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# A clinical study on management of oral submucous fibrosis using Curcumin and Tulsi

**Dr. Prasanna Kumar P[1], Dr. Ankita Raj[2], Dr. Ankur Rathaur[3], Dr. Akash Tiwari [4]Dr Debapriya Roy[5] Dr. Isheeta Verma[6]**

## Author :

**Dr. Prasanna Kumar P**,Professor, Department Of Oral & Maxillofacial Surgery,Rama Dental College

**Dr. Ankita Raj**,Professor, Department Of Oral & Maxillofacial Surgery,Rama Dental College

**Dr. Ankur Rathaur**,Senior Lecturer, Department Of Oral & Maxillofacial Surgery,Rama Dental College

**Dr. Akash Tiwari**,Senior Lecturer, Department Of Oral & Maxillofacial Surgery,Rama Dental College**Dr Debapriya Roy** ,Post Graduate , Department of Oral and Maxillofacial Surgery, Rama Dental College and Research Centre , Kanpur

**Dr. Isheeta Verma**,Post Graduate , Department of Oral and Maxillofacial Surgery, Rama Dental College and Research Centre , Kanpur

## Corresponding Author :

Dr. Prasanna Kumar P
Mail: drprasannakumar.p.fds@ramauniversity.ac.in

**ABSTRACT**

**Aim &Objective:** Assessment of utility of Tulsi and Curcumin in treatment of oral submucous fibrosis: a clinical study.

**Material and methods:** The study included 30 individuals. All the clinical parameters including mouth opening and burning sensation were evaluated and recorded in specially designed proforma. The burning sensation and inter-incisal distance were measured on visual analogue scale (VAS) and vernier calibre (in millimetres), respectively. The patients were instructed to apply the gel (combination of tulsi and curcumin) to the affected areas of oral cavity five times in a day. Patients were recalled after every fifteen days for continuous three months (total 6 visits for each patient). On each visit, the mouth opening and burning sensation were recorded.

**Results:** The difference between the mouth opening before and after the treatment was found to be statistically significant. Similar significant findings were observed with reference to the reduction in burning sensation in the present study. The mean of the burning sensation before treatment was 5.43±2.02 and after treatment was 0.20±.76 as assessed by VAS. On correlation of the findings of mouth opening and burning sensation in the subjects of different grades, the results were found to statistically significant. No clinically eminent adverse reactions to the therapy were seen in any patient.

**Clinical significance:** The combination of Tulsi and Curcumin can be considered as a better alternative to the modern treatmentmodality in the management of all grades of OSMF..

**Keywords:**Mouth opening, , Tulsi, Curcumin, Burning sensation, Oral submucous fibrosis

## INTRODUCTION

Oral submucous fibrosis (OSMF) is a chronic, complex precancerous condition of the mouth characterized by juxta-epithelial inflammatory reaction and progressive fibrosis of the submucousal tissues (the lamina propria and deeper connective tissues). The disease is progressive and its clinical features depend on the stage of the disease. The majority of patients present with an intolerance to spicy food, rigidity of lips, tongue and palate leading to varying degrees of limitation of opening of mouth and tongue movement. Arecoline in arecanut is the main etiological agent causing the disease. Other factors include betel nut chewing, capsaicin, autoimmunity and genetic predisposition [1].

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OSMF is the most poorly appreciated and inadequately managed disease. The progression of disease is more rapid in younger age group. All the available treatment modalities give only symptomatic relief which are of short duration. The incidence of OSMF still rising alarmingly and there is a dire need to search for an efficient and reliable remedy taking into account the shortcomings of the present treatment modalities to either provide a complete relief or treating the patients at the cost of adverse effects. In order to lower the symptoms of OSMF, natural ayurvedic treatment along with life style modification can help and thus provide comfort to the patient without causing side effects [2]. A number of medicinal properties of tulsi including antioxidant, antiinflammatory, chemopreventive, anticarcinogenic, immunomodulatory, etc have been studied and described in previous studies [3]. Similarly, it is well known that Turmeric (*Curcuma longa Linn*) has a wide range of therapeutic actions such as anti-inflammatory, a strong antioxidant etc [4].

Hence, the present study was undertaken to evaluate the efficacy of Tulsi and Curcumin in the management of OSMF

## MATERIALS AND METHOD

This prospective study was carried out in the Department of Oral and Maxillofacial Surgery , Rama Dental College, Kanpur, after getting approval from Institutional ethical committee. The sample size was 30 patients. Patients were included irrespective of age, gender, occupation, social status, ethnicity and stages of OSMF.

Subjects clinically diagnosed to have OSMF were included in the study after obtaining the informed written consent from them. The purpose and design of clinical trial was explained to each patient. The patients who were already undergoing or undergone treatment for OSMF and the patients suffering from any systemic disease which is known to cause oral ulcerations, burning of oral mucosa or reduction in mouth opening were excluded from the study.

A thorough clinical examination of the oral cavity was done after taking history of present illness. All the signs and symptoms were recorded in the case history proforma including the grade of OSMF.OSMF was graded according to clinical & functional staging of Haider SM, Merchant AT, Fikree FF, Rahbar MH (1999) [5]. The burning sensation and inter-incisal distance were measured on visual analogue scale (VAS) and vernier calibre (in millimetres), respectively. The patients were instructed to apply the given gel to the affected areas of oral cavity five times daily after drying the oral mucosa by a clean cotton cloth and not to eat or drink anything for next 15 minutes following the application. Patients were recalled after every fifteen days for continuous three months (total 6 visits for each patient). On each visit, the mouth opening and burning sensation were recorded.

We asked the patients to bring the used empty gel bottle on each follow up visit to check their compliance and to see whether all the gel was used or not.

**Ayurvedic drug dose and formulation.**

Materials required-

1. Carbopol-940- for base
2. Water extract of Tulsi leaves

3. Water extract of Curcumin powder
4. Stearic acid as a stabilizing agent and

5. Methyl paraben as preservative

Method of drug preparation- One gm of Carbopol-940was soaked in 99ml of distilled water for 24 hours, which was used as a base. Tulsi leaves*(ocimum sanctum Linn)*was soaked in 20ml water for 30 minutes, grinded, filtered and then water extract was prepared. Turmeric powder *(Curcuma longa Linn)*was boiled in 500ml of water for 30 minutes, filtered and then water extract was prepared. The prepared extract was transferred into carbopol base and homogenized. Stearic acid and Methyl paraben 0.2% was added as a stabilizing agent and preservative respectively. The preapared ayurvedic drug then filled into disposable bottles of 10 gram each. Only one bottle (10 gm) was given to each patient during their every visit.

The findings were recorded in tabular format and analyzed the data using paired and unpaired‘t’ test to find out the statistical significance

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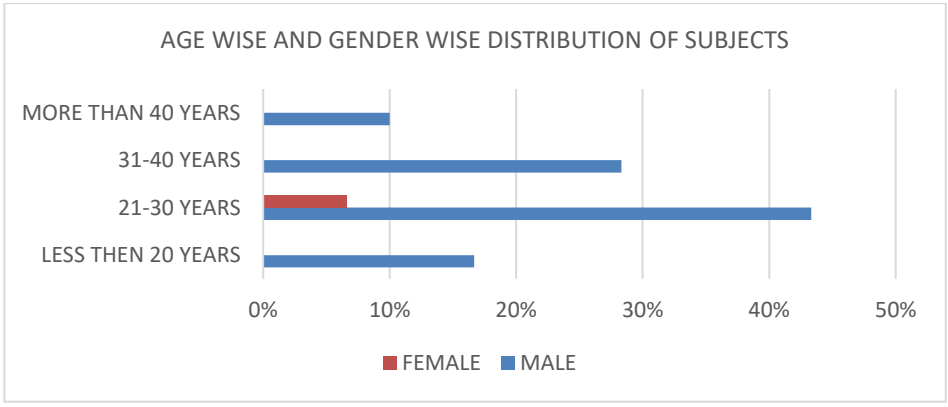
## OBSERVATION AND RESULTS

The present study included 30 subjects in the range of 18 years to 48 years. Amongst them 28(93.33%) were male and only 2(6.67%) subjects were female. Fifty percent of the patients (no. 15) were in 21-30 yrs age group suggesting that OSMF was common in males in third decade in this study. Age wise and gender wise distribution of the subjects is depicted in graph 1.




**Graph 1:** Age wise and gender wise distribution of subjects

The major clinical features of OSMF observed and recorded were mouth opening and burning sensation. The mean of the mouth opening before treatment was observed to be 23.00±6.29 and after treatment was 23.66±6.45 as measured by vernier calibre. The difference between the mouth opening before and after the treatment was found to be statistically significant as shown in Table 1. (t value-0.009, < 0.05)

**Table 1:** Improvement in mouth opening in patients with OSMF

| | **Mean** | **SD** | **Paired t test** | **t-value** |
|---|---|---|---|---|
| Before the treatment | 23.00 | 6.29 | 2.81 | 0.009,S |
| After the treatment | 23.66 | 6.45 | | |

Similar significant findings are observed with reference to the reduction in burning sensation in the present study, shown in Table 2. The mean of the burning sensation before treatment was observed to be 5.43±2.02 and after treatment was 0.20±.76 as assessed by VAS. Results were statistically significant on application of Paired t test. t-value was 0.0001.

**Table 2:** Improvement in burning sensation (VAS) in patients withOSMF

| | **Mean** | **SD** | **Paired t test** | **t-value** |
|---|---|---|---|---|
| Before the treatment | 5.43 | 2.02 | 15.03 | 0.0001, S |
| After the | 0.20 | 0.76 | | |

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| | | | | |
|---|---|---|---|---|
| treatment | | | | |

Concerning improvement in mouth opening and reduction in burning sensation, the results of the present study are significant, suggesting the efficacy of new ayurvedic preparation in treatment of OSMF.

In this study, 4 subjects had grade I OSMF, 25 subjects had grade II OSMF while only one subject was suffering from grade III OSMF. On correlation of the findings of mouth opening and burning sensation in the subjects of different grades, the results are found to statistically significant as shown in Table

**Table 3:** Correlation of grading of OSMF with mouth opening and burning sensation

| **Grading of OSMF** | | **Mean** | **N** | **Std. Deviation** | **Std. Error Mean** | **t-value** | **p-value** |
|---|---|---|---|---|---|---|---|
| Grade I MO | Before t/t | 31.25 | 4 | 2.50 | 1.25 | 20.78 | 0.0001,S |
| | After t/t | 3.75 | 4 | 1.25 | 0.62 | | |
| Grade I BS | Before t/t | 33.00 | 4 | 2.16 | 1.08 | 30.55 | 0.0001,S |
| | After t/t | 0.00 | 4 | 0.00 | 0.00 | | |
| Grade II MO | Before t/t | 22.48 | 25 | 4.34 | 0.86 | 16.23 | 0.0001,S |
| | After t/t | 5.56 | 25 | 1.93 | 0.38 | | |
| Grade II BS | Before t/t | 23.00 | 25 | 4.12 | 0.82 | 27.26 | 0.0001,S |
| | After t/t | 0.12 | 25 | 0.60 | 0.12 | | |
| Grade III MO | Before t/t | 3 | 1 | - | - | - | - |
| | After t/t | 9 | 1 | - | - | | |
| Grade III BS | Before t/t | 3 | 1 | - | - | - | - |
| | After t/t | 2 | 1 | - | - | | |

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No clinically evident adverse reactions to the therapy were seen in any patient

## DISCUSSION

The present treatment modalities for OSMF are not very efficient in every case. Different medicaments for OSMF have been proven to be successful but also have shown adverse effects and reappearance. Various studies have been carried out recently to explore the clinical efficacy of herbal medicines. The well known, well accepted herbals, curcumin and tulsi are tried in the present study considering the side effects of conventional OSMF treatment.

Turmeric is one of the well known herbal products, which includes three curcuminoids: curcumin, demethoxy curcumin and bisdemethoxycurcumin. Turmeric possesses number of beneficial effects like antioxidant, anti-inflammation, increases blood circulation and is anti-mutagenic [2]. Curcumin, being an anti inflammatory agent suppresses cellular transformation, proliferation, invasion, angiogenesis, and metastasis. It suppresses tumor necrosis factor induced NF-κB activation and NF-κB dependent reporter gene expression. (Such products which are involved in cellular proliferation (COX-2, cyclin 1, and c-myc), anti-apoptosis (IAP1, IAP2, XIAP, Bcl-2, Bcl-xL, Bfl-1/A1, TRAFI, and cellular cFLIP), and metastasis (VEGF, MMP-9, ICAM-1) are down regulated by curcumin [2].

The chemical constituents of tulsi are: oleanolic acid, ursolic acid, rosmarinic acid, eugenol, carvacrol, linalool, β-caryophyllene (about 8%), β-elemene (c.11.0%) and germacrene D (about 2%). Tulsi also has several benefits; relieves stress/adaptogen, bolsters immunity, enhances stamina, and promotes healthy metabolism and is a natural immunomodulator. Tulsi is a rich antioxidant and is renowned for its restorative powers.

The proposed mechanism of action of this medicament in OSMF is anti-inflammatory, antioxidant, anti-stress, analgesics and others [6].

In number of studies, turmeric is tried for management of OSMF and found good results but in the present study combination of turmeric with tulsi is used to take advantage of synergistic action of two herbs [7-8]. Mouth opening and burning sensation were significantly improved. The results are comparable to the studies by Srivastava A *et al.*,[2] and Madhulatha G *et al.*,[6].

The study by Patel KR *et al* opines that ayurvedic treatment protocol is effective in the management of OSMF without any adverse effect [9]. Similarly in the present study also no adverse effects of the drug are noted The results of the present study showed that the treatment with these herbal medicines brings out an early, sustained and significant relief from burning sensation clinically as soon as in a time span of one month.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.Limitation of the study was the small sample size as it was a pilot study. However, similar studies can be conducted with a large sample size which may enable to throw light on utility of combination tulsi and curcumin in OSMF on regular basis.

## CONCLUSION

The combination of Tulsi and Turmeric can be considered as a better alternative to the modern treatment modality in the management of OSMF

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