

A Comparative Efficacy Of Ayurvedic With That Of Modern Treatment Protocol In Management Of Oral Sub Mucous Fibrosis: A Prospective Clinical Study

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ABSTRACT

Introduction: Oral sub mucous fibrosis (OSMF) is a chronic, progressive, scarring precancerous condition of oral cavity seen predominantly in the Indian subcontinent and south-east Asia. In modern science, various medical and surgical treatment are available but all methods are quite painful, costly and not in the reach of every lay person but results obtained are not satisfactory due to recurrence and adverse effects worsening the condition. In Ayurvedic classical texts, no any direct references about the disease quoted but on understanding the disease condition OSMF can be correlated with Vata Pradhana Tridoshaja Mukharoga which needs to be treated at local and systemic level. **Aim:** To compare efficacy of Ayurvedic with that of modern treatment protocol in the management of patients of oral sub mucous fibrosis. **Materials and Methods:** It was an open-label randomized clinical trial and randomly divided into two groups. In Group A, comprising of Ayurvedic approach, 17 patients of OSMF completed the treatment in which Pratisarana (external application) with Madhupippalyadi Yoga, Kavala (gargling) with Nishadi Taila and internally Rasayana Yoga and in Group B, 17 patient advised Physiotherapy i.e. mouth opening exercise with the help of top to perform at home, daily- 30 minutes morning and 30 minutes evening from the first day of treatment and internally Methylocobalamine were given for 1 months and followed for 1 month. **Results:** It was shown statistically significant relief (<0.05) in almost all signs and symptoms as well in inter incisor distance improvement (25.16%) and also sustained relief was observed in follow-up period. **Conclusion:** It was concluded that Ayurvedic treatment protocol was effective in the management of OSMF.

KEY WORDS: Kavala, Mukharoga, oral submucous fibrosis, Pratisarana, Rasayana Yoga

INTRODUCTION

Oral sub mucous fibrosis (OSMF) is a chronic, progressive, scarring precancerous condition of oral cavity seen predominantly in the Indian subcontinent and south-east Asia (1). The commonest sites involved are buccal mucosa, labial mucosa, retro-molar pads, soft palate and floor of mouth. Early features of OSMF include burning sensation, hyper-salivation/xerostomia and mucosal blanching with marble like appearance (2). 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 and hearing defects and defective gustatory sensation (2), (3), (4). Habit of areca nut or betel quid and tobacco chewing, excessive consumption of chilies, autoimmunity, genetic and environmental factor, along with dietary deficiencies are thought to be the etiological factors of the OSMF. Due to areca nut alkaloids chiefly arecoline along catechin and tannin contents, mainly involved pathogenesis is stimulation of fibroblast production and increased collagen synthesis (5), (6).

Data published reported an estimate of 5 million OSMF patients in India (7). Its prevalence increased over past four decades from 0.03% to 6.42% in India (8), (9) seen commonly in younger 20-40 years age group. The disease now globally accepted as Indian disease, has one of the highest rates of transformation into malignancy among malignant oral lesions and conditions (3). However the most consistent factor identified through epidemiological studies is areca nut chewing in the form of quid (3), (10), (11). In India poor socioeconomic and tobacco chewing are the other factors which increases the risk of developing OSMF amongst peoples widely prevalent in all age group and across all socioeconomic strata in India.

OSMF has high morbidity and significant mortality rate due to progressive inability to open the mouth leading difficulty in eating and nutritional deficiencies. On the basis of cancer registry data report, estimated annually 75,000–80,000 new oral cancer develop associated with tobacco-areca nut chewing habits in the form of quid and usually preceded by premalignant lesions, most often a persistent OSMF in India (12).

In modern science, management of OSMF consist of nutritional therapy; physiotherapy; immunomodulatory drugs such as steroids; local steroidal injection, extracts of human placenta, etc. and surgical treatment are available but all methods are quite painful, costly and not in the reach of every lay person but results obtained are not satisfactory due to recurrence and adverse effects worsening the condition.

In Ayurvedic classical texts, no any direct references about the disease quoted. So the disease can be considered as Anukta Vyadhi (Unexplained disease) and hence can be treated according to methodology given by Acharya Charaka (13). In Ayurvedic literature, some scattered description of symptoms related to OSMF such as inability to open the mouth (KruchhenVivrunoti-Vataja Sarvasara) (7), burning sensation in mouth (Daha-PittajaSarvasara) (14), pain in mouth (Toda-Vatika Sarvasara) (15), blanching of the oral mucosa (Antahkapolamashritya Shyavpandu- Kapharbuda) (4), etc., are found in Mukharoga. On understanding the disease condition OSMF can be considered in the Vata Pradhana Tridoshaja Mukharoga which needs to be treated at local as well as systemic level.

The most consistent factor identified through epidemiological studies is areca nut chewing in the form of quid. In India poor socioeconomic and tobacco chewing are the other factors which increases the risk of developing OSMF amongst peoples widely prevalent in all age

group and across all socioeconomic strata in India. Ayurvedic treatment protocol is quite effective and also does not put an extra burden on the economic condition of the patient. So in the present study an attempt has been made to find an effective as well as economically balanced treatment protocol for the patients of OSMF which is the need of time.

MATERIALS AND METHODS

An open-label, randomized, clinical trial in which on basis of signs and symptoms of the disease OSMF, 34 patients were registered from the outpatient department of Shalakya Tantra ITRA, Jamnagar. After approval from the Institutional Ethics Committee, study was started (No. PGT/7/-A/Ethics/2017-18/2097) and registered in CTRI (Ref no. CTRI/2017/12/016236 Registered on: 13/12/2017). An informed consent letter was obtained based on subject's willingness and interest to participate in the research study. The study was designed comprising of multi-therapy approach.

Inclusion criteria

- ☐ Age group of either sex between 18-60 years.
- ☐ The patients having clinical signs and symptoms: blanching and stiffness of oral mucosa, trismus, repeated vesicular eruption and ulceration on buccal mucosa, palate, and pillars, burning sensation in mouth, intolerance to eat hot and spicy foods, reduced mobility of soft palate and tongue, loss of gustatory sensation.
- ☐ Interincisal distance of more than 15mm.

Exclusion criteria

- ☐ Age less than 18 years and more than 70 years.
- ☐ Extensive fibrosis of all the oral mucosa, severe trismus with an inter incisor distance (IID) <15mm.
- ☐ Disease is most advanced with premalignant and malignant changes.
- ☐ Oral manifestation of scleroderma.
- ☐ Oral lichen planus.
- ☐ Chronic debilitating conditions like DM, HTN, HIV, etc.
- ☐ Patients not willing to give up habits of gutkha, pan-masala, mawa, tobacco, betel quid or betel nut chewing.

Investigations

Routine haematological (Hb, ESR, TC, DC) examination before treatment were carried for screening general health condition.

Treatment protocol and posology

Group A:

Table 1: Following treatment was given simultaneously in the following sequence for 30 days.

| Posology | <i>Madhu - Pippalyadi Yoga for Pratisarana</i> | <i>Nishadi Taila for Kavala</i> | <i>Rasayana Yoga orally</i> |
|----------|--|---------------------------------|-----------------------------|
| Dose | 3-6gms BD | 15-20ml BD/ as per requirement | 6 gms BD before meal. |

| | | | |
|----------|-----------------------------|--------------|--|
| Time | 100-200 Matra (2-4 Minutes) | 5-15 Minutes | ---- |
| Duration | 30 days | 30 days | 30 days |
| Form | Churna mixed with Madhu | Taila | Churna mixed with Madhu and Ghrita in unequal quantity |

Group B

Physiotherapy - Mouth opening exercise with the help of top was explained to the patients which they can perform at home, daily- 30 minutes morning and 30 minutes evening from the first day of treatment.

Antioxidants Tablets contain Methylocobalamine (1500 mcg) in dose 1 tablet OD after meal for 30 days duration in tablet form given orally.

Madhupippalyadi Pratisarana

Pippalyadi Choorna (Table 2) 3–6 g was mixed with equal quantity of honey to make the paste like form, which was taken on the index finger and applied all over the oral mucosa and gentle massage was advised for about 10 min in clockwise, anticlockwise and round direction with finger. Then, the patient was allowed to spit out the drug and the secretions excreted during the procedure.

Table 1: Ingredients of ‘Madhupippalyadi Yoga (Anubhuta)’

| Sr. No | Name of the Ingredient | Latin name | Proportion |
|--------|------------------------|----------------------------------|-------------|
| 1. | Pippali | <i>Piper longum</i> Linn. | 1/2 Part |
| 2. | Yastimadhu | <i>Glycyrrhiza glabra</i> Linn. | 1 Part |
| 3. | Gairika | <i>Ochre</i> | 1 Part |
| 4. | Jati | <i>Jasminum officinale</i> Linn. | 1 Part |
| 5. | Haridra | <i>Curcuma longa</i> Linn. | 1/2 Part |
| 6. | Madhu | <i>Apis mellifica</i> | As required |

Nishadi Taila Kavala

Urdhwanga Abhyanga (supraclavicular massage) with lukewarm Tila Taila (sesame oil) followed by Swedana (fomentation), for this purpose a towel was soaked in boiling water, the water was squeezed out, the warm towel was then waved, touched and pressed was done. Then, luke warm Nishadi Taila (16) (Table 3) 10–15 ml was advised to fill in the mouth and move it between cheek and throat inside the mouth and was continued for a period until the patient developed Kaphapurnasyata (mouth fill with secretions), Ghranasrava and Akshisrava (watery discharge from nose and eyes). Then, the patient was allowed to spit out the oil and secretions, further mild Swedana (fomentation) and Mardana (massage) were done on the Urdhwanga (supraclavicular region).

Table 3: Ingredients of Nishadi Taila

| Sr. No | Name of the Ingredient | Latin name | Proportion |
|--------|------------------------|------------------------------------|------------|
| 1 | Haridra | <i>Curcuma longa</i> Linn. | 2 Part |
| 2 | Nimb Patra | <i>Azadirachta indica</i> A. Juss. | 1 Part |

| | | | |
|---|-------------------|---------------------------------|---------|
| 3 | <i>Madhuka</i> | <i>Glycyrrhiza Glabra</i> Linn. | 1 Part |
| 4 | <i>Neelotpala</i> | <i>Nymphaea Nouchali</i> Linn. | 1 Part |
| 5 | <i>Tila Taila</i> | <i>Sesamum indicum</i> Linn. | 16 Part |

Rasayana Yoga

Rasayana Yoga (Table 4) was administered in a dose of 6 g orally, with honey and ghee in unequal quantity twice a day before meal. After completing the treatment, after an interval of 15 days follow-up was carried out for 1 month. All the test drugs were prepared and procured from Pharmacy, ITRA, Jamnagar.

Table 4: Ingredients of Rasayana Yoga

| Sr. No | Name of the Ingredient | Latin name | Proportion |
|--------|------------------------|-------------------------------------|------------|
| 1 | <i>Guduchi</i> | <i>Tinospora cordifolia</i> Linn. | 1 Part |
| 2 | <i>Amalaki</i> | <i>Embelica officinalis</i> Gaertn. | 1 Part |
| 3 | <i>Gokshura</i> | <i>Tribulus terrestris</i> Linn. | 1 Part |
| 4 | <i>Haridra</i> | <i>Curcuma longa</i> Linn. | 1/2 Part |
| 5 | <i>Yastimadhu</i> | <i>Glycyrrhiza glabra</i> Linn. | 1 Part |

Criteria for assessment

The clinical trial was assessed for its efficacy on the basis of following subjective and objective criteria according to Seedat-HA (17) with slight modification.

Subjective parameters

Depending on their severity, all the signs and symptoms were given scoring.

Burning sensation in mouth (Mukhadaha)

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

Taste (Rasagana)

| | |
|--------------------|---|
| Normal | 0 |
| Altered /decreased | 1 |

Salivation (Lalasarava)

| | |
|-----------|---|
| Normal | 0 |
| Altered | 1 |
| Decreased | 2 |

Intolerance to spicy food (*Katu Rasa Ashahishnuta*) in comparison to previous tolerance

| | |
|----------|---|
| Nil | 0 |
| Mild | 1 |
| Moderate | 2 |
| Severe | 3 |

Pain in mouth (*Mukha Vedana*)

| | |
|---------------|---|
| Nil | 0 |
| While opening | 1 |
| Continuous | 2 |

The colour of oral mucosa

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

Ulceration in mouth

| | |
|----------|---|
| No | 0 |
| Mild | 1 |
| Moderate | 2 |
| Severe | 3 |

Consistency of the Oral mucosa on palpation

| | |
|-----------------------------------|---|
| Soft normal | 0 |
| In between soft and leathery hard | 1 |
| Leathery hard | 2 |

Fibrous bands- on palpation

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

Objective parameter

To evaluate improvement in the opening of the mouth, IID scoring was adopted. IID is a distance between the upper and lower central incisor, was measured by taking the distance between mesial angles of the upper and lower central incisor with Vernier Caliper. From previous studies, clinical stages and grading of the disease were adopted (Table 5).

Table 5: The scoring pattern for IID

| IID (mm) | Score | IID (mm) | Score |
|--------------------------------|-------|----------|-------|
| 41 or above considering normal | 0 | 25 – 28 | 4 |
| 37-40 | 1 | 21-24 | 5 |
| 33-36 | 2 | 17-20 | 6 |
| 29-32 | 3 | 15-16 | 7 |

Overall assessment

The overall improvement was assessed by adopting the following scoring pattern on the basis of subjective and objective parameters.

- ☐ Cured: 76-100% relief in signs and symptoms
- ☐ Marked improvement: 51-75% improvement in signs and symptoms
- ☐ Moderate improvement: 26-50% improvement in signs and symptoms
- ☐ Mild improvement: 0–25% improvement in signs and symptoms.

Statistical analysis

The data of 34 patients completed the treatment course was analyzed by statistical methods. Wilcoxon signed rank test applied to find effect of therapy before and after treatment on non-parametric data of individual group and for parametric data paired t test was applied. Fisher exact test applied to compare effect of therapy on nonparametric data between the group and unpaired t test was applied for comparison of parametric data between the groups. Test was performed by using sigma stat software. The level of significance are expressed as $P > 0.05$ as insignificant, $P < 0.05$ as significant and $P < 0.001$ as highly significant.

OBSERVATIONS

In the present study, 34 patients were completed the therapy. Age and sex-wise distribution of registered patients showed, 41.17% patients were in age group of 18–30 years followed by 31.42% in age group of 31–40 years and 88.57% patients were male. The socioeconomic status based distribution showed that 38.23% patients belonged to lower middle class and 29.41% from poor class. Personal history showed that 41.17% patients had moderate appetite and 38.23% had good appetite while 52.95% patients had irregular bowel.

Maximum 67.64% patients had reported mental stress. 41.17% patients were of Vata Pitta Prakriti while 82.90% patients were of Madhyama Satva. 76.47% of the patients were consuming Katu Rasa dominant diet, and 77.10% patients were taking Ushna Guna dominant diet. Observation on addiction revealed that 85.29% of the patients had chewing habit of Gutka/Mawa followed by 20% patients were having chewing habit of betel nut. 17.64% were having chewing habit of pan-masala and 14.29% were habit of tobacco chewing. 79.41% patients were habitual. Study reveals that 55.88% patients had chronicity between 5–8 years while 38.23% patients were having chronicity of up to 2–5 year and 14.70% had chronicity of more than 8 years. Most of the patients i.e. 79.41% were spitting the content of gutka etc. after chewing while rest were swallowing. Maximum 35.29% patients had wean the addiction habit from more than 6 months.

Symptoms wise distribution showed 79.41% patients had a complaint of inability to open the mouth, 100% burning sensation in mouth and 94.11% intolerance to spicy food. Blanching of mucosa was present in 82.35% patients. Decreased taste was present in 47.05% patients and 88.23% patients had ulceration.

On examination blanching of the mucosa i.e. 91.17% was observed in Rt. Buccal mucosa, Lt. buccal mucosa 88.23%, and lower lip 50.00% followed by soft palate 57.10%, ulceration of the mucosa i.e. 88.23% was observed in Rt. Buccal mucosa 82.35% in Lt. buccal mucosa, leathery hard consistency of the mucosa i.e. 85.29% was observed in Rt. Buccal mucosa, 79.41% in Lt. buccal mucosa and fibrous bands shows Rt. buccal mucosa 64.76% and 21.76% in Lt. buccal mucosa, followed by 11.76% in upper and lower lip were recorded in the patients. In the study maximum i.e. 76.47% patients' oral hygiene was poor. External stains were observed in 100% patients attributed to staining substance of chewing habits. TMJ affection by means of finding crepitation's and tenderness was observed in 8.60% which also possible in the advance disease.

RESULTS

Effect of therapies on subjective parameters i.e. on chief complaints

In group A, the results observed highly significant relief ($p < 0.001$) in burning sensation of

mouth (84.35%), intolerance to spicy food (77.45%), pain in the mouth (87.50%), ulcer of the mucosa upper lip (87.50%), lower lip (90%), Rt. buccal mucosa (83.33%), Lt. buccal mucosa (82.61%) and fibrous band of the Rt. buccal mucosa (70.14%). Significant results ($p<0.05$) in dryness of mouth (60.66%) and opening the mouth (25.16%) relief was noted.

In group B, highly significant relief ($p<0.001$) 50.98% was found in burning sensation of mouth and 51.96% in intolerance to spicy food, ulcer of the mucosa upper lip (77.77%), Rt. buccal mucosa (70.83%) and Lt. buccal mucosa (61.90%). Significant results relief ($p<0.05$) 50% was found in dryness of mouth, 30.32% in opening the mouth and 42.85% was found in pain was noted, while 55.55% relief was found in ulceration of the buccal mucosa of upper lip and fibrous band of the Rt. buccal mucosa was noted (Table 6 & 7).

Table 6: Effect of therapies on subjective parameters – on chief complaints

| Chief complaints | Group | N | Mean score | | % relief | SD | SE | t | P | Sig |
|-----------------------------|-------|----|------------|-------|----------|-------|-------|-------|--------|-----|
| | | | BT | AT | | | | | | |
| Burning sensation in mouth | A | 17 | 2.431 | 0.412 | 84.31 | 0.65 | 0.16 | 12.88 | <0.001 | HS |
| | B | 17 | 2.353 | 1.00 | 50.98 | 0.191 | 0.165 | 7.089 | <0.001 | HS |
| Intolerance to spicy food | A | 17 | 2.412 | 0.647 | 77.45 | 0.437 | 0.106 | 16.64 | <0.001 | HS |
| | B | 17 | 2.647 | 1.235 | 51.96 | 0.618 | 0.150 | 9.414 | <0.001 | HS |
| Dryness of mouth | A | 17 | 0.588 | 0.235 | 60.66 | 0.493 | 0.119 | 0.294 | <0.05 | S |
| | B | 17 | 0.353 | 0.176 | 50.0 | 0.393 | 0.095 | 1.852 | <0.05 | S |
| Inability to open the mouth | A | 17 | 3.353 | 2.824 | 25.16 | 0.514 | 0.125 | 4.243 | <0.05 | S |
| | B | 17 | 2.882 | 2.647 | 30.34 | 0.437 | 0.106 | 2.219 | <0.05 | S |

| Chief complaints | Group | N | Mean score | | % relief | SD | SE | W | P | Sig |
|------------------|-------|----|------------|-------|----------|-------|-------|-------|-------|-----|
| | | | BT | AT | | | | | | |
| Pain in mouth | A | 17 | 0.588 | 0.118 | 87.50 | 0.514 | 0.125 | 3.771 | <0.05 | HS |
| | B | 17 | 0.529 | 0.294 | 42.85 | 0.437 | 0.106 | 2.219 | <0.05 | S |

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

Table 7: Effect on clinical finding- ulcer of mucosa in particular parts of oral cavity

| Ulcer of the mucosa | Group | N | Mean score | | % relief | SD | SE | t | P | Sig |
|--|-------|----|------------|-------|----------|-------|-------|-------|--------|-----|
| | | | BT | AT | | | | | | |
| Upper lip | A | 9 | 1.33 | 0.00 | 87.50 | 0.516 | 0.211 | 6.325 | <0.001 | HS |
| | B | 6 | 1.500 | 0.33 | 77.77 | 0.408 | 0.167 | 7.00 | <0.001 | HS |
| Lower lip | A | 9 | 1.429 | 0.143 | 90 | 0.488 | 0.184 | 6.971 | <0.001 | HS |
| | B | 7 | 1.500 | 0.667 | 55.55 | 0.753 | 0.307 | 2.712 | <0.05 | S |
| Rt. Buccal mucosa | A | 13 | 1.846 | 0.308 | 83.33 | 0.877 | 0.243 | 6.325 | <0.001 | HS |
| | B | 17 | 1.714 | 0.500 | 70.83 | 0.426 | 0.114 | 10.67 | <0.001 | HS |
| Lt. Buccal mucosa | A | 11 | 1.769 | 0.308 | 82.61 | 0.776 | 0.215 | 6.789 | <0.001 | HS |
| | B | 17 | 1.545 | 0.545 | 61.90 | 0.447 | 0.135 | 7.416 | <0.001 | HS |
| Fibrous band of the mucosa (Rt. Buccal mucosa) | A | 9 | 1.750 | 0.750 | 70.14 | 0.426 | 0.123 | 8.124 | <0.001 | HS |
| | B | 12 | 1.769 | 1.462 | 55.55 | 0.480 | 0.133 | 2.309 | <0.05 | S |

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

Effect of therapies on objective parameters – on IID

In Group A, Ayurvedic treatment protocol provided statistically significant relief (<0.05) in mouth opening according to objective parameter IID (25.16%), also sustained relief was observed in the follow up period of 1 month.

In Group B, Modern treatment protocol also provided statistically significant relief (<0.05) in mouth opening according to objective parameter IID (30.34%). Forceful mouth opening exercise with the help of a ‘top’ may be reason for such result (Table 8).

Table 8: Effect of therapies on objective parameters – on IID

| Parameter | Group | N | Mean score | % relief | SD | SE | t | P | Sig |
|-----------|-------|---|------------|----------|----|----|---|---|-----|
|-----------|-------|---|------------|----------|----|----|---|---|-----|

| | | | BT | AT | | | | | | |
|-----|---|----|-------|-------|-------|-------|-------|-------|-------|---|
| IID | A | 17 | 3.353 | 2.824 | 25.16 | 0.514 | 0.125 | 4.243 | <0.05 | S |
| | B | 17 | 2.882 | 2.647 | 30.34 | 0.437 | 0.106 | 2.219 | <0.05 | S |

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error, IID: Inter incisal distance

Total effect of therapy

Out of 34 patients none of the patients was cured, marked improvement was found in 23.52% patients in Group A while it was 47.05% in Group B. Moderate improvement observed in Group A was 47.17% while in Group B it was 29.41%. Mild improvement observed in Group A was 35.29% and in Group B it was 23.52% (Table 9).

Table 9: Overall assessment of therapy of 34 patients of OSMF

| RESULTS | Group A (n=17) | | Group B (n=17) | |
|-----------------|-------------------|--------|-------------------|---------|
| | No. of Patients | % | No. of Patients | % |
| Cured | 00 | 00 | 00 | 00 |
| Marked relief | 06 | 35.29% | 04 | 23.52% |
| Moderate relief | 07 | 41.17% | 05 | 29.14% |
| Mild relief | 04 | 23.52% | 08 | 47.05 % |

DISCUSSION

In the present scenario, age group (18-30), facing maximum stress and also not psychologically stable to adjudge the favourable and unfavourable to the health and fall into so called tension relieving habits. More and more the younger people are falling prey to this condition due to the enforcing advertisements, lack of social stigma against it and easy availability at a cheaper rate. Most precancerous lesions and conditions are usually seen in middle aged to elderly people. But in the case of OSMF more prevalence is in younger groups as reported in other studies (18). Male are using areca nut and tobacco related products more because of easy availability in all the places where as females being more conscious about their health and aesthetic value, which may be responsible for a high male to female ratio (19). Due to low socioeconomic leads to poor quality of food, low vitamins and minerals especially iron deficiency and consumption of more spices and chillies in diet, and also lack of health awareness are the main reason for increasing numbers of OSMF cases (20).

In the present study and also from previous researches, most of the patients (92.79%) chewed areca nut in some form or other (21). The most commonly used areca nut products by the patients in this study were gutka/mawa which contain higher concentration of areca nut per chew and other ingredients like tobacco and lime which overall more harmful. The previous reports all showed longer duration of pan chewing before manifesting OSMF, which meant the traditional quid with betel leaf, slaked lime, areca nut etc. was not as harmful as the processed ones (22). A sharp increase in the incidence of OSMF was noted after Pan-masala and Gutka came into the market, and the incidence increased over a period of at least 2–5 years (6).

Pooga (areca nut) mainly have Kashaya Rasa, Ruksha, Sheeta and Vikasi properties (23) and excessive, constant chewing leads to Atiyoga of Kashaya Rasa (24) which affects locally causing Sthanadushti as well as systemically provoke the Vata Dosha which is the main cause in the pathogenesis leading to Rukshata, Kharata, Stambha and Shushkata in Sthanastha Dhatus (fibrosis of subepithelial tissue and atrophy of epithelium of oral cavity). Tamraparna (tobacco) (25) and lime (alkali) (26) are predominantly having Katu, Ushna, Tikshna and Pitta aggravating properties (26) and excessive and constant chewing results locally predominantly (Sthanadushti), as well to some extent systemically to provoke the Pitta Dosha which causes Shotha, Vrana in Mukha contributing to the disease process. Due to continuous and chronic chewing habits there is continuous irritation of Sthanik Mamsa Dhātu, leading to Utpati of Agantuka Vrana (local irritation and injury) (27) in Mukha. Alongwith formation of Vrana in oral cavity tobacco also cause vitiation of Pitta Dosha, due it Katu Rasa Pradhanta.

In present study 52.94% patients were taking Vidahi, Ushna, Teekshna Aahara, contributing to the pathogenesis of the disease. Also 61.76% patients were having a history of taking poor nutritional diet, as a result of which there are increased chances of developing the disease. Maximum 52.94% patient had fewer intakes of fruits and green leafy vegetables in their diet may responsible for vitamins and minerals deficiencies aggravating the disease condition. Consuming Alpa and Ruksha food are responsible for Vata aggravation and Dhatukshaya leading to disease condition.

Statistically highly significant relief ($P < 0.001$) on clinical finding ulcer and fibrous of mucosa in particular parts of oral cavity shows some extent fibrosis is reversed. IID is an objective parameter for assessing mouth opening. The more progress disease, will difficult in mouth opening. Statistically significant ($P < 0.05$) improvement in IID (25.26%) was noted and sustained relief was observed in the follow-up period of 1 month in Group A and in Group B, 30.34% improvement due to forceful mouth opening exercise with the help of a 'top' may be reason for such result. As the disease progresses, fibrosis becomes more and more dense decreasing the mouth opening which indicates the disease may become quite difficult to cure completely and can be considered Yappa at this stage and require long-term treatment for better result.

Probable mode of action of Ayurvedic management protocol

OSMF is a chronic supraclavicular disease. Pratisarana and Kavala /Gandusha are the local treatment mainly used in Mukharogas condition. Here, to prevent and reverse the fibrosis, local therapy were done. Most of the drugs of Madhupippalyadi Yoga Pratisarana are having Madhura Vipaka along with Lekhana, Shothahara, Vranashodhana, Vranaropana and Vata Pitta dominant Tridosha pacifying effect as well as drugs possess anti-inflammatory, antioxidant, wound healing and cleaning properties. Haridra due to fibrolytic and cancer preventive activities reported and its role in OSMF is also well-documented in few research journals works (28). Furthermore, gentle massage over the oral mucosa in Pratisarana improves blood circulation resulting in improving the health of the tissue of oral cavity and process may help in retarding the inflammation at vascular, cellular and immune level i.e. stimulates the mucosal epithelial cell might help in restoration of destroyed or atrophied epithelium in the disease thus might help in regeneration of epithelium.

Most of the ingredients of Nishadi Taila are having Madhura Rasa, Snigdha, Guru

Guna, Anushna Sheeta Veerya. Madhura Vipaka, Vata Pitta Shamaka properties. Madhura Rasa is Ropana, Snehana, Brimhana, Balya, Preenana, Dahashamaka and Vata-Pitta Shamaka properties and most of the drugs are anti-inflammatory, muscle relaxant and tonic in nature. The common base of Tila Taila due to its Shukshma and Vyavayi properties pervading to micro channels and pacify Vataja Vikara (29), also Swedana and Mardana done over Kapola, Lalata, Skandha help in improving circulation to local region and maximum absorption of the drugs through oral mucosa which helps in relieving the symptoms. Movement of mouth in Kavala procedure help to relieve stiffness in the disease OSMF and also useful as physiotherapeutic measure.

OSMF is the chronic debilitating disease and localized collagen disorder. All these factors favour the use of Rasayana Yoga which bring homeostasis and enhance the vitality of the oral mucosa at systemic level. Most of the drugs of Rasayana Yoga are having Rasayana, Balya, Deepana, Pachana, Shothahara, Vranapaha Dahashamaka, Vishagna, Kusthagna, Panduhara and Tridosha predominantly Vata Pitta pacifying properties. Rasayana properties of most of the drugs help to improve the health of Dhatus and it is Ojovardhaka thus, correcting the pathology of the disease and also possess immunomodulatory, antioxidant, anti-inflammatory, anti-ulcerogenic and cancer preventive properties. Madhu having Tridosha Shamaka, Yogavahi and Sukshmamarganusari properties while Ghrita have Vata Pitta Shamana, Rasayana and Sanskaranuvarti directly act on the Vikara as well act as a best vehicle for the drugs which enhanced the effect of Rasayana yoga.

CONCLUSION

From the present study, it can be concluded that Ayurvedic treatment protocol is effective in the management of OSMF without having any adverse effect as well as sustained relief in follow-up and ensures the regain of the normalcy of oral mucosa, hence considered as a better alternative to the modern treatment protocol in the management of OSMF.

COMPETING INTEREST

No competing interest exist.

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