as a predominantly white lesion of oral mucosa that cannot be characterized as any other definable lesion clinically or pathologically, often associated with tobacco products, some of which will transform into cancer.<sup>[2,3]</sup> Other well-known etiological features of oral leukoplakia are alcohol, microbial infection, chronic irritability malnutrition, uv radiation and galvanism. Use of spirulina in the successful management of OMFS is attributed to its antioxidant, anti-inflammatory and immune-modulating properties so we implemented thick properties for treating oral leukoplakia.<sup>[4,5]</sup> Spirulina is blue - green algae famous for its nutritional values which are packed with vitamins, minerals, antioxidants and protein.<sup>[6,7]</sup> It has antioxidant like phycocyanin, beta carotene etc. Phycocyanin is a blue pigment.<sup>[8,9]</sup> It is marine natural extract and effective

against cancer. It is toxin on cancer cells while it is non-toxic to normal cells. It is a kind of photosynthetic assistant protein which can effectively capture light energy.<sup>[10]</sup> This study aims to Evaluate the efficacy of spirulina algae capsules (500 mg) as an adjuvant in the management of oral leukoplakia.

## METHODS

The study obtained approval from the institutional ethics committee – Tagore dental college and Hospital (Certificate number: IEC/TDCH/69/2024, approval date: 24th April 2024). A pilot study was performed for 3 months with sample size of 20 patients at Tagore dental college and Hospital. The inclusion criteria of the study were patients diagnosed with oral leukoplakia. The exclusion criteria include pregnant women and lactating mothers, children, patient with autoimmune disease, allergy to herbal medications, medically compromised patients such as uncontrolled diabetes mellitus, hypertension, dialysis patient and other systemic illness.

**Technique:** A detailed informed consent was obtained from the participants. 20 oral leukoplakia patients were examined from OPD in the department of oral medicine

and radiology at Tagore dental college and hospital. Required treatments for diagnosed condition were provided as per the protocol. Spirulina capsules were advised only as an adjuvant. Baseline parameter at day one were recorded that includes burning sensation, peri-lesional erythema and size of the lesion. Patients were advised for spirulina oral capsules 500 mg (Parry's organic spirulina tablets, India) once daily in the morning for 21 days. Baseline parameters were recorded at the interval of day 0, 7, 14 and 21.

## RESULTS

There were 17 males and 1 female. There were 2 dropouts from the study due to gastrointestinal discomfort (Diarrhoea). The patients were monitored for

about a period of 21 days. Efficacy of spirulina oral capsules (500mg) in improvement of baseline parameters were analysed. Post hoc test showed statistically significant improvement ( $p=0.000$ ) of the mean rank of all parameters from day 0 to day 21. [Table 1] Also all 18 patients were analysed for association between burning sensation and severity of inflammatory signs and size of lesion at day 0, 7, 14 and 21. [Table 2 and Table 3] Higher lesion severity aligns with elevated burning sensation suggesting that lesion progression intensifies sensory symptoms. Oral Spirulina capsules reduced burning sensation, inflammatory signs and size of the lesion which were statistically significant ( $p$  value  $< 0.0005$ ).



Figure 1: Spirulina (500 MG) Oral Capsules.



Figure 2: Oral Leukoplakia In Buccal Mucosa.

Table 1: Post hoc test for efficacy of spirulina capsules in improvement of baseline parameters.

Participant Visit	n	Mean Rank	F value	P value
Base Line	18	4.22 ± 1.11	59.791	0.000*
First Visit	18	3.66 ± 0.97		
Second Visit	18	2.44 ± 0.55		
Third Visit	18	0.55 ± 0.51		

$p$  value  $< 0.005$  statistically significant

Table 2: Association between Burning sensation and severity of leukoplakia at baseline.

Burning sensation scores	Baseline parameters – Leukoplakia			Total	P value
	Mild	Moderate	Severe		
3	5 (100%)	0	0	5 (27.8%)	0.000*
4	0	7 (100%)	0	7 (38.9%)	
5	0	0	4 (100%)	4 (22.2%)	
6	0	0	1 (100%)	1 (5.6%)	
7	0	0	1 (100%)	1 (5.6%)	
Total	5 (27.8%)	7 (38.9%)	6 (33.3%)	18 (100%)	

$p$  value  $< 0.005$  statistically significant

**Table 3: Association between Burning sensation and severity of leukoplakia during third visit.**

Burning sensation scores	Baseline parameters – Leukoplakia		Total	P value
	Normal	Mild		
1	8 (100%)	0	8 (44.4%)	0.000*
2	0	10 (100%)	10 (55.6%)	
Total	8 (44.4%)	10 (55.6%)	18 (100%)	

p value < 0.005 statistically significant

## DISCUSSION

Leukoplakia is a premalignant lesions often examined by routine examinations usually it relies on the clinical appearance. In a previous study by petti et al the global incidence was estimated to be between 1.7% and 2.7%.<sup>[11]</sup> The incidence of leukoplakia in India ranged between 3.1% and 3.4% in the three years among our studied population.it is potentially malignant lesion of oral mucosa. It was defined as a white patch or plaque that cannot be characterized, clinically, or pathologically as any other diseases” by WHO in 1978. The incidence of leukoplakia is higher in tobacco users than in non-users. There exists a dose response association between use of tobacco and the prevalence of oral leukoplakia.<sup>[12]</sup>

After provisional diagnosis of leukoplakia, if patient has habit of smoking or any other cause elimination of the etiology is advised and observed for response after 2-4 weeks. If patient does not responses well, biopsy is done and management is taken according to degree of dysplasia. Some baseline treatments are carried out like providing antioxidants, retinols, vitamin A, cytotoxic agents. spirulina is a blue-green algae, is one such antioxidants. It is a ‘super food’ because of nutritious, concentrated whole food. Some of the vitamins required for metabolic activities in all living things are found in spirulina.<sup>[9,10]</sup> These includes all the B vitamins, including vitamins B12, vitamin K. Clinical trials have evaluated spirulina doses up to 10 grams daily with no side effects. It contains phycocyanin, beta carotene, zeaxanthin, iron, vitaminB1, vitamin K, GLA (gamma linolenic acid), trace minerals, and SOD (superoxidase dismutase). Spirulina boosts energy and strengthens the body's defenses. Spirulina has more carotenoids than any other whole food, and it's also a great source of protein. additionally it is abundant in phytonutrients and antioxidants. The study had evaluated the association between burning sensation intensity and lesion severity by observing size of lesion and inflammatory signs. The study concludes that increase in severity of lesion with marked increase in burning sensation levels.<sup>[12]</sup>

## CONCLUSION

Early detection and treatment of oral leukoplakia is important. The main cause of leukoplakia is tobacco smoking. Quitting of habit provides better intervention and improvement in disease. This study highlights the role of oral Spirulina capsules (500 mg) as an adjuvant in the management of oral leukoplakia, showing promising outcomes in reducing burning sensation, inflammation

and lesion size. These findings emphasize its potential as supportive therapeutic agents, paving the way for further research to solidify its benefits in clinical practice.

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