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Management of OSMF : Intralesional Steroids Vs Antioxidants A 5 Year Comparative Retrospective Study

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Abstract

Aim: To study and compare the efficacy of intralesional steroids versus oral antioxidants combined with aggressive physiotherapy in the management of oral submucous fibrosis.

Materials And Methods: In the present study 20 previously treated patients of OSMF were registered. Out of which 10 patients(Group A) had received Inj. Triamcinolone Acetonide (10mg/ml) mixed with Hyaluronidase (1500 I.U.) at biweekly interval for 12 weeks and 10 patients were given Tab SM FIBRO (antioxidant & multivitamin) 400mg twice times daily for a period of 1 year accompanied with aggressive physiotherapy(Group B). Long term outcome of 5 years was evaluated on the basis of maximum mouth opening (MMO) , burning sensation and blanching of mucosa at regular intervals.

Results:The results showed almost 61.3 % increase in the mouth opening of Group A as compared to 10.9% in Group B at the end of 3 months . Gradual increase was noticed in group B at the end of 1 year (53.4 %) . The MMO Preop was 19.3 ± 4.6 (group A)and after 5 years

it was 32 ± 3.94, which was definitely must higher compared to group B. Symptomatic relief of burning sensation (90 %) and blanching was better observed in Group B within first few months. Five year follow up showed more stable results and less relapse with Group B .

Conclusion: The immediate mouth opening was higher in intralesional injections compared to oral antioxidants which takes a longer time. On the contrary, the long term results showed that conservative techniques yielded better and stable results . Conventional injection technique showed higher incidence of relapse and recurrence of symptoms.

Keywords: Oral Submucous Fibrosis, Trismus , Triamcinolone, Intralesional Steroids, Antioxidants, SM Fibro

Introduction

Pindborg and Satyavati Sirsat (1966) defined oral submucous fibrosis as "An insidious chronic disease affecting any part of the oral cavity and sometimes the pharynx. Although occasionally preceded by and/or associated with vesicle formation, it is always associated with a juxta-epithelial inflammatory reaction followed by a fibro-elastic change of the lamina propria, with epithelial atrophy that leads to stiffness of the oral mucosa causing trismus and inability to eat "[1]

The consumption of areca nut (Areca catechu) containing products with or without tobacco is currently believed to be the primary cause OSMF in individuals .[2]The other etiological factors include excessive consumption of spicy food, nutritional deficiencies like chronic iron and vitamin B complex deficiency, hereditary and immunological conditions.

There has been a statistically alarming increase of cases in india from 0.03% to 6.42% over the past four decades. [3] The potential of malignant conversion in patients with OSMF ranges from 3% to 6%. Pindborg et al. demonstrated a malignant transformation rate of 4.5% in the same area over a 15 year follow-up ; Murti et al., suggested malignant transformation rate of 7.6% for 17 yr follow up of same area.[4] This shows how much importance must be given to the intial diagnosis , treatment and management of osmf to curb the increasing rates for the future generations.

In our study we have tried to evaluate and compare the efficacy of intralesional steroid injections versus oral antioxidants alongwith aggressive physiotherapy done. Their long term effect was studied with a follow up period of 10 years .

Materials And Methods

This study was conducted on 20 previously diagnosed and treated cases of oral submucous fibrosis that have already completed their full course of treatment. All the patients were diagnosed as Grade II and Grade III based on clinical grading and maximium mouth opening scale .Out of these 20, Group A had 10 patients , who received Injections Triamcinolone Acetonide (10 mg / ml) mixed with 1500 IU Hyaluronidase at biweekly interval for 12 weeks and Group B included 10 patients, who had been treated by Tab SM FIBRO 400 mg twice daily for a period of 12 months. These patients were properly explained about the study and their consent was taken.

The symptoms and signs were noted on a working proforma. Scoring of symptoms like burning sensation in mouth upon consumption of spicy or hot foods, reduced opening of mouth and blanching of oral mucosa was done. The pre-treatment and immediate post-treatment symptom and sign scores were taken from previous records of medically treated patients. In the long term follow up symptom and sign scores were noted by thorough history and examination as done earlier. The response to treatment and long-term effectiveness of

treatment was assessed by noting subjective improvement in symptom scores and objective improvement in sign scores between immediate post treatment scores and long term follow up scores. Long term follow up means observation of effects after a minimum period of 5 years .

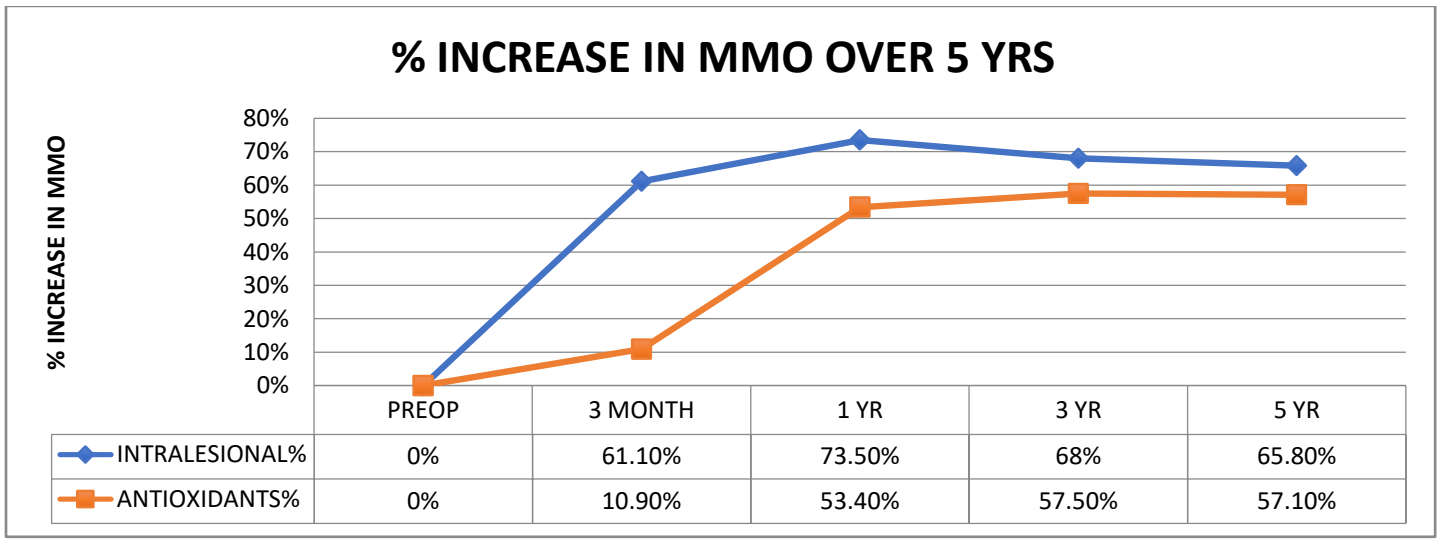
Results

In our study, 65% of patients were males & 35% were females. The patients were diagnosed with Grade II and Grade III OSMF based on the clinical grading and maximum mouth opening scale. The results was evaluated and tabulated as shown Table 1 and Graph 1 . Group A patients showed a highly significant improvement in trismus (61.1 %) over a short period of 3 months compared to Group B (10.9%) . Symptomatic relief of burning sensation was more pronounced in Group B (90 % were relieved)within the 3rd month of study (graph 2). Group A patients showed increase signs of burning and pain in the site of administration of injections(90% had pain). Long term use of antioxidants and physiotherapy resulted in better improvement of MMO which was slow and gradual over a period of 1 year (53.4 %). Following 3 years there was higher incidence of relapse in Group A as compared to Group B. Table 2 shows the final results of the percentage of relief in symptoms between the two comparative study groups.[5]

Table 1 : Shows the amount of increase in Maximum Mouth Opening Pre-op , immediate post-op and during the follow up period.

Sn.	Maximum mouth opening (mmo)	Group a (intralesional inj)	Group b (antioxidants)
1.	Preop mmo	19.3 ± 4.6	21.9 ± 3.33
2.	Immediate post-op (3 months)	31.1 ± 4.3	24.3 ± 3.4
3.	1 yr post-op	33.5 ± 4.43	33.6 ± 2.9
4.	3 yr post-op	32.4 ± 3.77	34.5 ± 2.6
5.	5 yr post-op	32 ± 3.94	34.5 ± 2.54

Graph 1 : Comparison between the percentage increase in MMO over 5 yr follow up period



Graph 2 : Shows the presence of burning sensation before and after treatment.

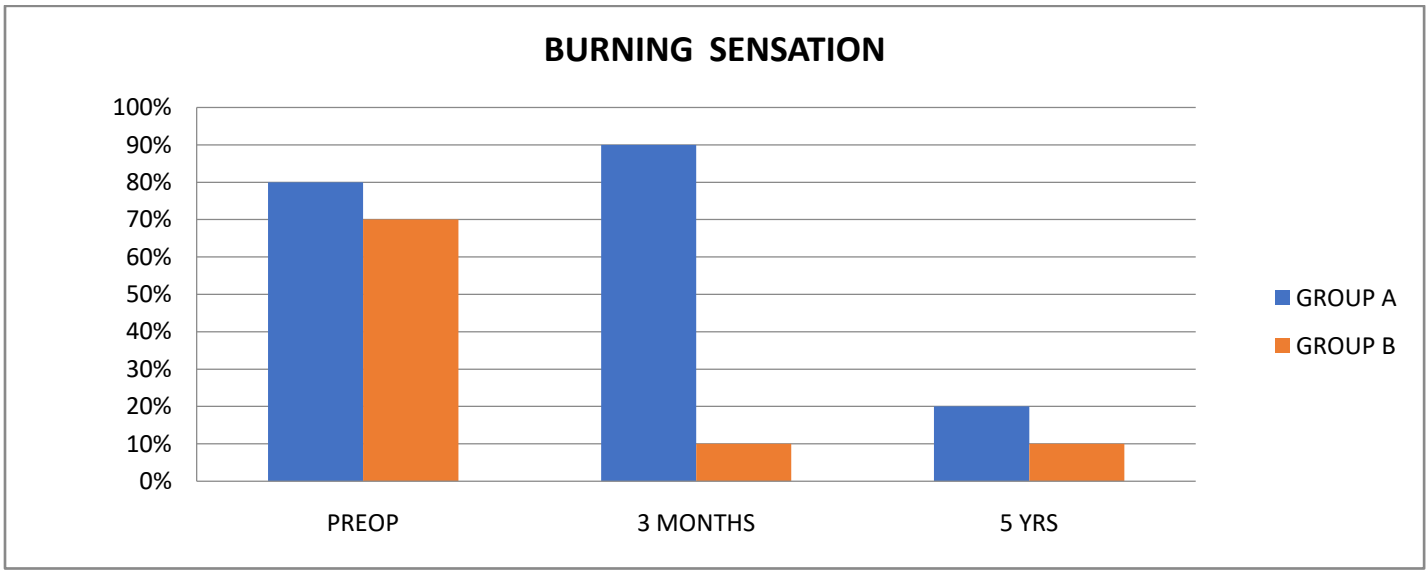


Table 2 : Percentage of relief of symptoms post treatment follow up of 5 yrs

Sn.	Symptoms Relieved	Group A	Group B
1.	Limited Mouth Opening	90%(9/10)	80%(8/10)
2.	Burning Sensation	80%(8/10)	90%(9/10)
3.	Blanching	70% (7/10)	90%(9/10)

Discussion

Schwartz in 1952 described a potentially malignant disease as "Atropicaidiopathica mucosae oris" . Later in 1952 Joshi reported a similar condition in India and he coined the term submucous fibrosis of palate and faucial pillars. Futher more other researchers used various terminologies like diffuse oral submucous fibrosis (Lal, 1953), idiopathic scleroderma of the mouth (Su,1954), idiopathic palatal fibrosis (Rao, 1962) and sclerosing stomatitis (Behl, 1962)[6]

Chandramani More and Naman Rao in 2019 clincally defined oral submucous fibrosis as 'A debilitating, progressive, irreversible collagen metabolic disorder induced by chronic chewing of areca nut and its commercial preparations; affecting the oral mucosa and occasionally the pharynx and esophagus; leading to mucosal stiffness and functional morbidity; and has a potential risk of malignant transformation.'[7]

The subjective signs and symptoms include xerostomia, recurrent ulceration, pain in the ear or deafness , nasal intonation of voice , restriction of the movement of the soft palate , a budlike shrunken uvula , thinning and stiffening of the lips , pigmentation of the oral mucosa , dryness of the mouth and burning sensation (stomatopyrosis) , decreased mouth opening and tongue protrusion .[8]

As proposed by **Kakkar and Puri**, for the purpose of treatment, the patients can be graded on the basis of the clinical condition.[9]

Grade I: Only blanching of oral mucosa without symptoms

Grade II: Burning sensation, dryness of mouth, vesicles or ulcer in the mouth without tongue involvement

Grade III: In addition of Grade II, restriction of mouth opening

Grade IV: In addition to Grade III palpable bands all over the mouth without tongue involvement

Grade V: Grade IV and also tongue involvement

GradeVI: OSMF along with histopathlogically proven cancer.

Khanna and Andrade in 1995 developed a group classification system for the surgical management of trismus:[9]

- Group I: Earliest stage without mouth opening limitations with an interincisal distance of greater than 35 mm.
- Group II: Patients with an interincisal distance of 26–35 mm.
- Group III: Moderately advanced cases with an interincisal distance of 15–26 mm. Fibrotic bands are visible at the soft palate, and pterygomandibular raphe and anterior pillars of fauces are present.
- Group IVA: Trismus is severe, with an interincisal distance of less than 15 mm and extensive fibrosis of all the oral mucosa.
- Group IVB: Disease is most advanced, with premalignant and malignant changes throughout the mucosa.

Through the many years of research and study there have been various advances in the medical and surgical line of management .The medical line of treatment includes use of several glucocorticoids for the treatment of OSMF, short acting (hydrocortisone), intermediate acting (triamcinolone) and long acting (betamethasone and dexamethasone) in the form of intralesional steroid injections .Other conservative medical management comprises of Lycopene supplements, physiotherapy, hyaluronidase, placental extracts pentoxifylline, Colchicine,IFN-γ ,Curcuma longa , Aloe vera , Tea pigments and Spirulina.[10] Surgical line of treatment depends on the clinical stage of osmf and the amount of restricted mouth opening . It includes buccal stripping of fibrotic bands to unilateral/bilateral coronoidectomy depending on the severity and reconstruction with local or free flaps.

In our study Group A received intralesional injection of triamcinolone acetate with hyaluronidase weekly for a period of 8 weeks .They were given antioxidant and multivitamin supplements daily for a period of 6 months. Cessation of habit was given primary importance and patients were monitored for the same throughout the study and follow up period. In Group B patients were started on oral antioxidant (Tab SM FIBRO) twice daily for a period of 1 year . In addition aggressive physiotherapy was done daily for 6 months using hyrax appliance and mouth opening exercises at home on daily basis. Both the study groups were prescribed to continue oral antioxidants for a period of 2 years as a part of the maintenance regimen.

SM Fibro

Composition : Alpha lipoic acid (50 mg), Beta-carotene (10 mg) , Elemental copper (1mg) , Elemental selenium (75 mcg), Lycopene (5 mg), Vitamin E (10 IU) and Zinc sulphate (27.45 mg)

The capsule works by inducing the oxidative stress response and chelating iron; protecting cells from damage; producing and storing iron in the body; increasing the action of antioxidants; acting an antioxidant by fighting free radicals in the body; slowing down the processes that damage cells; inhibiting the herpes simplex virus growth. Lycopene is a major carotenoid which is found in tomato have antioxidant and chemopreventive properties against potentially malignant disorders.

Hyaluronidase

It acts by breaking down hyaluronic acid (the ground substance in connective tissue) lowers the viscosity of

intercellular cement substance. Better results were observed with respect to trismus and fibrosis.

Triamcinolone Acetonide

Triamcinolone is known as a intermediate acting corticosteroid hormone (glucocorticoid). It works by decreasing your body's immune response to these diseases and reduces symptoms such as swelling.

It was noted that Group B treated with antioxidants showed better overall improvement and the number of patients having relapse was lower than those treated with triamcinolone injections(Group A).

A majority of group A patients had drastic improvement in mouth opening within 3 months of treatment . They almost reported 61.3 % increase in MMO as compared to 10.9 % in Group B. The trismus was relieved slowly and gradually over a period of 1 yr in Group B patients. Group B patients had symptomatic relief after a 4 weeks period .The disease became reactivated within 1–2 years. A relapse to eruptive phase was seen in 2-3 years, but lesser number of patients had relapse when compared to group A patients. This relapse can be anticipated due to patient incompliance to the treatment regimen, continuation of habit , lack of maintenance with multivitamin and antioxidants , or injury caused by the needle prick which stimulates fibrosis.

In this study, all the patients stopped their habit of chewing from the beginning of treatment and following treatment we found improvement in trismus, recurrent ulcerations, burning sensation in oral cavity, and also in blanching of oral mucosa. However, since these parameters need subjective evaluation, objective parameter of inter-incisal mouth opening was used as a criterion to assess the clinical improvement. Highly significant improvement in inter-incisal mouth opening was noted following treatment as compared to pre treatment mouth opening. Pre-treatment mean inter-incisal mouth opening 19.3 ± 4.6 mm in Group A . Post treatment mean inter-incisal mouth opening 32 ± 3.94 mm.

The shortcomings of most of the previous studies were lack of long term follow up. The follow up in these studies were up to the completion of treatment. So the present study was planned to see the long term effect of above mentioned drugs for the treatment of OSMF. In the present study our aim is to evaluate the long term result of the treatment which was given in our centre. From the observation it is clear that there was significant subjective and objective improvement after the completion of treatment and this improvement is maintained or increased in long term follow up (up to 5 years).

Conclusion

The present study showed that intralesional injections are highly effective in improving trismus in Grade II and Grade III oral submucous fibrosis cases. But on long term follow up , it showed higher incidence of relapse as compared to the conservative method . The use of antioxidants and aggressive physiotherapy show better symptomatic relief and more stable results in the long run . Hence the choice of mode of treatment is multifactorial and varies according to patient compliance , co-morbities and severity of the condition.

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