RESEARCH PAPER



"Oral Submucous Fibrosis Scoring Index" to Predict the Treatment Algorithm in Oral Submucous Fibrosis

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Abstract

Purpose The main aim of the study is to propose a treatment protocol based on scoring system.

Materials and Methods One hundred patients were selected randomly having oral submucous fibrosis. They were classified into five groups based on clinical signs and symptoms, radiological and histopathological grading and severity of fibrosis. Patients of particular group were subjected to specific treatment for each group and followed for 2 years regularly.

Results We found that almost all patients got symptomatic relief and they are able to take regular diet. Patient's interincisal mouth opening increased significantly.

Conclusion Based on this scoring and grouping we can give definite and prompt treatment to the patients with satisfactory results. This proposed scoring and staging can

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play major role in controlling and treating this widespread global disease. Thus, OSMF scoring index is very effective to decide the severity of disease and progress.

Introduction

Oral submucous fibrosis (OSMF) is a chronic, debilitating disease characterised by juxtaepithelial fibrosis of the oral cavity. It is regarded as a precancerous and potentially malignant condition. Oral submucous fibrosis (OSMF) may be defined as an insidious, chronic disease affecting any part of the oral cavity and sometimes the pharynx. Although occasionally preceded by and/or associated with vesicle formation, it is always associated with a juxta-epithelial inflammatory reaction followed by a fibroelastic change of the lamina propria, with epithelial atrophy leading to stiffness of the mucosa and causing trismus and inability to eat [1]. The characteristic features of OSMF are loss of pigmentation, blanching and leathery texture of oral mucosa, depapillation and reduced movement of tongue, progressive reduction of mouth opening and sunken cheeks.

OSMF occurs at any age but is most commonly seen in adolescents and adults especially between 16 and 35 years [2]. The prevalence rate in India is about 0.2–0.5 % [3] with prevalence by gender varying from 0.2 to 2.3 % in males and 1.2 to 4.57 % in females [4] and malignant transformation rate of 7–30 % [5]. The aetiology of OSMF is multifactorial but remains obscure. Although areca nut is considered to be the most important causative agent [3, 6] and responses observed in individuals using areca nut vary in relation to quantity and duration. Once initiated, OSMF is not

 Table 1 Illustrating the mouth opening denominated with letter 'o' and its score

Grade	Mouth opening in mm	Score
Grade I	40-30	1
Grade II	29–20	2
Grade III	<20	3

amenable to reverse at any stage of the disease process even after cessation of the causative factor of areca nut chewing [4]. Because of variable clinical presentation in different patients it is needful to understand the progress and severity. To understand this we propose the scoring index.

In establishment of OSMF scoring index, four parameters like, mouth opening, site involvement in oral cavity, severity and extent of fibrosis and presence of any malignant changes were denominated and depending on the score, it was divided into five groups. The purpose of proposing this OSMF scoring index is to provide uniformity while treating the disease according to the stages depending upon the scoring index.

Materials and Methods

For this study 100 patients suffering from oral submucous fibrosis were randomly selected. The study was approved by Institutional ethical committee. Patients were classified into five different stages based on OSMF scoring index (Table 2). To predict scoring index, OSMF where O—corresponds to interincisal mouth opening, S—involvement of site in the oral cavity, M—malignant changes if any and F denotes severity of fibrous bands. Mouth opening which was denominated by letter 'O' was divided into three groups (Table 1).

Letter 'S' denotes site of involvement in the oral cavity by oral submucous fibrosis. Depending upon the site involvement like, pterygomandibular raphe, buccal mucosa, soft palate, hard palate, tongue, floor of the mouth, five different scores were established Table 2. Letter 'M' denotes presence of any malignant changes associated with oral submucous fibrosis. They were categorized into three groups depending upon their absence or presence and were scored as shown in Table 3.

Letter 'F' denotes the severity of the fibrotic bands which are grouped and were scored as shown in Table 4.

The final scoring for the disease which ranges from 1-13, is the summation of the Score 'O' + Score 'S' + Score 'M' + Score 'F'. Depending on the score it is divided into five groups with a specific score which are as shown in Table 5.

Patients with established malignant lesion (M2) are directly placed in Group V.

One hundred patients suffering from oral submucous fibrosis were selected randomly and categorized into 5 groups. In all the groups, patients were explained about the ill effects areca nut in different forms and its role in development of OSMF. Counseling of all the patients was done for cessation of consuming areca nut or that mixed with other products. Along with stoppage of the habit, nutritional supplements with dietary modifications were done in all the patients along with physiotherapy. Depending upon the score, all patients were placed in different groups and were treated with specific treatment modality (Table 6) as follows:

Group I (OSMF score 1–3): There were 39 patients in this group. They were treated with topical triamcinolone ointment thrice a day on the buccal mucosa and pterygomandibular raphe area, and patients with ulcers were given topical anaesthetic gel for the relief of pain. Multivitamin supplements containing lycopene, beta carotene, alpha carotene, lipoic acid and minerals like zinc and selenium were given twice a day for the effective result.

Group II (OSMF score 6–7): 30 patients were treated with intra-lesional submucosal injections of triamcinolone acetonide (40 mg) and hyaluronidase (1500 IU) with 2% xylocaine at intervals of 15 days for 3–4 months in the affected areas like faucial pillars, retromolar area, and buccal mucosa. Additionally multivitamin supplements and extensive physiotherapy was adviced.

 Table 2 Illustrating the site involvement denominated with letter 'S' and its score

Site	Site involvement in oral cavity	Score
S1	Pterygomandibular raphe area	1
S2a	Pterygomandibular raphe and buccal mucosa (unilateral)	2
S2b	Pterygomandibular raphe and buccal mucosa (bilateral)	3
S 3	Pterygomandibular raphe, buccal mucosa, hard palate, soft palate and lip	4
S4	Pterygomandibular raphe, buccal mucosa, hard palate, soft palate, uvula, lip, floor of mouth and tongue	5

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 Table 3
 Illustrating the
 malignant changes denominated with letter 'M' and its score

Malignant changes	Presence or absence of malignant changes	Score
M0	Absence of any malignant changes	0
M1	Presence of mild to moderate dysplasia	1
M2	Presence of established malignant disease	2

Table 4	Illustrating the type of
fibrotic b	ands denominated with
letter 'F'	and its score

Fibrotic bands	Type of fibrotic bands	Score
F1	Mild fibrosis with normal elasticity of mucosa	1
F2	Mottled and marble like mucosa with moderate widespread sheet	2
F3	Thick broad fibrous bands and immovable mucosa	3

Table 5 OSMF scoring index

OSMF score	Groups	Mouth opening (O)	Site (S)	Presence of malignant feature (clinical and histopathological) (M)	Severity of fibrosis (F		
1–3	Group I	O1	S1	M0	F1		
6–7	Group II	O2	S2a	M0	F2		
			S2b				
9–10	Group III	03	S2b	M0	F3		
			S 3				
11-12	Group IV	03	S 3	M1	F3		
			S4				
13	Group V	O3	S4	M2	F3		

Table 6 Illustrating the groupsand their respective scores	Groups		
-	Ι		
	II		

Groups	Score
Ι	1–3
II	6–7
III	9–10
IV	11-12
V	13

Group III (OSMF score with 9-10): 17 patients belonging to this group were treated by surgical intervention in the form of fibrotomy to remove fibrous band, bilateral coronoidectomy, extractions of all third molars. Nasolabial flap or buccal fat pad was used to cover the fibrotomy defect.

Group IV (OSMF score with 11-12): 10 patients of this group were subjected to surgical intervention in the form of fibrotomy, bilateral coronoidectomy, extractions of all third molars, nasolabial and buccal fat pad to cover the fibrotomy defect as in group III. But additionally the presence of any hyperkeratotic and mild dysplastic lesions was excised.

Group V (OSMF score with 13): 4 patients of oral submucous fibrosis with advanced established malignant disease were treated with definitive radical surgical treatment with neck dissection and removal of lesion followed by radiotherapy.

All these patients were followed up for 2 years.

Results

According to particular group based on OSMF scoring index, all the patients were subjected to specific treatment as mentioned in the methodology. They were followed up for 2 years and showed satisfactory result as mentioned below (Tables 7, 8):

Group I: Almost all the patients of this group showed marked relief of symptoms after 3 months.With vigorous physiotherapy, patients achieved increase in the interincisal mouth opening in mean range of 5-6 mm in 3 month. Patients were kept under close observation for 2 years at regular interval to check the post treatment relapse and recurrence of symptoms

Groups	No. of patients		Improvements of sympt	oms	The decrease in the interincisal	
			Burning sensation (%)	Stomatitis (%)	Trismus (%)	distance in the range of 3–5 mm after 2 years of follow up
I	39	1st month	76.92	71.79	79.48	No
		3rd month	89.74	87.17	84.66	
		6th month	100	100	100	
II	30	1st month	90	83.33	80	20 %
		3rd month	96.66	90	93.33	
		6th month	100	100	100	

Table 7 Illustration of results for Group I and Group II

Group II: All the patients responded favorably and showed improvement in the clinical picture. There was an increase in mouth opening in mean range of 5–6 mm and regression of recurrent stomatitis, ulceration and burning sensation at the end of 6 months.

Group III: In general, surgical treatment resulted in significant improvement of trismus in patients with severe limitation of mouth opening (<20 mm). Buccal fat pad used for covering the surgical defect of fibrotomy revealed satisfactory healing within 2–3 weeks after surgery giving a good mucosalization with minimum morbidity whereas nasolabial flap took more time for epithelization. During 2 years of follow up, the interincisal mouth opening was declined by 5–10 mm postoperatively.

Group IV: Patients of this group were treated with excision of the lesion associated with OSMF along with surgical management for oral submucous fibrosis. Decrease in the interincisal mouth opening by 5–10 mm was observed during 2 years follow up.

Group V: All patients of this group were treated successfully with good results. Though no recurrence in any of the patients was noticed during 2 years of follow up, decrease in the mouth opening in majority of the patients was evident.

Discussion

Oral submucous fibrosis (OSMF) is a chronic, debilitating disease characterized by juxtaepithelial fibrosis of the oral cavity. It is regarded as a precancerous and potentially malignant condition. Oral submucous fibrosis is a disease of extensive fibrosis of juxta-epithelial tissue of the oral mucosa. Previously it was considered as a disease of Indian subcontinent [7] because of its high occurrence and confinement of the disease with South-East Asia. Because of the popularity and easy availability of the betel nut and its products the disease has broken all the borders of the region and the age of occurrence. So once known as disease of Indian subcontinent it has now spread all over the world with increasing rate of occurrence. Though by initial appearance of the sign and symptoms of the disease the condition seems to be benign, it has high malignant transformation potential. Its premalignant nature was first described by Paymaster in 1956 [8].

The oral submucous fibrosis is the disease of fibrosis resulting from disturbed metabolism of the collagen fibers secreted by the fibroblast of the sub epithelial connective tissue of the oral mucosa. Its pathogenesis is still not fully understood. There is compelling evidence that the arecanut has a primary role in the development of OSMF, but it has yet to be elucidated. The patient affected with oral submucous fibrosis reported with wide range of symptoms like burning sensation and stomatitis, stiffness of the mucosa, reduced mouth opening or trismus, altered speech and in advanced stages hearing impairment due to eustachian tube involvement, nasal twang with swellings and proliferative growths. Also the fibrosis may involve one part of the oral cavity or more than one at the same time like buccal mucosa, soft palate, hard palate, tongue, etc. So the patient with oral submucous fibrosis reports with different clinical presentation at different stages which demands the need of one definite system to determine the stage of the disease so as to evaluate the severity of disease and its effective management. Though the disease has a long history of more than 600 BC, the treatment for the condition is still only symptomatic. To implement accurate and curative treatment and prevent its further transformation into lethal malignant condition, it is imperative to diagnose and stage this disease at proper time. The disease is of obscure etiology so the main line of treatment is symptomatic relief only which varies with the stage of the

	The decrease in the interincisal distance in	the range of 3-3 mm after 2 years of follow up (%)	23.52			30			25		
	Intra-	operative mouth opening	30-40 mm			30-40 mm			30-40 mm		
	Mode of treatment		Fibrotomy, coronoidectomy, all 3rd molar extraction and covering the defect with various flaps			Excision of lesion, Fibrotomy, coronoidectomy, all 3rd molar extraction and covering the defect with various flaps			Excision of lesion with effective safety margin with neck dissection		
d Group V	suic	Trismus (%)	100	100	100	100	100	100	100	100	100
Group IV an	nts of sympto	Stomatitis (%)	88.23	94.11	100	70	80	100	50	75	100
Group III,	Improveme	Burning sensation (%)	76.47	88.23	100	60	70	100	75	100	100
n of result of			1st month	3rd month	6th month	1st month	3rd month	6th month	1st month	3rd month	6th month
Illustratio	No of	pauents	17			10			04		
Table 8	Groups		Ш			IV			>		

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disease. Various attempts have been made to classify this disease entity according to trismus and interincisal mouth opening with the symptoms, site of involvement and association of the disease with other premalignant conditions. But till date no classification system can give the idea of the site, severity, progress and its association with malignancy. This study proposes a system which can give all the above mentioned detailed features of the disease, its various stages and specific treatment protocol for each stage. It is an attempt to propose the group of disease considering all aspects of the disease including range of mouth opening, site of involvement by fibrosis, its association with other premalignant conditions and malignant transformation and severity of fibrosis.

As far as the involvement of the site is concerned there is variation in its location and number. In this study, the most common site for involvement by fibrosis was pterygomandibular raphe area followed by buccal mucosa, hard and soft palate respectively. In few cases unilateral involvement was noted illustrating the localized effect of the betel nut and its products on the mucosa to which it was subjected for the longer period of time [9]. Accordingly the involved site/sites in the oral cavity by fibrosis were scored and denominated with regards to site involvement and its progression.

The severity of trismus can be assessed with measurement of interincisal mouth opening. As the severity of fibrosis increases there is progressive reduction in the mouth opening, which not only affects the speech but also occlusal chewing efficiency of the patient thereby making patient more debilitating.

The next criteria considered for scoring is the severity of fibrosis. The fibrosis sets the base for all the symptoms we come across, so there is need to understand its extension. In initial mild fibrosis, symptoms are insignificant while they become more aggressive as fibrosis advances. So we scored fibrosis into three different grades.

In severe cases of oral submucous fibrosis there is marked trismus, which adversely affects the patient from the point of view of his regular diet and nutrition. Secondarily this leads to imbalanced food intake, various nutritional deficiencies, restricted or completely immovable buccal mucosa and other oral tissues make difficulty in maintaining oral hygiene, loss of vascular supply to the involved region and hyperplastic or dysplastic changes may lead to malignant changes in the mucosa. Presence of other premalignant conditions makes mucosa more prone to undergo dysplastic changes.

Taking into consideration four factors i.e. mouth opening, involvement of site and its number, severity of fibrosis and malignant changes if any, a new scoring index was proposed to decide the stage and severity of the disease. Depending upon the particular score, five different groups have been set according to the disease progression. We used these staging criteria in treatment and set a new algorithm in the management of oral submucous fibrosis.

This study included 100 patients who were divided into five groups. All the patients were followed up for 2 years on regular basis. Of these 100 patients, Group I (score 1-3) 39 patients were treated with topical triamcinolone ointment thrice a day and multivitamin supplements containing of lycopene, beta carotene, alpha carotene, lipoic acid and minerals like zinc and selenium. Satisfactory increase in mouth opening of about 3-4 mm within 6 months was noted. In Group II, 30 patients (score of 6-7) were treated with intralesional submucosal injections of triamcinolone acetonide (40 mg) and hyaluronidase (1500 IU) [10] with 2 % xylocaine at intervals of 15 days for 3-4 months in the affected areas. An average increase of mouth opening by 6-7 mm was observed in 6 months. Group III (score 9-10) and Group IV (score 11-12), 27 patients were treated with surgical management. In this surgical management, patients were treated by surgical intervention in the form of fibrotomy to remove fibrous band, bilateral coronoidectomy, extractions of all third molars. Nasolabial flap or buccal fat pad was used to cover the fibrotomy defect. In about 90 % of the cases satisfactory result with increased mouth opening and improvement in chewing was observed. In Group V, 4 patients were treated with radical surgery consisting of excision of the lesion using safety margin as well as neck dissection, without any recurrence for 2 years follow up.

This particular study is based on the proposed OSMF scoring index system. As treatment depends upon various staging, it gives uniform approach which is more effective as it involves all sites of the oral cavity. This scoring index system provides 5 stages and particular treatment for each stage helps to decide the particular treatment for better result and better prognosis.

This study shows that it is very effective to classify patient progress and severity of the disease with the scoring criteria mentioned above. This scoring criteria is used to implement different treatment options available effectively. So we are proposing an OSMF scoring index for staging of the oral submucous fibrosis and treatment algorithm according to the scoring index for prompt and effective treatment. This will help us to diagnose, control and manage this worldwide spreading disease more effectively with proper understanding and satisfactory results.

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