

EFFICACY OF OXITARD CAPSULES IN THE TREATMENT OF ORAL SUBMUCOUS FIBROSIS: A PILOT STUDY

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Abstract

Aim: Oral submucous fibrosis (OSMF) is a potentially malignant disorder mainly seen in the Indian subcontinent. The aim of the present study was to assess the efficacy of oxitard capsules in the management of OSMF.

Materials and Methods: Total number of 20 subjects diagnosed OSMF were included in the Pilot study and divided into 2 groups; Group A (oxitard group) and Group B (placebo group). Group A was given 2 oxitard capsules twice daily for one month and Group B was given placebo tablets twice daily, for 1 month. Assessment for different clinical parameters was done at regular interval of time.

Results: Results were analyzed statistically by means of a paired t-test analysis. It was noted - increase by 7.80% in mouth opening, 5.18% increase in tongue protrusion and 20.54% decrease in burning sensation from starting treatment (day 0) to last day of evaluation (day 30) was noted.

Conclusion: In the absence of a definitive treatment for the condition; this study concluded that the administration of Oxitard capsules showed improvement in mouth opening, tongue protrusion and decrease in the burning sensation in the oral cavity

Key words: Oral Submuocus Fibrosis, Oxitard Capsules, Antioxidants.

Introduction

Oral submucous fibrosis (OSMF) is a potentially malignant disorder of oral cavity, pharynx and upper digestive tract, characterized by progressive inability to open the mouth and by inflammation and progressive fibrosis of the submucosal tissues.¹

Oral Submucous Fibrosis (OSMF) is defined as an insidious, chronic disease which affects any part of the oral cavity and sometimes the pharynx and is occasionally preceded by and/or associated with vesicle formation and is always associated with a juxta-epithelial inflammatory reaction which is followed by progressive hyalinization of the lamina propria leading to stiffness of the oral mucosa and deeper tissues with progressive limitation in opening of the mouth and protrusion of the tongue leading to difficulty in eating, swallowing and phonation.²

It is a precancerous condition seen most commonly in the Indian sub-continent and has a reported incidence of between 0.2–1.2% of the urban population who attend the dental clinic. The condition shows a female: male predilection of 3:1 and characteristically first presents in adulthood between the ages of 45–54 years.² The pathogenesis of the disease is not notable, but rather the etiology is accepted to be multifactorial. The condition is especially connected with areca nut biting, which is the principle part of betel quid. The various hypothesis implicated include the role of local irritants such as capsaicin, tobacco, areca nut, pungent and spicy foods, and alcohol, iron and vitamin B-complex deficiency, anaemia, and a genetic predisposition to the disease.¹

Treatment modalities for alleviating the side effects have been upheld, yet have not been fruitful up until this point. Specific treatment incorporates organization of steroids, placental concentrates, interferon (IFN) gamma, pentoxifylline, lycopene, surgical extraction, and so forth. Yet, every treatment has its own particular restrictions.³

There are different treatment modalities for this condition, here one such treatment modality in the form of administration of antioxidants in the form of Oxitard capsules was carried out on 20 patients who attended the Outpatient Department of Oral Medicine & Radiology, Teerthanker Mahaveer Dental College & Research Centre, Moradabad.

Materials and Method

Twenty (20) patients who enrolled with signs and symptoms of OSMF reporting to the Department of Oral Medicine and Radiology. Each patient was informed about the condition, its precancerous potential and advised to discontinue use of areca nut in all forms. A detailed case history including habit of history with details of duration, in years, frequency of chews per day was taken. All patients underwent oral prophylaxis to remove extrinsic stains, in order to motivate the patient towards recovery and to inform the investigator if patient resumes habit. Ethical clearance was obtained from the Institutional Ethical Committee

The subjects were haphazardly divided similarly in 2 group; Group A (oxitard) and Group B (Placebo). Group A was controlled 2 oxitard containers twice day by day and Group B was given fake treatment tablets twice every day, for 1 month.

Method of data collection

Patients were evaluated for the following criteria

1. Mouth opening based on interincisal separation

Distance between the upper and lower central incisors when maximally extended with mouth wide open. In edentulous patients, the inter ridge (alveolar) distance along the midline was measured. (Figure 1).



Figure 1: Mouth Opening Measurement

2. Tongue protrusion

Measured on the distance from the mesial incisal edge of central incisor to the tip of the protruded tongue with a metal grade scale (Figure 2).



Figure 2: Tongue Protrusion

3. Burning sensation and Pain associated with the Lesion.

The clinical parameters, for example, burning sensation were assessed by utilizing a Visual Analog Scale (VAS). The score of 0-1 was considered as missing, score in scope of 1-6 was considered as decreased and a score of 7-10 was assessed as present.

Inclusion Criteria

Patients suffering from chronic oral mucous fibrosis lesions characterised by burning sensations in the mouth, particularly while taking hot and spicy foods. Adult patients of either sex aged between 18-50 years were included. Patient willing to give a written informed consent and follow the schedule.

Exclusion Criteria

Patients suffering from severe systemic disorders pertaining to cardiac, respiratory, central nervous system, renal or hepatic disorders. Patients who refused to sign informed consent. Patients having a known history or present condition of allergic response to similar pharmaceutical products, pre-existing systemic disease necessitating long-term medications and pregnant and lactating women were excluded from the study.

Method of data analysis

Results were analyzed statistically by means of a paired t-test analysis. It was noted - increase by 7.80% in mouth opening, 5.18% increase in tongue protrusion and 20.54% decrease in burning sensation from starting treatment (day 0) to last day of evaluation (day 30) was noted.

Results

	Oxitarad	Placebo	P value
Baseline	27.16± 6.80	26.02 ±6.02	<0.001
After 10 days	28.21 ± 7.83	28.3 ±7.0	
After 20 days	29.04 ±7.02	23.09± 6.08	
After 30 days	30.06± 8.02	23.8± 6.09	

Table 1: Effect of oxitard in improving mouth opening. (mean value in mm)

	Oxitarad	Placebo	P value
Baseline	26.16± 6.90	26.02 ±6.02	<0.001
After 10 days	27.21 ± 6.83	27.3 ±7.0	
After 20 days	29.04 ±6.02	22.09± 7.08	
After 30 days	31.06± 8.02	21.8± 6.09	

Table 2: Effect of oxitard in improving Tongue protrusion (mean value in mm)

	Oxitarad	Placebo	P value
Baseline	2.16± 0.86	2.02 ±0.93	<0.001
After 10 days	2.21 ±0.83	2.0 ± 0.89	
After 20 days	2.24 ±0.80	1.99± 0.85	
After 30 days	2.06± 0.78	1.9± .0.81	

Table 3: Effect of oxitard in improving burning sensation (mean value in mm)

	Oxitarad	Placebo	P value
Baseline	2.1± 0.96	2.02 ±0.93	<0.001
After 10 days	2.02 ±0.92	2.0 ± 0.89	
After 20 days	2.6 ±0.90	2.2± 0.75	
After 30 days	2.04± 0.88	1.9± .0.81	

Table 4: Effect of oxitard in pain associated with lesion (mean value in mm)

Discussion

OSMF is a precancerous state of the oral cavity and oropharynx, which is transcendently found in the Indian subcontinent and Southeast Asian nations and is presently internationally considered an Indian sickness. The general predominance rate in India is accepted to be around 0.2% to 0.5% and commonness by sexual orientation changing from 0.2-2.3% in males and 1.2-4.57% in females.⁴ It is considered to have a high level of threatening potential, which goes in the vicinity of 2.3% and 7.6%.⁵

The pathophysiology of OSMF is unpredictable, and different variables, for example, ingestion of chilies, hereditary defencelessness, nourishing lacks, changed salivary constituents, autoimmunity and collagen issue might be included in the pathogenesis. Areca nut and its items are the most well-known etiological elements. The condition is gone before by consuming vibrate of the oral mucosa, ulceration and pain. OSMF is characterized by whitening of oral mucosa,

decreased development and depapillation of tongue, depigmentation of oral mucosa, and dynamic decrease of mouth opening. Nasal twang because of fibrosis of nasopharynx and hearing hindrance because of stenosis of eustachian tube might be seen in cutting edge phases of the condition.⁴

Treatment options include initially stoppage of habit followed by avoidance of spicy food and ingestion of chillies followed by intralesional steroid injections, placental extracts, pentoxifylline, lycopene, surgical excision and laser therapy can be used to a greater effect in reducing the signs and symptoms of OSMF. The antioxidant property of a particular food/drug is based on the ability of that particular drug to neutralize free radicals by means of a process known as oxygen radical absorbance capacity (ORAC).

Treatment modalities for calming the indications have been upheld, however have not been effective up until now. The initial step of preventive measure ought to be in encouraging the patient to end the propensity for betel nut biting, tobacco, hot sustenances and chillies. This can be empowered through training, advising and backing. Restorative treatment is symptomatic and transcendently gone for enhancing mouth developments. Be that as it may, every treatment has its own particular restrictions. As indicated by Caniif et al, the medicinal administration of OSMF is both exact and unsatisfactory.⁵ The discoveries of the present review were like the discoveries of Singh et al.⁷ who demonstrated a critical change in mouth opening, agony of the mouth, hyperkeratosis and size of the sore by utilizing oxitard for 3 months in 48 OSMF subjects. Notwithstanding, the present review assessed the adequacy of oxitard cases in the change of different other clinical parameters, for example, tongue projection, consuming sensation when contrasted and the control group. According to Patil S⁸, Oxitard has shown significant improvement in mouth opening, tongue protrusion, pain with the lesion, difficulty in swallowing and speech when compared to aloe vera. Similar results found with the study done by V.Shwetha et al,⁹ which conclude that oxitard prove to be relatively safe, non-invasive and efficacious in bringing about significant improve in symptoms like mouth opening, reduction in burning sensation in patients with OSMF.

Rehana et al, different minerals and micronutrients indicated noteworthy change in mouth opening of 41% of the patients, like the consequences of the present study.¹⁰ Whereas, Borle et al, indicated change in side effects of OSMF yet irrelevant change in mouth opening with vitamin A, in contrast with oxitard capsule, which demonstrated critical change in mouth opening and in addition in manifestations of burning sensation, pain associated with the lesion, difficulty in speech and swallowing.¹¹

Lycopene has likewise indicated huge change in mouth opening in the review by Karemore et al. like the discoveries of the present study.¹² Sudarshan et al., have demonstrated critical change in the mouth opening with aloe vera, like that seen with oxitard in the present review. Sudarshan et al, shows a change of 80% in burning sensation in the aloe vera group while 65.7% patients shows in antioxidant group improves in burning sensation. The difference was statistically significant (P = 0.008), similar to the finding of the present study where

the difference in both group was statistically significant (P = 0.0001).¹³

New medicine pentoxifylline and spirulina have moreover shown promising results in the treatment of OSMF like oxitard, with quantifiably basic results (P = 0.000) in mouth opening, consuming sensation and tongue protusion by Mulk et al.¹⁴ Mehrotra et al furthermore watched vital change in hard and fast sign and sign score with the association of 400 mg pentoxifylline to 32 patients for a period of 7 months.¹⁵ Singh et al, have demonstrated essential change in mouth opening, hyperkeratosis, torment in mouth and size of the injury with oxitard capsules.⁷ However, the present review evaluated the ampleness of the prescription in the change of other clinical parameters, for instance, difficulty in gulping, discourse, tongue protusion and copying sensation when contrasted and a control gathering.

The detailing of the oxitard cases contains the concentrates of *Mangifera indica*, *Withania somnifera*, *Daucus carota*, *Glycyrrhiza glabra*, *Vitis vinifera*, powders of *Emblica officinalis* and *Yashada bhasma*, and oils of *Triticum sativum*. *Glycyrrhiza glabra* standardizes the dryness in voice and has immunomodulatory and anti-inflammatory properties. *Vitis vinifera* have anti-inflammatory, astringent and an impact to control the consuming sensation. *Triticum sativum* is a rich wellspring of minerals and has a cancer prevention agent property. *Withania somnifera* gives general wellbeing and health with its anti-stress, anti-anxiety, anti-inflammatory, anti-convulsive and anti-arthritis properties. *Emblica officinalis* is a rich wellspring of vitamin C and is a powerful anti-microbial. *Yashada bhasma* contains zinc, which assumes a critical part in protein union, cell division and wound mending. *Daucus carota* goes about as a decent clean as it is a rich wellspring of vitamin A. *Mangifera indica* is appeared to have anti-infection, anti-asthmatic, sterile, antiviral, hypotensive, anti-emetic properties.⁷

Conclusion

The discoveries of the present rstudy shows that oxitard capsule essentially enhance the mouth opening, tongue protusion, burning sensation, pain associated with the lesion, with no reactions. Be that as it may, it doesn't realize any critical changes in the size of the lesion. Larger the sample size, with longer time of treatment and follow-up are supported.

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