



ISSN: 0976-3031

Available Online at <http://www.recentscientific.com>

CODEN: IJRSFP (USA)

International Journal of Recent Scientific Research  
Vol. 8, Issue, 10, pp. 20505-20510, October, 2017

**International Journal of  
Recent Scientific  
Research**

DOI: 10.24327/IJRSR

## Research Article

### EFFECT OF INTRALESIONAL BETAMETHASONE INJECTIONS AND LOCAL APPLICATION OF ALOE VERA GEL IN PATIENTS WITH ORAL SUBMUCOUS FIBROSIS AND BURNING SENSATION. A COMPARATIVE STUDY

**Danish Uz Zama Khan<sup>1</sup>, Karabi Das<sup>\*2</sup>, Shivakumar G C<sup>3</sup>, Mehak Dogra<sup>4</sup>,  
Kushal Singh<sup>5</sup>, Sunil Kumar K<sup>6</sup> and Smriti Singh<sup>7</sup>**

<sup>1</sup>Department of Dentistry, Era's Medical College and Hospital, Lucknow, Uttar Pradesh, India

<sup>2</sup>Department of Oral Medicine and Radiology, Guwahati, Assam, India

<sup>3</sup>Department of Oral Medicine and Radiology, Babu Banarasi Das College,  
Lucknow, Uttar Pradesh, India

<sup>4</sup>Department of Pedodontics and Preventive Dentistry, Jammu and Kashmir, India

<sup>5</sup>Department of Prosthodontics & Crown and Bridge, Agra, Uttar Pradesh, India

<sup>6</sup>Department of Oral Medicine and Radiology, Tenali, Andhra Pradesh, India

<sup>7</sup>Department of Oral Medicine and Radiology, Ghaziabad, Uttar Pradesh, India

DOI: <http://dx.doi.org/10.24327/ijrsr.2017.0810.0905>

#### ARTICLE INFO

##### Article History:

Received 17<sup>th</sup> July, 2017

Received in revised form 21<sup>st</sup>

August, 2017

Accepted 05<sup>th</sup> September, 2017

Published online 28<sup>th</sup> October, 2017

##### Key Words:

Oral Submucous Fibrosis, Antioxidant  
Clik Capsule, Intralesional Injections

#### ABSTRACT

**Aim:** To compare the efficacy of intra lesional steroid preparation with aloe vera gel in the treatment of oral submucous fibrosis.

**Materials and method:** In the present study, Group A patients were given Aloe vera gel for 2 months along with antioxidant clik capsule for a period of 6 months. Group B patients were given intralesional injections for 2 months along with antioxidant clik capsule for a period of 6 months

**Result:** Decrease in the score of burning sensation was found to be significant among patients both in Group A and Group B. The decrease in the burning sensation score was found to be statistically significant i.e. (p value <0.001). Though it was observed that the burning sensation intensity reduction in group B was more than group A, the difference between the groups was statistically significant (p =0.001).

**Conclusion:** Aloe vera being a soothing, simple, non-invasive and safe mode of treatment, can be considered to be an effectual protocol in the management of Oral submucous fibrosis.

**Copyright © Danish Uz Zama Khan et al, 2017**, this is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution and reproduction in any medium, provided the original work is properly cited.

#### INTRODUCTION

Oral submucous fibrosis (OSMF) a precancerous condition affecting the oral mucosa.<sup>1</sup> Its literature dates back to as far as 2500 to 3000 BC when a renowned Indian physician Sushruta mentioned about a condition-"Vidari" features of which simulate oral submucous fibrosis.<sup>2</sup> In 1952, Schwartz described five Indian women from Kenya with a condition of the oral mucosa including the palate and pillars of the fauces, which he called "atrophiaidiopathica (tropica) mucosae oris". Later it was termed Oral submucous fibrosis (OSMF); other names are "diffuse oral submucous fibrosis", "idiopathic scleroderma of the mouth", "idiopathic palatal fibrosis", "sclerosing stomatitis" and "juxta-epithelial fibrosis."<sup>3</sup> The pathogenesis of the disease is thought to be multifactorial, with chewing of betel nut or

betel quid being recognized as one of the most significant risk factors for Oral submucous fibrosis. A wide range of treatment modalities both medical and surgical have been proposed for Oral submucous fibrosis, but none have proved curative or reduced the morbidity significantly.<sup>4</sup> Many authors are of the opinion that conservative treatment is preferable than the conventional ones. Hence, the search for an effective treatment modality still continues.

Plants have been a major source of medicine since the time immemorial and many incurable oral diseases when treated with alternate medicine like ayurveda had good prognosis, which has been well documented in the literature. One such ayurvedic medicine is Aloe vera.<sup>1</sup> Lycopene is a major carotenoid obtained from tomato with potent anticancer activity

\*Corresponding author: **Karabi Das**

Department of Oral Medicine and Radiology, Guwahati, Assam, India

due to its preventive effects in chronic diseases. It also has potent benefits in oral potentially malignant lesions like leukoplakia. Betamethasone dipropionate is a long acting glucocorticoid with anti-inflammatory and immunosuppressive abilities. It is applied as a topical cream, ointment, lotion or gel to treat itching and other minor skin conditions<sup>1</sup>.

## MATERIALS AND METHODOLOGY

30 patients presenting with burning sensation of Oral submucous fibrosis reporting to Department of Oral medicine and radiology after informed consent were included for the study. These patients were randomly divided into two groups:

Group A will include 15 patients with OSMF who will receive Aloe vera gel for a period of 2 months along with antioxidant “Clik” capsule daily for a period of six months. Aloe vera gel applied topically on each side of buccal mucosa twice daily for 2 months. Patients will be educated to replicate the instructions at home and advised to avoid solid and liquid diet for half an hour after application.

Group B consists of 15 patients diagnosed with OSMF who will receive intralesional betamethasone injections biweekly for 2 months along with antioxidant “Clik” capsule daily for a period of six months.

### Criteria for patient selection

#### Inclusion criteria

1. Patients of either sex with OSMF diagnosed clinically.
2. Patients who had not taken any treatment earlier for OSMF.
3. Patients who are ready to quit the habit of gutka chewing and accepted for regular follow ups.

#### Exclusion criteria

1. Patients with OSMF coexisting systemic illness.
2. Patients with other mucosal lesions like leukoplakia and malignant lesions.
3. History of hypersensitivity to Aloe vera.
4. Pregnant women and lactating mothers.

### Method of data collection

A detailed history was taken regarding chief complaint along with the clinical classification and habit history.

After confirming the diagnosis each patient was made aware of the malignant potential of Oral submucous fibrosis condition. The subjects were counseled and encouraged to discontinue the various existing habits and to restrain from such habits in future.

Group A included 15 patients with oral submucous fibrosis who received Aloe vera gel for two months along with antioxidant “Clik” capsule daily for six months. Detailed procedure about the placement of cotton rolls and application of Aloe vera gel was explained to the patient. Patients were instructed to avoid solid and liquid diet for half an hour after application.

Group B received intralesional injections biweekly for 2 months along with antioxidant “Clik” capsule daily for a period of six months.

Burning sensation was recorded by VAS every time the patient visited the hospital for follow ups.

### Products used for the study

#### Aloe vera gel product

#### Preparation of the Aloe vera gel

The gel is made from freshly harvested leaves. Firstly the pulp is extracted from the leaves and juice is made by crushing the pulp. Then it is mixed with CARBOPOL (a lightly cross linked polymer which produces highly viscous gels with less flow. It has been used worldwide in oral suspensions since the mid 1960s).

This solution is heated along with continuous stirring upto 80 centigrade for 20 minutes. The solution is then homogenized for 10 mnts and then sonicated for 5 minutes. It is then allowed to cool down for an hour as the solution gellifies.

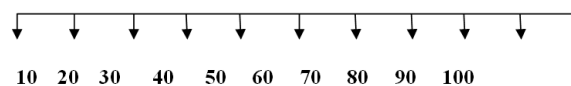
The primary healing part of Aloe vera is the gel, and “only the gel”. Unlike the gel, the skin and sap of the Aloe vera leaf are not food. In fact, they are extremely bitter precisely for the reason of discouraging desert animals from eating the plants.

#### Clinical parameters

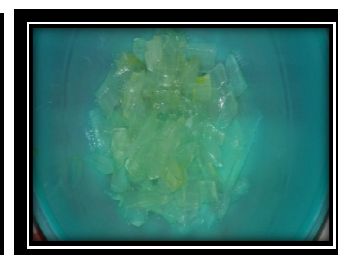
The following clinical parameter is recorded and assessed:

**Burning sensation:** Patient who complained of burning sensation were explained about the visual analogue scale in their vernacular language. Then burning sensation was recorded according to verbal complaint rating scale of 10-100 points, where 10 represented no burning sensation while 100 represented the worst burning sensation possible as perceived by the patients subjectively.

#### Visual analogue scale for burning sensation



Aloe vera plant



Pulp extracted from the pulp



Juice is made



Carbopol is added and heated for 20 mts



A homogenized solution is made



Solution is sonicated



Gel is formed

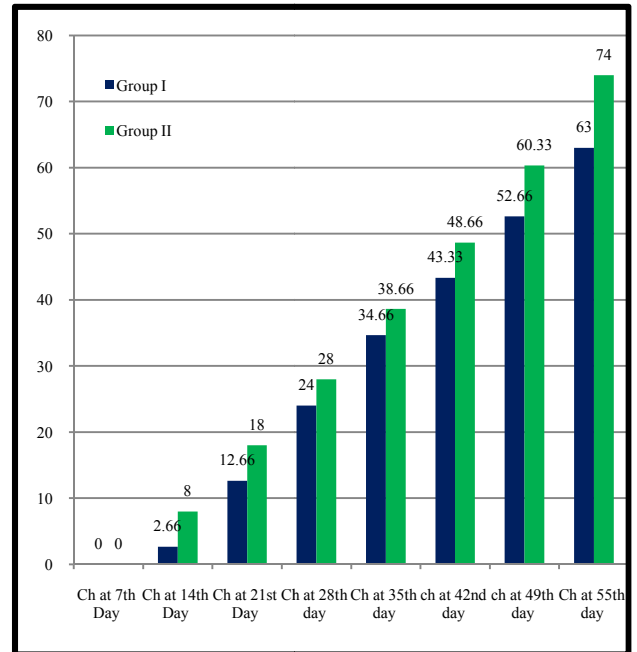
**Statistical Analysis**

The intragroup comparison for the different time intervals was done using One WAY ANOVA and post Hoc Tukey Analysis to find the difference between the individual time intervals. The level of the significance for the present study was fixed at 5%. Independent t Test can be used to determine if two sets of data are significantly different from each other, and is most commonly applied when the test statistic would follow a normal distribution.

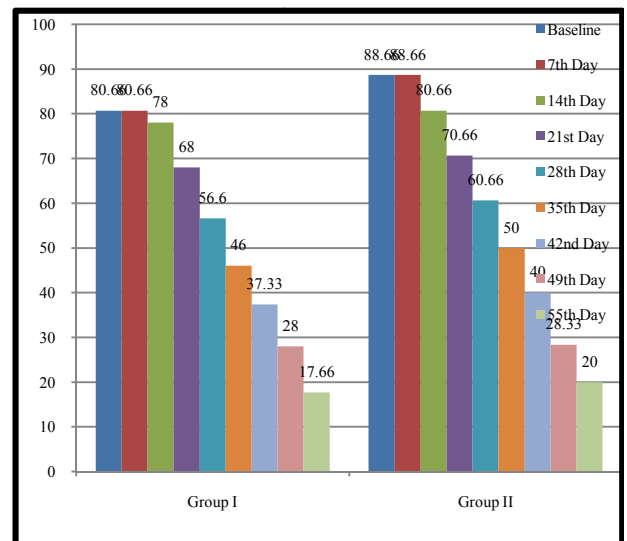
**Intergroup Comparison of Change in Scores at Different Intervals**

	Group A	Group B	P value	Significance
Change from Baseline at 7 <sup>th</sup> Day	0.00±0.00 (0%)	0.00±0.00 (0%)	1.000	Non-Significant
Change from Baseline at 14 <sup>th</sup> Day	-2.66±4.57 (-3.14%)	-8.0±4.14 (-8.88%)	0.004	Significant
Change from Baseline at 21 <sup>st</sup> Day	-12.66±4.57 (-15.60%)	-18.00±4.14 (-20.18%)	0.012	Significant
Change from Baseline at 28 <sup>th</sup> Day	-24.00±5.07 (-29.73%)	-28.00±4.14 (-31.48%)	0.337	Non-Significant
Change from Baseline at 35 <sup>th</sup> Day	-34.66±5.16 (-42.93%)	-38.66±3.51 (-43.51%)	0.699	Non-Significant
Change from Baseline at 42 <sup>nd</sup> Day	-43.33±4.87 (-53.73%)	-48.66±3.51 (-54.81%)	0.409	Non-Significant
Change from Baseline at 49 <sup>th</sup> Day	-52.66±4.57 (-65.35%)	-60.33±2.28 (-68.10%)	0.042	Significant
Change from Baseline at 55 <sup>th</sup> Day	-63.00±4.55 (-78.23%)	-74.00±4.30 (-83.47%)	0.002	Significant

Table 2, graph 1, indicates the intergroup comparison between both the groups. Using independent t test, the difference between the treatment was statistically significant at 14<sup>th</sup>, 21<sup>st</sup>, 49<sup>th</sup>, 55<sup>th</sup> days. Group B was better than group A and the difference was statistically significant. (p < 0.05)

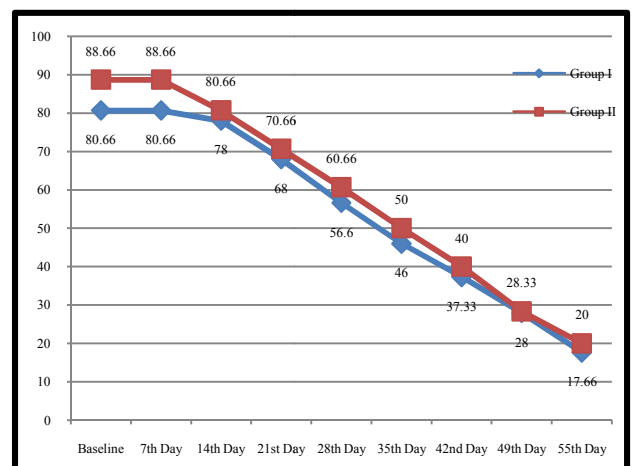


**Graph 1** Intergroup Comparison of Change In Scores At Different Intervals



**Graph 2** Intragroup Comparison At Different Time Intervals

**Line Diagram 1: Intragroup Comparison At Different Time Intervals**



**Table 3** Intragroup Comparison at Different Time Intervals

	Baseline	7 <sup>th</sup> Day	14 <sup>th</sup> Day	21 <sup>st</sup> Day	28 <sup>th</sup> Day	35 <sup>th</sup> Day	42 <sup>nd</sup> Day	49 <sup>th</sup> Day	55 <sup>th</sup> Day	P value
Group I	80.66±5.93	80.66±5.93	78.00±5.60	68.00±5.60	56.60±6.12	46.00±5.00	37.33±4.57	28.00±4.16	17.66±4.14	0.001 (Sig)
Group II	88.66±3.51	88.66±3.51	80.66±2.52	70.66±2.58	60.66±2.58	50.00±0.00	40.00±0.00	28.33±3.08	20.00±14.66	0.001 (Sig)

Table 3, graph 2, line diagram 1 indicates the intergroup comparison of both the groups. Using one way anova test, group A showed a reduction in the burning sensation from 80.66±5.93 at baseline to 17.66±4.14 at the completion of 56 days of follow up and was statistically significant ( p=0.001). Similarly, in group B showed a reduction in the burning sensation from 88.66±3.51 at baseline to 20.00±14.66 at the completion of 56 days follow up and was statistically significant ( p=0.001)

tissues become rigid and mouth opening becomes difficult) and mortality (when transformation into squamous cell carcinoma occurs). It is a chronic inflammatory disorder with altered immunity.<sup>5</sup> In the condition of Oral submucous fibrosis, soluble irritants, such as capsaicin present in chillies and alkaloids of areca nut, act as initiating factors causing a juxta-epithelial inflammatory reaction. Thus leading to burning sensation, vesiculation and ulceration of the oral mucosa. An atrophic epithelium makes the oral mucosa vulnerable to the soluble irritants and causes improper vascular channel formation resulting in decreased

**Table 4** Post Hoc Tukey Analysis-Group A

	Baseline	7 <sup>th</sup> Day	14 <sup>th</sup> Day	21 <sup>st</sup> Day	28 <sup>th</sup> Day	35 <sup>th</sup> Day	42 <sup>nd</sup> Day	49 <sup>th</sup> Day	55 <sup>th</sup> Day
Baseline	-	0.00 (p=1.000)	2.66 (p=0.90)	12.66 (p=0.001)	24.00 (p=0.001)	34.66 (p=0.001)	43.33 (p=0.001)	52.66 (p=0.001)	63.00 (p=0.001)
7 <sup>th</sup> Day			2.66 (p=0.90)	12.66 (p=0.001)	24.00 (p=0.001)	34.66 (p=0.001)	43.33 (p=0.001)	52.66 (p=0.001)	63.00 (p=0.001)
14 <sup>th</sup> Day				10.00 (p=0.01)	21.33 (p=0.001)	32.00 (p=0.001)	40.66 (p=0.001)	50.00 (p=0.001)	60.33 (p=0.001)
21 <sup>st</sup> Day					11.33 (p=0.001)	22.00 (p=0.001)	30.66 (p=0.001)	40.00 (p=0.001)	50.33 (p=0.001)
28 <sup>th</sup> Day						10.66 (p=0.001)	19.33 (p=0.001)	28.66 (p=0.001)	39.00 (p=0.001)
35 <sup>th</sup> Day							8.66 (p=0.001)	18.00 (p=0.001)	28.33 (p=0.001)
42 <sup>nd</sup> Day								9.33 (p=0.001)	19.66 (p=0.001)
49 <sup>th</sup> Day									10.33 (p=0.001)
55 <sup>th</sup> Day	63.00 (p=0.001)	63.00 (p=0.001)	60.33 (p=0.001)	50.33 (p=0.001)	39.00 (p=0.001)	28.33 (p=0.001)	19.66 (p=0.001)	10.33 (p=0.001)	-

Using Tukey analysis, the intra group comparison in group A was found statistically significant except for 7<sup>th</sup> (p=1.000) and 14<sup>th</sup> day (p=0.90)

vascularity. This leads to derangement in the inflammatory reparative response of the lamina propria resulting in defective healing and scarification.

**Table 5** Post Hoc Analysis-Group B

	Baseline	7 <sup>th</sup> Day	14 <sup>th</sup> Day	21 <sup>st</sup> Day	28 <sup>th</sup> Day	35 <sup>th</sup> Day	42 <sup>nd</sup> Day	49 <sup>th</sup> Day	55 <sup>th</sup> Day
Baseline		0.00 (p=1.000)	8.00 (p=0.001)	18.00 (p=0.001)	28.00 (p=0.001)	38.66 (p=0.001)	48.66 (p=0.001)	60.33 (p=0.001)	74.00 (p=0.001)
7 <sup>th</sup> Day			8.00 (p=0.001)	18.00 (p=0.001)	28.00 (p=0.001)	38.66 (p=0.001)	48.66 (p=0.001)	60.33 (p=0.001)	74.00 (p=0.001)
14 <sup>th</sup> Day				10.00 (p=0.001)	20.00 (p=0.001)	-30.66 (p=0.001)	-40.66 (p=0.001)	52.33 (p=0.001)	66.00 (p=0.001)
21 <sup>st</sup> Day					10.00 (p=0.001)	20.66 (p=0.001)	30.66 (p=0.001)	42.33 (p=0.001)	56.00 (p=0.001)
28 <sup>th</sup> Day						10.66 (p=0.001)	20.66 (p=0.001)	32.33 (p=0.001)	46.00 (p=0.001)
35 <sup>th</sup> Day							10.00 (p=0.001)	21.66 (p=0.001)	35.33 (p=0.001)
42 <sup>nd</sup> Day								11.66 (p=0.001)	25.33 (p=0.001)
49 <sup>th</sup> Day									13.66 (p=0.001)
55 <sup>th</sup> Day	-74.00 (p=0.001)	-74.00 (p=0.001)	-66.00 (p=0.001)	-56.00 (p=0.001)	-46.00 (p=0.001)	-35.33 (p=0.001)	-25.33 (p=0.001)	-13.66 (p=0.001)	

Using Tukey analysis, the intra group comparison in group B was found statistically significant except for 7<sup>th</sup> day(p=1.000).

Thus, the cumulative effect of these initiating and promoting factors leads to further fibrosis, which is a hallmark of Oral submucous fibrosis.<sup>6</sup>

## DISCUSSION

Oral submucous fibrosis (OSMF) is a disease which causes significant morbidity (in terms of loss of mouth function as

Although a vast array of therapeutic modalities have been offered to OSMF patients, there is paucity of clinical trials, to suggest appropriate management of these patients.

Many invasive treatment modalities which includes intralesional injection of steroids, placentrax, fibrinolytic agents and surgical elimination of the fibrotic bands are used which is traumatic. No definitive treatment is currently acceptable.

A non invasive treatment includes application of aloe vera gel. Aloe vera is absorbed four times faster than water and it also has soothing and cooling qualities.<sup>3</sup> It reduces the number of micronucleated cells (which are found to be increased in exfoliated oral mucosal cells and circulating lymphocytes of precancerous oral lesions) both in exfoliated oral mucosal cells and in circulating lymphocytes. Certain studies proves that Aloe vera significantly reduces burning sensation.<sup>7,8</sup>

On extensive literature search, no indigenous data on effectiveness of aloe vera gel in the management of OSMF was found. Hence the present study was conducted to compare the effectiveness of aloe vera gel along with antioxidant capsules in the management of OSMF.

In the present study, Group A patients (Aloe vera gel with antioxidant capsule), showed a reduction in the burning sensation from 80.66±5.93 at baseline to 17.66±4.14 at the completion of 56 days of follow up.

Group B patients (intralesional injections with antioxidant capsule), showed a reduction in the burning sensation from 88.66±3.51 at baseline to 20.00±14.66 at the completion of 56 days follow up.

Decrease in the score of burning sensation was found to be significant among patients both in Group A and Group B. The decrease in the burning sensation score was found to be statistically significant i.e. (p value <0.001). Though it was observed that the burning sensation intensity reduction in group B was more than group A, the difference between the groups was statistically significant (p =0.001).

Sudarshan R *et al*<sup>1</sup> conducted a study which showed an improvement of 80% in burning sensation in patients receiving Aloe vera gel and only 65.7% improvement was seen in the antioxidant group

Alam S *et al*<sup>9</sup> studied and found considerable decrease in burning sensation in the medicinal group (submucosal injection of hyaluronidase and dexamethasone with Lycostar and Capsule Becosules-Z) with Aloe vera (1.73 ±1.01) in comparison to the group without Aloe vera, in follow-up study for period of 6 months.

Patil S *et al*<sup>10</sup> conducted a study to compare the efficacy of the 2 herbal antioxidants - Oxitard and Aloe vera in the improvement of burning sensation on 120 subjects with Oral submucous fibrosis patients and divided them equally in 2 groups. 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. There was significant improvement in burning sensation in both the groups. Thus, he concluded that both the medicaments can be considered to be an effectual protocol in the management of Oral submucous fibrosis.

Ardra anuradha *et al* (2016)<sup>11</sup> conducted a study where 74 patients of OSMF were randomly divided into 2 groups. Group A patients were treated with systemic juice and topical aloe

vera(gel) for 3 months . Group B patients were treated with intralesional injections of hydrocortisone and hyaluronidase for 6 weeks with antioxidant supplements for 3 months. The results of the study concluded that both the groups showed statistically significant and so group A can be alternative, safe and effective treatment regime in the management of OSMF.

The analgesic effects of Aloe vera can be attributed to its various properties and composition of substances such as salicylic acid, magnesium, lupeol, free anthraquinones and their derivatives, barbaloin, aloe-emodin-9-anthrone, Isobarbaloin, anthrone-C-glycosides and chromones.<sup>12</sup>

## CONCLUSION

The improvement in burning sensation in the patients was much satisfactory compared to previous studies conducted. Based on these results, Aloe vera being a soothing, simple, non-invasive and safe mode of treatment along with physiotherapy exercises and proper habit restriction, can be considered to be an effectual protocol in the management of Oral submucous fibrosis. However, the small sample size in the present study requires replication of these findings in a larger sample of patients, possibly a cross over design study can be considered within the two groups. A long term follow up of patients could substantiate the present study and determine the long term effects of both treatment protocols.

***“If the diet is wrong, then medicines are of no use. If the diet is right, then the medicines are of no need.”-A text from the ayurvedic records-500BC***

**Conflict of Interest:** No potential conflict of interest relevant to this article.

## Bibliography

1. Ramachandran Sudarshan, Rajeshwari G. Annigeri, G. Sree Vijayabala. Aloe vera in the treatment for oral submucous fibrosis - a preliminary study. *J Oral Pathol Med.*2012; 1-6.
2. Vijayavel. T, Ponni V. Management for Oral Submucous Fibrosis - A comprehensive review. *Indian Journal of Multi disciplinary Dentistry.* November 2013 - January 2014; 4(1):869-874.
3. Pindborg J.J. and Sirsat S.M. Oral submucous fibrosis *Oral Surg Oral Med Oral Pathol*, 2001, 22(6): 764-79.
4. Revant H. Chole. Review of drug treatment of oral submucous fibrosis. *Oral Oncology.*2012; 48: 393-398.
5. Dayanarayana U, Doggalli N, Patil K, Shankar J , K.P Mahesh, Sanjay Non surgical approaches in treatment of OSF IOSR-JDMS Volume 13, Issue 11 Ver. III (Nov. 2014), PP 63-69
6. Sajjad A, Sajjad S S Aloe vera: An Ancient Herb for Modern Dentistry-A Literature Review *Journal of Dental Surgery* Volume 2014, Article ID 210463, 6 pages
7. Pareek S, Nagaraj A, Sharma P, Naidu S, Yousuf A ALOE-VERA: A HERB WITH MEDICINAL PROPERTIES IJOCR Jul - Sep 2013; Volume 1 Issue 1
8. Dyavanagoudar N S Oral Submucous Fibrosis: Review on Etiopathogenesis *JCST/Vol.1 Issue 2*
9. Stephen Cox, Hans Zoellner: Physiotherapeutic treatment improves oral opening in oral submucous fibrosis. *J Oral Pathol Med.* 2009; 38: 220-226.

10. Deepa Das A, Anita Balan, Sreelatha KT. Comparative Study of the efficacy of curcumin and turmeric oil as chemopreventive agents in oral submucous fibrosis: A Clinical and Histopathological evaluation. *Journal of Indian Academy of Oral Medicine and Radiology*, 2010; 22(2):88-92.
11. Ardra Anuradha, Bharati Patil, Venkataswamy Reddy Asha. Evaluation of Efficacy of Aloe Vera in The Treatment of OSMF-A Clinical Study. *Journal of Oral Pathology And Medicine* June 2016
12. Tapasya Vaibhav Karemore, Mukta Motwani. Evaluation of the effect of newer antioxidant lycopene in the treatment of oral submucous fibrosis. *Indian Journal of Dental Research*.2012; 23(4):524-528.

**How to cite this article:**

Danish Uz Zama Khan et al.2017, Effect of Intralesional Betamethasone Injections And Local Application of Aloe Vera Gel In Patients With Oral Submucous Fibrosis And Burning Sensation. A Comparative Study. *Int J Recent Sci Res*. 8(10), pp. 20505-20510. DOI: <http://dx.doi.org/10.24327/ijrsr.2017.0810.0905>

\*\*\*\*\*