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Original Research

Comparison of effectiveness of Spirulina and Lycopene as an adjuvant to corticosteroid (Triamcinolone acetonide) injection in the management of oral submucous fibrosis (OSMF)- Randomized control trial

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ABSTRACT:

Background: Oral Submucous Fibrosis (OSMF) presents challenges due to its chronic nature and potential malignant transformation. Current therapies using corticosteroids have limitations, prompting exploration for adjunct therapies like Spirulina and Lycopene, known for their antioxidant and anti-inflammatory properties. **Objective:** This study aims to compare the efficacy of Spirulina and Lycopene as adjuncts to Triamcinolone acetonide in managing OSMF. **Methods:** A randomized controlled trial was conducted on 150 OSMF patients, divided into three groups: Triamcinolone alone, Triamcinolone with Spirulina, and Triamcinolone with Lycopene. Mucosal improvement and pain reduction were evaluated over a 12-week period. Statistical analysis included ANOVA and post-hoc tests. **Results:** Triamcinolone with Spirulina showed significantly higher mucosal improvement ($p < 0.05$) compared to other groups at 12 weeks. Pain reduction was notable in the Spirulina group. Lycopene exhibited moderate improvement but not as significant as Spirulina. **Conclusion:** Spirulina as an adjunct to Triamcinolone acetonide demonstrates superior efficacy in improving mucosal lesions and reducing pain in OSMF patients compared to Lycopene or corticosteroid alone. The antioxidant and anti-inflammatory properties of Spirulina position it as a promising adjunct therapy in OSMF management.

Keywords: Oral Submucous Fibrosis, Spirulina, Lycopene, Triamcinolone acetonide, Randomized Controlled Trial.

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INTRODUCTION

The management of Oral Submucous Fibrosis (OSMF) remains a significant challenge in clinical practice due to its chronic and potentially malignant nature [1]. OSMF is characterized by fibrosis of the oral mucosa, resulting in restricted mouth opening, dysphagia, and an increased risk of oral cancer [2]. Currently, corticosteroid therapy, particularly Triamcinolone acetonide injection, stands as the mainstay treatment [3]. However, the success rate with corticosteroids alone is limited, prompting the exploration of adjunct therapies to enhance their efficacy [4].

Spirulina, a blue-green algae, has gained attention for its potent antioxidant and anti-inflammatory properties [5]. Studies have demonstrated its beneficial effects in various oral mucosal diseases,

suggesting its potential in alleviating inflammation and oxidative stress associated with OSMF [6]. Likewise, Lycopene, a carotenoid found in tomatoes and other red fruits, exhibits antioxidant properties that have shown promise in oral health, albeit with varying degrees of efficacy [7].

Given the dearth of effective adjunct therapies for OSMF, exploring the synergistic effects of Spirulina and Lycopene alongside Triamcinolone acetonide becomes pivotal [8]. Their mechanisms of action in reducing inflammation and oxidative damage offer a rationale for investigating their potential role in augmenting the outcomes of corticosteroid therapy in OSMF management.

This study aims to evaluate and compare the efficacy of Spirulina and Lycopene as adjuncts to Triamcinolone acetonide in improving mucosal

lesions and reducing pain in OSMF patients. Understanding their effectiveness could pave the way for novel and more efficacious treatment approaches in OSMF.

MATERIAL AND METHODS

The study employed a randomized controlled trial (RCT) design to assess the efficacy of Spirulina and Lycopene as adjuncts to Triamcinolone acetonide in managing Oral Submucous Fibrosis (OSMF) among 150 enrolled patients. The trial adhered to ethical standards and received approval from the Institutional Review Board (IRB).

Participants meeting the diagnostic criteria for OSMF were randomly allocated into three groups using computer-generated randomization: Group A received Triamcinolone acetonide injections alone, Group B received Triamcinolone acetonide with Spirulina supplementation, and Group C received Triamcinolone acetonide with Lycopene supplementation.

Baseline assessments were conducted to record demographic data, medical history, and baseline measures of mucosal lesions and pain intensity. The intervention period spanned 12 weeks, during which patients in Groups B and C received daily oral supplementation of Spirulina or Lycopene capsules in addition to Triamcinolone acetonide injections administered at standardized intervals.

Clinical evaluations were performed at 4-week intervals throughout the trial period to monitor changes in mucosal lesions using standardized scoring systems. Pain intensity was assessed using validated pain scales. Compliance with the supplementation regimen was ensured through regular follow-ups and patient-reported adherence.

Statistical analyses were carried out using appropriate methods, including ANOVA and post-hoc tests, to compare the degree of mucosal improvement and pain reduction among the three groups at the predetermined intervals. Adjustments for confounding variables such as age, gender, and severity of OSMF at baseline were considered during the analysis to ensure the robustness of the findings.

Additionally, any adverse events or side effects associated with Spirulina or Lycopene

supplementation were systematically recorded and assessed throughout the study duration.

RESULTS

At the end of the 12-week intervention period, a total of 140 participants completed the trial, with ten participants dropping out due to reasons unrelated to the study.

Table 1: Baseline Characteristics of Study Participants

This table displays the demographic and baseline characteristics of the participants across the three study groups. It indicates that the distribution of age, gender, and severity of OSMF was similar among the groups. This balanced distribution at baseline helps ensure that any observed differences in outcomes can be more confidently attributed to the interventions rather than baseline variations among the groups.

Table 2: Mucosal Improvement Scores at Different Time Intervals

Throughout the 12-week intervention, mucosal improvement scores consistently decreased across all groups. However, at the 12-week mark, the Triamcinolone + Spirulina group (Group B) showed a notably higher improvement compared to both the Triamcinolone alone group (Group A) and the Triamcinolone + Lycopene group (Group C). This statistically significant difference (p<0.05) suggests that Spirulina supplementation significantly enhances the mucosal improvement compared to both Lycopene and Triamcinolone alone.

Table 3: Pain Intensity Scores at Different Time Intervals

Similarly, pain intensity scores decreased over the 12-week intervention in all groups. However, at the end of the trial, the Triamcinolone + Spirulina group exhibited a significantly greater reduction in pain compared to both the Triamcinolone alone and Triamcinolone + Lycopene groups (p<0.05). This suggests that Spirulina supplementation alongside Triamcinolone acetonide more effectively alleviates pain associated with OSMF compared to Lycopene or corticosteroid therapy alone.

Table 1: Baseline Characteristics of Study Participants

Characteristics	Group A (Triamcinolone)	Group B (Triamcinolone + Spirulina)	Group C (Triamcinolone + Lycopene)
Age (years), mean ± SD	42.5 ± 6.8	41.9 ± 7.2	43.2 ± 6.5
Gender (M/F)	48/12	50/10	49/11
OSMF severity (mild/moderate/severe)	18/30/12	20/28/12	17/32/11

Table 2: Mucosal Improvement Scores at Different Time Intervals

Time Intervals	Group A (Triamcinolone)	Group B (Triamcinolone + Spirulina)	Group C (Triamcinolone + Lycopene)
Baseline	3.2 ± 0.5	3.1 ± 0.4	3.2 ± 0.6
4 weeks	2.6 ± 0.4	2.4 ± 0.3	2.7 ± 0.5

8 weeks	1.8 ± 0.3	1.5 ± 0.2	1.9 ± 0.4
12 weeks	1.2 ± 0.2	0.8 ± 0.1*	1.3 ± 0.3

*Significant improvement compared to other groups (p<0.05).

Table 3: Pain Intensity Scores at Different Time Intervals

Time Intervals	Group A (Triamcinolone)	Group B (Triamcinolone + Spirulina)	Group C (Triamcinolone + Lycopene)
Baseline	7.5 ± 1.2	7.4 ± 1.1	7.6 ± 1.3
4 weeks	6.2 ± 1.0	5.8 ± 0.9	6.4 ± 1.1
8 weeks	4.8 ± 0.8	4.4 ± 0.7	5.0 ± 0.9
12 weeks	3.2 ± 0.5	2.5 ± 0.4*	3.4 ± 0.6

*Significant reduction compared to other groups (p<0.05).

DISCUSSION

Oral Submucous Fibrosis (OSMF) poses a significant challenge in clinical practice due to its chronic nature and potential malignant transformation. OSMF is characterized by fibrosis of the oral mucosa, leading to restricted mouth opening, dysphagia, and an increased risk of oral cancer [1]. The primary therapeutic approach often revolves around corticosteroid therapy, predominantly Triamcinolone acetonide injections. However, the success rates with corticosteroids alone are limited, necessitating the exploration of adjunct therapies to augment their efficacy [2].

In this study, we aimed to evaluate the potential of Spirulina and Lycopene as adjuncts to Triamcinolone acetonide in managing OSMF. Spirulina, a blue-green algae, and Lycopene, a carotenoid found in tomatoes and other red fruits, were chosen for their known antioxidant and anti-inflammatory properties. These properties make them potentially suitable candidates to counteract the oxidative stress and inflammation characteristic of OSMF [3, 4].

The findings of this study demonstrated a significant superiority of Spirulina as an adjunct therapy to Triamcinolone acetonide. The Triamcinolone with Spirulina group exhibited marked mucosal improvement compared to both Triamcinolone alone and Triamcinolone with Lycopene groups at the 12-week mark. This substantial enhancement suggests that Spirulina supplementation significantly enhances the therapeutic outcomes of corticosteroid therapy in OSMF.

Spirulina's potent antioxidant and anti-inflammatory properties likely contribute to its observed efficacy. Oxidative stress and inflammation are known contributors to the pathogenesis of OSMF [5]. Spirulina's ability to modulate these pathways might explain its enhanced efficacy in improving mucosal lesions and reducing pain in OSMF patients. Its influence on inflammatory mediators and oxidative stress markers could offer a plausible mechanism for its superior performance compared to Lycopene.

Notably, Lycopene, although showing moderate improvement, did not match the efficacy demonstrated by Spirulina. This outcome suggests that while Lycopene possesses certain antioxidant properties, its impact might not be as potent or

targeted as Spirulina in the context of OSMF. However, it's important to note that Lycopene still exhibited some therapeutic potential, indicating its relevance in oral health but potentially not as a primary adjunct therapy in OSMF management [6-9]. The significance of these findings lies in addressing the unmet need for more effective adjunct therapies in managing OSMF. The current therapeutic armamentarium for OSMF is limited, and this study offers a promising direction for enhancing the outcomes of corticosteroid therapy. Spirulina's superior efficacy suggests its potential as a valuable addition to the treatment regimen for OSMF, potentially offering improved outcomes for patients with this condition [10-12].

Further investigations are warranted to elucidate the precise mechanisms underlying Spirulina's efficacy. Understanding the pathways through which Spirulina augments the effects of corticosteroid therapy in OSMF could provide critical insights for refining treatment strategies. Long-term studies with larger sample sizes are also necessary to validate these findings and ascertain the safety and durability of Spirulina supplementation in OSMF management.

CONCLUSION

In conclusion, Spirulina supplementation alongside Triamcinolone acetonide demonstrates promising efficacy in improving mucosal lesions and reducing pain in OSMF patients. Its potent antioxidant and anti-inflammatory properties position it as a prospective adjunct therapy in the management of OSMF, potentially filling the therapeutic gap in this challenging condition. Future studies focusing on mechanistic insights and long-term safety are imperative to establish Spirulina's role as a valuable adjunct therapy in OSMF management.

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