

## **Clinical evaluation of efficacy of two herbal mouthwash for management of burning sensation in oral submucous fibrosis patients**

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**Type of Publication:** Original Research Article

**Conflicts of Interest:** Nil

### **Abstract**

**Aims:** The Aim of present study was to evaluate the efficacy of two herbal mouthwash in the management of burning sensation in OSMF patients.

**Methods and Material:** Total of 60 subjects, clinically diagnosed OSMF and with the complain of burning sensation were included in the study and equally divided in two groups; Group A (Oro-T mouthwash) and Group B (SMF mouthwash). Both the groups were asked to rinse with the mouthwash twice daily for 4 weeks. Evaluation of symptom of burning sensation was done on weekly basis for four weeks.

Statistical analysis used: The data was analyzed using One Way ANOVA test and Independent t test.  $P < 0.001$  was considered to be statistically significant.

**Results:** Decrease in the score of burning sensation was found to be statistically significant among patients both in Group A and Group B, where (p value  $< 0.001$ ). Though it was observed that reduction in the degree of

symptom of burning sensation in group A was more than group B. So group A was found to be better than group B.

**Conclusions:** Though there is no definitive treatment for the condition, mouthwashes can give symptomatic relief to the patient and thereby improving the quality of life of the affected individuals.

**Keywords:** Oral Submucous Fibrosis , Burning Sensation, Herbal mouthwash, Oro-t mouthwash and SMF mouthwash.

**Key Messages:** Burning sensation and fibrosis are the most common features in OSMF that impede normal function and further curtail dietary intake leading to nutritional deficiencies in patient. Herbal mouthwash can be used as adjuvant therapy to reduce burning sensation and thus improves quality of life in Oral Submucous Fibrosis (OSMF) patients.

## **Introduction**

Oral Submucous Fibrosis (OSMF) is a condition that causes burning sensation while consuming spicy food, blanched oral mucosa with fibrous bands.<sup>1</sup> In OSMF, soluble irritants, such as capsaicin in chillies and alkaloids of arecanut, causing a juxta inflammatory reaction.<sup>2</sup> Epithelial atrophy primarily leads to burning sensation which further curtails their dietary intake and leads to nutritional deficiencies.<sup>3</sup> Natural ayurvedic treatment of OSMF along with life style modification can help in lowering the symptoms of OSMF and may help in curing the symptoms of disease.

Hence the purpose of the present study was to evaluate and compare the efficacy of two herbal mouthwashes for the management of burning sensation in OSMF patients.

## **Materials and Methods**

The present study was conducted at the Department of Oral Medicine and Radiology. The study was carried out after the ethical clearance was obtained from the Institutional Ethical Committee. The study population consisted of 60 patients with clinically diagnosed OSMF with the complain of burning sensation were included in the study. The exclusion criteria were patients with severe grading, patients with other mucosal lesion having burning sensation and patient's previously undergone treatment for OSMF was not included in the study. A written informed consent was obtained from the patients prior to the inclusion in the study. The subjects were equally divided in two groups 30 patients in each group; Group A (Oro-T mouthwash) and Group B (SMF mouthwash). Both the Groups were asked to rinse with mouthwash as per instructions given by the manufacturer and then spit it after one minute and not to take anything for half an hour. Then subjects were evaluated for symptom of burning sensation which was

recorded by VAS scale (0-10) , weekly for four weeks in OSMF patients where zero is no burning sensation and ten is worst burning sensation. The data was recorded and was analyzed statistically by using one way ANOVA and with SPSS 16.0 software.

## **Results**

Table 1 and table 2 (Graph 1 and Graph 2), indicates the degree of symptom of burning sensation from the baseline till the 4<sup>th</sup> week was evaluated. In group A (Oro t mouthwash) subjects the baseline include 17.86% (5) patients with worst burning sensation, 53.57% (15) patients with severe burning and 28.57% (10) patients with moderate burning sensation , whereas after 4<sup>th</sup> week of evaluation , the degree of burning sensation reduced to 10.71% (4) patients with moderate burning, 85.71% (24) patients with mild burning and 3.57% (2) patients with no burning sensation. In group B (SMF mouthwash) subjects the baseline include 21.43% (8) patients with worst burning, 53.57% (15) patients with severe burning and 25% (7) patients with moderate burning sensation, whereas after 4<sup>th</sup> week of evaluation, the degree of burning sensation reduced to 42.86% (13) with moderate burning, 57.14% (17) patients with mild burning sensation .

Table 3 (Graph-3), indicates the intragroup comparison of both the groups. Using one way anova test, group A (Oro-T mouthwash) showed a reduction in the burning sensation from  $7.5 \pm 1.75$  at baseline to  $2.14 \pm 1.08$  at the completion of 4<sup>th</sup> week of follow up and was statistically significant ( $P < 0.001$ ) and group B (SMF mouthwash) showed a reduction in burning sensation from baseline  $7.6 \pm 1.54$  to  $3.07 \pm 1.02$  at the completion of 4<sup>th</sup> week and P value was statistically significant ( $P < 0.001$ ).

Table 4 (Graph- 4), indicates the intergroup comparison between both the groups. The intergroup comparison of

VAS Score at every 1 week of interval till the completion of 4<sup>th</sup> week was evaluated. At the baseline VAS Score was 7.5 of group A (Oro t mouthwash ) whereas 7.64 for the group B ( SMF mouthwash) and at the completion of the 4<sup>th</sup> week VAS score for Oro t mouthwash was 2.14 , whereas SMF mouthwash VAS score was 3.07. Using independent t test, there was no significant difference from 1<sup>st</sup> week to 3<sup>rd</sup> week but there was a stastically significant reduction in burning sensation at 4<sup>th</sup> week , (P<0.001 is significant) and shows that Oro t mouthwash is better than the SMF mouthwash.

### **Discussion**

Oral submucous fibrosis (OSMF) is a precancerous condition affecting the oral mucosa.<sup>4</sup> The pathogenesis of the disease is thought to be multifactorial, with chewing of betel nut or betel quid being recognized as one of the most significant risk factors for OSMF.<sup>5</sup> The main problems plaguing the patients with OSMF are the burning sensation and progressive trismus which impedes normal function.

The habit of betel quid chewing is practiced predominately in the Indian subcontinent from a long time.<sup>6</sup> The ingredients of arecanut induce excessive reactive oxygen species leading to damage of the cell structures.<sup>7</sup> This in turn leads to atrophic oral mucosa, which becomes more susceptible to the effects of areca nut.<sup>2</sup> Less protection for superficial cells of the oral epithelium causing their rapid exfoliation even by normal physiologic friction.<sup>8</sup> It is reported in the literature that proliferative activity of oral epithelium in OSMF is high<sup>9</sup> which ideally is supposed to cause epithelial hyperplasia. This epithelial atrophy reduced the distance of intra-epithelial nerve endings from the surface making it more sensitive to burning sensation.<sup>8</sup>

Thus leading to burning sensation, vesiculation and ulceration of the oral mucosa.<sup>2</sup> Iron deficiency anemia, vitamin B complex deficiency, and malnutrition are promoting factors that derange the repair of the inflamed oral mucosa, leading to defective healing and resultant scarring. The resulting atrophic oral mucosa is more susceptible to the effects of chilies and betel nuts.<sup>10</sup> Thus, the cumulative effect of these initiating and promoting factors leads to further fibrosis, which is a hallmark of OSMF.<sup>11</sup>

Treatment modalities both medical and surgical, for relieving the symptoms have been advocated, but have not been successful so far. The first step of preventive measure should be in discontinuation of habit which can be encouraged through education, counseling and to maintain proper oral hygiene.<sup>12</sup>

Considering the severity of the condition, and relieving the clinical symptoms of the condition many topical agents have been tried in the treatment of OSMF. Most of the previous studies have focused on the topical use of curcumin in the form of oil or powder or the use of steroid gel. As application of these forms are limited to all the mucosal areas due to the limited access into oral cavity and due to loss of elasticity of tissue secondary to fibrosis and decreased mouth opening. But mouth rinse are safe, simple to use and non invasive agent that is believed to pacify the clinical symptoms of the condition. Many natural plants extracts, synthetic drugs etc have been introduced and tried for the treatment of OSMF which promotes wound healing and also has anti-inflammatory, immunomodulatory and antioxidant properties.<sup>7</sup> As the herbal mouthwash are consist of natural products like curcumin, honey, triphala, pudina , tulsi etc have found great attentions in recent decades

and have been a boon in health care of both ancient and modern cultures.

The composition of the Oro-T mouthwash is turmeric, triphala and honey whereas the composition of SMF mouthwash is clove extract, cinnamon extract, cardamom extract, pudina, tulsi, Kapoor and madhuyasthi.

Curcumin, a chief component of *Curcuma longa* was responsible for the majority of turmeric's therapeutic effects. Turmeric has also been widely used for its antioxidant, analgesic, and anti-inflammatory properties. Curcumin's potent antioxidant and free radical quenching properties play an important role in the inhibitory effects of the compound on the initial stages of carcinogenesis.<sup>13</sup> Topical curcumin can be formulated to be better absorbed through the skin, particularly when the skin barrier becomes defective. The unique ability of curcumin is to inhibit the enzyme, phosphorylase kinase. Inhibition of phosphorylase kinase activity by curcumin results in modulation of the inflammatory response because of downregulation of transcription factors, cytokines, adhesion molecules, cyclin kinases, and a variety of protein kinases. The topical preparations can be more easily formulated to increase penetration of the hydrophobic curcumin through the skin. Skin penetration of topical curcumin may also be enhanced in dermatologic disorders because of inflammation and loss of the normal skin barrier function. These factors make the potential therapeutic value of topical curcumin much more promising.<sup>14</sup> On the other hand, triphala which is a polyherbal ayurvedic preparation contains *Terminalia chebula*, *Terminalia bellerica*, and *Emblica officinalis* used in cancer as anti-cancer, chemoprotective, and radioprotective agent.<sup>15</sup> Anti-inflammatory effect of triphala shows significant inhibition in levels of

lysosomal enzymes, lipid peroxidation (LPO), and inflammatory mediator tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ). Triphala produces excellent analgesic and antipyretic effect without any gastric damage.<sup>16</sup> The effect of honey on infection is not only related to antibacterial agents but also to its effect on the immune system by stimulating antibodies in primary and secondary immune response. It also stimulates the production of inflammatory cytokines.<sup>17</sup> Clove extract, Cinnamon extract, Cardamom extract, tulsi and Kapoor shows the antioxidant and anti-inflammatory properties. Pudina shows the cooling effect to the mouth and madhuyasthi helps in healing ulcer. Thus, the positive outcome observed in the study subjects might be due to the synergistic mechanism of action of all the ingredients of Oro t mouthwash and SMF mouthwash. But as Oro t mouthrinse shows better effect due to the therapeutic effect of turmeric which is safe, non toxic.

In the present study, the reduction of burning sensation took 3 weeks to occur, as mouthwash has a better action on overall mucosa and is not limited to specific areas as in gels where it is locally applied. We found both the mouthwash were effective in reducing the burning sensation in OSMF patients at the end of the 4<sup>th</sup> week. In this study we found Oro-T mouthwash is better than SMF mouthwash as the mean reduction of VAS is  $2.14 \pm 1.08$  and SMF mouthwash is  $3.07 \pm 1.02$ . Similar study concluded that the mean reduction of VAS at the 4<sup>th</sup> week was  $3.50 \pm 2.05$  and found Oro t mouthwash to be safe and effective in relieving symptom of OSMF.<sup>12</sup> In another study that clinically evaluated the role of tulsi and turmeric in management of OSMF suggested a significant improvement in burning sensation.<sup>17</sup> Accordingly also, present study indicates good clinical efficacy of both mouthwash and helps in symptomatic

relief in OSMF patients. So, herbal mouthwash can be used additively as the OSMF is generalized condition of the oral cavity and are easy to use and also there was no

clinically significant adverse effect reported during the study process.

Table 1: Baseline data of symptom of burning sensation

Baseline	VAS Score for burning			P value
	Moderate	Severe	Worst burning	
Group A	10(28.57%)	15(53.57%)	5(17.86%)	0.15 NS
Group B	7(25%)	15(53.57%)	8(21.43%)	

Graph 1: Baseline data of symptom of burning sensation

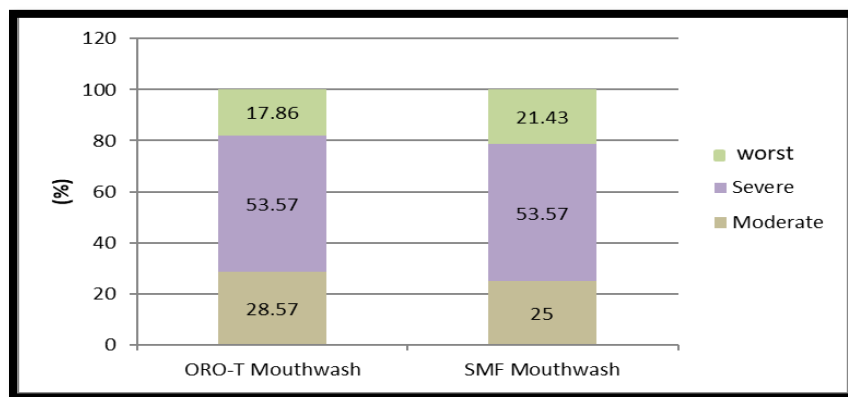


Table 2: After 4<sup>th</sup> week data of symptom of burning sensation

After 4 <sup>th</sup> week	VAS Score for burning					P value
	No burning	Mild	Moderate	Severe	Worst burning	
Group A	2(3.57%)	24(85.71%)	4(10.71%)	--	--	0.018
Group B	(0%)	17(57.14%)	13(42.86%)	--	--	

Graph 2: After 4<sup>th</sup> week degree of symptom of burning sensation

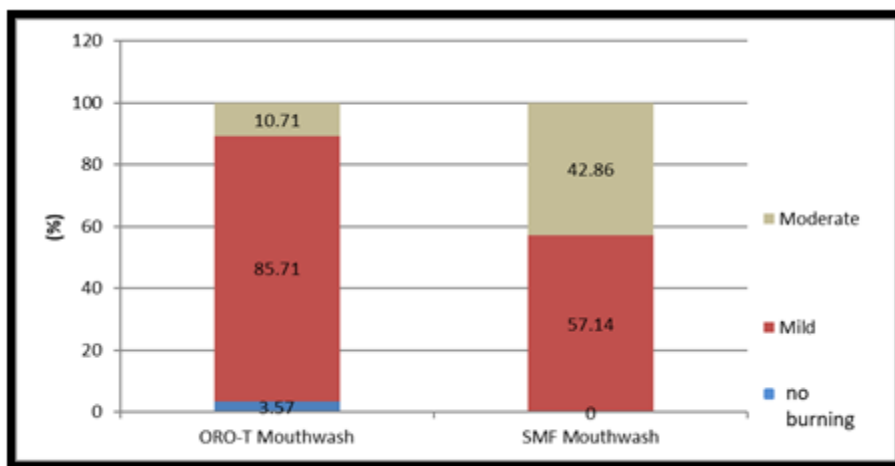


Table 3: Intragroup comparison of VAS at every 1 week interval

VAS Scale	on entry day	1st week	2nd week	3rd week	4th week	ANOVA Test (P value)
Group A	7.5±1.75	5.79±1.73	4.43±1.64	3.18±1.33	2.14±1.08	<0.001
Group B	7.64±1.54	6.11±1.47	4.96±1.32	3.82±1.06	3.07±1.02	<0.001

Graph 3: Intragroup comparison of VAS at every 1 week interval

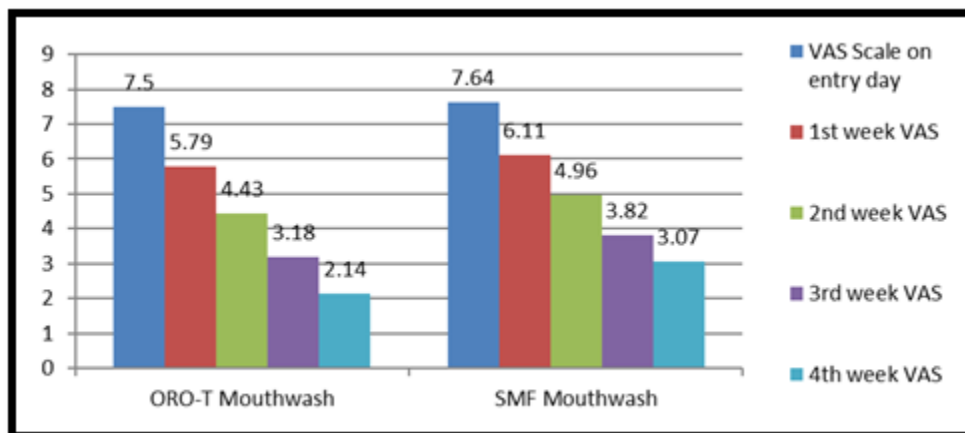
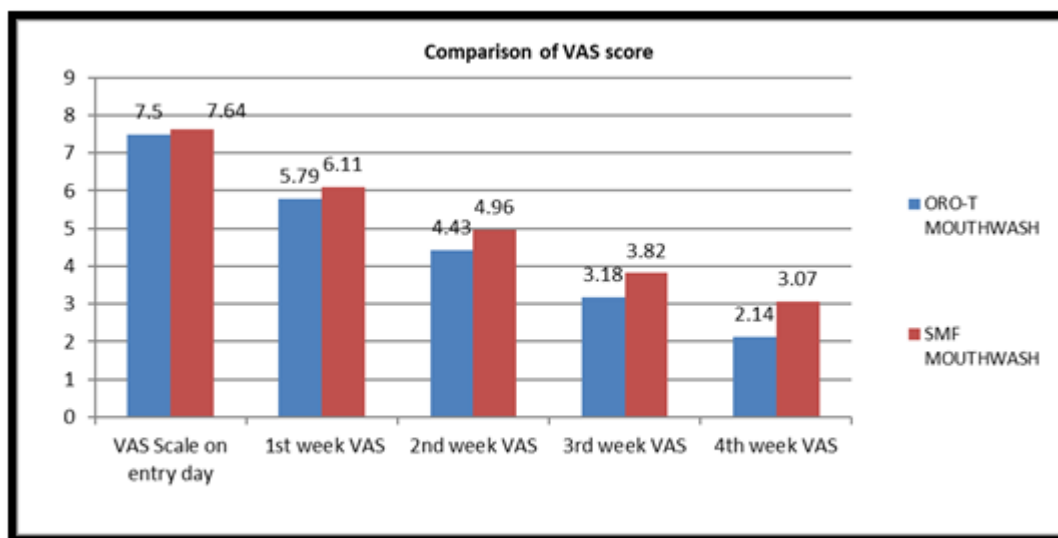


Table 4: Intergroup comparison of reduction in VAS at every 1 week interval

VAS Scale	ORO-T Mouthwash	SMF Mouthwash	P value
on entry day	7.5±1.75	7.64±1.54	0.74 NS
1st week	5.79±1.73	6.11±1.47	0.46 NS
2nd week	4.43±1.64	4.96±1.32	0.18 NS
3rd week	3.18±1.33	3.82±1.06	0.051 NS
4th week	2.14±1.08	3.07±1.02	0.0016

Graph 4: Intergroup comparison of reduction in VAS at every 1 week interval



## **Conclusion**

The improvement in burning sensation in the patients was much satisfactory in the present study. Based on these results, mouthwashes are simple, non-invasive, effective and safe mode of treatment in the symptomatic relief of Oral Submucous Fibrosis. There were no clinically significant short and long term adverse events. We can conclude that turmeric, triphala, tulsi and other contents of both the mouthwashes has a beneficial therapeutic effects in improving burning sensation in the patients with OSMF and also shows the good clinical efficacy in relieving the symptoms associated with OSMF .

## **References**

1. Lambade P, Dawane P, Thorat P. Oral Submucous Fibrosis – A Treatment Protocol based on Clinical study of 100 patients in Central India. *Oral Maxillofac. Surg.* 2015;19: 201-207.
2. Khan Z, Das K, Shivakumar G, Dogra M, Singh K, Kumar SK et al., Effect of Intralesional Betamethasone Injections And Local Application of Aloe Vera Gel In Patients With Oral Submucous Fibrosis And Burning Sensation. A Comparative Study. *Int J Recent Sci Res.* 2017; 8(10): 20505-20510.
3. Jain N, Annigeri RG and Pipalia PR. Efficacy of Garlic in Conjunction with Pentoxifylline in the Management of Oral Submucous Fibrosis – A preliminary Study. *Int J Pharm Sci Res.* 2016; 7(12): 5017-23.
4. Sudarshan R, Rajeshwari G, Annigeri G, Vijayabala S. Aloe vera in the Treatment for Oral Submucous Fibrosis - A Preliminary Study. *J Oral PatholMed.*2012:1-6.
5. Revant H, Gondivkar SM, Gadbail AM, Balsaraf S, Dhore SV, Ghonmode S et al., Review of Drug Treatment of Oral Submucous Fibrosis. *Oral Oncology.* 2012;48:393-398
6. Patil S, Zarea BK, Maheshwari S, Sahu R. Comparative Evaluation of Natural Antioxidants Spirulina and Aloe vera for the Treatment of Oral Submucous Fibrosis. *J Oral Biol Craniofac Res.*2015; 5(1):11-5.
7. Patil S, Halgatti V, Maheshwari S, Santosh BS. Comparative Study of the Efficacy of Herbal Antioxidants Oxitard and Aloe vera in the Treatment of Oral Submucous Fibrosis. *J Clin Exp Dent.* 2014; 6(3):e265-e270.
8. Sarode C, Sarode G. Burning Sensation in Oral Submucous Fibrosis and Its Possible Association with Mucin Secreted by affected Minor Salivary Glands. *Oral Oncology.* 2013; 49: e16-e17.
9. Srinivasan M, Jewell SD. Quantitative Estimation of PCNA, cmyc, EGFR and TGF-alpha in Oral Submucous Fibrosis- An Immunohistochemical Study. *Oral Oncology.* 2001; 37: 461-7.
10. Aziz SR. Oral Submucous Fibrosis : An Unusual Disease. *J N Dent Assoc .*1997;68:17-9.
11. Sajjad A, Sajjad S., Aloe vera : An Ancient Herb for Modern Dentistry- A Literature . Review Journal of Dental Surgery. 2014:1-6
12. Murti PR, Bhonsle RB, Pindborg JJ, Daftary DK, Gupta PC. Malignant Transformation rates in Oral Submucous Fibrosis over a 17year Period. *Community Dent Oral Epidemiol.* 1985; 13:340-1.
13. Aich R, Ghanta S, Das A, Giri D, Majumdar M, Bhattacharjee S. Evaluation of the Role of a Mouth Rinse containing Turmeric, Triphala and Honey in the Treatment of Oral Submucous Fibrosis: An Open

- Label Clinical Study. *J Indian Acad Oral Med Radiol* .2018;30:376-9.
14. Heng MCY .Topical Curcumin: A Review of Mechanisms and uses in Dermatology. *Int J Dermatol Clin Res*. 2017; 3(1):010-017.
15. Belapurkar P, Goyal P, Tiwari-Barua P. Immunomodulatory Effects of Triphala and Its Individual Constituents: A Review. *Indian J Pharm Sci* . 2014;76:467-75.
16. Ganjre A, Kathariya R, Bagul N, Pawar V. Anti-carcinogenic and Anti-bacterial Properties of Selected Spices: Implications in Oral Health. *Clin Nutr Res*. 2015; 4:209-15.
17. Srivastava A, Agarwal R, Chaturvedi TP, Chandra A, Singh OP. Clinical Evaluation of the Role of Tulsi and Turmeric in the Management of Oral Submucous Fibrosis: A Pilot, Prospective Observational Study. *J Ayurveda Integr Med*. 2015; 6: 45-9.