Original Research Article

A demographic study of clinically diagnosed patients of oral submucous fibrosis visiting ENT outpatient department of a tertiary care hospital in Muzaffarnagar district, Uttar Pradesh, India

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ABSTRACT

Background: Oral submucous fibrosis is a premalignant condition affecting the oral cavity. It is characterized by fibrosis of the submucosal tissues, leading to restricted mouth opening, dryness, burning sensation etc. It causes significant mortality after its transformation into squamous cell carcinoma (SCC). It has now become a global health concern.

Methods: The study was conducted amongst the patients aged 18-65 years who visited the ENT OPD of Muzaffarnagar Medical College with oral lesions from 01 January 2024 to 30 June 2024 (6 months). Of these patients that were clinically diagnosed with oral submucous fibrosis (OSMF), were given a detailed questionnaire and further studied. It was a hospital based cross sectional study conducted by Department of ENT and HNS, Muzaffarnagar Medical College and Hospital.

Results: Of the 120 cases clinically diagnosed cases of OSMF. Mean age was 42.7 years. Most patients were in 4th and 5th decade of life and specifically in 31-40-years age range. Male to female ratio was 3.61: 1. Most patients came from rural areas. Gutkha was the most commonly used habit in these patients. M2 was the most common stage at which the patients visited the hospital. Muslims were predominant in the study population.

Conclusions: OSMF is an irreversible process, it has been linked to habitual consumption of betel nut, due to its high prevalence, special emphasis should be given towards its prevention and awareness. Also, due to its increased risk of malignant transformation, prompt cessation of the particular etiological agent and early management of the disease is required. Primary healthcare professionals and dentists should be familiar with its clinical presentation, diagnosis and management.

Keywords: OSF, OSMF, Oral lesions, Oral disease, Fibrosis, Betel nut, Areca nut, Tobacco, Mouth opening, Burning sensation

INTRODUCTION

Oral submucous fibrosis (OSMF) stands as a significant challenge in oral healthcare, marked by its insidious onset, relentless progression, and profound impact on oral function and patients' quality of life. This chronic, pre malignant disorder predominantly affects the oral mucosa, marked by fibrosis of the submucosal tissues, leading to restriction of mouth opening, dryness, burning sensation, mucosal rigidity, and increased risk of malignant transformation. While initially prevalent in regions where betel nut chewing is customary, OSMF has now emerged as a global health concern, transcending geographical boundaries and cultural practices.

The aetiology of OSMF is intricate, involving a complex interplay of genetic predisposition, environmental factors, and habitual behaviours. The habitual consumption of

areca nut, often in the form of betel quid, pan masala, gutkha etc. remains the foremost risk factor, compounded by the synergistic effects of tobacco, slaked lime and other additives. However, the exact mechanisms underlying fibrosis initiation and progression in OSMF are yet to be fully elucidated, underscoring the need for continued research into its pathogenesis. OSF leads to substantial health issues and can result in a high mortality rate if it progresses to squamous cell carcinoma (SCC). Management of OSF involves a comprehensive approach that includes prevention, early detection, and treatment of complications to address the disease effectively.

The combination of areca nut or betel nut and tobacco leaf has led to a sharp increase in the frequency of OSMF.[1]

OSMF is characterized by chronic fibrotic changes within the oral mucosa that produces scars, and precancerous lesions. This condition predominantly affects the buccal mucosa.[2,3]

OSF is characterized by abnormal collagen deposition. Symptoms include submucous fibrosis, ulceration, xerostomia, a burning sensation, and restricted mouth opening.[4]

The frequency of OSMF differs with ethnicity and religion and is closely linked with diet, habits, and culture.[5-7]

India has the largest population of OSMF patients worldwide but, this disease is also common in other Asian countries.[8,9]

More than 5 million patients are affected with OSMF worldwide according to World Health Organization (WHO).[10,11]

OSMF is caused by various factors including autoimmunity, deficiency of vitamin B, C, and iron. It is also caused by chewing betel nut, consuming spicy foods, human papilloma virus (HPV) infection, and genetic mutations.[12-16]

Aim and objectives

The aim of this study is to perform a cross sectional study which consists of collecting and assessing data such as mean age, gender distribution, residence distribution, habit distribution and distribution according to stage of clinically diagnosed patients of OSMF visiting ENT OPD of a Medical College in Muzaffarnagar district, Uttar Pradesh.

This data can further be used to better understand the disease so that it can be diagnosed earlier and better treatment modalities can be researched upon.

This demographic study will help us in focusing on the target population, so that more awareness can be created amongst those exposed or those at risk.

Also, this data can help justify the allocation of resources and funding to areas with the greatest need, supporting more effective public health strategies.

METHODS

Study design and place

It was a hospital based cross sectional study which was done at the Department of ENT and HNS, Muzaffarnagar Medical College and Hospital, Muzaffarnagar, Uttar Pradesh, a tertiary care hospital.

Study population

All patients clinically diagnosed with OSMF were included in the study population.

Study duration

The study was conducted for a duration of 6 months starting from 01 January 2024 to 30 June 2024.

Sample size

Total 120 patients were included in this study according to the below given inclusion and exclusion criteria.

Sampling technique

No fixed number of cases was decided for the study. All the patients presenting with oral lesions and related symptoms were sent to the OPD of the concerned unit. After taking an informed written consent (also in their local language), such cases were screened for inclusion and exclusion criteria. Only those patients who gave their consent and fulfilled the criteria were taken into the study, Thus, a total of 120 patients were taken for the study.

Statistical method and tools used in the study

Data obtained was entered into Microsoft excel spreadsheet and exported to data editor of statistical package for the social sciences (SPSS) version 23. Categorical variables were described as frequencies and percentages. Continuous variables were described as mean and standard deviation. Chi square test was used to analyze the relationship between two categorical variables and t test was used to compare two continuous variables. Appropriate graphics like pie chart, bar chart and box plots were used to describe and present the data. A p value of <0.5 was considered as statistically significant. Analysis was done using SPSS.

Inclusion criteria

Subjects above 18 years up to 65 years of age with clinically diagnosed OSMF were selected for the study.

Exclusion criteria

Pregnant and breast feeding women, subjects with previous treatment history for OSMF, with any collagen diseases or immune mediated disorders, history of head and neck tumors, breast cancer and gastric cancer, prior neoplastic surgeries and cancer metastases, and subjects with immunocompromised immune system such as human immune-deficiency virus (HIV), and diabetes mellitus were excluded.

Study procedure

The study was conducted in Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh on outdoor patients of ENT and HNS Department by following inclusion and exclusion criteria, history taking, and relevant clinical examinations.

All patients were further divided into four groups based upon the habit or type of substance used by them - habit A: betel nut/betel quid/pan/pan masala/gutkha (contains areca nut or betel nut, with or without tobacco); habit B: khaini/zarda/chewing tobacco (does not contain areca nut or betel nut, may or may not contain lime, or smokeless tobacco); habit C: smoking (beedi/cigarette/cigar/hookah, or smoking tobacco); and habit D: more than one form of any of the above habits. For the group subjects the following criteria were considered for the clinical diagnosis of OSF: clinically evident blanching and pallor, palpable fibrous bands, restricted mouth opening (<35 mm), and burning sensation in mouth.

Staging

Functional staging included - M1: inter-incisional mouth opening up to or greater than 35 mm, M2: inter-incisional mouth opening between 25 and 35 mm, M3: inter-incisional mouth opening between 15 and 25 mm, and M4: inter-incisional mouth opening less than 15 mm.[17]

RESULTS

The mean age in the study population is 42.87 years, with the age range starting from 19 years of age up to 65 years of age. The SD for age is 13 years. Also, it can be interpreted that OSMF is more common in later stages of life i.e. 4th and 5th decades of life. Most were in 31–40-year age group (Table 1).

Table 1: Age distribution.

Age (in years)	N
Minimum	19
Maximum	65
Mean	42.87
Standard deviation	13

Out of the total 108 subjects, 86 were males and 22 were females. Male: female ratio was 3.9: 1. Clearly indicating predominance for OSMF in males (Table 2).

Table 2: Gender distribution.

Gender	Frequency	Percentage
Male	86	79.6
Female	22	20.4
Total	108	100

Out of the total 108 subjects, 69 belonged to rural areas and 39 belonged to urban areas. Rural: urban ratio was 1.76: 1. Clearly indicating a predominance of OSMF in rural areas (Table 3).

Table 3: Residence distribution.

Residence	Frequency	Percentage
Urban	39	36.1
Rural	69	63.9
Total	108	100

Most common habit in this study was habit A, followed by habit C and D, and lastly habit B. Also, in habit A the most commonly used substance was gutkha (Table 4).

For reference - habit A: betel nut/betel quid/pan/pan masala/gutkha (contains areca nut or betel nut, with or without tobacco); habit B: khaini/zarda/chewing tobacco (does not contain areca nut or betel nut, may or may not contain lime, or smokeless tobacco); habit C: smoking (beedi/cigarette/cigar/hookah, or smoking tobacco); and habit D: more than one form of any of the above habits.

Table 4: Habit distribution.

Habit	Frequency	Percentage
A	33	30.55
B	17	15.74
C	29	26.85
D	29	26.85
Total	108	100

In this study the most common stage at which the patients came to visit the OPD was M2, followed by M3 and M4, and lastly M1 (Table 5).

For reference - M1: inter-incisional mouth opening up to or greater than 35 mm, M2: inter-incisional mouth opening between 25 and 35 mm, M3: inter-incisional mouth opening between 15 and 25 mm, and M4: inter-incisional mouth opening less than 15 mm.

Out of the 108 subjects, 67 were Muslims and 41 were Hindus (Table 6).

Table 5: Distribution according to stage.

Stage	Frequency	Percentage
M1	18	16.66
M2	35	32.4
M3	27	25
M4	27	25
Total	108	100

Table 6: Distribution according to religion.

Religion	Frequency	Percentage
Hindu	41	38
Muslim	67	62
Total	108	100

DISCUSSION

Age distribution

The inclusion criteria for this study was 18-65 years of age. Youngest patient was 19 years and the eldest was 65 years of age. The mean age in group A is 43.47 years, mean age in group B is 43.60 years, mean age in group C is 39.47 years, mean age in group D is 44.27 years. Mean age of all the participants regardless of their groups is 42.7 years. Most patients were in 4th and 5th decade of life and specifically, most were in 31-40-years age group.

In a study showing similarity with our study, done by Cai et al in 2019, namely, "oral submucous fibrosis: a clinicopathological study of 674 cases in China in 2019". The age range was 16-67 years, the mean age was 35.23±10.08 years old and OSF was most frequent in the age range of 30-39 years (33.68%).[18]

In a study showing similarity with our study, done by Ariyawardana et al in 2005, namely, "conservative management of oral submucous fibrosis". Mean age for the 43 patients included in the study was 43.4 years.[19]

Gender distribution

In our study out of the total 60 participants 47 are males and 13 are females. Male: female ratio is 3.61: 1, which clearly suggests a male predominance.

In a study showing similarity with our study, done by Hazarey et al in 2007, namely, "oral submucous fibrosis: study of 1000 cases from central India". The male-to-female ratio of OSF was 4.9: 1, which also suggests a male predominance.[20]

In a study showing similarity with our study, done by Rai et al in 2017, namely, "conservative management of oral submucous fibrosis in early and intermediate stage". Out of 48 patients, 9 were females showing the predominance of males (81.2%).[21]

Residence distribution

In our study out of the total 60 patients, 38 patients came from rural areas and 22 patients came from urban areas. The rural: urban ratio in our study is 1.72: 1, showing a predominance of rural patients. In a study showing similarity with our study, done by Rela et al in 2018, namely, "oral submucous fibrosis: clinical study". Maximum number of patients were residing in rural areas (63%) with rural: urban ratio of 1.7:1 and there was no significant difference in M: F in rural (1.42:1) and urban (1.46:1).[22]

Habit distribution

In our study out of the total 60 participants, habit A is the most used habit with 18 patients, followed by habit C and D with 16 patients each and group D is the least used with 10 patients only. Also, in habit A the most used substance was gutkha.

In a study showing similarity with our study, done by Nigam et al in 2013, namely, "prevalence of oral submucous fibrosis among habitual gutkha and areca nut chewers in Moradabad district". Out of 63 OSMF patients, 42 (66.66%) were gutkha chewers, 14 (22.22%) were pan chewers and 7 (11.11%) were areca nut chewers.[23]

Distribution according to stage

In our study out of the total 60 participants, M2 is the most common stage at which the patients came to the hospital for treatment. This was followed by M3 and M4 with 15 patients each and M1 is the least common with 10 patients only.

In a study showing similarity with our study, done by Rai et al in 2018, namely, "conservative management of oral submucous fibrosis in early and intermediate stage". Out of 72 patients, 48 were finally included in the study, the mean age of the patients was 32.2 years (range: 19–65). The mean duration of habit was 5.7 years (range: 1–25). 27 patients were in stage II (mouth opening: 26–35 mm) and 21 patients were in stage III (mouth opening: 15–25 mm).[24]

In a study showing similarity with our study, done by Kumar et al in 2016, namely, "oral submucous fibrosis: a demographic study". Of the 1006 cases of OSF studied, 422 (41.94%) cases were stage II. Two hundred and twenty-six (22.29%) were stage IV, 184 (18.29%) stage III, and 174 (17.29%) stage I.[25]

Distribution according to religion

In our study Out of the 108 subjects, 67 were Muslims and 41 were Hindus.

In contrast to our study, a study done by Raina et al in 2005, namely, "clinical profile and serum beta-carotene

levels in oral submucous fibrosis". Out of the 100 patients, there were 91 Hindus and 9 Muslims. This may be due to the fact that there is predominance of Muslim population in rural areas of Muzaffarnagar where our tertiary hospital exists.[26]

Limitations

The study only reflects the characteristics, behaviors, or health outcomes of patients within that particular hospital, which may not represent the broader population. Also, results may be specific to the region or demographic served by that hospital, and may not be applicable to other regions or countries.

CONCLUSION

OSMF is an irreversible process, and due to its high prevalence, stress should be given towards its prevention and awareness. Also, due to its increased risk of malignant transformation, prompt cessation of the particular etiological agent and management of the disease is required. Primary healthcare professionals and dentists should be familiar with its clinical presentation, diagnosis and management.

It is recommended that a similar study with a larger sample size is required for further research in the treatment of OSMF.

Also, focus should be given to the amount, duration and frequency of the particular etiological agent that caused OSMF in the first place.

New laws should be formulated by the governments to discourage and even ban surrogate advertisements indirectly promoting the substances leading to OSMF.

REFERENCES

1. Haider SM, Merchant AT, Fikree FF, Rahbar MH. Clinical and functional staging of oral submucous fibrosis. Br J Oral Maxillofac Surg. 2000;38(1):12-5.
2. Dionne KR, Warnakulasuriya S, Zain RB, Cheong SC. Potentially malignant disorders of the oral cavity: Current practice and future directions in the clinic and laboratory. Int J Cancer. 2015;136:503-15.
3. Chole RH, Gondivkar SM, Gadbail AR, Balsaraf S, Chaudhary S, Dhore SV, et al. Review of drug treatment of oral submucous fibrosis. Oral Oncol. 2012;48(5):393-8.
4. Shih YH, Wang TH, Shieh TM, Tseng YH. Oral Submucous Fibrosis: A Review on Etiopathogenesis, Diagnosis, and Therapy. Int J Mol Sci. 2019;20(12):2940.
5. Zhang X, Reichart PA. A review of betel quid chewing, oral cancer and precancer in Mainland China. Oral Oncol. 2007;43:424-30.
6. Tilakaratne WM, Ekanayaka RP, Warnakulasuriya S. Oral submucous fibrosis: a historical perspective and a review on etiology and pathogenesis. Oral Surg Oral Med Oral Pathol Oral Radiol. 2016;122(2):178-91.
7. Chattopadhyay A, Ray JG. Molecular Pathology of Malignant Transformation of Oral Submucous Fibrosis. J Environ Pathol Toxicol Oncol. 2016;35(3):193-205.
8. Chang MC, Chiang CP, Lin CL, Lee JJ, Hahn LJ, Jeng JH. Cell-mediated immunity and head and neck cancer: with special emphasis on betel quid chewing habit. Oral Oncol. 2005;41(8):757-75.
9. Cox SC, Walker DM. Oral submucous fibrosis. A review. Aust Dent J. 1996;41:294-9.
10. Nigam NK, Aravinda K, Dhillon M, Gupta S, Reddy S, Srinivas Raju M. Prevalence of oral submucous fibrosis among habitual gutkha and areca nut chewers in Moradabad district. J Oral Biol Craniofac Res. 2014;4(1):8-13.
11. Gottipamula S, Sundarrajan S, Moorthy A, Padmanabhan S, N Sridhar K. Buccal Mucosal Epithelial Cells Downregulate CTGF Expression in Buccal Submucosal Fibrosis Fibroblasts. J Maxillofac Oral Surg. 2018;17(2):254-9.
12. Balakrishnan C, Aswath N. Estimation of serum, salivary immunoglobulin G, immunoglobulin A levels and total protein, hemoglobin in smokeless tobacco chewers and oral submucous fibrosis patients. Contemp Clin Dent. 2015;6:S157-62.
13. Arakeri G, Rai KK, Hunasgi S, Merkx MAW, Gao S, Brennan PA. Oral submucous fibrosis: An update on current theories of pathogenesis. J Oral Pathol Med. 2017;46(6):406-12.
14. Guruprasad R, Nair PP, Singh M, Singh M, Singh M, Jain A. Serum vitamin c and iron levels in oral submucous fibrosis. Indian J Dent. 2014;5(2):81-5.
15. Wang YP, Wu YC, Cheng SJ, Chen HM, Sun A, Chang JY. High frequencies of vitamin B12 and folic acid deficiencies and gastric parietal cell antibody positivity in oral submucous fibrosis patients. J Formos Med Assoc. 2015;114(9):813-9.
16. Tilakaratne WM, Klinikowski MF, Saku T, Peters TJ, Warnakulasuriya S. Oral submucous fibrosis: review on aetiology and pathogenesis. Oral Oncol. 2006;42(6):561-8.
17. More C, Gupta S, Joshi J, Verma S. Classification System for Oral Submucous Fibrosis. J Indian Acad Oral Med Radiol. 2012;24:24-9.
18. Cai X, Yao Z, Liu G, Cui L, Li H, Huang J. Oral submucous fibrosis: A clinicopathological study of 674 cases in China. J Oral Pathol Med. 2019;48:321-5.
19. Ariyawardana A, Nawagamuwa T, Ranasinghe AW, Sitheeque M, Vithanaarachchi N. Conservative Management of Oral Submucous Fibrosis. Asian J Oral Maxillofac Surg. 2005;17(1):26-30.

20. Hazarey VK, Erlewad DM, Mundhe KA, Ughade SN. Oral submucous fibrosis: study of 1000 cases from central India. J Oral Pathol Med. 2007;36(1):12-7.
21. Rai S, Rattan V, Gupta A, Kumar P. Conservative management of Oral Submucous Fibrosis in early and intermediate stage. J Oral Biol Craniofac Res. 2018;8(2):86-8.
22. Rela R, Dongarwar GR. Oral submucous fibrosis: Clinical study. Int J Appl Dent Sci. 2018;4(4):302-4.
23. Nigam NK, Aravinda K, Dhillon M, Gupta S, Reddy S, Srinivas Raju M. Prevalence of oral submucous fibrosis among habitual gutkha and areca nut chewers in Moradabad district. J Oral Biol Craniofac Res. 2014;4(1):8-13.
24. Rai S, Rattan V, Gupta A, Kumar P. Conservative management of Oral Submucous Fibrosis in early and intermediate stage. J Oral Biol Craniofac Res. 2018;8(2):86-8.
25. Kumar S. Oral submucous fibrosis: A demographic study. J Indian Acad Oral Med Radiol. 2016;28:124-8.
26. Raina C, Raizada RM, Chaturvedi VN, Harinath BC, Puttewar MP, Kennedy AK. Clinical profile and serum beta-carotene levels in oral submucous fibrosis. Indian J Otolaryngol Head Neck Surg. 2005;57(3):191-5.