BULLETIN OF STOMATOLOGY AND MAXILLOFACIAL SURGERY
Volume 21, Issue 5

DOI: 10.58240/1829006X-2025.21.5-89

ORIGINAL RESEARCH

CORRELATION BETWEEN FAGERSTRÖM TEST FOR NICOTINE DEPENDENCE AND PREVALENCE OF ORAL MUCOSAL LESIONS: A CROSS-SECTIONAL STUDY

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Received: *May 5, 2025;* ***Accepted:*** *June.8, 2025;* ***Published:*** *June. 15,2025*

ABSTRACT

Tobacco use is a major risk factor for oral mucosal lesions (OMLs), including potentially malignant disorders. The Fagerstrom Test for Nicotine Dependence (FTND) is a tool for assessing nicotine dependence. This study investigates the potential correlation between FTND scores and the prevalence of OMLs. The present study aims to determine if a correlation exists between FTND scores, indicating nicotine dependence levels, and the prevalence of Oral mucosal lesions. Patient records from a Dental Information Archiving System Software were analyzed to identify individuals with tobacco use habits. FTND scores were calculated to assess nicotine dependence levels, and oral mucosal changes were recorded. Male patients aged 18 years above with a history of cigarette smoking and tobacco usage, 70 participants in each group were included. The mean age of the patients was 37.6 +/- 13.2 years with an age range of 18 to 75 years. Individuals with more severe oral mucosal lesions tend to have higher scores on the Fagerstrom Test for Nicotine Dependence, suggesting a stronger nicotine addiction. A weak, positive correlation between Age and Mucosal Changes was observed (r = 0.089). A moderate, negative correlation between Mucosal Changes and Tobacco Cessation Form (r = -0.279). This correlation was statistically significant at the 0.01 level (p = 0.001). The present study highlights a link between nicotine dependence and oral lesions, emphasizing the need for targeted intervention toward habit cessation.

Keywords: Fagerstrom test, nicotine dependence, oral mucosal lesions, prevalence,

INTRODUCTION

Tobacco, originating from the *Nicotiana* genus in the Nightshade family, has been used since the first century BC by the Maya tribe in Central America for religious ceremonies, and its consumption spread across South Asia in various forms such as hookah, cigarettes, and smokeless tobacco [1,2]. Cultural influences and genetic predispositions continue to shape tobacco use, with habits such as gutkha consumption providing users with benefits like focus and relaxation [3, 4].

India's tobacco industry is a major economic contributor, employing millions and generating substantial foreign exchange. As the world's second-largest producer and fourth-largest exporter of unmanufactured tobacco, India offers a diverse range of products to over 125 countries. While the industry provides economic benefits, it also faces challenges related to labor conditions, particularly in bidi manufacturing, and environmental concerns. Government initiatives are essential to promote alternative livelihoods and reduce dependence on tobacco cultivation and production [5, 6, 7].

The primary biohazardous substances found in tobacco include at least eighty-three carcinogens, including nitrosamines and nicotine, and radionuclides that produce alpha particles, such as polonium 210 [8]. Tobacco smoke is packed with chemicals that harm the body's defenses against disease [9], including tars, thiocyanates, herbicides, fungicides, and pesticide residues, as well as carbon monoxide. Tobacco smoke contains toxic chemicals which adversely affect almost all types of living cells. First and foremost, smoking has a detrimental effect on the host's immune system, which in turn affects how the host and parasite interact. In addition to its obvious negative health effects tobacco use, whether inhaled, sniffed, sucked, or chewed has an addictive quality. Researchers have conclusively shown that tobacco users experience the three Ds: disease, disability, and death [10].

When any cell is exposed to a carcinogen of any kind it often strives to adapt to it. A possible adaptation strategy could be a rise in cell division, a decrease in cytosolic capacity, and an increase in the load of related organelles [11, 12]. The early consequences of an accelerated growth phase in the oral epithelium are indicated by hyperplasia or enlargement of the progenitor compartment. The epithelium exhibits characteristics of cellular degeneration, a well-known adaptive feature (atrophy) when the irritant persists. The cells eventually progress to an irreversible cell damage stage, which can take the form of either apoptosis or malignant transformation, after the stages of adaptation and reversible cell damage are over. The accelerated rate of cell division seen in the early phases of transformation is an adaptive response that promotes more genetic damage and drives the cells farther down the path toward malignant transformation [13].

The Fagerström Test for Nicotine Dependence(FTND) is a widely used tool to assess the level of physical addiction to nicotine. Apart from FTND other scales such as the Heavy smoking index (2-item scale), and cigarette dependence scale(5-item scale) are also used however FTND remains the gold standard [14]. FTND scale is designed to provide a graded measure of nicotine dependence related to cigarette smoking, the test includes six questions that evaluate cigarette consumption, the urge to smoke, and overall dependence. A higher total score on the Fagerström test indicates a greater physical dependence on nicotine. A doctor may use the Fagerström test in the clinic to record when a patient needs a prescription for medicine to aid with nicotine withdrawal. Karl-Olov Fagerström originally developed the Fagerström Tolerance Questionnaire. In 1991, Todd Heatherton and colleagues modified this questionnaire, resulting in the Fagerström Test for Nicotine Dependence[15, 16]. This scale is also used to determine the level of nicotine dependency based on the form of tobacco used (ie) smoking, or chewing. The present study aims to determine the relationship between the Nicotine dependency score and the corresponding mucosal changes observed concerning the patient's habit.

Methodology

A retrospective study was carried out in the Department of Oral Pathology at Saveetha Dental College, Chennai. This retrospective design utilized stored patient records to identify patterns and associations. The data for this study was sourced from the Dental Information Archiving Software (DIAS). This digital database stores patient information, including dental records and treatment histories at Saveetha Dental College and Hospitals. Patients with tobacco habits reporting to the dental OP for routine treatment were assessed for Nicotine dependence based on the Fagestorm score for nicotine dependency. Further information on the mucosal changes observed in the patient was also recorded. The study was conducted under the Declaration of Helsinki, and ethical clearance was obtained. **(IHEC/SDC/DS/FACULTY/23/OPATH/141)**

Population: The study focused on individuals who reported to a dental clinic for regular treatment and had a history of tobacco use, including both smoking and smokeless forms.

Sample Size: Sample size was calculated using the odds ratio value obtained from a reference article [17] using G power software v 3.1.9.4. It was calculated to be 78 samples with 39 samples in each group. A total of 500 patients were screened for the study of which only male patients were included in the study. The final sample size included 140 patients including 70 tobacco smokers(cigarettes) and 70 tobacco chewers to eliminate the risk of bias among both forms of tobacco usage. Inclusion criteria were, Male patients above the age of 18 years with a history of tobacco usage. In the smoking category, only cigarette smokers were included to maintain homogeneity. Case records were excluded if they lacked sufficient information due to missing scores and incomplete forms. Participants who smoked beedi and other smoke forms of tobacco were excluded due to insufficient sample size. Female participants were excluded due to insufficient sample size in both categories compared to male participants. Male smokers were chosen to ensure homogeneity in the study population and to minimize gender-based variations in physiological and behavioral responses. Participants using both forms of tobacco were excluded to maintain consistency in the categorization.

Data Collection:

Patient Selection: Existing patient records were reviewed to identify individuals who met the inclusion criteria (tobacco use, and regular dental visits). Data Extraction: Relevant information, such as patient demographics, tobacco use history, frequency of smoking and tobacco chewing, details of oral mucosal changes, and Fagerstrom score were noted, were extracted from the DIAS database. The data obtained were entered into Microsoft Excel version 2022 and statistical analysis was done using SPSS software version 26.

The FTND questionnaires were used by the clinicians to assess the level of nicotine dependence through a one-on-one interview with the patient. Fagerstrom Test for Nicotine Dependence consisted of yes/no items which were scored from 0 to 1 and multiple-choice items scored from 0 to 3. The items are summed to yield a total score of 0-10. Scores are categorized as very low (0–2), low (3–4), medium (5), high (6–7), and very high dependence (8 or more). The higher the total Fagerström score, the more intense is the patient's physical dependence on nicotine [15,16]. This questionnaire was then assessed by a senior clinician following which the questionnaire was scanned and uploaded into the dias software with prior informed consent from the patient.

Data Analysis:

Descriptive Statistics: Summary statistics were calculated to describe the characteristics of the study population, including age, gender, duration of tobacco use, and type of tobacco products.

Statistical tests - Pearson's correlation was employed to examine the relationship between the frequency or severity of tobacco use (as measured by the Fagerstrom Score) and the presence of mucosal changes in the oral cavity. Significance was set as p-value < 0.05.

RESULTS

The mean age of the patients was 37.6 +/- 13.2 years with an age range of 18 to 75 years. Of the total 140 male participants, all participants had a history of tobacco usage in both forms ie; smoking as well as chewing. Maximum participants belonged to the 21–30 years age group (**30.71%**, 43/140), followed by the 31–40 years age group (**25.0%**, 35/140) and the 41–50 years age group (**23.57%**, 33/140).
Among the 70 smokers, **62.85%** (44/70) smoked less than 10 cigarettes per day, while **32.85%** (23/70) smoked 11–20 cigarettes daily. Only **4.28%** (3/70) smoked more than 20 cigarettes per day, indicating that the majority were light to moderate smokers. (Figure 1).

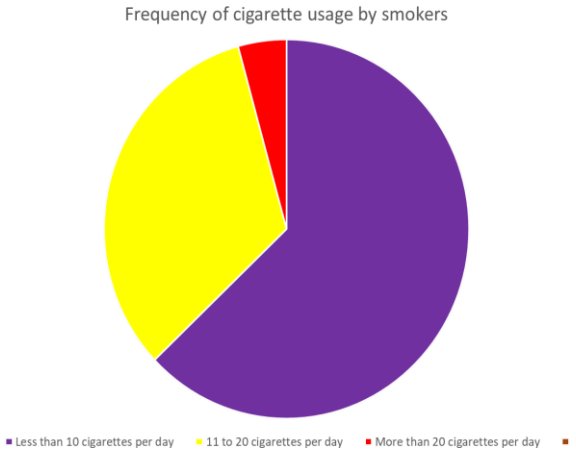

Figure 1. Graphical representation depicting the frequency of smoking tobacco(cigarettes) (No. of times per day)
Of the total 70 chewers, 93% of the participants chewed tobacco around 1-9 times a day and 7% chewed tobacco 10-15 times a day (Figure 2).

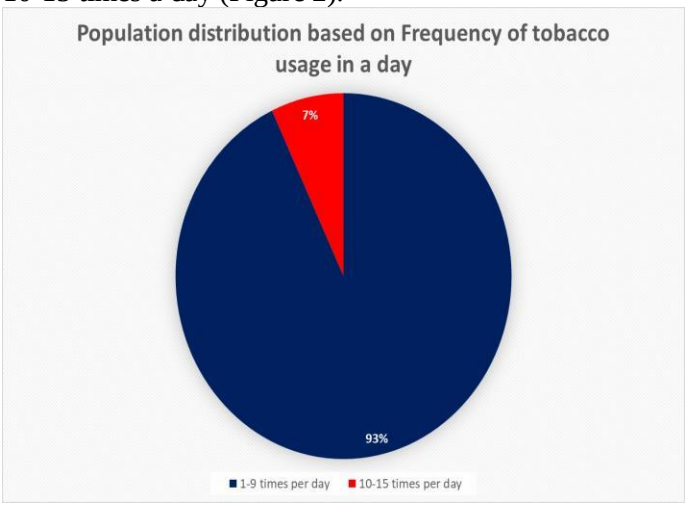

Figure 2. Graphical representation depicting the frequency of chewing tobacco (No. of times per day)

Age-wise distribution of Fagerstrom score among smokers and non-smokers
Smokers: Participants with a nicotine dependency score of 3 were predominantly in the 31–40 years (**10.0%**, 7/70) and 41–50 years (**8.57%**, 6/70) age groups. This highlights that middle-aged smokers (31–50 years) largely fell into the low-dependency category.
Chewers: Among chewers, the highest nicotine dependency score of 5 was observed in the 21–30 years age group (**10.0%**, 7/70), indicating a medium dependency level.

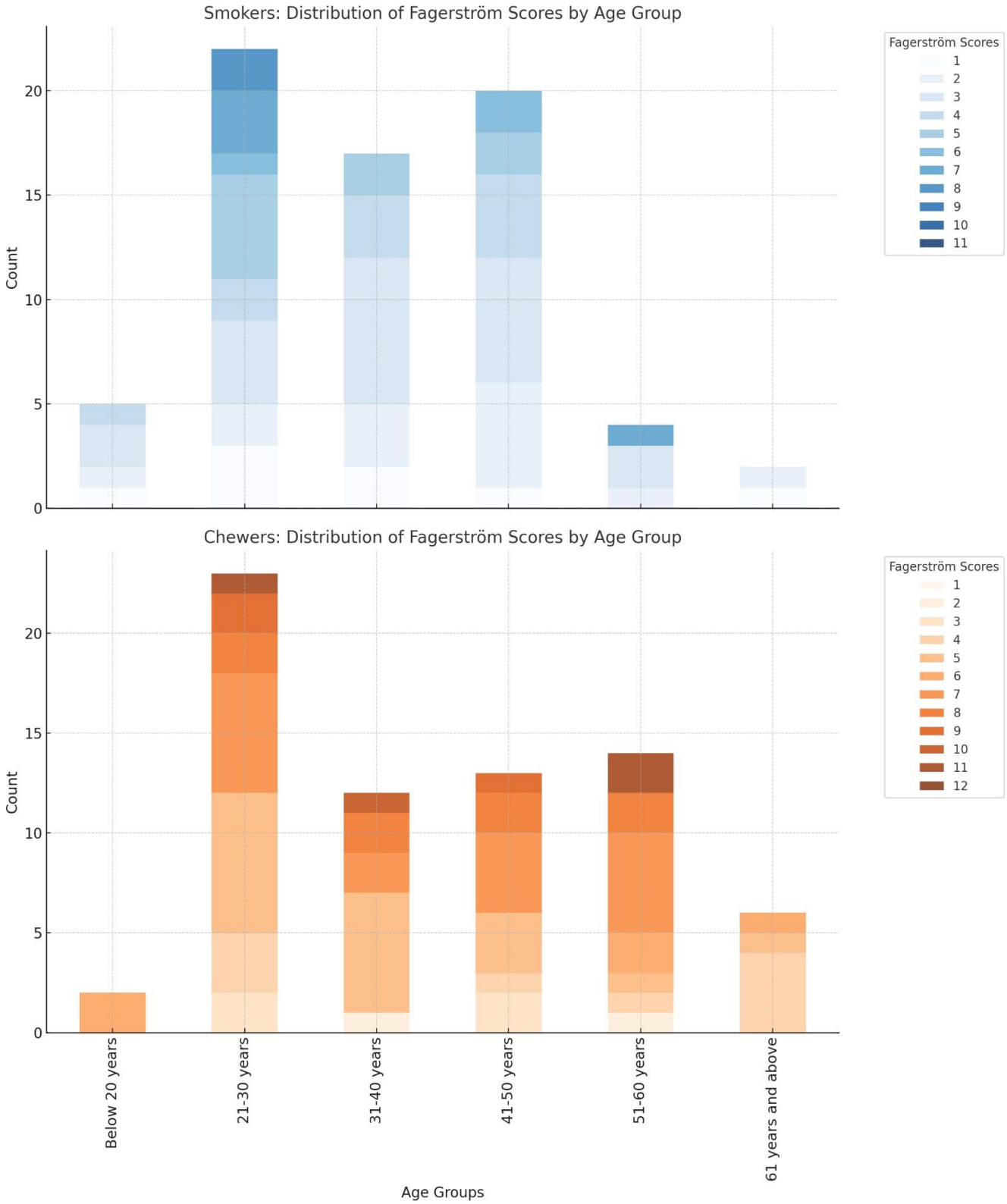

Figure 3 Age-wise distribution of Fagerstrom score among smokers and chewers

Descriptive statistics of Fagerstrom scores among smokers and chewers

The mean age of participants in both categories was 37.66 with a standard deviation of 13.2. The average Fagerstrom score observed was 4.78 +/- 2.304 among both the categories of smokers and chewers.The mean FTND scores among smokers was 3.49 +/- 1.767 and among chewers is 6.07 +/- 2.045 (Table 1&2)

	Mean	Std. Deviation	N
Age	37.664	13.2005	140
Tobacco cessation form (Fagerstrom score)	4.78	2.304	140

1.Smokers/ 2.Chewers		N	Minimum	Maximum	Mean	Std. Deviation
1	**Tobacco cessation form (Fagestorm score among smokers)**	**70**	**1**	**8**	**3.49**	**1.767**
	Valid N (listwise)	**70**				
2	**Tobacco cessation form (Fagestorm score among chewers)**	**70**	**2**	**11**	**6.07**	**2.045**
	Valid N (listwise)	**70**				

Table 1&2: Descriptive statistics

Age Wise distribution of presence and absence of mucosal changes among smokers and chewers

Smokers: Of the 70 smokers, **25.71%** (18/70) presented with oral mucosal lesions, with the majority (**27.78%**, 5/18) found in the 31–40 years age group.

Chewers: Among the 70 chewers, **44.28%** (31/70) exhibited oral mucosal changes. The highest prevalence was in the 21–30 years age group (**32.26%**, 10/31), followed closely by the 51–60 years group (**29.03%**, 9/31). (Figure 4).

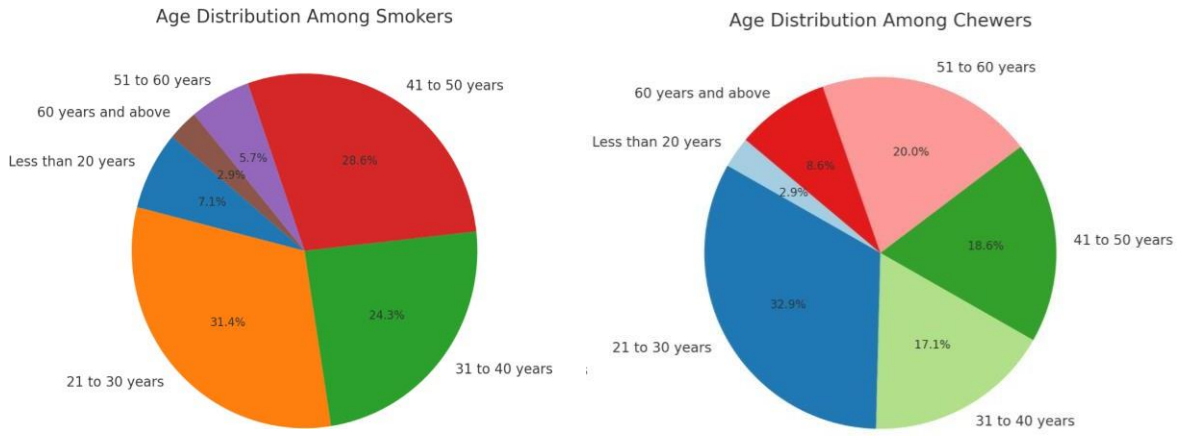

Figure 4. Age Wise distribution of presence and absence of mucosal changes among smokers and chewers

Oral Lesions:

In smokers, the most frequently observed lesions were smoker's palate(figure 5) (83.33%, 15/18) and leukoplakia(figure 6) (27.78%, 5/18). Among chewers, all participants with lesions (100%, 31/31) exhibited tobacco pouch keratosis(figure 7). Additionally, leukoplakia was present in 5.0% (7/140) of participants, observed in both smokers and chewers, while o ral submucous fibrosis (OSMF) was noted in 1.% (2/140) of participants.

Figure 5. Clinical image showing Smoker's palate
Figure 6. Clinical image showing Tobacco pouch keratosis of lower labial mucosa

Figure 7. Clinical images showing Leukoplakia on the buccal mucosa

Pearson's correlation

There is a weak, positive correlation between Age and Mucosal Changes (r = 0.089). This correlation was not statistically significant (p = 0.293). This suggests that there is no reliable linear relationship between age and mucosal changes in this dataset.

There is a very weak, negative correlation between Mucosal Changes and Tobacco Cessation Form (r = -0.279). This correlation was statistically significant at the 0.01 level (p = 0.001). This indicates that individuals with higher mucosal changes tend to have low to intermediate scores on the tobacco cessation form (Fagerstrom Score).

There is a very weak, negative correlation between Age and Tobacco Cessation Form (r = -0.074). This correlation is not statistically (p = 0.386). This suggests that there is no reliable linear relationship between age and tobacco cessation form scores in this dataset (Table 2).

Correlations

Table 2: Correlation statistics

		Age	Mucosal changes	Tobacco cessation form (Fagerstrom score)
Age	Pearson Correlation	1	.089	-.074
	Sig. (2-tailed)		.293	.386
	N	140	140	140
Mucosal changes	Pearson Correlation	.089	1	-.279**
	Sig. (2-tailed)	.293		.001
	N	140	140	140
Tobacco cessation form (Fagerstrom score)	Pearson Correlation	-.074	-.279**	1
	Sig. (2-tailed)	.386	.001	
	N	140	140	140

**. Correlation is significant at the 0.01 level (2-tailed).

DISCUSSION

The **Fagerström Test for Nicotine Dependence (FTND)** is a widely used tool to assess nicotine addiction. It evaluates cigarette consumption, the urge to smoke, and overall dependence, scoring responses from 0 to 10. [15, 16]. This tool is particularly useful in determining the intensity of nicotine dependence and guiding cessation strategies [17]. A study among the Narikuravar tribal population in Thoothukudi district found that over 60% of adults used tobacco, with medium nicotine dependency being prevalent. Gum bleeding and tooth erosion were frequently reported among users, emphasizing the need for targeted awareness programs for this vulnerable population [18]. The present study, however, observed that medium dependence was predominantly found among younger chewers (aged 21–30 years), highlighting the specific vulnerability of this age group.

Similarly, Nalini et al.'s systematic review highlighted a lack of research on FTND scores for beedi smokers and smokeless tobacco users in India, with only one study addressing this gap [19]. This finding is consistent with the present study, where both smoking and chewing tobacco habits were examined, emphasizing the importance of filling this research gap.

A rural study in the Kancheepuram district revealed that 48.7% of tobacco users exhibited high nicotine dependence, with the duration of use and age of initiation identified as significant risk factors [20].

The present study showed lower dependency levels among smokers, with most participants in the low-dependence category (FTND score = 3). This contrast may be attributed to differences in population demographics or awareness levels.

In Bhimavaram, reverse smoking, predominantly among older females, was associated with smoker's palate and carcinomatous lesions. Conventional smoking, prevalent among males, was linked to leukoplakia and tobacco-associated melanosis. Chewing tobacco was common among younger males and associated with conditions such as tobacco pouch keratosis and oral submucous fibrosis [21]. The present study corroborates these findings, reporting smoker's palate and leukoplakia among smokers, and tobacco pouch keratosis among all chewers with lesions.

A study in Bagalkot found that 80% of participants had stage I OSMF, and FTND was beneficial in assessing smokeless tobacco dependence. However, no significant correlation was found between FTND scores and OSMF stages due to the small sample size [22]. In the present study, OSMF was observed in only two participants, limiting comparisons. However, the study confirmed the utility of FTND in evaluating nicotine dependence.

A systematic review on the psychometric properties of FTND found uncertainties in its application across cultural groups and in predicting habits among light smokers, e-cigarette users, and smokeless tobacco users. It emphasized the need for improving the psychometric qualities of FTND [23]. The present study aligns with these findings, as the tool proved effective in evaluating dependence among both smokers and chewers but highlighted the need for culturally specific adaptations.

A cross-sectional study in Nepal reported high nicotine dependence among tobacco chewers, correlating with prolonged usage, low socioeconomic status, and failed quit attempts [24]. Similarly, the present study observed a moderate negative correlation between mucosal changes and FTND scores ($r = -0.279$, $p = 0.001$), indicating intermediate dependency levels among those with mucosal changes.

In Goa, a study assessing exhaled carbon monoxide levels found a strong correlation with nicotine dependency and oral mucosal lesions. However, it noted limitations such as self-reported data and environmental factors influencing CO levels [25]. The present study similarly reported a significant association between mucosal changes and tobacco habits but lacked data on CO levels, suggesting an area for future exploration.

A study assessing the effectiveness of the STAR scoring system in oral surgical documentation emphasized the importance of high-quality records for patient follow-up [26]. This underscores the importance of systematic and detailed data collection which paved way for the current research to be carried out.

A prevalence study in Modinagar, India, found a 16.8% occurrence of oral mucosal lesions (OML), with smoker's palate being the most common. It recommended targeted oral health education for high-risk groups [27]. The present study supports this, reporting similar findings of smoker's palate and leukoplakia among tobacco users.

In Dharwad, a higher prevalence of OML (26.8%) was observed among tobacco users compared to non-users (2.8%), with lesions like leukoplakia and OSMF strongly linked to cancer risk [28]. The present study concurs, showing a strong association between tobacco habits and lesions such as smoker's palate, leukoplakia, and tobacco pouch keratosis.

A systematic review reported a significant association between tobacco use and oral premalignant lesions, with an odds ratio of 15.22 for users compared to non-users [29]. This aligns with the present study, which found a higher prevalence of mucosal changes among tobacco users, reinforcing the need for targeted interventions. Heavy Smoking Index (HSI), a shorter two-item version of the FTND, is designed for broader population use. A study conducted in the Galician region of Spain involving 1655 daily smokers compared the validity of the HSI against the FTND. The results demonstrated substantial agreement between the HSI and FTND ($\kappa = 0.7$) and high specificity ($Sp = 96.2\%$), however the sensitivity analysis among females were inconsistent. Thus FTND remains more suitable for populations with lower nicotine dependence, such as women [30].

Limitations of the study include the exclusive focus on male participants, which may limit generalizability. Additionally, as a single-center study, the findings may not apply universally, and the retrospective design restricts control over confounding factors. Additional number of participants among various age groups and an equal number of participants for each category of nicotine dependence can give more data on the correlation aspect. Future research could explore the influence of other factors, such as socioeconomic status, oral hygiene practices, and systemic health conditions, on the development of mucosal changes in tobacco users.

CONCLUSION

From the findings of the current study it can be observed that among smokers, smokers palate is the most common form of lesion noted and is observed even in cases of low dependency. Leukoplakia is also noted among smokers and the associated Fagestorm nicotine dependence score is 6 and 7 which corresponds to High dependence. Among chewers, tobacco pouch keratosis is the most common form of lesion noted, however, the associated score ranges from 3 (Low dependence) to 11

(Very high dependence), also the highest number of patients with lesions belonged to Medium and High dependence categories rather than very high dependence. This could be due to less number of patients recorded under the very high dependency category. One more reason could be because all these scoring is done based on self-reported assessment which can always be manipulated from the participant's end, thereby leading to lower scores in patients with lesions.

In the Fagerstrom scale for nicotine dependence (smokeless), there are questions such as number of hours of chewing per day, length of dipping time per day, how many minutes each dip lasts and number of times used per week, at times few participants who use dips for 10 to 15 times per day have mentioned that they use tobacco less than 2 times per week. These factors can contribute to low and medium scores on occasions were a high or very high score is anticipated. Hence this question regarding the number of times used per week can be modified in terms of question or the choice of answers (choice given in the scale: Less than 2 times, More than 2 times, More than 4 times).

Contributions

NishaJaisree, Pratibha Ramani and Meignana Arumugham have made substantial contributions to the conception and design of the work, the acquisition, analysis, and interpretation of data; and have drafted the work or substantively revised it. NishaJaisree, Pratibha Ramani and Meignana Arumugham have approved the submitted version (and any substantially modified version that involves the author's contribution to the study); NishaJaisree, Pratibha Ramani and Meignana Arumugham have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

DECLARATIONS

Acknowledgments

We thank Dr. Deepak Nallaswamy, Pro-Chancellor, Saveetha Institute of Medical and Technical Sciences for initiating digital records in our institution that have enabled data search for this study.

Funding

No funding was received from any financially supporting body, and there was no associated grant number. No funder was involved in manuscript writing, editing approval, or decision to publish.

Consent for publication

Informed consent was obtained from every participant for documentation and examination.

Competing interests

The authors declare no competing interests.

Ethical approval

Ethical approval was granted by the Institutional Human Ethical Committee under reference number: IHEC/SDC/DS/FACULTY/23/OPATH/141.

Informed patient consent

All patients' clinical records were obtained with informed consent.

Clinical trial registration details

A clinical trial number is not applicable. It is only an observation of clinical records. This study did not use any clinical intervention or treatment procedures on patients.

CONCLUSION

Patients together with workflow efficiency experienced significant improvement in dental practice through AI-driven virtual assistants. Thorough examination of quantitative alongside qualitative information in the study showed major enhancements affecting domains from patient satisfaction results to clinical results as well as appointment bookings and administrative performance time alongside operational workflow efficiency. The research demonstrates how AI technology will transform dental practice management to give clinicians enhanced power for delivering quality healthcare with optimized operational performance. The identification of patient satisfaction score and staff attitude predictors offers important directions for deploying strategies that yield optimal support for continuous improvement.

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