

A PILOT STUDY ON AYURVEDIC MANAGEMENT OF ORAL SUBMUCOUS FIBROSIS

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ABSTRACT

Oral sub mucous fibrosis (OSMF or OSF) is a complex, premalignant with ,1% transformation risk lesion of the oral cavity, characterized by juxta-epithelial inflammatory reaction and progressive fibrosis of the sub mucosal tissues (the lamina propria and deeper connective tissues).various medical & surgical intervention used in modern science are not satisfactory owing to recurrence. With *Ayurvedic* approach it can correlate with chronic *sarvasara mukharoga* so needs to be treated at locally at first. This study was conducted on the basis of open nonrandomized clinical trial with black box design comprising of holistic *Ayurvedic* approach in which 30 patients of OSMF were treated with *Mukha Pralepa* (External application) with Turmeric & *Aloevera* followed by *kaval* (gargling) with *Dashamula taila* 1 month and followed for 1 month. It revealed statistically significant relief in almost all signs & symptoms as well as improvement in inter incisal distance & in the associated sign & symptoms.

Key words: *pralepa, kaval, mukharoga*, oral submucous fibrosis, premalignant condition.

INTRODUCTION

Oral submucous fibrosis (OSMF) is a chronic, insidious, disabling disease involving oral mucosa, the oropharynx, and rarely, the larynx. It is exclusively reported in Indian population.¹ The disease is characterised by stiffness of the oral mucosa, trismus, burning sensation in the mouth, hypomobility of the soft palate and tongue, loss of gustatory sensation, and occasionally, A variety of aetiological factors including capsaicin, betel nut alkaloids, hypersensitivity, autoimmunity, genetic predisposition (HLA-A₁₀, DR₃, DR₇ and halotypes A₁₀/DR₃, B₃/DR₃ and A₁₀/B₈) and malnutrition have been suggested by various authors². It has also been suggested that it is a nonspecific inflammatory reaction to trauma yet the exact aetiology is unknown.

The disease can be classified clinically into two phases (1) an eruptive phase, characterised by formation of erythema, vesicles, ulceration and a burning sensation in the mouth. (2) The fibrosis induction phase, characterised by the disappearance of the vesicles and healing of the ulcers by fibrosis.³ The burning sensation decreases and blanching and stiffness of the oral and oropharyngeal mucosa occur. The two phases appear in a cyclic manner. The common sites involved are buccal mucosa, labial mucosa, retromolar pads, soft palate and floor of the mouth. Rarely fibrotic changes of the pharynx, esophagus and paratubal muscles of eustachian tubes have also been observed. Early features of OSMF include burning sensation, hypersalivation/xerostomia and muco-

sal blanching with marble like appearance.⁴ Later on, the mucosa becomes leathery and inelastic with palpable fibrous bands resulting in restricted mouth opening. Eventually, OSMF leads to difficulty in swallowing, speech & hearing defects and defective gustatory sensation.

The management of OSMF comprises of nutritional support & antioxidants, Life style modification, physiotherapy, steroid injections, human placental extracts, etc & surgical measures for advanced cases. But unfortunately all these interventions have very limited success, as they are not free of adverse effect & recurrence is also there.

On looking into the *Ayurvedic* classics, some scattered description of symptoms related to OSMF such as *krichchhen vivrinoti mukham*⁵ (difficulty in opening the mouth), *mukhadaha*,⁶ *usha* (burning sensation), *tikshna asaha* (intolerance to spicy food), *mukhasosha*⁷ (dryness of mouth), *mukhantagata vrana*⁸ (ulceration of the oral mucosa), *dusta vrana*⁹ (fibrosis), can be found. Thus analyzing the disease condition, OSMF can be considered as *tridoshaja chronic sarvasara mukharoga*¹⁰ (disease affecting the whole oral cavity) and it is obvious that it needs to be treated locally first. In jaipur and the surrounding area, it is common to find chewing habit of betel quid, other betel nut related products and the products that aggravates the disease OSMF. Considering the social acceptance of the habit and due lack of social stigma against these habits, it is necessary to formulate a proper treatment plan with some life style modification tips against these deleterious habits. Hence this study was planned with a holistic *Ayurvedic* approach.

Materials and Methods:

In this open label, nonrandomized clinical trial 30 patients were registered from the outpatient department of *shalakya tantra*. A consent letter based on subject's willingness

and interest to participate in the study was obtained. The study was designed on black box method comprising of multi therapy approach in a single group.

Inclusion criteria:

- Age between 18 and 60 years
- The patients having clinical signs and symptoms of OSMF

Exclusion criteria:

- Extensive fibrosis with an inter incisal distance (IID) 15mm
- Premalignant and malignant changes
- Oral lichen planus
- Chronic debilitating conditions such as DM, HT, HIV etc.
- Patient not willing to give up addiction habits of *Gutka*, *pan-masala*, tobacco & other narcotics.

Investigation:

Routine haematological, serum lipid profile, routine urine examination before treatment was carried to rule out any other disorders.

Treatment protocol:

Haridra (turmeric) and *Aloevera* whole total 5gram paste were administered twice in a day as *pralepa* (external application) and *kaval* (gargling) with *dashamula oil* 10ml were done once in a day simultaneously for 30 days.

Haridra and Ghrithkumari pralepa

2.5 gram *haridra* and same quantity of *aloevera* was mixed with 1gram of honey to make the paste, which was taken on the index finger and applied all over the oral mucosa and then, the patient was allowed to spit out the drug and the secretions with lukewarm water, after 30 minute of application.

Dashamula oil

Lukewarm *Dashamula* oil 10 ml was advised to fill in the mouth and it between cheek and throat. It was continued for a period until the patient developed *kaphapurnasyata* (mouth fill with secretions), *Ghranasrava* (watery discharge from nose) and *akshisrava* (watery dis-

charge from eyes). Then, the patient was allowed to spit out the oil and secretions.

Criteria for assessment:

Subjective parameters

All the signs and symptoms were given scoring depending on their severity.

Objective parameter

IID was measured by taking the distance between mesial angles of the upper and lower central incisor with vernier calliper. Clinical stages and grading of the disease were adopted from previous studies.

Signs and Symptoms	Score
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Mukhadaha

(Burning sensation in mouth)

Nil	0
On taking spicy food	1
On taking food	2
Continuous	3

Colour of Oral mucosa

Pink normal	0
Red or deep pink	1
Pale white	2
Blanched white	3

Ulceration in mouth

Nil	0
Mild	1
Moderate	2
Severe	3

Fibrous bands on palpations

No fibrous bands	0
One or two solitary fibrous bands	1
Bands felt nearly in entire surface	2
Adherent fibrous bands producing rigidity of mucosa	3

The scoring pattern of IID

Inter incisal distance (mm)

41 or above	0
37-40	1
33-36	2
29-32	3
25-28	4
21-24	5
17-20	6
13-16	7

Overall assessment

The overall improvement was assessed on the basis of subjective and objective parameters.

Cured: 100% relief in signs and symptoms

Marked improvement: 76-99% improvement

Moderate improvement: 51-75%

Mild improvement: 26-50%

Unchanged: 0-25% improvement

Statistical analysis

The values of data were expressed as a percentage of relief and mean standard error of the mean. The data were analyzed by Student's t – test for comparing before and after treatment obtained scores. The level of significance are expressed as P > 0.05 as insignificant, P < 0.05 and 0.01 as significant, P < 0.001 as highly significant.

Observations

In the present study 23 out of 30 patients were completed the therapy. Age and sex wise distribution of registered patients showed that, 50% patients were in age group of 20-30 years and 85% patients were male. The socioeconomic status based distribution showed that 40% patients belong to lower middle class and 20% from poor class. 84% of the patients had chewing habit of *gutka* (containing chiefly areca nut, lime, catechu, and tobacco) followed by 8% had chewing habit of *pan masala* (containing chiefly areca nut, lime, catechu). Quantity wise distribution showed that 43% taking 1-5 packets of *gutka*, followed by 33% taking more than 10 packets in a day.

On examination blanching of the mucosa, ulceration of the mucosa, leathery hard consistency of the mucosa and fibrous bands were recorded in 100% of the patients.

In 100% patients, there was stage 2 OSMF. In maximum 80% patients, there was grade 3 OSMF and grade 2 OSMF in 20%.

Results

Statistically highly significant (P < 0.001) results were found in symptoms such as

burning sensation of mouth, intolerance to spicy food, dryness of mouth, pain in opening the mouth. Clinically marked improvement was observed in over all signs and symptoms. Out of 13 patients none of the patients was cured, 10% showed marked improvement, maximum 75% showed moderate improvement and 15% showed mild improvement.

DISCUSSION

In spite of various present treatment modalities practiced for OSMF, not a single is totally effective in every case. More and more young males of the third and even the second decade are being affected which is noted after *gutka*, *panmasala* came into the market. *Turmeric* constituents include three curcuminoids (curcumin, demethoxycurcumin, bisdemethoxycurcumin). Curcumin an anti-proliferation, invasion, angiogenesis and metastasis. Curcumin suppresses tumour necrosis factor (TNF)-induced NF-kB activation and NF-kB dependant reporter gene expression.

The results of the study showed that the synergistic action of these two herbs results in higher efficacy and highly potent anti-OSMF treatment. *Pooga* (areca nut) is having *kashaya rasa* (astringent taste), *Ruksha* (Dry), *sheeta* (cold) and *vikasi* (causing looseness of tissues and joints by the diminution of vital essence) properties.¹¹ Its excessive and constant chewing seems to be the *atiyoga* (over

use) of *kashaya rasa*. That affects locally predominantly causing *sthanadusti* (local tissue harm) as well systemically to provoke the *vata dosha* which is the prime factor in the pathogenesis leading to *Rukshata* (dryness), *kharata* (hardness), *stambha* (stiffness), *shushkata* (atrophy) in *sthanastha dhatus* (fibrosis of subepithelial tissue and atrophy of epithelium of oral cavity). Excessive consumption of chillies and spices can be taken as *atiyoga* (excessive use) of *katu rasa*¹² and *Tikshna, ushna dravyas* which act locally as irritant and also provoke pitta along with vata aggravating the disease. Consuming *alpa* (less in quantity and *ruksha* (ununctous) food is responsible for the *vata* provocation and *dhatukshya* (nutritional deficiency) promoting the disease condition. Treatment with *Aloevera* and *Turmeric* has no side effect. Drugs used in this study were not synthetically manufactured. Drugs used in this study are freely available in India. Therefore this treatment modality can be used by masses at a low cost. Present study not only demonstrated superior rate in relieving symptoms in OSMF patients but also was associated with minimal side effects such as bad taste, mild headache, which disappeared after treatment. Emphasis was also given by motivating all patients before, during and after the study to discontinue tobacco, beetle nut and alcohol. These drugs can be attributed to dramatic improvement in OSMF cases.

Table 1: Effect on clinical findings		Mean score		SD	SE	T	P
Clinical findings	N	BT	AT				
Blanching of mucosa	23	17.34	14.22	1.94	0.42	7.51	<0.001
Ulceration of mucosa	23	8.6	0.22	2.18	0	17.48	<0.001
Palpable fibrous bands	23	1.82	1.77	0.23	0.06	1	>0.05
IID	23	5.74	3.64	0.88	0.17	10.66	<0.001

BT- before treatment, **AT-** after treatment, **SD-** standard deviation. **SE-** standard error\

Effect on chief complaints such as burning sensation in mouth, dryness of mouth, decreased taste, pain while opening in mouth

also reduced remarkably after treatment with a statistical value $p < 0.001$.

IID is an objective parameter used to assess mouth opening. The more advanced the disease the less will be mouth opening. Statistically highly significant ($p < 0.001$) improvement in IID (39.85%) was noted. Furthermore sustained relief was observed in the follow up period of 1 month. As the disease progresses, fibrosis becomes more dense reducing the mouth opening which indicates the disease may become *Yapya* (that can be maintained as it is) at this stage or may require a long term treatment to have better result.

CONCLUSION

Turmeric, Aloevera along with life style modification is safe and efficacious remedy for the treatment OSMF. It has no adverse effect as well as having sustained relief in follow-up. Further studies will be followed to access the comparative efficacy with already existing treatment for OSMF.

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