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#### **RESEARCH ARTICLE**

# ORAL SUBMUCOUS FIBROSIS - efficacy of conservative management with Hydrocortisone & Hyaluronidase against Dexamethasone & Hyaluronidase against Triamcinolone & Hyaluronidase

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#### Abstract

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Oral sub mucous fibrosis is a chronic debilitating disease of the oral cavity characterized by inflammation and progressive fibrosis of the sub mucosal tissues (lamina propria and deeper connective tissues). Oral sub mucous fibrosis results in marked rigidity and an eventual inability to open the mouth. The buccal mucosa is the most commonly involved site, but any part of the oral cavity can be involved, even the pharynx. The condition is well recognized for its malignant potential and is particularly associated with areca nut chewing, the main component of betel quid. Betel quid chewing is a habit practiced predominately in Southeast Asia and India.

Objectives of our study was to study the efficacy of intraoral injections of steroids; hydrocortisone, dexamethasone, triamcinolone along with Hyaluronidase and assess and compare the extent of clinical improvement.

A prospective randomized study was conducted on 30 cases of oral sub-mucous fibrosis reporting to the department of ENT, in a tertiary care hospital, for a period of one and half year from 1st October 2012 to 30th April 2014. The complete data was collected from the patients in a case record form by taking history of illness, detailed clinical examination and relevant investigation.

Patients were divided into three groups of 10 each randomly and were given intraoral injections in the reteromolar trigone. Patients in Group A were treated with hydrocortisone and hyaluronidase, Group B with dexamethasone and hyaluronidase, and Group C with triamcinolone and hyaluronidase at weekly intervals for 12 weeks.

Treatment outcome was evaluated on the basis of improvement in symptoms, signs and clinical improvement. Majority of our patients had excellent results when compared to the initial symptoms, Burning sensation showed excellent results in all the three groups A, B, C with 100%,90%,and 100% improvement. There was relief from ulceration and vesiculation of 100% of cases in group A and C, compared with 75% in group B. Decrease in fibrous bands was seen in 90% of patients in group C, compared to 80% and 66.6% in group A and B respectively. While 90% of patients in group C had good improvement in mouth opening, only 77.7% had improvement in group A & B. Overall results were very significant in group C (95%) and then group A (87%) compared to group B (80%).

The malady of sub-mucous fibrosis is one of the most poorly understood and unsatisfactorily treated diseases. This is mainly because an exact etiology has not been identified, although considerable data has been accrued over the years in support of the role of areca nut. Symptoms such as burning sensation in the oral cavity and progressive difficulty in mouth opening can be disturbing and distressing to the patient. Innumerable modalities of treatment have been tried ranging from vitamin supplements, topical steroid applications to sub-mucosal steroid injections. We recommended a combination of multi vitamins, iron and topical triamcinolone gel, daily massage of the affected area, along with sub-mucosal injections of steroids and hyaluronidase. This achieved a good results.

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### **INTRODUCTION**

Oral submucous fibrosis is an insidious chronic fibrotic disease of the oral cavity and oropharynx characterized by fibroblastic changes in the mucosa and an increased deposition of collagen in the juxtaepithelial and submucosal tissues resulting in fibrous scarring and limitation of mouth opening.<sup>(1)</sup>Oral Submucous Fibrosis has been well established in Indian medical literature since the time of Susrutha, a renowned Indian Physician who lived in the era 2500-3000B.C. The exact etiology of oral submucous fibrosis (OSF) is still obscure, although various etiological factors are being mentioned such as genetic, autoimmune, nutritional and environmental. The chewing of areca nut has been associated with OSF. However, the pathogenic mechanism involved in developing OSF with the areca nut chewing is not clear.<sup>(2)</sup>Therefore, it is assumed that OSF may be due to trauma caused by areca nut particles and there after a result of repair. During the repair process, destroyed cells and tissues are replaced with live cells and new tissue components<sup>(2)</sup>. Repair is the body's defense mechanism in an attempt to restore the injured tissue to its original state. Epithelial and fibrous connective tissues have the ability to undergo repair. Further, fibroblasts play a key role in repair which may lead to fibrosis and is characterized by accumulation of extra cellular matrix in a tissue. Predominantly type 1 collagen with variable amounts of other types of collagen constitutes fibrosis <sup>(3,4)</sup>. However the amount of fibrosis after injury depends on many factors including heredity<sup>(2,1)</sup>.

Oral submucous fibrosis is a chronic condition characterized by mucosal rigidity of varying intensity due to fibro elastic transformation of juxta-epithelial layer. This leads to progressively restricted oral cavity opening, and when the tongue is involved its protrusion may also be impaired. Most of the affected individuals report a burning sensation of the oral cavity aggravated by spicy food. The presence of palpable fibrous bands is a requisite diagnostic criterion for this condition, as otherwise other oral mucosal conditions such as anemic states are likely to be misdiagnosed as OSF. However a more serious implication is the risk of developing oral malignancy which is as high as 3 - 7.6%. Various modalities of treatment ranging from conservative treatment such as multivitamins and physiotherapy to surgical procedures have been attempted by various authors with varying success rates<sup>(4,2)</sup>.

### MATERIALS AND METHODS

#### MATERIALS

The present study on oral submucous fibrosis, and its management was done on 30 randomly selected patients irrespective of their age, sex and socio- economic status; who reported to the department of ENT, in a tertiary care hospital during a period from 1st October 2012 to 30th April 2014.

A detailed personal history regarding use of chilies, areca nut, paan masala, betel quid, alcohol, smoking and tobacco chewing with regard to frequency and duration of habit were taken. Complaints like burning sensation of mouth, difficulty in mouth opening, dryness of mouth, ulceration & vesiculation, dysphagia and defective gustatory sensation with duration of the symptoms were noted.

Local examination included measuring inter - incisal distance (ID), presence of blanching of mucosa, ulceration and vesiculation, presence of fibrous bands and their sites, restriction of tongue movements, leukoplakia and co- existing malignancy.

### **METHODS:**

A total of 30 subjects were selected for the study, and were divided randomly into three groups: - Group A, Group B and Group C.

Study Groups:

- Group A 10 subjects for local injection with Hyaluronidase and Hydrocortisone.
- Group B 10 subjects for local injection with Hyaluronidase and Dexamethasone.
- Group C 10 subjects for local injection with Hyaluronidase and Triamcinolone.

For the Group subjects the following criteria were considered for the clinical diagnosis of OSF:-

- Clinically discernible blanching and pallor.
- Palpable fibrous bands.
- Restriction of mouth opening.
- Severe burning sensation of mouth, aggravated by use of even moderately spicy food.

#### Inclusion criteria were:-

Subjects above 18 years of age were selected for the study.

#### Exclusion criteria were:-

- 1. Pregnant and lactating women.
- 2. Subjects with previous treatment history for OSF.
- 3. Subjects with any collagen diseases or immune mediated disorders.
- 4. Subjects with history of head and neck tumors, breast cancer and gastric cancer.
- 5. Subjects with prior neoplastic surgeries and cancer metastases.

#### The following modalities of treatment were used:-

- 1. All patients were instructed to avoid the use of the particular etiological agent as the case was.
- 2. IRON & VIT B complex, given as capsule in the dose of once daily.
- 3. Oral triamcinolone steroid gel for local application.
- 4. Intra oral submucosal injections in the reteromolar trigone, given in 3 forms:-

a) Inj. DEXAMETHASONE, 4mg/ml +Inj HYALURONIDASE, 1500IU/ml were diluted in 0.5 ml of XYLOCAINEto reduce local irritation and ensure better spread was injected intra oral sub-mucosal, weekly for 12 weeks over the involved sites using an insulin syringe and needle.

b) Inj. TRIAMCINOLONE + Inj. HYALURONIDASE - The steroid and enzyme combination of KENOCORT ( 40 mg/dl) and HYALURONIDASE, 1500IU/ml in a ratio of 1:2 were diluted in 0.5 ml of XYLOCAINE- to reduce local irritation and ensure better spread was injected intraoral submucosal, using aninsulin syringe and needle over the involved site once a week for 12weeks.

c) Inj. HYDROCORTISONE,50mg/ml +Inj HYALURONIDASE , 1500IU/ml were diluted in 0.5 ml of XYLOCAINE- to reduce local irritation and ensure better spread was injected sub-mucosal weekly for 12 weeks over the involved sites using aninsulin syringe and needle.

Patients were asked not to rinse their mouth for at least 1 hour after taking the above 3 types of sub mucosal injections. 5. Daily massaging: - Patients were instructed to do local massage of the oral cavity by placing the fingers in the mouth and the thumb over the cheek, to help break the fibrous bands and improve local vascularity.

### FOLLOW UP

The patients were followed up once a week for a period of 12 weeks. The observations were tabulated and the results analyzed in terms of:

- a) Decrease in burning sensation,
- b) Decrease in ulceration and vesiculation,
  - c) Decrease in blanching of mucosa,
  - d) Improvement in mouth opening.  $^{(1,3,4,5)}$

# **OBSERVATIONS AND RESULTS**

#### **1.** AGE AND SEX DISTRIBUTION (table:-1)

AGE	MALES	%	FEMALES	%
(YEARS)				
15-25	7	23.33	0	0
26-35	13	43.33	3	10
36-45	6	20	1	3.33
46-55	0	0	0	0

The study revealed a majority of the patients to be in the age group of 26-35 years with 43.33% males and 10% females. The youngest patientwas of the age of 17 years old and the oldest 47 years. Males were predominant in the study group, being 26 and females being 4. The male to female ratio was 6.5:1. (table:- 1)

## 2. Predisposing Factors(table:-2)

Predisposing factors	Number of cases	%
Areca nut	21	70
Paan masala/ Gutkha	26	86.66
Betel quid	15	50
Tobacco	17	56.66
Chillies	7	23.33
Smoking	15	50
alcohol	4	13.33

Areca nut was by far the most common aetiological agent, which was taken alone as well as in the form of paan masala, gutkha and betel quid.(table:-2)

#### 3. SYMPTOMS(table:-3)

Symptoms	Number of cases	%				
Burning sensation	30	100				
Decreased mouth opening	28	93.3	93.3			
Dryness	23	76.6				
Altered taste	12	40				
Ear pain	2	6.6				
Nasal twang	0	0				
Dysphagia	2	6.6				
Ulceration and vescication	18	60				

Burning sensation on eating spicy food and decreased mouth opening were the most common symptoms, seen in 100% and 93.33% of the cases respectively.(table:-3)

### 4. SIGNS(table:-4)

Signs	Number of cases	%		
Trismus	28	93.33		
Blanching of mucosa	29	96.66		
Fibrous bands	29	96.66		
Ulceration and vesciculation	18	60		
Fibrosis of faucial pillars	19	63.33		
Restriction of tongue movement	16	53.33		
Depigmentation of vermillion	19	63.33		
border				
Fibrotic rim around rimaoris	3	10		
Leukoplakia	0	0		
Ulcero-exophytic mass	0	0		

In our study trismus was present in 93.33% cases. Blanching of mucosa and presence of fibrous bands were each seen in 96.66% of the cases respectively. Ulceration and vesiculation in 60% of cases, fibrosis of faucial pillars in 63.33% cases, restriction of tongue movement in 53.33%, depigmentation of vermillion border in 63.33% and fibrotic rim around Rima Oris was seen in 10% cases.(table:-4)

#### 5. DISTRIBUTION OF SIGNS BASED ON SEVERITY OF DISEASE:

Depending on the severity of symptoms of disease our patients were randomly divided into 3 groups, according to their inter – incisaldistance $(ID)^{(3)}$ 

- Mild more than 30 mm.
- Moderate 16 to 30 mm.
- Severe less than /equal to 15mm.<sup>(3)</sup>

In the >30 mm ID group blanching and ulceration, vesiculation was seen in 100% of the patients, fibrous bands and fibrosis of faucial pillars were seen in 66.6% of the patients and trismus ,restriction of tongue movements and depigmentation of vermillion border were seen in 33.3% of patients

In the 16-30 mm ID group blanching was seen in in 87.5% of the patients, trismus and fibrous bands were seen in 100%, depigmentation of vermillion border is seen in 62.5% of patients, ulceration and vesiculation, restriction of tongue movements in 50% of the patients, fibrosis of faucial pillars in 58.3% and fibrotic ring around the Rima Oris in 8.3% of the patients.

In the <15 mm ID group all the signs of submucous fibrosis were seen in 100% of patients and fibrotic rim around Rima oris was seen in 33.3% of patients.

#### 7. TREATMENT MODALITIES:(table:-5)

In group A, 10 patients were treated with Inj. Hydrocortisone 50 mg/ml + Inj. Hyaluronidase 1500 IU/ml Intraoralsubmucosal injection for 12 Weeks, along with Multivitamin and iron supplementation, oral triamcinolone gel for local application. These patients showed 100% improvement in burning sensation in mouth on consumption of spicy foods, dryness of mouth and ulceration and vesicles, and improved mouth opening and decreased fibrous bands in 80% of patients, and 85.7% of patients showed improvement in depigmentation.

In group B, 10 patients were treated with Inj. Dexamethasone 4mg/ml + Inj. Hyaluronidase 1500 Iu/mlintraoral submucosal injection for 12 Weeks, along with Multivitamin and iron supplementation, oral triamcinolone gel for local application and Mouth opening exercises. These patients showed 90% improvement in burning sensation in mouth on consumption of spicy foods, 66.6% showed improvement in fibrous bands and depigmentation, and 77.7% showed improved mouth opening, and only 75% had improvement in ulceration and vesiculation.

In group C, 10 patients were treated with Inj. Triamcinolone 40mg/ml + Inj. Hyaluronidase 1500 IU/ml intraoral submucosal injection for 12 Weeks, along with Multivitamin and iron supplementation, oral triamcinolone gel for local application and Mouth opening exercises. These patients showed 100% improvement in burning sensation in mouth on consumption of spicy foods, dryness of mouth and ulceration and vesicles, altered gustatory sensation, and 90% showed improved mouth opening and fibrous bands.

	GROUP A				GROUP B			GROUP C				
	Inj. Hydrocortisone 50 mg/ml + Inj. Hyaluronidase 1500 IU/ml Intralesionally For 12 Weeks				Inj.Dexamethasone 4mg/ml +Inj.Hyaluronidase1500 IU/ml Intralesionally For 12 Weeks			Inj. Triamcinolone 40mg/ml + Inj. Hyaluronidase 1500 IU/ml Intralesionally For 12 Weeks				
Symptom / Signs score	Pre- Trea tme nt N=1 0	%	Post- Treat ment	%	Pre- Treat ment N=10	%	Post- Treat ment	%	Pre- Treat ment N=10	%	Post- Treat ment	%
Burning sensation in mouth on consumption of spicy foods	10	100	0	0	10	100	1	10	10	100	0	0
Decreased mouth opening / Trismus	9	90	2	20	9	90	2	20	10	100	1	10
Dryness of mouth	6	60	0	0	9	90	1	10	8	80	0	0
Altered gustatory sensation	4	40	1	10	3	30	0	0	5	50	0	0
Ulceration and Vesicles	6	60	0	0	8	80	2	20	4	40	0	0
Fibrous bands	10	100	2	20	9	90	3	30	10	100	1	10
Restriction of tongue movement	5	50	1	10	5	50	1	10	6	60	1	10
Depigmentation of vermillion border	7	70	1	10	6	60	2	20	6	60	0	0

(N:- number of patients)

### 8. OVERALL RESULTS:-(table:-6)

GROUP	No. of Pts	Treatment modality	Burning Sensation	Decrease d mouth opening/ Trismus	Dryne ss of mouth	Altered gustatory sensation	Ulceration and vesicles	Fibrous bands	Restri cted tongu e move ments	Depigment ation of vermillion border	Averag e score.
Group A	10	Inj. Hydrocortis one 50 mg/ml + Inj. Hyaluronida se 1500 IU/ml submucosal For 12 Weeks	100%	77.7%	100%	75%	100%	80%	80%	85.7%	87.03%
Group B	10	Inj. Dexametha sone 4mg/ml + Inj. Hyaluronida se 1500 IU/ml submucosal For 12 Weeks	90%	77.7%	88.8%	100%	75%	66.6%	80%	66.6%	80.58%
Group C	10	Inj. Triamcinolo ne 40mg/ml + Inj. Hyaluronida se 1500 IU/ml submucosal For 12 Weeks	100%	90%	100%	100%	100%	90%	83.3 %	100%	95.41%

Burning sensation showed excellent results in all the three groups A,B, C with 100%,90%,and 100% improvement. There was relief from ulceration and vesiculation of 100% of cases in group A and C, compared with 75% in group B. Decrease in fibrous bands had excellent results in 90% of patients in group C, compared to 80% and 66.6% in group A and B respectively. While 90% had good improvement in mouth opening in group C, only 77.7% had improvement in group A & B. Overall results were very significant in group C (95%) and then group A (87%) compared to group B (80%).

## DISCUSSION

#### Age and sex incidence

Borle and Borle3 in their study in 1991 reviewed 326 cases of OSMF over a period of 7 years (1982-1989). Their study revealed an age range of 15 to 58 years, and a peak incidence in 20-25yrs age group. D.R. Lai et al in their study in 1995 reviewed 150 cases of OSMF over a period of 10 years (1982-1991). In their study the age range was 17-68 years. The ratio of male patients to female patients was 29: 1.

Khanna and Andrade16 in their series in 1995 reviewed 100 cases of OSMF over a period of 6 years. The peak incidence was seen in the 20-30 year age group; while the sex ratio of male to female was 2.1:1. We in our study of 30 cases of OSMF had an age range of 15-55 yrs. The peak incidence of disease in our series occurred in the 26-35 year age group. The sex ratio revealed a male preponderance of 6.5:1.

*Inference*: It is evident from the various studies that the peak incidence of OSMF is seen in the age group of 20-30 years. However in our study the peak incidence was found in the age group of 26-35 years this could be attributed to loco- regional difference in the consumption of the various predisposing factors. The youngest patient was seen in the Khanna and Andrade series and was 8 years old. The sex ratio in our study was in close concurrence with the Khanna and Andrade series.

### Predisposing factors

P.R Murti et al<sup>(8)</sup> in 1995 studied the etiology of OSF in great detail and reviewed 275 patients over a period of 5 years. They compared the work of several authors in India, Pakistan and South Africa and tabulated their results. Areca nut emerged as the most common etiologicalagent with a chewing habits ranging from as low as 31 % in the study of De Sa (1954) to as high as 100% seen in the studies of; Bhonsle et al (1968), Seedat (1985), Seed at and Van Wyk (1988) and Caniff et al (1986). In our study the incidence of areca nut chewing habit was 100%, this included areca nut chewed alone or in combination of pan masala,gutkha and betel quid.

*Inference:* Thus the various studies conducted all over the world have brought forward areca nut as the most likely agent to induce the pathological changes associated with OSMF. The incidence seen in our study concurs closely with the work done by several authors already mentioned and especially so with the study done by Sind et al (1990) and Maher et al (1994).

### Symptoms:-

In the study conducted by C.W.VanWyk et al<sup>(21)</sup> in 1994 122 patients of OSMF were reviewed. Burning sensation of mouth and dryness of mouth were the most common occurrences with a rate of 39% and 53% respectively. Decreased mouth opening was present in only 14% of patients and the least likely symptoms to occur were dysphagia (12%) and nasal twang, which was not reported at all. In our study of 30 cases, burning sensation of mouth (100%) was the most common symptom followed by decreased mouth opening (93.3%). Ear ache and dysphagia were the least reported symptoms occurring in each 6.6% cases.

*Inference:* Thus our study concurs with that of Van Wyk et al in that burning sensation on eating spicy foods is one of the most common symptoms seen in OSMF patients whereas ear-ache, dysphagia and nasal twang though reported were less frequently seen.

### Signs:-

In their study of 122 cases, Van Wyk et al<sup>(21)</sup> (1994) observed fibrous bands (39%) as their commonest sign. However blanching and trismus were seen only in 11% and 14 % of their patients respectively. In the study done by Khanna and Andrade<sup>(16)</sup> in 1995 where they reviewed 100 cases, 97% of the cases showed signs of trismus, blanching and fibrous brands. Three of the cases had leukoplakic lesions on the dorsum and lateral surface of the tongue, while 5 cases had co-existent ulceroexophytic growth. Three of the patients had a growth involving the retro-molar trigone and buccal mucosa, 1 upper alveolus and 1 the floor of mouth and lower alveolus.

In our study of 30 cases 93.3% of the patients had trismus, 96.6% cases had blanching of mucosa and fibrous bands, 63.3% had fibrosis of faucial pillars, ulceration & vesiculation 60%, restriction of tongue movement 53.3%, and depigmentation of vermillion border 63.3%.

*Inference:*Our study closely concurred with that of Khanna and Andrade in that the most common signs seen were trismus, blanching of mucosa and presence of fibrous bands.

### Distribution of signs based on severity of disease:-

In the study conducted by Khanna and Andrade<sup>(16)</sup> (1995) a total of 100 patients were divided into 3 groups based on the inter-incisal distance(ID). The mild group (ID 26-35mm) had 22 patients. Blanching, trismus, fibrous bands and fibrosis of faucial pillars was seen in 100% of these patients. The moderate (15-25mm) group had 42 patients, while

100% of patients showed blanching, fibrous bands, trismusand fibrosis of faucial pillars; 66% of patients showed depigmentation of vermillion border. The severe group (102-15mm) had 33 patients. Apart from blanching, trismus, fibrous bands, and of faucial pillars; afibrotic ring around Rima oris was also seen in 100% of cases. Restriction of tongue movements and depigmentation of vermillion border were seen in 33% and 72.7% respectively. Leukoplakia was seen in 9% and ulceroexophytic growth in 15% of cases.

In our study of 30 patients the patients were again divided into 3 groups based on inter-incisal distance. The mild group (ID >30 mm) had 3 patients. Blanching was seen in 100% of the cases, 33.3% had trismus, 100% had vesiculation and ulceration, 66.6% of the cases had fibrous bands and fibrosis of faucial pillars. The moderate group (ID 16- 30mm) had 24 patients in which blanching seen in 87.5%, trismus and fibrous bands were seen in 100% of patients. Fibrosis of faucial pillars in 58.3%, and restriction of tongue movements and depigmentation of vermillion border were seen in 50% and 62.5% of the patients respectively. The least common sign in this group was fibrotic ring around Rima oris with 8.33%. In the severe group (ID less than or equal 15mm) with 3 patients, blanching, trismus, fibrous bands , fibrosis of faucial pillars , restriction of tongue movements, ulceration and vesiculation and depigmentation of vermillion border were seen in 100% of patients. In this group 33.3% had fibrotic ring around Rima oris.

*Inference:* Our study is in close concurrence with the Khanna and Andrade study in that, with increasing severity of the disease the incidence of blanching, trismus, fibrous bands and fibrosis of faucial pillars increases.

#### Treatment:-

In their study of 150 patients, D.R. Lai et  $al^{(19)}$  (1995) divided their patients into various groups and treated them on the basis of their inter incisal distance (ID). Fifty patients with moderate severity (ID 20-35mm) were treated with submucosal injections of steroid Dexamethasone+ inj. hyaluronidase combination in addition to the topical triamcinolone and oral multivitamin treatment. Burning sensation, ulceration vesiculation improved in 95% and 90% respectively. Both the mouth opening (83.5%) and blanching (76%) also showed considerable improvement.

Khanna and Andrade<sup>(16)</sup> (1995) in their study of 100 cases treated 25 cases of mild severity (ID 26-35mm) with submucosal injections of triamcinolone. Their results were very encouraging with 92% of patients showing an improvement in burning sensation, ulceration and vesiculation, blanching and mouth opening.

In our study of 30 patients, the patients were divided into 3 groups of 10 patients each. In group A, 10 patients were treated with Inj. Hydrocortisone 50 mg/ml + Inj. Hyaluronidase 1500 IU/ml intraoralsubmucosal injection for 12 Weeks, along with Multivitamin and iron supplementation, oral triamcinolone gel for local application and Mouth opening exercises. These patients showed 100% improvement in burning sensation in mouth on consumption of spicy foods, ulceration &vesiculation, 77.7% improvement in blanching and mouth opening. In group B, 10 patients were treated with Inj. Dexamethasone 4mg/Ml + Inj. Hyaluronidase 1500 IU/ml intraoralsubmucosal injection for 12 Weeks, along with Multivitamin and iron supplementation, oral triamcinolone gel for local application and Mouth opening exercises. These patients showed 90% improvement in burning sensation in mouth on consumption of spicy foods, 66.6% showed improvement in blanching, and 77.7% showed improved mouth opening, and only 75% had improvement in ulceration and vesiculation. In group C, 10 patients were treated with Inj. Triamcinolone 40mg/ml + Inj. Hyaluronidase 1500 IU/ml intraoral submucosal injection for 12 Weeks, along with Multivitamin and iron supplementation. In group C, 10 patients were treated with Inj. Triamcinolone 40mg/ml + Inj. Hyaluronidase 1500 IU/ml intraoral submucosal injection for 12 Weeks, along with Multivitamin and iron supplementation for 12 Weeks, along with Multivitamin and iron supplementation, oral triamcinolone gel for local application and vesiculation. In group C, 10 patients were treated with Inj. Triamcinolone 40mg/ml + Inj. Hyaluronidase 1500 IU/ml intraoral submucosal injection for 12 Weeks, along with Multivitamin and iron supplementation, oral triamcinolone gel for local application and Mouth opening supplementation, oral triamcinolone gel for local application and Mouth opening supplementation, oral triamcinolone gel for local application and Mouth opening exercises. These patients showed 100% improvement in burning sen

*Inference:* It is evident from the from the above discussion that a conservative approach with iron and vitamin supplements antioxidants and physiotherapy alone or in combination with steroids gives encouraging results; especially in reducing symptoms of burning sensation and ulceration and vesiculation. Our study is in concurrence with the D.R. Lai et al series and Khanna and Andrade series in this respect. due to the use of daily massaging and use of the wooden mould by the patients, the use of steroid(Hydrocortisone/Dexamethasone/Triamcinolone)+hyaluronidase combination along with conservative management yielded good results and in this respect both series and our study concur.

#### **Overall results:-**

Majority of our patients had excellent results when compared to the initial symptoms. Burning sensation showed excellent results in all the three groups A,B, C with 100%,90%,and 100% improvement. There was relief from ulceration and vesiculation of 100% of cases in group A and C, compared with 75% in group B. Decrease in fibrous bands had excellent results in 90% of patients in group C, compared to 80% and 66.6% in group A and B respectively. While 90% had good improvement in mouth opening in group C, only 77.7% had improvement in group A & B. Overall results were very significant in group C (95%) and then group A (87%) compared to group B (80%).

## Conclusion

The malady of submucous fibrosis is one of the most poorly understood and unsatisfactorily treated diseases. This is mainly because an exact etiology has not been identified, although considerable data has been accrued over the years in support of the role of areca nut, Symptoms such as burning sensation in the oral cavity and progressive difficulty in mouth opening can be disturbing and distressing to the patient. Innumerable modalities of treatment have been tried ranging from vitamin supplements, topical steroid applications and submucosal steroid injections. We recommended a combination of multi vitamins, iron and topical triamcinolone gel, daily massage of the affected area and submucosal injections of steroids. This achieved a good result, however relapses and recurrences are common, as patients are not amenable to prolonged treatment and regular follow-up, expecting a complete cure within a short period of time. In addition, any form of treatment is required to be coupled with cessation of the pre-disposing factor and daily mouth exercises. A follow up study is required to see long term effects.

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