

# Comparative Assessment of Aloe Vera and Antioxidant in the Treatment of Oral Submucous Fibrosis

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## ABSTRACT

**Background:** To compare the efficacy of aloe vera gel and antioxidants in the treatment of oral submucous fibrosis. **Methods:** This is Randomized Control trial study conducted at Department of Oral & Maxillofacial surgery LUMHS Jamshoro from 1st March 2018 to 28th February 2019. 168 patients with clinically diagnosed delicate to moderate cases of OSMF were haphazardly allotted into 2 groups. Eighty four patients of group A were given Aloe Vera gel and eighty four groups B received inhibitor capsule. Patients were suggested to recall for follow-up when fifteen days, 1 month, two months and so three months and also the results were assessed at every visit. All data was recorded in predesigned proforma. **Results:** The average age of the patients was 28.94±5.30 years. The typical mouth gap score increase from bottom line to three months post treatment follow-up in each teams, however it was considerably high in group A as compare to B [32.67±1.15 vs. 31.66±0.92; 0.0005]. 91.48% reduction in burning sensation in group A and 74.56% reduction was determined in B, that is additionally statistically vital distinction (p=0.0005). **Conclusion:** It was finished that Aloe Vera is effective alternative of treatment regime within the management of OSMF.

**Keywords:** Oral submucous, Pathology, Mastication, Arecanut, Aloe Vera gel.

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## INTRODUCTION

Oral submucous fibrosis is a chronic disease which may lead to potentially malignant condition of oral cavity. The etiology is multi factorial but chewing arecanut/ tobacco is the main causative agent. The traditional etiological factors could be chillies, vitamin B deficiencies and genetical and immunological predisposition.<sup>[1,4]</sup> Oral submucous fibrosis may cause meaningful morbidity when spread towards palate, pharynx, digestive tract, and anteriorly towards cheeks and lips so mouth opening become difficult and advancing vertical fibrosis and bands in labial and buccal tissues anticipated by symptoms like burning sensation, ulceration and pain.<sup>[1,5,7]</sup>

No successful treatment has been advised till date, however characteristic treatment contains deposition of steroids, placental extracts, Interferon gamma, pentoxifylline, lycopene, surgical excision etc, many natural plant extracts, and synthetic drugs have been brought in and tried for the management of oral submucous fibrosis. One such plant is aloe vera which allows wound healing, anti-inflammatory,

immunomodulatory and antioxidant properties.<sup>[3,8]</sup> The management criteria has been divided into surgical, physical and medical treatment. A surgical treatment is an option in advance cases, while physical management helps remodeling tissues includes physiotherapy exercises, and medical treatment can be given orally, topically or by submucosal injections.<sup>[2,7]</sup>

Aloe vera also known as wound healing hormone containing vitamin A,C,E,B1,B2,B3,B6, choline, folic acid, alpha tocopherol, beta-carotene and vitamin B12. It helps in fighting against damaging free radicals. The sterols in the aloe vera has capability to restrict inflammation as action of cortisone and having no side effects. Aloe vera can play a meaningful role in dentistry in the management of lichen planus, OSMF, recurrent aphthous stomatitis, alveolar osteitis, periodontitis etc. Studies have showed that it can be applied topically and effective in the treatment of oral submucous fibrosis.<sup>[6,8]</sup>

The antioxidant defense mechanism of the body is exacerbated to inhibit the adverse effects of reactive oxygen species (ROS) which has been generated due to chewing impact of areca nut. Vitamin E a antioxidant can lowers the oxidative damage by scavenging free radicals, it inhibits cellular proliferation, platelet aggregation and monocyte adhesion, reflecting specific interactions with

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enzymes, structural proteins, lipids and transcription factors and fight against damaging free radicals.<sup>[9]</sup> Though there are different management options but in studies it is seen that there is reduction in burning sensation 80% and improvement in mouth opening 20% after the treatment of aloe vera and reduction in burning sensation 65.7% and improvement in mouth opening 9% after having treatment with antioxidant for oral submucous fibrosis.<sup>[8]</sup>

The aim of this study is to evaluate the benefits of using topical aloe vera gel and antioxidants in the patients of oral submucous fibrosis along with physiotherapy and cessation of habits. On literature search it has been noted that the research on this topic locally and internationally is very scanty. In our routine practice we just observe the patients and ask for quitting the habit along with physiotherapy and sometimes multivitamins and antioxidants, if aloe vera gel shows better results than antioxidants then it could be recommended as a management option in oral submucous fibrosis.

## MATERIALS & METHODS

This is a Randomized control trial study conducted at Oral & Maxillofacial Surgery Department of Dentistry, Liaquat University Hospital Hyderabad/Jamshoro from 1st March 2018 to 28th February 2019.

### Sampling technique:

Non-probability/consecutive.

### Sample Selection

#### Inclusion Criteria:

- Clinically diagnosed mild to moderate cases of OSMF i.e. mouth opening between 20 and 39mm.
- Patients who had not taken any earlier treatment for OSMF previously.
- Patients who are ready to quit the habit and accepted for regular follow ups.
- Age range from 18-45 years.
- Irrespective of gender.

#### Exclusion Criteria:

- Patients diagnosed as severe case of OSMF i.e. mouth opening less than 20mm.
- Patients with other malignant lesions confirmed by history, clinical examination and biopsy.
- Patients having history of hypersensitivity to aloe vera.
- Pregnant woman and lactating mothers confirmed by history.
- Patients not willing to participate in this study.

### Data Collection Procedure

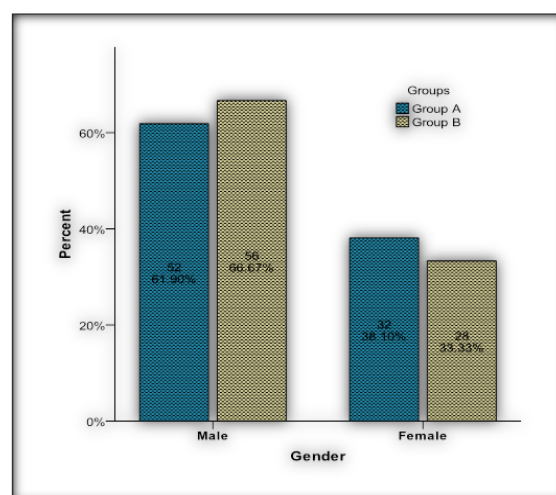
Patients present as oral submucous fibrosis was diagnosed clinically. Informed and written consent was taken before enrollment in study and after explaining the procedure. Patients were randomly divided into two groups, Group A and B by lottery

method. A detailed history of chief complaint and habit history (arecanut/ mainpuri) was noted and the intensity of burning sensation was determined using a Numerical Rating Visual Analogue Scale (VAS) and mouth opening was examined by inter incisal distance.

Both the groups was advised to restrict the habits, Patients of group A was given with forever aloe vera gel to be applied topically on each side of buccal mucosa 3 times daily for 3 months along with physiotherapy daily 5 times by inter positioning tongue spatulas between teeth and adding a new spatula every 5-10 days, patients was advised not to eat or drink for 15 minutes after the application of aloe vera gel. Patients of Group B will receive antioxidant capsule i.e. Vitamin E 400mg (Evion) capsules 2 times daily for 3 months along with same physiotherapy. Patients was advised to recall for follow-up after 15 days, 1 month, 2 months and than 3 months and the results was assessed after each visit. Mouth opening was measured in millimeters through metallic scale (ruler) by taking the distance between the center of incisal edges of maxillary central incisors and mandibular central incisors at maximum opened mouth. Based on mouth opening the subjects were groups as Mild cases: 30-39.9mm, Moderate cases: 20-29.9mm and Severe cases: < 20mm which was not be included the study. Burning sensation was assessed on the basis of Visual Analogue Scale (VAS) in which the score 0-1 was considered as absent, score in between 1-6 was taken as reduced and the score of 7-10 was considered as severe.

Statistical analysis was performed using computer software SPSS version 20.0.

## RESULTS



**Figure 1: Age Distribution of the Patients According To Groups n=168**

A total of 168 patients with clinically diagnosed mild to moderate cases of OSMF were randomly allocated into two groups. 84 patients of group A

was given with forever aloe vera gel and 84 groups B was received antioxidant capsule. The average age of the patients was  $28.94 \pm 5.30$  years Mean duration of complain and chewing habit was  $4.44 \pm 1.47$  months and  $7.55 \pm 2.42$  years respectively. These were also presented with respect to groups [Table 1]. There were 108(64.3%) male and 60(35.7%) female. Gender distribution according to groups is also shown in [Figure 1]. Effect site of involvement is also shown in [Figure 2]. Burning sensation and Limited mouth opening was 100% cases and laceration was observed in 38.1% [Table 2]. In this study, most of the chewing habit was areca nut i.e. 108(64.3%), follow by mainpuri 40(23.8%) and gutka 20(11.9%) as shown in [Figure 3].

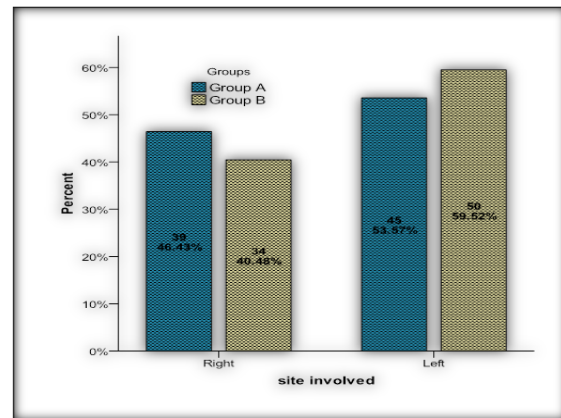


Figure 2: Site Involved According to Groups n=168

Table 1: Descriptive Statistics of the Patients n=168

Variables	Group A n=84		Group B n=84		Overall n=168	
	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Age (Years)	28.55	5.71	29.33	4.86	28.94	5.30
Duration of complain (months)	4.57	1.33	4.31	1.59	4.44	1.47
Duration of Chewing habit (years)	7.40	2.29	7.69	2.53	7.55	2.42

Table 2: Symptoms with Respect to Groups

Symptoms	Group A n=84	Group B n=84	Total n=168
Laceration	36(42.9%)	28(33.3%)	64(38.1%)
Burning Sensation	84(100%)	84(100%)	168(100%)
Limited mouth opening	84(100%)	84(100%)	168(100%)

Table 3: Comparison of Mean Mouth Opening Between Groups

Mouth Opening (mm)	Group A n=84		Group B n=84		P-Value
	Mean	Std. Deviation	Mean	Std. Deviation	
Pre treatment	29.98	1.74	29.79	1.62	0.465
At 3-months post treatment	32.67	1.15	31.33	0.92	0.0005
Percent Improvements at 3 months (%)	9.35	7.71	5.43	5.16	0.0005

Table 4: Comparison of Mean Burning Sensation Between Groups

Burning Sensation (VAS)	Group A n=84		Group B n=84		P-Value
	Mean	Std. Deviation	Mean	Std. Deviation	
Pre treatment	7.36	0.78	7.29	0.913	0.588
At 3-months post treatment	0.64	1.83	0.69	0.07	0.0005
Percent Reduction at 3 months	91.48	9.39	74.56	7.41	0.0005

Independent sample t test applied

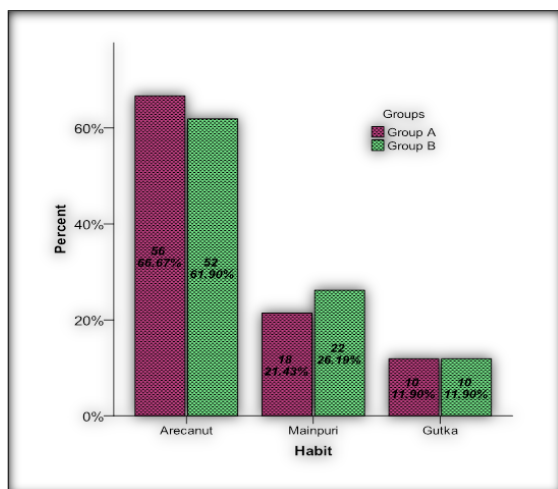


Figure 3: Chewing Habit of the Patients According to groups n=168

The average mouth opening score increase from base line to 3-months post treatment follow-up in both groups but it was significantly high in group A as compare to group B [ $32.67 \pm 1.15$  vs.  $31.66 \pm 0.92$ ; 0.0005]. In term of percent improvement, at 3-month it was observed 9.35 percent improvement in mouth opening in group A and 5.43 percent improvement in group B. Percent improvement was also significantly high in group A than B [ $p=0.0005$ ] as shown in [Table 3].

Burning sensation was assessed by visual analogue score and observed that 91.48 percent reduction in burning sensation in group A and 74.56 percent reduction was observed in group B (Table 4). which is also statistically significant difference ( $p=0.0005$ ). According to mean VAS score at 3-month fallow up, mean VAS score was significantly low in group A than groups B [ $0.64 \pm 1.83$  vs.  $0.68 \pm 0.07$ ;  $p=0.0005$ ].

Stratification analysis was performed with respect to effect modifiers but similar improvement in mouth opening and reduction in burning sensation was observed in all stratified groups as shown in 5 to 22 which showed that group A is better than group B.

## DISCUSSION

A total of 168 patients, 18-45 years of age, clinically diagnosed with mild to moderate cases of OSMF were enrolled in this study. Patients were randomly allocated into two groups, 84 patients of group A were treated with aloe vera gel and 84 patients in group B received antioxidant capsule.

Approximately 600 million persons are betel chewing, with a hot spot throughout the Western Pacific basin and South Asia. This makes betel the fourth most-consumed drug after nicotine, ethanol, and caffeine.<sup>[10,11]</sup> Betel is composed of the areca nut (Areca catechu), the fresh leaf of betel pepper (Piper betle), spices, and calcium hydroxide (lime) Pan or paan masala is a quid of piper betel leaf.<sup>[12]</sup> Mawa is a mixture of tobacco, lime, and areca nut. In this study, most of the chewing habit was areca nut i.e. 108 (64.3%), follow by mainpuri 40 (23.8%) and gutka 20 (11.9%). In our study the average age of the patients was 28.94±5.30 years, there were 108 (64.3%) male and 60 (35.7%) female. A study from Gujarat has shown that about 85% of patients were younger than 35 years.<sup>[13]</sup> In 2005, the OSF prevalence among visitors at a dental school in Manipal, India was estimated as 2%, with a preference for male sex and an age range of 40–60 years.<sup>[14]</sup> In a study from India, 239 OSF patients were studied; 46% were in their 3rd decade of life. Trismus was observed in 37.2% of patients, 25.9% suffered from burning sensations, 22.5% reported excessive salivation, and 14.2% suffered from recurrent oral ulcerations.<sup>[15]</sup> In our study Burning sensation and Limited mouth opening was found in 100% cases and laceration was observed in 38.1%

While comparing the efficacy of aloe vera gel and antioxidants in the treatment of oral submucous fibrosis, The average mouth opening score increase from base line to 3-months post treatment follow-up in both groups but it was significantly high in group A (Alovera) as compare to group B [32.67±1.15 vs. 31.66±0.92; 0.0005]. At 3-month it was observed 9.35 percent improvement in mouth opening in group A and 5.43 percent improvement in group B. Burning sensation was assessed by visual analogue score and observed that 91.48 percent reduction in burning sensation in group A and 74.56 percent reduction was observed in group B. which is also statistically significant difference (p=0.0005). According to mean VAS score at 3-month follow up, mean VAS score was significantly low in group A than groups B [0.64 ±1.83 vs. 0.68±0.07; p=0.0005] Our observations show that Topical aloevera appears to be useful in the management of OSMF as

evidenced from before-mentioned studies in the literature. The results of the present study can be compared with the preliminary study carried out by Sudarsan et al. in 2012. They have reported an improvement in various parameters such as burning sensation, mouth opening, cheek flexibility, and tongue protrusion using aloe vera on OSMF patients.<sup>[16]</sup> Alam et al. in 2013,<sup>[7]</sup> used aloe vera as an adjunct with dexamethasone, hyaluronidase, and showed statistically significant improvement in various parameters in OSMF patients. They also reported aloe vera to be useful in the prevention of relapse of the improved mouth opening achieved after surgery. The results of the above-mentioned studies are in accordance with our study, whereas different studies by Patil S et al. in 2014, and 2015 have reported better results in various parameters for OSMF patients with the use of oxtard, lycopene, and spirulina when compared with aloe vera.<sup>[3,17]</sup>

## CONCLUSION

In the study, Aloe Vera showed comparable clinical response to it of antioxidants within the treatment of oral submucous pathology. No serious facet effects were rumored. Simple convenience, safety of use, cost-effectiveness, and non-invasiveness attributes of Aloe Vera create it another, effective alternative of treatment regime within the management of OSMF. Additional studies involving a bigger sample size with longer amount of treatment follow-up area unit counseled.

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