(p) ISSN Print: 2348-6805

ORIGINAL ARTICLE

ASSESSMENT OF VARIOUS TREATMENT MODALITIES FOR THE TREATMENT OF ORAL SUBMUCOUS FIBROSIS: A COMPARATIVE STUDY

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ABSTRACT:

Background: Oral submucous fibrosis is chronic progressive diseases of the oral cavity with potential of malignant transformation. For the treatment of this pathologic condition, a wide range of modalities consisting of drug management, surgical therapy, and physiotherapy have been attempted till date; with varying degrees of benefit, but none of them have proved to be a cure for this disease. Hence; we planned this study to compare the effectiveness of levamisole and ANTOXID (ATD) in the treatment of oral submucous fibrosis. **Materials & Methods:** The present study included comparative assessment of OSMF patients who underwent treatment by LVM and ATD. All the patients were divided randomly into two study groups. Group A included patients who were given LVM thrice daily and group B included patients who were given ATD twice daily. Records of all the readings and values of the patients before starting of the treatment and during the follow-up time were maintained. All the results were analyzed by SPSS software. **Results:** The initial mouth opening among group A and group B patients was 3.2 and 3.3 cm respectively. Significant results were obtained while comparing the mean mouth opening in both the groups at different interval of time. **Conclusion:** Significant reduction in the mouth opening of the patients occurs with both LVM and ATD.

Key words: Antoxid, levamisole, submucous fibrosis

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This article may be cited as: Chalkoo AH, Oberoi IS, Dhingra K. Assessment of various treatment modalities for the treatment of oral submucous fibrosis: A comparative study. J Adv Med Dent Scie Res 2017;5(1):120-122.



NTRODUCTION

One of the chronic progressive diseases of the oral cavity with potentially of malignant transformation is oral submucous fibrosis (OSMF).¹ OSMF is predominantly seen in people of Southern Asian countries or Southern Asian immigrants to the other parts of the world and now globally accepted as an Indian disease.² It is strongly associated with the use of areca nut in various forms with significant duration and frequency of chewing habits. It has been reported in the Indian literature since the time of Sushruta as 'Vidari'.³

For the treatment of this pathologic condition, a wide range of modalities consisting of drug management, surgical therapy, and physiotherapy have been attempted till date; with varying degrees of benefit, but none of them have proved to be a cure for this disease.⁴ Hence; we planned this study to compare the effectiveness of levamisole (LVM) and Antoxid (ATD) in the treatment of OSMF.

MATERIALS & METHODS

The present study was conducted in the department of Oral Medicine of the dental institution and included comparative assessment of OSMF patients who underwent treatment by LVM and ATD. Ethical approval was taken from institutional ethical committee and written consent was obtained water explaining in detail the entire research protocol. Both clinical and histopathology criteria as described previously in the literature were used to confirm the diagnosis of OSMF. Patients who satisfied the characteristic clinical features of OSMF with histopathologic confirmation and had burning sensation, patients who were not taking any medication for their disease condition, patients who agreed to the biopsy, blood and immunological examination and patients who were willing for follow-up visits, and those who were willing to quit the habit of chewing areca nut/ gutkha/ and tobacco in any form were included in the study.

All the patients were divided randomly into two study groups. Group A included patients who were given LVM thrice daily and group B included patients who were given ATD twice daily. Divider was used for the measurement of the inter-incisal mouth opening starting from the mesio-incisal angle of upper central incisor to the mesio-incisal angle of lower central incisor and recorded in millimeters. Visual Analogue Scale (VAS) of 0-100 readings was used for the measurement of the intensity of burning sensation, where 0 is no burning sensation and 100 is the worst possible burning sensation. Patients were re-examined during the followup time after one month and two months time. Records of all the readings and values of the patients before starting of the treatment and during the follow-up time were maintained. All the results were analyzed by SPSS software. Chi-square test and student t test were used for the assessment of level of significance. p-value of less than was taken as significant.

RESULTS

Comparison of mouth opening of both the groups with time during follow-up period is shown in **Table 1** and **Graph 1**. The initial mouth opening among group A and group B patients was found to be 2.9 and 3.1 cm respectively. The mouth opening during the first followup period at the end of first month of treatment among group A and Group B patients was 3.2 and 3.3 cm respectively. Significant results were obtained while comparing the mean mouth opening in both the groups at different interval of time.

 Table 1: Comparison of mouth opening

Group	Mean value at initial time	Mean value at one month time	Mean value at two month time	p- value
Α	2.9	3.2	3.3	0.02
В	3.1	3.3	3.5	



Graph 1: Comparison of mouth opening

DISCUSSION

One of the pain problem associated with patients suffering from OSMF is burning sensation and progressive trismus which impedes normal function.⁵ The treatment should aim at alleviating the symptoms as

well as try to stop the progression of fibrosis. The treatment modalities which are currently being used can be broadly divided into three main categories, viz.: Medical therapy, surgical therapy and physiotherapy. But, whatever the treatment method may be, the first step of preventive measure should be in discontinuation of habit, which can be encouraged through education, counselling and advocacy.^{6, 7} Hence; we planned this study to compare the effectiveness of LVM and ATD in the treatment of OSMF.

In the present study, we observed that in both the study groups, significant improvement in the patients suffering from OSMF was seen. Angadi et al reviewed the drug treatment of OSMF. Seventeen publications were identified of which 15 were included. The rate of those lost to follow-up reached 30% in some studies. The drugs used to treat oral submucous fibrosis (OSF) were categorised into steroids, enzymes, cardiovascular drugs, antioxidants, vitamins and microelements. There are few high-quality studies available and the present drug treatments are in general empirical and treat only symptoms. There is a need for high-quality RCT in this area, especially studies involving combined and sequential therapy.⁸

Patil et al compared the efficacy of spirulina and aloe vera in the management of OSMF. 42 subjects with clinico-pathologically diagnosed OSMF were included in the study and divided equally in 2 groups, Group A (spirulina group) and Group B (aloe vera group). Group A was administered 500 mg spirulina in 2 divided doses for 3 months and Group B was given 5 mg aloe vera gel to be applied topically thrice daily for 3 months. Evaluation for different clinical parameters was done at regular intervals and data was analyzed using the Chisquare test. P-value <0.05 was considered to be statistically significant. The patients in Group A showed significant clinical improvement in mouth opening and ulcers/erosions/vesicles (p < 0.05). However, there was no significant improvement in burning sensation (p = (0.06) and pain associated with the lesion (p = (0.04)) among the 2 groups. Both the drugs showed improvement in the condition; however spirulina can bring about significant clinical improvements in the symptoms like mouth opening and ulcers/erosion/vesicles. Thus, spirulina appears to be more promising when compared to aloe vera for the treatment of OSMF.⁹

Patil et al compared compare the efficacy of oxitard and aloe vera in the management of OSMF. 120 subjects with OSMF were included in the study. The patients were clinico-pathologically diagnosed and divided equally in 2 groups, Group A (oxitard group) and Group B (aloe vera group). Group A was administered 2 oxitard capsules twice daily and Group B was given 5 mg aloe vera gel to be applied topically thrice daily for 3 months. Different clinical parameters were evaluated at regular intervals. Though there is no definitive treatment for the condition however, overall assessment of symptoms like mouth opening, tongue protrusion, difficulty in swallowing and speech and pain associated with the lesion showed that oxitard capsules can bring about significant clinical improvements than aloe vera gel in the treatment of OSMF..¹⁰

CONCLUSION

From the above results, the authors conclude that significant reduction in the mouth opening of the patients occurs with both LVM and ATD. However, future studies are recommended.

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Source of support: Nil

Conflict of interest: None declared

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