Original Research Paper

Volume - 11 | Issue - 01 | January - 2021 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Clinical Research

EFFICACY OF NON-INVASIVE IN OSMF COMPARATIVE TO INVASIVE THERAPY: A CLINICO-PHYSIOTHERAPICAL STUDY

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ABSTRACT **Background and Objectives:** Oral sub-mucous fibrosis (OSMF) is an oral precancerous condition characterized by inflammation and progressive fibrosis of the sub-mucosal tissues resulting in marked rigidity and trismus and successful management still remains a challenging for clinicians. Our study aims to compare the efficacy of commonly used treatment such as physiotherapy, physiotherapy with antioxidants, and intra-lesional therapy. It aimed to ascertain the most effective treatment modality among the three which one of them helped improve the maximum mouth opening (MMO), tongue protrusion (TP) and reduced oral burning sensation.

Materials and Methods: This randomized study was conducted on 90 patients visiting the outpatient Department of Dentistry and ENT, over a 1 year period diagnosed with OSMF. A detailed history of burning sensation, in the mouth and the severity was recorded using numerical analogue scale (NAS), for mouth opening and tongue protrusion was recorded by vernier calliper on 1st and last visit of treatment duration.

Results: Physiotherapy alone was not effective in alleviating neither burning sensation nor significantly improves the MMO and TP. The percentage decrease in burning sensation was highest in the interventional group receiving an intra-lesional injection. Physiotherapy with antioxidant group showed almost similar percentage.

Conclusion: A non-invasive treatment modality is as effective as an invasive intra-lesional injection, in the management OSMF. The findings suggest that non-invasive modality of physiotherapy with antioxidant treatment can be considered as standard care for the management of OSMF.

KEYWORDS : MMO (Maximum Mouth Opening), TP (Tongue Protrusion), Burning sensation

INTRODUCTION

Oral sub-mucous fibrosis (OSMF) is a potentially malignant condition affecting the oral cavity and the pharynx along with effect on phonation and hearing system. Initially, symptoms showing burning sensation in oral cavity with difficulty in eating spicy, hot food and beverages and gradually increases with restricted mouth opening along with blanching and stiffness of oral mucosa which ultimately leads to trismus.[1-4] It also produces hypo-mobility of the soft palate and tongue, and loss of gustatory sensation.[1] It is associated with the various etiological factors has been proposed earlier including chillies, nutritional deficiency, autoimmunity and genetic susceptibility.[5] Presently, associated with areca nut (betel nut) chewing and the incidence further increases when betel chewing is combined with tobacco use.[3,6.] There are no standardized treatment options available for OSMF and it is managed symptomatically and physiological changes. Pharmacological treatment includes anti-inflammatory, antioxidants and micronutrients apart from pharmacological therapy, intra-lesional therapy given in those patients whom under grade 2 and 3 category of OSMF. The other treatment options include physiotherapy and surgery. There are very few studies that are available on the management of OSMF according to so many clinicians or researchers. The paucity of studies regarding the conservative and surgical management of OSMF as well as lack of standardized treatment due to the lack of understanding of the exact aetiology of this disease.[8-10]

We conducted a multiphase, randomized open-label study comparing common treatment modalities of physiotherapy alone; physiotherapy combined with antioxidants; and intra-lesional therapy in patients with OSMF. In the present study, burning sensation which is a subjective measure and reduced inter-incisal distance, the most objective criteria for evaluation of improvement in OSMF were used as primary parameters for assessing the efficacy of the three treatment modalities. Subjects in the group comprising physiotherapy with antioxidants were administered lycopene supplements. Studies documented in 2007 and more recently in 2012 suggest lycopene used as the first line of treatment for OSMF was effective in burning sensation as well as improving mouth opening.[11,12]

AIM OF THE STUDY:

To assess the efficacy of non-invasive therapy (physiotherapy alone, along with antioxidants) compare to invasive therapy like intra-lesional therapy in improving maximum mouth opening (MMO), tongue protrusion (TP) and reducing oral sensitivity to spicy food as measured on numeric analogue scale (NAS) in patients with OSMF.

MATERIALS AND METHODS

The study was conducted in the department of dentistry and ENT. A total of 100 patients visiting the outpatient Department of dentistry and ENT, Vikash Multi-Specialty Hospital, Bargarh, Odisha, over a 1-year period were evaluated for study participation. Among them, 100 patients were screened for the study and 90 patients, who satisfied the study criteria and were willing to participate in the study, were enrolled. Sample collected on the bases of clinical and functional staging of OSMF.[13] After completion of clinical evaluation data recorded on the bases of maximum mouth opening, tongue protrusion and burning sensation. In this study patients included with the history of burning sensation and MMO <35 mm and >20 mm, restricted tongue protrusion, and who willing for study. Only those patients excluded who suffering from Temporo-mandibular joint disorder, any systemic disease and not willing for study procedure.

At the initial visit, a comprehensive habit history was elicited and the data were recorded in a pre-designed pro forma. Patient's habit history for the use of various forms of areca nut products was recorded.

A detailed clinical history, burning sensation of the mouth, mouth opening and tongue protrusion recorded. Burning sensation was recorded using the numerical analogue scale (NAS). A Vernier caliper was used for measuring the maximum mouth opening (MMO) and maximum tongue protrusion. After collection of sample, sample divided into three groups, first was treated with physiotherapy (group 1), second was treated with physiotherapy with antioxidant systemic drug therapy (group 2) and third group was intra-lesional therapy. Each group contains 30 patients of OSMF. In this study two time reading recorded in whole duration of study, first one is recorded at the first visit and another one was recorded at end of study that mean final or last visit, but in this period patients visit time to time as per required for this study. The MMO was measured between the left maxillary and mandibular central incisors, if absent the adjacent appropriate teeth were selected.

All the 90 OSMF patients were counselled individually and educated about the harmful effects of the areca nut, gutka chewing, or other proprietary preparations. The subjects were motivated to quit the habit and were explained about the benefits and treatment modalities. An

informed consent was obtained from the patient before enrolment into the study. In this study, group 1 treated with physiotherapy with antioxidabt (Lycopene 5000mcg) 1BID, group 2 treated with physiotherapy alone group 3 was treated with intalesional therapy (1.5 ml dexamethasone + 1500 IU hyaluronidase).

STATISTICAL ANALYSIS AND RESULTS:

In this study, 90 patients in which, 69 (62.1%) male and 21 (18.9%) female subjects aged between 20 to 40 years with the mean age of 28.72 years were present. In our study sample was divided into three groups first group 1 consist OSMF patients treated with physiotherapy alone, second group 2 consist OSMF patients treated with physiotherapy along with antioxidant (Lycopene 5000 mcg) 1BID and third group consist OSMF patients treated with intra-lesional therapy (1.5 ml dexamethasone + 1500 IU hyaluronidase) each group consist 30 patients. In this study, age group divided in two groups, first age group 20-30 consist 51 patients and group 30-40 consist 39 patients of OSMF considered for study.

Table1. Sample distribution according to treatment plan

	Physiotherapy and antioxidant Group 1	Physiotherapy Group 2	Intra-lesional therapy Group 3
N	30	30	30
Total	90		

Restricted mouth opening is very common symptom in OSMF patients along with mucosal blanching, burning sensation, ulceration, deviated or shrunken uvula with advanced sign and symptoms such as oro-pharynx involvement hearing impairment etc. Our study conducted on the three common symptoms based such as, maximum mouth opening, tongue protrusion and burning sensation. In this study one way ANOVA test used for calculation of data and found results as following table 2, 3 and 4.

Table2. Results showing on the bases of maximum mouth opening in Group 1, Group2 and Group 3

Maximum Mouth Opening				
	Group 1	Group 2	Group 3	Total
N	30	30	30	90
Mean	30.46	29.60	31.86	30.64
Std. Dev.	1.69	2.38	1.69	2.14
F value	10.27981			
P value	**0.000098**			

Above table shows, after treatment maximum mouth opening mean value found in group 3 (31.64) which was treated with Intra-lesional therapy followed by group 1 (30.46) treated with physiotherapy with antioxidant and group 2 (29.60) treated with alone physiotherapy completion of three months treatment duration. So not more difference found in group 1 and group 2 (31.89-30.49=1.43), after analysis of mouth opening data we have found significant result p value 0.000098.

Table3. Results showing on the bases of Tongue protrusion in Group 1, Group2 and Group 3

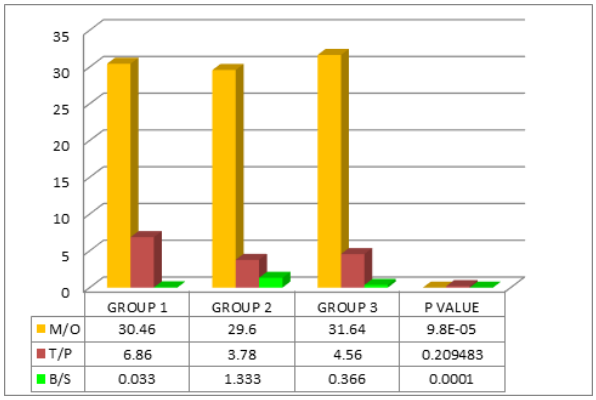
Tongue protrusion				
	Group 1	Group 2	Group 3	Total
N	30	30	30	90
Mean	6.86	3.78	4.56	5.079
Std. Dev.	12.13	0.51	0.29	7.06
F value	1.59154			
P value	0.209483			

Shows as table 3, compare among group 1, group2 and group 3 on the bases of tongue protrusion, results found as mentioned above mean value of group 1 in higher comparatively group 2 and group 3 and p value is 0.209483 obtained that's not significant.

Table2. Results showing on the bases of Burning sensation in Group 1, Group2 and Group 3

Burning sensation				
	Group 1	Group 2	Group 3	Total
N	30	30	30	90
Mean	0.0333	1.3333	0.3667	0.578
Std. Dev.	0.18	0.75	0.66	0.80
F value	38.8878			
P value	**0.00001**			

Above table shows, after treatment burning sensation mean value found in group 1 (0.03) which was treated with physiotherapy with antioxidant therapy followed by group 3 (0.36) treated with intra-lesional therapy and group 2 (1.33) treated with alone physiotherapy completion of three months treatment duration. So significant difference found in group 1, group 2 and group 3 after analysis of burning sensation data we have found significant result p value is 0.00001.



Comparative graph showing summarized results of group1 group 2 and group3

DISCUSSION AND CONCLUSION

In the present study, among 90 patients, 61 were male, suggestive of male preponderance. This is supported by findings from various studies which have shown that OSMF is predominantly seen in males.[6] Lai *et al.* reported that 96.67% of those affected with OSMF were male.[14] Most of the patients were in the age group of 20–30 years. This was similar to the reports of Borle and other studies that it predominantly occurs in the 3rd decade.[6]

The results of the present comparative study depict that physiotherapy with antioxidant, physiotherapy alone and intra-lesional. Physiotherapy alone as a mode of treatment is not effective in alleviating burning sensation and does not significantly improve MMO and tongue protrusion. This is in contrast with the results of a study conducted in 54 Nepali patients, which showed that physiotherapy improved was effective in increasing moth opening compared with patients treated with intra-lesional, Cox and Zollinger showed in their study that physiotherapy is effective in increasing MMO.[15]

In our study, patients treated with physiotherapy with antioxidant shown good and significant results, increases mouth opening, tongue protrusion and reduced burning sensation that's Similarly, studies have shown that lycopene is beneficial in improving MMO as well as burning sensation in OSMF. Kumar *et al.* in their study showed that lycopene alone and lycopene with intralesional steroid injection resulted in a 3.4 mm and 4.6 mm increase in MMO, respectively. Karemore *et al.* also showed that lycopene significantly improved MMO.[16,17]

The current study showed that a combination of physiotherapy with antioxidants resulted in a significant reduction in burning sensation as well as improvement in MMO when compared with physiotherapy alone. Studies have also shown that intralesional injections of dexamethasone and hyaluronidase are effective in the management of OSMF but this is a invasive treatment.[3] The findings from the current study also showed intralesional injections of dexamethasone and hyaluronidase significantly reduced the burning sensation and improved the MMO.[18] The current study is unique as it compared the efficacy of physiotherapy alone, antioxidant along with physiotherapy, and intralesional injection. Analysis of the study results showed that the improvement seen in the antioxidants with physiotherapy group was comparable to that seen in the intralesional therapy group. The finding showed that conservative management is as effective as an interventional therapy in the management of OSMF. Conservative management is beneficial in the management of OSMF and can be considered as a suitable first-line treatment option.

However, the drawback of the current study is the small sample size as well as the absence of staging of OSMF. A larger study with more number of patients, in patients with different stages of OSMF, needs to

be conducted so that the efficacy of antioxidant plus physiotherapy can be better evaluated and established.

From the findings of the present study, it can be concluded that physiotherapy alone does not provide relief for burning sensation, which is the primary subjective criteria of patients with OSMF. Physiotherapy with antioxidant therapy as well as intralesional therapy, both provide good results in relieving burning sensation and improving mouth opening. A non-invasive treatment modality of physiotherapy with antioxidants is effective in the management of patients with OSMF.

Further research with a larger number of patients is required to establish the efficacy of physiotherapy with antioxidant (non-invasive) treatment as the preferred treatment option for OSMF.

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