International Journal of Research in Medical Sciences
Madhulatha G et al. Int J Res Med Sci. 2017 Nov;5(11):4719-4723
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20174644

Original Research Article

Tulasi a magical herb and a boon for management of oral submucous fibrosis: a clinical study

G. Madhulatha*, N. Vijayalaxmi, T. Harshavardhan

Department of Oral Medicine and Radiology, Meghna Institute of Dental Sciences, Nizamabad, Telangana, India

Received: 15 September 2017
Accepted: 19 September 2017

***Correspondence:**
Dr. G. Madhulatha,
E-mail: honeylatha_22@yahoo.com

ABSTRACT

Background: Plants are a good source of drugs in traditional and modern medicine. One among these plants is *"tulasi" The queen of herbs"* which is used in ayurveda for its diverse properties like antioxidant, analgesic, anti-inflammatory, antidiabetic, and others. It belongs to labiate family and is the most sacred and valued in traditional culture of India. AIMS of the study was to evaluate the efficacy of Tulasi in the treatment of OSMF.
Methods: The study included 20 individuals, females and males of age group 20-50yrs who visited the outpatient department who were diagnosed clinically as having OSMF, categorized according to pindborg's classification. Patients were asked to apply 500mg of Tulasi medicine paste (Tulasi powder mixed with glycerine) twice daily for 1month and were recalled for follow up every week for 1month. All the clinical parameters - mouth opening, burning sensation, pain with the lesion and others were evaluated and recorded in specially designed proforma.
Results: Friedman test and wilcoxon signed rank test was used for statistical evaluation. Significant improvement with P value <0.05 was noticed in burning sensation, mouth opening and pain associated with the lesion.
Conclusions: The study concludes that Tulasi can be used as a main treatment modality in the management of patients with OSMF.

Keywords: Antioxidant, Burning sensation, Mouth opening, Oral submucous fibrosis, Pain associated with lesion, Tulasi

INTRODUCTION

Oral Submucous Fibrosis (OSMF) is defined as an insidious chronic condition of unknown etiology affecting the oral mucosa characterized by dense collagen tissue deposition within submucosa, occasionally extending to the pharynx and esophagus.[1] The disease is characterized by blanching and stiffness of oral mucosa, trismus, burning sensation, loss of mobility of tongue and loss of gustatory sensation. Due to easy availability of areca nut and its consumption in excess, majority of these cases are seen in Indian population.[2] The prevalence varies from 0.20-0.5% in India with a higher percentage being found in the southern parts of the country.[3] If left untreated it can progress to oral cancer and its malignant transformation rate is found to be in the range of 0.5-6%.[4]

Numerous treatment modalities are being used for managing OSMF as its etiology is multifactorial and pathogenesis is still opaque. In majority of cases, the main culprit is found to be betel nut chewing. Hence, discontinuation of this habit serves as a substantial measure for dealing with it. But as the incidence of OSMF is still rising alarmingly, there is a dire need to search for an effective and safe remedy because of lack of present therapies to either provide a complete cure or treat the patients at the cost of adverse effects.[1,5] Natural ayurvedic preparations are being appraised to be effective

in treatment of osmf but they have to be assessed in proper clinical trials. One among these natural preparations is tulasi, which along with life style modification can lower the symptoms of OSMF and help in healing the disease fractionally.

Tulasi (*Ocimum sanctum Linn*) 'basil' is a plant with many medicinal values. Ayurveda recommends tulasi in several formulations to enhance immunity and metabolic functions. It helps in reducing inflammation by inhibiting the inflammation-causing enzymes.[6]Our main intention behind preferring this drug is that there are no sufficient clinical trials on OSMF in spite of their proven efficacy as anti-metabolite and anti-inflammatory actions which are crucial in the treatment of OSMF.[7]

METHODS

A prospective observational clinical study was conducted at department of oral medicine and radiology, Meghna institute of dental sciences, Telangana state. Institutional ethical committee approval was taken before commencing the study. Informed consent was obtained from each individual who participated in the study. A total of 20 patients who were clinically diagnosed as OSMF and categorized according to pindborg, pertaining to the age group of 20-50 years were recruited for the study.

Patients who were diagnosed clinically having characteristic features of oral submucous fibrosis and belonging to the age group of 20-50 years, irrespective of gender were included in the study. Patients who were undergoing treatment for oral submucous fibrosis with medications other than Tulasi, showing malignant features such as non-healing ulcer, induration, positive lymph nodes etc and who are systemically compromised were excluded from the study. Armamentarium used includes Tulasi tablets 500mg (pathanjali product), glycerine (unison product), mortar pestle for pulverization, scoops, sterile containers, diagnostic instruments and measuring tools for mouth opening (Figure 1).

Figure 1: Materials and methods.

Procedure

In the beginning of the study all the patients were instructed to quit the habit of chewing gutkha, pan, betel nut and tobacco smoking and use of alcohol. Following this, they were given sterile containers of Tulasi medicine (Tulasi powder mixed with glycerine) along with a measuring scoop and were advised to apply 500mg of paste twice daily for a period of one month, all over the oral mucosa and were instructed not to drink or eat anything for next 15 minutes.

Prior to the treatment, mouth opening was measured using mouth opening scale and burning sensation, pain associated with the lesion were measured using visual analogue scale and difficulty in speech and swallowing, other secondary changes were also recorded. The patients were recalled every week for a period of one month for evaluation and each time the parameters were measured and recorded in proforma. No biopsy was performed on completion of the treatment and only clinical improvement was taken into consideration. At the end of the study, results were statistically analyzed using Friedman test and wilcoxon signed rank test to evaluate the efficacy of treatment.

RESULTS

Table 1: Mean comparison of burning sensation, mouth opening and pain associated with the lesion among different weeks.

Clinical parameters	Burning sensation Mean±SD	Chi-square value	P value
First week	4.75±2.51	57.284	<0.001 S
Second week	3.75±2.51		
Third week	2.85±2.37		
Fourth week	2.05±2.14		
Clinical parameters	Mouth opening Mean±SD	Chi-square value	P value
First week	28.65±8.59	57.000	<0.001 S
Second week	30.20±8.40		
Third week	31.25±8.32		
fourth week	32.25±8.24		
Clinical parameters	Pain associated with lesion Mean±SD	Chi-square value	P value
First week	4.05±2.09	52.027	<0.001 S
Second week	3.35±1.69		
Third week	2.35±1.76		
Fourth week	1.55±1.50		

Statistical analysis: Friedman test. Statistically significant if P<0.05

The study was accomplished with 20 clinically diagnosed OSMF patients who were between age group of 20-50years. The major clinical features of OSMF were observed and recorded which include burning sensation, mouth opening, pain associated with the lesion, difficulty in swallowing and difficulty in speech and at the end of 1st, 2nd, 3rd and 4th week of the therapy. The mean burning sensation as recorded on the visual analogue scale in first week was 4.75±2.51 and this was reduced to 2.05±2.14 as recorded in 4th week of the therapy [P value <0.001] (Table 1). The mean mouth opening as recorded in first week was 28.65±8.59 which was increased to 32.25±8.24 as recorded in 4th week of the therapy [P value <0.001] (Table 1). The pain associated with the lesion as recorded on the visual analogue scale in first week was 4.05±2.09 which was reduced to 1.55±1.50 as recorded in 4th week of the therapy [P value <0.001] (Table 1). Difficulty in swallowing and speech and vesiculations among study groups observed at different weeks was not significant in the study with P value P <0.05 (Table 2, Table 3). No clinically significant adverse reactions to the treatment were seen in patients taking the treatment.

Table 2: Mean and SD, Chi-square and P value of clinical parameters among different weeks.

Clinical parameters	First week	Second week	Third week	Fourth week	Chi-square value	P value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD		
Burning sensation	4.75±2.51	3.75±2.51	2.85±2.37	2.05±2.14	57.284	<0.001 S
Mouth opening	28.65±8.59	30.20±8.40	31.25±8.32	32.25±8.24	57.000	<0.001 S
Pain associated with lesion	4.05±2.09	3.35±1.69	2.35±1.76	1.55±1.50	52.027	<0.001 S
Ulcers/vesicles	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	****	****
Difficulty in swallowing	0.55±0.51	0.60±0.50	0.55±0.51	0.50±0.51	4.000	0.261 NS
Difficulty in speech	0.55±0.51	0.60±0.50	0.55±0.51	0.40±0.50	1.562	0.211 NS

Table 3: Comparison of different clinical parameters between weeks.

Weeks	Burning sensation		Mouth opening		Pain associated with the lesion		Ulcers/ vesicles		Difficulty in swallowing		Difficulty in speech	
	Mean±SD	P value	Mean±SD	P value	Mean±SD	P value	Mean±SD	P value	Mean±SD	P value	Mean±SD	P value
1ST week	4.75±2.51	<0.001 S	28.65±8.59	<0.001 S	4.05±2.09	<0.001 S	0.00±0.00	1.000 NS	0.55±0.51	0.317 NS	0.55±0.51	0.317 NS
2ND week	3.75±2.51		30.20±8.40		3.35±1.69		0.00±0.00		0.60±0.50		0.60±0.50	
1ST week	4.75±2.51	<0.001 S	28.65±8.59	<0.001 S	4.05±2.09	<0.001 S	0.00±0.00	1.000 NS	0.55±0.51	1.000 NS	0.55±0.51	1.000 NS
3RD week	2.85±2.37		31.25±8.32		2.35±1.76		0.00±0.00		0.55±0.51		0.55±0.51	
1ST week	4.75±2.51	<0.001 S	28.65±8.59	<0.001 S	4.05±2.09	<0.001 S	0.00±0.00	1.000 NS	0.55±0.51	0.317 NS	0.55±0.51	0.083 NS
4TH week	2.05±2.14		32.25±8.24		1.55±1.50		0.00±0.00		0.50±0.51		0.40±0.50	
2ND week	3.75±2.51	<0.001 S	30.20±8.40	<0.001 S	3.35±1.69	<0.001 S	0.00±0.00	1.000 NS	0.60±0.50	0.317 NS	0.60±0.50	0.317 NS
3RD week	2.85±2.37		31.25±8.32		2.35±1.76		0.00±0.00		0.55±0.51		0.55±0.51	
2ND week	3.75±2.51	<0.001 S	30.20±8.40	<0.001 S	3.35±1.69	<0.001 S	0.00±0.00	1.000 NS	0.60±0.50	0.157 NS	0.60±0.50	0.050 NS
4TH week	2.05±2.14		32.25±8.24		1.55±1.50		0.00±0.00		0.50±0.51		0.40±0.50	
3RD week	2.85±2.37	<0.001 S	31.25±8.32	<0.001 S	2.35±1.76	<0.001 S	0.00±0.00	1.000 NS	0.55±0.51	0.317 NS	0.55±0.51	0.083 NS
4TH week	2.05±2.14		32.25±8.24		1.55±1.50		0.00±0.00		0.50±0.51		0.40±0.50	

Statistical analysis: Wilcoxon signed rank test. statistically significant if P<0.05

DISCUSSION

Though various treatment modalities are available for treating OSMF, complete success is not being attained by a single modality in all the cases. Many pharmaceutical products have been proved to be successful in treating osmf, yet they are found to have adverse effects and recurrences.[1,2] In recent times, the focus on the plant research has increased all over the world because they are considered to be one of the most important sources of

medicines. The important advantages claimed for the therapeutic use of medicinal plants in various ailments are their safety besides being economical, effective and their easy availability.[8]

Tulasi is rich in antioxidant and renowned for its restorative powers, it has several benefits: relieves stress/adaptogen, bolsters immunity, enhances stamina, promotes healthy metabolism and a natural immunomodulator.[9] Some of the main chemical constituents of tulasi are: oleanolic acid, ursolic acid, rosmarinic acid, eugenol, carvacrol, linalool, β-caryophyllene (about 8%), β-elemene (c.11.0%) and germacrene D (about 2%).[10] The proposed mechanism of action of this medicament in OSMF is anti-inflammatory, antioxidant, anti-stress, analgesics and others (Figure 2).[11-13]

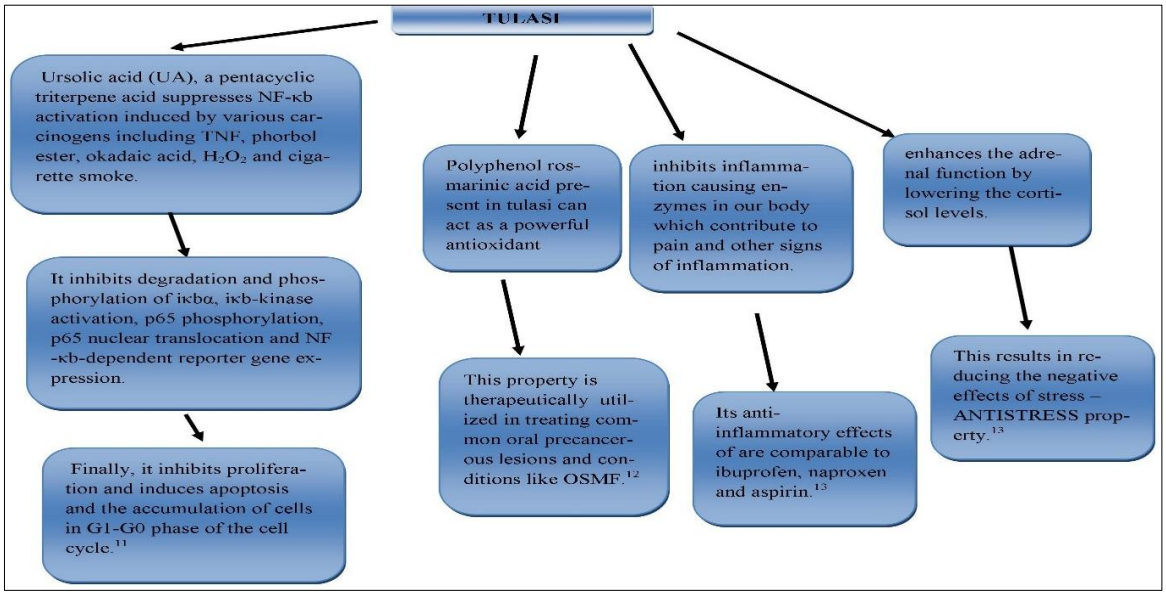

Figure 2: Mechanism of action.

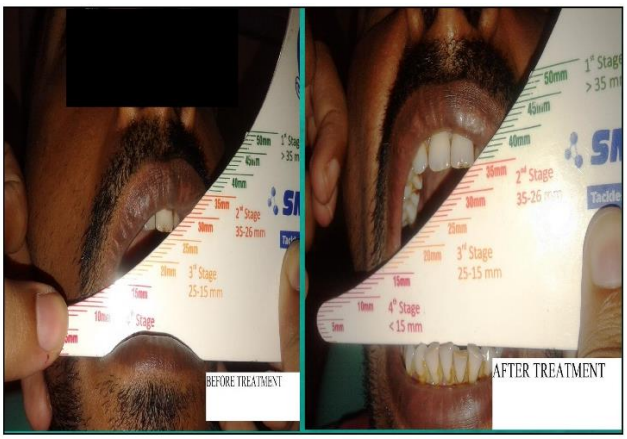

Figure 3: Improvement in mouth opening clinical parameter.

The results obtained from the present study shows that the treatment with this herbal medicine, "*tulasi"* brings out an early, sustained and significant relief from burning sensation clinically as soon as in a time span of one month. Mouth opening and pain associated with the lesion have also showed significant improvement in this study (Figure 3). Life style modification was also given a priority by motivating the patients to discontinue the deleterious habits during the study as well as after its completion.

In the study conducted by Adit Srivastava et al, Clinical evaluation of the role of Tulasi and turmeric in the management of oral submucous fibrosis, the results showed that synergistic action of turmeric and Tulasi produced statistically significant improvement in mouth opening and burning sensation and it was also associated with minimal side effects like bad taste, mild headache, which disappeared after the treatment.[14] When compared with the above study, we employed only Tulasi as a main treatment modality for osmf and it showed a statistically significant improvement not only in burning sensation and mouth opening clinical parameters but also in pain associated with the lesion. Our study did not show any side effects associated with the use of Tulasi.

In the study, conducted by Alam S et al, the efficacy of Aloe-vera gel as an adjuvant therapy of OSMF, the results showed that the groups receiving aloe vera had a significant improvement in most symptoms of OSMF compared with the non-*aloe vera* groups in both the

medicinal and surgical categories.[15] In the above study aloe vera was used as an adjuvant therapy where as in our study tulasi is used as a main therapy for osmf. Besides this they employed invasive techniques (injections and surgery) where as our therapy needs no invasion. In the study conducted by Sande et al, Comparison of mouth opening with different non-surgical treatment modalities in oral submucous fibrosis, the results showed that turmeric and jaggery application improves mouth opening in osmf patients.[16] Lycopene has shown significant improvement in mouth opening in the study by Karemore et al.[17] When compared with the above two studies, in the present study tulasi has shown an effective improvement not only in mouth opening but also in other two clinical parameters of osmf namely burning sensation and pain associated with the lesion which are the main symptoms for which the patient seeks treatment for in OSMF.

OSMF a potentially malignant disorder having a long list of medical treatments available but till now we are unable to get a solution, hence needs an urgent attention for its treatment and for improvement of quality of life of the patient. The answer would be natures store and the miraculous plant tulasi. This can be explained by the fact that this is a primary study using herbal medicines- tulasi. Further studies are to be conducted to evaluate its comparative efficacy with already existing OSMF treatment modalities.

CONCLUSION

Oral submucous fibrosis is one of the most poorly understood and unsatisfactorily treated oral diseases. Though variety of treatments is available for OSMF the most effective is the one which is affordable and effective in treating the patients. “Tulasi- the queen of herbs” along with life style modification is a safe and efficacious medicament for treating OSMF patients as it can provide a safer, economical and effective alternative to the current conventional treatment, which can be useful in a country like India.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Borle RM, Borle SR. Management of oral submucous fibrosis: A conservative approach. J Oral Maxillofac Surg. 1991;49:788-91.
2. Scully C. The oral cavity. In: Champion RH, Burton IL, Ebling FJ, editors. Textbook of Dermatology. 5th Ed. London: Oxford Blackwell Scientific Publication; 1992:2689-2276.
3. Saraswathi TR, Ranganathan K, Shanmugam S, Sowmya R, Narasimhan PD, Gunaseelan R. Prevalence of oral lesions in relation to habits: Cross-sectional study in South India. Indian J Dent Res. 2006;17:121-5.
4. George A, Sreenivasan BS, Sunil S, Varghese SS, Thomas J. Potentially malignant disorders of oral cavity. J Oral Maxillofac Pathol. 2011;2:95-100.
5. Canniff JP, Harvey W, Harris M. Oral submucous fibrosis: Its pathogenesis and management. Br Dent J. 1986;160:429-34.
6. Prakash P, Gupta N. Therapeutic uses of Ocimum sanctum linn (Tulsi) with a note on eugenol and its pharmacological actions: A short review. Indian J Physiol Pharmacol. 2005;49:125-31.
7. Kelm MA, Nair MG, Strasburg GM, DeWitt DL. Antioxidant and cyclo-oxygenase inhibitory phenolic compounds from Ocimum sanctum Linn. Phytomedicine. 2000;7:7-13.
8. Siddiqui HH. Safety of herbal drugs an overview. Drugs and over views. 1993;1(2):7-10.
9. Maheshwari R, Prasad M. Usage of Holy Basil for Various Aspects: Bull. Environ. Pharmacol. Life Sci. September 2012;1(10):67-9.
10. Maheshwari R, Rani B. multifaceted usage of holy basil. Journal of Drug Discovery and Therapeutics. 2013;1(5):1-4.
11. Aggarwal BB, Prasad S, Reuter S, Kannappan R, Yadev VR, Park B, et al. Identification of novel anti-inflammatory agents from ayurvedic medicine for prevention of chronic diseases: Reverse pharmacology and bedside to bench approach. Curr Drug Targets. 2011;12:1595-653.
12. MP Bhattathiry, 15 benefits of the holy basil Available at https://www.thoughtco.com/benefits-of-the-holy-basil-tulsi-1770035.
13. Gupta SK, Prakash J, Srivastava S. Validation of claim of Tulasi, Ocimum sanctum Linn as a medicinal plant. Indian J Experimental Biology 2002;40(7):765-73.
14. 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(1):45-9.
15. Alam S, Ali I, Giri KY, Gokkulakrishnan S, Natu SS, Faisal M, et al. Efficacy of aloe vera gel as an adjuvant treatment of oral submucous fibrosis. Oral Surg Oral Med Oral Pathol Oral Radiol. 2013;116:717-24.
16. Karthik PM, Sande A, Ashwinirani SR, Nayak A, Pawar R, Patil P. Comparison of Mouth Opening with Different Non-Surgical Treatment Modalities in Oral Submucous Fibrosis. AJDDT. 2015;2(3):072-7.
17. Karemore TV, Motwani M. Evaluation of the effect of newer antioxidant lycopene in the treatment of oral submucous fibrosis. Indian J Dent Res. 2012;23:524-8.

Cite this article as: Madhulatha G, Vijayalaxmi N, Harshavardhan T. Tulasi a magical herb and a boon for management of oral submucous fibrosis: a clinical study. Int J Res Med Sci 2017;5:4719-23