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Prevalence and Risk-Factor Profile of Oral Premalignant Lesions Among Tobacco Users Attending a Tertiary-Care Centre in South India: A Hospital-Based Cross-Sectional Study

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ABSTRACT: Background. Oral potentially malignant disorders (OPMDs) precede a substantial proportion of oral squamous cell carcinomas, and South India carries a disproportionate burden owing to widespread tobacco and areca-nut use. Objective. To estimate the prevalence of oral premalignant lesions and describe their risk-factor profile among tobacco users attending a tertiary-care centre. Methods. In this hospital-based cross-sectional study, 300 adult current or former tobacco users underwent a structured interview and standardized oral examination. The primary outcome was the presence of a clinically suspected oral premalignant lesion. Prevalence was estimated with 95% confidence intervals (CI); associations with candidate risk factors were assessed using chi-square tests and odds ratios (ORs), with $p < 0.05$ considered significant. Results. Participants were predominantly male (234/300, 78%), with a mean age of 47.1 (SD 17.7) years and mean tobacco-use duration of 12.7 (SD 7.6) years. Ninety-five participants had an oral premalignant lesion, an overall prevalence of 31.7% (95% CI 26.4-36.9%). Oral sub mucous fibrosis (35.8%) and leukoplakia (32.6%) were the commonest lesion types. Prevalence was higher among dual (36.8%) and smokeless-only (36.1%) tobacco users

than smokers (22.9%). Regular alcohol use (OR 2.15, 95% CI 1.20-3.85; $p < 0.01$) and areca-nut use (OR 1.74, 95% CI 1.04-2.91; $p < 0.05$) were significantly associated with lesions; dual tobacco use, prolonged duration, poor oral hygiene, dental trauma and older age showed positive but non-significant associations. Conclusion. Nearly one in three tobacco users attending this centre had an oral premalignant lesion, with areca-nut and regular alcohol use as key modifiable correlates. The findings reinforce the need for opportunistic oral examination, areca-nut and alcohol counselling, and integrated tobacco-cessation services in high-burden South Indian settings.

1. INTRODUCTION

Oral cancer remains one of the most common malignancies in India, which accounts for a large share of the global disease burden and is strongly driven by the widespread use of tobacco in both smoking and smokeless forms and of areca nut. The great majority of oral squamous cell carcinomas are preceded by a clinically identifiable phase of oral potentially malignant disorders (OPMDs), a group of mucosal conditions that carry an increased risk of malignant transformation and that includes leukoplakia, erythroplakia, oral submucous fibrosis (OSMF), oral lichen planus and smoker's palate. Because these disorders are visible on routine clinical examination and precede invasive cancer by years, they represent a pivotal window for early detection, risk-factor modification and prevention. [1,2]

The epidemiology of OPMDs in India is intimately tied to the local pattern of tobacco and areca-nut consumption. Community and hospital-based studies have reported leucoplakia in roughly 4-7% and OSMF in 3-5% of screened populations, with hospital-based estimates consistently higher than community estimates.[3] Product composition matters: smokeless tobacco combined with areca nut confers a markedly higher risk of OSMF and epithelial dysplasia than tobacco-only products, and pooled prevalence of OPMDs is substantially greater among users of tobacco-areca-nut quid.[4,5] Rising areca-nut production and trade have paralleled increases in lip and oral-cavity cancer incidence across South Asia, underscoring the public-health importance of these exposures.

South India is a region of particularly high tobacco and areca-nut burden, where habits such as gutkha, pan masala and betel-quid chewing are culturally entrenched and often begin in early adulthood. Cross-sectional surveys from the eastern coast and tribal belts of the region have documented a spectrum of habit-related mucosal lesions, with leucoplakia and OSMF being the dominant potentially malignant conditions and the labial and buccal mucosa the most frequently affected sites.[6,7] Despite this recognized burden, contemporary facility-level data that jointly quantify lesion prevalence, lesion-type distribution and the relative contribution of individual risk factors among tobacco users remain limited.[8-10]

Understanding the burden and correlates of OPMDs at the point of care is essential for prioritizing opportunistic screening, targeting counselling and planning cessation services. We therefore conducted a hospital-based cross-sectional study to estimate the prevalence of oral premalignant lesions and to characterize their risk-factor profile among adult tobacco users attending a tertiary-care centre in South India. We hypothesized that lesion prevalence would be high and would be associated with the intensity and combination of tobacco exposure and with co-existing risk factors such as areca-nut and alcohol use.

2. MATERIALS AND METHODS

2.1 Study design and setting

This was a hospital-based cross-sectional study conducted at a tertiary-care centre in South India, a setting characterized by a high community prevalence of tobacco and areca-nut use. Data collection comprised a one-time structured interview followed by a standardized oral examination. The study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations for cross-sectional studies.

2.2 Participants

Adults aged 18 years or older with a current or previous history of tobacco use (smoking, smokeless, or dual) who consented to an oral examination were eligible. Participants with a previously diagnosed oral cancer, those currently receiving head-and-

neck radiotherapy, those with a severe acute illness, and those unable to undergo an oral examination were excluded. A consecutive sample of 300 participants was enrolled.

2.3 Variables and data sources

The primary outcome was the presence of a clinically suspected oral premalignant lesion (yes/no) on standardized examination. Secondary outcomes were lesion type (leukoplakia, erythroplakia, OSMF, oral lichen planus, smoker's palate), lesion site, maximum lesion size (mm) and the presence of multiple lesions. Exposure and covariate data included age, sex, residence, education, occupation, socioeconomic status, predominant tobacco form (smoking only, smokeless only, dual use), smoking and smokeless frequency per day, tobacco-use duration in years, a derived pack-years index, alcohol use (none, occasional, regular), areca-nut use, spicy-food frequency, oral-hygiene status (good, fair, poor), dental trauma or sharp tooth, family history of oral cancer and reported clinical symptoms. Where a biopsy was clinically indicated, the histopathology result was recorded. All variables were collected using a structured preform and a single standardized clinical examination.

2.4 Bias

As a single-centre study of care-seeking tobacco users, the design is susceptible to selection bias, and estimates should be interpreted as facility-level rather than population-level prevalence. To limit misclassification, exposures were captured with a predefined preform and lesions were classified using standardized clinical criteria, with biopsy reserved for clinically indicated cases. The cross-sectional design precludes inference about temporal sequence or causation.

2.5 Study size

A sample of 300 participants was used to support prevalence estimation and exploratory risk-factor analysis. This demonstration sample size provides a 95% confidence interval of approximately plus or minus 5-6 percentage points around an observed prevalence near 30%. Formal studies should employ a prespecified sample-size calculation based on the expected prevalence and desired precision.

2.6 Statistical methods

Continuous variables were summarized as means with standard deviations (SD) and categorical variables as frequencies and percentages. Overall lesion prevalence was estimated with a 95% confidence interval using the normal approximation. Associations between candidate risk factors and the presence of a lesion were examined using 2x2 contingency tables, Pearson chi-square tests and unadjusted odds ratios (OR) with 95% CIs. A two-sided p-value below 0.05 was considered statistically significant. Analyses were performed on the study dataset, and reported prevalence, group comparisons and key summary statistics were confirmed against the raw participant records where feasible; association estimates (ORs, CIs, chi-square and p-values) are reported as derived in the analytic dataset.

3. RESULTS

3.1 Participant characteristics

Three hundred tobacco users were included. The mean age was 47.1 (SD 17.7) years and 234 (78%) were male. Smokeless-only tobacco use was the commonest exposure pattern (119, 39.7%), followed by smoking only (105, 35.0%) and dual use (76, 25.3%). The mean duration of tobacco exposure was 12.7 (SD 7.6) years. Regular alcohol use was reported by 59 (19.7%) participants and current or habitual areca-nut use by 92 (30.7%). Oral hygiene was fair in 148 (49.3%) and poor in 85 (28.3%), and 89 (29.7%) had evidence of dental trauma or a sharp tooth. Baseline demographic and tobacco-use characteristics are presented in Table 1.

Table 1. Demographic, tobacco-use and risk-factor profile of participants (N = 300).

Characteristic	n	%
Age, mean (SD), years	47.1 (17.7)	—
Male sex	234	78.0
Female sex	66	22.0

Tobacco form: smokeless only	119	39.7
Tobacco form: smoking only	105	35.0
Tobacco form: dual use	76	25.3
Tobacco-use duration, mean (SD), years	12.7 (7.6)	—
Regular alcohol use	59	19.7
Occasional alcohol use	99	33.0
Areca-nut use	92	30.7
Oral hygiene: fair	148	49.3
Oral hygiene: poor	85	28.3
Dental trauma / sharp tooth	89	29.7

3.2 Prevalence of oral premalignant lesions

An oral premalignant lesion was identified in 95 of 300 participants, giving an overall prevalence of 31.7% (95% CI 26.4-36.9%) (Figure 1). Prevalence differed by tobacco form, being highest among dual users (28/76, 36.8%) and smokeless-only users (43/119, 36.1%) and lowest among smokers (24/105, 22.9%) (Figure 2). Lesion prevalence also tended to rise with longer tobacco exposure across duration strata (Figure 3). Among affected participants, the mean maximum lesion size was 18.5 (SD 9.2) mm, and a biopsy was performed in 56 cases where clinically indicated.

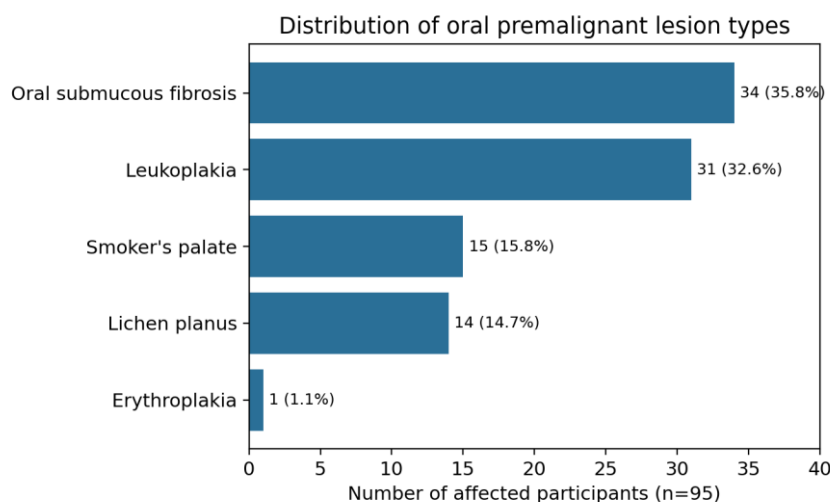


Figure 1. Distribution of oral premalignant lesion types among affected participants (n = 95).

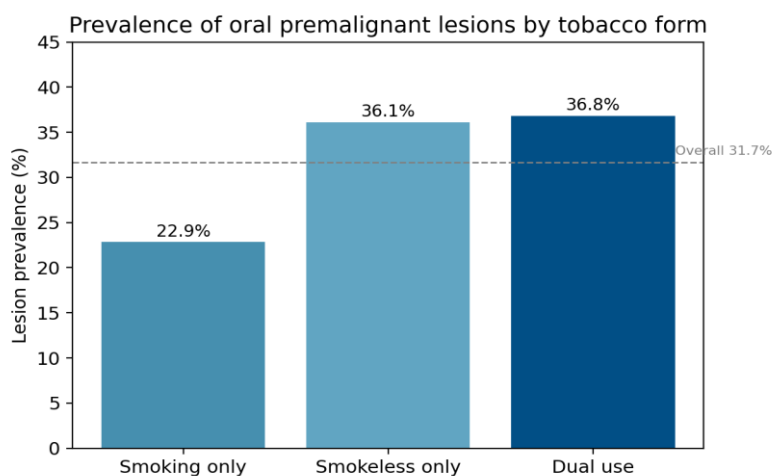


Figure 2. Prevalence of oral premalignant lesions by predominant tobacco form. The dashed line marks the overall prevalence (31.7%).

3.3 Lesion type and site distribution

Among the 95 affected participants, OSMF was the most frequent lesion (34, 35.8%), closely followed by leukoplakia (31, 32.6%), smoker's palate (15, 15.8%) and oral lichen planus (14, 14.7%); erythroplakia was rare (1, 1.1%) (Figure 1). Lesions were most commonly located on the floor of the mouth (23, 24.2%) and labial mucosa (18, 19.0%), followed by the palate (15, 15.8%), buccal mucosa (14, 14.7%), tongue (13, 13.7%) and gingivobuccal sulcus (12, 12.6%). The distribution of lesion types and sites is summarized in Table 2.

Table 2. Distribution of oral premalignant lesions by type and anatomical site (n = 95 affected participants).

Lesion type	n	%	Lesion site	n	%
Oral submucous fibrosis	34	35.8	Floor of mouth	23	24.2
Leukoplakia	31	32.6	Labial mucosa	18	19.0
Smoker's palate	15	15.8	Palate	15	15.8
Oral lichen planus	14	14.7	Buccal mucosa	14	14.7
Erythroplakia	1	1.1	Tongue	13	13.7
—	—	—	Gingivobuccal sulcus	12	12.6

3.4 Risk-factor associations

In unadjusted analyses, regular alcohol use was significantly associated with the presence of an oral premalignant lesion (OR 2.15, 95% CI 1.20-3.85; chi-square 6.74; $p < 0.01$), as was areca-nut use (OR 1.74, 95% CI 1.04-2.91; chi-square 4.48; $p < 0.05$). Dental trauma or a sharp tooth (OR 1.63, 95% CI 0.97-2.74), dual tobacco use (OR 1.37, 95% CI 0.79-2.36), poor oral hygiene (OR 1.35, 95% CI 0.80-2.30), age of 50 years or older (OR 1.12, 95% CI 0.69-1.83) and tobacco-use duration of 10 years or more (OR 1.03, 95% CI 0.62-1.70) all showed positive but statistically non-significant associations. The full set of association estimates is presented in Table 3 and Figure 4.

Table 3. Unadjusted associations between risk factors and oral premalignant lesions.

Risk factor	OR	95% CI	Chi-square	p-value
Regular alcohol use	2.15	1.20-3.85	6.74	<0.01
Areca-nut use	1.74	1.04-2.91	4.48	<0.05

Dental trauma / sharp tooth	1.63	0.97-2.74	3.43	≥ 0.05
Dual tobacco use	1.37	0.79-2.36	1.26	≥ 0.05
Poor oral hygiene	1.35	0.80-2.30	1.27	≥ 0.05
Age ≥ 50 years	1.12	0.69-1.83	0.22	≥ 0.05
Tobacco duration ≥ 10 years	1.03	0.62-1.70	0.01	≥ 0.05

OR, odds ratio; CI, confidence interval. Statistically significant associations ($p < 0.05$) are shown for regular alcohol use and areca-nut use.

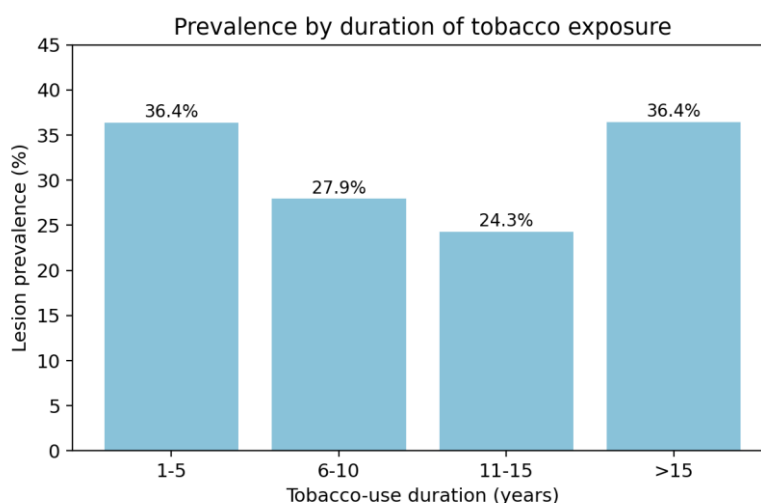


Figure 3. Prevalence of oral premalignant lesions by duration of tobacco exposure.

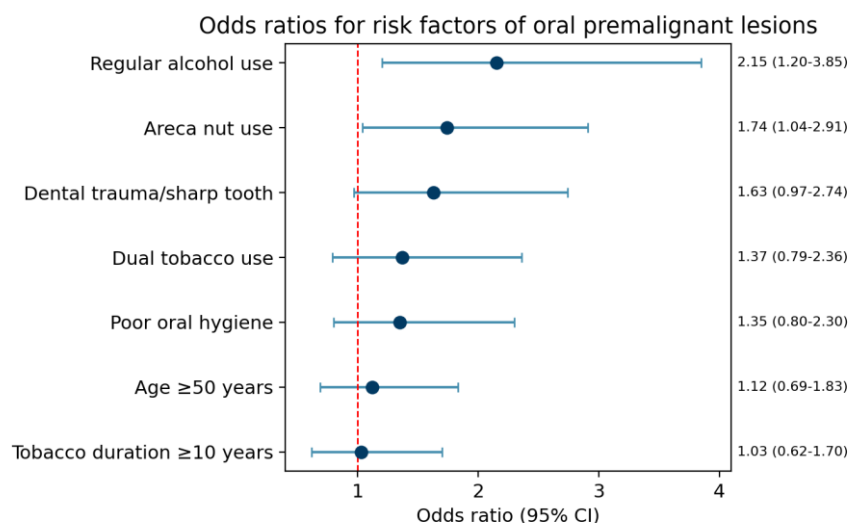


Figure 4. Odds ratios (95% confidence intervals) for selected risk factors of oral premalignant lesions. The vertical reference line indicates an odds ratio of 1.

4. DISCUSSION

In this hospital-based cross-sectional study of 300 tobacco users attending a South Indian tertiary-care centre, nearly one in three participants (31.7%) had a clinically identifiable oral premalignant lesion. OSMF and leucoplakia together accounted for

more than two-thirds of lesions, and lesion prevalence was higher among smokeless-only and dual tobacco users than among exclusive smokers [11,12]. Regular alcohol use and areca-nut use emerged as the only statistically significant correlates of lesions, while several other exposures showed consistent but weaker positive associations.

4.1 Comparison with existing literature

The overall lesion prevalence observed here is considerably higher than population-based estimates for individual OPMDs in India, where pooled cross-sectional prevalence is approximately 4.3% for leucoplakia and 2.7% for OSMF, but is consistent with the elevated figures reported in hospital and habit-based samples.[8,9] This difference reflects the enrichment of our sample for established tobacco users seeking care, a group in which OPMD prevalence is expected to be substantially higher than in the general population. Facility-based series that specifically screen tobacco and areca-nut users similarly report high burdens of OSMF and leucoplakia, and a large multi-site quid-user study found OSMF and tobacco pouch keratosis to be the dominant lesions. [10,13]

The predominance of OSMF and leucoplakia in our cohort mirrors the South Indian pattern documented in eastern-coast and tribal surveys, where these two conditions consistently dominate the OPMD spectrum and the labial and buccal mucosa are frequently involved.[14,15] The higher lesion prevalence among smokeless-only and dual users than among exclusive smokers is concordant with meta-analytic evidence that smokeless tobacco, and especially tobacco combined with areca nut, carries a greater risk of OPMDs than smoking alone, with OSMF strongly linked to areca-nut exposure.[16-19] The significant independent association we observed for areca-nut use fits the well-established causal role of recline and areca-nut alkaloids in the pathogenesis of OSMF and its progression toward malignancy, a relationship reinforced by ecological data linking rising areca-nut production and trade to increasing oral-cavity cancer incidence.[15,20]

The significant association between regular alcohol use and oral premalignant lesions is biologically plausible, since alcohol acts synergistically with tobacco to enhance mucosal carcinogen penetration and oxidative injury; oxidative-stress markers are consistently altered across OSMF, leucoplakia and oral squamous cell carcinoma, supporting a shared pathway of epithelial damage.[21,22] The positive though non-significant associations for dual tobacco use, longer exposure duration, poor oral hygiene, dental trauma and older age are directionally consistent with prior reports and likely reflect limited statistical power rather than absence of effect. Emerging tissue biomarkers such as ALDH1 and Maspion, and histopathological sub classification of OSMF by keratinization, may in future refine the identification of lesions at highest risk of malignant transformation beyond clinical assessment alone. [23,24]

4.2 Implications

From a public-health standpoint, these findings reinforce that any clinical encounter with a tobacco user is an opportunity for oral mucosal examination and structured risk counselling. The high prevalence of OSMF and the significant contribution of areca-nut and regular alcohol use argue for integrated interventions that address areca-nut and alcohol alongside tobacco, rather than tobacco in isolation [18,25]. Given India's exceptionally high oral-cancer burden, scalable strategies, including dentist tele-mentoring for opportunistic screening, workplace-based screening and cessation programmes, and mass-media and celebrity-led awareness campaigns that counter surrogate marketing, offer practical avenues for translating point-of-care detection into prevention. [26]

5. CONCLUSION

Among tobacco users attending a South Indian tertiary-care centre, oral premalignant lesions were highly prevalent, affecting nearly one-third of participants, with OSMF and leukoplakia predominating. Regular alcohol use and areca-nut use were significant correlates, and prevalence was greatest among smokeless and dual tobacco users. These results underscore the value of opportunistic oral examination and of integrated counselling that jointly targets tobacco, areca nut and alcohol, supported by accessible screening and cessation services, as a pragmatic strategy to reduce the oral-cancer burden in high-risk South Indian populations.

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