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STUDY ON AYURVEDIC MANAGEMENT OF SARVASARA MUKHAROGA WSR ORAL SUBMUCOUS FIBROSIS (OSMF)

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ABSTRACT

Introduction: Oral Submucous Fibrosis (OSMF) is a chronic debilitating disease of the oral cavity resulting from habits like areca nut and its related products. OSMF has a high rate of morbidity due to its progressive inability to open the mouth. On analyzing the diseases condition it can probably be compared with *Vata Pitta Pradhana Sarvasara Mukharoga*. Aims: 1) To interpret the disease OSMF in the light of *Ayurvedic* principles 2) To evaluate the effect of proposed treatment protocol in patients of OSMF. Material and Methods: It was an open label randomized control clinical trial .Total 35 patients of age group 18-60 years were registered and out of them 30 patients completed this treatment. Patients were divided into two groups. Group A (*Erandabhrishta Haritaki* for *Kosthashudhdhi*, *Shodhana Nasya* with *Shadabindu Taila*, *Madhupippalyadi Yoga Pratisarana*, *Nishadi Taila Kavala and Rasayana Yoga* orally) and Group B (MV Nerve along with physiotherapy). Assessment was done based on objective and subjective criteria. The data obtained in clinical study was analyzed by using suitable statistical test. Results: Statistically highly significant results were found in subjective criteria in both the groups and significant result was found in inter incisor distances. Conclusion: *Ayurvedic* treatment protocol ensures the regain of normalcy of oral mucosa than modern treatment protocol.

Keywords: Sarvasara Mukharoga, Nishadi Taila, Madhupippalyadi Pratisarana, OSMF.

INTRODUCTION

OSMF now globally accepted as an Indian disease has one of the highest rates of malignant transformation amongst potentially ma-

lignant oral lesions and conditions¹. The new hallmark of the disease is submucosal fibrosis that affects most of parts of the oral cavity,

pharynx and upper third of the esophagus leading to dysphagia and progressive trismus due to rigid lips and cheeks. Worldwide estimate of OSMF indicates that 2.5 million people are affected with most cases connected on the Indian subcontinents especially Southeast India². Rapid increase of the disease are reported due to an upsurge in the popularity of commercially prepared areca nut & tobacco preparation in India and an increased uptake of these products by young people due to easy access .low price rates and marketing strategies. In Modern medical science local & systemic use of steroid injection, placental extract injection & surgeries are the main stay of the treatment but the results are not satisfactory, recurrences are there and treatment is also expensive. This disease is newly emerged so it cannot be described in Ayurvedic classics but while on analyzing the diseases condition some scattered references are seen in Mukha-Roga and Vrana related chapters. Few symptoms like inability to open the mouth (Kruchhen Vivrunoti-Vataja Sarvasara)3, burning sensation in mouth (Daha- Pittaja Sarvasara) ⁴ pain in mouth (Toda-Vatika Sarvasara)⁵, blanching of the oral mucosa (Antahkapolamashritya Shyavpandu- Kapharbuda) ⁶ etc are found in Mukharoga. On analyzing at the disease condition OSMF can be considered as the Vata- Pitta Pradhana Tridoshaja Mukharoga . It is obvious that it needs to be treated at local as well as systemic level. Local therapy is to prevent and reverse the fibrosis along with it to relieve burning sensation and irritation of the buccal mucosa. Systemic therapy of the OSMF is to bring homeostasis and to enhance vitality of the oral mucosa.

In Jamnagar and the surrounding area, it is common to found chewing habit of betel quid, other betel nut related products as well the disease OSMF and oral malignancies. Considering the social acceptance of the habit this study was planned.

Materials and Methods:

In this randomized clinical control trial, 35 patients, 19 in Group A and 16 in Group B were registered from the O.P.D. of *Shalakya Tantra*. The study was started after approval from the Institutional Ethics Committee (No. PGT/7-A/Ethics/2015-16/1490, dated: 25-08-2015) and registered in CTRI (CTRI/2016/06/006987, dated: 02/06/2016). A consent letter based on subject's willingness and interest to participate in the study was obtained.

Study design:

 Study was computerized open random control Clinical Trial.

INCLUSION CRITERIA:

- Age group between 18-60 years.
- The patients having clinical signs and symptoms of the disease OSMF.
- Interincisal distance of more than 15mm.

EXCLUSION CRITERIA:

- Extensive fibrosis by means of severe trismus with an inter incisal distance of less than 15mm.
- Disease is most advanced with premalignant and malignant changes.
- Generalized fibromatosis.
- Oral manifestation of scleroderma.

- Oral lichen planus.
- Pale oral mucosa of anaemia mimicking blanching.
- Chronic debilitating conditions like DM, HT, HIV etc.
- Patients not willing to give up the habits of chewing gutka, tobacco etc

Investigations

 Routine hematological, routine biochemical RBS and routine urine examination before treatment were carried to rule out any systemic disorder.

Treatment protocol and drug posology Group A:

For the initial *Erandabhrishta Haritaki* ⁷5-10 gms at bed time with luke warm water orally for 3 days followed by *Shadabindu Taila* ⁸ 4-6 drops in each nostril for 5 days. After that *Pratisarana*, *Kaval*, *Rasayana Yoga* was given twice a day for 45 days.

Duration: Total treatment duration was of 53 days.

Madhupippalyadi Yoga Pratisarana

MadhupippalyadiYoga [Table 1] 3–6 g was mixed with equal quantity of honey to make the paste, which was taken on the index finger and applied all over the oral mucosa and gentle massage was advised for about 10 min. Then, the patient was allowed to spit out the drug and the secretions.

Nishadi Taila Kavala

Supraclavicular massage with lukewarm *Tila Taila* (sesame oil) was done followed by fomentation. Then, luke warm *Nishadi Taila*⁹

[Table 2] 10–15 ml was advised to fill in the mouth and move it between cheek and throat. It 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. Again mild fomentation and massage were done on the supraclavicular region.

Rasayana Yoga

Rasayana Yoga [Table 3] was administered in a dose of 6 g orally, with honey and ghee in unequal quantity after meal twice a day.

Group B:

Physiotherapy: Mouth opening exercise with the help of top was explained to the patient which he performed himself at home, daily-30 minutes morning and 30 minutes evening.

Dose: 1 Tablet OD after meal orally for 45 days.

Follow Up:

After completing the treatment, follow-up was carried out for 1 month at the interval of 15 days.

CRITERIA FOR THE ASSESSMENT:

The clinical trial was assessed for its efficacy on the basis of following subjective and objective criteria according to Seedat-HA with slight modification.¹⁰

Subjective:

Burning sensation in mouth (*Mukhadaha*) (Table no.4); Taste (*Rasagyana*) (Table no.5)

Salivation (*Lalasrava*) (Table no.6); Intolerance to spicy food (*Katu Rasa Ashahishnuta*) (Table no.7); Pain in mouth (*Mukha Vedana*) (Table no.8)

Objective:

The colour of oral mucosa (Table no.9); Ulceration in mouth (Table no.10)

Consistency of the Oral mucosa on palpation (Table no.11); Fibrous bands- on palpation (Table no.12)

Objective parameter: inter incisor distance (IID) measurement.

It is a distance between the upper and lower central incisor. In this study it is measured by taking distance between mesial angles of the upper and lower central incisor with digital vernier caliper. (Table no.13)

Table 1: *Madhupippalyadi Yoga* (*Anubhuta*)

| Sr. No. | Name Of The Drug | Botanical/Latine Name | Part |
|---------|------------------|--|--------------|
| 1 | Pippali | Pipper Longum | 1/2 |
| 2 | Yastimadhu | Glycyrriza Glabra | 1 |
| 3 | Gairika | Ochre(Fe ₂ O ₃) | 1 |
| 4 | Jati | Jasminum Officinale | 1 |
| 5 | Haridra | Curcuma Longa | 1/2 |
| 6 | Madhu | Apis Mellifica | As Required. |

Table 2: *Nishadi Taila*: (*Bh.Pra*. Chap 66 *Mukhrogadhikar*)

| Sr.No. | Name Of The Drug | Botanical/Latin Name | Part |
|--------|------------------|----------------------|------|
| 1 | Haridra | Curcuma Longa | 2 |
| 2 | Nimb Patra | Azadirachta Indica | 1 |
| 3 | Madhuka | Glycyrrhiza Glabra | 1 |
| 4 | Neelotpala | Nymphea Nouchali | 1 |
| 5 | Tila Taila | Sesamum Indicum | 16 |

Table 3: Rasayana Yoga (Anubhuta)

| Sr. No. | Name Of The Drug | Botanical /Latin Name | Part |
|---------|------------------|-----------------------|------|
| 1 | Guduchi | Tinospora Cordifolia | 1 |
| 2 | Amalaki | Embelia Officinalis | 1 |
| 3 | Gokshura | Tribulas Terrestris | 1 |
| 4 | Haridra | Curcuma Longa | 1/2 |
| 5 | Yashtimadhu | Glycyrriza Glabra | 1 |

Table 4: Burning sensation in mouth (*Mukhadaha*)

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

Table 5: Taste (*Rasagyana*)

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

Table 6: Salivation (Lalasrava)

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

Table 7: Intolerance to spicy food (Katu Rasa Ashahishnuta) in comparison to previous tolerance

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

Table 8: Pain in mouth (*Mukha Vedana*)

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

Objective:

Table 9: The colour of oral mucosa

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

Table 10: Ulceration in mouth

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

Table 11: Consistency of the Oral mucosa on palpation

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

Table 12: Fibrous bands- on palpation

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

Table 13: Inter Incisor Distance (IID) measurement

| 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 assessment was done by adopting the following scoring pattern.

- 1. **Cured**: 76% to 100 % relief in signs and symptoms was considered as cured.
- 2. **Marked improvement**: 51% to 75% improvement in signs and symptoms was recorded as marked improvement.
- 3. **Moderate improvement**: 26% to 50% improvement in signs and symptoms was considered as moderate improvement.
- **4. Unchanged**: 0 to 25% improvement in signs and symptoms was considered as Unchanged.

Statistical Estimation of Results:

The data of 30 patients who completed the treatment course was analyzed by statistical methods. Wilcoxon signed rank test was 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 was applied to compare effect of therapy on non parametric 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.

Observations:

In the present study, 35 patients were registered and out of them 30 patients completed the therapy. Age wise distribution of registered patients showed that maximum patient's i.e.45.72% reported in the age group of 31-40 years and 88.57% patients were male.42.86% patients belonged to lower middle and poor economical status. 80% patients were having mental stress. 62.90% patients were having Vata- Pitta Prakruti. 91.43% were having complaint of inability to open the mouth, 94.29% were having burning sensation in mouth and intolerance to spicy food. Dryness of mouth was present in 37.14% patients, De-

creased taste in 14.29% patients and 60% patients had pain while opening the mouth. In maximum patients i.e. 50.00% 1-2 solitary fibrous bands was noted followed by in 27.10% having fibrous bands nearly on entire surface while multiple fibrous bands, adherent and giving rigidity to the mucosa was observed in 22.90% patients. 77.10% patients were having IID <25mm. 74.30% patients were having poor oral hygiene. Among 91.40% patients there was stage 2 OSMF. In maximum 57.10% patients there was grade 3 OSMF followed by 13.33% having grade 2 OSMF.

100% of patients had chewing habit of arecanut, tobacco and its related products while along with these 17.14% of patients had smoking habit.62.86% patients were having chewing habit from both side and 71.43% were having chewing habit of more than 8 years.

88.60% patients were taking *Ushna*, *Tikshna* and *Vidahi Ahara* in the form of consuming

excessive chilies and spices. Among *Viharaja Nidana* 74.30 % patients oral hygiene is poor due to *Dantadhavana Dwesha* or improper method of *Kavala* and *Gandusha*.

Result:

The effect of therapy in 30 patients of OSMF is presented below.

On symptoms

Group A in ability to open the mouth (11.11%) while in group B (8.75%) result found. In the symptom burning sensation in mouth in Group A (80.95%) and in Group B (76.47%) relief found. In intolerance to spicy food 86.66% relief found in Group A while 65.21% relief found in Group B. Dryness of mouth, decreased taste, pain while mouth opening in this symptoms both the group shows equal effect to relieve them. [Table 1-6]

IID Both the group shows significant result.[Table 7]

Table 1: Effect of therapy on inability to open the mouth

| Group | N | Mean score | | Mean diff | % relief | Wilcoxon signed rank test | | | | |
|-------|----|------------|-------|-----------|----------|---------------------------|-------|-------|--------|-----|
| | | BT | AT | | | SD | SE | W | P | Sig |
| A | 14 | 4.5 | 4 | 0.5 | 11.11 | 0.519 | 0.139 | -28.0 | < 0.05 | S |
| В | 14 | 5.71 | 5.214 | 0.5 | 08.75 | 0.650 | 0.174 | -21.0 | < 0.05 | S |

Table 2: Effect of therapy on burning sensation in mouth

| | | - | • | • | | | | | | |
|-------|----|-----------|-------|-----------|----------|---------------------------|-------|-----|---------|-----|
| Group | N | Mean scor | re | Mean diff | % relief | Wilcoxon signed rank test | | | | |
| | | BT | AT | | | SD | SE | W | P | Sig |
| A | 14 | 1.5 | 0.286 | 1.214 | 80.95 | 0.802 | 0.214 | -78 | < 0.001 | HS |
| В | 14 | 1.21 | 0.286 | 0.929 | 76.47 | 0.616 | 0.165 | -66 | < 0.001 | HS |

Table 3: Effect of therapy on intolerance to spicy food

| Group | N | Mean sco | ore | Mean diff | % relief | Wilcoxon signed rank test | | | | |
|-------|---|----------|-----|-----------|----------|---------------------------|----|---|---|-----|
| | | BT | AT | | | SD | SE | W | P | Sig |

| A | 14 | 1.86 | 0.286 | 1.571 | 86.66 | 0.770 | 0.206 | -105 | < 0.001 | HS |
|---|----|------|-------|-------|-------|-------|-------|------|---------|----|
| В | 14 | 1.77 | 0.538 | 1.231 | 65.21 | 0.725 | 0.201 | -66 | < 0.001 | HS |

Table 4: Effect of therapy on dryness of mouth

| Group N | N | Mean sco | ore | Mean diff | % relief | Wilcoxon signed rank test | | | | | |
|---------|----|----------|----------|-----------|----------|---------------------------|-------|-----|--------|----|--|
| | BT | AT | Mean din | 70 101101 | SD | SE | W | P | Sig | | |
| A | 8 | 1.909 | 0 | 1.909 | 100 % | 0.701 | 0.211 | -36 | < 0.05 | S | |
| В | 4 | 1.75 | 0 | 1.75 | 100 % | 0.500 | 0.250 | -10 | >0.05 | NS | |

Table 5: Effect of therapy on decreased taste

| Group N | N | Mean sco | ore | Mean % relief | | Wilcoxon signed rank test | | | | | |
|---------|----|----------|------|---------------|-------|---------------------------|---|----|-------|----|--|
| | BT | AT | diff | % rener | SD | SE | W | P | Sig | | |
| A | 3 | 1.25 | 0.5 | 0.75 | 100 % | 0 | 0 | -6 | >0.05 | NS | |
| В | 2 | 1 | 0 | 1 | 100 % | 0 | 0 | -3 | >0.05 | NS | |

Table 6: Effect of therapy on pain in mouth

| Group N | | Mean score Mean | | Mean | Mean % relief | | Wilcoxon signed rank test | | | | | |
|---------|----|-----------------|------|----------|---------------|-------|---------------------------|-----|--------|---|--|--|
| Gloup N | BT | AT | diff | % Tellel | SD | SE | W | P | Sig | | | |
| A | 9 | 1.444 | 0 | 1.444 | 100 % | 0.527 | 0.176 | -45 | < 0.05 | S | | |
| В | 10 | 1.60 | 0 | 1.60 | 100 % | 0.516 | 0.163 | -55 | < 0.05 | S | | |

Table 7: inter incisor distance (IID) – indicator of improvement in cardinal feature Inability to open the mouth in patients of OSMF (Paired t Test)

| Inability to | | No. of | Mean Sco | ore | D 11 60/ | a 5 | a 5 | · ₄ , | - | a. |
|----------------|-------|--------|----------|------|----------|-------|-------|------------------|--------|------|
| open the mouth | Group | pts | B.T. | A.T. | Relief % | S.D. | S.E. | 't' | P | Sigs |
| IID | A | 14 | 4.500 | 4.00 | 11.11 | 0.519 | 0.139 | 3.606 | < 0.05 | S |
| Ш | В | 14 | 5.714 | 5.24 | 8.75 | 0.650 | 0.174 | 2.876 | < 0.05 | S |

Statistically no significant difference was obtained between Group A and Group B in subjective and objective Criteria. So both the drugs have nearly equal effect in *OSMF*. But

percentage wise better results were obtained in group A in subjective and objective Criteria.[table 8-9]

Table 8: Comparison of difference of symptoms between Group A and Group B (Fisher's exact test)

| Symptoms | Group | N | <50% | >50% | P | Sigs |
|---------------------------|-------|----|--------|--------|-------|------|
| Inability to open mouth | A | 14 | 13(46) | 1(4) | >0.05 | NS |
| madmity to open mouth | В | 14 | 14(50) | 0(0) | >0.03 | No |
| Burning sensation in | A | 14 | 2(7) | 12(43) | >0.05 | NS |
| Mouth | В | 14 | 1(4) | 13(46) | >0.03 | No |
| Intolerance to spicy food | A | 14 | 2(7) | 12(44) | >0.05 | NS |

| | В | 13 | 5(19) | 8(30) | | | |
|------------------------|---|----|-------|--------|-------|------|--|
| Drungs of Mouth | A | 8 | 1(8) | 7(58) | >0.05 | NS | |
| Dryness of Mouth | В | 4 | 0(0) | 4(34) | >0.03 | IND. | |
| Decreased Taste | A | 3 | 0(0) | 3(60) | >0.05 | NS | |
| Decreased Taste | В | 2 | 0(0) | 2(40) | >0.03 | No | |
| Pain while opening the | A | 9 | 0 | 9(47) | >0.05 | NS | |
| Mouth | В | 10 | 0 | 10(53) | >0.03 | No | |

Table 9: Comparison of difference of sign between Group A and Group B (Unpaired't' test)

| Sign | Df | Mean | | т | D | Sign |
|------------------------|----|-------|-------|------|-------|------|
| | DI | Gr. A | Gr. B | 1 | Г | Sigs |
| Inter incisor distance | 26 | 0.500 | 0.500 | 0.00 | >0.05 | NS |

Overall effect of therapy

Among 15 patients of Group A, 6 (40%) patients had moderate relief, 1 (26.67%) patient each had marked relief and 3 (20%) had cured. Among 15 patients of Group B, 14 (93.33%) patients had moderate relief while 1 (6.67%) patient had cured.

DISCUSSION

Chief complaints:-

91.43% were having complaint of inability to open the mouth, 94.29% were having burning sensation in mouth and intolerance to spicy food. Dryness of mouth was present in 37.14% patients. Decreased taste was present in 14.29% patients and 60.00% patients had pain while opening the mouth. These all are the presentation of advanced OSMF. This shows the ignorance of the patients to the disease up to the full fledge presentation.

Chronicity:-

In present study maximum 71.43% patients were having chronicity of more than 8 years, 17.14% patients were having chronicity of 2-5 years. This data is a reflection of the fact that

OSMF is a chronic disease. This also suggests patient's ignorance for the disease.

Addiction: - particular habit

Maximum i.e. 71.43% patients were having chewing habit of Gutka/Mawa followed by 20% patients each were having chewing habit of Pan masala, Betel nut, and Tobacco. Habit of Cigarette smoking was found in only 17.14% patients along with chewing habits. The etiopathogenesis of OSMF is still unknown. . In this study most of the patients chewed areca nut and its related products in some form or other which also proves the previous researches but, it is also evident that mixed products of arecanut and tobacco seems to be more responsible than the areca nut alone. The most commonly used areca nut products by the patients in this study were gutka/mawa which contain higher concentration of areca nut, tobacco and lime which overall cause more harm. Incidence of oral sub mucous fibrosis was noted after Pan masala and Gutka came into the market, and the incidence continues to increase.

Habit of smoking was found in only 17.14% patients along with chewing areca nut and to-

bacco suggesting no separate role of smoking in the causation of the disease.

Addiction: habit mode

100% patients were habitual. No one was using it casually suggesting only excessive and constant use of these products is responsible for the disease.

Addiction: habit duration

Maximum 71.43% patient had chewing habit since more than 8 years, followed by 17.14% had since 2 to 5 years. 11.43% patients had chewing habit since 5 to 8 years. This data support that the disease is of gradual onset over a period of 8 years.

Addiction: chewing habits content –spitting or swallowing

Most of the patients i.e. 91.43% were spitting the content of gutka etc. after chewing while rest were swallowing; showed that disease entirely seems due to local pathological process. But absorption through oral mucosa is quite possible so systemic effects of these habits cannot be neglected.

Oral cavity examination:-

Blanching of the mucosa, Ulceration of the mucosa, Leathery hard consistency of the oral tissue and Fibrous bands were observed in most of the patients. These are established features of advance OSMF. In this study most of the patients had stage II and grade 3 OSMF, so it is obvious to have these findings. Recurrent/persistent stomatitis and glossitis is the invariable feature in any stage of the disease OSMF with more or less severity.

Blanching of the mucosa:

Maximum blanching i.e. 91.40% was observed in Rt. Buccal mucosa, Lt. buccal mucosa, and lower lip followed by upper lip 62.90%, soft palate 57.10%, gingiva 51.40%, floor of the mouth 11.40% and in tongue 37.10%. It is observed that disease mostly involve B/L buccal mucosa and soft palate initially and as the disease progress it involves lips, gingiva, floor of the mouth and lastly tongue. It may be attributed to the contact of areca products in this area or the mucosal structure variation. But definite correlation required more sample size along with histopathological support.

Ulceration of the mucosa

Maximum ulceration of the mucosa i.e. 88.70% was observed in Lt. Buccal mucosa, 85.70% Rt. buccal mucosa followed by upper lip 45.70%, lower lip 25.70%, 25.70% on tongue. It may be attributed to the contact of areca products and chilies like irritants in this area or ongoing inflammatory process in the tissues.

Leathery consistency of the mucosa

Maximum leathery consistency i.e. 40% was observed in Rt. Buccal mucosa, 34.30% Lt.buccal mucosa, followed by upper lip 31.40%, lower lip 28.60%. This also signifies the reason explained above in context of Blanching of the mucosa.

Fibrous bands

In maximum patients i.e. 50.00% 1-2 solitary fibrous bands was noted followed by 27.10% fibrous bands nearly in entire surface while multiple fibrous bands, adherent and giving rigidity to the mucosa was observed in 22.90% patients. Fibrous bands are indicative of advanced stage of disease. Again in this study most of the patients had stage 2 and grade III fibrosis so it is obvious to have these findings.

Objective parameter Inter incisal distance

Inter incisal distance is used to assess mouth opening as objective parameter. Mouth opening is an indicator of the degree of severity of the disease. The more advanced the disease the less will be the mouth opening. In maximum i.e.25.70% patients IID was between 17-20mm followed by in 20% between 25-28mm. In 17.10% patients IID was between 21-24mm. IID was noted suggesting most of the patients had advanced disease having more severity.

Discussion on Nidana:

All the patients i.e. 100% had chewing habit of areca nut, tobacco and its related products. Areca nut (*Pooga*) is having *Kashaya Rasa*, *Ruksha*, *Sheeta* and *Vikasi* properties¹¹; its excessive and constant chewing seems to be the *Atiyoga* of *Kashaya Rasa*¹². *Atiyoga* of *Kashaya Rasa* affects locally predominantly (*Sthanadushti*) and to some extent also systemically to provoke the *Vata Dosha* which is the prime factor in the pathogenesis of the disease causing *Rukshata*, *Kharata*, *Kathinya*, *Stambha* in *Mukhagata dhatus*. As areca nut is the substance prominently used in chewing habits and kept in oral cavity for long dura-

tion, its hazard is well known. For other substance having *Kashaya Rasa Pradhanya*, its local action due to excessive use is yet to be evaluated. In this study most of the patients (71.43%) were chewing mixed products of areca nut and tobacco.

Probable mode of action of *Madhupippalya-di Yoga*:

Madhupippalyadi Yoga Pratisarana pacifies Vata Pitta Pradhana Tridoshas as well purify and improves the qualities of local tissues by means of Lekhana, Ropana, Shothahara, Vranasodhana, Vranaropana, Dahashamaka and Srotovishodhana. etc. as well anti inflammatory, antioxidant, wound healing and cleaning properties. Haridra has proven fibrolytic activity and its use in OSMF are also documented in few journals and research works. It has also cancer preventive activity. Thus it acts as local (Mukhagata) Rasa, Rakta, and Mamsa Dhatu Prasadana causing Shamana of OSMF.

Probable mode of action of Nishadi Taila Kavala

When Kavala Dharana is done, one gets maximum absorption of the drugs through oral mucosa which helps in relieving the symptoms, also movements of mouth helps to relieve stiffness in the disease OSMF. It is useful as physiotherapeutic measure. Most of the drugs are Snehana, Balya, Brimhana, Rasayana, Ropana and Dahashamaka as well as possesses anti inflammatory, analgesic, muscle relaxant, antioxidant and tonic properties. The common base of Tila Taila makes the whole drugs pervading to micro channels due to its Sukshma and Vyavayi Gunas. Nishadi Taila

Kavala pacifies Vata Pitta Doshas as well nourishes local tissues by means of Balya, Brimhana etc. effects which can be included under the heading of local (Mukhagata) Rasa, Rakta, and Mamsa Dhatu Pushti.

Probable mode of action of Rasayana Yoga:

Most of the drugs are Balya, Brimhana, Rasayana, Deepana, Pachana, Shothahara, Vranapaha, Dahashamaka, Vishaghna, Kusthagna and Panduhara. Rasayana properties of most of the drugs help to improve the health of Dhatus and it is Ojovardhaka, immunomodulatory, antioxidant, anti inflammatory, anti ulcerogenic and cancer preventive properties. Haridra has proven fibrolytic activity. By virtue of all these properties Rasayana Yoga pacifies Vata Pitta Pradhana Tridoshas. It overall improves the quality of *Dhatus* and nourishes them by means of its Rasayana, Balya etc properties which might improve the quality of the local tissues and prevents malignant changes too that can be included under the heading of Dhatu Pushti and Dhatu Prasadana.

CONCLUSION

Ayurveda can be of great help to deal this problem by its preventive and curative approach. According to Ayurveda excessive and constant consumption of Kashaya Rasa, Ruksha, Vikasi Dravyas could be considered as a main etiological factor to precipitate the clinical entity of the OSMF. By analyzing the disease it seems to be Vata Pitta Pradhana Sarvasara Mukharoga. Here Vata Prakopa increasing its Ruksha Guna has the prime role in the Samprapti of disease OSMF which leads

to *Kharata*, *Kathinya*, *Shushkata* and *Stambha* of *Mukhagata Dhatus* which ultimately results in *Mukhasankocha*-cardinal symptom of the disease OSMF.

The use of local therapy in the form of *Pratisarana* with *Lekhana*, *Vranashodhana*, *Vranaropana*, *Shothahara* drugs; *Snehana*, *Shamana Kavala* and *Rasayana* drugs internally constitutes the basic therapeutic approach in combating most of the symptoms of the OSMF.

Thus from the present study it can be concluded that Ayurvedic treatment protocol ensures the regain of normalcy of oral mucosa than modern treatment protocol and we can say that Ayurvedic treatment protocol comprising of *Madhupippalyadi Pratisarana*, *Nishadi taila Kavala* and *Rasayana yoga* internally with prior *Koshthashudhhi* and *Shiroshudhdhi* is effective in management of OSMF without having any adverse effect as well as with sustained relief in follow up.

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