Medical Treatment Modalities of Oral Sub Mucous Fibrosis

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Abstract Background: The incidence of Oral sub mucous fibrosis disease has been found to about 13% of the general population, varying from 0 to 4% depending on the geographic location, On epidemiological survey shows this disease was found in India especially in southern states with prevalence of 0.36% Ernakulum in Kerala, 0.4% in Srikakulam district in Andra Pradesh, 0.16% in Bhavnagar in Gujarat, 007% in Bihar and 0.03% in Maharashtra. The prime causes suspected are prolonged use of chilly (capsicum), betel nut, tobacco, alcohol, Pan-masala and Pan which are considered to be local factors. This study is one of the pioneer studies in the treatment of oral sub mucous fibrosis. Aim: The purpose of this study to assess the efficacy of the medical treatment modalities of oral sub mucous fibrosis and to evaluate the visceral organ involvement mainly cardiac in oral sub mucous fibrosis. Material and Method: The study consisted of 40 patients suffering from oral sub mucous fibrosis of various grades who were selected from outpatient department of oral medicine and radiology, Tamilnadu government dental college. On first visit of the patient, the selected patients were clinically divided in to various grades based on the clinical grading by Gupta et al. Result: Study was observed, statically proved and that combined therapy employing nutritional and iron supplement with intralesional injection therapy using Hyaluronidase, Dexamethasone, and Placentrex and topical application of Triamcinolone Acetonide 0.1% caused a marked improvement in the patient. Conclusion: patients signs and symptoms evidenced by increase the mouth opening, increase in tongue protrusion, improvement in the patient colour of mucosa. [Jayavelu P et al NJIRM 2011; 3(2): 147-151]

Key Words: Oral sub mucous fibrosis, chronic disease.

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Introduction: Oral sub mucous Fibrosis is a well known clinical entity since the time of sushruta when it was known as Vidari[1]. It has been a subject of controversy ever since SchWartZ[2] described an arcaine and inexplicable Fibrotic condition affecting the oral cavity in 5 Indian women of East Africa in 1952.

Pindborg and Sirsat[3] described oral sub mucous fibrosis as an insidious Chronic disease affecting any part of the oral cavity and sometimes the Pharynx although occasionally preceded by 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 leading to stiffness of oral mucosa and causing trismus and inability to eat.

The management of oral Sub Mucous Fibrosis falls under two broad categories medical and surgical. The medical management includes intralesional injections of hyalouronidase4, hydrocortisone[4], placental extract[5], interferon[6] gamma[6] and topical application of triamcinolone acetonide with systemic intake of vitamins, antioxidants and iron supplements3. The recent medical treatment includes oral administration of milk from cows5 immunized with human intestinal bacteria.

Visceral Organ7 involvement evidenced by systemic fibrosis has not been explored much in oral sub Mucous Fibrosis. The investigations in this aspect were limited to loco regional sites of naso-oropharynx and oesophagus, whether the oral Sub Mucous Fibrosis is a part of the systemic spectrum of disease involving multiple organs is an interesting pursuit.

Material and Methods: This clinical study was carried out in the department of oral medicine and radiology, Tamil Nadu Government dental College and Hospital, Chennai. The study consisted of 40 patients suffering from oral Sub Mucous Fibrosis of various grades who were selected from the outpatient department of oral medicine and Radiology, Tamil Nadu Government Dental College.

On the first visit of the patient all details of patients like name, age, sex, occupation and address was recovered. A detailed complete case history was taken. Routine blood and Urine investigations with a through check-up by a physician along with a cardiovascular investigation like electrocardiography and echocardiography to rule out endomyocardial fibrosis was done. All the findings were recorded in a preformed proforma.

The selected patients were clinically divided in to various grades based on the clinical grading by Gupta Dinesh Chandra's[8], Dolas Rameshwar and Ali Iqbal (1992). The grading was slightly modified for the ease of the treatment as follows.

Clinical Grading:

Grade I: Presence of only blanching of oral mucosa without symptoms.

Grade II: Presence of blanching and burning sensation, dryness of the mouth, Vesicles or ulcers in the mouth.

Grade III: Presence of blanching and burning sensation, dryness of the mouth, vesicles or ulcers in the mouth with restriction of mouth opening and palpable bands all over the mouth without tongue involvement.

Grade IV: Presence of blanching and burning sensation, dryness, of the mouth, vesicles or ulcers in the mouth with restriction of mouth opening and palpable bands all over the mouth with tongue involvement.

Grade V: Presence of all features of grade IV associated with chronic Ulcer and histopathological proven carcinoma.

Grave VI: Cases were not included in the study

The assessment of blanching based on colour of mucosa:[8,9,10]

Score (0): Normal Pink colour
Score (1): Red or deep Pink colour
Score (2): Pale white colour
Score (3): Blanched white colour

As mentioned by katharia S.K. and B.K. Varma, The assessment of presence and absence of burning sensation: [8,9,10]

Score (0): No burning sensation
Score (1): Mild burning sensation
Score (2): Moderate Burning sensation
Score (3): Severe burning sensation.

The assessment of inter incisal distance (Mouth opening) was based on the following grades: [2,8,10]

Grade I : Mouth opening 36 mm (or) above
Grade II: Mouth opening 26 mm to 35 mm
Grade III: Mouth opening 16 mm to 25 mm
Grade IV: Mouth opening 6 mm to 15 mm

The assessment of tongue protrusion was based on the following grades: [8,9,10]

- Grade I : Beyond the border of Lower Lip.
- Grade II : Within the Vermilion border of Lower Lip.
- Grade III: Up to the incisal third of lower mandibular anteriors.
- Grade IV: Cannot protrude, tongue within the floor of mouth

The Cardiovascular assessment [8] for the presence of endomyocardial fibrosis was done based on electrocardiography and echocardiography as highlighted by Rajendran R.[8].The selected and graded cases were subjected to various treatment modalities as done by Gupta Dinesh Chandra S, Dolas Rameshwar and Ali Iqbal [7]. A post treatment analysis, assessment was performed and a follow up of six month was done.

Results: The clinical study consisted of 40 patients. Grade 1 = 10, Grade 2 = 10, Grade 3 = 10, Grade 4 = 10

Age :The mean age in Grade 1 = 38.5, Grade 2 = 35.1, Grade 3 = 38.2, Grade 4 = 33.2, Total mean age was 36.25, the age range was 19 to 61.

Sex: There were 28 males and 12 females constituting about 70 and 30 percent respectively

Pan Variety: 32.5% of the patients used betel nut, 32.5% of the patients used pan masala, 22.5% of the patients used gutka, 5% of the patients used zarda, 7.5% of the patients used others.

Duration: The duration ranged from 1 to 11 years, The mean duration for Grade 1 cases was 4.2 years, The mean duration for Grade 2 cases was 4.2 years, The mean duration for Grade 3 cases

was 6 years, The mean duration for Grade 4 cases was 6.5 years and the total mean duration was calculated to be about 5.22 years.

Colour of Mucosa

Pre treatment	Post treatment
The No of cases of score 0 = 0	= 1
The No of cases of score 1 = 1	= 7
The No of cases of score 2 = 7	= 32
The No of cases of score 3= 32	= 0

The chi square Mcnemar test was used to analyse the improvement of the colour of the mucosa before and after treatment. The following results were derived X2 = 80, p = 0.01 which was found to be statistically significant.

Burning Sensation

Pre treatment	Post treatment
The No of cases of score 0 = 0	= 10
The No of cases of Score 1= 10	= 15
The No of cases of score 2 =15	= 15
The No of cases of score 3=15	= 0

The chi square Menemar test was used to analyse the improvement of the burning sensation of the mucosa before and after treatment. The following results were derived. X2 = 80 p = 0.01 which was found to be statistically significant.

Interincisal Distance: In Grade 3 cases the mean interincisal distance before treatment was 12mm and post treatment was 22mm. In Grade 4 cases the mean interincisal distance before treatment was 17mm and post treatment was 28mm. The average mean increase in interincisal distance was 10mm.

The paired t test was done and the p value was calculated for Grade 3 and Grade 4 cases as p = 0.001 which was found to be statistically significant.

Tongue Protrusion

Pre treatment	Post Treatment
The No of cases of score 0= 0	= 3
The No of cases of score 1= 3	= 6
The No of cases of score 2= 6	= 1
The No of cases of score 3= 1	= 0

The chi square Mcnemar test was used to analysis the improvement of the tongue protrusion before and after treatment. The following results were derived X2 = 20, p = 0.01 which was found to be statistically significant.

Endomyocardialfibrosis: There was no case detected with Endomyocardial fibrosis, all the 40 patients showed negative report. Normal Pink colour

Figures:

GRADE 1 CASE (MOUTH OPENING)

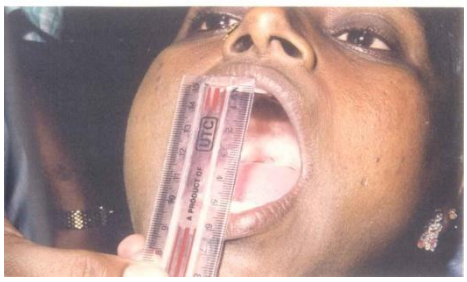

Figure 1

TONGUE PROTRUSION

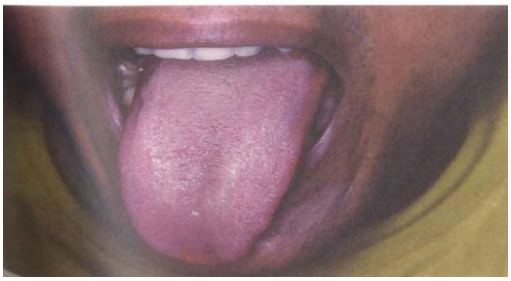

Figure 2a

GRADE-III CASE (PRE TREATMENT RESTRICTED MOUTH OPENING)

Figure 2b

POST TREATMENT MOUTH OPENING

Figure 2c

GRADE IV CASE PRETREATMENT MOUTH OPENING

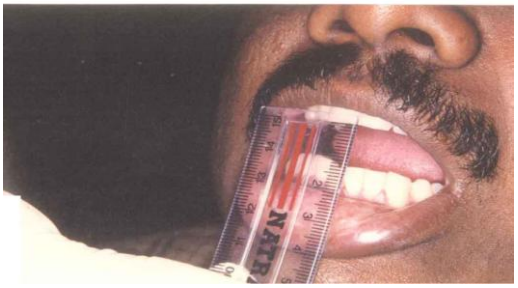

Figure 2d

POST TREATMENT MOUTH OPENING

Figure 2e

Discussion: Oral sub mucous fibrosis is one of the most poorly understood and unsatisfactorily treated diseases. An estimated 2.5 million people suffer from this disease in India. All available treatment gives the patients only symptomatic relief, which is short, lived. This is mainly due to the fact that the etiology of oral sub mucous fibrosis is not fully understood and the disease is progressive in nature. In our clinical study for the ease of treatment the patients were classified into Five Clinical grades namely,

Grade I	Presence of only blanching of oral mucosa without symptoms.
Grade II	Presence of blanching and burning sensation, dryness of the mouth, vesicles or ulcers in the mouth.
Grade III	Presence of blanching and burning sensation, dryness of the mouth, vesicles or ulcers in the mouth with restriction of mouth opening and palpable bands all over the mouth without tongue involvement.
Grade IV	Presence of blanching and burning sensation, dryness of the mouth , vesicles or ulcers in the mouth with restriction of mouth opening and palpable bands all over the mouth with tongue involvement.
Grade V	Presence of all features of grade IV associated with chronic ulcer and histopathologically proven. Carcinoma.

TABLE 1 : Various Medical Treatment Modalities:

	Drug Administered	Dose	Duration	Mode
Grade I	Antioxidants & Multivitamins	1 tab once daily	10 weeks	Orally
	Iron Supplements	1 tab once daily	10 weeks	Orally
	Ointment Triamcinolone Acetonide	0.10%	4 weeks	Topically
Grade II	Antioxidants & Multivitamins (Tablets A to Z)	1 tab once daily	10 weeks	Orally
	Iron Supplements (Cap.Hemfer)	1 tab once daily	10 weeks	Orally
	Ointment Triamcinolone Acetonide	0.10%	8 weeks	Topically
	Inj.Hyaluronidase (Hynidase)	1500 IV	Biweekly for 10 weeks	Intra lesionally in combination
	Inj.Dexamethasone	2 ml	Biweekly for 10 weeks	
	Local Anaesthetic	1 ml 2% without adrenaline	Biweekly for 10 weeks	
Grade III	Antioxidants & Multivitamins	1 tab once daily	10 weeks	Orally

	Iron Supplements (Cap. Hemfer)	1 tab once daily	10 weeks	Orally
	Inj. Placentrex	2 ml	Weekly once for 4 weeks	Intra lesionally (Separately)
	Ointment Triamcinolone Acetonide	0.10%	4 weeks	Topically
	Inj.Hyaluronidase (Hynidase)	1500 IV	Biweekly for 10 weeks	Intra lesionally in combination
Grade IV	Antioxidants & Multivitamins (Tablets A to Z)	1 tab once daily	10 weeks	Orally
	Iron Supplements (Cap.Hemfer)	1 tab once daily	10 weeks	Orally
	Inj. Placentrex	2 ml	weekly once for 4 weeks	Intra lesionally (Separately)
	Ointment Triamcinolone Acetonide	0.10%	4 weeks	Topically

Conclusion: It was observed, statistically proved and concluded that combined therapy employing nutritional and iron supplements with intralesional injection therapy using Hyalouronidase, Dexamethasone, and placentrex in addition to local anaesthetic topical gel and topical application of Triamcinolone Acetonide 0.1% caused a marked improvement in the patients signs and symptoms evidenced by, Decrease in the severity and elimination of burning sensation. Increase in mouth opening. Increase in tongue protrusion Reduction of occurrence of painful vesicles and ulcers. Psychological satisfaction of the patient as a preventive measure against oral cancer was initiated and visceral organ involvement in oral sub mucous fibrosis. Improvement in the patient's colour of mucosa.

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