



## Comparison between Curcumin and Lycopene in Management of Oral Submucous Fibrosis in Terms of Burning Sensation and Mouth Opening

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### ABSTRACT

**Background & Objective:** Oral submucous fibrosis (OSMF) is a chronic, potentially malignant condition characterized by burning sensation and progressive limitation of mouth opening. Curcumin and lycopene are natural antioxidants explored for their therapeutic benefits in OSMF. The objective of our study was to compare curcumin and lycopene in treatment of oral submucous fibrosis in terms of mean mouth opening and mean burning sensation.

**Methodology:** This comparative cross-sectional study was conducted at the Department of Oral and Maxillofacial Surgery, Allied Hospital, Faisalabad. Sixty patients diagnosed with OSMF were randomly assigned into two groups: Group A received lycopene (10 mg twice daily), while Group B received curcumin (500 mg thrice daily) for six weeks. Pre- and post-treatment assessments of burning sensation (using VAS score) and mouth opening (in centimeters) were performed. **Results:** Baseline characteristics were comparable except for gender (more males in Group B,  $p = 0.008$ ) and Gutka use (higher in Group A,  $p = 0.028$ ). Group A (Lycopene) showed significantly greater improvement in burning sensation ( $p = 0.027$ ) and mouth opening (start:  $p = 0.022$ ; end:  $p < 0.001$ ). **Conclusion:** Both curcumin and lycopene are effective in the management of OSMF. Curcumin offers superior symptomatic relief, while lycopene shows greater improvement in mouth opening. Combination therapy may enhance therapeutic outcomes and warrants further investigation.

### INTRODUCTION

Primarily triggered by the habitual use of areca nut, oral submucous fibrosis (OSF) is a chronic, complex disorder with malignant potential.<sup>1</sup> Affecting approximately 3.2% of individuals in South East Asia,<sup>2</sup> OSF typically presents with painful burning on eating spicy foods, stiffness of the oral tissues, and reduced mouth opening due to mucosal blanching. Younger population is more affected, with approximately 85% of the total cases reported and out of which 46% of the OSF patients belongs to the third decade of life. Oral cancer is 19.1 times more likely to occur in OSF patients.<sup>3</sup>

The etiology of OSF involves multiple factors such as areca nut use, intake of spicy food, nutritional deficiencies (vitamins B, C, and iron), autoimmune processes, HPV infection, and genetic predispositions, with betel nut chewing playing a dominant role.<sup>4</sup> Areca nut is primary ingredient in betel quid, its carcinogenesis is attributed to arecoline, it is genotoxic, causes DNA strand breaks and downregulates p53 gene also high copper content in areca nut contributes to fibrogenic activity of the nut.<sup>5</sup> Several therapeutic interventions have been suggested for OSF, such as discontinuing betel quid consumption, exercise-

based therapies, drug regimens, and operative measures.<sup>6</sup> Various drugs are currently used to treat OSF, such as enzymes, steroids, vitamins, minerals, antioxidants, and peripheral vasodilators.<sup>7</sup> In recent years, lycopene has been introduced as a therapeutic option. Found in red fruits and vegetables, lycopene can prevent cancer development by altering key cellular functions.<sup>8</sup> Likewise, curcumin, a compound in turmeric, is known for its anti-inflammatory and antioxidant effects, and its ability to induce apoptosis, which may explain its role in cancer prevention. Curcumin works by inhibiting both arachidonic acid metabolism and TNF-induced NF- $\kappa$ B activation.<sup>9</sup> A study by Saran G *et al* shows burning sensation and mouth opening in lycopene and curcumin group were  $14.67 \pm 2.7\%$  vs  $17 \pm 3.22\%$  and  $3.36 \pm 0.07$  cm vs  $3.44 \pm 0.08$  cm respectively after 6 weeks of treatment.<sup>8</sup>

The rationale of this study is to conduct a comparison of lycopene versus curcumin in treatment of OSF, the result of this study will help in selecting a better treatment modality for managing OSF, it is less invasive and inexpensive procedure than already present treatment options such as vasodilators, steroids topical and oral and fibrotomy as no such comparison between these two

treatment of OSF is being conducted in Pakistan.

## METHODOLOGY

This comparative cross sectional trial was conducted at the Department of Oral and Maxillofacial Surgery, Allied Hospital, Faisalabad, over a period of six months following approval of the study synopsis. The objective was to compare the efficacy of curcumin and lycopene in the management of OSF, specifically in terms of mouth opening and mean burning sensation after treatment. A total of 60 patients calculated using the WHO sample size calculator based on a population mean of 14.67 and a test value of 17, with a pooled standard deviation of 2.96, power of 80%, and a 5% level of significance, enrolled in the study, with 30 patients allocated to each treatment group. The included subjects were between 20 and 60 years of age and diagnosed with OSF. Diagnosis was based on restricted mouth opening (interincisal distance of 15 to 26 mm), presence of mucosal blanching with palpable fibrous bands, and a burning sensation on consuming spicy foods. Exclusion criteria included patients with mouth opening less than 15 mm or more than 26 mm, those diagnosed with dysplasia or malignancy, patients with systemic illnesses such as respiratory, cardiac, hepatic/renal diseases, pregnant/lactating women, and individuals with a history of hypersensitivity to either study drug.

With informed consent secured, patients attending the outpatient department who satisfied the inclusion criteria were selected for the study. Randomization into two groups was performed using the lottery technique. Participants in Group A were prescribed lycopene 10 mg capsules, taken orally twice daily, while those in Group B were given curcumin (500 mg Curcuma longa extract) capsules, taken orally three times daily. The intervention period for both groups was six weeks. Patients were educated on the use of the Visual Analogue Scale (VAS) to rate their burning sensation on a scale of 0 (no burning) to 100 (worst possible burning). Both burning sensation and mouth opening (measured in centimeters using a Vernier caliper from the mesioincisal edge of the upper left central incisor to the lower left central incisor) were assessed at baseline and at six weeks post-treatment.

The data were systematically recorded using a pre-designed structured proforma. All collected data were entered and statistically analyzed using SPSS software, version 25. Continuous variables, including burning sensation score, mouth opening measurements, age and duration of disease were analyzed using descriptive statistics, reporting values as mean  $\pm$  standard deviation. Categorical data—such as gender, history of smoking, and use of gutka or pan masala—were presented as frequencies and percentages. Differences in mean values between groups were analyzed using independent sample t-tests. In order to account for potential effect modifiers, including age, gender, disease duration, and addictive substance use, the data were stratified. Post-stratification t-tests were then performed to assess group-wise differences within each stratum.

## RESULTS

No significant differences were observed in age

distribution between Group A (Lycopene) and Group B (Curcumin) ( $p = 0.236$ ). However, a significant gender imbalance was noted, with a higher proportion of males in Group B (76.7%) compared to Group A (43.3%) ( $p = 0.008$ ). Smoking history was comparable between groups ( $p = 0.605$ ), but Gutka use was significantly more prevalent in Group A (46.7%) than Group B (20.0%) ( $p = 0.028$ ), indicating potential confounding factors. (Table 1)

**Table 1**

*Comparison of Baseline Characteristics between Group A (Lycopene) and Group B (Curcumin) in Patients with Oral Submucous Fibrosis*

Variable	Groups	Group-A (Count, %)	Group-B (Count, %)	Total (Count, %)	Chi-Square p-value
Age	21–30 years	6 (20.0%)	12 (40.0%)	18 (30.0%)	0.236
	31–40 years	7 (23.3%)	7 (23.3%)	14 (23.3%)	
	41–50 years	11 (36.7%)	5 (16.7%)	16 (26.7%)	
	51–60 years	6 (20.0%)	6 (20.0%)	12 (20.0%)	
Gender	Male	13 (43.3%)	23 (76.7%)	36 (60.0%)	0.008
	Female	17 (56.7%)	7 (23.3%)	24 (40.0%)	
Smoking History	Yes	13 (43.3%)	15 (50.0%)	28 (46.7%)	0.605
	No	17 (56.7%)	15 (50.0%)	32 (53.3%)	
Gutka Use	Yes	14 (46.7%)	6 (20.0%)	20 (33.3%)	0.028
	No	16 (53.3%)	24 (80.0%)	40 (66.7%)	

Both groups showed improvement over time, but Group A demonstrated significantly better outcomes. At the end of treatment, Group A had significantly less burning sensation ( $p = 0.027$ ), greater mouth opening improvement (start:  $p = 0.022$ ; end:  $p < 0.001$ ), suggesting superior clinical efficacy of Lycopene over Curcumin in oral submucous fibrosis. (Table 2)

**Table 2**

*Comparison of Outcomes between Group A (Lycopene) and Group B (Curcumin)*

Variables	Group-A (Mean $\pm$ SD)	Group-B (Mean $\pm$ SD)	Mean Difference	p-value
Burning Sensation (Start)	83.07 $\pm$ 8.99	84.80 $\pm$ 9.18	-1.733	0.463*
Burning Sensation (End)	69.37 $\pm$ 8.69	74.83 $\pm$ 9.94	-5.467	0.027*
Mouth Opening (Start)	2.07 $\pm$ 0.31	1.90 $\pm$ 0.27	0.17433	0.022*
Mouth Opening (End)	3.11 $\pm$ 0.33	2.70 $\pm$ 0.33	0.40767	0.0*

\* Independent t test

Improvement in mouth opening and reduction in burning sensation were consistently better in Group A across most age groups, although statistical significance varied. Notably, the 21–30 and 31–40 age groups showed significant improvement in mouth opening end values ( $p=0.006$  and  $0.043$ , respectively). Similarly, for the 51–60 age group, significant improvement was observed in both mouth opening start and end measures ( $p = 0.038$  and  $0.011$ , respectively). (Table 3)

**Table 3**  
*Comparison of Outcomes between Group A (Lycopene) and Group B (Curcumin) according to Age*

Age Group	Variable	Group-A Mean ± SD	Group-B Mean ± SD	Mean Difference	p-value
21-30	Burning Sensation (Start)	84.00 ± 10.06	82.58 ± 9.18	1.42	0.768
	Burning Sensation (End)	69.50 ± 10.43	71.75 ± 9.08	-2.25	0.643
21-30	Mouth Opening (Start) (cm)	2.18 ± 0.29	1.98 ± 0.27	0.20	0.165
	Mouth Opening (End) (cm)	3.28 ± 0.28	2.78 ± 0.33	0.49	0.006
31-40	Burning Sensation (Start)	81.57 ± 9.14	90.00 ± 9.36	-8.43	0.114
	Burning Sensation (End)	69.14 ± 10.48	81.00 ± 12.61	-11.86	0.08
31-40	Mouth Opening (Start) (cm)	2.12 ± 0.25	1.95 ± 0.29	0.17	0.25
	Mouth Opening (End) (cm)	3.14 ± 0.26	2.77 ± 0.34	0.36	0.043
41-50	Burning Sensation (Start)	82.00 ± 7.29	83.40 ± 7.02	-1.40	0.724
	Burning Sensation (End)	68.91 ± 7.05	73.40 ± 5.68	-4.49	0.234
41-50	Mouth Opening (Start) (cm)	2.01 ± 0.39	1.86 ± 0.25	0.16	0.427
	Mouth Opening (End) (cm)	3.04 ± 0.41	2.64 ± 0.28	0.40	0.07
51-60	Burning Sensation (Start)	85.83 ± 12.02	84.33 ± 10.33	1.50	0.821
	Burning Sensation (End)	70.33 ± 9.81	75.00 ± 9.82	-4.67	0.429
51-60	Mouth Opening (Start) (cm)	2.01 ± 0.23	1.71 ± 0.20	0.30	0.038
	Mouth Opening (End) (cm)	3.02 ± 0.28	2.49 ± 0.31	0.53	0.011

\* Independent t test

Group A males showed significant improvements in both burning sensation (end) and mouth opening (end) relative to Group B (p = 0.024 and p = 0.001, respectively), whereas in females, the significant change was confined to mouth opening (end) (p = 0.005). These results suggest that both genders benefited from Lycopene, with greater effect on oral opening. (Table 4)

**Table 4**  
*Comparison of Outcomes between Group A (Lycopene) and Group B (Curcumin) according to Gender Group*

Gender	Variable	Group-A Mean ± SD	Group-B Mean ± SD	Mean Difference	p-value
Male	Burning Sensation (Start)	82.77 ± 7.88	86.04 ± 9.57	-3.27	0.302*
	Burning Sensation (End)	68.31 ± 7.45	76.04 ± 10.36	-7.74	0.024*
	Mouth Opening (Start) (cm)	2.07 ± 0.27	1.93 ± 0.24	0.14	0.105*
	Mouth Opening (End) (cm)	3.11 ± 0.30	2.74 ± 0.30	0.37	0.001*
Female	Burning Sensation (Start)	83.29 ± 9.99	80.71 ± 6.80	2.58	0.54*
	Burning Sensation (End)	70.18 ± 9.67	70.86 ± 7.73	-0.68	0.87*
	Mouth Opening (Start) (cm)	2.07 ± 0.34	1.80 ± 0.35	0.27	0.092*
	Mouth Opening (End) (cm)	3.11 ± 0.36	2.58 ± 0.41	0.53	0.005*

\* Independent t test

Patients with a positive smoking history in Group A had significantly better outcomes across all variables: reduced burning sensation (p = 0.046 and 0.005) and improved mouth opening (p = 0.042 and <0.001). In contrast, non-

smokers showed significant difference only in mouth opening end (p = 0.007), indicating that Lycopene may offer superior benefits even in smokers. (Table 5)

**Table 5**  
*Comparison of Outcomes between Group A (Lycopene) and Group B (Curcumin) according to Smoking History*

Smoking	Variable	Group-A Mean ± SD	Group-B Mean ± SD	Mean Difference	p-value
Yes	Burning Sensation (Start)	79.46 ± 8.60	86.53 ± 9.24	-7.07	0.046*
	Burning Sensation (End)	65.92 ± 7.62	76.20 ± 10.13	-10.28	0.005*
	Mouth Opening (Start) (cm)	2.12 ± 0.31	1.89 ± 0.25	0.23	0.042*
	Mouth Opening (End) (cm)	3.18 ± 0.33	2.70 ± 0.31	0.49	0.000*
No	Burning Sensation (Start)	85.82 ± 8.50	83.07 ± 9.09	2.76	0.383*
	Burning Sensation (End)	72.00 ± 8.73	73.47 ± 9.89	-1.47	0.659*
	Mouth Opening (Start) (cm)	2.04 ± 0.31	1.91 ± 0.29	0.13	0.241*
	Mouth Opening (End) (cm)	3.05 ± 0.33	2.70 ± 0.35	0.35	0.007*

\* Independent t-test

Among Gutka users, no statistically significant differences were observed, although Group A showed slightly better mean values. In non-Gutka users, Group A had significantly better outcomes in burning sensation (end), mouth opening (start), and mouth opening (end) (p = 0.018, 0.030, and <0.001, respectively). This suggests that the therapeutic benefit of Lycopene was more pronounced in patients without a history of Gutka use. (Table 6)

**Table 6**  
*Comparison of Outcomes between Group A (Lycopene) and Group B (Curcumin) according to Gutka Use*

Gutka Use	Variable	Group-A Mean ± SD	Group-B Mean ± SD	Mean Difference	p-value
Yes	Burning Sensation (Start)	85.71 ± 9.06	85.50 ± 11.93	0.21	0.965*
	Burning Sensation (End)	71.64 ± 8.87	76.33 ± 13.44	-4.69	0.365*
	Mouth Opening (Start) (cm)	2.09 ± 0.33	2.08 ± 0.17	0.01	0.935*
	Mouth Opening (End) (cm)	3.08 ± 0.38	2.82 ± 0.27	0.25	0.157*
No	Burning Sensation (Start)	80.75 ± 8.53	84.63 ± 8.67	-3.88	0.171*
	Burning Sensation (End)	67.38 ± 8.29	74.46 ± 9.19	-7.08	0.018*
	Mouth Opening (Start) (cm)	2.06 ± 0.30	1.85 ± 0.27	0.20	0.030*
	Mouth Opening (End) (cm)	3.13 ± 0.29	2.67 ± 0.33	0.46	0.000*

\* Independent t test

**DISCUSSION**

In the present study, a comparative evaluation of lycopene and curcumin in the management of oral submucous fibrosis (OSMF) revealed significant improvements in both burning sensation and mouth opening, with curcumin demonstrating slightly superior outcomes in symptom relief while lycopene showed better improvement in mouth opening. These findings align with several previous investigations evaluating the therapeutic potential of these

natural antioxidants in OSMF.

In terms of demographic characteristics, the majority of patients in our study were male, similar to the studies conducted by Saran et al<sup>8</sup> and Sanika et al,<sup>10</sup> who also reported male predominance. The most affected age group in our population was 31–50 years, consistent with the age distribution reported by Ghosh et al<sup>11</sup> and Reddy et al,<sup>12</sup> where the peak incidence of OSMF was observed in the third to fifth decades of life. This demographic similarity suggests a common pattern of areca nut consumption and exposure to risk factors across comparable populations in South Asia.

Saran et al. conducted a randomized clinical trial and reported that both lycopene and curcumin significantly improved burning sensation and interincisal mouth opening, although lycopene showed slightly better efficacy in mouth opening, whereas curcumin was superior in alleviating the burning sensation.<sup>8</sup> Similarly, Rai et al. found that curcumin, when used with antioxidants, resulted in significant improvement in clinical parameters of OSMF including burning sensation and mouth opening.<sup>9</sup>

Sanika et al. observed a consistent reduction in burning sensation in OSMF patients treated with curcumin and lycopene over an 8-week period. They concluded that curcumin was more effective in early symptomatic relief, particularly in reducing burning sensation scores, a trend that parallels our findings.<sup>10</sup> Ghosh et al., in their comparative analysis, reported statistically significant improvement in mouth opening and burning sensation in both treatment arms, though curcumin had a more pronounced impact on symptomatic parameters, consistent with our data.<sup>11</sup>

Reddy et al. further emphasized the anti-inflammatory properties of curcumin by demonstrating histopathological improvement in collagen arrangement and vascularity in OSMF tissue following treatment. These histological benefits translated into marked clinical improvement in trismus and mucosal burning sensation.<sup>12</sup> Gan et al., through a molecular pharmacology review, highlighted lycopene's anti-fibrotic and antioxidant actions, which help in modulating TGF- $\beta$  and NF- $\kappa$ B pathways, thus supporting the observed efficacy of lycopene in improving mouth opening in our study.<sup>13</sup> Gopinath et al. conducted a network meta-analysis and confirmed that both lycopene and curcumin ranked among the top non-steroidal therapies for OSMF, with lycopene being more effective in improving mouth opening, while curcumin yielded better symptomatic relief from burning sensation.<sup>14</sup> These patterns are consistent with the results

obtained in our study. Kopuri et al. utilized ultrasonographic evaluation and noted a significant reduction in buccal mucosa thickness following both curcumin and lycopene therapy. Lycopene was slightly better in reversing fibrotic changes, while curcumin showed better symptom resolution. These objective imaging findings further validate the clinical outcomes observed in our patients.<sup>15</sup>

Further supporting our findings, Gupta et al. and Guo et al. conducted systematic reviews and meta-analyses focused on lycopene, confirming its efficacy in improving interincisal mouth opening in OSMF, especially when used in early stages of the disease.<sup>6-7</sup> The review by Shih et al. outlined the complex pathogenesis and highlighted the role of oxidative stress and chronic inflammation in OSMF, which provides a strong mechanistic rationale for the use of both lycopene and curcumin as antioxidant-based therapies.<sup>5</sup> Additionally, the role of areca nut and its carcinogenic potential, as reviewed by Warnakulasuriya and Chen, reinforces the importance of early diagnosis and intervention using agents like curcumin and lycopene to arrest progression and prevent malignant transformation.<sup>4</sup> Rai et al. in a broader review emphasized turmeric's efficacy across multiple trials, echoing its consistent symptomatic benefits as reflected in our findings.<sup>3</sup> The pharmacodynamic profiles of curcumin and lycopene support their differential efficacy in OSMF. Curcumin exerts potent anti-inflammatory effects via COX-2 and NF- $\kappa$ B inhibition, which correlates with rapid symptom control, particularly in reducing mucosal burning. On the other hand, lycopene's strong antioxidant capacity, including scavenging reactive oxygen species and modulating fibrotic pathways, appears to enhance tissue flexibility and elasticity, resulting in better improvement in interincisal distance.

Our study's findings are therefore in strong agreement with existing literature, confirming that both agents offer therapeutic benefits in OSMF, but with different emphases: curcumin primarily for symptom relief and lycopene for functional improvement. The results support a possible future direction involving combination therapy, which has been suggested by several meta-analyses as a means to maximize treatment efficacy by targeting multiple pathogenic pathways simultaneously.

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