

Fagerstrom Scoring for Smokeless Tobacco Dependence and its Correlation with OSMF Status.

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ABSTRACT

Introduction: Oral submucous fibrosis, though a chronic disease of insidious onset, necessitates a thorough evaluation of the biochemical status of an individual. It has a prevalence rate of 0.5%, with a malignant transformation rate of 7.6-13%, most commonly affecting persons aged 20-40 years with a peak incidence of 29.094 yrs.

Materials and Methods: The present cross-sectional prospective questionnaire survey included 147 subjects between 18 and 58 years of age.

Results: A statistical attempt was made to compare the clinical and functional stages of OSMF, and though the results turned out to be non-significant ($p > 0.05$), it also relieved that 80% of subjects were in Stage 1 of OSMF.

Conclusion: The Fagerstrom test was beneficial in assessing the subjects' dependence level on smokeless tobacco. However, the statistical correlation between Fagerstrom and OSMF stages was statistically not possible due to the small sample size, which could be the limitation of the study.

Key words: Oral submucous fibrosis, Fagerstrom Scoring, Tobacco Dependence

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INTRODUCTION

Tobacco consumed worldwide can potentially modify an individual's systemic and oral health profoundly. In India, 274.9 million are tobacco users, among which 84% are daily users, 14% are smokers, and 25.9% are smokeless tobacco users. Gutkha brand was found to contain 2.04 gm of nicotine/100 gm of the product, which on testing has shown pH levels sufficient to contribute to the quick absorption of nicotine in the blood, delivering to the consumer the desired euphoric effect.¹

Available literature suggests that nicotine affects gingival blood flow, cytokine production, neutrophil, and other immune cell function and connective tissue turnover. This could be a significant contributing factor to the exacerbation of periodontal diseases.

The relationship between smokeless tobacco and oral carcinoma has also been well documented.² These lesions are commonly found in the areas of the mouth where smokeless tobacco products are placed and occur in 50-60% of smokeless tobacco users. In general, localized attachment loss in the form of gingival recession occurs in 25 to 30% of smokeless tobacco users. This attachment loss is most prevalent adjacent to mandibular buccal areas owing to the placement of smokeless tobacco products in the vestibule.³

OSMF, though a chronic disease of insidious onset, necessitates a thorough evaluation of the biochemical status of an individual. OSMF has a prevalence rate of 0.5%, with a malignant transformation rate of 7.6-13%, most commonly

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affecting persons aged 20-40 years with a peak incidence of 29.094 yrs and male: female ratio of 34:15.^{4, 5, 6}

In India, the prevalence of OSMF increased over in past four decades from 0.03% to 6.42%.⁷ Reports show an estimated 5 million OSMF patients in India.⁸ Fagerstrom and Eissenberg have proposed that continuum dependence on tobacco and nicotine products would contribute to the formation of submucous fibrosis.⁹ various studies to

authenticate the application of the Fagerstrom test on smokers have been conducted and proved informative. Although scanty information is available as to the use of similar tests in smokeless tobacco users, Fagerstrom came up with the Test in the form of a questionnaire to evaluate the level of tobacco dependence among smokeless tobacco users [FTND-ST].¹⁰

Because of the increasing number of OSMF cases in non-teaching and daily wage personnel, as well as tobacco dependence that goes undiagnosed in College, this study was conducted as an initial step toward evaluating the level of dependence and assessing the OSMF status in order to educate them in the future further and to provide early treatment. As a result, the study's goal was to assess tobacco dependence through the Fagerstrom scale, clinical and functional staging of OSMF and correlation between clinical and Functional staging of OSMF.

MATERIALS AND METHODS

The present cross-sectional prospective questionnaire survey included 147 subjects between 18 and 58 years of age, with a male: female ratio of 90: 13. They all were the non-teaching staff and Daily wage workers of the College.

The study protocol was approved by the Research Cell of the same College. The study followed the Helsinki Declaration of 1975 as revised in 2002.¹¹

Clinical recording of OSMF: Smokeless tobacco chewers only in the form of gutkha, pan masala, areca nut, quid, areca chamen, and panparag from the past five years, subjects present on the day of the survey and willing to participate by giving verbal consent were included in the study. However, individuals with known local or systemic disorders, a tobacco

smoking history, and mouth opening limitations due to other odontogenic infections and joint disorders were excluded.

OSMF staging was recorded according to Chandramam More classification, as shown below.¹²

Clinical staging:

Interincisal mouth opening.

M1: up to or >35mm

M2: between 25-35mm

M3: between 15-25mm

M4: less than 15mm

Functional staging:

S1: stomatitis &/ blanching of the oral mucosa.

S2: palpable fibrous bands in buccal mucosa &/ oropharynx, with/without stomatitis.

S3: palpable fibrous bands in buccal mucosa &/ oropharynx & in other parts of the oral cavity with/without stomatitis.

S4A: any of the above stages and other potential malignant disorders.

S4B: any one of the above stages along with oral carcinoma.

The nicotine dependence in smokeless tobacco users was assessed using the well-formatted questionnaire.¹⁰ Further, the final calculations were scored as 5 / > =significant dependence and 4 / < = low to moderate dependence. (Figure. 1)

Statistical analysis: The Fishers extract test was used to determine non-random associations between two categorical variables, and One-Way ANOVA was applied to establish the statistically significant difference between two or more groups. The statistical analysis was performed using Statistical Package for Social Scientists (SPSS) software (version11), and the results were presented as mean and standard deviation. The p-value,

Table 1: Dependence distribution in relation to the early tobacco placement

	Points	Frequency (n= 73)	Percentage (%)	Mean (SD)
Q1	0	37	50.7	0.77(0.95)
	1	22	30.1	
	2	8	11.0	
	3	6	8.2	

Table 2: Dependence distribution in relation to the intentional tobacco juice swallowing

	Points	Frequency (n=73)	Percentage (%)	Mean (SD)
Q2	0	61	83.6	0.21 (0.50)
	1	9	12.3	
	2	3	4.1	

Table 3: Dependence distribution in when we asked what they chew to give up?! would they hate to do so

	Points	Frequency (n=73)	Percentage (%)	Mean (SD)
Q3	0	52	71.2	0.29(0.46)
	1	21	28.8	

Table 4: Dependence distribution in relation to number of pouches per week

	Points	Frequency (n=73)	Percentage (%)	Mean (SD)
Q4	2	36	49.3	0.74(0.82)
	1	20	27.4	
	0	17	23.3	

Table 5: Dependence distribution of chewing in the first hour after awakening.

	Points	Frequency (n=73)	Percentage (%)	Mean (SD)
Q5	0	44	60.3	0.40(0.49)
	1	29	39.7	

Table 6: Dependence distribution while not well

	Points	Frequency (n=73)	Percentage (%)	Mean (SD)
Q6	0	67	91.8	0.08(0.28)
	1	6	8.2	



i.e., $p \leq 0.5$, was considered statistically significant.

RESULTS

Item /Questions	Answers	Point
1. How soon after you wake up to do you place your first dip?	Within 5 min	3
	6-30 min	2
	31-60 min	1
	After 60 min	0
2. How often do you intentionally swallow tobacco juice?	Always	2
	Sometimes	1
	Never	0
3. Which chew would you hate to give up most?	The first one in the morning	1
	Any other	0
4. How many cans/pouches per week do you use?	More than 3	2
	2-3	1
	1	0
5. Do you chew more frequently during the first hours after awakening than during the rest of the day?	Yes	1
	No	0
6. Do you chew if you are so ill that you are in bed most of the day?	Yes	1
	No	0

Fig. 1: The Fagerstrom Test for the Nicotine Dependence-Smokeless Tobacco (FTND-ST)

On assessing how soon after they woke up, subjects will place the first dip in which 50% answered after 60minutes which showed less tobacco dependence, but the remaining 50% were used within 60minutes after wakeup, which relieved their dependency on tobacco. [Table 1] On questioning whether they will intentionally swallow the tobacco juice while chewing, 84% answered never, but the remaining 12% said sometimes, and 4% of subjects always answered, which shows their dependency. [Table 2]

In [Table 3], when asked which chew they would hate to give up, 71% answered any chew other than the first one in the morning, which showed their dependency. In [Table 4], several tobacco pouches used per week were analyzed in which 49.3%used more than three pouches which relieved their addiction, and the remaining subjects used less than three pouches.

Subjects were questioned regarding the frequency of chewing time, whether during the first hours after awakening or during the rest of the day is more in, which 60% answered during the rest of the day, but about 40% answered that their frequency of morning chew is higher. [Table 5] On further

Table 7: Distribution of clinical staging of OSMF

Clinical staging of OSMF	N	Mean (sd)	Range	Median (Q1-Q3)	Kruskal wallis test	
					Chi square value	p-value
1	49	2.16 (1.85)	0 – 8	2(1- 3)	5.58	0.06(NS)
2	21	3.15 (1.84)	0 – 7	3(1.5 -4.75)		
3+4	6	3.00 (1.23)	1 – 4	3(2 -4)		

* $p < 0.05$ statistically significant

$p > 0.05$ Non significant, NS

Table 8: Distribution of Functional Staging of OSMF:

Functional staging of OSMF	N	Mean (SD)	Range	Median (Q1-Q3)	Kruskal wallis test	
					Chi square value	p-value
1	45	2.40 (1.88)	0 - 8	2(1 – 3)	0.83	0.66(NS)
2	22	2.75 (1.99)	0 - 6	3(1 – 4.75)		
3+4	6	2.50 (1.41)	0 - 4	3(1.25 – 3.75)		

* $p < 0.05$ statistically significant

$p > 0.05$ Non significant, NS

Table 9: Comparison of clinical and functional staging of OSMF

Functional staging of OSMF	Clinical staging of OSMF				Total
	1.0	2.0	3.0	4.0	
1.0	39(79.6%)	5(23.8%)	1(20.0%)	0	45(59.2%)
2.0	8(16.3%)	13(61.9%)	0	1(100.0%)	22(28.9%)
3.0	2(4.1%)	3(14.3%)	3(60.0%)	0	8(10.5%)
4.0	0	0	1(20.0%)	0	1(1.3%)
Total	49	21	5	1	76

Fisher’s exact test, $p < 0.001^*$

* $p < 0.05$ statistically significant

$p > 0.05$ Non significant, NS



questioning, 92% of subjects were relieved that they will not chew tobacco when ill, but the remaining 8% use it even if bed-ridden. [Table 6]

Though the results turned out to be non-significant ($p>0.05$), the statistical analysis of clinical staging of OSMF also relieved that majority were in Stage 1 with restricted mouth opening up to or $> 35\text{mm}$ and six subjects in clinical stages of 3 and 4 with mouth opening $<25\text{mm}$. [Table 7]

In table 8, though the results turned out to be non-significant ($p>0.05$), the statistical analysis of functional staging of OSMF also relieved that majority were in Stage 1 along with stomatitis and blanching of oral mucosa and six subjects in functional stages of 3 and 4 who exhibited erythroplakia and leukoplakia along with OSMF. [Table 8]

A statistical attempt was made to compare the clinical and functional stages, and though the results turned out to be non-significant ($p>0.05$), it also relieved that 80% of subjects were in Stage 1 of OSMF. [Table 9]

DISCUSSION

Data published earlier reported an estimated 5 million OSMF patients in India and was seen most commonly in males between 20-40yrs age.¹³ Similar to this study, Male: Female = 90:13 and 21-40yrs were the typical age group affected in the Indian subcontinent revealed a maximum number of patients in 20-30 yrs and 21-40yrs.

Babu et al. 1996 reported that habitual chewing of gutkha/pan masala resulted in the early occurrence of OSMF than areca nut.¹⁴ Following the present study, 77.66% were gutkha chewers, 11.22% quid users, and 11.12% others (aracchaman, panparag), which also justifies the highest amount of low-moderate dependence seen in the population with the total Fagerstrom score being 4/.

In the present study, the prevalence of SI (47.6%) was followed by SII (20.4%) and SIII and SIV (5.9 %), respectively. Another study from India Raina et al. (2011) was contradictory wherein SI (9%), SII (39%), and SIII (52%).¹⁵ The difference could be because the present study is a population screening study revealed that most patients were in the asymptomatic stage, whereas the study mentioned above-included hospital OPDs.

When considering the functional staging of OSMF, Kiran Kumar et al.¹⁶ showed in their study that 6.66% had $>40\text{mm}$, 76% had 20-40mm, and 17-33% had 22mm of mouth opening. Similarly, in the present study, as many belonged to stage I OSMF,

F1 was 43.7% with .35mm of mouth opening, but only 2-3 persons showed the F3 stage with $<15\text{mm}$, who also had an OSMF stage 4 with the presence of erythroplakia on buccal mucosa.

CONCLUSION

The Fagerstrom test was beneficial in assessing the subjects' dependence level on smokeless tobacco. However, the statistical correlation between Fagerstrom and OSMF stages was statistically not possible due to the small sample size, which could be the limitation of the study.

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