

Clinical evaluation of different treatment methods for OSMF: A five-year experience with 144 cases

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Abstract

Introduction: Oral submucous fibrosis (OSMF) is chronic, insidious, debilitating condition of oral cavity and sometimes pharynx, characterized by progressive hyalinization of juxtaepithelial tissue and progressive fibrosis of the oral cavity. It is a premalignant disease. The repeated ulceration in mouth and the progressive reduction of mouth opening is very debilitating to the patient. The disease once occurs does not reverse. None of the modalities provide the complete remission of the disease and are aimed at improving the functions of the mouth like chewing and opening of mouth.

Aims and Objectives: The aim of this study is to establish a treatment protocol for OSMF depending on the stage of the disease. As the disease has multiple stages, a single treatment modality is not adequate for the treatment. The treatment has to be devised according to the symptoms of the patient and the stage of the disease.

Materials and Methods: It is a retrospective study done on 144 patients who are followed up for six months. The treatment was done depending on the stage of disease and the outcomes were evaluated.

Results: The cessation of the arecanut chewing habits and regular physiotherapy is a single most important factor for the success of treatment. Noninvasive treatment methods give good results with patient in stage I and Stage II disease. In our institute, single stage pedicled nasolabial flap worked well for the patients in stage III and Stage IV disease. The good mouth opening was achieved even in patients with mouth opening less than 5mm.

Conclusion: The proposed protocol is very effective in treating patients with OSMF. The medicinal treatment is effective in patients with mouth opening more than 20 mm. It helps in the resolution of symptoms and improvement of mouth opening. However, in severe cases with mouth opening less than 20mm, surgical treatment is required. Among the surgical treatments used by us single stage pedicled nasolabial flap gave the best results.

Keywords: Treatment protocol, Arecanut, Fibrosis.

Introduction

Oral submucous fibrosis (OSMF) is chronic, insidious, debilitating condition of oral cavity and sometimes pharynx, characterized by progressive hyalinization of juxtaepithelial tissue and progressive fibrosis of the oral cavity. This precancerous condition is caused by betelnut chewing and is mainly endemic to the Asian subcontinent.^{1,2} Arecanut is identified as group one carcinogen by International Agency for research on cancer (IARC).³⁻⁵ OSMF has a high malignant transformation rate of 7-30%.¹⁻⁵ A variety of treatment modalities are suggested.⁴⁻⁶ 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.⁷ The suggested pathogenesis is the arecoline and flavonoid, components of areca nut when exposed to buccal mucosal fibroblast results in the accumulation of collagen. Reduced collagenase activity and increased cross-linking of the fibers results in decreased degradation of collagen. This evidence implies that OSF may be considered a collagen-metabolic disorder resulting from exposure to areca nut. OSMF occurs at any age but is most commonly seen in adolescents and adults especially between 16 and 35 years.⁸ The prevalence rate in India is about 0.2–0.5%⁹ with prevalence by gender varying from 0.2 to

2.3% in males and 1.2 to 4.57% in females.¹⁰ None of the modalities provide the complete remission of the disease and are aimed at improving the functions of the mouth like chewing and opening of mouth.

Aims and Objectives

The aim of this study is to establish a treatment protocol for OSMF depending on the stage of the disease. As the disease has multiple stages, a single treatment modality is not adequate for the treatment. The treatment has to be devised according to the symptoms of the patient and the stage of the disease.

Our protocol to address the OSMF was as follows:

1. Stop the areca nut, betel quid and any other tobacco habits
2. Medicinal treatment with lycopene 16 mg per day for three months for the patient with mouth opening more than 20mm
3. Surgical treatment for patients with mouth opening less than 20mm.

Material and Methods

The study was approved by institutional review board and the protocol complied with the world medical association declaration of helinski. 144 patients with OSMF were included in this study.

The patients were divided in to five groups based on the interincisal mouth opening and clinical presentation.

Stage I: Mouth opening – 35 to 45mm, burning sensation in mouth

Stage II: Mouth opening – 25 to 35mm, mottled and marble like appearance of buccal mucosa and involvement of soft palate and faucial pillars.

Stage III: Mouth opening – 15 to 25mm, palpable vertical fibrous bands in buccal mucosa, soft palate, pterygomandibular raphae, lips.

Stage IVa: Mouth opening – < 15mm, thickend fauces, shrunken fibrous bud like uvula.

Stage IVb: Mouth opening – <15mm with premalignant changes or malignancy.

Pre-operative evaluation: Among 144 patients, 63 were in stage I, 39 were in stage II, 32 were in stage III, 8 in stage IVa and 2 in stage IVb. There were 79 females and 65 males (Table 1).

Table 1

Stage	No. of patients	Gender distribution
I	63	Male 18, Female 45
II	39	Male 23, Female 16
III	32	Male 15, Female 17
IVa	8	Male 7, Female 1
IVb	2	Male 2

Table 3

Type of Intervention	No. of patients	Mean increase in mouth opening	Mean resolution of symptoms according to visual analogue scale used by patient	Recurrence
Non-surgical with lycopene	112	6mm	Mean increase of 4 points as compared to preoperative score	38 patients
Double stage inferiorly based nasolabial flap	6	11mm	Mean increase of 2 points as compared to preoperative score	4 patients
Buccal pad flap	7	10mm	Mean increase of 1 points as compared to preoperative score	3 patients
Tongue flap	2	6mm	Same as before	2 patients
Skin grafting	2	7mm	Mean increase of 1 points as compared to preoperative score	2 patients
Lasers	7	8mm	Same as before	7 patients
Single stage nasolabial flap	8	21mm	Mean increase of 6 points as compared to preoperative score	None

Discussion

The treatment of Oral submucous fibrosis is mainly aimed at relieving the symptoms of the disease and to detect the malignant changes at the early stage.

Nonsurgical treatment was done in 112 cases. Surgical intervention was done in 32 of cases. Among 32 cases, 6 were treated with double stage nasolabial flap, 7 with buccal fat pad, 2 with tongue flap, 2 with skin grafting, 7 with lasers and 8 with single stage pedicled nasolabial flap (Table 2).

Table 2: Type of surgical intervention done

Type of surgical intervention	No. of cases
Nasolabial flap double stage	6
Buccal fat pad	7
Tongue flap	2
Skin grafting	2
Laser	7
Single stage nasolabial flap	8

Results

Among the patient treated with different modalities, there was 100% recurrences in patients treated with skin graft, tongue graft and lasers, 66.66% recurrences in patient treated with double stage nasolabial flap, 42.85% recurrences in patient treated with Bucca fat pad flap and 33.92% recurrences with nonsurgical intervention with lycopene. We did not have any cases of recurrences with single stage pedicled nasolabial flap. Maximum mean increase of mouth opening and maximum patient satisfaction was with single stage pedicled nasolabial flap (Table 3).

Previously it was considered as a disease of Indian subcontinent¹¹ 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 1956.¹² A variety of surgical and nonsurgical treatment modalities have been suggested in literature. Habit cessation is considered a single most important factor for the resolution of symptoms of OSMF. Nonsurgical methods mainly use antioxidants and are reserved for initial mild cases. Lycopene is a potent antioxidant and has been shown to have potent benefits in oral premalignant lesions where it has been shown to modulate dysplastic changes. The mean increases in mouth opening with the use of antioxidant only was around 6mm. Out of 112 patients treated, 38 patients had relapse of symptoms and mouth opening due to non-compliance with habit cessation and postop physiotherapy. In a study done by Abhinav Kumar.⁴ They found that the increase in mouth opening after using lycopene was statistically significant and lycopene should be used as first line treatment for the patients with oral submucous fibrosis. In surgical treatments, the excision of fibrous bands with split thickness skin grafting, buccal fat pad grafting, tongue graft, nasolabial flap and free flaps have been used. The results of split thickness skin grafting have been very disappointing because of postoperative contracture of graft during healing period, in our cases too we had severe relapse with the skin grafts. In our centre we did not get good results with the buccal fat pad grafting and tongue flaps also. Though, the buccal fat pad is easily accessible, the amount of graft available is highly variable and many a times insufficient, it also undergoes atrophy. The BFP also heals by secondary epithelization which leads to relapse of the mouth opening achieved. Adeyemo et al reported that major hurdles included the rather limited reach of the flap for coverage of the anterior regions of the oral cavity, the chances of damage to the parotid papilla and duct during harvesting and secondary infection in the post-operative phases.¹³ The tongue is usually involved by the disease and the transfer of this tissue did not give a good postoperative mouth opening, also the second surgery added to the discomfort of the patient. Apart from the short-term morbidity of the donor site in terms of speech and mastication, post-operative fibrosis and constriction of tongue mass can have deleterious effects on the lifestyle of the patient. Kamath VV in their systematic review reported that the most important factor against usage of a tongue flap, or for that matter any intraoral flap, is the possibility of the donor area being afflicted with the disease process.¹⁴ Chaudhry, Z., Gupta, S.R. & Oberoi, S.S. reported that lasers can provide an alternative and better means for surgical fibrotomy in moderate OSMF as they are

minimally invasive and have the advantage of short operating time, less hemorrhage, faster healing, less morbidity, less surgical-site scarring and relapse,¹⁵ in our cases we could get only around 8mm of increasing mouth opening which too underwent some relapse. Before we were doing a two-stage nasolabial flap and sometimes we had failures because of strangulation of the pedicle leading to the fibrosis of flap. It was also uncomfortable for the patients to undergo two surgeries. The use of the nasolabial flap for repair of orofacial defects is well established. Apart from the easy accessibility, the availability of a healthy vascular pedicle based on the inferior nasal vessels and the possibility of using this flap to cover almost all regions in the oral cavity make it a well justified choice for the treatment of OSMF. Shah and Tauro did a clinical and histological study to determine the faith of nasolabial flap and concluded that it is a reliable and versatile flap for reconstruction in cases with OSMF.¹⁴ In addition, the non-involvement of the flap in the disease condition is an advantage.^{14,16} The pedicled single stage nasolabial flap has minimal chances of strangulation of feeder vessel, postoperative mouth opening is maintained and comparatively more comfortable for the patient. The only complication is minimal postoperative scar which was acceptable for most of the patients.

Conclusion

The proposed protocol is very effective in treating patients with OSMF. The medicinal treatment is effective in patients with mouth opening more than 20 mm. It helps in the resolution of symptoms and improvement of mouth opening. However, in severe cases with mouth opening less than 20mm, surgical treatment is required. Among the surgical treatments used by us single stage pedicled nasolabial flap gave the best results. In our series we did not use the free flaps because of the complexity of the procedure and the special equipment required which are not readily available. The cessation of arecanut chewing habit remains the mainstay of any treatment protocol and considered as a major factor leading to relapse. Patient counselling to abstain from the habit and to continue the physiotherapy is required to maintain the mouth opening achieved. The understanding of patient of progressive nature of the disease and the possible complications does motivate the patient to cooperate with the treatment.

Compliance with ethical standards

Funding: None

Conflict of interest: Author declares there is no conflict of interest.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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