

Original Research

Effectiveness of Various Treatment Modalities in the Management of Oral Submucous Fibrosis-A Clinical Study

Shrinivas¹, Aradhana Rathod², Deepa B.V³

¹Assistant professor, Department of Dentistry, Koppal Institute of Medical Sciences, Koppal, Karnataka, India;

²Assistant professor, Department of Prosthodontics, Al-Badar Rural Dental College and Hospital, Kalaburgi, Karnataka, India;

³Senior Lecturer, Department of Oral and Maxillofacial Surgery, JSS Dental College and Hospital, Mysore, Karnataka, India

ABSTRACT:

Aim: The aim of the present study was to evaluate clinically the effectiveness of various treatment modalities in the management of oral submucous fibrosis. **Materials and Methods;** Forty five patients were in the study, based on habitual history and clinical findings they were diagnosed to have oral submucous fibrosis. Three groups were made after randomization, i.e. Group A: Physiotherapy group (Control group), Group B: Lycopene group, Group C: Injection Dexamethasone with hyaluronidase group. Symptom severity was done by VAS scoring system viz burning sensation/pain in the patients, Patient satisfaction was assessed. Patients' maximum mouth opening was measured at baseline, 1st month and 3rd month. **Results;** The more number of fairly unsatisfied patients were there in Group A (Physiotherapy group). VAS score in the study groups did not have statistical significance differences at baseline. Study subjects with no pain were more in group C followed by group B on 3rd month and there was a statistically significant difference found at 1st and 3rd month between the groups. In group C, the mouth opening had improved more in 1st month and 3rd month (24.28±0.36, 27.84±0.09) followed by group B (23.98±0.13, 25.15±1.29) and group A (20.64±1.24, 22.12±1.03) respectively. On 1st and 3rd month, statistically significant difference was observed between the study groups.(Table 3). **Conclusion;** This study concludes that the treatment with Dexamethasone with Hyaluronidase group showed better results in improvement of mouth opening in oral submucous fibrosis patients compared to Lycopene and Physiotherapy groups.

Keywords: Antioxidants, Dexamethasone, Hyaluronidase, Lycopene, Oral submucous fibrosis.

Received: 12 January, 2021

Accepted: 26 February, 2021

Corresponding author: Dr. Aradhana Rathod, Assistant professor, Department of Prosthodontics, Al-Badar Rural Dental College and Hospital, Kalaburgi, Karnataka, India

This article may be cited as: Shrinivas, Rathod A, BV Deepa. Effectiveness of Various Treatment Modalities in the Management of Oral Submucous Fibrosis-A Clinical Study. J Adv Med Dent Scie Res 2021;9(3):135-138.

INTRODUCTION:

Oral cavity is rightly described as mirror of the body as it reflects the health of the individual. Oral mucosa is a unique tissue, lined by keratinized and nonkeratinized stratified squamous epithelium and underlying connective tissue (lamina propria). The oral mucosa is continuously exposed to chemicals, microorganisms, thermal changes and mechanical irritants (tobacco, areca nut, alcohol, etc). The epithelial and connective tissue components of the oral mucosa

demonstrate acute and chronic reactive changes in response to the above stressors.¹

Oral Submucous fibrosis (OSMF), is a chronic, insidious, progressive, debilitating premalignant oral condition, was first described by Schwartz (1952) which frequently affects the buccal mucosa. Clinical features of this disease include restricted mouth opening, burning sensation, tongue protrusion, and decreased cheek flexibility. Limited mouth opening further leads to restricted food consumption, oral

hygiene maintenance issues, and also speech impairment. The disease has a multifactorial pathogenesis, ranging from areca nut chewing, chilli ingestion, genetic and immunologic processes, and nutritional deficiencies. It is widely prevalent in South Asian countries and has a malignant transformation rate of 5–15 %.²

Pindborg and his associates defined the condition as “an insidious chronic disease affecting any part of the oral cavity and sometimes pharynx. Although occasionally preceded by and/ or associated with vesicle formation, it is always associated with juxta-epithelial inflammatory reaction followed by fibroelastic changes in the lamina propria, with epithelial atrophy leading to stiffness of the oral mucosa causing trismus and difficulty in eating.”³

There are no standardized treatment options available for OSMF and it is managed symptomatically and empirically. Pharmacological treatment includes anti-inflammatory drugs such as corticosteroids, oxygen radical scavengers such as vitamins, micronutrients, and antifibrotic agents such as HMG-CoA inhibitors.⁴ Various other agents such as lycopene and isoxsuprine have also been evaluated. The other treatment options include physiotherapy and surgery. OSMF is predominantly seen in the Asian countries such as India, Pakistan, Sri Lanka, and Bangladesh. However, with the increasing availability of various areca nut products in other countries in recent times, the incidence of OSMF is set to increase.⁵ Hence the present study was conducted to evaluate the effectiveness of various treatment modalities in the management of oral submucous fibrosis.

MATERIALS AND METHODS:

The present study was conducted in the department of dentistry, Koppal institute of medical sciences, Koppal. Total of 45 patients were selected for this study from who visited our department. An informed consent was obtained from the patients before including them in the study. A detailed case history of the patient with emphasis on their habits (chewing betel nut, pan parag, etc.) and a thorough clinical examination was recorded.

Criteria for selection of patients:

Patients between 20 years and 50 years of age, patients complaining of difficulty in mouth opening. History of consumption of areca nut in various forms. Palpable fibrotic bands with blanched oral mucosa. Patient complaining of ulceration or burning sensation. Patients who met all these inclusion criteria were considered for the study.

Patients those were not willing to participate in the study despite motivation. Patients diagnosed with systemic conditions like anemia, edentulous patients,

OSMF superimposed by any other lesion. Patients complaining of difficulty in opening the mouth due to other reasons like inflammation/infection, trauma and temporo-mandibular joint disorders. The patients giving history of more than one chewing habit were excluded from the study.

Group A: Physiotherapy group (Control group)

Patients were advised to perform jaw opening exercises. Subjects were advised to perform the exercise 5 times per session and to do five sessions per day. In case of severe discomfort and pain, subjects were advised to take paracetamol (250 mg), 30 min before performing the exercise.

Group B: Lycopene group

These Capsules containing 100% natural lycopene. This capsule was given orally, twice daily for 3 months, where each capsule contained 2000 microgram of lycopene.

Group C: Injection Dexamethasone with hyaluronidase group

Intralesional injection of 0.5 ml of local anesthesia with 4 mg/ml of dexamethasone and 1500 I.U of hyaluronidase was administered twice weekly. These were given on different sites of buccal mucosa bilaterally using insulin syringe biweekly for three months with the half dose on each side. The sites of injection were center of buccal mucosa in 3rd molar, 1st molar and 1st premolar region. The response to treatment was assessed by improvement in the patients sign and symptoms.

All the patients underwent the clinical examination of the oral cavity. The severity of symptoms was measured by VAS scale, viz burning pain/ sensation in the patients, with the score ranged from a numerical 0 (no pain or discomfort) to 10 (severe most pain /discomfort). Patient satisfaction was evaluated. Vernier calipers were used to measure patients' maximum mouth opening at Baseline, 1st month, 3rd month.

The measurement of the distance between the center of incisal edges of maxillary and mandibular central incisor at maximum opened mouth position was used to measure mouth opening. The interalveolar distance along the midline was measured in edentulous patients.

Statistical Analysis:

The statistical procedures were done on windows version 20.0 using SPSS. The significance of study parameters between three groups of patients is done by Analysis of Variance (ANOVA) and qualitative data were analyzed using Fischer exact test.

The P value less than 0.05 is considered to determine the level of significance.

RESULTS:

Patient satisfaction by a grading scale in table 1 reveals that the results for satisfaction of the different treatment modalities. The more number of fairly unsatisfied patients were there in Group A (Physiotherapy group) and there was a statistically significant (p<0.001) difference found between the groups.

Table 2 depicts the severity of burning sensation/pain recorded using VAS score where the study groups did not have statistical significance differences at baseline. But patients in group A had more number of patients

with severe pain. There was a reduction in the number of study subjects with severe pain in the group C on 1st month, when compared with group A and B. Study subjects with no pain were more in group C followed by group B on 3rd month and there was a statistically significant difference found at 1st and 3rd month between the groups.

In group C, the mouth opening had improved more in 1st month and 3rd month (24.28±0.36, 27.84±0.09) followed by group B (23.98±0.13, 25.15±1.29) and group A (20.64±1.24, 22.12±1.03) respectively. On 1st and 3rd month, statistically significant difference is observed between the study groups.(Table 3)

Table 1: Comparison of patient’s satisfaction of the various treatments for OSMF

Patient satisfaction grade	Group A (n=15)	Group B (n=15)	Group C (n=15)	P value
Very satisfied	1	4	5	0.001(HS)
Fairly satisfied	4	9	9	
Fairly unsatisfied	9	2	1	
very unsatisfied	1	0	0	

p>0.05, HS – Highly Significant

Table 2: Assessment of Burning sensation/pain (VAS) between all the three groups

Groups		No pain	Mild pain	Moderate pain	severe pain	Fischer exact test
Baseline	Group A	0	2	6	7	$\chi^2 = 4.162$ p = 0.214
	Group B	0	3	7	5	
	Group C	0	3	6	6	
1 st month	Group A	0	2	9	4	$\chi^2 = 6.518$ p = 0.01*
	Group B	1	7	5	2	
	Group C	1	8	5	1	
3 rd month	Group A	4	3	7	1	$X^2 = 9.176$ p = 0.01*
	Group B	8	4	3	0	
	Group C	12	2	1	0	

* – Significant

Table 3: Evaluation of mean score mouth opening for various treatment for OSMF

Duration	Groups	Mean±SD	F value	p value and significance
Baseline	Group 1	18.26±0.60	6.238	0.724
	Group 2	18.98±1.82		
	Group 3	19.10±0.44		
1 st month	Group 1	20.64±1.24	11.125	0.001
	Group 2	23.98±0.13		
	Group 3	24.28±0.36		
3 rd month	Group 1	22.12±1.03	12.104	0.001
	Group 2	25.15±1.29		
	Group 3	27.84±0.09		

* – Significant

DISCUSSION:

Oral submucous fibrosis is a premalignant condition of the oral cavity and oropharynx seen predominantly in the Indian subcontinent and Southeast Asian countries. The pathophysiology of this condition is complex, and various factors such as, ingestion of spicy food, genetic susceptibility, nutritional deficiencies, altered salivary constituents, autoimmunity and collagen disorders are thought to be involved in the pathogenesis. The fibrotic potential of arecanut alkaloids and tannin have been proved to have an effect in the etiology of this chronic inflammatory mucosal disease.⁶

In the treatment of OSMF, various categories of drugs have been used, but their effectiveness leaves much to be desired and definitive cure has not been afforded by any treatment.⁷ Increased potential for side effects is high while oral administration as it limits the concentration of drugs in lesional tissue and significant mechanical injury and noncompliance on the patient's part is high with intralesional injections due to the accompanying discomfort and pain.⁸ The health of the consumers has been compromised immensely by the use of arecanut in different forms with or without tobacco as it has unfortunately permeated the ordinary household. The major fatal sequel to their usage is the onset of OSMF and cancer of the oral cavity and India is the globally leading country in this.

The literature however is scarce on the importance of physiotherapy after surgery to reduce chances of scar contracture and relapse. A study done by Cox and Zoellner on 54 OSMF patients highlighted the importance of physiotherapy in improving mouth opening.⁹ To overcome the pain, we advocate keeping the patient under a strong analgesic cover.

Several studies in humans have confirmed the cancer preventive nature of antioxidants. Lycopene also up-regulates the lymphocyte resistance to stress and suppresses the inflammatory response.¹⁰ The unifying mechanism, which underlies these diseases is cumulative oxidative damage. Hence, antioxidants can influence or prevent seemingly unrelated conditions. It is clear from this that a long term maintenance treatment is necessary, if there has to be an impact on oral cancer incidence. Another point in favor of the use of lycopene for the prevention of OSMF is that it is relatively non-toxic and can be easily supplemented in the diet.¹¹

Dexamethasone with Hyaluronidase group showed more increase in mouth opening than with capsule Lycopene group, this was statistically significant. Definite reduction in burning sensation and

improvement in mouth opening was observed by Shah et al¹² by evaluating the efficacy of hyaluronidase and dexamethasone combination in the treatment of OSMF. These findings are in agreement with our study.

CONCLUSION:

This study concludes that the treatment with Dexamethasone with Hyaluronidase group showed better results in improvement of mouth opening in oral submucous fibrosis patients compared to Lycopene and Physiotherapy groups.

REFERENCES:

1. Bhatnagar P, Rai S, Bhatnagar G, Kaur M, Goel S, Prabhat M, et al. Prevalence study of oral mucosal lesions, mucosal variants, and treatment required for patients reporting to a dental school in North India: In accordance with WHO guidelines. *J Family Community Med.* 2013;20:41–8.
2. Ekta Ingle. Turmeric in the management of oral submucous fibrosis – A systematic review and meta-analysis. *International Journal of Health Sciences* 2020;14(3):41-46.
3. Pindborg JJ, Sirsat SM. Oral submucous fibrosis. *Oral Surg Oral Med Oral Pathol* 1966;22:764-79.
4. Chole RH, Gondivkar SM, Gadbail AR, Balsaraf S, Chaudhary S, Dhore SV, et al. Review of drug treatment of oral submucous fibrosis. *Oral Oncol* 2012;48:393-8.
5. Wollina U, Verma SB, Ali FM, Patil K. Oral submucous fibrosis: An update. *Clin Cosmet Investig Dermatol* 2015;8:193-204.
6. Rajendran R, Rani V, Shaikh S. Pentoxifylline therapy: A new adjunct in the treatment of oral submucous fibrosis. *Indian J Dent Res* 2006;17:190-8.
7. Borle RM, Borle SR. Management of oral submucous fibrosis: A conservative approach. *J Oral Maxillofac Surg* 1991;49:788-91.
8. Sinha SN, Jain PK. Intraoral injection of hydrocortisone & placental extract in oral submucous fibrosis. *Indian J Otolaryngol Head Neck Surg* 1978;30:103.
9. S. Cox and H. Zoellner, "Physiotherapeutic treatment improves oral opening in oral submucous fibrosis," *Journal of Oral Pathology and Medicine* 2009;38(2):220–226.
10. Tupkari JV, Bhavthankar JD, Mandale MS. Oral submucous fibrosis. A study of 101 cases. *JIAOM* 2007;19:311-18.
11. Lavina T, Bagewadi A, Keluskar V. Haemoglobin levels in patients with oral submucous fibrosis. *JIAOM* 2007;19:329-33.
12. Shah PH, Venkatesh R, More CB, Vassandacoumara V. Comparison of Therapeutic Efficacy of Placental Extract with Dexamethasone and Hyaluronic Acid with Dexamethasone for Oral Submucous Fibrosis - A Retrospective Analysis. *J Clin Diagn Res.* 2016;10(10):ZC63-ZC66.