



## RESEARCH ARTICLE

### EFFICACY OF OCCIMUM SANCTUM (TULSI) AND ORAL ANTIOXIDANTS (SM FIBRO) IN THE MANAGEMENT OF ORAL SUBMUCOUS FIBROSIS: A RANDOMIZED CLINICAL TRIAL

Dr. Sunita Kulkarni, \*Dr. Usha Rathod, Dr. Vaishali Agrawal and Dr. Rucha Pandhripande

Department of Oral Medicine and Radiology, Sdks Dental College, Nagpur, India

#### ARTICLE INFO

##### Article History:

Received 27<sup>th</sup> December, 2017  
Received in revised form  
23<sup>rd</sup> January, 2018  
Accepted 04<sup>th</sup> February, 2018  
Published online 30<sup>th</sup> March, 2018

##### Key words:

Ocimum Sanctum (Tulsi),  
Glycerine, Oral Antioxidants,  
Oral Submucous Fibrosis.

#### ABSTRACT

**Introduction:** Oral submucous fibrosis (OSMF) is one of the most prevalent premalignant conditions in India and difficult to treat. Recently many plants and fruit extract has been used. Tulsi (*Ocimum sanctum* Linn) 'basil' is one such plant with many medicinal values. Although the disease is advancing rapidly, its reliable treatment modality for its various stages has not yet evolved. So the aim of the study is to evaluate the efficacy of tulsi and oral antioxidants (SM FIBRO) in the treatment of OSMF.

**Aim:** To evaluate the efficacy of tulsi and oral antioxidants (SM FIBRO) in the treatment of OSMF. Materials and method- A randomized clinical trial of 100 OSMF patients were carried out in the department of oral medicine and radiology to evaluate the efficacy of *ocimum sanctum* (TULSI) and oral antioxidants (SM FIBRO) in the management of oral submucous fibrosis.

**Result:** The result of study showed statistically significant improvement in mouth opening, burning sensation, cheek flexibility and tongue protrusion in tulsi plus antioxidant group.

**Conclusion:** Tulsi and oral antioxidant combination is safe and promising treatment modality for oral submucous fibrosis.

Copyright © 2018, Sunita Kulkarni et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Citation: Dr. Sunita Kulkarni, Dr. Usha Rathod, Dr. Vaishali Agrawal and Dr. Rucha Pandhripande, 2018. "Efficacy of *ocimum sanctum* (tulsi) and oral antioxidants (sm fibro) in the management of oral submucous fibrosis: A randomized clinical trial", *International Journal of Current Research*, 10, (03), 67182-67186.

## INTRODUCTION

Oral sub mucous fibrosis (OSMF) is one of the most prevalent premalignant conditions in India. Etiopathogenesis of disease remains elusive till today. Malignant transformation rate is 3-7.6% (Harvey *et al.*, 1986). A plethora of treatments have been advocated, hypothesized and justified by many oral medicine clinicians, like systemic administration of antioxidants, immune milk, interferon gamma and intralésional injection of enzymes, steroids and placental extracts. Surgery has its own limitations and causes disfigurement. There is a constant endeavor to find a treatment modality that will be non-invasive yet effective and will also help in disease reversal (Keerthana *et al.*, 2013). Many natural plant extracts have been tried for the management of OSMF. Tulsi (*Ocimum sanctum* Linn) 'basil' is one such plant with many medicinal values. As described in ayurveda tulsi in several formulations can enhance immunity and metabolic functions (Bhateja, 2012). So the present study has been planned to evaluate the efficacy of tulsi and oral antioxidant in the treatment of OSMF.

\*Corresponding author: Dr. Usha Rathod,  
Department of Oral Medicine and Radiology, Sdks Dental College,  
Nagpur, India.

## Aim

To evaluate the efficacy of *ocimum sanctum* (TULSI) and oral antioxidants (SM FIBRO) in the management of oral submucous fibrosis.

## METHODS AND MATERIALS

The randomized clinical trial conducted between July 2015 to July 2016 in the Department of Oral Medicine and Radiology, Swargiya Dadasaheb Kalmegh Smruti Dental College and Hospital, Hingna, Nagpur. 100 OSMF patients, between the age group of 20 to 60 years, were chosen for the study. All the patients were diagnosed clinically and histopathologically for OSMF. Ethical clearance was obtained from the Institutional Ethical Committee. A written informed consent was obtained from the patients prior to their inclusion in the study.

## Inclusion Criteria

- Patients with stage 1, 2 and 3 of Oral Sub Mucous Fibrosis
- Patients who are ready to quit the habit and accept regular follow up protocol.

### Exclusion Criteria

- Patients with known history of systemic diseases, undergone surgery or under any drug therapy.
- Patient previously undergone treatment for OSMF.
- Pregnant women.
- Any evidence of hypersensitivity to tulsi.

### METHODOLOGY

A thorough clinical examination was carried out and relevant findings were recorded. Final diagnosis was confirmed on clinical and histo-pathological examination. 100 subjects were randomly divided in 2 equal groups, Group A (Tulsi group) and Group B (Tulsi and Sm Fibro group). Each group containing 50 subjects. Intensity of burning sensation was recorded using a Numerical Rating, Visual Analogue Scale. The interincisal mouth opening was measured using a vernier caliper from the mesioincisal angle of upper central incisor to the mesioincisal angle of lower central incisor and recorded in millimeters. In edentulous patients, the inter ridge (alveolar) distance along the midline were measured. Cheek flexibility and tongue protrusion were measured. Three measurements was recorded consecutively and the average value was calculated and recorded at regular intervals of 1 month for 3 months during the treatment. The Group A patients were instructed to mix glycerine and 1 gm of tulsi powder to make a paste. The patients were instructed to apply this paste all over the oral mucosa 4 times per day for 3 months. The subject patients were advised not to eat or drink for 15 minutes after the application of the tulsi. Group B were given the combination of Tulsi and SM Fibro capsule for 3 months. Result- 100 patients were included in the study of which 50 were in tulsi plus sm –fibro group and 50 in tulsi group. The mean age of patient in tulsi plus sm –fibro was 31.02±9.39 and in tulsi group it was 30.20±8.56. There were 19 female and 31 male in tulsi plus sm –fibro group and 4 female and 46 male in tulsi group. The mean of the mouth opening, cheek flexibility, tongue protrusion, burning sensation were recorded. There was statistically significant improvement in burning sensation and mouth opening, cheek flexibility, tongue protrusion at the end of therapy. Mean mouth opening (Figure 1 and Table 1)

was 27.1 mm before the treatment and 36.2 mm after the treatment in sm-fibro plus tulsi group and 26.78 before the treatment and 33.08 after the treatment in tulsi group ( $t = 3.29$ ;  $P < 0.001$ ) which was found statistically significant. Mean burning sensation was (Figure 2 and Table 2) 5.10 before the treatment and 1.06 after the treatment in tulsi group and 5.60 before the treatment and 0.74 after the treatment in sm-fibro plus tulsi group ( $t = 26.89$ ;  $P < 0.0001$ ) which was found statistically insignificant. Mean cheek flexibility was (Figure 3 and Table 3) 7.38 before the treatment and 10.54 after the treatment in tulsi group and 7.6 before the treatment and 12.68 after the treatment in sm-fibro plus tulsi group ( $t = 9.46$ ;  $P < 0.0001$ ) which was found statistically significant. Mean tongue protrusion was (Figure 4 and Table 4) 36.06 before the treatment and 45.16 after the treatment in tulsi group and 43.88 before the treatment and 50.5 after the treatment in sm-fibro plus tulsi group ( $t = 4.78$ ;  $P < 0.0001$ ) which was found statistically significant.

### DISCUSSION

Oral submucous fibrosis (OSMF) is one of the classic “Disease of Civilization” and now globally accepted as an Indian disease which has one of the highest rates of malignant transformation amongst various potentially malignant oral lesions and conditions.<sup>3</sup> A malignant transformation rate of OSMF is 7.6% over a period of 10 years and relative risk for malignant transformation may be as high as 11.7% (Balaji *et al.*, 2015). It is characterized by burning sensation of oral mucosa, depigmentation of oral mucosa, depapillation of tongue, reduced movement of tongue, reduction of mouth opening (More *et al.*, 2012). Number of treatment modalities are available for OSMF, not a single one is completely effective. Many of them have their adverse effects and recurrences. Herbal medicines has been gaining the attraction day by day. In this study tulsi and sm-fibro were tried because of non satisfactory results of conventional OSMF Treatment. Tulsi is known as ‘QUEEN’ of herb. The Latin name of the plant is *Ocimum sanctum* (Linn). The name Tulsi, which means “the matchless,” has been derived from Sanskrit language; and it belongs to family Lamiaceae.

Table.1

	Group	N	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Baseline	SM-Fibro	50	27.10	5.63	0.79	0.31	0.75,NS
	Tulsi	50	26.78	4.60	0.65		
1 month follow up	SM-Fibro	50	29.62	5.59	0.79	1.48	0.14,NS
	Tulsi	50	28.10	4.59	0.65		
2 month follow up	SM-Fibro	50	32.62	5.83	0.82	1.89	0.06,NS
	Tulsi	50	30.68	4.29	0.60		
3 month follow up	SM-Fibro	50	36.20	5.45	0.77	3.29	0.001,S
	Tulsi	50	33.08	3.88	0.54		

Table. 2

	Group	N	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Baseline	SM-Fibro	50	5.60	1.27	0.18	2.01	0.046,S
	Tulsi	50	5.10	1.19	0.16		
1 month follow up	SM-Fibro	50	3.96	1.10	0.15	0.17	0.85,NS
	Tulsi	50	4.00	1.12	0.15		
2 month follow up	SM-Fibro	50	1.52	1.18	0.16	5.54	0.0001,S
	Tulsi	50	2.70	0.93	0.13		
3 month follow up	SM-Fibro	50	0.74	0.82	0.11	1.83	0.069,NS
	Tulsi	50	1.06	0.91	0.12		

Table. 3

	Group	N	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Baseline	SM-Fibro	50	7.38	1.65	0.23	0.75	0.45,NS
	Tulsi	50	7.60	1.21	0.17		
1 month follow up	SM-Fibro	50	8.32	1.36	0.19	0.86	0.39,NS
	Tulsi	50	8.54	1.18	0.16		
2 month follow up	SM-Fibro	50	9.80	0.90	0.12	2.49	0.014,S
	Tulsi	50	10.34	1.23	0.17		
3 month follow up	SM-Fibro	50	10.54	0.97	0.13	9.46	0.0001,S
	Tulsi	50	12.68	1.26	0.17		

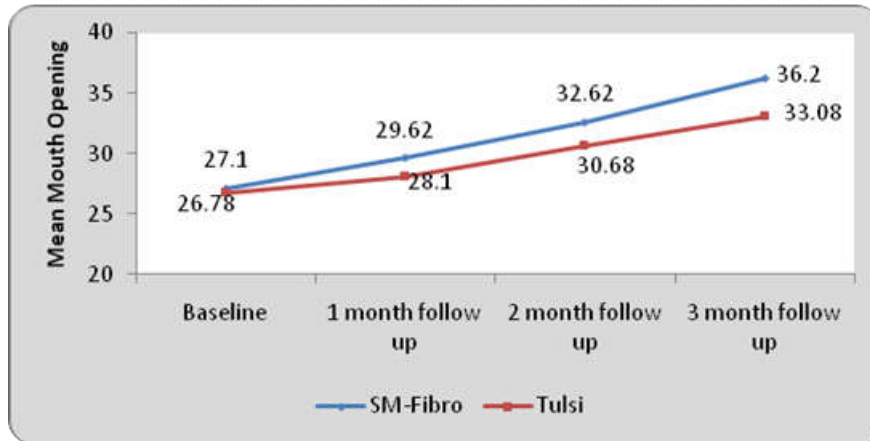


Figure. 1

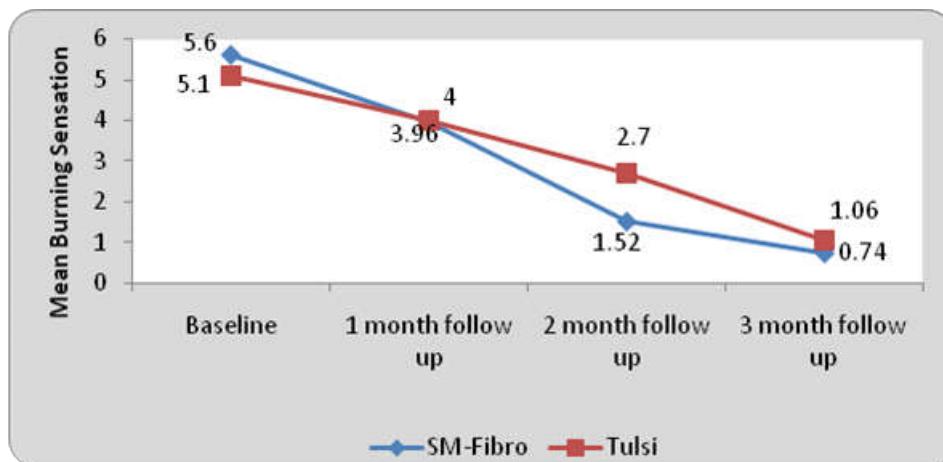


Figure. 2

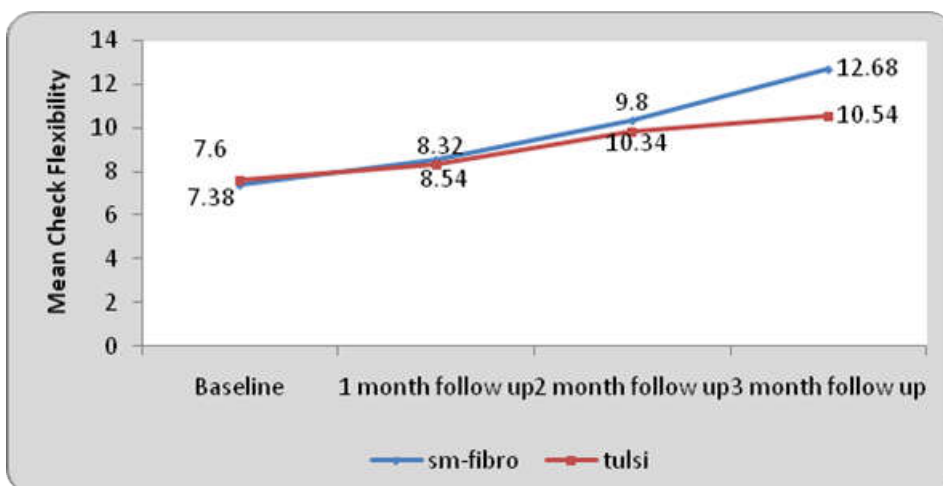


Figure. 3

It enhances immunity and improves metabolic functions. By inhibiting enzymes it reduces inflammation. The polyphenol rosmarnic acid present in tulsi is a strong antioxidant. It induces apoptosis and inhibits proliferation (Bhateja, 2012). Dokania et al. revealed that there was enhancement of memory in mice when intraperitoneal injection of *O. sanctum* water extract was given and they said that this effect might be due to its antioxidant activity. Mahesh Subramanian et al. reported a new polysaccharide (OSP) from *O. sanctum* as an efficient water soluble antioxidants that can prevent oxidative damages to lipids, DNA and splenocytes caused by various oxidation inducers (Wahi et al., 1966). Along with antioxidant property *occimum sanctum* has demonstrated good efficacy as an anti-caries, antibacterial agent.

P. Agarwal et al. proposed that at 4% concentration *occimum sanctum* extract was effective as an antibacterial agent against bacterial flora of the oral cavity. Agarwal P, Nagesh L, Murlikrishnan showed the *O. sanctum* has antibacterial property against *Streptococcus mutans*. At 4% concentration the maximum antibacterial potential was seen which was as effective as 0.2% Chlorhexidine and Listerine in reducing the levels of *Streptococcus mutans* (Wahi et al., 1966). We have taken oral antioxidant (SM-FIBRO) which contains Lycopene, Betacarotene, Selenium, Zinc Sulphate Copper, Alpha Lipoic Acid. Lycopene, an effective antioxidant has been proved to be the most potent radical scavenger. In the present study total 100 patients were included which were divided into 2 groups. The age of the patients in OSMF group ranged from 20 to 60 years. The mean age was 30.96 years. Peak incidence of OSMF was most prevalent in the 3<sup>rd</sup> decade of life. This observation was in accordance with that of Wahi PN et al. (1966), (Kumar and Kumari, 2015) Sinor PN et al. (1990) etc. But study conducted by Wahab et al. maximum percentage of patients (73%) were seen in the second decade followed by third decade of life. We have taken oral antioxidant (SM-FIBRO) which contains Lycopene, Betacarotene, Selenium, Zinc Sulphate Copper, Alpha Lipoic Acid. Lycopene, an effective antioxidant has been proved to be the most potent radical scavenger. In the present study total 100 patients were included which were divided into 2 groups. The age of the patients in OSMF group ranged from 20 to 60 years. The mean age was 30.96 years. Peak incidence of OSMF was most prevalent in the 3<sup>rd</sup> decade of life. This observation was in accordance with that of Wahi PN et al. (1966), (Kumar and Kumari, 2015), Sinor PN et al (1990) etc.

But study conducted by Wahab et al. (2014) maximum percentage of patients (73%) were seen in the second decade followed by third decade of life. There are different reports on sex ratio in the different published studies. In present study, out of 100 OSMF patients; 77 were males and 23 were females. The frequency of male involvement was seen more at the age of 3<sup>rd</sup> decade because of more social contacts at this age and easy availability of newer chewing material like gutkha, betel nut etc. which were the most prevalent habit associated with the disease and females were more conscious about their health and probably feeling uncomfortable to ask the vendors in getting gutkha products (Nandhini and Jagannathan, 2016). The results of the study showed that the combined action of tulsi and antioxidant results in higher efficacy and highly potent treatment for OSMF. The results of the present study were compared with the results of other studies. In the study, conducted by Srivastava, et al. in 41 OSMF patient with tulsi and turmeric in glycerine showed

mark improvement in mouth opening and burning sensation. Alam S et al. conducted a study on 60 subjects to see the efficacy of aloe-vera gel in OSMF as an adjuvant. Significant improvement was seen in the groups receiving aloe vera most symptoms of OSMF compared with the non-Aloe vera groups (Srivastava et al., 2015). In a study conducted by Rohit et al in 64 OSMF patient showed that anti-oxidant drugs are overall favourable for early cases of oral submucous fibrosis clinically as well as histopathologically (Rohit Mehrotra et al., 2013). Santosh patil et al. showed that lycopene can bring about significant clinical improvements in the symptoms like mouth opening and tongue protrusion when compared to aloe vera (Niranzena Panneer Selvam and Arjun Anand Dayanand Lycopene, 2013). Niranzena et al conducted a study on 45 OSMF patient and concluded that lycopene in combination with intralesional steroids and Hyaluronidase, is an effective treatment modality in OSMF patient (Patil et al., 2015).

## Conclusion

Tulsi and antioxidant is safe and effective treatment modality for OSMF. It is effective for all age group. It will be effective alternative to the present conventional treatment.

## REFERENCES

- Balaji, P., Govindraju, P., Gupta, A., Pawar, Y. and Gazge Nm. 2015. Oral Squamous Cell Carcinoma In Background Of Oral Submucous Fibrosis: A Case Report. *Ijss Case Reports & Reviews*, 1 (12):40-44.
- Bhateja, S. 2012. Therapeutic Benefits Of Holy Basil (Tulsi) In *General And Oral Medicine*, Ijrap, 3(6).
- Gupta, M.K., Shubhangi Mhaske, Raju Ragavendra and Imtiyaz. 2008. Oral Submucous Fibrosis - Current Concepts In Etiopathogenesis. *People's Journal Of Scientific Research.*, 1:39-44.
- Harvey, W., Scutt, A., Meghji, S. et al. 1986. Stimulation Of Human Buccal Mucosa Fibroblasts In Vitro By Betel-Nut Alkaloids. *Arch Oral Biol.*, 31:45-9.
- Keerthhana, Balabaskaran1, Dr.Arathy.Srinivasan, L. et al. 2013. Treatment Options For Oral Submucous Fibrosis. *Iosr Journal Of Dental And Medical Sciences (Iosr-Jdms)* E-Issn: 2279-0853, P-Issn: 2279-0861. Volume 10, Issue 5 Pp 33-35.
- Kumar, P. and Kumari, S. 2015. Pharmacological Properties Of Tulsi: A Review. *International Journal Of Ayurvedic & Herbal Medicine*, 5(4) (1941-1948)
- More, Cb., Das, S., Patel, H., Adalja, C., Kamatchi, V. and Venkatesh, R. 2012. Proposed Clinical Classification For Oral Submucous Fibrosis. *Oral Oncology*, 31;48(3):200-2.
- Nandhini T, Jagannathan N. Prevalence Of Oral Submucous Fibrosis Among Different Habitual Chewers. *J. Pharm. Sci. & Res.* 2016; 8(9): 1106-1109.
- Niranzena Panneer Selvam and Arjun Anand Dayanand Lycopene, 2013. In The Management Of Oral Submucous Fibrosis *Asian J Pharm Clin Res*, Vol 6, Issue 3, 58-61.
- Noor-Ul-Wahab, Sa., Khan, M., Khan, S., Mehdi, H. and Sawani, A. 2014. Frequency And Clinical Presentation Of Oral Submucous Fibrosis. *Pakistan Journal Of Medicine And Dentistry*, 3(04):48-53.
- Patil, et al. 2015. Comparative Efficacy Of Lycopene And Aloe Vera In OSMF *International Journal Of Health & Allied Sciences*, • Vol. 4 • Issue 1.
- Rohit Mehrotra, Sanjay Kumar Nigam and Nitu Nigam. 2013. Role Of Antioxidants On Oral Submucous Fibrosis: A

- Clinico – Pathological Study. *Journal Of Evolution Of Medical And Dental Sciences*, Vol. 2, Issue 47, November 25; Page: 9174-9183.
- Sinor, Pn., Gupta, Pc., Murti, Pr., Bhonsle, Rb., Daftary, Dk., Mehta, Fs. *et al.* 1990. A Case-Control Study Of Oral Submucous Fibrosis With Special Reference To The Etiologic Role Of Areca Nut. *J Oral Pathol Med.*, 90 (2):94-8.
- Srivastava. A., Agarwal. R., Chaturvedi, T.P., Akhilesh, C. and Singh, O. 2015. 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*, 15.
- Wahi, Pn., Kapur, Vl., Luthra, Uk. and Srivastava, Mc. 1966. Submucous Fibrosis Of The Oral Cavity 1. Clinical Features. *Bull World Health Organ.*, 35:789–92.