



Evaluation of efficacy of turmix in treatment of OSMF.

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Abstract:

Aim: The aim of this study is to evaluate the efficacy of turmix in the treatment of oral submucous fibrosis patients.

Objectives: To check the treatment efficacy of turmix in the terms of burning sensation on visual analog scale, and to check the treatment efficacy of turmix in the terms of mouth opening on a calibrated scale.

Materials and methods: 30 patients diagnosed with Oral Submucous Fibrosis (OSMF) were included in this study. The patients were administered commercially available turmix tablets, their mouth opening and burning sensation on Visual Analogue Scale (VAS) scale were evaluated at regular intervals, and the data was then compared.

Results: The improvement in mouth opening was not significant, however the change in burning sensation on VAS was significant.

Conclusion: It is evident from the study that turmeric holds good promise in the treatment of OSMF in future.

Keywords: Oral Submucous Fibrosis, Turmeric, Visual Analogue Scale, Reduced mouth opening, Burning sensation.

Introduction:

OSMF has been well established in Indian medical literature since the time of Sushruta-- a renowned Indian physician who lived in the era 600 B.C and was termed as 'Vidari'.¹ It is a potentially malignant condition of the oral cavity characterized by juxtaepithelial inflammatory reaction and progressive fibrosis of the lamina propria and deeper connective tissues of the upper

digestive tract involving the oral cavity, oropharynx and frequently the upper third of the oesophagus. OSMF results in an increasing loss of tissue mobility, marked rigidity and an eventual inability to open the mouth, difficulty in swallowing and phonation. The most commonly involved site is buccal mucosa, followed by palate, retromolar region, faucial pillars and pharynx. It is most common in the countries of south-east Asia and shows greater predisposition towards the Indian ethnic group.^{2,3}

The etiology of this crippling disease is complex, the condition has a multifactorial origin but is commonly associated with chewing of areca nut (betel nut) habitually.⁴ It has been associated with an increased risk of malignancy with a malignant transformation rate of about 7.6%.⁵

The management of OSMF poses a great challenge.¹ There are extensive researches conducted in past few decades of the herbal medicines. Plants with medicinal properties are commonly used for treatment of various diseases since ancient times. Turmeric, a rhizome of *curcuma longa* is well known for its excellent therapeutic effects, turmeric and its active ingredient curcumin acts as a chemopreventive agent. It also inhibits many disease processes through its anti-inflammatory, antioxidant and anti-cancer properties.⁶ It protects against free radical damage as it is a strong antioxidant, helps in reducing inflammation by lowering histamine levels and also increases the production of natural cortisone. Curcuminoids isolated from turmeric, has been found to have effective antioxidant, DNA-protectant and antimutagen action. It has been seen that curcumin lowers the activity of STE (smokeless tobacco extract)- or NNK (nicotine derived nitrosamine ketone)-induced NF- κ B (nuclear factor kappa-light-chain-enhancer of activated B cells) and COX-2 in oral premalignant and cancer cells.⁷ Due to its wide range of therapeutic actions, this study was planned with the aim of evaluating its efficacy in OSMF.

Materials and Methods:

This study was conducted in the Department of Oral Medicine and Radiology after obtaining clearance from the institutional ethical committee. Thirty patients who were clinically diagnosed with OSMF were selected for this study. Subjects within the age group of 18-60 years were selected for this study. The protocol of the study was thoroughly explained to the patients and written consent was obtained from them. All the patients gave a positive habit history of chewing arecanut. Patients who showed malignant changes or who were not willing for treatment were excluded.

Clinical examination of the patient was carried out wearing sterile hand gloves and mouth mask along with recording of case history & physical examinations in a systematic manner at baseline visit.

For the study, the patient's mouth opening was measured using a calibrated scale and divider and the burning sensation was recorded on the Visual Analog Scale (VAS). Using the inter-incisal distance the patients were divided into four different groups based on Khanna and Andrade in 1995.⁸

- Group I: Very early stage without mouth opening limitations with an inter-incisal distance of greater than 35 mm.
- Group II: Early stage with an interincisal distance of 26-35 mm.
- Group III: Moderately advanced cases with an inter-incisal distance of 15-25 mm. Fibrotic bands are visible at the soft palate, and pterygomandibular raphe and anterior pillars of fauces.
- Group IV: Advanced stage: Trismus is severe, with an inter-incisal distance of less than 15 mm and extensive fibrosis of the oral mucosa.

Each patient was given commercially available turmeric, Turmix tablet (Sanat Products Ltd, Laxminagar Distt, New Delhi India) containing curcumin 300 mg and piperine 5 mg. This tablet was given orally thrice daily for 1 month. The responses were assessed clinically on a trimonthly basis. Every time the patient was recalled, the patient's mouth opening and burning sensation on VAS were recorded and compared.

Results:

Out of the total 30 patients diagnosed with OSMF included in this study, the maximum number of patients was in the age group 19-52 years, accounting for 36.7% of the study group. The mean age of the study group patients was 37.7 ± 7.57 years. The male: female ratio in the study group was 4:1. These subjects were then divided into four different groups based upon Khanna and Andrade classification, and the maximum number of patients ie 21 out of 30 patients (70%) belong to group II stage of OSMF and the least number of patients ie 2 out of 30 patients (6.7%) belong to group I stage of OSMF. The remaining 7 patients belong to group III stage of OSMF, while no patients were seen in group IV.

Table 1 shows the overall evaluation of changes in mouth opening and VAS scores. When the overall improvement was considered, the changes in mouth opening was statistically not significant ($P=0.83$), with the improvement in mouth opening being 3.4%. The change in burning sensation on VAS was statistically significant ($P=<0.001$).

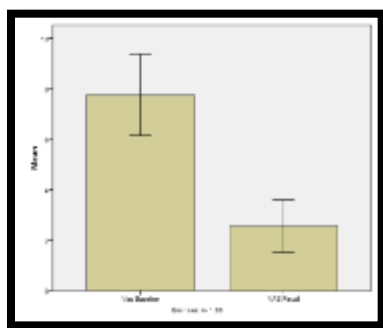
Graph A and B shows the comparison of improvement in mouth opening and burning sensation on VAS. There was significant improvement of 70% seen in terms of burning sensation and 3.4% increase seen in terms of mouth opening which was statistically not significant.

Table 2 shows multiple comparison between the groups in terms of burning sensation on VAS and mouth opening. Maximum improvement in burning sensation was seen in group I ie ($P=.000$) that was highly significant followed by group III ($P=.001$) statistically significant and group II patients. maximum improvement in mouth opening was seen in group III ($P=0.03$) as compared to group I and group II. The graphs C and D depicts the same.

Table 1

	AT BASELINE (MEAN± S.D.)	AT RECALL (MEAN± S.D.)	PAIRED DIFF.(%)	P VALUE
MOUTH OPENING	29.07±5.26 (18-38 MM)	30.92±5.13 (20-40 MM)	- 1.0000±.3051 3 (3.4%)	.083 NS
BURNING SENSATION ON VAS	7.77±1.61 (4-10)	2.57±1.04 (0-5)	5.200±3.124 (70%)	<0.001 S

GRAPH A



GRAPH B

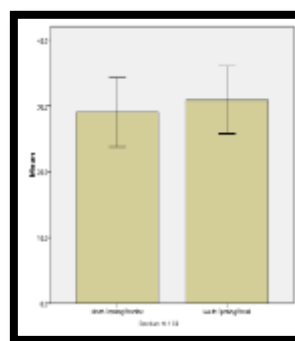
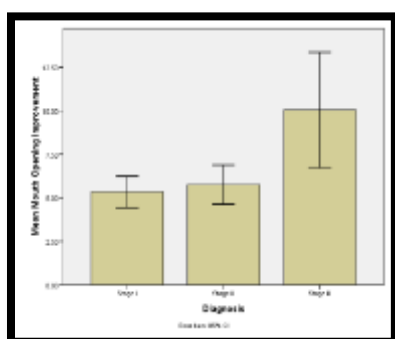


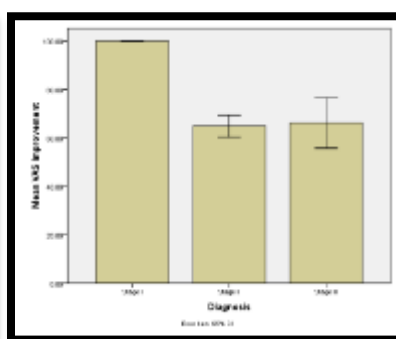
TABLE 2

Dependent Variable	(I) Diagnosis	(J) Diagnosis	Mean Difference (I-J)	Std. Error	P value
Mouth Opening Improvement	Stage I vs	Stage II	-.43029	2.01113	.975
	Stage I vs	Stage III	-4.71932	2.17901	.096
	Stage II vs	Stage III	-4.28902*	1.18610	.003
VAS Improvement	Stage I	Stage II	35.05291*	7.42121	.000
	Stage I vs	Stage III	33.80952*	8.04068	.001
	Stage II vs	Stage III	-1.24339	4.37679	.957

GRAPH C



GRAPH D



Discussion

OSMF was first described in the modern literature by Schwartz in 1952 who coined the term atrophica idiopathica mucosa oris to describe an oral fibrosing disease, he discovered in 5 Indian women from Kenya.⁹ Joshi subsequently coined the termed oral submucous fibrosis (OSMF) for the condition in 1953.¹

Oral submucous fibrosis is a chronic insidious disease that affects the oral mucosa as well as the pharynx and the upper two-thirds of the oesophagus. It is a well-recognized potentially malignant

condition of the oral cavity. Besides being regarded as a precancerous condition, it is a seriously debilitating and progressive disease. The strongest risk factor for OSMF is the chewing of betel quid (BQ) containing areca nut. The amount of areca nut in betel quid and the frequency and duration of chewing betel quid are clearly related to the development of OSMF.¹⁰

In spite of various present treatment modalities practiced for OSMF, not a single is totally effective in every case. Many pharmaceutical products have been proven to be successful in treating OSMF but found to have adverse effects and recurrences. Recently, interest in herbal medicines have been increased and various studies are being carried out to explore clinical efficacy of compound preparations.¹¹

Turmeric is known to be strong antioxidant and reduces inflammation. It increases blood circulation and is anti-mutagenic. Turmeric constituents include three curcuminoids: Curcumin, demethoxycurcumin and bisdemethoxycurcumin. Curcumin (diferuloylmethane), an anti-inflammatory agent used in traditional medicine, has been shown to suppress cellular transformation, proliferation, invasion, angiogenesis, and metastasis. Curcumin suppresses tumor necrosis factor (TNF)-induced NF- κ B activation and NF- κ B-dependent reporter gene expression. Such products which are involved in cellular proliferation (COX-2, cyclin D1, and c-myc), anti-apoptosis (IAP1, IAP2, XIAP, Bcl-2, Bcl-xL, Bfl-1/A1, TRAF1, and cellular cFLIP), and metastasis (VEGF, MMP-9, ICAM-1) are down regulated by curcumin.^{12, 13}

When 30 patients were administered turmeric, an improvement in mouth opening and burning sensation was noticed. Graph B showed total improvement of 3.4% in mouth opening with a significant increase seen in group III patients ie ($P < 0.05$) as compared to group I and group II as shown in graph C. An overall improvement of 70% was seen in burning sensation as shown in graph A.

Maximum improvement in burning sensation was seen in group I ie ($P = .000$) that was highly significant followed by group III ($P = .001$) statistically significant and group II patients as shown in graph D.1

The findings in our study in terms of increase in mouth opening and improvement in burning sensation were similar to the studies done by Das et al in 2010¹⁴ and Agarwal et al in 2014¹⁵ where they noticed no significant improvement in mouth opening, but a significant reduction in burning sensation.

The improvement in mouth opening and burning sensation observed in the study could be due to the fact that curcumin exerts chemoprevention through its anti-inflammatory and antioxidant, antimicrobial, antiseptic, hepato protective, immune stimulant, and anti-mutagenic properties.¹⁶ Curcumin also has a fibrinolytic property due to its ability to inhibit lipid peroxidation and check cellular proliferation, thereby reducing the rate of collagen synthesis.⁶

Conclusion:

It is evident from the study that turmeric holds good promise in the treatment of OSMF in future. Thus turmeric is considered a safe, non-toxic, and effective herb that can act as an alternative for many conventional drugs due to its enormous therapeutic properties on various systems of our body. However, there is scarcity of information and research in this field. There are many uses of turmeric in dentistry. The use of plants and herbs for dental care is a very common indigenous system of medicine and we must include it in our everyday life rather than depending on other synthetic drugs which may have certain side effects. Further researches are to be carried out to determine the bioavailability and bio-efficacy of turmeric.¹⁷

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