



A Clinico-Demographic Evaluation of Patients with Oral Submucous Fibrosis: a Cross Sectional Study

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Authors' contributions

This work was carried out in collaboration among all authors. Author ABM designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors AAUR and KAC managed the analyses of the study. Author NK managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Aim: To evaluate the Clinico-Demographic variables in patients of Oral Submucous Fibrosis
Study Design: Descriptive Cross Sectional
Place and Duration of Study: Department of Oral and Maxillofacial Surgery, Liaquat Medical University Hospital from December 2017 to February 2019.
Methodology: The recruitment of patients was done after the clinical diagnosis of oral sub mucous fibrosis (OSMF) patients. The demographic information and associated factors were recorded on the proforma. Mouth opening (MO) was measured between upper and lower central incisors with vernier caliper. Burning sensation (BS) and pain were measured using Visual Analog Scale (VAS). The data were analyzed by SPSS Version-16.

Results: Male and female were (66%) and (34%) respectively. The mean age was 41.04±11.24. The frequency of gutka usage was 44% and 43% followed by betel nut as 21% and 23% in functional stages as per Inter Incisal Mouth Opening (IIMO-2) and (IIMO-3) respectively. The BS was shown as severe 49% and 40% followed by moderate as 32% and 37% in functional stages IIMO-2 and IIMO-3 respectively whereas pain was shown as severe 82% and 18% and as moderate 63% and 37% in functional stage M2 and M3 respectively showed statistically significant relationship ($p=0.041$).

Conclusion: Males were more affected and middle aged patients were more involved. Majority of patients were using gutka and had 3rd functional stage of mouth opening. The burning sensation and pain were the most common clinical complains. There was significant relationship of functional stages with pain.

Keywords: Pre malignant lesions; oral sub mucous fibrosis; smokeless tobacco products; demographic, functional Staging.

ABBREVIATIONS

BS	:	Burning Sensation
IIMO	:	Inter Incisal Mouth Opening
MO	:	Mouth Opening
OSMF	:	Oral Sub Mucous Fibrosis
SES	:	Socio Economic Status
SLT	:	Smokeless Tobacco
VAS	:	Visual Analogue Scale

1. INTRODUCTION

Oral sub mucous fibrosis is an epidemiological problem affecting majority of population of subcontinent including Pakistan, where the number of patients is increasing by the time [1]. The type of smokeless tobacco (SLT) product, areca nut with or without tobacco is being considered as established cause of oral cancer, but epidemiological studies do not support that only areca nut can be the cause [2-4]. The most common chewing SLT products are gutka, chalia, paan and naswar in Pakistan and south Asian subcontinent. The use of these products is acceptable and deemed it as a cultural practice in our country [3]. The incidence of OSMF is common in both genders [3-4]. Study conducted in Karachi shows higher consumption of betel quid among boys than girls [4]. Teenagers and youths are getting more attracted to commercially available SLT products due to wide publicity, marketing and easy availability in markets [5].

The consumption of smoked tobacco products is high in Pakistan. The frequency of increased use of certain products is linked with socio-demographic profiles [6]. There are always more chances of development of oral cancer in those peoples who consume betel quid with tobacco as compared to without tobacco [7]. Migration of

such peoples to other parts of the world has made it a public health issue. Pre malignant lesion like OSMF can transform into squamous-cell carcinoma, in a range of 7 to 13% [1].

OSMF patients have complained of stiffness in the oral cavity which limits mouth opening and cause difficulty in movement of tongue; subsequently encounter difficulties in eating, speaking, and swallowing [8]. Peoples consume SLT products, alcohol and smoking for getting rid from stressful condition. These deleterious habits do harm to peoples. In day-to-day clinical practice medical practitioners and dental surgeons often encounter a wide spectrum of oral mucosal alterations might be due to consumption of such products.

Keeping in view the OSMF as malignant potential disorder and increased consumption of SLT products in population of Pakistan, the present study was conducted to determine clinical profile like mouth opening, burning sensation, pain associated with lesion and demographic variables like age gender, habits etc among the patients suffering from OSMF patients so that the policies and focused interventions can be developed to control the use of smoked and SLT products.

2. MATERIALS AND METHODS

This cross sectional study was conducted from December 2017 to February 2019 at the Department of Oral & Maxillofacial Surgery, Liaquat University of Medical and Health Sciences Jamshoro. Total 112 patients were recruited using the convenient sampling technique. The recruitment of patients was done after the clinical diagnosis of OSMF patients by two maxillofacial surgeons. The inclusion criteria of the study were patients of either gender,

patients greater than 18 years, patients not receiving treatment for OSMF. The exclusion criteria were patients having other causes of limited mouth opening (Temporo-Mandibular Problems or pericoronitis, scleroderma, burns), patients with any other mucosal disease, and patients with psychiatric illness.

2.1 Data Collection Procedure

All patients were diagnosed clinically by two maxillofacial surgeons having clinical experience of more than five years. In case of disagreement, 3rd opinion was taken from the oral & maxillofacial surgeon.

The following clinical features were used for the classification of OSMF. OSMF was based on severity of the disease with functional staging [9].

M1: Inter incisal mouth opening (IIMO) \geq 35 mm.
M2: IIMO from 25-35 mm.
M3: IIMO from 15-25 mm.
M4: IIMO \leq 15 mm.

However the patients having IIMO between 25-35 and 15-25 were included in this study.

The MO was measured from the central incisor of upper jaw to central incisor of lower jaw with maximum mouth open using vernier calipers (Kawasaki, Japan). BS and pain associated with lesion was measured using VAS.

The demographic information like age, gender, ethnicity, marital status, household income and education were recorded on proforma. A detailed history of the disease and associated factors such as habit history, duration, frequency and kind of SLT products used were recorded. Moreover, smoking history was also recorded.

Data were analyzed using SPSS version 16. Qualitative variables (i.e. gender, ethnicity, age categories and OSMF stages) were presented as frequency and percentage. The quantitative variables (i.e. age, frequency and duration of habits) were presented as Mean \pm SD. The chi square test was applied to check the relationship of clinico-demographic variables. Probability value of \leq 0.05 was considered to be significant.

3. RESULTS

The mean age was 41.04 \pm 11.24. The age was categorized in three groups. The Single and married were (28%) and (72%) respectively. The majority of patients were Muhajirs (54.5%) followed by Sindhi (19%) and Punjabi (12.5%).

The education level was as primary (21%), matric (20.5%) and intermediate (20.5%). Socio economic status (SES) was categorized as Very low SES 50% followed by Low SES 31% and Moderate 19%. The average duration and frequency of chewing was 8.8 years and 7.4 per day respectively. Smoking history was positive in 21% patients (Table 1).

Male and female were (66%) and (34%) respectively. According to functional staging the MO was categorized as IIMO-2: from 25-35 mm 27% IIMO-3: from 15-25 mm 73%. There was insignificant association between gender and functional stage of MO ($p = .595$) (Fig. 1).

Habit of chewing products data showed that 44% patients were consuming gutka followed by 21% betel nut. The frequency of gutka usage was 44% and 43% followed by betel nut as 21% and 23% in functional stages IIMO-2 and IIMO-3 respectively showed insignificant relationship ($p = .983$) (Fig. 2).

The Intensity of BS observed as severe 49% and 40% followed by moderate as 32% and 37% in functional stage IIMO-2 and IIMO-3 respectively showed insignificant relationship (Table 2).

Pain observed as severe 82% and 18% and as moderate 63% and 37% in functional stage IIMO-2 and IIMO-3 respectively showed statistically significant relationship (Table 3).

4. DISCUSSION

OSMF is prevalent disease of subcontinent where chewing of SLT products has increased gradually. In spite of very high prevalence of OSMF in Pakistan; the evidence based studies are very scant to highlight this pre-cancerous disease and public issue.

Males (66%) were more affected than females (34%) with the ratio of 1.9:1 similar to results of Sinor et al. [10] and Shahid H et al. [11]. Males were dominated because they use gutka and other ST products more due to easy availability, whereas females consume less products because they are bound at homes and have not that much access outside.

The majority of OSMF patients were in the age category of 31-50 years (61%) which is in agreement with the Study of Pindborg JJ [12]. However our results are not in agreement with study results of Shahid H et al. [11] and Agrawal et al. [13] in which the peak age for same

patients were 20-29 and 21-30 years respectively [11,13]. The reason for increased consumption at middle age may be the controlled and the restriction sale of SLT in youngsters or may be the delayed effect of products and may also be the late arousal of symptoms.

In this study it was evident that 44% patients were consuming gutka followed by 21% betel nut is similar with the findings of Shah PH, Sharma R et al. [14] and Selvam et al. whereas in other study 95% patients were using areca nut which strongly supports that gutka, betel nut and areca nut with or without tobacco causes OSMF [14-17]. The majority of the OSMF patients had used commercially available smoked or SLT products may be due to the easy availability, low cost, more advertisement by manufacturing companies of such products [18-19]. SES or level of education did not seem to affect the

choice of product in this study 50% patients were from very low SES and majority of educated patients having level of education at 10th, 12th standard, graduated and post graduated were also engaged in using SLT products.

The average duration and frequency of chewing was 8.8 years and 7.4 per day respectively are not similar with the results of Yadav M et al. [20] who showed the average duration and frequency as 5.4 years and 4.5 per day respectively [20]. The duration and frequency of chewing habit has a definite role in increased severity of developing OSMF.

Majority of patients in this study were not habitual smokers, it might be due to more consumption of SLT products or may be not affording due to very low SES. Smoking consumption alone is not as harmful as used with SLT products [21].

Table 1. Descriptive statistics of demographic characteristics

Characteristics	Frequency	Percent
Age of patients		
18-30 Years	24	21.4
31-50 Years	68	60.7
> 50 Years	20	17.9
Mean Age	41.04±11.24	
Marital Status		
Single	32	27.7
Married	80	72.3
Ethnicity		
Sindhi	21	18.5
Punjabi	14	12.5
Balouchi	12	10.7
Muhajir	61	54.5
Pakhtun	4	3.6
Education		
No Education	14	12.4
Primary	24	21.4
Matric	23	20.5
Inter	23	20.5
Graduation	10	8.9
Masters	13	11.6
Madarsa taleem	5	4.5
Socio economic status (SES)		
Very Low SES<15000 Rs	56	50
Low SES 15000–30000 Rs	35	31.2
Moderate SES 30000–50000 Rs	21	18.8
Smokeless Tobacco Chewing Habits		
Average frequency per day	7.48±2.32	
Smoking Status		
Yes	24	21.4
No	88	78.6
Average duration (year)	8.88±5.42	

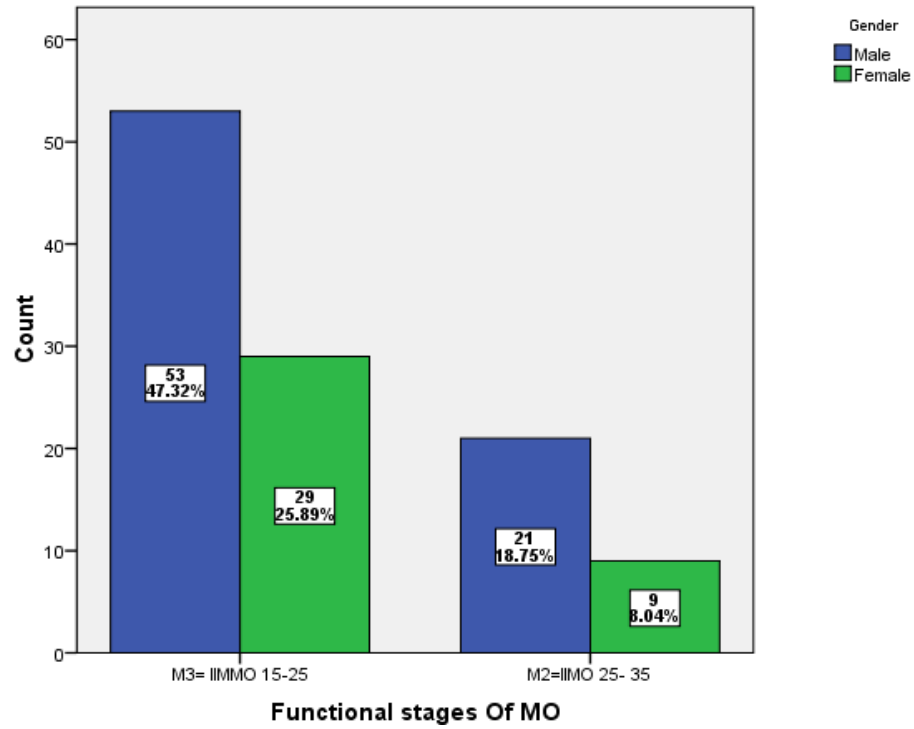


Fig.1. Relationship of functional stages with gender $p= .595$

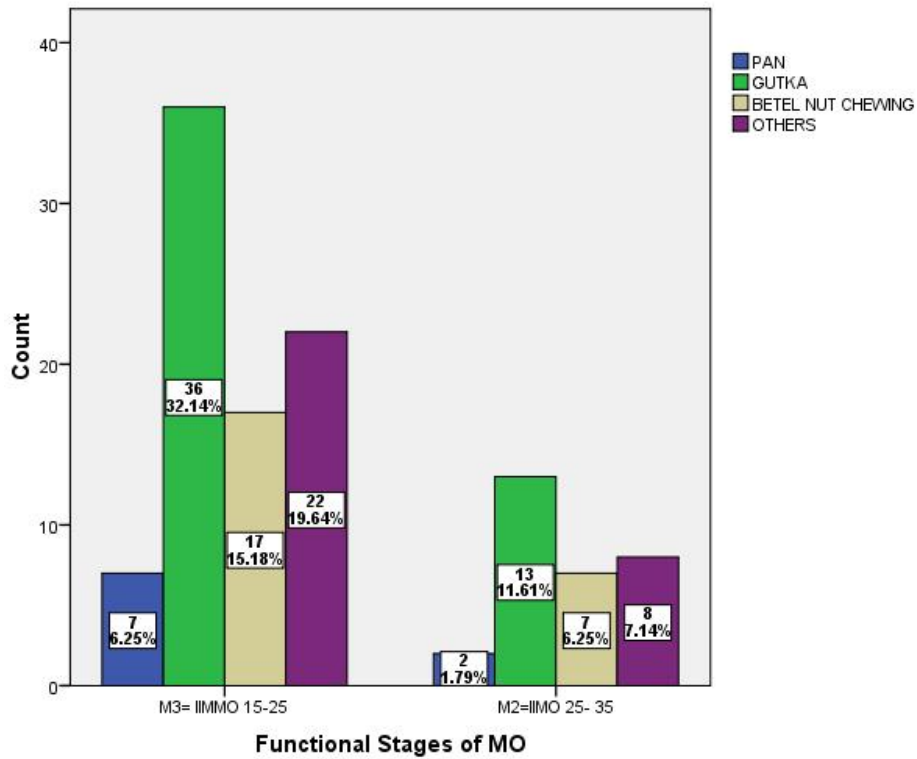


Fig. 2. Relationship of functional stages with chewing habits

Table 2. Relationship of functional stages with Burning sensation

Mouth Opening	Burning Sensation				Total	p= value
	None	Mild	Moderate	Severe		
Mouth Opening 15-25 (IIMO-2)	7 8.5%	9 11%	26 31.7%	40 48.8%	82 100%	.876
Mouth Opening 25-35 (IIMO-3)	3 10%	4 13.3%	11 36.7%	12 40%	30 100%	
Total	10 8.9%	13 11.6%	37 33%	52 46.4%	112 100.0%	

Table 3. Relationship of functional stages with Pain

Mouth Opening	Intensity of Pain		Total	p= value
	Moderate	severe		
Mouth Opening 15-25	15 18.3%	67 81.7%	82 100%	.041*
Mouth Opening 25- 35	11 36.7%	19 63.3%	30 100%	
Total	26 32.2%	86 76.8%	112 100.0%	

The functional staging was not significant with respect to gender ($p=.595$). Majority of patients were in stage-3 according to functional stage of MO followed by stage-2 whereas Nigam NK et al. [18] observed stage-1 disease (45%) was common followed by Stage-2 (30%) and Stage 3 (25%) [18]. This difference could be due to the fact that only 2 stages were analyzed in this study. In our study, patients consuming gutka showed high occurrence of stage 2 and stage 3 whereas Ali FM et al. [22] observed Grade III and Grade IV cases in the subjects consuming gutkha only or areca nut only [22]. The occurrence of OSMF was not significant ($p=.983$) in the patients who consumed SLT in one or other form.

In our study, 73% had MO from 15-25 mm and 27% had 25-35 mm whereas Kiran Kumar et al. [23] observed as 7% patients had MO >40 mm, 76% had MO from 20-40 mm and 17% patients had MO < 20 mm. This variation might be due to the difference in cut off defined for IIMO in both studies [23]. The complain of BS in the patients of this study was 91% which is in agreement with the study results of Morawetz et al. [24] and Wahab N et al. [25] who also reported the BS as a major complain [24-25].

Pain associated with lesion was present in all patients included in this study whereas Nigam NK et al. [18] reported 62% patients had pain. The patients were feeling pain during eating and mouth opening [18]. The difference might be due to the setting of study, as this study was

institutional and other one was community based.

5. CONCLUSION

Males were more affected. Middle age group i.e 31-50 was common. Majority of patients were using gutka. Third functional stage of MO was most common. The BS and pain were the most common clinical complains felt as severe by the patients. There was significant relationship of functional stage with pain. Considering the OSMF as a common pre-malignant disorder and increased consumption of SLT products and smoking in population of Pakistan, the health education programs should be arranged to aware the public regarding the hazards of tobacco which is considered as the main culprit for development of pre malignant and malignant conditions. Focused interventions, and preventive measures using media as well as personal campaign should be developed and introduced to control the use of smoked and SLT products particularly among adolescents and younger people. The government and stake holders should plan more strictly to stop the sale and increase the tax to many folds on such hazardous products

CONSENT

The written informed consent was taken from each patient prior to study. The confidentiality was maintained.

ETHICAL APPROVAL

The ethical permission was sought from the Ethical Review Committee (ERC) of the LUMHS, Jamshoro, Pakistan. In addition, departmental permission was also sought from the Chairman, Department of Oral and Maxillofacial Surgery of the same university (NO.LUMHS/REC/-640 dated 26-12-2017).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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