

Efficacy of Muscle Relaxants in Routine Treatment Protocol of OSMF: A Pilot Study

Aparna Upadhye Chavan* and Gajanan Namdeorao Chavan

Department of Anesthesia, Jawaharlal Nehru Medical College, Maharashtra, India

*Corresponding author: Gajanan Namdeorao Chavan, Associate Professor, Department of Anesthesia, Jawaharlal Nehru Medical College, Sawangi Meghe, Wardha, Maharashtra, India, Tel: 917694014955; E-mail: gcgcnny@gmail.com

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Abstract

Oral submucous fibrosis is a chronic disorder presenting with the plagues symptoms of burning sensation in mouth, intolerance to spicy food and progressive trismus. OSMF is insidious in onset characterized by fibrosis of the lining mucosa of the upper digestive tract involving the oral cavity, oropharynx and hypopharynx and the upper third of oesophagus. The fibrosis involves the lamina propria and the submucosa and may extend into the underlying musculature resulting in the deposition of dense fibrous bands, resulting in limited mouth opening. It is widely prevalent in all age groups and across all socioeconomic strata in India. OSMF is etiologically related to chewing of areca nut [betel nut] and its commercial products, a habit prevalent in India and South-East Asia. This increasing prevalence is not only our concern but its treatment challenges is also our concern. Though a benign disease, the frequency of malignant change in patients with OSMF ranges from 3% to 6%. We have various established treatment modalities available, medical and surgical both. But the results vary. Hence after understanding its etiopathogenesis and reviewing various treatment modalities, we planned to carry out the study to find out the efficacy of muscle relaxants to treat OSMF.

Keywords: Oral submucous fibrosis; Epidemiological trends; Muscle relaxants

Introduction

Oral submucous fibrosis is a chronic disorder presenting with the plagues symptoms of burning sensation in mouth, intolerance to spicy food and progressive trismus. OSMF is insidious in onset characterized by fibrosis of the lining mucosa of the upper digestive tract involving the oral cavity, oropharynx and hypopharynx and the upper third of oesophagus. The fibrosis involves the lamina propria and the submucosa and may extend into the underlying musculature resulting in the deposition of dense fibrous bands, resulting in limited mouth opening [1]. It is widely prevalent in all age groups and across all socioeconomic strata in India. OSMF is etiologically related to chewing of areca nut [betel nut] and its commercial products, a habit prevalent in India and South-East Asia [2].

This increasing prevalence is not only our concern but its treatment challenges is also our concern. Though a benign disease, the frequency of malignant change in patients with OSMF ranges from 3% to 6% [3]. We have various established treatment modalities available, medical and surgical both. But the results vary. Rooban et al. [4], in their light microscopic study of OSF revealed varying degrees of alterations involving the muscle fibres as the disease progresses.

Trismus could not only due to muscle fibrosis but also due to inflammatory spasm. This spasm could be relieved by muscle relaxant [5]. Hence after understanding its etiopathogenesis and reviewing various treatment modalities, we planned to carry out the study to find out the efficacy of muscle relaxants to treat OSMF [6].

Aims and Objectives

To study the efficacy of muscle relaxants [chlorzoxazone] in the routine treatment protocol of OSMF.

To study the epidemiological trends in the patients with oral submucous fibrosis in our region.

Materials and Methods

The present study was conducted on 40 patients with OSMF, attending as outpatients in the department of ENT, JNMC, Sawangi [Meghe], Maharashtra, after getting approval from Institutional ethical committee. At the beginning of the study, the mouth opening [interincisional distance of maxillary and mandibular incisors at maximum possible mouth opening] was measured with the help of vernier calipers and graded as follows [6].

Grade 1 [>40 mm], Grade 2 [20–39 mm], Grade 3 [<19 mm].

Inclusion criteria:

Patients of OSMF with grade II and III.

Patients coming for regular follow up.

Extension criteria:

OSMF patients with grade I disease.

Patients who lost follow up.

Patients with trismus other than OSMF.

These 40 patients were randomly divided into two groups. 20 patients of these underwent the routine treatment protocol of weekly injection of hyaluronidase with hydrocortisone and antioxidant

capsules with added lycopene for 1 month. This group was labelled as control group.

The remaining 20 patients, in addition to the routine injections and antioxidants, were given skeletal muscle relaxants like chlorzoxazone. This group was labelled as case group.

This measurement was repeated after the study period of 1 month.

Data analysis

The required data was collected and analyzed by using unpaired t-test.

Observations

Sex distribution

Among 40 patients, only 3 patients were females. Amongst these 3 females, only 1 female had habit of chewing tobacco and commercial preparation of areca nut. This explains that apart from areca nuts, there are some other factors contributing to OSMF. Nutritional deficiency or immunological factor can be attributed to cause OSMF. These findings have been shown in Table 1.

Group	Males	Females	Total
Case	18	2	20
Control	19	1	20

Table 1: Sex distribution.

Age distribution

Usually OSMF is prevalent in age group of 20 to 40 years. In our study group, 31 patients [77.5%] were in 20 to 40 years of age group. The youngest patient in this study was 8 years old male child. He did not have any habits related to areca nut or tobacco chewing.

This explains that apart from habits, nutrition, autoimmune factors and genetics also may play role in causation of disease. The other two male patients, who were 14 and 16 years old, had positive history of commercial preparation of areca nut and kharra. Kharra, which is different from ghutka, is locally made preparation of tobacco, areca nut, lime and masala.

Group	1-10 yrs	11-20 yrs	21-30	31-40	Above 40	Total
Case	1	4	10	5	0	20
Control	0	3	10	6	1	20

Table 2: Age wise distribution of patients.

Amongst 40 patients, 37 patients [92.5%] had positive history of chewing areca nut in one form or the other. This explains the strong association of areca nut and OSMF. The following Table 2 shows the age wise distribution of the patients.

After one month study, Mouth Opening [MO] was measured with vernier callipers and the findings observed are shown in Table 3.

The Table 4 shows the mouth opening noted in control group before and after the treatment.

S. No.	MO before treatment	MO after treatment	Overall improvement
1	25	40	15
2	23	38	15
3	26	38	12
4	22	39	17
5	21	40	19
6	25	39	14
7	27	39	12
8	28	38	10
9	25	38	13
10	22	39	17
11	14	23	9
12	15	23	8
13	18	24	6
14	16	22	6
15	16	23	7
16	17	21	5
17	15	24	9
18	15	19	4
19	19	24	5
20	16	24	8

Table 3: Mouth opening [MO] noted in tests subjects.

S. No.	MO before treatment	MO after treatment	Overall improvement
1	29	35	4
2	23	27	4
3	24	31	7
4	21	29	8
5	24	26	2
6	25	24	1
7	20	25	5
8	25	26	1
9	27	24	3
10	26	22	4
11	19	24	5
12	14	18	4
13	16	24	8

14	15	16	1
15	19	18	Progression
16	18	20	2
17	15	18	3
18	14	17	Progression
19	16	19	3
20	14	16	2

Table 4: Mouth opening [MO] noted in control subjects.

In two cases, amongst the control group, we noticed the progression of disease. They came for regular treatment and follow up. Though they had stopped commercial preparations and tobacco, they continued with chewing plain areca nut.

From above observations, following overall improvement in mouth opening after the treatment was noted this has been tabulated in Table 5.

Group [Control]	Overall improvement [control]	Overall improvement [cases]
Grade 2	5.8	14.4
Grade 3	3	6

Table 5: Average overall improvement in mouth opening [in mm].

In our study, we found that group II [case] and group II [control] has significant difference in mean value [t=7.549, P=0.00], this means that the improvement in group II [cases] is significantly more than group II [controls]. This means that patients were benefitted with muscle relaxants.

Group III [case] and group III [control] has significant difference in mean value [t=3.72, P=0.001], this means that the improvement in case- grade III is significantly more than controls. This again proves the efficacy of muscle relaxants, when added to the routine treatment protocol.

The improvement in grade III cases is significantly higher than grade III controls.

Discussion

OSMF was mentioned by Sushruta [2500-3000 BC] as Vidari in ancient Indian literature. Later In modern literature it was described by Schwartz in 1952. Since then enormous research is going on to study its etiopathogenesis, epidemiological trends, clinical features, treatment, etc.

Even today, in spite of so much of research, OSMF poses a challenge in various aspects.

OSMF is etiologically related to chewing of areca nut [betel nut] and its commercial products, a habit prevalent in India and South-East Asia. This habit is not only popular in urban population but also becoming popular among rural adolescents too. The increased prevalence of OSMF in the last two decades or so corresponds with the increased processing and commercialization of areca nut products, like

ghutka, kharra, masala supari, etc. It is a chronic disorder characterized by fibrosis of the lining mucosa of the upper digestive tract involving the oral cavity, oro- and hypopharynx and the upper third of oesophagus. The fibrosis involves the lamina propria and the submucosa and may extend into the underlying musculature resulting in the deposition of dense fibrous bands, resulting in limited mouth opening. It also results from increased production of collagen by fibroblasts. In addition to this there is decreased breakdown leading to accumulation of excessive amount of collagen. The pre-cancerous nature was first described by Paymaster in 1956 that was later confirmed by various studies. A malignant transformation rate was shown to be in the range of 7 to 13% and a transformation rate of 4.5% was reported by Murti et al. [7]. Previous data indicated that the prevalence of OSMF was in the range of 0.03% to 3.2%. The prevalence of OSMF was 6.3% was mentioned by Nitin et al. [8]. The incidence is progressively increasing owing to the excessive usage of areca nut among various groups of population. Oral submucous fibrosis is widely prevalent in all age groups and across all socioeconomic strata in India. Younger generations in India are getting attracted to the advent of attractive

The main problems plaguing the patients with OSF are the burning sensation and progressive trismus which impedes normal function. The treatment should aim at alleviating the symptoms as well as try to stop the progression of fibrosis. But, whatever the treatment method may be, the first step of preventive measure should be in discontinuation of habit, which can be encouraged through education, counselling and advocacy [9,10]. This was the first challenge in our study. Patients needed very intense and continuous motivation to quit the habit and come for treatment and follow up.

In spite of increasing prevalence, there are no known effective treatments for OSF till date. The treatment modalities which are currently being used can be broadly divided into three main categories, viz.: Medical therapy, surgical therapy and physiotherapy [11,12].

When literature was reviewed for various treatment modalities, we came across the study regarding use of muscle relaxants. After studying various literature and researches regarding pathophysiology of OSMF, we decided to find out the efficacy of muscle relaxants in the routine protocol of treatment of oral submucosal fibrosis which we thought will probably help us to alleviate the symptom of trismus.

In our study, we found that muscle relaxants were effective in treating OSMS, if they were added to routine treatment protocol. In fact they were more effective in grade II cases rather than grade III cases. This means that if muscle relaxants are added at early stage of the disease, patient will be benefitted more. Probably in grade II cases muscles relaxants helps to relieve muscle spasm caused by the inflammation facilitating mouth opening. The major drawback of this study was none of the patient consented for biopsy, whatever hard we tried to convince. So we could not study the histopathological changes occurring before study and after study. Medications works better with discontinuation of the habit. This explains the role of areca nut in etiopathogenesis of OSMF. Severe cases of trismus may need surgical intervention to break the extensive and tough fibrous bands. Thus patient counselling; motivation and education to quit habit, forms the important part of the treatment [13]. Apart from ghutka, we across new and locally made preparation of beetle nut and tobacco called "kharra" in Maharashtra which is found to be equally hazardous. We would like to continue our research further with stem cell therapy [14].

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